

Draft for consultation

## Urinary incontinence and pelvic organ prolapse in women: management

**[I] Surgical management of pelvic organ prolapse**

*NICE guideline tbc*

*Evidence review*

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*These evidence reviews were developed by  
the National Guideline Alliance hosted by the  
Royal College of Obstetricians and  
Gynaecologists*



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## 1 **Surgical management of pelvic organ prolapse**

### 2 **Review questions**

3 This evidence report covers several reviews within subsections. The following are the three  
4 review questions that are going to be covered in this document:

- 5 • What are the most effective surgical management options (including mesh and non-mesh  
6 procedures) for pelvic organ prolapse?
- 7 • What is the role of surgery to prevent postoperative urinary incontinence in women having  
8 surgery for pelvic organ prolapse, including the sequence of interventions?
- 9 • What are the effectiveness of surgical options for pelvic organ prolapse, compared to  
10 pessaries?

11

## 1 Surgical options (including mesh and non-mesh procedures) 2 for pelvic organ prolapse

### 3 Surgery for pelvic organ prolapse

4 What are the most effective surgical management options (including mesh and non-mesh  
5 procedures) for pelvic organ prolapse?

### 6 Introduction

7 Estimated risk of surgery for pelvic organ prolapse (POP) in women is approximately 11%  
8 and a number of surgery options are available. Determining the effectiveness of different  
9 surgical options is important to allow women to make informed decisions.

### 10 Summary of the protocol

11 Please see Table 1 for a summary of the Population, Intervention, Comparison and Outcome  
12 (PICO) characteristics of this review.

13 **Table 1: Summary of the protocol (PICO table)**

<b>Population</b>	Women (aged 18 and over) undergoing surgery for pelvic organ prolapse.  Women having repeat surgery or those that are treatment naïve will be included.
<b>Intervention</b>	<u>Anterior</u> <ul style="list-style-type: none"><li>• Anterior repair or colporrhaphy or cystocele repair</li><li>• Paravaginal repair</li></ul> <u>Apical</u> <ul style="list-style-type: none"><li>• Uterus</li><li>• Vault (vaginal, post-hysterectomy)</li></ul> <u>Posterior</u> <ul style="list-style-type: none"><li>• Rectocele repair or posterior repair or colporrhaphy</li><li>• Perineorrhaphy</li><li>• Enterocoele repair</li></ul>
<b>Comparison</b>	<u>Anterior</u> <ul style="list-style-type: none"><li>• Mesh versus no mesh use</li><li>• Mesh (synthetic) versus mesh (biologic)</li></ul> <u>Apical- Uterus</u> <ul style="list-style-type: none"><li>• Hysterectomy versus vaginal hysteropexy</li><li>• Hysterectomy versus mesh hysteropexy</li><li>• Open versus laparoscopic hysteropexy</li></ul> <u>Apical- Vault</u> <ul style="list-style-type: none"><li>• Open or laparoscopic sacrocolpopexy (SCP) versus vaginal sacrospinous fixation</li><li>• Open versus laparoscopic sacrocolpopexy</li></ul> <u>Posterior</u> <ul style="list-style-type: none"><li>• Mesh versus no mesh use</li></ul>

<b>Outcomes</b>	<ul style="list-style-type: none"><li>• Mesh (synthetic) versus mesh (biologic)</li></ul> <p><b>Critical</b></p> <p><b>Adverse events:</b></p> <ul style="list-style-type: none"><li>• Severe bleeding during surgery (requiring a transfusion)</li><li>• Internal organ injury during surgery</li></ul> <p><b>Long term adverse events:</b></p> <ul style="list-style-type: none"><li>• Recurrence of any POP (same or different compartment). Same compartment recurrence RCT data for anterior pelvic organ prolapse synthesised using network meta-analysis.</li><li>• Quality of life</li><li>• Complications (short term/midterm/long term)<ul style="list-style-type: none"><li>◦ Pain</li><li>◦ Mesh erosion/extrusion/exposure</li><li>◦ Fistula</li><li>◦ Bladder function (SUI, urge incontinence, Voiding difficulty)</li><li>◦ Bowel function (faecal incontinence, constipation, obstructed defecation)</li><li>◦ Sexual function (de novo dyspareunia, aperunia)</li></ul></li></ul> <p><b>Important</b></p> <ul style="list-style-type: none"><li>• Cure</li><li>• Repeat surgery</li><li>• Patient satisfaction</li></ul>
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1      POP: *pelvic organ prolapse*; RCT: *randomised controlled trial*; SCP: *sacrocolpopexy*; SUI: *stress urinary incontinence*

2      For full details see the clinical review protocol in appendix A and the separate review protocol  
3      detailing the methods for the related network meta-analysis in appendix N.

#### 4 Methods and process

5      This evidence review was developed using the methods and process described in  
6      [Developing NICE guidelines: the manual 2014](#). Methods specific to this review question are  
7      described in the review protocol in appendix A and appendix N (network meta-analysis). For  
8      a full description of the methods, see supplementary material C.

9      Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy  
10     until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to  
11     NICE's 2018 [conflicts of interest policy](#). Those interests declared until April 2018 were  
12     reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

#### 13 Clinical evidence

#### 14 Included studies

15     This review is comprised of two parts, 1) effectiveness of surgery and 2) complications of  
16     surgery:

17     • Effectiveness of surgery is subdivided into four sections: 1) anterior surgery for POP, 2)  
18       apical surgery for POP, 3) posterior surgery for POP, and 4) pairwise comparison of  
19       different mesh types for anterior POP surgery. The effectiveness of surgery review also  
20       included network meta-analysis which was used to synthesise recurrence data for anterior  
21       repair.

1 Complications of surgery data are subdivided into three sections: 1) complications occurring  
2 in the short term ( $\leq 24$  months follow up), 2) complications occurring in the mid-term (25 to 59  
3 months follow up), and 3) complications occurring in the long term ( $\geq 60$  months follow up).  
4 For the short-term complications, these are further separated into anterior, apical and  
5 posterior compartment data; however, for mid- and long-term data, all compartments have  
6 been combined, due to the nature of the evidence included.

7 In total 81 studies were identified and included within this review

8 To determine the effectiveness of surgery 41 Randomised controlled trials (RCT) were  
9 included:

- 10     • Twenty two studies provided data on anterior surgery for POP, of these 21 provided  
11 data for the comparison anterior colporrhaphy versus mesh surgery, (Altman 2011,  
12 Delroy 2013, De Tayrac 2013, Dias 2015, El-Nazer 2012, Feldner 2010, Gandhi  
13 2005, Glazener 2016, Guerette 2009, Hiltunen 2007, Hviid 2010, Lamblin 2014,  
14 Menefee 2011, Meschia 2007, Nguyen 2008, Robert 2014, Sivaslioglu 2008,  
15 Tamanini 2013, Turgal 2013, Vollebregt 2011 and Weber 2001). One study  
16 (Glazener 2016) provided two comparisons for this analysis. One study (Minassian  
17 2014) provided data for the comparison anterior colporrhaphy plus mesh versus  
18 paravaginal defect repair.
- 19     • Fourteen RCT provided data on apical surgery for POP, of these, two studies  
20 provided data on Laparoscopic versus abdominal sacrocolpopexy (Coolen 2017,  
21 Costantini 2016), two studies provided data on vaginal hysterectomy versus  
22 sacrospinous hysteropexy (Detollenaire 2015, Dietz 2010), one study provided data  
23 on Infracoccygeal sacropexy versus sacrospinous suspension (De Tayrac 2008), one  
24 study provided data on Sacrospinous ligament fixation with native tissue as compared  
25 to mesh (Svabik 2014), one study provided data on sacrocolpopexy with fascia tissue  
26 as compared to sacrocolpopexy with mesh (Culligan 2005/Tate 2011), two studies  
27 provided data on laparoscopic sacral colpopexy versus vaginal mesh kit (Lucot 2018,  
28 Maher 2011), two studies provided data on abdominal sacral colpopexy versus  
29 vaginal sacrospinous colpopexy (Lo 1998, Maher 2004), one study provided data on  
30 high uterosacral vault suspension versus abdominal sacrocolpopexy (Rhondini 2015),  
31 one study provided data on high levator myorrhaphy versus uterosacral ligament  
32 fixation (Natale 2010), and one study provided data on laparoscopic sacrocolpopexy  
33 with porcine mesh versus laparoscopic sacrocolpopexy with polypropylene mesh  
34 (Culligan 2013/Salamon 2014).
- 35     • Three RCT provided data for posterior surgery for POP, (Glazener 2016, Paraiso  
36 2006 and Sung 2012) comparing standard repair to mesh surgery. One study  
37 (Glazener 2016) provided two comparisons for this analysis.
- 38     • Five RCT provided data to compare different types of mesh material for use within  
39 POP surgery. Of these (Culligan 2013, Damiani 2016, Glazener 2016, Menefee 2011,  
40 and Natale 2009) compared porcine graft to polypropylene mesh. Four of the studies  
41 (Damiani 2016, Glazener 2016, Menefee 2011 and Natale 2009) used mesh during  
42 anterior surgery for POP. One study (Culligan 2013) used mesh during laparoscopic  
43 sacrocolpopexy, sub-analysis was conducted to include this study.

44 In total 68 studies provided evidence to determine the complications following surgery for  
45 POP.

- 46     • Forty six studies provided data on short-term complications of POP surgery. Of these  
47 studies, 24 RCT were for anterior surgery (Altman 2011, Delroy 2013, De Tayrac  
48 2013, Dias 2015, El-Nazer 2012, Feldner 2010, Gandhi 2005, Guerette 2009,  
49 Glazener 2016, Gupta 214, Hiltunen 2007, Hviid 2010, Lamblin 2014, Lundarelli

1                   2009, Menefee 2011, Meschia 2007, Nguyen 2008, Robert 2014, Rudnicki 2015,  
2                   Sivaslioglu 2008, Tamanini 2013, Turgal 2013, Vollebregt 2011 and Weber 2001).  
3                   One study provided data for two comparisons, (Glazener 2016). Seventeen studies  
4                   were on apical surgery (Coolen 2017, Freeman 2013, Culligan 2013/Salamon 2014,  
5                   Culligan 2013/ Tate 2011, Detollenaire 2015, De Tayrac 2008, Halaska 2012, Lo  
6                   1998, Lopes 2010, Maher 2004, Maher 2011, Natale 2010, Rahmanou 2015,  
7                   Rhondini 2015, Roovers2004/Roovers 2005, and Svabik 2014, Unlubilign 2013) and  
8                   three studies were for posterior surgery (Glazener 2016, Paraiso 2006 and Sung  
9                   2012) one study (Glazener 2016) provided two comparisons. Six studies provided  
10                  data on complications following surgery with different mesh types, five studies  
11                  (Culligan 2013, Damiani 2016, Glazener 2016, Natale 2009 and Menefee 2011)  
12                  compared porcine to polypropylene mesh and one study (Farthman 2013) compared  
13                  a non-absorbable to a partially absorbable mesh.  
14

- 15                  • Twenty four studies provided data for mid-term complication outcomes following POP  
16                  surgery. Of these, three were RCT (Constantini 2016, Rudnicki 2015 and Hiltunen  
17                  2007), one was a cross sectional study (Kowalik 2016) and 20 were prospective  
18                  studies (Balci 2011, Cervigini 2008, Chen 2012, Dari 2009, Deprest 2009, Funfgeld  
19                  2017, Granes 2009, Hefni 2006, Jacquetin 2010, Kdos 2014, Long 2012, Meidel  
20                  2008, Mourtialon 2013, Ramanah 2012, Sayer 2012, Schiavi 2017, Sergent 2011a,  
21                  Sergent 2011b, Thompson 2004, and Wang 2013).  
22  
23                  • Seventeen studies provided data on long-term complications. Of these, three were  
24                  RCT (Constantini 2016, Tate 2011 and Unlubilgin 2013) and 14 were prospective  
25                  cohort studies (Bedford 2015, Chen 2013, Jacquetin 2013, Joshi 2013, Laso-Garcia  
26                  2017, Miedel 2008, Miller 2011, Natale 2008, Rahkola-Soisalo 2017, Sarlos 2014,  
27                  Silva 2012, Souviat 2012, Ubachs 1973 and Weintraub 2016).

28                  For summaries of included studies in different comparisons see Table 2 to Table 18.

29                  See also the literature search strategy in appendix B, study selection flow chart in appendix  
30                  C, clinical evidence tables in appendix D, forest plots in appendix E and GRADE tables in  
31                  appendix F.

32                  **Excluded studies**

33                  Studies excluded from the review and reasons for their exclusion are provided in appendix K.

34

## 1 Summary of clinical studies included in the evidence review

2 The included studies are summarised in Table 2 to Table 18.

3 **Table 2: Summary of randomised controlled trials comparing anterior colporrhaphy  
4 to mesh surgery for anterior surgery**

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Altman 2011  Sweden/Norway/ Finland and Denmark  N =389	Transvaginal mesh repair	Traditional colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP stage 0-1)</li> <li>• Pain</li> <li>• Mesh erosion</li> </ul>	12 month data  Mean age: 65 years
Delroy 2013  Brazil  N = 79	Transvaginal synthetic mesh (Nazca TC)	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Anatomical success Ba&lt;-1)</li> <li>• Dyspareunia</li> <li>• Voiding difficulties</li> <li>• Mesh exposure</li> </ul>	12 months data  Mean age: 61 years
De Tayrac 2013  France  N = 147	Mesh surgery: Ugtex, highly porous polypropylene monofilament mesh	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Anatomical success (Ba&lt;-1)</li> <li>• Pain</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Anal incontinence</li> <li>• Obstructed defecation</li> <li>• Mesh exposure</li> <li>• POPDI</li> <li>• UDI</li> <li>• CRADI</li> </ul>	12 months data  Mean age: 70 years
Dias 2015  Brazil  N = 88	Transvaginal synthetic mesh Trocar-guided kit Nazca TC™	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Anatomical success (Ba &lt; -1)</li> <li>• Dyspareunia</li> <li>• Pain</li> <li>• Mesh exposure</li> </ul>	24 month data  Mean age: 61 years
EI-Nazer 2012  Egypt  N = 54	Gynemesh- synthetic non- absorbable mono- filamentous polypropylene lightweight mesh	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Dyspareunia</li> <li>• Mesh exposure</li> <li>• Voiding difficulties</li> <li>• SUI</li> </ul>	24 months data  Mean age: 41 years
Feldner 2010  Brazil  N = 56	SIS graft Traditional anterior repair with SIS insertion	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q Stage 0-1)</li> <li>• Dyspareunia</li> <li>• Voiding difficulties</li> </ul>	12 month data  Mean age: 55 years

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## Surgical management of pelvic organ prolapse

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Gandhi 2005 USA N = 154	Traditional AC with the addition of allograft	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1) calculated from recurrence at 12 months]</li> <li>• Pain</li> <li>• Voiding difficulties</li> </ul>	12 month data  Mean age: 65 years
Glazener 2016a UK N = 371	Synthetic mesh (Non-absorbable, type 1 filament macroporous polypropylene mesh)	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Pain</li> <li>• Constipation</li> <li>• Faecal incontinence</li> <li>• POP-SS</li> <li>• ICIQ-UI</li> <li>• ICIQ-VS</li> </ul>	12 and 24 months data  Mean age: 60 years
Glazener 2016b UK N = 264	Biological graft [Porcine acellular collagen matrix, porcine small intestinal submucosa or bovine dermal grafts ]	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q Stage 0-1)</li> <li>• Pain</li> <li>• Constipation</li> <li>• Faecal incontinence</li> <li>• POP-SS</li> <li>• ICIQ-UI</li> <li>• ICIQ-VS</li> </ul>	12 and 24 months data  Mean age: 60 years
Guerette 2009 USA N = 94	Anterior colporrhaphy plus graft	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Anatomical success (Ba &lt;1)</li> <li>• Dyspareunia</li> <li>• Mesh exposure</li> </ul>	12 month data  Mean age: 61 years
Gupta 2014 India N = 106	Non-absorbable low-weight monofilament, vicryl-polypropylene mesh	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Optimal outcome (Aa and Ba at stage 0)</li> <li>• Mesh exposure</li> </ul>	12 month data  Mean age: 51 years
Hiltunen 2007 Finland N = 202	Anterior colporrhaphy plus non-absorbable low-with monofilament polypropylene mesh	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q Stage 0-1)</li> <li>• SUI</li> <li>• Voiding difficulties</li> </ul>	12 month data  Mean age: 66 years
Hviid 2010 Denmark N = 61	Pelvicol graft	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Mesh exposure</li> </ul>	12 months  Mean age: 61 years
Lamblin 2014 France	Trocars-guided transvaginal mesh repair	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Dyspareunia</li> <li>• Mesh extrusion</li> </ul>	12 and 24 months data (mesh extrusion and dyspareunia only at 24 months)

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<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
N=68			<ul style="list-style-type: none"> <li>• PFDI-20</li> <li>• PFIQ-7</li> </ul>	Mean age: 65 years
Lundarelli 2009 Brazil N = 32	Monofilament polypropylene mesh	Anterior colporrhaphy (AC)	<ul style="list-style-type: none"> <li>• Mesh erosion</li> </ul>	9 months data Mean age: 63 years
Meneffe 2011 USA N = 99	Anterior colporrhaphy plus graft	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1) [<i>calculated from failure rates</i>]</li> <li>• Dyspareunia</li> <li>• Mesh erosion</li> <li>• SUI</li> </ul>	24 month data Mean age: 62 years
Meschia 2007 Italy N = 206	Anterior colporrhaphy with Pelvicol implant	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Anatomical success (Ba &lt; 1)</li> <li>• Dyspareunia</li> <li>• Mesh extrusion</li> <li>• SUI</li> </ul>	12 month data Mean age 65 years
Nguyen 2008 USA N = 76	Perigee, non-polypropylene mesh repair	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Optimal or satisfactory cure (both Aa or Bb stage 0-1)</li> <li>• Dyspareunia</li> <li>• Mesh extrusion</li> <li>• PFDI-20</li> <li>• PFIQ-7</li> </ul>	12 months data Mean age: 60 years
Robert 2014 Canada N = 57	Submucosa mesh	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• PFDI-20</li> <li>• PFIQ-7</li> </ul>	12 month data Mean age 58 years
Rudnicki 2015 Norway/Sweden/Finland/ Denmark N = 169	Collagen-coated mesh repair system	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Voiding difficulties</li> </ul>	12 month data Mean age: 65 years
Sivasliogul 2008 Turkey N = 90	Anterior colporrhaphy plus low-weight mesh	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Pain</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Mesh exposure</li> </ul>	12 month data Mean age: 54 years
Tamanini 2013 Brazil	Transvaginal synthetic mesh Trocar guided Nazca TC device	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Voiding difficulties</li> </ul>	12 and 24 month data (Cure, mesh exposure and dyspareunia at 24 months)

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
N = 100	(monofilament and macroporous)		<ul style="list-style-type: none"> <li>• Urge incontinence</li> <li>• ICIQ-VS</li> <li>• Mesh exposure</li> </ul>	Mean age: 65 years
Turgal 2013 Turkey N = 40	Anterior colporrhaphy plus polypropylene mesh	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Anatomical success (Ba &lt; 1)</li> <li>• Pain</li> <li>• Mesh erosion</li> <li>• Urinary incontinence</li> <li>• Faecal incontinence</li> </ul>	12 month data Mean age: 54 years
Vollebregt 2011 Netherlands N=125	Trocars guided transobturator mesh Avaulta system	Anterior colporrhaphy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Dyspareunia</li> <li>• Mesh exposure</li> </ul>	12 month data Mean age: 60 years
Weber 2001 USA N = 109	Anterior colporrhaphy plus mesh	Anterior colporrhaphy  Ultralateral anterior colporrhaphy (UAC)	<ul style="list-style-type: none"> <li>• Satisfactory or optimal outcome (Aa or Ba &lt; 2)</li> <li>• Mesh erosion</li> </ul>	23 month data Mean age: 65 years

1 AC: anterior colporrhaphy; CRADI: colorectal-anal distress inventory; ICIQ-UI: international consultation on  
2 incontinence questionnaire-urinary incontinence; ICIQ-VS: international consultation on incontinence modular  
3 questionnaire-vaginal symptoms; PFDI: pelvic floor distress inventory; PFIQ: pelvic floor impact questionnaire;  
4 POPDI: pelvic organ prolapse distress inventory; POP-Q: pelvic organ prolapse questionnaire; POP-SS: pelvic  
5 organ prolapse-symptom score; SIS: small intestinal submucosa; SUI: stress urinary incontinence; UAC:  
6 ultralateral anterior colporrhaphy; UDI: urinary distress inventory

7 **Table 3: Summary of clinical studies comparing anterior colporrhaphy plus mesh to**  
8 **paravaginal defect repair for anterior repair**

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Minassian 2014 USA N=70	Anterior colporrhaphy plus polyglactin 910 mesh	Paravaginal defect repair	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> </ul>	12 and 24 months data Mean age: 54 years

9 POP-Q: pelvic organ prolapse questionnaire

10 **Table 4: Summary of clinical studies comparing Laparoscopic to abdominal**  
11 **sacrocolpopexy for apical surgery**

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Coolen 2017 Netherlands N = 74	Laparoscopic sacrocolpopexy	Abdominal sacrocolpopexy	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Urge incontinence</li> </ul>	12 months data Mean age: 67 years

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<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Costantini 2016 Italy N = 121	Laparoscopic sacrocolpopexy	Abdominal sacrocolpopexy	• Cure (not defined) n/N	42 month data Mean age: 61 years
Freeman UK N = 54	Laparoscopic sacrocolpopexy	Abdominal sacrocolpopexy	• SUI • Mesh exposure • Constipation	12 month data Mean age: 62 years

1 N: number; POP-Q: pelvic organ prolapse questionnaire; SUI: stress urinary incontinence

2 **Table 5: Summary of clinical studies comparing vaginal hysterectomy to**  
3 **sacrospinous hysteropexy**

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Detollenaere 2015 Netherlands N= 208	Vaginal hysterectomy	Sacrospinous hysteropexy	• Cure (POP-Q < 2) • PSIQ-12	12 month data Mean age: 62 years
Dietz 2010 Netherlands N=71	Vaginal hysterectomy	Sacrospinous hysteropexy	• Cure (POP-Q 0-1)	12 month data Mean age: 63 years

4 POP-Q: pelvic organ prolapse questionnaire; PSIQ-12: pelvic organ prolapse/urinary incontinence sexual  
5 questionnaire

6 **Table 6: Summary of clinical studies comparing Infracoccygeal sacropexy to**  
7 **sacrospinous suspension**

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
De Tayrac 2008 France N = 49	Infracoccygeal sacropexy	Sacrospinous suspension	• Cure (POP-Q stage 0-1) • SUI • Voiding difficulties • Constipation • POPDI • POPIQ	16.8 month data Mean age: 61 years

8 POPDI: pelvic organ prolapse distress inventory; POPIQ: pelvic organ prolapse impact questionnaire; POP-Q:  
9 pelvic organ prolapse questionnaire; SUI: stress urinary incontinence

**Table 7: Summary of clinical studies comparing Sacrospinous ligament fixation to native tissue versus mesh**

Study	Interventions	Comparison	Outcomes	Comments
Halaska 2012 Czech Republic N = 168	Prolift mesh	Sacrospinous fixaton	• Recurrence	12 month data Mean age: 65 years
Lopes 2010 Brazil N = 32	posterior polypropylene kit	Sacrospinous ligament fixation	• Recurrence (Ba >0) • Mesh erosion	12 month data Mean age: 64 years
Svabik 2014 Turkey N = 94	Prolift Total mesh for sacrospinous fixation	native tissue sacrospinous fixation	• Cure (POP –Q stage <2) • Dyspareunia • Mesh exposure • SUI • PSIQ-12 • POPDI	12 month data Mean age: 63 years

POPDI: pelvic organ prolapse distress inventory; POP-Q: pelvic organ prolapse questionnaire; PSIQ-12: pelvic organ prolapse/urinary incontinence sexual questionnaire; SUI: stress urinary incontinence

**Table 8: Summary of clinical studies comparing fascia to mesh sacrocolpopexy**

Study	Interventions	Comparison	Outcomes	Comments
Culligan 2005 / Tate 2011 USA N = 100	Sacrocolpopexy with fascia tissue	Sacrocolpopexy with mesh	• Cure (POP- Q stage 0-1) • Mesh exposure	12 month data Mean age: 59 years

POP-Q: pelvic organ prolapse questionnaire

**Table 9: Summary of clinical studies comparing Laparoscopic sacral colpopexy to vaginal mesh kit**

Study	Interventions	Comparison	Outcomes	Comments
Lucot 2018 France N = 262	Laparoscopic mesh sacropexy	Transvaginal mesh repair	• Cure (POP stage 0-1)	12 month data Mean age: 63 years
Maher 2011 Australia N= 108	Laparoscopic sacral colpopexy	Total vaginal mesh kit	• Cure (POP-Q stage 0-1) • Mesh erosion	6 and 24 months data (mesh erosion only at 6 months) Mean age: 63 years

LSC: laparoscopic mesh sacropexy; POP: pelvic organ prolapse; POP-Q: pelvic organ prolapse questionnaire; TVM: transvaginal mesh repair

**Table 10: Summary of clinical studies comparing abdominal sacral colpopexy to vaginal sacrospinous colpopexy**

Study	Interventions	Comparison	Outcomes	Comments
Lo 1998 China N = 118	Abdominal colposacropexy	Sacrospinous ligament fixation	<ul style="list-style-type: none"> <li>Cure (no protrusion &gt; stage II ICS)</li> <li>Dyspareunia</li> </ul>	24 month data Mean age: 61 years
Maher 2004 Australia N = 95	Abdominal sacral colpopexy	Vaginal sacrospinous colpopexy	<ul style="list-style-type: none"> <li>Cure (POP-Q stage &lt; 2)</li> <li>Dyspareunia</li> <li>SUI</li> <li>Voiding dysfunction</li> <li>Constipation</li> </ul>	24 month data Mean age: 63 years

ICS: international continence society; POP-Q: pelvic organ prolapse questionnaire; SUI: stress urinary incontinence

**Table 11: Summary of clinical studies comparing high uterosacral vault suspension to abdominal sacrocolpopexy**

Study	Interventions	Comparison	Outcomes	Comments
Rhondini 2015 Chile N = 124	abdominal sacrocolpopexy	High uterosacral vault suspension	<ul style="list-style-type: none"> <li>Cure (POP-Q stage 0-1)</li> <li>Mesh exposure</li> </ul>	6 and 12 month data (mesh exposure at 6 months only) Mean age: 57 years

POP-Q: pelvic organ prolapse questionnaire

**Table 12: Summary of clinical studies comparing high levator myorrhaphy to uterosacral ligament fixation**

Study	Interventions	Comparison	Outcomes	Comments
Natale 2010 Italy N = 229	High levator myorrhaphy	Uterosacral ligament suspension	<ul style="list-style-type: none"> <li>Cure (Ba stage 0-1)</li> <li>Dyspareunia</li> <li>Mesh erosion</li> <li>Urge incontinence</li> <li>SUI</li> <li>Constipation</li> </ul>	12 month data Mean age: 65 years

SUI: stress urinary incontinence

**Table 13: Summary of clinical studies comparing porcine mesh to polypropylene mesh**

Study	Interventions	Comparison	Outcomes	Comments
Culligan 2013 / Salomon 2014 USA N= 120	Laparoscopic sacrocolpopexy with porcine mesh (Pelvisoft porcine dermis mesh)	Laparoscopic sacrocolpopexy with polypropylene mesh	<ul style="list-style-type: none"> <li>Cure (POP-Q stage 0-1)</li> <li>Dyspareunia</li> <li>Mesh exposure</li> <li>PSIQ-12</li> <li>PFDI-12</li> <li>PFIQ-7</li> </ul>	12 month data Mean age: 57 years

PFDI: pelvic floor distress inventory; PFIQ: pelvic floor impact questionnaire; POP-Q: pelvic organ prolapse questionnaire; PSIQ-12: pelvic organ prolapse/urinary incontinence sexual questionnaire

**Table 14: Summary of clinical studies comparing vaginal hysterectomy to Manchester repair**

Study	Interventions	Comparison	Outcomes	Comments
Unlubilgin 2013 Turkey N = 94	Vaginal hysterectomy	Manchester repair	• Repeat surgery for POP	61 month data Mean age: 51 years

POP: *pelvic organ prolapse***Table 15: Summary of clinical studies comparing sacral colpopexy to vaginal hysterectomy**

Study	Interventions	Comparison	Outcomes	Comments
Roovers 2004/Roovers 2005 Netherlands N = 82	Abdominal sacro-colpopexy	Vaginal hysterectomy	• Repeat surgery for POP	12 month data Mean age: 58 years
Rahmanou 2015 UK N = 101	Laparoscopic hysteropexy	Vaginal hysterectomy	• Repeat surgery for POP	12 month data Mean age: 65 years

POP: *pelvic organ prolapse***Table 16: Summary of clinical studies included in the evidence review comparing standard posterior prolapse repair to mesh surgery**

Study	Interventions	Comparison	Outcomes	Comments
Glazener 2016a UK N = 252	Standard repair	Synthetic mesh (Non-absorbable, type 1 filament macroporous polypropylene mesh)	• Cure (POP-Q stage 0-1) • Pain • Constipation • Faecal incontinence • POP-SS • ICIQ-UI • ICIQ-VS	12 month data Mean age: 60 years
Glazener 2016b UK N = 220	Standard repair	Biological graft [Porcine acellular collagen matrix, porcine small intestinal submucosa or bovine dermal grafts ]	• Cure (POP-Q stage 0-1) • Pain • Constipation • Faecal incontinence • POP-SS • ICIQ-UI • ICIQ-VS	12 month data Mean age: 60 years
Paraiso 2006 USA N = 106	Posterior colporrhaphy	Defect specific rectocele repair with graft	• Cure ( $B_a \leq 2$ ) • Dyspareunia • Straining • PSIQ012 • PFDI-20 • PFIQ-7	12 month data Mean age: 61 years
Sung 2012 USA	Rectocele repair with native tissue	Rectocele repair with SIS graft [Porcine sub-intestinal	• Cure (POP-Q stage 0-1) • Dyspareunia • Straining	12 month data Mean age: 55 years

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<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
N = 160		submucosal graft (surgiSIS)]		

1 ICIQ-UI: international consultation on incontinence questionnaire-urinary incontinence; ICIQ-VS: international  
2 consultation on incontinence modular questionnaire-vaginal symptoms; PFDI: pelvic floor distress inventory;  
3 PFIQ: pelvic floor impact questionnaire; POP-Q: pelvic organ prolapse questionnaire; POP-SS: pelvic organ  
4 prolapse-symptom score

5 **Table 17: Summary of clinical studies included comparing mesh types for POP**  
6 **surgery**

<b>Study</b>	<b>Interventions</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Damiani 2016 Italy N = 58	Pelvisoft [porcine dermal collagen matrix]	Avaulta Solo [polypropylene mesh]	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Mesh exposure</li> </ul>	12 month data  Mean age: 57 years
Glazener 2016 UK N = 319	Biological graft [Porcine acellular collagen matrix, porcine small intestinal submucosa or bovine dermal grafts ]	Synthetic mesh (Non-absorbable, type 1 filament macroporous polypropylene mesh)	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Mesh exposure</li> <li>• Constipation</li> <li>• Faecal incontinence</li> </ul>	12 month data  Mean age: 60 years
Menefee 2011 USA N = 67	Porcine graft	Polypropylene mesh	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Mesh erosion</li> <li>• Dyspareunia</li> <li>• SUI</li> </ul>	24 month data  Mean age: 62 years
Natale 2009 Italy N = 190	Pelvicol Porcine dermis graft	Gynemesh Polypropylene mesh	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Mesh erosion</li> <li>• Constipation</li> <li>• Dyspareunia</li> </ul>	24 month data  Mean age: 65 years
Culligen 2013 USA N = 119	Pelvisoft porcine dermis	Polypropylene mesh	<ul style="list-style-type: none"> <li>• Cure (POP-Q stage 0-1)</li> <li>• Mesh exposure</li> <li>• Dyspareunia</li> </ul>	12 month data  Mean age: 57 years
Farthman Germany N = 200	Polypropylene, non-absorbable mesh	Partially absorbable mesh	<ul style="list-style-type: none"> <li>• Mesh exposure</li> </ul>	12 month data  Mean age: 68 years

7 POP-Q: pelvic organ prolapse questionnaire; SUI: stress urinary incontinence

8

**Table 18: Summary of prospective studies included in the evidence review with complication data**

Study	Intervention	Comparison	Outcomes	Quality assessment	Surgery Classification
Sayer 2012 UK N = 110 Mean age: 65 years	Polypropylene mesh, Gynecare posima and vaginal support device	No comparison	<ul style="list-style-type: none"> <li>• 29 months data</li> <li>• Mesh erosion</li> <li>• Dyspareunia</li> <li>• SUI</li> </ul>	Low quality	Vaginal mesh
Deprest 2009 Netherlands N = 150 Mean age: 61 years	Laparoscopic sacrocolpopexy with xenografts (porcine grafts)	Laparoscopic sacrocolpopexy with synthetic polypropylene mesh	<ul style="list-style-type: none"> <li>• 30 months data</li> <li>• Mesh erosion</li> <li>• Pain</li> </ul>	Moderate to low quality	Abdominal biological vs abdominal synthetic
Ramanah 2012 France N = 151 Mean age: 61 years	Laparoscopic sacrocolpopexy	Transvaginal total hammock with sacrospinous ligament suspension	<ul style="list-style-type: none"> <li>• 30 months data</li> <li>• SUI</li> <li>• Recurrence</li> <li>• Urge incontinence</li> <li>• Voiding difficulties</li> </ul>	Moderate to low quality	Abdominal mesh vs vaginal mesh
Sergent 2011a France N = 114 Mean age: 66 years	Transobturator infracoccygeal hammock, using non-absorbable synthetic mesh	No comparison	<ul style="list-style-type: none"> <li>• 34 months data</li> <li>• Mesh erosion</li> <li>• Dyspareunia</li> <li>• Pain</li> </ul>	Low quality	Vaginal mesh
Chen 2012 China N = 116 Mean age: 70 years	Monofilament polypropylene mesh (Gynemesh) plus vaginal hysterectomy	Prolift mesh plus vaginal hysterectomy	<ul style="list-style-type: none"> <li>• 36 months data</li> <li>• Mesh erosion</li> <li>• Recurrence</li> </ul>	Moderate to low quality	Vaginal mesh
Funfgeld 2017 Germany N = 292 Mean age: 67 years	Alloplastic mesh, titanized polypropylene mesh (TiLOOP) for cystocele	No comparison	<ul style="list-style-type: none"> <li>• 36 months data</li> <li>• Recurrence</li> <li>• Mesh erosion</li> <li>• Dyspareunia</li> </ul>	Low quality	Vaginal mesh
Kdos 2014	Transobturator four arm polypropylene mesh for cystocele	No comparison	<ul style="list-style-type: none"> <li>• 36 months data</li> <li>• Mesh erosion</li> </ul>	Low quality	Vaginal mesh

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Study	Intervention	Comparison	Outcomes	Quality assessment	Surgery Classification
Tunisia  N = 114  Mean age: 63 years			<ul style="list-style-type: none"> <li>Dyspareunia</li> <li>Pain</li> <li>SUI</li> <li>Urge incontinence</li> <li>Constipation</li> <li>Faecal incontinence</li> </ul>		
Long 2012  Taiwan  N = 124  Mean age: 58 years	Total vaginal mesh repair using Perigee and/or Apogee devices	Total vaginal mesh repair using Prolift devices	<ul style="list-style-type: none"> <li>36 months data</li> <li>Mesh erosion</li> </ul>	Moderate to low quality	Vaginal mesh
Mourtialon 2013  France  N = 116  Mean age: 63 years	Rectocele repair via the Infracoccygeal route via sacrospinous ligament fixation using polypropylene mesh	No comparison	<ul style="list-style-type: none"> <li>36 months data</li> <li>Mesh erosion</li> <li>Dyspareunia</li> </ul>	Low quality	Vaginal mesh
Wang 2013  Germany  N = 80  Mean age: 61 years	Transobturator mesh kit (Prolift) with Vaginal hysterectomy	No comparison	<ul style="list-style-type: none"> <li>36 months data</li> <li>Mesh erosion</li> </ul>	Low quality	Vaginal mesh
Cervigni 2008  Italy  N = 218  Mean age: 63 years	Tension free cystocele repair using polypropylene mesh	No comparison	<ul style="list-style-type: none"> <li>38 months data</li> <li>Pain</li> <li>Dyspareunia</li> <li>Urge incontinence</li> <li>Constipation</li> </ul>	Low quality	Vaginal mesh
Daria 2009  France  N = 101  Mean age: 67 years	Porcine skin collagen implant and bilateral sacrospinous fixation	No comparison	<ul style="list-style-type: none"> <li>38 months data</li> <li>Dyspareunia</li> <li>Recurrence</li> </ul>	Low quality	Vaginal mesh
Kowalik 2016*  Netherlands  N = 188	Vaginal mesh surgery using polypropylene mesh	No comparison	<ul style="list-style-type: none"> <li>40 months data</li> <li>Pain</li> <li>Mesh erosion</li> </ul>	Low quality	Vaginal mesh

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Study	Intervention	Comparison	Outcomes	Quality assessment	Surgery Classification
Mean age: 60 years					
Granese 2009 Italy N = 165 Mean age: 67 years	Laparoscopic sacrocolpopexy	No comparison	<ul style="list-style-type: none"> <li>• 43 months data</li> <li>• Pain</li> <li>• SUI</li> <li>• Constipation</li> </ul>	Low quality	Abdominal mesh
Thompson 2004 USA N = 156 Mean age: 58 years	Abdominal sacral colpopexy	No comparison	<ul style="list-style-type: none"> <li>• 43 months data</li> <li>• Mesh erosion</li> </ul>	Low quality	Abdominal mesh
Balci 2011 Turkey N = 175 Mean age: 53 years	Vaginal hysterectomy	Vaginal hysterectomy, supporting the IP ligament	<ul style="list-style-type: none"> <li>• 48 months data</li> <li>• Dyspareunia</li> <li>• Recurrence</li> </ul>	Moderate to low quality	Vaginal no mesh
Schiavi 2017 Italy N = 146 Mean age: 62 years	Vaginal hysterectomy and vaginal vault suspension	No comparison	<ul style="list-style-type: none"> <li>• 48 months data</li> <li>• Dyspareunia</li> <li>• Pain</li> <li>• SUI</li> <li>• Urge incontinence</li> <li>• Voiding difficulties</li> <li>• Constipation</li> <li>• Recurrence</li> </ul>	Low quality	Vaginal no mesh
Hefni 2006 UK N = 305 Mean age: 60 years	Transvaginal sacrospinous colpopexy	No comparison	<ul style="list-style-type: none"> <li>• 57 months data</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Recurrence</li> </ul>	Low quality	Vaginal no mesh
Sargent 2011b France N = 124 Mean age: 53 years	Laparoscopic sacral colpopexy  Anterior, apical and/or posterior repair	No comparison	<ul style="list-style-type: none"> <li>• 58 months data</li> <li>• Mesh erosion</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Urge incontinence</li> <li>• Voiding difficulties</li> <li>• Constipation</li> <li>• Faecal incontinence</li> </ul>	Low quality	Abdominal synthetic mesh
Bedford 2015 Australia	Laparoscopic cystocele repair	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Recurrence</li> </ul>	Low quality	Abdominal no mesh

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Study	Intervention	Comparison	Outcomes	Quality assessment	Surgery Classification
N = 223  Mean age: 62 years					
Chen 2013  Australia  N = 135  Mean age: 70 years	Ultra lateral anterior repair for cystocele	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Recurrence</li> </ul>	Low quality	Vaginal no mesh
Costantini 2016*  Italy  N = 121  Mean age: 61 years	Laparoscopic sacrocolpopexy	Abdominal sacrocolpopexy	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Mesh exposure</li> <li>• Constipation</li> <li>• Recurrence</li> </ul>	NA	Abdominal mesh RCT data
Jacquetin 2013  France  N = 90 Mean age: 63 years	Total transvaginal mesh Prolift system	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Dyspareunia</li> <li>• Mesh exposure</li> <li>• Pain</li> <li>• Recurrence</li> </ul>	Low quality	Vaginal mesh
Joshi 2013  India  N = 119  Mean age: 44 years	Pectineal ligament suspension Using polyester mesh  Open or laparoscopic	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Mesh erosion</li> </ul>	Low quality	Abdominal mesh
Laso-Garcia 2017  Spain  N = 75  Mean age: 68 years	Tension free transvaginal mesh. Prolif	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Pain</li> <li>• Dyspareunia</li> <li>• Mesh extrusion</li> <li>• SUI</li> <li>• Constipation</li> <li>• Urge incontinence</li> </ul>	Low quality	Vaginal mesh
Natale 2008  Israel  N = 272  Mean age: 60 years	High levator myorrhaphy  If cystocele repair, used polypropylene mesh by TRC	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Pain</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Urge incontinence</li> <li>• Constipation</li> <li>• Recurrence</li> </ul>	Low quality	Vaginal mesh

# DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

<b>Study</b>	<b>Intervention</b>	<b>Comparison</b>	<b>Outcomes</b>	<b>Quality assessment</b>	<b>Surgery Classification</b>
Sarlos 2014  Switzerland  N = 99  Age range: 36-81 (mean not stated)	Laparoscopic sacrocolpopexy  And if needed macroporous polypropylene mesh (Gynemesh) for anterior and/or posterior	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Dyspareunia</li> <li>• Mesh extrusion</li> <li>• Constipation</li> <li>• Faecal incontinence</li> <li>• Recurrence</li> </ul>	Low quality	Abdominal and vaginal mesh combined
Silva 2012  USA  N = 72  Mean age: 64 years	Uterosacral vault suspension	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Dyspareunia</li> <li>• Constipation</li> <li>• Faecal incontinence</li> <li>• Recurrence</li> </ul>	Low quality	No mesh vagina
Miedel 2008  Sweden  N = 185  Mean age: 65 years	Anterior and/or posterior mesh repair by midline plication  Synthetic or biological mesh used in a percentage of cases	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Dyspareunia</li> <li>• SUI</li> <li>• Urge incontinence</li> <li>• Constipation</li> <li>• Faecal incontinence</li> </ul>	Low quality	Vaginal mesh
Miller 2011  USA  N = 85  Mean age: 62 years	Total vaginal mesh for anterior and/or posterior. Prolift	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Dyspareunia</li> <li>• Mesh exposure</li> <li>• Pain</li> <li>• Recurrence</li> </ul>	Low quality	Vaginal mesh
Rahkola-Soissalo 2017  Sweden, Finland, Denmark, Norway  N = 207  Mean age: 70 years	Uphold Lite monofilament polypropylene mesh for apical surgery	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• Pain</li> <li>• Mesh erosion</li> </ul>	Low quality	Vaginal mesh
Ubachs 1973  Netherlands  N=141  Mean age: 66 years	Partial colpocleisis Plus high levator plasty	No comparison	<ul style="list-style-type: none"> <li>• 60 months data</li> <li>• SUI</li> <li>• Urge incontinence</li> <li>• Recurrence</li> </ul>	Low quality	Vaginal no mesh
Weintraub 2016	Posterior mesh repair	No comparison	<ul style="list-style-type: none"> <li>• 72 months data</li> <li>• Dyspareunia</li> </ul>	Low quality	Vaginal mesh

Study	Intervention	Comparison	Outcomes	Quality assessment	Surgery Classification
Israel  N = 80  Mean age: 62 years			<ul style="list-style-type: none"> <li>• Mesh complications</li> <li>• Recurrence</li> </ul>		
Souviat 2012  France  N = 178  Mean age: 67 years	Sacrospinous ligament fixation	No comparison	<ul style="list-style-type: none"> <li>• 115 months data</li> <li>• Dyspareunia</li> </ul>	Low quality	Vaginal no mesh

1 RCT: randomised controlled trial; SUI: stress urinary incontinence; TiLOOP: titanized polypropylene mesh

2 See also the clinical evidence tables in appendix D.

3 Meta-analysis was conducted on effectiveness data and short term complication data (forest  
4 plots can be found in appendix E). The majority of studies for mid-term and short-term  
5 complications did not provide comparative data. The studies were prospective cohorts, and  
6 reported only the number of events for a specific intervention (see Table 18 for details).  
7 Weighted average for the rate of complications was calculated for complications occurring  
8 during mid-term and long-term follow up periods. Data can be found in Table 21. In addition  
9 the short-term rate of mesh exposure was only provided in one arm of the included RCT;  
10 therefore, weighted average for rate of mesh exposure in the short-term has also been  
11 calculated, and can be seen in Table 19.

## 12 Quality assessment of clinical studies included in the evidence review

13 GRADE analysis was conducted for critical and important outcomes, including effectiveness  
14 of surgery and short-term complications; GRADE profiles can be found in appendix F. The  
15 studies included for the mid-term and long-term complications are non-comparative studies;  
16 therefore GRADE analysis is not appropriate. For these non-randomised studies each study  
17 was quality assessed using the Cochrane ROBIS-I tool, and ratings are presented in the  
18 clinical evidence summary tables in appendix D.

19 **Table 19: Short term weighted average rate\* of mesh exposure**

Complication	Number of studies	Total population	Weighted average rate
Mesh exposure/extrusion	28	2913	5.53%

20 \*Calculated from mesh arm of intervention studies

2 **Table 20: Rate of complications, calculated as weighted average (mid-term, complications reported 25 to 59 months following surgery)**

Surgery classification	Total			Vaginal mesh surgery			Abdominal mesh surgery			Non-mesh surgery		
Complication	Number of Studies	Total number of women	Rate	Number of Studies	Total number of women	Rate	Number of Studies	Total number of women	Rate	Number of Studies	Total number of women	Rate
<b>Mesh erosion/exposure</b>	16	2177	6.84%	12	1626	7.93%	3	430	3.72%	-	-	-
<b>Dyspareunia</b>	10	1514	4.95%	8	1113	5.48%	-	-	-	2	321	8.10%
<b>Pain</b>	8	1176	5.53%	5	715	7.41%	2	315	2.54%	-	-	-
<b>SUI*</b>	9	1493	7.84%	5	569	7.38%	3	376	7.45%	3	548	3.83%
<b>Urge incontinence</b>	7	1094	9.51%	4	572	13.99%	3	376	4.79%	-	-	-
<b>Voiding difficulties</b>	4	586	3.75%	-	-	-	3	376	3.72%	-	-	-
<b>Constipation</b>	6	943	16.44%	3	508	15.16%	2	289	6.92%	-	-	-
<b>Faecal incontinence</b>	3	229	2.90%	2	290	3.79%	-	-	-	-	-	-
<b>Recurrence of POP*</b>	8	1464	8.95%	7	954	9.43%	-	-	-	5	805	10.06%

3 \*Where number of studies across rows do not add up (for example total number is different to number of studies in vaginal, abdominal and non-mesh combined)  
4 more than one arm may be split across surgery type

2 **Table 21: Rate of complications reported at 60 to 115 month follow up, calculated as weighted average (long-term, complications  
3 reported 60 to 115 months following surgery)**

Surgery classification	Total			Vaginal mesh surgery			Abdominal mesh surgery			Non-mesh surgery		
Complication	Number of Studies	Total number of women	Rate	Number of Studies	Total number of women	Rate	Number of Studies	Total number of women	Rate	Number of Studies	Total number of women	Rate
<b>Mesh erosion/exposure</b>	9	976	5.94%	5	537	8.75%	3	221	2.65%	-	-	-
<b>Dyspareunia</b>	9	1136	10.74%	6	787	12.07%	-	-	-	2	250	6.80%
<b>Pain</b>	5	729	4.25%	5	7.29	4.25%	-	-	-	-	-	-
<b>SUI</b>	6	866	11.32%	3	532	8.83%	-	-	-	2	235	8.09%
<b>Urge incontinence</b>	5	758	21.55%	3	532	25.19%	-	-	-	-	-	-
<b>Voiding difficulties</b>	1	99	11.11%	-	-	-	-	-	-	-	-	-
<b>Constipation</b>	6	824	17.45%	3	532	18.61%	-	-	-	-	-	-
<b>Faecal incontinence</b>	2	257	9.73%	-	-	-	-	-	-	-	-	-
<b>Recurrence of POP</b>	10	1408	8.59%	4	527	9.49%	-	-	-	3	438	9.13%

**1 Clinical evidence profile for the network meta-analysis (NMA) outcome**

**2 Recurrence of anterior pelvic organ prolapse**

3 Twenty-seven studies of 8 treatments were included in the network for recurrence of pelvic  
4 organ prolapse with a total sample size of 3,194 women (Figure 1).

5 Of the included studies in the NMA:

- 6 • One study was at high risk, 7 at unclear risk, and 19 at low risk of selection bias (random  
7 sequence generation);
- 8 • One study was at high risk, 7 at unclear risk, and 19 at low risk of selection bias  
9 (allocation concealment);
- 10 • Fourteen studies were at high risk, 12 studies at unclear risk, and 1 study at low risk of  
11 performance bias (participant and treatment administrator blinding);
- 12 • Six studies were at high risk, 12 studies at unclear risk, and 9 studies at low risk of  
13 detection bias (blinding of outcome assessors);
- 14 • Ten studies were at high risk and 17 studies at high risk of attrition bias (incomplete  
15 outcome data);
- 16 • One study was at high risk, 7 studies were at unclear risk, and 19 studies at low risk of  
17 reporting bias (selective reporting);
- 18 • Four studies were at high risk, 6 studies were at unclear risk, and 17 studies at low risk of  
19 other biases.

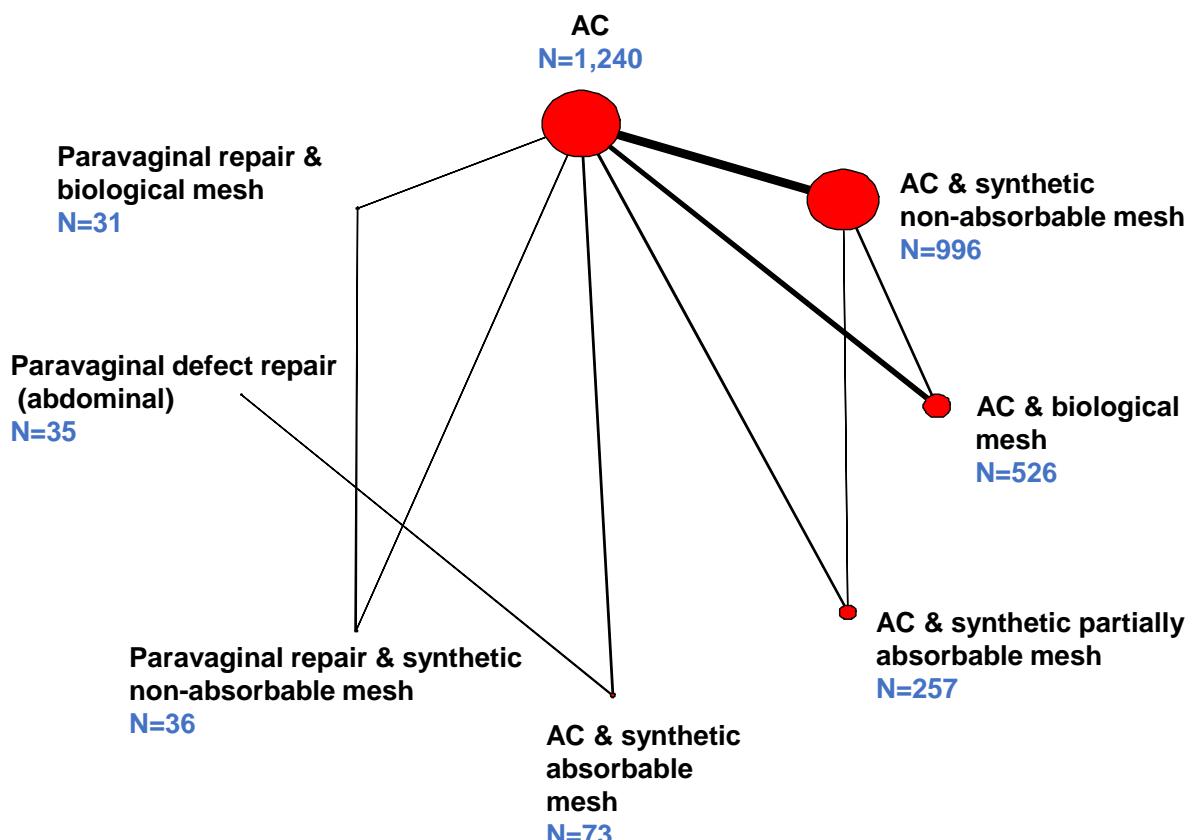
20 Risk of bias graph and summary are presented in Figure 2 and Figure 3, respectively.

21

22

23

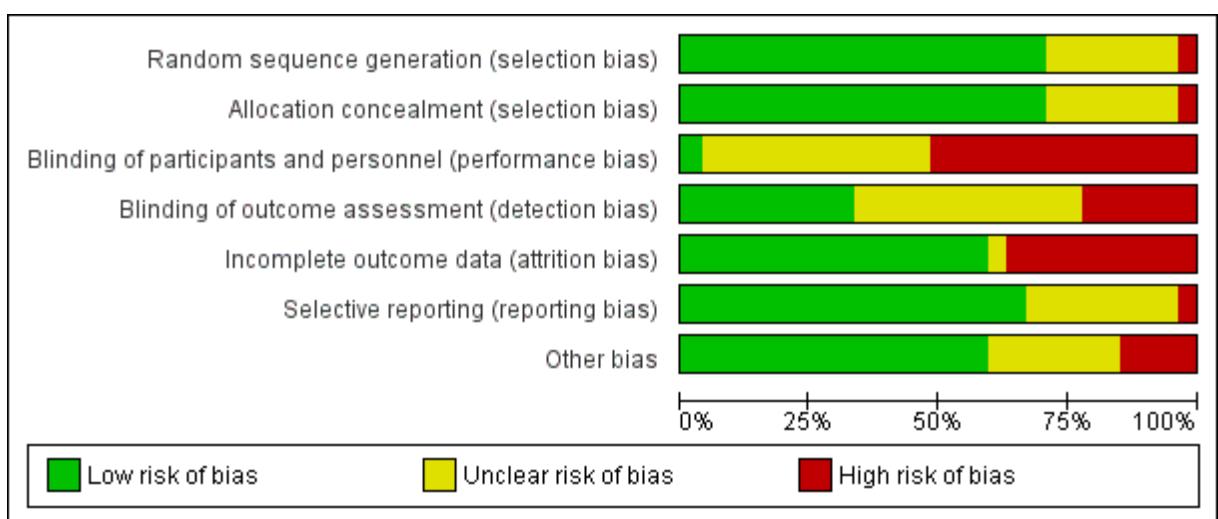
1 **Figure 1: Network for recurrence of anterior pelvic organ prolapse**



2

3 Note: The size of nodes is proportional to the number of women in the network who were randomised to a  
4 particular surgical procedure. The thickness of connecting lines is proportional to the number of studies  
5 directly comparing 2 surgical procedures.

6 **Figure 2: Risk of bias graph: review authors' judgement about each risk of bias item  
7 presented as percentages across all included studies in the NMA.**



8  
9

1   **Figure 3: Risk of bias summary: review authors' judgement about each risk of bias**  
 2   **item for each included study in the NMA.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Delroy 2013	+	+	-	?	?	?	?
deTayrac 2013	?	?	-	?	-	+	-
Dias 2016	+	+	-	?	-	+	?
El Nazeer 2012	+	+	?	+	+	?	+
Farthmann 2013	+	?	-	-	+	+	-
Feldner 2010	+	+	-	+	+	+	+
Gandhi 2005	+	+	-	-	+	+	?
Glazener 2017 (a)	+	+	-	+	+	+	+
Glazener 2017 (b)	+	+	-	+	+	+	+
Guerette 2009	+	+	-	-	-	+	+
Gupta 2014	?	?	?	?	-	-	+
Hiltunen 2007	+	+	?	?	+	+	+
Hvild 2010	+	+	?	?	+	?	?
Lyer 2018	+	+	-	+	-	?	-
Menefee 2011	+	+	?	+	-	+	+
Meschia 2007	?	+	?	?	+	+	+
Minassian 2014	+	+	-	-	-	+	+
Natale 2009	+	?	?	?	+	+	?
Nguyen 2008	+	+	?	+	+	?	-
Robert 2014	+	?	+	+	+	+	+
Rudnicki 2014	?	+	?	-	-	?	+
Sivaslioglu 2008	?	?	?	?	+	+	?
Tamanini 2015	-	-	-	-	-	?	+
Turgal 2013	+	?	?	?	+	+	+
Vollebregt 2011	?	+	-	+	+	+	+
Weber 2001	+	+	-	?	-	?	?
Yuk 2012	?	+	?	?	+	+	+

3

- 1 Table 22 presents direct estimates of pairwise comparisons when available (upper right section  
2 of table), together with the NMA estimates for every possible treatment comparison (lower left  
3 section of table), presented as posterior median hazard ratios (HRs) and 95% credible intervals  
4 (CrI). The direct estimates were obtained from a random unrelated mean effects model, while  
5 the NMA estimates were obtained from a random effects model. For the description of the  
6 unrelated mean effects model see appendix S.
- 7 The committee made an a priori assumption that there would need to be at least 100 women  
8 randomised to a surgical procedure across all included trials in the NMA for them to make a  
9 recommendation with confidence on that surgical procedure

2 **Table 22: Matrix of direct and NMA estimates of pairwise comparisons in terms of recurrence of anterior pelvic organ prolapse (HRs and  
3 95% Crl)**

<b>Paravaginal repair &amp; biological mesh</b>	-	-	-	-	-	-	-	0.84 (0.17, 4.22)
0.72 (0.05, 9.90)	<b>Paravaginal defect repair (abdominal)</b>	-	-	-	-	-	-	-
3.44 (0.66, 19.17)	4.79 (0.32, 73.79)	<b>Paravaginal repair &amp; synthetic non-absorbable mesh</b>	-	-	-	-	-	0.25 (0.04, 1.37)
0.95 (0.12, 7.42)	1.31 (0.27, 6.58)	0.28 (0.03, 2.41)	<b>AC &amp; synthetic absorbable mesh</b>	-	-	-	-	0.88 (0.20, 3.96)
3.17 (0.56, 18.37)	4.36 (0.45, 44.13)	0.92 (0.14, 5.99)	3.31 (0.67, 17.30)	<b>AC &amp; synthetic partially absorbable mesh</b>	-	-	0.82 (0.17, 4.01)	<b>0.25 (0.08, 0.72)</b>
1.91 (0.39, 9.68)	2.66 (0.30, 24.16)	0.56 (0.09, 3.15)	2.01 (0.46, 8.98)	0.61 (0.22, 1.63)	<b>AC &amp; biological mesh</b>	0.85 (0.27, 2.46)	-	<b>0.48 (0.26, 0.89)</b>
2.19 (0.46, 10.88)	3.04 (0.35, 27.35)	0.64 (0.11, 3.58)	2.31 (0.55, 10.13)	0.70 (0.28, 1.71)	1.15 (0.63, 2.13)	<b>AC &amp; synthetic non-absorbable mesh</b>	<b>0.36 (0.20, 0.60)</b>	-
0.84 (0.18, 3.82)	1.17 (0.14, 9.80)	0.25 (0.04, 1.26)	0.89 (0.22, 3.52)	<b>0.27 (0.11, 0.62)</b>	<b>0.44 (0.26, 0.73)</b>	<b>0.38 (0.24, 0.59)</b>	<b>AC</b>	-

4 AC: anterior colporrhaphy; Crl: credible intervals; HR: Hazard ratio; NMA: network meta-analysis

5 Note: Lower diagonal: Posterior median HRs and 95% Crls from NMA. HRs lower than 1 favour the column defining treatment, HRs higher than 1 favour the row defining  
6 treatment. Upper diagonal: HR and 95% CIs from direct pairwise MA. HRs lower than 1 favour the row defining treatment, HRs higher than 1 favour the column defining treatment.

1 **Table 23: Probabilities of being the best surgical procedure and the rank and 95% CrI**

Surgical procedure	Number of women	Number of studies	Probability of being best	Median (95% CrI) treatment rank
AC	1240	22	0.00	7 (5, 8)
AC & synthetic non-absorbable mesh	996	15	0.05	3 (1, 6)
AC & biological mesh	526	10	0.03	4 (1, 6)
AC & synthetic partially absorbable mesh	257	3	0.37	2 (1, 5)
AC & synthetic absorbable mesh	73	2	0.02	6 (2, 8)
Paravaginal repair & synthetic non-absorbable mesh	36	1	0.48	2 (1, 7)
Paravaginal defect repair (abdominal)	35	1	0.05	7 (1, 8)
Paravaginal repair & biological mesh	31	1	0.02	6 (2, 8)

2 AC: anterior colporrhaphy; CrI: Credible intervals

3 Although paravaginal repair & synthetic non-absorbable mesh had a 48% probability of being  
4 the best treatment (Table 23) for reducing the risk of recurrence of anterior pelvic organ  
5 prolapse, the results were based on very small numbers and this is reflected in the 95% CrI  
6 of the hazard ratio compared to AC ( $HR = 0.25$ , 95% CrI =  $0.04 - 1.26$ ). AC & synthetic  
7 partially absorbable mesh had the next highest probability of being best (37%) and there was  
8 evidence to suggest that it reduced the risk of recurrence compared to AC and this is  
9 reflected in the 95% CrI of the hazard ratio compared to AC ( $HR = 0.27$ , 95% CrI =  $0.11 -$   
10  $0.62$ ). Both paravaginal repair & synthetic non-absorbable mesh and AC & synthetic partially  
11 absorbable mesh had the highest median rank (2), although there was more certainty in the  
12 latter's rank (Table 23).

13 There was evidence that AC & synthetic partially absorbable mesh, AC & synthetic non-  
14 absorbable mesh, and AC & biological mesh resulted in the reduction in the risk of  
15 recurrence when compared with AC and the 95% CrIs excluded the possibility of no effect  
16 (Table 22). However, there was evidence of no difference between these surgical  
17 procedures. Also, AC & synthetic partially absorbable mesh was associated with a much  
18 higher probability of being best and median rank when compared with AC & synthetic non-  
19 absorbable mesh and AC & biological mesh (Table 23).

20 Paravaginal repair & biological mesh and AC & synthetic absorbable mesh appear to be  
21 more likely to reduce the risk of recurrence compared to AC, but there is not enough  
22 evidence to infer the direction of effect with certainty (Table 22). Also, paravaginal defect  
23 repair (abdominal) appears to be more likely to increase the risk of recurrence compared to  
24 AC, but there is not enough evidence to infer the direction of effect with certainty (Table 22).

25 The inconsistency checks did not identify any evidence of inconsistency between direct and  
26 indirect evidence included in the network meta-analysis for recurrence of anterior pelvic  
27 organ prolapse (appendix S).

## 1 Economic evidence

### 2 Included studies

3 The systematic search of the economic literature undertaken for the guideline identified 3  
4 studies examining the costs or cost-effectiveness of surgical management options (including  
5 mesh and non-mesh procedures) for anterior and/or posterior pelvic organ prolapse. Out of  
6 these:

- 7 • One UK study on the cost-utility of standard repair, synthetic mesh, and biological graft in  
8 women with anterior and/or posterior pelvic organ prolapse (Glazener 2016);
- 9 • One UK study on the cost-utility of mesh versus non-mesh repair in women with anterior  
10 pelvic organ prolapse (Jacklin 2013);
- 11 • One USA study examining the costs associated with anterior colporrhaphy, hand-cut  
12 mesh, and mesh kit in women with anterior pelvic organ prolapse (Murray 2011).

13 The systematic search of the economic literature identified 12 further studies examining the  
14 costs or cost-effectiveness of surgical management options (including mesh and non-mesh  
15 procedures) for apical pelvic organ prolapse. Out of these:

- 16 • One USA study on the cost-minimisation of robotic-assisted, laparoscopic, and abdominal  
17 sacrocolpopexy in women with advanced pelvic organ prolapse (Judd 2010);
- 18 • One USA study on the cost-utility of laparoscopic compared with robotic sacrocolpopexy  
19 in women with symptomatic apical pelvic organ prolapse (Anger 2014);
- 20 • One USA study on the cost-effectiveness of robotic laparoscopic sacrocolpopexy  
21 compared with laparoscopic sacrocolpopexy in women with vaginal apex prolapse  
22 (Paraiso 2011);
- 23 • One USA study examining the costs associated with abdominal open compared with  
24 robotic sacrocolpopexy in women with apical vaginal vault prolapse (Elliot 2012);
- 25 • One USA study on the cost-minimisation of abdominal open compared with robotic  
26 sacrocolpopexy in women with apical prolapse (Hoyle 2012);
- 27 • One USA study examining the costs associated with sacrospinous fixation (SSF)  
28 compared with abdominal sacrocolpopexy (ASC) and laparoscopic sacrocolpopexy (LSC)  
29 (Lua 2017);
- 30 • One USA study on the cost-utility of abdominal sacral colpopexy compared with  
31 sacrospinous ligament fixation in women with apical prolapse (Ohno 2016);
- 32 • One Spanish study examining the costs associated with laparoscopic sacral colpopexy  
33 (LS) compared with vaginal mesh (VM) in women with uterovaginal prolapse (Carracedo  
34 2017);
- 35 • One USA study on the cost-utility of vaginal mesh hysteropexy compared with robotic  
36 sacrocolpopexy in women with uterovaginal pelvic organ prolapse (Culligan 2013);
- 37 • One USA study that assessed the costs associated with robotic sacrocolpopexy  
38 compared with transvaginal mesh repair in women who require surgical repair of pelvic  
39 organ prolapse (Ehlert 2016);
- 40 • One Australian study on the cost-minimisation of laparoscopic sacral colpopexy (LSC)  
41 compared with total vaginal mesh (TVM) in women with vaginal vault prolapse (Maher  
42 2012);
- 43 • One Danish study that assessed the costs associated with Manchester–Fothergill  
44 procedure compared with uterosacral ligament suspension (with vaginal hysterectomy) in  
45 women with apical prolapse (Husby 2018).

46 Evidence tables for all economic evaluations included in the systematic literature review are  
47 provided in appendix H. Completed methodology checklists of the studies are provided in  
48 appendix M. Economic evidence profiles of studies considered during guideline development

1 (that is, studies that fully or partly met the applicability and quality criteria) are presented in  
2 appendix I.

3 **Excluded studies**

4 Studies excluded from the review and reasons for their exclusion are provided in appendix K.

5 **Summary of studies included in the economic evidence review**

6 ***Anterior and/or posterior pelvic organ prolapse***

7 **Glazener 2016**

8 Glazener (2016) evaluated the cost-utility of surgical options for the management of anterior  
9 and/or posterior vaginal wall prolapse in the UK. The economic analysis was conducted  
10 alongside RCTs and supplemented with modelling.

11 The first analysis was conducted alongside an RCT in women who were having their first  
12 anterior or posterior prolapse repair (n=1,348 randomised). The interventions included  
13 standard repair, synthetic mesh, and biological graft. The second analysis was conducted  
14 alongside an RCT in women who were having their secondary anterior or posterior prolapse  
15 repair (n=154 randomised).

16 The analysis was conducted from NHS perspective and included a range of direct health  
17 care costs including intervention procedure costs (mesh cost, staff time in theatre, cost of  
18 drugs in theatre, cost of catheterisation, cost of vaginal packing, theatre overheads), inpatient  
19 and follow-up secondary care costs (including new prolapse and incontinence procedures,  
20 other related readmissions, further prolapse related surgery, outpatient visits) and costs of  
21 primary care services relating to the index prolapse surgery (including physiotherapy, GP  
22 nurse, GP doctor, shelf pessary, ring pessary, incontinence drugs, oestrogen, intermittent  
23 catheter, absorbent pads, other drug treatments).

24 The supplementary analysis was undertaken and incorporated out of pocket expenses and  
25 productivity losses (that is, participant travel costs, opportunity costs of time for participants  
26 and companions spent attending appointments, self-purchased health care and time off work  
27 as a result of prolapse symptoms).

28 The resource use estimates were based on the RCTs. The unit costs were obtained from  
29 national sources and manufacturer price lists (cost of devices).

30 The measures of outcome for the economic analysis was QALYs with utility weights based  
31 on EQ-5D-3L, the UK population tariff. The time horizon of the main analysis was up to 2  
32 years. The results are reported using complete case data and also using imputed data for the  
33 missing values. Incremental costs and outcomes were adjusted for covariates including age  
34 group, type of prolapse, concomitant continence procedure and concomitant upper  
35 compartment prolapse surgery, as well as surgeon and baseline EQ-5D-3L score.

36 For the primary repair analysis Markov modelling was undertaken to model costs and  
37 outcomes beyond the trial follow-up (that is, over the 5 year follow-up).

38 In the model all women start in the primary prolapse repair state. After surgery they may  
39 enter the 'post-prolapse surgery' health state (defined as women who are not experiencing  
40 serious complications or requiring repeat prolapse surgery). Within this health state, some  
41 women will still experience some prolapse-related symptoms or other (non-serious)  
42 complications and may receive treatments for this, including physiotherapy or oestrogen  
43 treatments. Others will not require any further treatment and are considered stable. Women  
44 might stay in this state for the duration of the model (if they do not experience serious  
45 complications or require repeat prolapse surgery). At the end of each monthly cycle, they

1 may transition from this state if they have serious complications, require further prolapse  
2 surgery or die. Within the model women may suffer serious complications at any point  
3 following their surgery. If a woman experiences serious complications, she enters the serious  
4 complications health state and receives treatment. Serious complications modelled included  
5 mesh or non-mesh related, and some required surgical management. A woman who is  
6 experiencing serious complications might have these resolved during a single monthly cycle  
7 or might require to remain in the health state for a longer time period until the complications  
8 resolve. Within a model women might suffer a recurrence of their prolapse, which requires  
9 further repeat prolapse surgery at any time. Women who experience failures that are not  
10 requiring surgery remain in the post-prolapse surgery health state. Women who were having  
11 a failure requiring surgery enter the second surgery health state, for which they go through a  
12 similar model process as those following their first repair. The model also incorporated the  
13 death state that considers all-cause mortality. All costs and outcomes beyond 1 year of  
14 follow-up are discounted at a rate of 3.5%.

15 *Primary anterior and/or posterior repair*

16 Using the complete case data (n=581) at 1 year follow-up the standard repair resulted in  
17 0.790 (SD: 0.236) QALYs, synthetic mesh 0.808 (SD: 0.174), and biological graft in 0.781  
18 (SD: 0.231) QALYs. From an NHS perspective the mean total costs per participant over 1  
19 year were £3,216 (SD: £1,301) for the standard repair, £3,698 (SD: £1,387) for the synthetic  
20 mesh, and £3,823 (SD: £1,500) for the biological graft, in 2013/14 prices. Synthetic mesh  
21 when compared with standard repair resulted in the adjusted incremental QALYs of 0.012  
22 (95% CI: -0.021 to 0.044) and adjusted incremental costs of £429 (95% CI £161 to £697).  
23 Based on the above costs and outcomes, the biological graft was dominated by both  
24 standard repair and synthetic mesh (that is, standard repair and synthetic mesh resulted in  
25 higher QALYs and lower costs). The incremental cost-effectiveness ratio (ICER) of synthetic  
26 mesh when compared with standard repair was £35,750 per additional QALY gained. At  
27 NICE's lower and upper threshold values of £20,000 and £30,000 per QALY gained the  
28 probability of standard repair being cost effective was 0.70 and 0.57, respectively; the  
29 probability of synthetic mesh being cost-effective was 0.29 and 0.40; and the probability of  
30 biological graft being cost-effective was 0.02 and 0.04. Overall, the data do not allow to draw  
31 clear conclusions on the cost-effectiveness at 1 year follow-up.

32 Using the complete case data (n=503) at 2 year follow-up the standard repair resulted in  
33 1.569 (SD: 0.502) QALYs, synthetic mesh 1.643 (SD: 0.304), and biological graft in 1.582  
34 (SD: 0.455) QALYs. From an NHS perspective the mean total costs per participant over 2  
35 years were £3,664 (SD: £1,777) for the standard repair, £4,081 (SD: £1,762) for the synthetic  
36 mesh, and £4,165 (SD: £1,691) for the biological graft. Synthetic mesh when compared with  
37 standard repair resulted in the adjusted incremental QALYs of 0.075 (95% CI: 0.000 to  
38 0.150) and adjusted incremental costs of £337 (95% CI -£73 to £747). Based on the above  
39 costs and outcomes, the biological graft was dominated by synthetic mesh (that is, synthetic  
40 mesh resulted in higher QALYs and lower costs). The ICER of synthetic mesh when  
41 compared with standard repair was £4,493 per QALY. At NICE's lower and upper threshold  
42 values of £20,000 and £30,000 per QALY gained the probability of standard repair being  
43 cost-effective was 0.08 and 0.05, respectively; the probability of synthetic mesh being cost-  
44 effective was 0.83 and 0.84; and the probability of biological graft being cost-effective was  
45 0.10 and 0.12.

46 Using a wider economic perspective (NHS plus indirect costs) and complete case data at 2  
47 year follow-up the mean total costs per participant over 2 years were £5,479 (SD: £6,026) for  
48 the standard repair, £5,740 (SD: £4,657) for the synthetic mesh, and £5,813 (SD: £4,582) for  
49 the biological graft. Synthetic mesh when compared with a standard repair resulted in an  
50 incremental adjusted QALY gain of 0.075 (95% CI: 0.000 to 0.150) and incremental adjusted  
51 costs of -£26 (95% CI: -£1,302 to £1,250) and was found to be the dominant treatment.  
52 Biological graft resulted in higher costs and lower QALYs when compared with synthetic  
53 mesh. At NICE's lower and upper threshold values of £20,000 and £30,000 per QALY gained

the probability of standard repair being cost-effective was 0.07 and 0.04, respectively; the probability of synthetic mesh being cost-effective was 0.82 and 0.84; and the probability of biological graft being cost-effective was 0.11 and 0.11.

Using the imputed data set (n=1,941) at 2 years the standard repair resulted in 1.559 (SD: 0.297) QALYs, synthetic mesh 1.555 (SD: 0.297), and biological graft in 1.554 (SD: 0.297) QALYs. From an NHS perspective the mean total costs per participant over 2 years were £3,570 (SD: £468) for the standard repair, £3,889 (SD: £468) for the synthetic mesh, and £4,098 (SD: £468) for the biological graft. Based on the above costs and outcomes, both synthetic mesh and biological graft were dominated by standard repair (that is, standard repair resulted in higher QALYs and lower cost). At NICE's lower and upper threshold values of £20,000 and £30,000 per QALY gained the probability of standard repair being cost-effective was 0.57 and 0.52, respectively; the probability of synthetic mesh being cost-effective was 0.28 and 0.29; and the probability of biological graft being cost-effective was 0.16 and 0.20.

According to the economic modelling at 5 years the standard repair resulted in 3.753 QALYs, synthetic mesh 3.748, and biological graft in 3.749 QALYs. From an NHS perspective the expected mean total costs per participant over 5 years were £4,811 for the standard repair, £5,264 for the synthetic mesh, and £5,304 for the biological graft. Based on the above costs and outcomes, both synthetic mesh and biological graft were dominated by standard repair (that is, standard repair resulted in higher QALYs and lower cost). The probability of standard repair being cost effective was 50% at any willingness-to-pay (WTP) value per QALY gained. According to the deterministic sensitivity analysis only when using treatment specific utilities synthetic mesh was the preferred treatment with an ICER of £5,933 (versus standard repair) and it also had a highest probability of being cost-effective. Extending the time horizon to 10 and 30 years resulted in standard repair being the preferred treatment.

The authors concluded that there was no clear evidence of the most cost-effective treatment strategy for the primary prolapse repair.

#### *Secondary repair anterior and/or posterior repair*

Using the complete case data (n=124) at 1 year follow-up the standard repair resulted in 0.728 (SD: 0.272) QALYs, synthetic mesh inlay 0.816 (SD: 0.148), and mesh kits in 0.764 (SD: 0.191) QALYs. From an NHS perspective the mean total costs per participant over 1 year were £3,454 (SD: £1,639) for the standard repair, £3,734 (SD: £1,808) for the synthetic mesh inlay, and £4,165 (SD: £1,386) for the biological graft, in 2013/14 prices. Synthetic mesh inlay (versus standard repair) resulted in the adjusted incremental QALYs of 0.007 (95% CI: -0.060 to 0.074) and adjusted incremental costs of £471 (95% CI -£404 to £1,346). Based on the above costs and outcomes, the mesh kit was dominated by mesh inlay (that is, mesh inlay resulted in higher QALYs and lower costs). The ICER of synthetic mesh inlay (versus standard repair) was £67,286 per QALY gained. At NICE's lower and upper threshold values of £20,000 and £30,000 per QALY gained the probability of standard repair being cost-effective was 0.64 and 0.55, respectively; the probability of synthetic mesh inlay being cost-effective was 0.33 and 0.39; and the probability of mesh kit being cost-effective was 0.04 and 0.06.

Using the complete case data (n=104) at 2 year follow-up the standard repair resulted in 1.486 (SD: 0.493) QALYs, synthetic mesh inlay 1.600 (SD: 0.335), and mesh kit in 1.614 (SD: 0.306) QALYs. From an NHS perspective the mean total costs per participant over 2 years were £3,883 (SD: £2,127) for the standard repair, £4,133 (SD: £2,153) for the synthetic mesh inlay, and £4,528 (SD: £1,721) for the mesh kit, in 2013/14 prices. Mesh inlay when compared with standard repair resulted in the adjusted incremental QALYs of -0.023 (95% CI: -0.163 to 0.118) and adjusted incremental costs of £236 (95% CI -£1,091 to £1,564). Mesh kit when compared with standard repair resulted in the adjusted incremental QALYs of 0.050 (95% CI: -0.085 to 0.185) and adjusted incremental costs of £542 (95% CI -£309 to £1,592). Based on the above costs and outcomes, mesh inlay was dominated (that is,

standard repair resulted in higher QALYs and lower costs). The ICER of mesh kit (versus standard repair) was £12,840 per QALY. At NICE's lower and upper threshold values of £20,000 and £30,000 per QALY gained the probability of standard repair being cost-effective was 0.36 and 0.32, respectively; the probability of synthetic mesh inlay being cost-effective was 0.21 and 0.19; and the probability of mesh kit being cost-effective was 0.44 and 0.49.

Using the complete case data (n=104) at 2 year follow-up and a wider economic perspective (NHS plus indirect costs) the standard repair resulted in 1.486 (SD: 0.493) QALYs, synthetic mesh inlay 1.600 (SD: 0.335), and mesh kit in 1.614 (SD: 0.306) QALYs. The mean total costs per participant over 2 years were £3,883 (SD: £2,127) for the standard repair, £4,133 (SD: £2,153) for the synthetic mesh inlay, and £4,528 (SD: £1,721) for the mesh kit, in 2013/14 prices. Synthetic mesh inlay was dominated (that is, standard repair resulted in higher QALYs and lower costs). Mesh kit when compared with standard repair resulted in the adjusted incremental QALYs of 0.050 (95% CI: -0.085 to 0.185) and adjusted incremental costs of £293 (95% CI -£1,839 to £2,426). Based on the above costs and outcomes, the ICER of mesh kit (versus standard repair) was £5,860 per QALY gained. At NICE's lower and upper threshold values of £20,000 and £30,000 per QALY gained the probability of standard repair being cost-effective was 0.35 and 0.33, respectively; the probability of synthetic mesh inlay being cost-effective was 0.11 and 0.11; and the probability of mesh kit being cost-effective was 0.54 and 0.56.

There was no clear evidence of the most cost-effective treatment strategy for the secondary prolapse repair.

The analysis was directly applicable to the NICE decision-making context and had minor methodological limitations.

#### 24 **Jacklin 2013**

Jacklin (2013) evaluated the cost-utility of anterior repair augmented with synthetic mesh compared with non-mesh repair in the UK. The study population comprised of women with prolapse of vaginal wall. This was a modelling study (Markov decision model) with efficacy based on authors' assumptions informed by published sources including RCTs, systematic reviews, and observational cohort studies. The health states in this model included the initial primary surgical procedure, a post-surgery state free of symptomatic vaginal wall prolapse and a state where recurrent prolapse has occurred, requiring revision surgery. Only one revision surgery was modelled. The analysis was conducted from the UK's NHS perspective. The study considered a range of direct health care costs including costs associated with standard and mesh anterior wall repair, mesh revision surgery, and the management of mesh complications. The costs were obtained from national sources and where necessary were supplemented with data from other published sources (for example, cost of a mesh kit). The measure of outcome for the economic analysis was QALYs with a utility loss arising from POP approximated using published evidence on the health state utility loss arising from urinary incontinence. It hasn't considered QALY losses arising from different complications due to the lack of suitable data. The time horizon of the main analysis was 5 years. Costs and outcomes occurring after the first year were both discounted at an annual rate of 3.5%.

Mesh resulted in slightly higher QALYs at 5 years when compared with non-mesh procedure (0.27465 versus 0.27455, respectively; the difference of 0.0001). The mean total costs per woman over 5 years were £4,146 for the mesh procedure and £2,607 for the non-mesh procedure, the difference of £1,539 in 2008/09 prices. Based on the above costs and outcomes the ICER of mesh procedure (versus non-mesh procedure) was £15.0 million per QALY gained which is well above the upper NICE cost-effectiveness threshold of £30,000 per QALY.

A sensitivity analysis was conducted were costs and outcomes were modelled over 10 year follow-up. In this sensitivity analysis it was assumed that in women receiving mesh surgery no further recurrence will occur beyond 5 years and there will be no further mesh erosion

requiring repair beyond 5 years. However, in women having a non-mesh surgery, it was assumed that recurrence will reach 6% by year 10. At 10 year follow-up mesh procedure resulted in slightly higher QALYs when compared with non-mesh procedure (0.46473 versus 0.46462; the difference of 0.00011). The mean total costs per woman over 10 years were £4,197 and £2,649 for mesh and non-mesh procedure, respectively; the difference of £1,548. Based on the above costs and outcomes the ICER of mesh (versus non-mesh) procedure was £13.4 million per QALY gained which is still well above the upper NICE cost-effectiveness threshold of £30,000 per QALY.

A scenario analysis was undertaken where the model inputs were given an explicit bias in a direction that would challenge the base case result including the only additional cost of mesh surgery was the cost of the mesh itself; the recurrence with mesh surgery was halved for every time period and recurrence with non-mesh surgery was doubled at every time period; allowed for a 10-year follow-up (since this favoured mesh); doubled the complication rate in non-mesh surgery; halved the complication rate in mesh surgery; doubled the gain in health state utility from a successful surgery; doubled the health state utility loss from a complication and a much higher cost associated with complications was assumed; halved the rate of mesh complications for each time period and assumed that any such complication was only half as likely to require a revision. Even in this scenario the ICER of mesh (versus non-mesh) procedure was £104,276 per QALY gained which is well above the upper NICE cost-effectiveness threshold of £30,000 per QALY.

The analysis was directly applicable to the NICE decision-making context and had minor methodological limitations.

### Murray 2011

Murray (2011) evaluated the costs associated with traditional anterior colporrhaphy (AC), hand-cut mesh, and mesh kit in women requiring anterior vaginal prolapse repair in the USA. This was a cost analysis based on modelling. The analysis was conducted from a health care perspective. The model considered costs associated with the initial surgical procedures (hospital stay, mesh supply), complication management (outpatient care, hospital stay), and recurrence management (outpatient care, hospital stay). The resource use estimates were based on the review of RCTs with some resource use data including mesh excision operating time obtained from a single centre. The unit costs were obtained from local and national sources. The time horizon of the analysis was 17 months. The expected mean costs were \$3,380 for non-kit mesh repair, \$3,461 for AC, and \$4,678 for mesh kit. Hand cut mesh resulted in the cost savings of \$81 and \$1,298 when compared with AC and mesh kit, respectively.

According to the one-way sensitivity analyses the recurrence rate of AC would need to be 28% (base case 30%) for AC to be cost equivalent with non-kit mesh repair. Non-kit mesh cost must remain below \$480 (base case \$400) for it to remain cost saving when compared with AC. Mesh kit repair did not reach a cost-equivalence even at an operating time of zero minutes.

Two-way sensitivity analysis comparing mesh extrusion and AC recurrence demonstrated that if the recurrence rate of traditional repair is below 20% (base case 30%), AC is a cost saving procedure even if the extrusion rate for mesh repair is 0% (base case 12%). When the recurrence rate for AC is 30% (base case 30%), non-kit mesh repair is a cost saving only if the extrusion rate is less than 25% (base case 12%). If the recurrence rate is 50% for AC, then hand-cut mesh is a cost saving procedure even with a 50% extrusion rate (base case 12%).

The analysis was partially applicable to the NICE decision-making context and had potentially serious methodological limitations.

1 **Apical pelvic organ prolapse**

2 **Judd 2010**

3 Judd (2010) conducted cost-minimisation analysis of robotic-assisted, laparoscopic, and  
4 abdominal sacrocolpopexy in women with POP in the USA. The authors assumed that all  
5 three surgical techniques were equally effective in the treatment of advanced prolapse. This  
6 was a modelling study (decision tree model). The study population comprised of a  
7 hypothetical cohort of women with advanced pelvic organ prolapse who have elected to  
8 undergo surgical repair with sacrocolpopexy with synthetic polypropylene mesh. In a model  
9 for the robotic-assisted and laparoscopic surgery the possibility of early and late switching to  
10 abdominal procedure was included. Early switching was defined as switching occurring before  
11 robot docking or during the diagnostic portion of the case in the laparoscopic procedure. Late  
12 switching was defined as switching once hysterectomy or sacrocolpopexy was under way. In  
13 the model, for each surgical procedure following switching or no switching a woman may or  
14 may not require blood transfusion. The analysis was conducted from a health care  
15 perspective. The study considered a range of direct health care costs including anaesthesia,  
16 physician, operating room, disposable equipment, postanaesthesia care unit, and room and  
17 board for the duration of hospital stay, medication, and laboratory tests. Switching costs were  
18 also included and late switching costs comprised of the full cost of the current surgical  
19 approach along with the cost of the additional time required for switching. Early conversion  
20 costs comprised of the abdominal surgery costs with an additional operative time required for  
21 the initial laparoscopic portion of the procedure and time to convert. The clinical model input  
22 parameters including operative time, risk of switching, risk of blood transfusion, and length of  
23 stay were obtained from a review of observational studies. The source of resource use data  
24 and unit costs was unclear. However, it seems that most of the resource use data was  
25 derived from authors' institution (that is, a medical centre) and the unit cost data was  
26 obtained from a mix of local and national sources (that is, Medicare reimbursement rates and  
27 hospital billings). The time horizon was unclear. However, it seems to be the immediate post-  
28 operative period. The results were reported assuming that robotic surgical equipment were  
29 already present and also assuming that any new equipment will need to be acquired (that is,  
30 considered the robotic equipment acquisition and maintenance costs).

31 Assuming that all surgical equipment were already present the mean total costs per  
32 procedure were \$8,508 for the robotic-assisted sacrocolpopexy, \$7,353 for the laparoscopic  
33 sacrocolpopexy, and \$5,792 for the abdominal sacrocolpopexy in 2008 USA dollars.

34 Sensitivity analyses indicated that the cost equivalence between the robotic-assisted  
35 sacrocolpopexy and the laparoscopic sacrocolpopexy was achieved only when mean  
36 operative time was 149 minutes (base case: 328 minutes) for robotic procedure and it  
37 remained at the base case value of 269 minutes for laparoscopic procedure. In a further  
38 sensitivity analysis where robotic disposable costs were reduced to less than \$2,132 (base-  
39 case: \$3,293) and laparoscopic disposable costs were increased to more than \$3,413 (base-  
40 case: \$2,244) robotic-assisted sacrocolpopexy became less costly when compared with  
41 laparoscopic sacrocolpopexy. Varying other model inputs including the length of stay, the risk  
42 of switching, the risk of transfusion, anaesthesia costs, surgeon fees, postanaesthesia costs,  
43 hospital room and board costs, medication costs, and laboratory costs failed to make the  
44 robotic-assisted approach less costly when compared with the laparoscopic approach.

45 In the sensitivity analysis comparing the laparoscopic approach with abdominal approach,  
46 laparoscopic approach remained more expensive in the most analyses explored. The  
47 laparoscopic sacrocolpopexy became the least expensive option only when (1) the mean  
48 length of stay for the abdominal approach was increased to more than 5.6 days (base case:  
49 2.7 days) and laparoscopic approach remained at 1.8 days, (2) when the surgeon costs for  
50 the abdominal approach was increased to as much as \$2,213 (base case: \$638), (3) and  
51 when disposable equipment costs for the laparoscopic approach were lowered to less than

1 \$668 (base case: \$1,677 and \$2,244 for early and late switching). In all other scenarios the  
2 abdominal approach remained the least costly option.

3 When including robot purchase costs, the mean costs per procedure were \$9,962 for robotic  
4 sacrocolpopexy, \$7,353 for laparoscopic procedure, \$5,792 for abdominal approach. In the  
5 base case analysis the number of procedures was assumed to be 24 per month. In the  
6 sensitivity analysis where the number of procedures per month were varied from 60 to 20  
7 procedures the robotic-assisted base case cost of \$8,508 increased by \$581-\$1,724 per  
8 procedure. The results of the sensitivity analyses where robotic and laparoscopic  
9 sacrocolpopexy was compared in no scenario the robotic approach was less costly when  
10 compared with the laparoscopic approach.

11 Based on the above cost estimates the abdominal approach is likely to be the least costly  
12 surgical procedure in women requiring surgical repair for pelvic organ prolapse.

13 The analysis was partially applicable to the NICE decision-making context and had minor  
14 methodological limitations.

## 15 **Anger 2014**

16 Anger (2014) evaluated the cost-utility of laparoscopic sacrocolpopexy compared with robotic  
17 sacrocolpopexy in women alongside an RCT (Anger 2014) (n=78) conducted in the USA.  
18 The study population comprised women with symptomatic stage POP II (POP-Q) or greater,  
19 including significant apical loss. Twenty-one women had previous POP surgery and 42% of  
20 women had prior hysterectomy. Concurrent procedures at surgery included hysterectomy  
21 (58%), retropubic midurethral sling (60%), and 6% anterior or posterior repair. The analysis  
22 was conducted from a health care payer perspective. The study considered a range of direct  
23 health care costs including hospital care, physician, robot and its maintenance, disposable  
24 instruments, and readmission. The resource use estimates were based on the RCT and  
25 other published sources. The source of unit costs was unclear, but seems to include local  
26 sources (for example, local facility cost to charge ratios, purchase price of robots at each  
27 facility). The measure of outcome for the economic analysis was QALYs with EQ-5D-3L, the  
28 USA population norms. The time horizon of the analysis was 6 weeks.

29 The robotic sacrocolpopexy resulted in fewer QALYs at 6 weeks when compared with  
30 laparoscopic sacrocolpopexy (0.098 [SD: 0.011] versus 0.101 [SD: 0.009], respectively; the  
31 difference of -0.003, p-value was not significant). The mean total costs per woman over 6  
32 weeks were \$20,898 (SD: \$3,386) for the robotic sacrocolpopexy and \$12,170 (SD: \$4,129)  
33 for the laparoscopic sacrocolpopexy, the difference of \$8,728 (p <0.001) in likely 2013 USA  
34 dollars. However, when the costs of robot purchase and maintenance were excluded the  
35 costs were reduced to \$12,170 (SD: \$64,129) and \$13,867 (SD: \$3,386) for the laparoscopic  
36 and robotic sacrocolpopexy, respectively; the difference of -\$1,697). However, this difference  
37 did not reach statistical significance. In both cases laparoscopic sacrocolpopexy was the  
38 dominant procedure when compared with robotic sacrocolpopexy (that is, laparoscopic  
39 sacrocolpopexy resulted in greater QALYs and lower costs).

40 The analysis was partially applicable to the NICE decision-making context and had  
41 potentially serious methodological limitations.

## 42 **Paraiso 2011**

43 Paraiso (2011) conducted the cost-minimisation analysis of laparoscopic compared with  
44 robotic-sacrocolpopexy in adult women with stage 2-4 vaginal apex prolapse alongside an  
45 RCT (Paraiso 2011) (n=68) conducted in the USA. The analysis was conducted from a  
46 health care payer perspective. The study considered a range of direct health care costs  
47 including costs associated with the surgical procedures, inpatient care and other surgery  
48 related outpatient care. The resource use estimates were based on the RCT. The source of  
49 unit costs was unclear. The primary measures of outcome utilised in the RCT were total  
50 operative time (from incision to the closure) and the rate of complications. It has also looked

1 at anatomical outcomes and QoL. The time horizon of the analysis was 6 weeks post-surgery  
2 for costs and 6 months and 1 year for outcomes. So in effect the authors assumed that there  
3 will be no difference in costs during the follow-up (that is, the costs are the same).

4 The RCT found no difference in effectiveness (complications, anatomical outcome, and QoL)  
5 between the two interventions. The mean total costs per participant over 6 weeks were  
6 \$16,278 (SD: \$3,326) and \$14,342 (SD: \$2,941) for robotic and laparoscopic  
7 sacrocolpopexy, respectively, a difference of \$1,936 (95% CI: \$417 to \$3,454); p=0.008 in  
8 2011 USA dollars. The laparoscopic sacrocolpopexy was the preferred treatment option on  
9 the basis of lower costs.

10 The analysis was partially applicable to the NICE decision-making context and had  
11 potentially serious methodological limitations.

## 12 **Elliot 2012**

13 Elliot (2012) performed the cost-minimisation analysis of abdominal open sacrocolpopexy  
14 compared with robot-assisted sacrocolpopexy in women with apical vaginal vault prolapse in  
15 the USA. The analysis was based on retrospective cohort study (n=59). A substantial  
16 proportion of women underwent concomitant procedures (43% versus 11% in robot assisted  
17 and open group, respectively; p = 0.031). Concomitant procedures included mid-urethral  
18 slings, mid-urethral slings and other prolapse repairs, prolapse only repair, hysterectomy,  
19 mid-urethral plus other repairs, and other repairs only. Other repairs included  
20 abdominoplasty, oophorectomy, suprapubic tube insertion, vaginal sinus tract excision, burch  
21 procedure and artificial urinary sphincter removal. The analysis was conducted from a health  
22 care payer perspective. The study considered a range of direct health care costs including  
23 operating room costs, anaesthetist, hospital stay, robot and disposable instruments,  
24 surgeon, mesh, and concomitant procedures. The resource use estimates were based on the  
25 observational cohort study. The unit costs were obtained from local and national sources.  
26 The time horizon of the analysis was 30 days.

27 The mean total costs per woman over 30 days were \$10,178 for the robot-assisted  
28 sacrocolpopexy and \$11,307 for abdominal open sacrocolpopexy; difference of \$1,129 in  
29 favour of the robot-assisted sacrocolpopexy (in 2008 USA dollars). According to deterministic  
30 sensitivity analyses the number of robotic cases done at an institution has the greatest  
31 impact on the costs of robot-assisted sacrocolpopexy. The next most important variables  
32 driving costs were cost per day of hospital stay, length of stay, operating room time and  
33 disposable costs.

34 The analysis was partially applicable to the NICE decision-making context and had  
35 potentially serious methodological limitations.

## 36 **Hoyte 2012**

37 Hoyte 2012 evaluated the costs of a robotic sacrocolpopexy compared with open  
38 sacrocolpopexy in women requiring prolapse repair surgery in the USA. The analysis was  
39 based on an observational cohort study (n=164). Study population comprised of women with  
40 a median preoperative prolapse stage III. Women with prolapses III-IV accounted for 79% of  
41 the open group and 76% of the robotic-assisted group. Women in the open had a median of  
42 1 prior open abdominal surgery, compared with 0 in the robotic group. Median prior  
43 laparoscopic abdominal surgeries was 0 in the open group versus 1 in the robotic group.  
44 There were 28% of women in the open group and 47% in the robotic group who underwent  
45 concurrent hysterectomy. Median added procedures (including hysterectomy, oophorectomy,  
46 rectopexy, and lysis of adhesions) were 2 in the robotic group and 2 in the open group. The  
47 analysis was conducted from a health care payer perspective. The study considered a range  
48 of direct health care costs including operating room costs, surgical supplies including mesh,  
49 supply distribution, pharmacy, anaesthesia, laboratory radiology, hospital stay. The resource  
50 use estimates were based on the observational study. The source of unit costs was unclear.

1 However, it is reported that costs were based on local procurement database implying that  
2 local unit costs were used. The time horizon of the analysis is unclear. However, it seems  
3 that only immediate postoperative period was considered (30 days post-surgery). The mean  
4 total costs per woman over 30 days were \$9,725 for the robotic sacrocolpopexy and \$11,214  
5 for open sacrocolpopexy, a difference of \$1,489 in favour of the robotic sacrocolpopexy ( $p =$   
6 0.001); in likely 2011 USA dollars.

7 The analysis was partially applicable to the NICE decision-making context and had  
8 potentially serious methodological limitations.

9 **Lua 2017**

10 Lua (2017) assessed the costs of sacrospinous ligament fixation (SSF), abdominal  
11 sacrocolpopexy (ASC), laparoscopic sacrocolpopexy (LSC) in women with apical prolapse in  
12 the USA. The analysis was conducted from a health care payer. The study considered a  
13 range of direct health care costs including intervention costs, inpatient readmissions,  
14 emergency room visits, and outpatient visits. The resource use estimates were based on the  
15 retrospective observational cohort study, commercial claims and encounter database (SSF  
16 [ $n=17,549$ ]; ASC [ $n= 6,126$ ]; LSC [ $n = 10,708$ ]). The source of unit costs was unclear.  
17 However, most likely unit costs were obtained national sources (national claims database).  
18 The time horizon of the analysis was 90 days.

19 The mean total costs per woman were \$13,916 for SSF, \$15,716 for ASC, and \$16,838 for  
20 LSC in likely 2016 USA dollars. The difference between ASC and SSF was \$1,800.69 (95%  
21 CI: \$1,476.50 to \$2,124.88),  $p < 0.0001$ . The difference between LSC versus SSF was  
22 \$2,922.03 (95% CI: \$2,648.56; \$3,195.50),  $p < 0.0001$  and the difference between LSC  
23 versus ASC was \$1,122,  $p$ -value was not reported. Based on the above cost estimates SSF  
24 was cost saving when compared with both ASC and LSC.

25 The analysis was partially applicable to the NICE decision-making context and had minor  
26 methodological limitations.

27 **Ohno 2016**

28 Ohno (2016) evaluated the cost-effectiveness of abdominal sacral colpopexy (ASC)  
29 compared with sacrospinous ligament fixation (SSLF) in women with apical prolapse in the  
30 USA. This was a modelling study with effectiveness data from systematic review and other  
31 published literature. The analysis was conducted from a health care payer perspective. In the  
32 decision tree model following the initial surgical treatment a women could develop post-  
33 operative dyspareunia, post-operative SUI, or recurrent prolapse. If a woman developed  
34 postoperative SUI she had the option of receiving a mid-urethral sling. Similarly, if a woman  
35 developed recurrent prolapse she had the option of re-operation.

36 The study considered a range of direct health care costs including intervention costs  
37 including ASC, SSLF, mid-urethral sling (in outpatient setting); hospital stay; and mesh. The  
38 resource use estimates were based on Medicare reimbursement data and published  
39 literature. The unit costs were obtained from national sources (Medicare reimbursement  
40 data). The source of unit cost data included national sources and published literature. The  
41 measure of outcome for the economic analysis was QALYs. The utility weights were  
42 generated by a focus group. The time horizon of the analysis was 2 years.

43 ASC resulted in a greater number of QALYs compared with SSLF (1.53 versus 1.45,  
44 respectively; difference 0.08). The mean total costs per woman were \$13,988 for ASC and  
45 \$11,950 for SSLF, a difference of \$2,038 in 2013 USA dollars. Based on the above costs and  
46 outcomes the ICER of ASC (versus SSLF) was \$24,574 per QALY.

47 According to the one-way sensitivity analyses ASC remained cost-effective treatment over  
48 reasonable ranges for the cost of MUS, the rate of re-operation for recurrent prolapse, and all  
49 of the utilities included in the model (recurrent prolapse, dyspareunia, and SUI).

1 The analysis was partially applicable to the NICE decision-making context and had  
2 potentially serious methodological limitations.

3 **Carracedo 2017**

4 Carracedo (2017) assessed the costs associated with laparoscopic sacrocolpopexy (LS) and  
5 transvaginal mesh (TVM) in women with POP in Spain. The analysis was conducted from a  
6 health care payer perspective. The study considered a range of direct health care costs  
7 including personnel, pharmaceutical products, prosthesis and implants, functioning,  
8 operating room, anaesthesia and resuscitation, hospital meals, intermediate services,  
9 structure, TVT, and TOT procedure costs.

10 The resource use estimates were based on the retrospective cohort study and associated  
11 administrative hospital databases (n=138). RCT and other published sources. The source of  
12 unit costs was unclear. However, these were most likely obtained from local hospital  
13 sources. The time horizon of the analysis was also unclear, but it seems to have considered  
14 only the immediate postoperative period.

15 The mean total costs per woman were €5,985.7 (95% CI: €5,613.1 to €6,358.3) for LS and  
16 €6,534.3 (95% CI: €6,290.4 to €6778.3) for TVM, a difference of -€548.6 (p = ns) in likely  
17 2016 Euros. Based on the above costs LS is cost saving when compared with TVM.

18 The analysis was partially applicable to the NICE decision-making context and had  
19 potentially serious methodological limitations.

20 **Culligan 2013**

21 Culligan (2013) evaluated the cost-effectiveness of robotic sacrocolpopexy compared with a  
22 vaginal mesh hysteropexy in women with uterovaginal prolapse in the USA. This was an  
23 economic evaluation based on modelling. In the decision tree model following the initial  
24 surgical treatment a women could die, develop bleeding, cystotomy, infection, erosion, LUTs;  
25 experience pain or prolapse recurrence. The analysis was conducted from a health care  
26 payer perspective. The study considered a range of direct health care costs including  
27 surgical procedures including equipment and materials used during the surgery, payments to  
28 the surgeons and anaesthetists, and salary costs of the operating room personnel. The  
29 resource use estimates were based on the published literature where possible systematic  
30 reviews were used. Where there was a lack of data expert opinion was used. The unit costs  
31 were obtained from local sources. The measure of outcome for the economic analysis was  
32 QALYs with utility weights obtained from a panel of health care providers and lay women.  
33 The time horizon of the analysis was 12 months.

34 Robotic sacrocolpopexy resulted in a greater number of QALYs (0.9645 versus 0.9309,  
35 respectively; difference 0.0366). The mean total costs per woman were \$21,853 for robotic  
36 sacrocolpopexy and \$14,890 for vaginal mesh hysteropexy, a difference of \$6,963 in 2009  
37 USA dollars. Based on the above costs and outcomes the ICER of robotic sacrocolpopexy  
38 (versus vaginal mesh hysteropexy) was \$207,232 per QALY gained (which is well above  
39 NICE's lower and upper cost-effectiveness threshold of £20,000-30,000 per QALY gained).  
40 As a result, vaginal mesh hysteropexy is the preferred treatment option for women with  
41 uterovaginal prolapse.

42 Extensive sensitivity analyses indicated that the results were robust to changes in the  
43 estimates of surgical mortality, probabilities of complications (bleeding, cystotomy, surgical  
44 site infection, mesh exposure, de novo lower urinary tract symptoms, and de novo chronic  
45 pain); probability of reoperation; utility weights; surgical costs; and simultaneous changes in  
46 the probabilities of complications and surgical costs.

47 The analysis was partially applicable to the NICE decision-making context and had minor  
48 methodological limitations.

1   **Ehlert 2016**

2   Ehlert (2016) assessed the costs associated with robotic sacrocolpopexy when compared  
3   with transvaginal mesh repair in women (n=226) that require surgical repair of POP in the  
4   USA. The economic analysis was based on a retrospective cohort study. Vaginal procedures  
5   included anterior-apical mesh repair (n=92), posterior-apical mesh repair (n=26), and  
6   anterior-posterior apical mesh repair (n=2). The results were categorised according to  
7   whether women received concomitant hysterectomy.

8   The analysis was conducted from a narrow health care perspective and considered only  
9   hospital costs including recovery room costs, operating room, anaesthesia, inpatient room and  
10   board, laboratory, surgical supplies and mesh. The resource use estimates were based on  
11   the retrospective cohort study participants. The source of unit costs was unclear. The time  
12   horizon of the main analysis was not reported but seems to be immediate post-operative  
13   period.

14   In women who were also undergoing concomitant hysterectomy the mean total costs per  
15   woman were \$12,483 for robotic sacrocolpopexy and \$9,820 for transvaginal mesh repair, a  
16   difference of \$2,663 ( $p < 0.001$ ) in likely 2015 USA dollars. Similarly, when considering  
17   women without concomitant hysterectomy the mean total costs per woman were \$9,676 for  
18   robotic sacrocolpopexy and \$6,719 for transvaginal mesh repair, a difference of \$2,957 ( $p$   
19    $< 0.001$ ). Based on the above costs the transvaginal mesh repair is a cost saving procedure.  
20   This was mainly due to lower surgical supplies costs and also shorter operating time.

21   The analysis was partially applicable to the NICE decision-making context and had  
22   potentially serious methodological limitations.

23   **Maher 2012**

24   Maher (2012) conducted the cost-effectiveness analysis of a laparoscopic colpopexy (LSC)  
25   compared with total vaginal mesh (TVM) in women with prolapse of the vaginal wall  
26   alongside an RCT (Maher 2012) (n=108) conducted in AUS. The analysis was conducted  
27   from a societal perspective. The study considered a range of health care costs including  
28   operating room, labour costs (anaesthetist, surgeon, assistant, theatre nursing labour),  
29   inpatient costs, consumable costs (total vaginal mesh, sub urethral obturator tape, trocars,  
30   hernia tracker), insurer expenditures, reoperation costs, and productivity losses of the  
31   participants during their treatment and recovery. The resource use estimates were based on  
32   the RCT. The unit costs were obtained from local hospital sources. To estimate productivity  
33   costs the opportunity cost per day of recovery was approximated by the average adult  
34   ordinary total earnings. The measures of outcome for the economic analysis included  
35   objective success defined as POP-Q stage 0 or 1 prolapse at all vaginal sites), patient  
36   satisfaction on a scale (0-100), Australian Pelvic Floor Questionnaire (APFQ), and pelvic  
37   organ prolapse quality of life (P-QoL). The time horizon of the analysis was 2 years. No  
38   discounting was undertaken.

39   LSC resulted in a greater proportion of women achieving objective success compared with  
40   TVM (0.77 versus 0.43, respectively; difference 0.34,  $p < 0.001$ ; the mean patient satisfaction  
41   score was 87 (SD: 21) versus 79 (SD: 20) for the LSC and TVM, respectively (the difference  
42   of 8.09 points,  $p < 0.002$ ); the mean reduction in APFQ scores (change from baseline to  
43   post) was 59% and 53% for LSC and TVM, respectively (the difference of 6%,  $p = ns$ ). The  
44   P-QoL scale doesn't provide a summary score. However, there was no significant difference  
45   in the pre- and post-operative quality of life changes between the groups. The mean total  
46   costs per woman were \$14,296 (SE: \$279) for LSC and \$18,289 (SE: \$358) for TVM, a  
47   difference of -\$4,013 ( $p < 0.001$ ) in 2008 USA dollars (all costs were converted to USA  
48   dollars). Based on the above costs and outcomes LSC was dominant when compared with  
49   TVM using objective success and mean patient satisfaction scores as outcome measures.  
50   LSC was also dominant using APFQ as an outcome measure. However, it was based on

1 non-significant differences in APFQ scores. It was unclear which intervention was preferred  
2 when using P-QoL as an outcome measure since it does not provide a summary score.

3 Deterministic sensitivity analysis indicated that the cost equivalence was achieved when the  
4 following threshold values were reached for cost variables: consumable cost was reduced to  
5 \$0 in the TVM and increased by \$900 in the LSC group; operating time in the LSC was 130  
6 min longer; operating room labour cost increases from \$47 to \$128 per min; hospital stay  
7 was reduced to 0 in TVM group and increased from 2.93 to 4.8 days in the LSC group; and  
8 recovery time was reduced from the mean 24 days to 8 days in the TVM group or having no  
9 reoperations in the TVM group.

10 The analysis was partially applicable to the NICE decision-making context and had  
11 potentially serious methodological limitations.

## 12 **Husby 2018**

13 Husby (2018) assessed the costs associated with Manchester–Fothergill procedure versus  
14 uterosacral ligament suspension (with vaginal hysterectomy) in women requiring POP repair  
15 in Denmark. The economic analysis was based on a retrospective cohort study (n=590) and  
16 included women with primary apical prolapse.

17 The analysis was conducted from a health care payer perspective and considered a range of  
18 direct health care costs including primary operation (surgeon, surgical nurses, anesthetic  
19 nurse, post-anesthesia care nurse, operating theatre, overnight hospital stays, utensils,  
20 pathological evaluations, contacts, CT urography related to primary operation), complication  
21 management (postoperative bleeding, unacknowledged obstruction of ureter, and urinary  
22 retention), recurrences, uterus-dependant issues (pathological tests, contacts and  
23 procedures). The resource use estimates were based on the cohort study participants. The  
24 unit costs were obtained from local sources (that is, hospital departments and administration  
25 databases) and where necessary were supplemented with expert opinion. The time horizon  
26 of the analysis was 20 months.

27 When considering only the primary operation the mean total costs per woman over 20  
28 months were €3,514 for uterosacral ligament suspension (with vaginal hysterectomy) and  
29 €2,318 for Manchester–Fothergill procedure, a difference of €898 (95% CI: €818; €982) in  
30 favour of Manchester–Fothergill procedure; in likely 2017 Euros. Similarly, when considering  
31 all subsequent activities within 20 months the cost difference increased to €1,196 (95% CI:  
32 €927; €1,465) in favour of Manchester–Fothergill procedure;  $p < 0.0001$ .

33 The conclusions were robust to various scenarios explored including changes in the costs  
34 associated with hospital stay, operating theatre costs, and the percent of a health care  
35 professional's working time involved in direct patient contact. Excluding women costing more  
36 than 300% of the median costs, including the costs of sampling the pathological specimen  
37 irrespective of whether performed in the primary sector or at private gynecologists, or  
38 excluding women with missing information about duration of surgery and/or anesthesia  
39 and/or post-anesthesia care did not change the conclusions. In all of the above scenarios the  
40 cost difference between Manchester–Fothergill procedure and uterosacral ligament  
41 suspension (with vaginal hysterectomy) remained statistically significant.

42 Overall the results suggest that Manchester–Fothergill procedure is less expensive when  
43 compared with uterosacral ligament suspension (with vaginal hysterectomy) in women with  
44 apical POP. This was mainly due to the differences in the surgical procedure costs and also  
45 greater reoperations costs post uterosacral ligament suspension (with vaginal hysterectomy).

46 The analysis was partially applicable to the NICE decision-making context and had minor  
47 methodological limitations.

## 1 Economic model

2 The choice of a surgical procedure in women with anterior POP was identified by the  
3 committee and the guideline health economist as an area with potentially major resource  
4 implications. Existing UK economic evidence in this area was limited and did not cover all  
5 relevant surgical procedures (that is, the committee wanted to explore the potential cost-  
6 effectiveness of different mesh products). The clinical evidence in the area of recurrence  
7 prevention was judged to be sufficient and adequate to inform primary economic modelling.  
8 Based on the above considerations, an economic model was developed to assess the  
9 relative cost effectiveness of surgical procedures aiming at preventing recurrence in women  
10 with anterior POP. The methodology adopted, the results and the conclusions from this  
11 economic analysis are described in detail in appendix J. This section provides a summary of  
12 the methods employed and the results of the economic analysis.

## 13 Overview of methods

14 A decision-analytic model in the form of a Markov model was constructed to evaluate the  
15 relative cost-effectiveness of surgical treatments for POP over 15 years. The surgical  
16 interventions assessed were anterior colporrhaphy (with no mesh), anterior colporrhaphy  
17 with partially absorbable mesh, anterior colporrhaphy with non-absorbable mesh, and  
18 anterior colporrhaphy with biological mesh. The choice of treatments assessed in the  
19 economic analysis was determined by the availability of respective clinical data (recurrence  
20 at the same site) included in the guideline systematic literature review. The economic  
21 analysis considered effective treatments, as demonstrated by the systematic review of  
22 clinical evidence, that were deemed appropriate by the committee as treatment options for  
23 women with anterior POP in the UK. The study population comprised of adult women with  
24 anterior POP that require surgical management.

25 Clinical data were derived from studies included in the guideline systematic review of clinical  
26 evidence and other published literature. NMA was used to synthesise clinical data (that is,  
27 recurrence at the same site). The inconsistency checks were also undertaken. Details on the  
28 methods and clinical data utilised in the NMA that was undertaken to estimate the recurrence  
29 for each surgical option considered in the economic analysis are presented in appendix Q  
30 and R. Results are summarised in the effectiveness review (see, clinical evidence profile for  
31 the NMA outcome). Supplementary NMA results and inconsistency checks are presented in  
32 the appendix R and S, respectively.

33 The measure of outcome in the economic analysis was the number of QALYs gained. The  
34 perspective of the analysis was that of the NHS. Resource use was based on the published  
35 literature and the committee expert opinion. National UK unit costs were used. The cost year  
36 was 2016. Two methods were employed for the analysis of input parameter data and  
37 presentation of the results. First, a deterministic analysis was undertaken, where data were  
38 analysed as point estimates and results were presented in the form of incremental cost-  
39 effectiveness ratios (ICERs) following the principles of incremental analysis. A probabilistic  
40 analysis was subsequently performed in which most of the model input parameters were  
41 assigned probability distributions. Subsequently, 10,000 iterations were performed, each  
42 drawing random values out of the distributions fitted onto the model input parameters. Mean  
43 costs and QALYs for each surgical option were calculated by averaging across the 10,000  
44 iterations. This approach allowed more comprehensive consideration of the uncertainty  
45 characterising the input parameters and captured the non-linearity characterising the  
46 economic model structure. Results of probabilistic analysis were also summarised in the form  
47 of cost effectiveness acceptability curves, which express the probability of each surgical  
48 procedure being cost effective at various levels of willingness-to-pay per QALY gained (that  
49 is, at various cost-effectiveness thresholds).

1 **Findings of the economic analysis**

2 According to the deterministic analysis, anterior colporrhaphy (with no mesh) was dominant  
3 surgical procedure (that is, it resulted in lower costs and greater QALYs) when compared  
4 with anterior colporrhaphy with partially absorbable mesh, anterior colporrhaphy with non-  
5 absorbable mesh, and anterior colporrhaphy with biological mesh. The deterministic  
6 sensitivity analyses indicated that the findings were robust to changes in model inputs  
7 including the effectiveness data, the risk of mesh extrusion and pain complications, cost  
8 data, and utility values (that is, in all scenarios explored anterior colporrhaphy without mesh  
9 remained the most cost-effective option). Conclusions of the probabilistic analysis were  
10 similar to those of the deterministic analysis (that is, anterior colporrhaphy with no mesh was  
11 dominant surgical procedure). At the lower NICE cost-effectiveness threshold of £20,000 per  
12 QALY (NICE, 2008b) the probability of anterior colporrhaphy with no mesh being cost-  
13 effective was 0.70. A further sensitivity analysis indicated that the risk of mesh complications  
14 would need to be very low for anterior colporrhaphy with mesh to be considered cost-  
15 effective.

16 **Strengths and limitations**

17 Clinical data on recurrence were synthesised using network meta-analytic techniques. Such  
18 methods enabled evidence synthesis from both direct and indirect comparisons between  
19 treatments. The time horizon of the economic analysis was 15 years which is substantially  
20 longer than in existing economic evaluations. The economic analysis also attempted to  
21 capture the impact of long-term mesh complications including mesh extrusion and pain. Due  
22 to the lack of suitable data some of the model inputs were informed by the committee expert  
23 opinion.

24 **Clinical evidence statements**

25 The clinical evidence statements are presented in accordance with the analysis for this  
26 review; firstly the evidence statements for the effectiveness of anterior, apical, posterior and  
27 different mesh types for anterior surgery are presented, followed by the clinical evidence  
28 statements for the mid-, and long-term complications.

29 **Anterior surgery**

30 **Mesh surgery compared to anterior colporrhaphy**

31 ***Cure of anterior prolapse***

- 32 • Very low quality evidence from two RCT (n=469) showed a clinically important difference  
33 favouring mesh surgery over AC in the number of women with objectively measured cure  
34 at 3 months: RR 1.33 (95% CI 1.02 to 1.62).
- 35 • Low quality evidence from 17 RCT (n=1,933) showed a clinically important difference  
36 favouring mesh surgery over AC in the number of women with objectively measured cure  
37 at 12 months: RR 1.44 (95% CI 1.24 to 1.57).
- 38 • Moderate quality evidence from nine RCT (n=902) showed there may be a clinically  
39 important difference favouring mesh surgery over AC in the number of women with  
40 objectively measured cure at 24 months: RR 1.2 (95% CI 1.04 to 1.39).
- 41 • Low quality evidence from one RCT (n=97) showed no clinically important difference  
42 between mesh surgery and AC in the number of women with objectively measured cure at  
43 36 months, RR 0.94 (95% CI 0.86 to 1.02).

44

1    ***Repeat surgery***

- 2    • Evidence from seven RCT (n=1,015) showed a clinically important difference between  
3    mesh surgery and anterior colporrhaphy in the number of women requiring repeat surgery  
4    up to 36 months for anterior prolapse RR 0.38 (95% CI 0.15 to 0.95) . Of these 7 studies,  
5    3, 2 and 2 provided follow-up data at specific follow-up times (12, 24 or 36 months,  
6    respectively). This evidence was considered very low, moderate and very low evidence  
7    respectively and showed clinically important differences, but with a degree of uncertainty,  
8    (RR 0.35, 95% CI 0.03 to 3.74; RR 0.31, 95% CI 0.09 to 1.06, RR 0.26, 95% CI 0.03 to  
9    2.74).

10    ***Recurrence of any POP, same compartment***

- 11    • NMA outcome, see Clinical evidence profile for NMA outcomes.

12    ***Adverse events during surgery***

- 13    • Very low quality evidence from eight RCT (n=677) showed a clinically important difference  
14    between mesh surgery and AC in the number of blood transfusions required, RR 1.45  
15    (95% CI 0.84 to 2.57).  
16    • Low quality evidence from three (n=203) showed a clinically important difference between  
17    anterior colporrhaphy and mesh surgery in urethral perforations during surgery for anterior  
18    prolapse, there was a high degree of uncertainty in the data, RR 2.86 (95% CI 0.31 to  
19    26.83).  
20    • Very low quality evidence from four RCT (n=738) showed a clinically important difference  
21    favouring AC over mesh surgery in the number of bladder perforations occurring during  
22    surgery for anterior prolapse, RR 5.57 (95% CI 1.24 to 24.98).

23    ***Short-term complications***

- 24    • Moderate quality evidence showed a clinically significant difference in the occurrence of  
25    vaginal bulge following mesh surgery as compared to AC at 12 (six RCT, n= 891, RR 0.68  
26    [95%CI 0.52 to 0.89]) and 36 months (one RCT, n=161, RR 0.39 [95%CI 0.22 to 0.70])  
27    respectively. There was no difference at 2 or 24 months.  
28    • Low quality of evidence from 10 RCT (n=1,043) showed no clinically important difference  
29    in number of women with de novo dyspareunia at 12 to 24 months following mesh surgery  
30    as compared to AC, RR 1.18 (95% CI 0.69 to 2.02).  
31    • Very low quality from two RCT (n=302) showed a clinically important difference in the  
32    number of women with SUI, but a high degree of uncertainty at 12 months following mesh  
33    surgery as compared to AC, RR 1.38 (95% CI 0.68 to 2.79). This was not consistent at 24  
34    or 36 months, RR 0.27 (95% CI 0.03 to 2.26) and RR 0.92 (95%CI 0.48 to 1.79)  
35    respectively.  
36    • Very low quality evidence from seven RCT (n=796) showed there may be clinically fewer  
37    women with voiding difficulties following mesh surgery as compared to AC at 12 to 24  
38    months, but there is a high degree of uncertainty, RR 0.73 (95%CI 0.41 to 1.29).  
39    • Very low quality evidence from seven RCT (n=1,001) showed no clinically important  
40    difference in the number of women who report pain following mesh surgery as compared  
41    to AC at 12 to 24 months, RR 0.9 (95%CI 0.55 to 1.46).  
42    • Very low quality evidence showed from three (n= 624) showed no clinically important  
43    difference in sexual function following mesh surgery as compared to AC at 12 to 24  
44    months, MD 1.48 (0.7 to 2.27).  
45    • Low quality evidence from one RCT (n=100) showed no clinically important difference in  
46    quality of life as reported by PQoL (MD 1.6 [-6.38 to 9.58]) or ICIQ-VS (at 12 months MD -  
47    1.05 [-1.73 to -0.37] or 24 months MD -0.7 [-1.38 to -0.02]) following mesh surgery as  
48    compared to AC.

- 1     • Moderate quality evidence showed conflicting data on quality of life on PFIQ-7 and PFDI-  
2       20 in women who had mesh surgery as compared to AC, for example at 24 months PFIQ-  
3       7 showed improved quality of life in those who underwent AC (MD 8 [4.6 to 11.4]) yet  
4       PFDI showed greater quality of life in those who underwent mesh surgery (MD -8 [-10.92  
5       to -5.08].

6     **Mesh surgery as compared to paravaginal repair for anterior prolapse**

7     **Cure**

- 8     • Very low quality evidence from one RCT (n=70) showed no clinically important difference  
9       between mesh surgery and paravaginal repair surgery in objectively measured cure for  
10      anterior prolapse at 12 months (RR 0.1.04 [95% CI 0.92 to 1.30]) and 24 months (RR 1.08  
11      [95% CI 0.82 to 1.42])

12    **Apical surgery**

13    **Laparoscopic sacrocolpopexy compared to abdominal sacrocolpopexy**

14    **Cure**

- 15    • Low quality evidence from two RCT (n =195) showed no clinically important difference  
16       between laparoscopic sacrocolpopexy and abdominal sacrocolpopexy in cure of apical  
17       prolapse at 12 months to 42 months following surgery, RR 1.00 (95%CI 0.92-1.08).

18    **Repeat surgery**

- 19    • Very low quality data from one RCT (n =74) showed a clinically important difference  
20       between laparoscopic sacrocolpopexy and abdominal sacrocolpopexy at 12 months in the  
21       need for repeat surgery for apical prolapse, however, there was a high degree of  
22       uncertainty, RR 4.00 (95% CI 0.47 to 34.11).

23    **Recurrence**

- 24    • Very low quality evidence from one RCT (n=121) showed a clinically important difference  
25       in recurrence of anterior POP with abdominal sacrocolpopexy as compared to  
26       laparoscopic sacrocolpopexy, but there was a high degree of uncertainty, RR 10.82 (95%  
27       CI 1.44 to 81.23). This was also consistent for recurrence of posterior prolapse, RR 0.59  
28       (95% CI 0.15 to 2.36).

29    **Adverse events during surgery**

- 30    • Very low quality evidence from one RCT (n=121) showed a clinically important difference  
31       between abdominal sacrocolpopexy and laparoscopic colpopexy in the number of blood  
32       transfusions required during surgery for apical prolapse, RR 0.14 (95% CI 0.02 to 1.11),  
33       but there is a high degree of uncertainty.

34    **Short-term complications**

- 35    • Very low quality of evidence from two RCT (n=128) showed a clinically important  
36       difference in the number of women with SUI following laparoscopic sacrocolpopexy as  
37       compared to abdominal sacrocolpopexy, but there was a high degree of uncertainty, RR  
38       2.07 (95% CI 0.7 to 6.07).

- 1     • Very low quality evidence from one RCT (n= 74) showed a clinically important difference in  
2       the number of women with dyspareunia following laparoscopic sacrocolpopexy as  
3       compared to abdominal sacrocolpopexy, but there is a degree of uncertainty, RR 1.33  
4       (95% CI 0.32 to 5.55).  
5     • Very low quality evidence from one RCT (n= 121) showed a clinically important difference  
6       in mesh exposure following laparoscopic sacrocolpopexy as compared to abdominal  
7       sacrocolpopexy, but there is a high degree of uncertainty, RR 2.95 (95%CI 0.32 to 27.58).  
8     • Moderate quality evidence showed no clinically important difference in quality of life as  
9       measured on the P-QoL between laparoscopic sacrocolpopexy and abdominal  
10      sacrocolpopexy MD 5.3 (-17.57 to 6.96).

11   **Vaginal hysterectomy as compared to sacrospinous hysteropexy**

12   **Cure**

- 13     • Very low quality evidence from two RCT (n =279) showed no clinically important  
14       difference between vaginal hysterectomy and sacrospinous hysteropexy in cure of apical  
15       prolapse at 12 months, RR 1.17 (95% CI 0.97 to 1.41).

16   **Repeat surgery**

- 17     • Very low quality data from one RCT (n=71) showed a clinically important difference  
18       between vaginal hysterectomy and sacrospinous hysteropexy in the requirement for  
19       repeat surgery, RR 0.54 (95% CI 0.11 to 2.78).

20   **Recurrence**

- 21     • Very low quality evidence from two RCT (n= 279) showed a clinically important difference  
22       in recurrence of prolapse between vaginal hysterectomy as compared to sacrospinous  
23       hysteropexy at 12 months, RR 4.1 (95%CI 1.33 to 12.62).  
24

25   **Short-term complications**

- 26     • Low quality of evidence from one RCT (n=105) showed no clinically important difference in  
27       sexual function between women who had vaginal hysterectomy or sacrospinous  
28       hysteropexy (MD 2 (-3.41 to 0.59)).

29   **Vaginal hysterectomy compared to sacral colpopexy/hysteropexy**

30   **Repeat surgery**

- 31     • Low quality evidence from two RCT (n=183) showed a clinically important difference  
32       between vaginal hysterectomy and sacral colpopexy/hysteropexy in the number of women  
33       requiring repeat surgery of apical prolapse (RR 0.42 [95% CI 0.12 to 1.53]). There was  
34       also a clinical difference in the number of women requiring repeat surgery for prolapse in  
35       any compartment; however, there is a high degree of uncertainty (one RCT, n=101, RR  
36       1.77 [95% CI 0.77 to 4.11]).

37   **Adverse events during surgery**

- 38     • Very low quality evidence from one RCT (n=82) showed no clinically important difference  
39       in the number of blood transfusions required during surgery for vaginal hysterectomy as  
40       compared to sacral colpopexy/hysteropexy, RR 0.5 (95% CI 0.05 to 5.3).

- 1     • Low quality evidence from one RCT (n=82) showed a clinically important difference in the  
2       number of bowel injuries during surgery for vaginal hysterectomy as compared to  
3       sacrocolpopexy/hysteropexy, RR 0.33 (95% CI 0.01 to 7.95).

4     **Infracoccygeal sacropexy compared to sacrospinous suspension**

5     **Cure**

- 6     • Very low quality evidence from one RCT (n=49) showed there may be a clinically  
7       important difference in cure of apical prolapse with between Infracoccygeal sacropexy and  
8       sacrospinous suspension at 16.8 months, RR 0.87 (95% CI 0.71 to 1.06).

9     **Repeat surgery**

- 10    • Very low quality data from one RCT (n=49) showed a clinically important difference  
11      between Infracoccygeal sacropexy and sacrospinous suspension in the requirement for  
12      repeat surgery for prolapse at 16.8 months, but there was a high degree of uncertainty RR  
13      3.12 (95% CI 0.13 to 73.04).

14    **Short-term complications**

- 15    • Low quality evidence from one RCT (n=49) showed a clinically important difference in SUI  
16      at 16.8 months following Infracoccygeal sacropexy or sacrospinous suspension, RR 0.15  
17      (95% CI 0.01 to 2.73).  
18    • Moderate quality evidence from one RCT (n=49) showed a clinically important differences  
19      in voiding difficulties 16.8 months following Infracoccygeal sacropexy or sacrospinous  
20      suspension, RR 0.43 (95% CI 0.18 to 1.05).  
21    • Moderate quality evidence from one RCT (n=49) showed clinically important differences in  
22      constipation at 16.8 months following Infracoccygeal sacropexy and sacrospinous  
23      suspension, RR 0.09 (95% CI 0.01 to 0.68).  
24    • Low quality evidence from one RCT (n=49) showed no clinically important difference in  
25      sexual function at 16.8 months following Infracoccygeal sacropexy and sacrospinous  
26      suspension, MD 3.1 (-0.43 to 6.63).

27    **Sacrospinous ligament fixation with mesh as compared to sacrospinous ligament  
28      fixation with native tissue**

29    **Cure**

- 30    • Very low quality evidence from one RCT (n=70) showed a clinically important difference  
31      favouring sacrospinous ligament fixation with mesh over sacrospinous ligament fixation  
32      with native tissue in the number of women cured of apical prolapse at 12 months, RR 7.08  
33      (95% CI 2.79 to 17.99).

34    **Recurrence**

- 35    • Low quality evidence from two RCT (n=200) showed there may be a clinically important  
36      difference in the number of women with recurrence of prolapse following sacrospinous  
37      ligament fixation with mesh as compared to sacrospinous ligament fixation with native  
38      tissue at 12 months but data is uncertain, RR 0.7 (95% CI 0.28 to 1.76).

39    **Short-term complications**

- 1     • Moderate quality evidence from two RCT (n= 238) showed a clinically important difference  
2       in the number of women with SUI following sacrospinous ligament fixation with mesh as  
3       compared to sacrospinous ligament fixation with native tissue, but there was a high degree  
4       of uncertainty, RR 1.48 (95% CI 0.99 to 2.21).
- 5     • Low quality evidence from two RCT (n= 238) showed a clinically important difference in the  
6       number of women with dyspareunia following sacrospinous ligament fixation with mesh as  
7       compared to sacrospinous ligament fixation with native tissue, but there was a high degree  
8       of uncertainty, RR 2.58 (95% CI 0.7 to 9.48).
- 9     • Low quality of evidence from 1RCT (n=70) showed no clinically important difference in  
10      quality of life following sacrospinous ligament fixation with mesh as compared to  
11      sacrospinous ligament fixation with native tissue, MD 10.5 (-24.41 to 3.41).
- 12     • Moderate quality evidence from one RCT (n=70) showed no clinically important difference  
13      in sexual function following sacrospinous ligament fixation with mesh as compared to  
14      sacrospinous ligament fixation with native tissue, MD 0.2 (-2.72 to 2.32).
- 15     • Very low quality evidence from two RCT (n=200) showed a clinically important difference  
16      in mesh erosion following sacrospinous ligament fixation with mesh as compared to  
17      sacrospinous ligament fixation with native tissue, RR 21.68 (95% CI 2.98 to 157.67).
- 18     • Low quality evidence from one RCT ( n=168) showed a clinically important difference in  
19      pelvic pain following sacrospinous ligament fixation with mesh as compared to  
20      sacrospinous ligament fixation with native tissue RR 1.95 (95% CI 0.51 to 7.55).

21     **Sacral colpopexy with fascia lata compared to synthetic mesh for sacral colpopexy**

22     **Cure**

- 23     • Low quality evidence from one RCT (n=100) showed a clinically important difference  
24       favouring sacrocolpopexy with mesh over sacrocolpopexy with fascia in the number of  
25       women cured of apical POP at 12 months, RR 0.73 (95% CI 0.56 to 0.95) and at 60  
26       months, RR 0.67 (95%CI 0.43 to 1.04). There was no clinically important difference when  
27       cure was defined using a combination of objective measure (POP-Q) and women's  
28       subjective opinion (subjective cure), RR 0.93 (95%CI 0.65 to 1.33).

29     **Short-term complications**

- 30     • Very low quality evidence from one RCT (n=100) showed no clinically important difference  
31       in mesh erosion at 12, RR 1.00 (95% CI 0.06 to 15.55), there may be a difference at 60  
32       months but data is uncertain, RR 0.5 (95% CI 0.05 to 5.34) following surgery with fascia  
33       lata or synthetic mesh for sacral colpopexy.

34     **Abdominal sacral colpopexy compared to vaginal sacrospinous colpopexy**

35     **Cure**

- 36     • Very low quality evidence from two RCT (n= 214) showed no clinically important  
37       difference between abdominal sacral colpopexy and vaginal sacrospinous colpopexy in  
38       the number of women who had cure of apical prolapse at 24 months RR 1.19 (95% CI  
39       1.03 to 1.36).

40     **Short-term complications**

- 41     • Low quality evidence from two RCT (n=213) showed a clinically important difference in  
42       dyspareunia following abdominal sacral colpopexy or vaginal sacrospinous colpopexy, but  
43       there was uncertainty, RR 0.34 (95%CI 0.09 to 1.25).

- 1     • Moderate quality evidence from one RCT (n=95) showed a clinically important difference in  
2       SUI following abdominal sacral colpopexy or vaginal sacrospinous colpopexy, but there  
3       was uncertainty, RR 0.26 (95%CI 0.06 to 1.14).
- 4     • Low quality evidence from one RCT (n=95) showed no clinically important difference in  
5       voiding difficulties following abdominal sacral colpopexy or vaginal sacrospinous colpopexy  
6       RR 1.02 (95%CI 0.07 to 15.86).
- 7     • Low quality evidence from one RCT (n=95) showed a clinically important difference in  
8       constipation following abdominal sacral colpopexy or vaginal sacrospinous colpopexy, but  
9       there was a high degree of uncertainty, RR 1.53 (95% CI 0.69 to 3.41).
- 10    • Moderate quality of evidence from one RCT (n=89) showed no clinically important  
11      difference in quality of life following abdominal sacral colpopexy or vaginal sacrospinous  
12      colpopexy MD 5 (-12.48 to 2.48).

13   **Vaginal hysterectomy compared to Manchester repair**

14   **Repeat surgery**

- 15    • Very low quality evidence from one RCT (n= 94) showed a clinically important difference  
16      between vaginal hysterectomy and Manchester repair in the number of women requiring  
17      repeat surgery for POP at 61 months, RR 0.31 (95% CI 0.03 to 2.84).

18   **Short-term complications**

- 19    • Very low quality evidence from one RCT (n=94) showed no clinically important difference  
20      in quality of life following vaginal hysterectomy or Manchester repair MD 1.79 (-4.85 to  
21      1.27).

22   **Abdominal sacrocolpopexy compared to high uterosacral vault suspension**

23   **Cure**

- 24    • Very low quality evidence from one RCT (n= 125) showed no clinically important  
25      difference between high uterosacral suspension and abdominal sacrocolpopexy in the  
26      number of women who had cure of apical prolapse at 12 months, RR 1.14 (5% CI 0.95 to  
27      1.37).

28   **Repeat surgery**

- 29    • Very low quality evidence from one RCT (n= 124) showed a clinically important difference  
30      between abdominal sacrocolpopexy and high uterosacral suspension in the number of  
31      women who needed repeat surgery for prolapse at 12 months, RR 0.29 (95% CI 0.08 to  
32      1.01).

33   **High levator myorrhaphy compared to uterosacral ligament suspension**

34   **Cure**

- 35    • Very low quality evidence from one RCT (n= 229) showed no clinically important  
36      difference between high levator myorrhaphy and uterosacral ligament fixation in the  
37      number of women who had cure of apical prolapse at 12 months RR 1.09 (95% CI 0.91 to  
38      1.31).

39   **Adverse events during surgery**

- 1     • Very low quality evidence from one RCT (n= 229) showed a clinically important difference  
2       between high levator myorrhaphy and uterosacral ligament fixation in the number of  
3       women who had rectal injury during surgery: RR 0.32 (95% CI 0.01 to 7.89).

4

## 5     ***Short-term complications***

- 6     • Low quality evidence from one RCT (n=229) showed there may be a clinically important  
7       difference in mesh and vaginal erosion at 12 months following high levator myorrhaphy or  
8       uterosacral ligament suspension, RR 0.73 (95% CI 0.36 to 1.47) and RR 0.79 (95% CI  
9       0.21 to 2.83).  
10    • Low quality evidence from one RCT (n= 229) showed there may be a clinically important  
11       difference in dyspareunia at 12 months following high levator myorrhaphy or uterosacral  
12       ligament suspension, RR 0.76 (95% CI 0.29 to 1.97).  
13    • Low quality evidence from one RCT (n= 229) showed a clinically important difference in  
14       constipation at 12 months following high levator myorrhaphy or uterosacral ligament  
15       suspension, RR 1.35 (95% CI 0.82 to 2.21).  
16    • Low quality evidence from one RCT (n= 229) showed a clinically important difference in  
17       SUI at 12 months following high levator myorrhaphy or uterosacral ligament suspension,  
18       but there is a high degree of uncertainty, RR 0.62 (95% CI 0.25 to 1.54).

## 19    **Sacrocolpopexy with porcine dermis compared to sacrocolpopexy with polypropylene 20       mesh**

### 21    ***Cure***

- 22    • High quality evidence from one RCT (n= 120) showed no clinically important difference  
23       between laparoscopic sacrocolpopexy with porcine mesh and laparoscopic  
24       sacrocolpopexy with polypropylene mesh in the number of women who had objective cure  
25       of apical prolapse (RR 0.98 [95% CI 0.82 to 1.18]) or clinical cure (subjective and  
26       objective) of apical prolapse (RR 0.99 [95% CI 0.84 to 1.16]) at 12 months.

## 27    ***Short-term complications***

- 28    • Moderate quality evidence from one RCT (n= 120) showed a clinically important difference  
29       in mesh exposure in women following sacrocolpopexy with dermis compared to  
30       polypropylene mesh at 12 months, but there is a high degree of uncertainty, (RR 3.2 95%  
31       CI 0.13 to 77.1)  
32    • Moderate quality evidence from one RCT (n= 120) showed there may be a clinically  
33       important difference in dyspareunia in women following sacrocolpopexy with dermis  
34       compared to polypropylene mesh at 12 months, and data is uncertain, RR 0.71 (95% CI  
35       0.12 to 4.11).  
36    • High quality of evidence from one RCT (n= 114) showed no clinically important difference  
37       in quality of life measured with PFDI-20, (MD -5.9 [-20.2 to 8.4], or PFIQ-7 (n=95, MD -6.2  
38       [-24.4 to 12])  
39    • High quality of evidence from one RCT (n= 114) showed no clinically important difference  
40       in sexual function in women following sacrocolpopexy with dermis compared to  
41       polypropylene mesh at 12 months, MD -1.8 (-3.67 to 0.07).

## 42    **Sacrospinous fixation with mesh compared to native tissue**

### 43    ***Cure***

- 1     • Very low quality evidence from one RCT (n=70) showed a clinically important difference in  
2       the number of women had cure of prolapse at 12 months following mesh surgery as  
3       compared to native surgery for sacrospinous fixation, RR 7.08 (95%CI 2.70 to 17.99).

4     ***Recurrence***

- 5     • Low quality evidence from two RCT (n=200) showed there may be a clinically important  
6       difference in the number of women with recurrence of prolapse following mesh surgery  
7       versus native tissue for at 12 months, RR 0.7 (95%CI 0.28 to 1.76).

8     ***Short-term complications***

- 9     • Low quality evidence from two RCT (n=238) showed a clinically important difference in SUI  
10      following sacrospinous fixation with mesh or with native tissue at 12 months, RR 1.48  
11      (95% CI 0.99 to 2.21).  
12     • Low quality evidence from two RCT (n=238) showed a clinically important difference in  
13       dyspareunia following sacrospinous fixation with mesh or with native tissue at 12 months,  
14       but data is uncertain, RR 2.58 (95% CI 0.7 to 9.48).  
15     • Low quality evidence from two RCT (n=70) showed no clinically important difference in  
16       quality of life following sacrospinous fixation with mesh or with native tissue at 12 months,  
17       MD -10.5 (-24.41 to 3.41).  
18     • Low quality evidence from one RCT (n=70) showed no clinically important difference in  
19       sexual function following sacrospinous fixation with mesh or with native tissue at 12  
20       months, MD -0.2 (-2.72 to 2.32).  
21     • Very low quality evidence from two RCT (n=200) showed a clinically important difference  
22       in mesh erosion at 12 months following sacrospinous fixation with mesh or with native  
23       tissue, but there was a high degree of uncertainty, RR 21.68 (95% CI 2.98 to 157.67).  
24     • Low quality evidence from one RCT (n=168) showed a clinically important difference in  
25       pelvic pain following sacrospinous fixation with mesh or with native tissue at 12 months,  
26       RR 1.95 (95% CI 0.51 to 7.55).

27     **Laparoscopic sacral colpopexy compared to total vaginal mesh kit**

28     ***Cure***

- 29     • Very low quality evidence from two RCT (n=370) showed a clinically important difference  
30       favouring laparoscopic sacral colpopexy over total vaginal mesh kit in the number of  
31       women with cure of apical prolapse, RR 1.25 (95% CI 1.01 to 1.54), this finding was  
32       consistent at 24 months, (one RCT, n=108, RR 1.85 [95% CI 1.31 to 2.61]); however the  
33       evidence from one RCT at 12 months showed no clinically important difference between  
34       the two procedures, RR 1.02 (95% CI 0.78 to 1.33).

35     ***Repeat surgery***

- 36     • Low quality data from one RCT (n=108) showed a clinically important difference between  
37       laparoscopic sacral colpopexy and total vaginal mesh kit in the requirement for repeat  
38       surgery after 12 months (RR 0.51 [95% CI 0.05 to 5.53]) and 24 months (RR 0.15 [95% CI  
39       0.01 to 2.80])

40     ***Adverse events during surgery***

- 41     • Very low quality evidence from one RCT (n=262) showed no clinically important difference  
42       in the number of bladder injuries (RR 1.02 [95%CI 0.21 to 4.94]) or rectal injuries (RR 1.02

1 [95%CI 0.06 to 16.76]) during laparoscopic sacral colpopexy as compared to total vaginal  
2 mesh surgery.

3 **Short-term complications**

- 4 • Low quality evidence from one RCT ( n= 262) showed no clinically important difference in  
5 vaginal bulge 12 months following laparoscopic sacral colpopexy as compared to vaginal  
6 mesh kit, RR 0.98 (95% CI 0.91 to 1.06).  
7 • Low quality evidence from one RCT ( n= 145) showed a clinically important difference in  
8 dyspareunia at 12 months following laparoscopic sacral colpopexy as compared to vaginal  
9 mesh kit, RR 0.48 (95% CI 0.24 to 0.96).

10 **Posterior surgery**

11 **Mesh surgery compared to standard surgery**

12 **Cure**

- 13 • Moderate quality evidence from four RCT (n=513) showed no clinically important  
14 difference between standard repair and mesh surgery in cure rates at 12 months for  
15 posterior prolapse, RR 0.90 (95% CI 0.77 to 1.04).

16 **Repeat surgery**

- 17 • Low quality evidence from four showed a clinically important difference between mesh  
18 surgery and standard repair in the number of repeat surgeries required at 12 months  
19 (n=513) (RR 1.57 [95% CI 0.46 to 5.41]) and 24 months (n=284) (RR 1.48 [95% CI 0.43 to  
20 5.13]). There was a high degree of uncertainty in the data.

21 **Adverse events during surgery**

- 22 • Very low quality evidence from four RCT (n= 513) showed no clinically important  
23 difference between standard repair and mesh surgery in the number of blood transfusions  
24 RR 1.16 (95% CI 0.08 to 17.75).  
25 • Low quality evidence from four RCT (n=513) showed a clinically important difference  
26 between standard repair and mesh surgery in the number of internal organ injuries, but  
27 there was a high degree of uncertainty, RR 1.78 (95% CI 0.24 to 12.97) during surgery for  
28 posterior prolapse.

29 **Short-term complications**

- 30 • Moderate quality evidence from one RCT (n=69) showed no clinically important difference  
31 in sexual function in women following mesh surgery to standard posterior repair at 12  
32 months, MD -3 (-5.55 to -0.45)  
33 • Low quality evidence from two RCT (n=229) showed no clinically important difference in  
34 dyspareunia in women following mesh surgery to standard posterior repair at 12 months,  
35 RR 1.05 (95% CI 0.40 to 2.74).  
36 • Moderate quality evidence from one RCT showed no clinically important difference in  
37 quality of life as measured by PFDI-20 or PFIQ-7 at 12 (n= 52) or 24 months (n=28).  
38 PFDI-20: MD -7 (-31.31 to 17.31), MD -14 (-42.07 to 14.07), and PFIQ-7: MD 2 (26.79 to  
39 30.79) and MD -9 (-48.05 to 30.05).  
40 • Moderate quality evidence from two RCT showed no clinically important difference in  
41 quality of life as measured by POP-SS at 12 (n=259) or 24 months (n=240), MD -0.4 (-  
42 1.45 to 0.65) and MD 0.59 (-0.49 to 1.67).

- 1     • Moderate quality evidence from two RCT showed no clinically important difference in  
2       quality of life as measured by ICIQ-UI at 12 (n=234) or 24 months (n=218), MD 0.75 (-0.22  
3       to 1.71) and MD 0.48 (-0.52 to 1.47).
- 4     • Moderate quality evidence from two RCT showed no clinically important difference in  
5       quality of life as measured by ICIQ-VS at 12 (n=218) or 24 months (n=200), MD -1.1 (-2.8  
6       to 0.59) and MD 0.64 (-2.44 to 1.17).
- 7     • Low quality evidence from two RCT (n= 284) showed no clinically important difference in  
8       faecal incontinence at 12 months following mesh surgery as compared to standard  
9       posterior repair, RR 1.17 (95% CI 0.78 to 1.74). There may be a clinical difference at 24  
10      months, but the data is uncertain, RR 0.40 (95% CI 0.82 to 2.39).
- 11     • Low quality evidence from two RCT (n= 284) showed no clinically important difference in  
12       constipation following mesh surgery as compared to standard posterior repair at 12  
13       months RR 0.97 (95% CI 0.69 to 1.36) or 24 months, RR 1.04 (95% CI 0.57 to 1.90).

#### 14 **Mesh types for anterior surgery**

##### 15 **Porcine mesh compared to polypropylene mesh**

###### 16 **Cure**

- 17     • Low quality evidence showed there a clinically important difference favouring surgery with  
18       polypropylene mesh over porcine graft in the number of women with prolapse cure at 12  
19       months (RR 0.70 [95% CI 0.55 to 0.89]) and 24 months (RR 0.82 [95% CI 0.70 to 0.96]).  
20       The inclusion of a study which was conducted on apical prolapse (Culligan 2013) also  
21       showed there may be a clinically important difference favouring surgery with  
22       polypropylene over porcine graft in the number of women with objective cure: RR 0.80  
23       (95% CI 0.68 to 0.94).

###### 24 **Short-term complications**

- 25     • Moderate quality evidence from four (814) showed a clinically important difference  
26       whereby porcine mesh resulted in fewer mesh complications at 12 months (RR 0.09  
27       [95%CI 0.02 to 0.39] and at 24 months (RR 0.14, [95%CI 0.03 to 0.6]) and respectively as  
28       compared to polypropylene mesh for women with anterior surgery.
- 29     • Low quality evidence from three (n=377) showed no clinically important differences in the  
30       number of women with dyspareunia following anterior surgery with porcine mesh as  
31       compared to polypropylene mesh at 24 months, RR 1.12 (95% CI 0.57 to 2.18).
- 32     • Low quality evidence from three (n=377) showed no clinically important differences in the  
33       number of women with dyspareunia following anterior surgery with porcine mesh as  
34       compared to polypropylene mesh at 24 months, RR 1.12 (95% CI 0.59 to 2.52).
- 35     • Low quality evidence from three (n=753) showed no clinically important differences in the  
36       number of women with constipation following anterior surgery with porcine mesh as  
37       compared to polypropylene mesh at 12 months, RR 0.88 (95% CI 0.56 to 1.39) or 24  
38       months (two RCT, n=563) RR 0.97 (95% CI 0.58 to 1.63).
- 39     • Low quality evidence from two RCT (n=563) showed no clinically important differences in  
40       the number of women with faecal incontinence following anterior surgery with porcine  
41       mesh as compared to polypropylene mesh at 12 months, RR 1.03 (95% CI 0.75 to 1.4) or  
42       24 months (RR 1.04 (95% CI 0.78 to 1.39).

##### 43 **Non-absorbable compared to partially absorbable mesh**

###### 44 **Short-term complications**

1 Low quality evidence from one RCT (n=200) showed no clinically important differences in  
2 mesh exposure at 12 months between non-absorbable and partially absorbable mesh for  
3 anterior surgery, RR 0.96 (95% CI 0.32 to 2.88), there was a clinically important difference  
4 at 36 months, with fewer exposures following partially absorbable mesh, however, the  
5 data was uncertain, RR 1.92 (95% CI 0.49 to 7.47).

6 **Clinical evidence statements: Mid-term complications**

7 Data relating to mid-term complications can be found in Table 20 in the main text, the studies  
8 were rated using ROBINS-I for quality, no GRADE was conducted.

- 9 • Evidence was rated as low quality, and suggests that overall rates of mesh exposure are  
10 approximately 7.17% over a 25 to 59 month follow up period.  
11 • Evidence was rated as low quality and suggest with a follow up ranging 25 to 59 months  
12 surgery suggests that vaginal mesh surgery for POP may be associated with higher rates  
13 of mesh exposure, pain and constipation as compared to surgery with abdominal mesh.  
14 • Evidence was rated as low quality and suggests that surgery with vaginal mesh may be  
15 associated with lower number of women with SUI and urge incontinence at 25 to 59  
16 months as compared to abdominal mesh surgery.

17 **Clinical evidence statements: Long-term complications**

18 Data relating to long-term complications can be found in Table 21 in the main text, the  
19 studies were rated using ROBINS-I for quality, no GRADE was conducted.

- 20 • Evidence was rated as low quality, and suggests that with a follow up period of greater  
21 than 60 months vaginal mesh surgery may be associated with greater numbers of mesh  
22 exposure as compared to surgery with abdominal mesh.  
23 • Evidence was rated as low quality and suggests that with a follow up period of greater  
24 than 60 months vaginal mesh surgery may be associated with a higher number of women  
25 with dyspareunia than as compared to non-mesh surgery.

26 **Economic evidence statements**

27 **Anterior and/or posterior surgery**

- 28 • There was evidence from the guideline's de novo economic analysis showing that anterior  
29 colporrhaphy without mesh was dominant when compared with anterior colporrhaphy with  
30 partially absorbable mesh, anterior colporrhaphy with non-absorbable mesh, and anterior  
31 colporrhaphy with biological mesh in women with primary anterior pelvic organ prolapse.  
32 This evidence came from a directly applicable study that was characterised by minor  
33 methodological limitations.  
34 • There was evidence from one UK study conducted alongside an RCT (primary repair  
35 [n=1,348] & secondary repair [n=154]) and modelling showing that mesh was potentially  
36 cost-ineffective when compared with standard repair in women with primary anterior  
37 and/or posterior pelvic organ prolapse. The results were inconclusive for secondary  
38 anterior and/or posterior pelvic organ prolapse repair. This evidence came from a directly  
39 applicable study that was characterised by minor methodological limitations.  
40 • There was evidence from one UK modelling study showing that mesh was cost-ineffective  
41 when compared with non-mesh in women with anterior pelvic organ prolapse. This  
42 evidence came from a directly applicable study that was characterised by minor  
43 methodological limitations.  
44 • There was evidence from one USA modelling study showing that non-kit mesh repair  
45 resulted in lower costs when compared with mesh-kit in women with anterior pelvic organ

1 prolapse. This evidence came from a partially applicable study that was characterised by  
2 potentially serious limitations.

3 **Apical surgery**

- 4 • There was evidence from one USA modelling study showing that abdominal approach  
5 was potentially the least costly surgical procedure when compared with robotic-assisted  
6 and laparoscopic sacrocolpopexy. This evidence came from a partially applicable study  
7 that was characterised by minor methodological limitations.
- 8 • There was evidence from one USA study conducted alongside an RCT (n=78) showing  
9 that laparoscopic sacrocolpopexy was dominant when compared with robotic  
10 sacrocolpopexy. This evidence came from a partially applicable study that was  
11 characterised by potentially serious methodological limitations.
- 12 • There was evidence from one USA study conducted alongside an RCT (n=68) showing  
13 that laparoscopic sacrocolpopexy was cost saving when compared with robotic  
14 sacrocolpopexy. This evidence came from a partially applicable study that was  
15 characterised by potentially serious methodological limitations.
- 16 • There was evidence from one USA study based on observational cohort study (n=59)  
17 showing that robotic sacrocolpopexy was cost saving when compared with abdominal  
18 sacrocolpopexy. This evidence came from a partially applicable study that was  
19 characterised by potentially serious methodological limitations.
- 20 • There was evidence from one USA study based on observational cohort study (n=164)  
21 showing that robotic sacrocolpopexy was cost saving when compared with abdominal  
22 sacrocolpopexy. This evidence came from a partially applicable study that was  
23 characterised by potentially serious methodological limitations.
- 24 • There was evidence from one USA study based on retrospective cohort study (n= 34,383  
25 procedures) showing that sacrospinous fixation was cost saving when compared with  
26 abdominal sacrocolpopexy and laparoscopic sacrocolpopexy. This evidence came from a  
27 partially applicable study that was characterised by minor methodological limitations.
- 28 • There was evidence from one USA modelling study showing that abdominal  
29 sacrocolpopexy was potentially cost-effective when compared with sacrospinous ligament  
30 fixation. This evidence came from a partially applicable study that was characterised by  
31 potentially serious methodological limitations.
- 32 • There was evidence from one Spanish study based on retrospective cohort study (n=138)  
33 showing that vaginal mesh was cost saving when compared with laparoscopic  
34 sacrocolpopexy. This evidence came from a partially applicable study that was  
35 characterised by potentially serious methodological limitations.
- 36 • There was evidence from one USA modelling study showing that vaginal mesh  
37 hysteropexy was potentially cost-effective when compared with robotic sacrocolpopexy.  
38 This evidence came from a partially applicable study that was characterised by minor  
39 methodological limitations.
- 40 • There was evidence from one USA study based on retrospective cohort study (n=226)  
41 showing that robotic sacrocolpopexy resulted in higher costs when compared with  
42 transvaginal mesh repair. This evidence came from a partially applicable study that was  
43 characterised by potentially serious methodological limitations.
- 44 • There was evidence from one Australian study conducted alongside an RCT (n=108)  
45 showing that laparoscopic sacral colpopexy was dominant option when compared with  
46 total vaginal mesh procedure. This evidence came from a partially applicable study that  
47 was characterised by potentially serious methodological limitations.
- 48 • There was evidence from one Danish study based on retrospective cohort study (n=590)  
49 showing that Manchester–Fothergill procedure was cost saving when compared with  
50 uterosacral ligament suspension (with vaginal hysterectomy). This evidence came from a  
51 partially applicable study that was characterised by minor methodological limitations.

## 1 Recommendations

### 2 Collection of data on mesh surgery and mesh-related complications

- 3 I1.1 In women having mesh surgery for stress urinary incontinence or pelvic organ prolapse, or who have mesh-related complications, seek consent to enter the data listed in rec 1.2.2 in a national registry and give them a copy of those data.
- 4
- 5
- 6 I1.2 Ensure that the following data are collected in a national registry of surgery involving mesh insertion to treat urinary incontinence (UI) or pelvic organ prolapse (POP) in women:
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- all surgical procedures for urinary incontinence or pelvic organ prolapse that involve the insertion of synthetic polypropylene mesh, including
    - date and details of the procedure
    - mesh material and type of sutures.
  - the woman's NHS number
  - hospital and consultant identifiers
  - follow-up information on key short- and long-term (at least 5 years) outcomes, including:
    - symptom improvement or deterioration
    - objective measures of UI or POP
    - adverse events
    - suspected and confirmed mesh-related complications
  - date and details of any investigation for mesh-related complications
  - date and details of any surgical or non-surgical intervention for mesh-related complications. **[2019]**
- 28
- I1.3 The national registry of surgery involving mesh insertion to treat urinary incontinence or pelvic organ prolapse in women should report annually and be quality assured. **[2019]**

### 28 Surgery for pelvic organ prolapse

- 29 I1.4 Offer surgery for pelvic organ prolapse to women whose symptoms have not improved with or who have declined non-surgical treatment. **[2019]**
- 30
- 31 I1.5 Do not offer surgery to prevent incontinence in women having surgery for prolapse who do not have incontinence. **[2019]**
- 32
- 33 I1.6 Explain to women considering surgery for anterior or apical prolapse who do not have incontinence that there is a risk of developing postoperative urinary incontinence and further treatment may be needed. **[2019]**
- 34
- 35
- 36 I1.7 If a woman has agreed to have a surgical procedure for pelvic organ prolapse, before surgery discuss:
- 37

- 1           • the risks and benefits of each procedure, including changes in urinary, bowel  
2           and sexual function
- 3           • the risks of recurrent prolapse
- 4           • the role of intraoperative prolapse assessment in finalising the choice of  
5           surgical procedure. [2019]
- 6   I1.8     If the woman's chosen procedure for pelvic organ prolapse is not available from  
7           the consulting surgeon, refer her to an alternative surgeon. [2019]
- 8   I1.9     If mesh is to be used in prolapse surgery, explain to the woman:  
9           • what type of mesh will be used and whether it is permanent.  
10          • the uncertainty about long-term complications associated with mesh and about  
11          the proportion of women affected. [2019]
- 12   I1.10    If mesh is to be used in prolapse surgery  
13          • give the woman written information on the implant including name,  
14          manufacturer, date of insertion, and implanting surgeon's name and contact  
15          details;  
16          • ensure that details of the procedure and its subsequent short- and long-term  
17          outcomes are collected in a national registry (see collecting data on mesh  
18          surgery and mesh-related complications in this guideline). [2019]

19

### 20 **Surgery for anterior prolapse**

- 21   I1.11    Offer anterior repair without mesh to women with anterior vaginal wall prolapse.  
22          [2019]
- 23   I1.12    Consider synthetic polypropylene or biological mesh insertion for women with  
24          recurrent anterior vaginal wall prolapse only after:  
25           • regional MDT review **and**  
26           • discussion with the woman about the risks of mesh insertion  
27          and if:  
28           • apical support is adequate **or**  
29           • an abdominal approach is contraindicated. [2019]
- 30   I1.13    If a synthetic polypropylene or biological mesh is inserted ensure that details of  
31          the procedure and its subsequent short- and long-term outcomes are collected in  
32          a national registry (see [collecting data on mesh surgery and mesh-related](#)  
33          [complications](#) in this guideline). [2019]

34

### 35 **Surgery for uterine prolapse**

- 36   I1.14    Discuss the options for surgery with women who have uterine prolapse, including  
37          surgery that will preserve the uterus and hysterectomy. [2019]
- 38   I1.15    For women with uterine prolapse who wish to preserve their uterus, offer a choice  
39          of:

- 1           • vaginal sacrospinous hysteropexy with sutures
- 2           • sacro-hysteropexy with mesh (abdominal or laparoscopic)
- 3           • Manchester repair (except for women who are considering a future pregnancy or who might become pregnant). **[2019]**
- 4
- 5   I1.16   For women with uterine prolapse who have no preference about preserving their uterus, offer a choice of:
  - 6           • vaginal hysterectomy, with or without sacrospinous fixation with sutures **or**
  - 7           • sacro-hysteropexy with mesh (abdominal or laparoscopic) **or**
  - 8           • vaginal sacrospinous hysteropexy with sutures **or**
  - 9           • Manchester repair. **[2019]**
- 10
- 11   I1.17   If sacro-hysteropexy with mesh (abdominal or laparoscopic) is used ensure that details of the procedure and its subsequent short- and long-term outcomes are collected in a national registry (see [collecting data on mesh surgery and mesh-related complications](#) in this guideline). **[2019]**
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#### **16 *Surgery for vault prolapse***

- 16   I1.18   Offer women with vault prolapse a choice of:
  - 17           • sacrocolpopexy (abdominal or laparoscopic) with mesh **or**
  - 18           • vaginal sacrospinous fixation with sutures. **[2019]**
- 19
- 20   I1.19   If sacrocolpopexy (abdominal or laparoscopic) with mesh is used ensure that details of the procedure and its subsequent short- and long-term outcomes are collected in a national registry (see [collecting data on mesh surgery and mesh-related complications](#) in this guideline). **[2019]**
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#### **24 *Colpocleisis for vault or uterine prolapse***

- 24   I1.20   Consider colpocleisis for women with vault or uterine prolapse who do not intend to have penetrative vaginal sex and who have a physical condition that may put them at increased risk of operative and postoperative complications. **[2019]**
- 25
- 26
- 27
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#### **29 *Surgery for posterior prolapse***

- 29   I1.22   Offer posterior vaginal repair without mesh to women with a posterior vaginal wall prolapse. **[2019]**
- 30
- 31

#### **32 *Follow-up after surgery***

- 32   I1.23   Offer women a review 6 months after surgery for prolapse and ensure that the review includes a vaginal examination and, if appropriate, a check for mesh exposure. **[2019]**
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- 34
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## 1 Research recommendations

- 2 1. What is the effectiveness of colpocleisis compared with sacrospinous fixation for  
3 pelvic organ prolapse in elderly women?  
4
- 5 2. What is the long-term patient satisfaction with pessaries compared with surgery for  
6 pelvic organ prolapse in women?  
7
- 8 3. What are the long-term risks of mesh surgery compared with non-mesh surgery for  
9 pelvic organ prolapse in women?  
10

## 11 The committee's discussion of the evidence

### 12 Interpreting the evidence

#### 13 *The outcomes that matter most*

14 The committee prioritised health related quality of life, adverse events during surgery,  
15 complications following surgery and recurrence of prolapse as critical outcomes. The  
16 committee agreed these were the factors most likely to significantly impact the woman in the  
17 short-, mid- and long-term. Data for all of these outcomes was identified including  
18 complication data on pain, mesh erosion, bladder function, bowel function and sexual function.  
19 Fistula was generally not reported. Prolapse cure, patient satisfaction and repeat surgery for  
20 POP were considered important outcomes. Data for both cure and repeat surgery were  
21 identified but patient satisfaction was only recorded using non-validated scales and was  
22 therefore not included in this review.

#### 23 *The quality of the evidence*

24 Randomised and comparative studies within this review were assessed using the Cochrane  
25 Collaborations tool for assessing risk of bias. In addition, the evidence in the pairwise  
26 comparisons was assessed using the GRADE methodology. The non-comparative cohort  
27 studies were assessed for quality using the Cochrane ROBINS-I tool.

28 The evidence considered for the effectiveness of anterior surgery ranged from low quality to  
29 moderate quality, and was downgraded due to the participants, care staff and assessors  
30 being aware of treatment allocation. The evidence included on adverse events was very low  
31 quality due to lack of blinding, and high levels of imprecision due to small study numbers,  
32 and wide confidence intervals. The evidence on short-term complications following anterior  
33 surgery was all either low or very low quality, and was downgraded due to lack of blinding,  
34 unclear allocation methods, high attrition rates and high levels of imprecision.

35 The quality of evidence presented on the effectiveness and short-term complications  
36 following apical surgery was all low or very low quality and was downgraded due to unclear  
37 allocation methods, unclear blinding methods and high levels of imprecision due to small  
38 study sizes.

39 The quality of evidence for the effectiveness of posterior surgery was considered moderate  
40 quality and was downgraded due to the overall small study population. The quality of  
41 evidence for short term complications and adverse events following posterior prolapse  
42 surgery ranged from very low to moderate quality and was downgraded due to unclear  
43 blinding procedures and high levels of imprecision.

44 The majority of the evidence presented on the mid-term and long-term complications  
45 following prolapse surgery was considered low quality. The studies were downgraded as

1 there was generally little detail regarding the interventions conducted, limited information on  
2 inclusion and exclusion criteria, studies were single armed, and often there was limited detail  
3 regarding missing data. These non-comparative studies were not designed to compare  
4 vaginal, abdominal or non-mesh surgery to one another, we have combined the data to  
5 estimate potential risks associated with the different types of surgery; therefore, data must be  
6 interpreted cautiously and regarded with care.

7 In terms of the NMA, considerable heterogeneity and uncertainty indicated by wide credible  
8 intervals and high between-study standard deviation was observed in the studies  
9 investigating recurrence of pelvic organ prolapse at the same site. The committee  
10 acknowledged this and attributed it to the heterogeneous populations across studies i.e. trials  
11 included women who are treatment naïve and also women who had prior pelvic organ  
12 prolapse repair; women in trials received a number of various concomitant surgeries;  
13 different definitions of recurrence used across trials, and surgeons of varying skills and  
14 experience.

15 The inconsistency checks did not identify any evidence of inconsistency between the direct  
16 and indirect evidence included in the NMA for recurrence of pelvic organ prolapse at the  
17 same site, thus there is no evidence that the underlying assumptions do not hold.

#### 18 **Benefits and harms**

19 Considering both the effectiveness and the complication data presented, the committee  
20 agreed that anterior repair without mesh should be the first line recommendation for anterior  
21 prolapse surgery. Despite the potential effectiveness of mesh surgery for anterior prolapse  
22 the data showed greater numbers of bladder perforations during surgery with mesh as  
23 compared to anterior colporrhaphy; in addition, there was no significant difference in the  
24 short term complications between the mesh surgery and anterior colporrhaphy. Furthermore  
25 the data on the effectiveness of surgery, and data on complications following surgery in the  
26 mid- and long-term was limited, taking all these considerations together the committee were  
27 not confident to recommend mesh.

28 The committee also discussed the data presented within the NMA, although anterior  
29 colporrhaphy with synthetic partially absorbable mesh has the highest probability of being the  
30 best treatment for reducing the recurrence, the use of mesh was associated with a higher  
31 incidence of complications when compared with non-mesh surgery including mesh erosion,  
32 pain complications, dyspareunia, SUI, and constipation.

33 The committee discussed that some women with recurrent prolapse may be prepared to  
34 accept the higher risk associated with mesh placement, and that this option should be  
35 available to them. The committee agreed some women are prepared to accept this higher  
36 risk as there quality of life can be greatly reduced by persistent POP, which has not been  
37 cured by alternative options. The committee wish to highlight that this recommendation is for  
38 a very limited number of women only, recently published data estimates that only 1% of  
39 women will undergo a further operation, these figures are based on women who had non-  
40 mesh surgery as the primary operation (Lowenstein 2017). The recommendation should be  
41 limited to these women who have tried, yet failed other available options, and now feel they  
42 have no alternative option. The committee noted it was important that these women have a  
43 choice to do something about their prolapse, as to do nothing has potentially serious  
44 consequences for the women, including persistent prolapse, persistent problems with  
45 bladder emptying, ulceration of vaginal skin, recurrent urinary tract infections, pain and  
46 discomfort, negative effects on sexual function, working and social life, all of which can  
47 negatively impact mental health and wellbeing of the woman. The committee agreed that  
48 when considering the balance between the risks associated with mesh surgery and the risk  
49 of long-term consequences of no treatment, women should be given the choice to make a  
50 fully informed decision regarding their own health.

- 1 The committee acknowledge that the evidence presented in this review was based on  
2 women who were either treatment naïve or had recurrent prolapse, despite this, the  
3 committee concluded that mesh surgery should not be offered to all women due to the  
4 potential risks associated with the surgery. The option of mesh surgery should be restricted  
5 to those women defined as having no alternative.
- 6 The committee were presented with thirteen different comparisons on the effectiveness of  
7 apical surgery for POP, with the majority including only one study. The committee discussed  
8 how the majority of comparisons showed no difference, and that across these many  
9 comparisons, one significant result could simply happen by chance. The committee  
10 discussed the possibility of grouping these comparisons further but after discussion,  
11 including input from the technical team deemed that it was not appropriate. The committee  
12 agreed it was difficult to make recommendations on the effectiveness of apical surgery on  
13 the evidence presented and clinical experience was needed to make the recommendations.
- 14 For apical surgery the committee agreed that the woman needs to decide if she wishes to  
15 keep her uterus or not, and this will influence the surgery options available to her. This  
16 decision needs detailed discussion regarding the benefits and harms for the women and  
17 must take in to consideration her particular circumstances. The committee agreed vaginal  
18 hysterectomy with or without sacrospinous fixation (with sutures), Sacro-hysteropexy with  
19 mesh (Abdominal or laparoscopic) and Vaginal sacrospinous hysteropexy (with sutures) are  
20 suitable options for women with uterine prolapse. The evidence presented demonstrated a  
21 trend towards benefit for vaginal hysterectomy as compared to sacrospinous hysteropexy;  
22 however, the data did not show a significant difference, and was based on two small studies,  
23 (Dietz 2010 and Dellotonare 2015) thus the committee did not think this warranted a firm  
24 recommendation of one procedure over the other. The committee are aware that there are  
25 other procedures available (such as high levator myorrhaphy, uterosacral ligament  
26 suspension, and Infracoccygeal sacropexy supported by limited evidence), but the committee  
27 was of the opinion that the most commonly performed procedures in the UK are  
28 sacrospinous hysteropexy and sacrospinous fixation. The committee also agreed that  
29 Manchester repair should be an option for women; the evidence presented showed fewer  
30 repeat surgeries were reported with Manchester repair as compared to vaginal hysterectomy.
- 31
- 32 The committee acknowledged that there may be differences in both effectiveness and  
33 complications according to the age of women. The median age of women included in the  
34 studies in this review was 62 years, only two studies included women younger than 50 years  
35 (El-Nazer 2012 and Joshi 2013) and these were studies conducted in Egypt India, and  
36 therefore may not be reflective of a UK population. In addition, there are likely differences  
37 between women pre and post hysterectomy yet again the evidence in this review did not  
38 provide adequate details to answer this question.
- 39 The committee agreed that giving women a choice in which procedure she undergoes was  
40 very important, and that women should be provided with all the potential benefits and harms  
41 regarding each procedure which are relevant to her prolapse was crucial. The committee felt  
42 women should be given information about the procedures but also about how their prolapse  
43 may develop over time. The lay members of the committee felt that women are not always  
44 given enough explanation or details about the procedures, for example, women do not  
45 always realise that mesh is a permanent fixture, to be able to make a fully informed choice,  
46 and this should be changed, empowering self-choice. A decision aid may also be useful for  
47 women to facilitate shared decision making. The committee also acknowledged that women  
48 need to be made aware that the full extent of their prolapse may not be determined until the  
49 surgery is underway, and this also needs to be fully discussed, with informed consent of the  
50 different options. The committee also agreed that all options of surgery should be discussed,  
51 not just the procedures that are undertaken in the centre where the consultation is taking

1 place. If women wish to have a specific procedure, they should have the option to attend a  
2 difference centre.

3 The committee also considered it was important that surgeon's should input all their data to a  
4 database to ensure all surgical outcomes are reported, along with any complications which  
5 arise.

6 In relation to the collection of data on mesh surgery and mesh-related complications the  
7 committee was aware of the widespread public concern about the use of synthetic mesh in  
8 the surgical management of women with UI and POP, of the Independent Medicines and  
9 Medical Devices Safety Review, of the final report of NHS England Mesh Working Group and  
10 of the pause on surgical procedures involving synthetic mesh imposed by NHS England.  
11 They were also concerned about the lack of reliable evidence on the adverse events  
12 following surgical interventions for UI and POP, especially those occurring after two years,  
13 despite extensive review of the existing research literature carried out for development of the  
14 guideline.

15 The committee was aware that in their joint letter sent on 9 July 2018 NHS England and NHS  
16 Improvement had committed to 'continue to pursue the commissioning of a national clinical  
17 audit/registry procedures for SUI and prolapse'. The committee strongly supported this action  
18 and felt that it would be helpful to make specific recommendations about data collection as  
19 part of the guideline. They did not think it was their role to specify the details of what  
20 information should be collected but agreed to give some broad indication of the information  
21 that would provide better evidence on adverse events to inform any future revision of the  
22 guideline.

23 Due to the limited evidence, the committee made three research recommendations covering  
24 surgical management options of pelvic organ prolapse. The first recommendation was to  
25 assess the effectiveness of colpocleisis compared to sacrospinous fixation in elderly women  
26 for treatment of pelvic organ prolapse. The committee felt that given the ageing population,  
27 more frail elderly women are presenting with prolapse and for some of these women  
28 colpocleisis is a surgical management option. There are no trials comparing colpocleisis to  
29 other surgical procedures such as sacrospinous hysteropexy with pelvic floor repair. Data is  
30 needed to counsel women on the safety and success rate of colpocleisis compared to other  
31 procedures.

32 The second research recommendation was for long-term patient satisfaction data to be  
33 collected following treatment with pessary or surgery. This is important because there are no  
34 studies evaluating the long term success rate of pessary use beyond 5 years compared with  
35 surgery. Women considering pessary use often ask if it is a successful long term option or is  
36 it delaying surgical intervention. The committee felt that long term information was required  
37 on the success and complications of pessary use compared with surgical intervention.

38 The third research recommendation was for the long-term risk data for mesh surgery  
39 compared to non- mesh surgery for treatment of pelvic organ prolapse in women. This is  
40 important because mesh can be used in prolapse surgery by both abdominal and vaginal  
41 placement but there is no data on the complications associated with mesh use greater than 5  
42 years. The committee felt it was very important for research to ascertain the success, safety  
43 and complications of mesh use over a 5-10 year period.

#### 44 Cost effectiveness and resource use

45 The committee explained that facilitating the discussion at the time of consent around the risk  
46 and benefits of each procedure, the uncertainty around long-term complications, the risks of  
47 recurrent prolapse, and the role of intraoperative evaluation may have modest resource  
48 implications, which are justifiable as this is essential in ensuring the appropriate treatment for  
49 the pelvic organ prolapse.

- 1 The committee acknowledged the existing UK-based economic evidence which showed that  
2 mesh was potentially cost-ineffective when compared with a non-mesh procedure in women  
3 with anterior pelvic organ prolapse. The guideline economic analysis with a 15 year time  
4 horizon demonstrated that anterior colporrhaphy without mesh was the dominant procedure  
5 (that is, it resulted in lower costs and higher QALYs) when compared with anterior  
6 colporrhaphy with biological mesh, anterior colporrhaphy with synthetic partially absorbable  
7 mesh, and anterior colporrhaphy with non-absorbable mesh. The cost ineffectiveness of  
8 mesh was attributed to a higher rate of mesh complications including mesh extrusion and  
9 pain, and high costs associated with managing mesh complications. Although, the mesh was  
10 favoured in terms of recurrence at the same compartment, only a small proportion of women  
11 require revision surgery. Also, in the majority of women the symptoms are not severe enough  
12 to require further management. The probability of anterior colporrhaphy without mesh being  
13 cost-effective was 0.70 at a NICE's lower cost-effectiveness threshold of £20,000 per QALY  
14 (NICE, 2008b). The findings were robust to changes in model inputs including the risk of  
15 recurrence, the risk of mesh extrusion and pain complications, cost data, and utility values. A  
16 further sensitivity analysis indicated that the risk of mesh complications including mesh  
17 extrusion and pain would need to be very low for the mesh to be considered cost-effective.
- 18 The committee explained that for women with a recurrent anterior wall prolapse with  
19 adequate apical support or when an abdominal approach is contraindicated, synthetic  
20 polypropylene or biological mesh placement could be considered. The committee expressed  
21 the view that in such women the benefits of synthetic polypropylene or biological mesh  
22 placement will potentially outweigh the costs associated with the higher risk of mesh  
23 complications.
- 24 The existing economic evidence for women with apical pelvic organ prolapse was non-UK  
25 based and was too heterogeneous. As a result, the committee could not draw any  
26 conclusions from it. The committee explained that the recommendations in this area do not  
27 represent a significant change in practice and generally the committee do not expect there to  
28 be important cost differences between the procedures recommended for women with apical  
29 prolapse. Although, it was noted that laparoscopic procedure is less invasive, quicker to  
30 perform, and is associated with a shorter recovery. However, there is a lack of training and it  
31 is not available in all centres.
- 32 The existing economic evidence pertaining to the posterior surgery was limited to one UK  
33 study. However, the study population comprised of women with anterior and/or posterior  
34 pelvic organ prolapse. Nevertheless, the non-mesh repair was found to be dominant when  
35 compared with synthetic mesh and biological graft at 5 years. The probability of standard  
36 repair being cost-effective was 0.50 at any willingness-to-pay value per QALY. Extending  
37 time horizon to 10 and 30 years also resulted in standard repair the preferred treatment. This  
38 supports the committee expert view that non-mesh repair is likely to have more favourable  
39 cost-effectiveness when compared with mesh repair, and is in line with the findings for  
40 anterior repair where non-mesh repair was found to be dominant (that is, it resulted in lower  
41 costs and QALYs when compared with synthetic mesh and biological mesh).
- 42 The committee expressed the view that offering women a six month review appointment to  
43 exclude mesh complications including mesh erosion represents a good clinical practice. Most  
44 women are already receiving a six month review appointment and this would have only  
45 modest resource implications which is justifiable as this is essential in ensuring timely  
46 identification of mesh complications and the initiation of appropriate treatment. Timely  
47 identification and treatment of mesh complications may prevent the need for more resource  
48 intensive management given that delays in treatment of mesh complications exacerbate  
49 problems and may result in the overall savings to the NHS.

## 1 Other factors the committee took into account

- 2 The committee discussed the evidence in relation to the published NICE Interventional  
3 Procedures Programme, and acknowledge the discrepancy between recommendation 1.7.17  
4 and that of IPG599, “*Interventional procedure overview of transvaginal mesh repair of*  
5 *anterior or posterior vaginal wall prolapse*”  
6 (<https://www.nice.org.uk/guidance/ipg599/evidence/overview-final-pdf-4669764013>). In  
7 recommendation 1.7.17 the committee agreed that synthetic polypropylene or biological  
8 mesh could be considered as a treatment option for women with anterior vaginal wall  
9 prolapse, yet IPG599 states that this procedure should only be used in the context of  
10 research. However, the committee concluded that their recommendation is warranted and  
11 highlighted the systematic methodology and analysis of evidence underpinning the guideline  
12 which draws them to this conclusion. The evidence included for this guideline is based on a  
13 systematic search of the evidence and includes data from 22 randomised controlled trials,  
14 conducted worldwide to determine the effectiveness of anterior repair with or without mesh;  
15 in addition, over 20 prospective cohort studies with follow up data ranging from 36 to 115  
16 months are included (these cover anterior, apical and posterior repair). The IPG review  
17 included four systematic reviews, two RCT, three cohorts, (with a maximum 60 months follow  
18 up) and one case series. The systematic reviews included in the IPG contained many of the  
19 studies within our review, those not included were generally excluded as it was unclear which  
20 compartment the primary surgery was conducted in (i.e. it was unclear if the study  
21 specifically examined anterior POP). In addition, we did not include these systematic  
22 reviews as we were concerned about double counting events (as the primary studies within  
23 were already included). The committee also believed it was important to note that the IPG  
24 report provides guidance on procedures in isolation from the clinical context, the IPG covers  
25 all women with prolapse, it does not consider any specific subgroups. The committee  
26 decided that the whole clinical picture is very important in this case, as women can  
27 experience consequences from either option (doing nothing or undergoing surgery), and that  
28 the recommendation is for a very specific clinical population. The committee acknowledge  
29 that the general findings from this guideline and the IPG are broadly similar; however, the  
30 committee decided that when balancing the benefits and harms between taking no action  
31 (persistent prolapse, persistent problems with bladder emptying, ulceration of vaginal skin,  
32 recurrent urinary tract infections, pain and discomfort, negative effects on sexual function,  
33 working and social life, all of which can impact mental health and wellbeing) and the risk of  
34 potential adverse events following mesh surgery, women should have the option to make a  
35 fully informed choice regarding their care.
- 36 The committee discussed the option of making a research only recommendation, as currently  
37 stated in the IPG; however, after discussion they agreed that it would be very unlikely that  
38 any suggested research would be conducted. The committee believe health care  
39 professionals would be hesitant to conduct studies due to the controversial nature of mesh  
40 surgery, and that recruitment would be difficult due potential risks of mesh surgery which  
41 have been discussed widely in the media, and the very small numbers of women meeting the  
42 inclusion criteria. The committee are recommending mesh surgery only in a very specific,  
43 restricted clinical context. The committee agreed that mesh surgery which has been shown  
44 to be effective, with lower recurrence rates than anterior colporrhaphy, should be available to  
45 this small number of women, when the only alternative is to do nothing, and only following full  
46 discussion with the woman regarding the potential risks regarding mesh surgery.
- 47 The NHS Digital Review, a retrospective audit which was released in April 2018 was  
48 published mid-way through the production of this guideline. The committee discussed this  
49 publication but decided it did not add any further information to influence their decisions.  
50

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## 1 Surgery to prevent occult SUI

- 2 What is the role of surgery to prevent postoperative urinary incontinence in women having  
3 surgery for pelvic organ prolapse, including the sequence of interventions?

## 4 Introduction

- 5 Post-operative urinary incontinence is a recognised complication after surgery for pelvic  
6 organ prolapse. This review aims to address the uncertainty as to the role of preventative  
7 concomitant surgery for stress incontinence surgery.

## 8 Summary of the protocol

- 9 Please see Table 24 for a summary of the Population, Intervention, Comparison and  
10 Outcome (PICO) characteristics of this review.

11 **Table 24: Summary of the protocol (PICO table)**

Population	Women (aged 18 years and over) undergoing surgery for anterior or apical pelvic organ prolapse. Women having repeat surgery or those who are on treatment naïve will be included. Women undergoing surgery for posterior pelvic organ prolapse will be excluded.
Intervention	Any surgery for anterior or apical pelvic organ prolapse plus concurrent preventative surgery for stress urinary incontinence. Surgery for posterior pelvic organ prolapse will be excluded. The following surgical treatments for the management of pelvic organ prolapse will be considered, as long as they are performed concurrently with any surgical option for the prevention of stress urinary incontinence: <ul style="list-style-type: none"><li>• Anterior prolapse</li><li>• Anterior repair or colporrhaphy or cystocele repair</li><li>• With or without mesh, biological or synthetic</li><li>• Mesh kit or inlay mesh</li><li>• Paravaginal repair (open or laparoscopic)</li></ul> <ul style="list-style-type: none"><li>• Apical prolapse</li><li>• Vaginal hysterectomy</li><li>• Vaginal sacrospinous hysteropexy</li><li>• Manchester repair</li><li>• Hysteropexy with mesh</li><li>• Laparoscopic or open</li><li>• Wrap around or posterior attachment</li><li>• Suture hysteropexy</li><li>• Laparoscopic or open</li></ul> <ul style="list-style-type: none"><li>• Vault prolapse</li><li>• Posterior IVS</li><li>• Sacrospinous fixation</li><li>• Sacrocolpopexy with mesh</li><li>• Laparoscopic or open</li><li>• Mesh kit or inlay mesh</li></ul>

	<ul style="list-style-type: none"> <li>• Colpocleisis</li> <li>• Uterosacral plication</li> <li>• Vaginal or laparoscopic</li> </ul> <p>The following surgical treatments for stress urinary incontinence were deemed appropriate for the prevention of urinary incontinence in conjunction with POP repair, and will be considered in this review:</p> <ul style="list-style-type: none"> <li>• Suburethral slings (synthetic mesh)</li> <li>• Retropubic bottom-up</li> <li>• Retropubic top-down</li> <li>• Transobturator outside-out</li> <li>• Transobturator outside-in</li> <li>• Single-incision</li> <li>• Mini-sling or single incision sling</li> <li>• Adjustable slings</li> <li>• Retropubic</li> <li>• Transobturator</li> <li>• Colposuspension</li> <li>• Open abdominal retropubic suspension</li> <li>• Laparoscopic retropubic suspension</li> <li>• Fascial slings (autologous/pubovaginal sling)/sling on a string/rectus sling/ fascia lata sling</li> <li>• Para or transurethral injections (bulking agents)</li> <li>• Artificial urinary sphincters</li> </ul>
<b>Comparison</b>	Any surgery for pelvic organ prolapse alone (that is, with no concurrent preventative surgery for stress urinary incontinence). Surgery for posterior pelvic organ prolapse will be excluded.
<b>Outcomes</b>	<p><b>Critical</b></p> <ul style="list-style-type: none"> <li>• Change in continence status</li> <li>• Self-reported symptoms</li> <li>• Objective cure rate</li> <li>• Negative stress (cough) test</li> <li>• Number of incontinence episodes per day</li> <li>• Long-term complications (&gt; 12 months)</li> <li>• Pain</li> <li>• Mesh erosion or extrusion (vaginal, bladder, urethra)</li> <li>• Fistula</li> <li>• Need for catheterisation</li> <li>• Infection (recurrent UTI, wound)</li> <li>• De novo overactive bladder symptoms</li> <li>• Occurrence of POP</li> <li>• Wound complications (hernia)</li> <li>• Repeated surgery for UI, POP or mesh complications</li> </ul> <p><b>Important</b></p> <ul style="list-style-type: none"> <li>• Continence specific health-related quality of life (ICIQ, BFLUTS, I-QOL, SUIQQ, UISS, SEAPI-QMM, ISI, KHQ and E-PAQ)</li> <li>• Adverse events (immediate post-op or perioperative)</li> <li>• Severe bleeding requiring a blood transfusion</li> </ul>

- Internal organ injury (to bladder or bowel)
- Patient satisfaction
- Patient reported improvement
- Patient global impression of improvement

1      *BFLUTS: Bristol female lower urinary tract symptoms; E-PAQ: electronic personal assessment questionnaire;*  
2      *ICIQ: international consultation incontinence questionnaire; IQOL: urinary incontinence quality of life scale; ISIS:*  
3      *incontinence severity index; IVS: intravaginal slingplasty; KHQ: kings health questionnaire; SEAPI-QMM: stress-*  
4      *related leak, emptying, anatomy, protection, inhibition, quality of life, mobility and mental status incontinence*  
5      *classification system; SUIQQ: stress and urgency incontinence and quality of life questionnaire; POP: pelvic*  
6      *organ prolapse; UI: urinary incontinence; UISS: urinary incontinence severity score; UTI: urinary tract infection.*

7      For further details see the review protocol in appendix A

## 8 Methods and process

9      This evidence review was developed using the methods and process described in  
10     [Developing NICE guidelines: the manual 2014](#). Methods specific to this review question are  
11     described in the review protocol in appendix A and for a full description of the methods see  
12     supplementary material C.

13     Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy  
14     until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to  
15     NICE's 2018 [conflicts of interest policy](#). Those interests declared until April 2018 were  
16     reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

## 17 Clinical evidence

### 18 Included studies

19     Six articles reporting five RCT were included in this systematic review (Burgio 2007/Brubaker  
20     2008; Costantini 2007/2011; van der Ploeg 2016; Wei 2012). For a summary of included  
21     studies see Table 25.

22     Four articles reporting two RCT (n=388) examined whether the addition of Burch  
23     colposuspension with sutures was effective in preventing occult SUI in women having  
24     abdominal sacrocolpopexy for POP (Burgio 2007/Brubaker 2008; Costantini 2007/2011).  
25     Women in both of these studies had at least stage 2 prolapse according to the POP-Q  
26     system and were subjectively continent before surgery.

27     One RCT (n=337) examined whether the addition of TVT, a synthetic retropubic bottom-up  
28     midurethral mesh sling, was effective in preventing occult SUI in women having vaginal POP  
29     repair (Wei 2012). Participants in these studies had anterior vaginal wall prolapse within 1 cm  
30     of hymen on straining and were subjectively continent.

31     One RCT (n=91) examined whether the addition of a synthetic transobturator mesh sling was  
32     effective in preventing occult SUI in women who had a negative cough stress test without  
33     POP reduction, ≤1 weekly episode of urine leakage, and vaginal POP repair for at least  
34     POP-Q Stage 2 prolapse (van der Ploeg 2016). Twelve per cent of the participants in this  
35     study had synthetic retropubic mesh sling, with the remaining all receiving transobturator  
36     mesh sling. Follow up in the included studies ranged from to 1 to 8 years.

37     See also the literature search strategy in appendix B, study selection flow chart in appendix  
38     C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in  
39     appendix F.

**1 Excluded studies**

2 Studies not included in this review and reasons for their exclusions are provided in appendix  
3 K.

4  
5

## Summary of clinical studies included in this review

A summary of the studies that were included in this review are presented in Table 25.

**Table 25: Summary of randomised controlled studies included in this review**

Study Country	Number of participants	Characteristics/Follow up	Intervention	Comparison	Outcomes
Burgio 2007/Brubaker 2008 USA	322	Women with POP-Q > Stage 1 and subjectively continent before surgery Follow up: 1 year, 2 years	Abdominal sacrocolpopexy + Burch colposuspension	Abdominal sacrocolpopexy	Change of continence status Complications Repeat surgery Adverse events Continence-specific health-related quality of life Adverse events
Costantini 2007/2011 Italy	66	Women with severe POP, and subjectively continent with negative cough stress test before and after prolapse reduction Follow up: 6 months, 3 years, 8 years	Abdominal sacrocolpopexy + Burch colposuspension	Abdominal sacrocolpopexy	Change of continence status Complications Adverse events
Van der Ploeg 2016 Netherlands	91	Women with POP-Q > Stage 1, negative cough stress test without POP reduction, and ≤1 weekly episode of urine leakage Follow up: 1 year	Vaginal POP repair + transobturator mesh sling	Vaginal POP repair	Change of continence status Complications Repeat surgery Adverse events Patient satisfaction
Wei 2012 USA	337	Women with anterior vaginal wall prolapse within 1 cm of hymen on straining, and subjectively continent Follow up: 1 year	Vaginal POP repair + TTV	Vaginal POP repair	Change of continence status Complications Continence-specific health-related quality of life Adverse events

Notes: <sup>a</sup>, Assessed using the Medical, Epidemiological and Social Aspects of Aging (MESA) questionnaire; <sup>b</sup>, Definition of 'severity' not provided. Subjective assessment of continence status using the Urogenital Distress Inventory Short Form (UDI-6). Abbreviations: POP, pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse Quantification System; SUI, stress urinary incontinence; TTV, Gynecare synthetic retropubic bottom-up mesh sling.

## **Quality assessment of clinical outcomes included in the evidence review**

GRADE analysis was conducted on critical and important outcomes, full clinical evidence profiles can be found in appendix F.

## **Economic evidence**

### **Included studies**

The systematic search of the economic literature undertaken for the guideline identified one USA study on the cost-utility of concurrent preventative surgery for stress urinary incontinence in women undergoing surgery for pelvic organ prolapse (Richardson 2013).

Evidence table for the economic evaluation is provided in appendix H. Completed methodology checklist of the study is provided in appendix M. Economic evidence profile of the study considered is presented in appendix I.

### **Excluded studies**

Studies not included in this review with reasons for their exclusions are provided in appendix K.

## **Summary of studies included in the economic evidence review**

Richardson (2013) evaluated the cost-utility of abdominal sacrocolpopexy (ASC) alone with a deferred option for mid-urethral sling (MUS), ASC with universal concomitant MUS, and preoperative urodynamic study (UDS) for selective MUS in women with pelvic organ prolapse in the USA. The study population comprised of women with uncomplicated, symptomatic, advanced pelvic organ prolapse and no pre-existing urinary symptoms. This was a modelling study with effectiveness data from published studies, mainly RCTs (CARE trial, Brubaker 2008).

In a decision analytic model after ASC with or without MUS, two outcomes of no SUI and SUI were modelled. After MUS surgery five outcomes were modelled including no SUI, SUI, de novo urge incontinence, mesh exposure removal, and urinary retention requiring surgical management. Those in whom SUI developed could opt to pursue further surgical treatment. De novo urge incontinence was treated with anticholinergic medication. Women with SUI after failed or removed MUS were able to undergo one additional MUS. In women undergoing a second MUS, the same outcome algorithm was applied with the exception that no further MUS was offered if SUI persisted.

The analysis was conducted from a healthcare payer perspective. The study considered a range of direct health care costs including inpatient surgical procedures, physician costs, urodynamic testing, outpatient care, complication management, and medication. The resource use estimates were obtained from Medicare reimbursement data. The unit costs were obtained from national sources (likely 2010 prices). The measure of outcome for the economic analysis was quality-adjusted life years (QALYs). The utility weights were derived from published sources. In one study utility weights were derived Health Utilities Index-Mark III (HUI-Mark III) with valuations obtained from the Canadian general population. In another study, vignettes were used to derive health state valuations using time trade-off from a sample of women with OAB symptoms and without. The time horizon of the analysis was 1 year.

Mean QALYs and costs per participant were not reported. According to the authors, UDS for selective MUS at the time of ASC was dominated by ASC with a universal MUS (that is, AC with MUS resulted in lower costs and a great number of QALYs). The incremental cost-

effectiveness ratio (ICER) of ASC plus MUS (versus ASC alone with MUS as needed) was \$2,867 per QALY gained.

Sensitivity analyses indicated that the ICER of ASC plus MUS never exceeded \$20,000 per QALY. The results were robust to changes in cost estimates ( $\pm 50\%$  around base case values). Even if the cost of concomitant MUS was reduced to as little as \$1,000 (base case \$13,090) the ICER of ASC plus MUS was still \$20,761 per QALY, which is below NICE lower cost-effectiveness ratio of £20,000.

If outpatient MUS cost was reduced to \$2,100 (from a base case \$4,340), the ICER of ASC plus MUS would be reduced to \$8,929 per QALY. It was further found that ASC alone was the least expensive option as long as 45% or more of women chose to pursue further SUI therapy following postoperative SUI (base case 36%). The cost of UDS and anticholinergic medication had little impact on the overall cost-effectiveness of the 3 strategies. Urodynamic testing for selective MUS was dominated regardless of the postoperative urinary retention rate and rates of risk of mesh exposure removal. Even at a risk of 6.0% of mesh exposure within 1 year of MUS placement (base case 1.3%), the AC plus MUS strategy remained the most cost-effective option with an ICER of \$6,490 per QALY. The conclusions were robust to changes in the utility values.

The analysis was partially applicable to the NICE decision-making context and had potentially serious methodological limitation.

## Economic model

A decision analytical model was developed to assess the relative cost-effectiveness of anterior repair with a preventative concomitant SUI surgery in women with anterior repair but no SUI. The rationale for economic modelling, the methodology adopted, the results and the conclusions from this economic analysis are described in detail in appendix J. This section provides a summary of the methods employed and the results of the economic analysis.

## Overview of methods

A decision-analytic model in the form of a decision-tree was constructed to evaluate the relative cost effectiveness of anterior repair with preventative concomitant SUI procedure over 2 years with complications captured over the long-term. The interventions assessed were anterior colporrhaphy with preventative concomitant RMUS procedure versus anterior colporrhaphy with a deferred option of RMUS. Anterior prolapse was prioritised over other prolapse types given a much higher prevalence of women with anterior prolapse. The choice of treatments assessed in the economic analysis was also guided by the availability of respective clinical data (presence of SUI at the follow-up) included in the guideline systematic literature review. The economic analysis considered effective treatments, as demonstrated by the systematic review of clinical evidence looking at the effectiveness of surgical treatments for women with anterior prolapse and also SUI that were deemed appropriate by the committee as treatment options for women in the UK. The study population comprised of adult women with anterior pelvic organ prolapse (but no SUI) considering surgery for their anterior pelvic organ prolapse. Clinical data were derived from studies included in the guideline systematic review of clinical evidence and other published literature. The complications were captured over the long-term follow-up and included de novo urge incontinence symptoms, urinary tract infection, mesh complications, and pain. The availability of the long-term complication data varied by complication with de novo urge incontinence modelled over 9 years, infection over 6 years, mesh extrusion over 11 years, and pain over 5 years.

The measure of outcome in the economic analysis was the number of QALYs gained. The perspective of the analysis was that of NHS. Resource use was based on the published literature and the committee expert opinion. National UK unit costs were used. The cost year

was 2016/2017. Two methods were employed for the analysis of input parameter data and presentation of the results. First, a deterministic analysis was undertaken, where data were analysed as point estimates and results were presented in the form of ICERs following the principles of incremental analysis. A probabilistic analysis was subsequently performed in which most of the model input parameters were assigned probability distributions. Subsequently, 10,000 iterations were performed, each drawing random values out of the distributions fitted onto the model input parameters. Mean costs and QALYs for each treatment option were calculated by averaging across the 10,000 iterations. This approach allowed more comprehensive consideration of the uncertainty characterising the input parameters and captured the non-linearity characterising the economic model structure. Results of probabilistic analysis were also summarised in the form of cost-effectiveness acceptability curves, which express the probability of each intervention being cost effective at various levels of willingness-to-pay per QALY gained (that is, at various cost-effectiveness thresholds). Also, a number of sensitivity analyses were undertaken to test the robustness of model findings to changes in various model inputs.

### **Findings of the economic analysis**

According to both deterministic and probabilistic analysis, anterior colporrhaphy with a deferred option for RMUS procedure was the dominant option when compared with the anterior colporrhaphy with a concomitant preventative RMUS. The conclusions were robust to changes in model inputs including the risk ratio of developing SUI post anterior repair with a preventative concomitant SUI surgery (when compared with anterior repair only), the baseline risk of SUI, the proportion of women choosing to undergo further SUI repairs, utility estimates, and cost data. The probability of anterior colporrhaphy with a deferred option of RMUS was more than 0.90 at any willingness to pay per QALY below of £100,000. The cost-effectiveness of anterior colporrhaphy with a deferred option for RMUS procedure was attributed to a low risk of SUI post anterior repair only, higher intervention costs associated with anterior repair with concomitant RMUS procedure, and also a higher proportion of women being exposed to unnecessary RMUS-related complications which have important costs and quality of life consequences.

### **Strengths and limitations**

Clinical data on postoperative SUI were synthesised using meta-analytic techniques. Such methods enabled evidence synthesis from multiple trials to be considered in the analysis. Although, only two trials with a limited follow-up were identified. The main strength of this analysis is that it attempted to incorporate mesh-related complications over the long-term follow-up. Due to the lack of suitable data, some of the cost estimates were based on the committee expert opinion. Also, the utility data for complications was derived from another economic evaluation where utility weights were assigned by a panel of experts.

### **Clinical evidence statements**

#### **Sacrocolpopexy and Burch colposuspension versus Sacrocolpopexy**

##### ***Change in continence status***

Moderate quality evidence from one RCT (n=322) showed no clinically important difference between sacrocolpopexy with or without concomitant Burch colposuspension on the number of women who show any sign of urge or mixed urinary incontinence within 1 year of surgery: RR 0.81 (95% CI 0.61-1.09).

Moderate quality evidence from two RCTs (n=388) showed a clinically important difference favouring sacrocolpopexy and concomitant Burch colposuspension over sacrocolpopexy on the number of women who show any sign of urge or mixed urinary incontinence between 1 and 5 years after surgery: RR 0.74 (95% CI 0.55-0.99).

Low quality evidence from one RCT (n=66) showed no clinically important difference between sacrocolpopexy with or without concomitant Burch colposuspension on the number of women who show any sign of urge or mixed urinary incontinence more than 5 years after surgery: RR 0.63 (95% CI 0.11-3.51).

Moderate quality evidence from one RCT (n=66) showed a clinically important difference favouring sacrocolpopexy over sacrocolpopexy and concomitant Burch colposuspension on the number of women who show any sign of urinary incontinence between 1 and 5 years after surgery: RR 3.76 (95% CI 1.17-12.12).

Low quality evidence from one RCT (n=66) showed no clinically important difference between sacrocolpopexy with or without concomitant Burch colposuspension on the number of women who show any sign of urinary incontinence more than 5 years after surgery: RR 1.69 (95% CI 0.64-4.52).

Moderate quality evidence from one RCT (n=322) showed a clinically important difference favouring sacrocolpopexy and concomitant Burch colposuspension over sacrocolpopexy on the number of women who show any sign of stress urinary incontinence within 1 year of surgery: RR 0.71 (95% CI 0.54-0.93).

Low quality evidence from two RCTs (n=388) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who any sign of stress urinary incontinence between 1 and 5 years after surgery: RR 1.96 (95% CI 0.15-25.52), random effects analysis.

Low quality evidence from one RCT (n=66) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who any sign of stress urinary incontinence more than 5 years after surgery: RR 3.29 (95% CI 0.74-14.7).

High quality evidence from one RCT (n=322) showed a clinically important difference favouring sacrocolpopexy and concomitant Burch colposuspension on the number of women who have symptoms of stress urinary incontinence within 1 year of surgery: RR 0.55 (0.38-0.79).

Moderate quality evidence from one RCT (n=322) showed a clinically important difference favouring sacrocolpopexy and concomitant Burch colposuspension on the number of women who have symptoms of stress urinary incontinence between 1 year and 5 years after surgery: RR 0.63 (0.45-0.89).

High to low quality evidence from one RCT (n=322) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who experience irritative symptoms (RR 1.05 [95% CI 0.92-1.2]) nor on the number of women who experience obstructive symptoms (RR 1.00 [95% CI 0.77-1.31]) within 1 year of surgery.

Low quality evidence from one RCT (n=66) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women have de novo storage symptoms more than 5 years after surgery: RR 4.71 (95% CI 0.23-94.58).

Moderate quality evidence from one RCT (n=322) showed there may be a clinically - important difference favouring sacrocolpopexy and concomitant Burch colposuspension over sacrocolpopexy on the number of women who have a positive cough stress test within 1 year of surgery (RR 0.67 (95% CI 0.43-1.03]) and between 1 and 5 years after surgery RR 0.65 (95% CI 0.41-1.02), although there is some uncertainty.

### ***Complications at ≤1 year***

Low quality evidence from one RCT (n=322 to 311) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who experience mesh erosion within 1 year of surgery (RR 0.41 [95% CI 0.13-1.29]) and between 1 and 5 years after surgery (RR 2.07 [95% CI 0.38-11.11]).

Low quality evidence from one RCT (n=66) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who experience the need for catheterisation within 1 year of surgery: RR 4.71 (95% CI 0.23-94.58).

Low quality evidence from one RCT (n=319 to 311) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who experience wound complications within 1 year of surgery (RR 0.77 [95% CI 0.27-2.18]) and between 1 and 5 years after surgery (RR 1.03 [95% CI 0.15-7.24]).

#### ***Repeat surgery for UI, POP or mesh complications***

Low quality evidence from one RCT (n=319 to 311) showed no clinically-important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who have repeat surgery for POP within 1 year of surgery (RR 1.03 [95% CI 0.07-16.35]) and between 1 and 5 years after surgery (RR 0.52 [95% CI 0.05-5.64]).

#### ***Continence-specific health-related quality of life***

Moderate to high quality evidence from one RCT (n=302) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the mean Incontinence Severity Index (ISI) score within 1 year of surgery (MD -1 [95% CI -1.63 to -0.37]) and between 1 year and 5 years after surgery (MD -0.8 [95% CI -1.43 to -0.17]).

High quality evidence from one RCT showed no clinically-important difference between sacrocolpopexy with or without Burch colposuspension on the mean Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short-form (PISQ-12) score within 1 year of surgery (MD -0.1 [95% CI -1.56 to +1.36]) and between 1 year and 5 years of surgery (MD=0.1 [95% CI -1.58 to +1.38]).

#### ***Adverse events***

Low quality evidence from one RCT (n=66) showed no clinically important difference between sacrocolpopexy with or without Burch colposuspension on the number of women who experience perioperative severe bleeding requiring a blood transfusion: RR 0.94 (95% CI 0.2-4.33).

### **Vaginal POP repair and synthetic retropubic bottom-up midurethral mesh sling**

#### ***Change in continence status***

Low quality evidence from one RCT (n=337) showed a clinically-important difference favouring vaginal POP repair and concomitant TTV over vaginal POP repair on the number of women who show any sign of urinary incontinence within 1 year of surgery: RR 0.63 (95% CI 0.47-0.86).

Moderate quality evidence from one RCT (n=337) showed a clinically-important difference favouring vaginal POP repair and concomitant TTV over vaginal POP repair on the number of women who have a positive cough stress test within 1 year of surgery: RR 0.17 (95% CI 0.07-0.42).

#### ***Complications at ≤1 year***

Moderate quality evidence from one RCT (n=337) showed no clinically important difference between vaginal POP repair with or without concomitant TTV on the number of women who experience mesh erosion/exposure within 1 year of surgery: RR 1.0 (95% CI 0.99-1.01), non-event.

Low quality evidence from one RCT (n=337) showed a clinically-important difference favouring vaginal POP repair over vaginal POP repair and concomitant TTV on the number of women who experience infection within 1 year of surgery: RR 1.7 (95% CI 1.14-2.54).

### ***Continence-specific health-related quality of life***

Low quality evidence from one RCT (n=306) showed no clinically-important difference between vaginal POP repair with or without concomitant TTV on the mean change from baseline on the Incontinence Severity Index (ISI) score in women within 1 year of surgery: MD -1 (-1.61 to -0.39).

### ***Adverse events***

Moderate quality evidence from one RCT (n=336) showed a clinically important difference favouring vaginal POP repair over vaginal POP repair and concomitant TTV on the number of women who experience perioperative bladder injury: RR 24.12 (95% CI 1.43-405.95).

## **Vaginal POP repair and synthetic transobturator mesh sling**

### ***Change in continence status***

Low quality evidence from one RCT (n=90) showed a clinically-important difference favouring vaginal POP repair and concomitant synthetic transobturator mesh sling over vaginal POP repair on the number of women who show any sign of incontinence within 1 year of surgery: RR 0.03 (95% CI 0-0.47).

Very low quality evidence from one RCT (n=90) showed no clinically-important difference between vaginal POP repair with and without concomitant synthetic transobturator mesh sling on the number of women who show any subjective urge incontinence symptoms within 1 year of surgery: RR 0.55 (95% CI 0.26-1.15).

Low quality evidence from one RCT (n=90) showed a clinically-important difference favouring vaginal POP repair and concomitant synthetic transobturator mesh sling over vaginal POP repair on the number of women who do not show any subjective sign of urinary incontinence within 1 year of surgery: RR 1.88 (95% CI 1.25-2.83).

Low quality evidence from one RCT (n=90) showed a clinically-important difference favouring vaginal POP repair and concomitant synthetic transobturator mesh sling over vaginal POP repair on the number of women who do not show any subjective sign of stress urinary incontinence within 1 year of surgery: RR 1.79 (95% CI 1.28-2.49).

Low quality evidence from one RCT (n=60) showed a clinically-important difference favouring vaginal POP repair and concomitant synthetic transobturator mesh sling over vaginal POP repair on the number of women who have a positive cough stress test within 1 year of surgery: RR 0.05 (95% CI 0-0.75).

Very low quality evidence from one RCT (n=90) showed no clinically-important difference between vaginal POP repair with or without concomitant synthetic transobturator mesh sling on the number of women who experience subjective frequency symptoms within 1 year of surgery: RR 1.09 (95% CI 0.5-2.37).

Very low quality evidence from one RCT (n=90) showed no clinically-important difference between vaginal POP repair with or without concomitant synthetic transobturator mesh sling on the number of women who experience subjective nocturia symptoms within 1 year of surgery: RR 1.82 (95% CI 0.89-3.73).

### ***Complications at ≤1 year***

Very low quality evidence from one RCT (n=90) showed no clinically-important difference between vaginal POP repair with or without concomitant synthetic transobturator mesh sling on the number of women who experience mesh extrusion/erosion within 1 year of surgery: RR 7.64 (95% CI 0.41-143.7).

Very low quality evidence from one RCT (n=90) showed no clinically-important difference between vaginal POP repair with or without concomitant synthetic transobturator mesh

sling on the number of women who experience infection within 1 year of surgery: RR 5.47 (95% CI 0.66-44.93).

### **Adverse events**

Low quality evidence from one RCT (n=90) showed no perioperative bladder injury occurred in women who had vaginal POP repair with or without synthetic transobturator mesh sling: RR 1.0 (95% CI 0.96-1.04), non-event.

### **Patient satisfaction**

Very low quality evidence from one RCT (n=90) showed no clinically-important difference between vaginal POP repair with or without concomitant synthetic transobturator mesh sling on the number of women who are satisfied within 1 year of surgery: RR 1.09 (95% CI 0.83-1.44).

### **Economic evidence statements**

There was evidence from the guideline economic analysis showing that anterior repair with a preventative concomitant retropubic mid-urethral sling (RMUS) procedure in women with anterior pelvic organ prolapse (and no SUI) was cost-ineffective when compared with anterior repair with a deferred option of RMUS. This evidence came from directly applicable study that was characterised by minor methodological limitations.

There was evidence from one USA modelling study showing that universal concomitant mid urethral sling is the most cost-effective prophylaxis strategy for occult stress urinary incontinence in women undergoing abdominal sacrocolpopexy when compared with abdominal sacrocolpopexy alone (with deferred option for mid urethral sling) and a strategy that utilises preoperative urodynamic study for selective mid urethral sling. This evidence came from a partially applicable study that was characterised by potentially serious limitations.

### **Recommendations**

I2.1 Offer surgery for pelvic organ prolapse to women whose symptoms have not improved with or who have declined non-surgical treatment. **[2019]**

I2.2 Do not offer surgery to prevent incontinence in women having surgery for prolapse who do not have incontinence. **[2019]**

I2.3 Explain to women considering surgery for anterior or apical prolapse who do not have incontinence that there is a risk of developing postoperative urinary incontinence and further treatment may be needed. **[2019]**

I2.4 If a woman has agreed to have a surgical procedure for pelvic organ prolapse, before surgery discuss:

- the risks and benefits of each procedure, including changes in urinary, bowel and sexual function
- the risks of recurrent prolapse
- the role of intraoperative prolapse assessment in finalising the choice of surgical procedure. **[2019]**

I2.5 If the woman's chosen procedure for pelvic organ prolapse is not available from the consulting surgeon, refer her to an alternative surgeon. **[2019]**

- I2.6 If mesh is to be used in prolapse surgery, explain to the woman:
- what type of mesh will be used and whether it is permanent.
  - the uncertainty about long-term complications associated with mesh and about the proportion of women affected. [2019]
- I2.7 If mesh is to be used in prolapse surgery
- give the woman written information on the implant including name, manufacturer, date of insertion, and implanting surgeon's name and contact details;
  - ensure that details of the procedure and its subsequent short- and long-term outcomes are collected in a national registry (see collecting data on mesh surgery and mesh-related complications in this guideline). [2019]

## The committee's discussion of the evidence

### Interpreting the evidence

#### *The outcomes that matter most*

The committee prioritised change in continence status, long-term complications, and repeat surgery for POP, UI or mesh complications as critical outcomes. The committee agreed these were the outcomes most likely to impact on the woman's quality of life, especially in the long term. Important outcomes were continence specific health-related quality of life, adverse events and patient satisfaction.

#### *The quality of the evidence*

The quality of evidence for the comparison of abdominal sacrocolpopexy and Burch colposuspension with sutures versus abdominal sacrocolpopexy was low to high. No evidence was identified for this comparison on the outcomes of repeat surgery for SUI, POP or mesh complications, continence-specific health-related quality of life, or patient satisfaction. Although there was some evidence identified on the risk of complications within 1 year of surgery, there was no evidence on this risk more than 1 year after surgery.

The quality of evidence for the comparison of vaginal POP repair and TVT versus vaginal POP repair was very low to moderate. No evidence was identified for this comparison on the outcome of patient satisfaction and repeat surgery. Although there was some evidence identified on the risk of complications within 1 year of surgery, there was no evidence on this risk more than 1 year after surgery.

The quality of evidence for the comparison of vaginal POP repair and transobturator mesh sling versus vaginal POP repair was very low to low. No evidence was identified for this comparison on the outcomes of repeat surgery for SUI, POP or mesh complications, or continence-specific health-related quality of life. Although there was some evidence identified on the risk of complications within 1 year of surgery, there was no evidence on this risk more than 1 year after surgery. Evidence from the 1 study that contributed to this comparison included 11 participants (12%) who had retropubic mesh sling. The committee agreed that outcomes including data from this study should be downgraded by one level since all 11 women were in the intervention arm and were of a sufficient number to have a clinically-relevant impact on the effect estimates.

### **Benefits and harms**

The committee agreed that the evidence presented did not allow them to make strong recommendations on the overall benefit or potential harm of providing concurrent surgery to prevent incontinence alongside prolapse surgery. Overall there were few studies on which to base recommendations and a dearth of long-term complications data (i.e. greater than 5 years after surgery).

For the comparison of abdominal sacrocolpopexy and Burch colposuspension with sutures versus abdominal sacrocolpopexy, evidence from two RCT showed no difference on any outcome except for change in continence status. The majority of change in continence status outcomes favoured concurrent surgery to prevent SUI alongside POP surgery over POP surgery only, with the latter having increased risks within 1 year of surgery of having symptoms of SUI and having a positive cough stress test, and increased risks between 1 and 5 years of surgery of having any SUI symptoms and showing a (subjective or objective) sign of urge or mixed urinary incontinence. There was also evidence that women who have POP surgery alone have increased risks of having a positive cough stress test at both within 1 year of surgery and between 1 and 5 years after surgery, although there is some uncertainty. However, evidence from one of the studies showed combined surgery to prevent SUI alongside POP surgery resulted in a greater risk of showing signs of urinary incontinence as compared to POP surgery only. The committee observed that this data was specifically from women who were having apical surgery and agreed that the possibility of undergoing combined surgery to prevent incontinence whilst undergoing POP surgery should be discussed with the woman and considered. The committee noted that there was limited data on the occurrence of complications more than 1 year after surgery, and agreed that this should be discussed with the woman. The committee agreed that clinically it made practical sense that a combined procedure would be less likely to increase the risk of surgical complications, as the preventative procedure only involves additional stitches. By contrast, the committee agreed preventative incontinence surgery during anterior surgery is likely to be more invasive and the risk of complications may be greater. The committee observed that this is consistent with the cost effective analysis which showed a clear benefit for conducting anterior colporrhaphy without concomitant preventative incontinence surgery.

For the comparison of vaginal POP repair and TVT versus vaginal POP repair, evidence from one RCT showed a benefit for combined surgery within 1 year on the number of women who show any sign of urinary incontinence and the number of women who have a positive cough stress test. Combined preventative incontinence surgery and POP surgery also had increased risks, compared to POP surgery alone, of perioperative bladder injury and of infection within 1 year of surgery. No other differences between interventions were observed.

For the comparison of vaginal POP repair and transobturator mesh sling versus vaginal POP repair, evidence from one RCT showed no difference on any outcome except for change in continence status. Combining transobturator mesh sling with vaginal POP repair resulted in decreased risks within 1 year of surgery of showing any (objective or subjective) sign of incontinence and of having a positive cough stress test, and increased probability of having no urinary incontinence symptoms and of having no SUI symptoms.

### **Cost effectiveness and resource use**

The guideline economic analysis demonstrated that anterior colporrhaphy with a preventative concomitant RMUS procedure was cost-ineffective when compared with anterior colporrhaphy with a deferred option of RMUS. The cost-effectiveness of anterior colporrhaphy with a deferred option for RMUS procedure was attributed to a low risk of SUI post anterior repair only, higher intervention costs associated with anterior repair with concomitant RMUS procedure, and also a higher proportion of women being exposed to unnecessary RMUS-related complications which have important costs and quality of life consequences. The probability of anterior colporrhaphy with a deferred option of RMUS

being cost-effective was >0.90 at any willingness to pay per QALY below of £100,000. The conclusions were robust to changes in model inputs including the risk ratio of SUI associated with anterior repair with preventative concomitant SUI when compared with anterior repair only, the baseline risk of SUI, the proportion of women choosing to undergo further SUI repairs, utility estimates, and cost data. The committee based their recommendations in this area on the guideline economic analysis.

The committee acknowledged the existing non-UK economic analysis which found the universal concomitant mid urethral sling to be cost-effective strategy in women with apical or vaginal vault prolapse undergoing abdominal sacrocolpopexy. However, it was acknowledged that the analysis has not considered long term complications. The committee also discussed that treatment effectiveness does not seem to be sustained beyond 2 years and this in combination with the long-term complications is likely to have a detrimental effect to the cost-effectiveness of the preventative concomitant SUI repair reported in this economic evaluation.

The committee noted that generally the current practice is not to perform a combined procedure. However, it was acknowledged that some surgeons are performing a combined procedure. The committee expressed their view that recommendations in this area may potentially lead to cost savings to the NHS.

The committee discussed that, except for anterior prolapse, non-mesh repair for SUI may be undertaken and the risk of concomitant surgery complications are likely to be minimal. Although, they noted that if treatment effectiveness is not sustained concomitant surgery is also unlikely to be cost-effective.

## References

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# 1 Surgical management of pelvic organ prolapse

## 2 Review question

- 3 What are the effectiveness of surgical options for pelvic organ prolapse, compared to  
4 pessaries?

## 5 Introduction

6 For women seeking further treatment of their prolapse symptoms the options include pessary  
7 management or surgery. There are a number of surgical options available depending on the  
8 type of prolapse and the woman's preferences. The aim of this review is assess the  
9 effectiveness of pessary management and surgery for anterior, apical and posterior pelvic  
10 organ prolapse. This review includes all commonly performed procedures for prolapse  
11 including vaginal mesh and abdominal mesh procedures as well as non mesh procedures.  
12 This review looks at the complications of the procedures including long term follow -up where  
13 this information is available.

## 14 Summary of the protocol

15 Please see Table 26 for a summary of the Population, Intervention, Comparison and  
16 Outcome (PICO) characteristics of this review.

17 **Table 26: Summary of the protocol (PICO table)**

<b>Population</b>	Women (aged 18 and over) with diagnosed pelvic organ prolapse. Women having repeat surgery or those that are treatment naïve will be included.
<b>Intervention</b>	Any type of POP surgery (anterior, apical, posterior)
<b>Comparison</b>	Any type of pessary
<b>Outcome</b>	<b>Critical</b> <ul style="list-style-type: none"><li>• Health related quality of life (measured through validated scales only)</li><li>• Adverse events<ul style="list-style-type: none"><li>◦ Severe bleeding requiring a blood transfusion</li><li>◦ Internal organ injury (to bladder or bowel)</li></ul></li><li>• Long-term adverse events<ul style="list-style-type: none"><li>◦ Pain</li><li>◦ Mesh erosion or extrusion (bladder, vagina, bowel, urethra)</li><li>◦ Fistula</li><li>◦ Bladder function<ul style="list-style-type: none"><li>- Stress UI</li><li>- Urge incontinence</li><li>- Voiding difficulty</li></ul></li><li>◦ Bowel function<ul style="list-style-type: none"><li>- Faecal incontinence</li><li>- Obstructed defecation</li><li>- Constipation</li></ul></li><li>◦ Sexual function<ul style="list-style-type: none"><li>- De novo dyspareunia</li><li>- Aperunia</li><li>- Prolapse and incontinence sexual questionnaire</li></ul></li><li>◦ Recurrence of any POP<ul style="list-style-type: none"><li>- Same compartment</li></ul></li></ul></li></ul>

- Different compartment

**Important**

- Cure/Prolapse
  - Subjective report or affirmation
  - Objective examination (POP-Q staging)
- Patient satisfaction
- Need for subsequent surgery (for UI or POP, mesh complications)

1    *POP: pelvic organ prolapse, POP-Q: pelvic organ prolapse quantification system, UI: urinary*  
2    *incontinence*

3    For full details see the review protocol in appendix A

#### 4 Methods and process

5    This evidence review was developed using the methods and process described in  
6    [Developing NICE guidelines: the manual 2014](#). Methods specific to this review question are  
7    described in the review protocol in appendix A and for a full description of the methods see  
8    supplementary material C.

9    Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy  
10   until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to  
11   NICE's 2018 [conflicts of interest policy](#). Those interests declared until April 2018 were  
12   reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

#### 13 Clinical evidence

##### 14 Included studies

15   Seven studies (from nine citations) were identified for inclusion (Abdool 2011, Barber 2006,  
16   Chan 2013, Coolen 2017, Lone 2015, Lowenstein 2010 and Sung 2016). Abdool 2008 and  
17   Madsen 2016 are abstracts with additional data that link to Abdool 2011 and Sung 2016  
18   respectively. For a summary of included studies see Table 27.

19   One study (Coolen 2017) was intended to be conduct as an RCT, however due to women  
20   expressing a strong preference between treatment with surgery and pessary, they struggled  
21   to recruit. In total, six women were randomised, and a further 107 women self-selected  
22   between surgery and pessary and entered the prospective observational arm of the study.  
23   Following the abandonment of the randomised element to the study, all data were presented  
24   as a prospective observational study. The remaining six studies (Abdool 2011, Barber 2006,  
25   Chan 2013, Coolen 2017, Lone 2015, Lowenstein 2010 and Sung 2016) were prospective  
26   observational studies. Two studies were conducted in the UK (Abdool 2011 and Lone 2015),  
27   three in the USA (Barber 2006, Lowenstein 2010 and Sung 2016) one in Hong Kong (Chan  
28   2013) and one in the Netherlands (Coolen 2017).

29   See also the literature search strategy in appendix B, study selection flow chart in appendix  
30   C, study evidence tables in appendix D, forest plots in appendix E, and GRADE tables in  
31   appendix F.

##### 32 Excluded studies

33   Studies excluded from the review and reasons for their exclusion are provided in appendix K.

##### 34 Summary of clinical studies included in the evidence review

35   A summary of the studies that were included in this review are presented in Table 35.

**Table 27: Summary of included studies**

<b>Study</b>	<b>Population</b>	<b>Intervention/Comparison</b>	<b>Outcomes</b>	<b>Comments</b>
Abdool 2011 Prospective cohort UK	Pessary: N=359  Surgery: N=195  Surgery group were younger (60 vs. 68 years)	Pessary Interventions: N=296 Ring pessary N=50 gelhorn pessary N=8 cube pessary N=5 donut pessary  Surgical interventions: N=30 posterior colporrhaphy, N=44 anterior colporrhaphy, N=15 anterior and posterior colporrhaphy, N=59 vaginal hysterectomy and anterior colporrhaphy, N=27 vaginal hysterectomy, Mc Call's culdoplasty and posterior colporrhaphy, N=10 sacrocolpopexy, N=6 vaginal hysterectomy and Mc Call's culdoplasty , N=4 sacrospinous fixation.	Postal questionnaires of changes in symptoms using the SPS-Q. Data at a median of 12 months for pessary vs. 14 months for surgery.	Data reported as number of women who report symptoms as better, worse or no change. Therefore could not be used in statistical analysis.
Barber 2006 Prospective cohort USA	Pessary: N=62  Surgery: N=64  Surgery group were younger (58 vs. 62 years)	Pessary interventions: Ring or Gelhorn pessary  Surgical interventions: N= 27 Vaginal hysterectomy N=48 Anterior colporrhaphy N=35 Posterior colporrhaphy N=43 Vaginal vault suspension N=26 Sling procedure N=2 Anal sphincteroplasty N=7 Colpocleisis N=5 Other (laparoscopic cholecystectomy n=2, urethrolysis n=1, transperineal rectopexy n=1 and cervical trachelectomy n=1)	PFDI and PFIQ questionnaires were completed after 3 months in the pessary group or 6 months in the surgery group.	Women in the pessary group were randomised to one of the pessaries first and then switched to the other after 3 months.
Chan 2013 Prospective cohort Hong Kong	Pessary: N=27  Surgery: N=62  Surgery and pessary groups were similar ages (60.3 and 60.7 years)	Pessary interventions: Vaginal ring pessary  Surgical interventions: Vaginal hysterectomy and anterior and or posterior colporrhaphy - VHPFR (generally for stage I-II uterine prolapse). VHPFR with sacrospinous ligament fixation or vaginal mesh repair surgery (generally for stage III-IV uterine prolapse). Vaginal mesh repair surgery / laparoscopic sacrocolpopexy (generally for vaginal vault prolapse)	PFDI and PFIQ questionnaires were completed after a median of 12 months (range 3-25) months in the pessary group and a median of 4 months (range 4-24 months) in the surgery group.	Additional data for women with pelvic floor and concomitant continence surgery also available (n=39)
Coolen 2017 RCT/Prospective cohort Netherlands	Pessary: N=74  Surgery: N=39  (N=2 were randomised to pessary and N=4 to surgery, the remaining participants self-selected)  Surgery group were younger	Pessary interventions: N=10 Shelf N=64 Ring  Surgical interventions: N=15 Anterior colporrhaphy N=1 Laparoscopic hysteropexy N=9 Sacrospinous fixation and anterior colporrhaphy N=1 Sacrospinous fixation, anterior colporrhaphy and posterior colporrhaphy N=7 Anterior colporrhaphy and posterior colporrhaphy N=1 Manchester Fothergill	UDI questionnaire - including the DDI and IIQ at 12 months follow-up	This study started as an RCT, but due to women expressing a strong preference between surgery and pessary, the randomising element to this study was abandoned.  Outcome data reported as median (10th to 90th percentile), therefore could not be used in statistical analysis.

# DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

Study	Population	Intervention/Comparison	Outcomes	Comments
	(58 vs. 64 years)	procedure and anterior colporrhaphy N=1 Manchester Fothergill procedure, anterior colporrhaphy and posterior colporrhaphy N=2 Transvaginal hysterectomy N=1 Transvaginal hysterectomy and anterior colporrhaphy N=1 Manchester Fothergill procedure, anterior colporrhaphy and posterior colporrhaphy		
Lone 2015  Prospective cohort  UK	Pessary: N=133  Surgery: N=154  Surgery group were younger (59 vs. 67 years)	Pessary Intervention: N=101 Ring N=2 Cube N=28 Gelhorn N=2 Doughnut  Surgical Intervention: N=49 Anterior colporrhaphy, N=18 Posterior colporrhaphy, N=8 Anterior and posterior colporrhaphy, N=42 Vaginal hysterectomy and anterior colporrhaphy, N=18 Vaginal hysterectomy, N=9 Sacrocolpopexy N=8 Sacrospinous fixation.	ICIQ-VS and the ICIQ-UI SF questionnaires to assess vaginal, sexual, urinary and quality of life symptoms at baseline and after a mean of 12 months for pessary group and 14 months for surgery	Changes in score reported without standard deviations, therefore data could not be used in statistical analysis.
Lowenstein 2010  Prospective cohort  USA	Pessary: N=33  Surgery: N=206  No age data reported	Pessary intervention: Type of pessary used not reported  Surgical intervention: N=112 Sacrocolpopexy N=67 Apical Suspension N=69 Hysterectomy N=52 Colpocleisis N=131 Site specific repair N=59 Vaginal Mesh N=84 Sling N=52 Burch	PFDI, PISQ and MBIS questionnaires at 6 months follow-up.	Only one outcome – sexual function, was reported by intervention, all other data combined interventions
Sung 2016  Prospective cohort  USA	Pessary: N=64  Surgery: N=72  Surgery group were younger (59 vs. 64 years)	Pessary intervention: Type of pessary used not reported  Surgical group: 44% hysterectomy 74% apical suspension 37% anterior vaginal repair 52% posterior vaginal repair 52% concomitant anti-incontinence procedure	PROMIS and validated symptom and quality-of-life questionnaires at 383 days for surgery group and 223 days for pessary group.	Only PROMIS data was reported for surgery and pessary groups.

DDI: defecatory distress inventory, ICIQ-UI SF: international consultation on incontinence questionnaire-urinary incontinence short form, ICIQ-VS: international consultation on incontinence questionnaire-vaginal symptoms, IIQ: incontinence impact questionnaire, MBIS: modified body image scale, N: number, PFDI: pelvic floor distress inventory, PFIQ: pelvic floor impact questionnaire, PISQ: pelvic organ prolapse/urinary incontinence sexual function questionnaire PROMIS: patient reported outcomes measurement information system, survey SPS-Q: Sheffield validated pelvic organ prolapse quality of life questionnaire, UDI: urogenital distress inventory, VHPFR: vaginal hysterectomy and pelvic floor repair

See also the clinical evidence tables in appendix D.

**1 Quality assessment of clinical outcomes included in the evidence review**

2 GRADE analysis was conducted on critical and important outcomes. The full clinical  
3 evidence GRADE profiles are presented in appendix F.

**4 Economic evidence**

**5 Included studies**

6 The systematic search of the economic literature undertaken for the guideline identified one  
7 USA study on the cost-utility of expectant management compared with pessary, surgical  
8 management including vaginal reconstructive surgery (VRS), traditional/open abdominal  
9 sacrocolpopexy (ASC), and robotic ASC in women with apical prolapse (Hullfish 2011).

10 No economic evidence was identified for other prolapse types.

11 Evidence table for the economic evaluation included in the systematic literature review is  
12 provided in appendix H. Completed methodology checklist of the included study is provided  
13 in appendix M. Economic evidence profile of the study considered during guideline  
14 development is presented in appendix I.

**15 Excluded studies**

16 Studies excluded from the review and reasons for their exclusion are provided in appendix K.

**17 Summary of studies included in the economic evidence review**

18 Hullfish (2011) evaluated the cost-utility of interventions for women requiring prolapse repair  
19 surgery in the USA. Study population comprised of post-hysterectomy women with stage 3 or  
20 greater apical prolapse. The analysis compared a number of interventions including  
21 expectant management, placement of pessary, surgical management including vaginal  
22 reconstructive surgery (VRS), traditional open abdominal sacrocolpopexy (ASC), and robot-  
23 assisted ASC. This was a modelling study (Markov decision model) with clinical inputs from  
24 various published sources. The model included the following health states: POP with no  
25 complications, POP with presenting complications (that is, voiding dysfunction), pessary with  
26 no complications, pessary with complications (that is, vaginal erosion), repaired POP without  
27 late/post-operative complications, repaired POP with minor late complications (that is, urinary  
28 tract infection), and repaired POP with major late complications (that is, reoperation for  
29 POP). For each treatment alternative, an individual could persist in an original health state,  
30 with or without a complication, or could transition to one of the other treatment states. The  
31 analysis was conducted from a health care payer perspective. The study considered a range  
32 of direct health care costs including costs associated with pessary use (pessary, professional  
33 fees, outpatient visit), surgical procedures; management of complications, reoperation,  
34 urinary tract infections, erosion and associated outpatient care, and pharmacological  
35 treatments (topical estrogen cream). The costs were obtained from national sources and  
36 where necessary were supplemented with authors' assumptions. The measure of outcome  
37 for the economic analysis was quality-adjusted life years (QALYs) with utility weights based  
38 on expert opinion. The time horizon of the analysis was 12 months.

39 At 12 months pessary resulted in 0.867 QALYs, the expectant management followed by VRS  
40 in 0.886 QALYs, the expectant management followed by laparoscopic ASC 0.864 QALYs,  
41 the expectant management followed by robotic-assisted laparoscopic ASC 0.864 QALYs,  
42 VRS 0.947 QALYs, laparoscopic traditional open ASC 0.907 QALYs, and robotic-assisted  
43 laparoscopic ASC 0.908 QALYs. The cost per person were \$10,287 for pessary, \$11,686 for  
44 the expectant management followed by VRS, \$13,191 for the expectant management  
45 followed by laparoscopic ASC, \$14,366 for the expectant management followed by robotic-

1 assisted laparoscopic, \$15,040 for the VRS, \$16,993 for the laparoscopic traditional open  
2 ASC, and \$18,472 for the robotic-assisted laparoscopic ASC (in likely 2010 USA dollars).

3 Based on the above costs and outcomes the expectant management followed by  
4 laparoscopic ASC and the expectant management followed by the robot-assisted  
5 laparoscopic ASC was dominated by pessary (that is, pessary resulted in lower costs and  
6 greater QALYs). Similarly, laparoscopic traditional open ASC and robot-assisted  
7 laparoscopic ASC was dominated by VRS (that is, VRS resulted in lower costs and greater  
8 QALYs).

9 The expectant management was extendedly dominated by a combination of pessary and  
10 VRS (that is, it would be more cost effective to provide a combination of pessary and VRS  
11 than the expectant management followed by VRS). The incremental cost-effectiveness ratio  
12 (ICER) of VRS when compared with pessary was approximately \$59,607 (£48,000) per  
13 additional QALY gained which is well above NICE lower cost-effectiveness threshold.

14 The probabilistic sensitivity analysis demonstrated that pessary use is the optimal strategy  
15 below the \$5,600 (£4,480) willingness to pay threshold and that the VRS strategy is the  
16 optimal strategy above this threshold.

17 Deterministic sensitivity analyses indicated that the model results were sensitive to the  
18 probability of POP complication, probability of surgery following pessary, utility of pessary  
19 use, probability of late complications for VRS, and the cost estimate for robotic-assisted ASC  
20 as a proportion of the total hospitalisation charge for traditional ASC. For example, the  
21 expectant management with VRS becomes the cost effective option when the baseline  
22 estimate of probability of POP complication was reduced to 0.15 (base case 0.19). VRS and  
23 expectant management with VRS become the cost-effective options if the probability of  
24 surgery following initial pessary use is increased to 0.17 (base case 0.12). Reducing the  
25 utility value associated with pessary use below the base case value of 0.90 makes the  
26 expectant management with VRS the cost-effective option along with pessary and VRS.  
27 Traditional open ASC becomes the cost-effective option if the probability of complications  
28 following VRS increases to 0.11 (base case 0.06). If this probability of complications  
29 increases to 0.18 both the VRS and the expectant management followed by VRS are not  
30 cost effective. Both the expectant management followed by robotic-assisted ACS and the  
31 initial robotic-assisted ACS strategy are cost-effective alternatives only when the proportional  
32 cost estimates for these strategies are at or below 75% of the median total hospitalization  
33 charge of traditional open ASC.

34 The analysis was partially applicable to the NICE decision-making context and had minor  
35 methodological limitations.

36 **Clinical evidence statements**

37

38 ***Health related quality of life: short-term follow-up (up to 12 months, measured  
39 through validated scales only)***

- 40 Very low quality evidence from two observational studies (n=195) showed a clinically  
41 significant improvement in the UDI questionnaire following surgery compared to pessary  
42 treatment: mean difference (MD) 32.22 (95% CI 17.13, 47.31).
- 43 Very low quality evidence from two observational studies (n=195) showed a clinically  
44 significant improvement in the POPDI questionnaire following surgery compared to pessary  
45 treatment: MD 41.24 (95% CI 21.82, 60.66).
- 46 Very low quality evidence from two observational studies (n=195) showed a clinically  
47 significant improvement in the CRADI questionnaire following surgery compared to pessary  
48 treatment: MD 28.96 (95% CI 12.07, 45.85).

- 1 Very low quality evidence from two observational studies (n=195) showed no statistical  
2 changes in the POPIQ questionnaire following surgery compared to pessary treatment: MD  
3 20.68 (95% CI -5.63, 47.00).
- 4 Very low quality evidence from two observational studies (n=195) showed a clinically  
5 significant improvement in the UIQ questionnaire following surgery compared to pessary  
6 treatment: MD 32.23 (95% CI 8.03, 56.43).
- 7 Very low quality evidence from two observational studies (n=195) showed a clinically  
8 significant improvement in the CRAIQ questionnaire following surgery compared to pessary  
9 treatment: MD 21.74 (95% CI 6.36, 37.13).
- 10 Very low quality evidence from one observational studies (n=239) showed a clinically  
11 significant improvement in the PISQ questionnaire following pessary use compared to  
12 surgery: -MD 14.00 (95% CI -15.88, -12.12).
- 13 Very low quality evidence from one observational studies (n=136) showed some statistical  
14 improvement for physical function (MD -5.20, 95% CI -7.84, -2.56) and social roles (MD -  
15 3.50, 95% CI -6.83, -0.17) for women treated with pessary compared to those with surgery  
16 using the PROMIS questionnaire. However, there were no differences between groups for  
17 social discretionary (MD -2.70, 95% CI -5.49, 0.09), anxiety (MD 1.80, 95% CI -1.46, 5.06)  
18 and depression (MD -2.00, 95% CI -4.78, 0.78).

## 19 Economic evidence statements

20 There was conflicting evidence from one USA modelling study. The deterministic analysis  
21 showed that expectant management, traditional open abdominal sacrocolpopexy, and robot-  
22 assisted abdominal sacrocolpopexy were cost ineffective when compared with placement of  
23 pessary or vaginal reconstructive surgery. The results for vaginal reconstructive surgery  
24 when compared with pessary were conflicting. The deterministic results indicated that the  
25 incremental cost-effectiveness ratio of vaginal reconstructive surgery (versus pessary) was  
26 above NICE's upper cost-effectiveness threshold of £30,000 per QALY gained. However, the  
27 probabilistic sensitivity analysis demonstrated that pessary use was the optimal strategy  
28 below the £4,480 willingness-to-pay threshold and that the vaginal reconstructive surgery  
29 was the optimal strategy above this threshold. This evidence came from a partially applicable  
30 study that was characterised by minor methodological limitations.

## 31 Recommendations

- 32 I1.21 Consider a vaginal pessary for women with symptomatic pelvic organ prolapse,  
33 alone or in conjunction with supervised pelvic floor muscle training. **[2019]**
- 34 I1.22 Refer women who have chosen a pessary to a urogynaecology service if pessary  
35 care is not available locally. **[2019]**
- 36 I1.23 Before starting pessary treatment:
- 37 • consider treating vaginal atrophy with topical oestrogen
- 38 • explain that more than one pessary fitting may be needed to find a suitable  
39 pessary
- 40 • discuss the effect of a pessary on sexual intercourse
- 41 • describe common complications including vaginal discharge, bleeding and  
42 pessary expulsion
- 43 • explain that the pessary should be removed at least once every 6 months.  
**[2019]**

1

2

### 3 **The committee's discussion of the evidence**

#### 4 **Interpreting the evidence**

##### 5 ***The outcomes that matter most***

6 The committee agreed that health related quality of life, adverse events and long-term  
7 adverse events were considered critical outcomes. The committee agreed these outcomes  
8 were the most likely to impact the woman. Other outcomes considered important by the  
9 committee were cure, patient satisfaction and repeat surgery. Only data related to short-term  
10 quality of life (less than 12 months) were identified.

11

##### 12 ***The quality of the evidence***

13 Pairwise outcomes were assessed for certainty using the GRADE tool. The evidence for all  
14 outcomes were considered to be very low quality, meaning there is very limited confidence in  
15 the outcome data presented. The evidence was downgraded because participants typically  
16 self-selected their treatment option, the studies only reported short-term follow up, and in  
17 some cases duration of follow-up was uneven across interventions. In addition, there were  
18 imbalances for participant numbers and characteristics between the two groups (for example  
19 women who were treated with surgery were generally younger than those treated with  
20 pessary).

##### 21 ***Benefits and harms***

22 The evidence included in this review was limited in quantity and quality. The evidence did  
23 however indicate clinically meaningful improvements following surgery (over a follow-up  
24 ranging from 4 to 7 months) and improvements but not always clinically meaningful in the  
25 pessary groups (over their follow-up ranging from 3 to 12 months) for the following  
26 questionnaires: Urogenital distress inventory (UDI), pelvic organ prolapse distress inventory  
27 (POPDI), colorectal-anal distress inventory (CRADI), pelvic organ prolapse impact  
28 questionnaire (POPIQ), urinary impact questionnaire (UIQ), colorectal-anal impact  
29 questionnaire (CRAIQ). In addition, surgery offered better outcomes when compared to  
30 pessary for the following questionnaires: Urogenital distress inventory (UDI), pelvic organ  
31 prolapse distress inventory (POPDI), colorectal-anal distress inventory (CRADI), urinary  
32 impact questionnaire (UIQ), colorectal-anal impact questionnaire (CRAIQ). However, these  
33 studies had imbalanced length of follow ups and participant numbers between the groups. In  
34 addition, after 6 months follow-up the prolapse urinary incontinence sexual function  
35 questionnaire (PISQ) indicated improvements follow pessary treatment and a decline  
36 following surgery. Given the short-follow up and the imbalances between arms of the  
37 evidence, the committee concluded that they were not able to definitively recommend one  
38 treatment option over another. Particularly given that outcomes between treatments for  
39 follow-ups longer than 12 months were not reported.

40 The committee noted that there are very few harms associated with treatment with pessary,  
41 physiotherapy or no treatment in comparison to surgery, and women should be informed of  
42 all the benefits and harms associated with each treatment.

43 The committee, based on their expertise and experience, were clear that women should be  
44 able to make informed choices between the different treatments available to them. To  
45 facilitate a shared decision making process the committee recommended, based on their  
46 experience, that a discussion should take place that would explore the woman's priorities  
47 that may inform treatment options. The management can then be tailored to the individual

1 women based on her personal circumstances and preferences, in particular desire for future  
2 childbearing, desire for future sexual activity (which could be impacted by surgery) and  
3 concurrent comorbidities including cognitive or physical impairments (which may make it  
4 difficult to follow detailed instructions or participate in physiotherapy).

**5 Cost effectiveness and resource use**

6 The committee discussed the lack of clinical and economic evidence comparing surgery with  
7 a pessary in women with pelvic organ prolapse. The limited economic evidence from the  
8 USA showed that surgery and vaginal surgery were the most cost-effective options when  
9 compared with other options including expectant management, traditional open  
10 sacrocolpopexy, and robot-assisted sacrocolpopexy at 12 months in women with apical  
11 prolapse. However, the committee noted that this was a USA study which is partially  
12 applicable to the NICE decision making with a very short time horizon. A time horizon of at  
13 least 5 years would be required to capture all important differences in costs and outcomes  
14 between pessary and surgery. The committee also noted that even though pessary has  
15 lower intervention costs when compared with surgery when taking into account the whole  
16 sequelae of events the cost differential is reduced. Although, surgery has a higher risk of  
17 complications that may require resource-intensive care and may incur high costs to the NHS.  
18 The committee noted that for the most women it is a choice and quality of life is the main  
19 outcome of interest.

**20 Other factors the committee took into account**

21 The committee explained that it was unsurprising that there were no randomised controlled  
22 trials. Given that women typically have a strong preference for their treatment option, it would  
23 be challenging to recruit women to a randomised controlled trial that compared surgery with  
24 pessary. However, it may theoretically be possible with a large multicentre trial.

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# Appendices

## Appendix A – Review protocols

**Review protocol for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

**Table 28: Review protocol for effective surgical management options for POP**

Field (based on PRISMA-P)	Content
Review question	What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?
Type of review question	Intervention
Objective of the review	The objective of this review is to identify effective surgical treatment for pelvic organ prolapse in women.
Eligibility criteria – population/disease/condition/is sue/domain	Women (aged 18 and over) undergoing surgery for pelvic organ prolapse. Women having repeat surgery (regardless of whether the repeat surgery is for the same or a different compartment) or those that are treatment naïve will be included.
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	<b>Surgical treatments:</b> <u>Anterior</u> <ul style="list-style-type: none"><li>• Anterior repair or colporrhaphy or cystocele repair<ul style="list-style-type: none"><li>◦ With or without mesh, biological or synthetic</li><li>◦ Mesh kit or inlay mesh</li></ul></li><li>• Paravaginal repair<ul style="list-style-type: none"><li>◦ Open or laparoscopic</li></ul></li></ul> <u>Apical</u> <ul style="list-style-type: none"><li>• Uterus<ul style="list-style-type: none"><li>◦ Vaginal hysterectomy</li><li>◦ Vaginal sacrospinous hysteropexy</li><li>◦ Manchester repair</li></ul></li></ul>

- Hysteropexy with mesh
  - Laparoscopic or open
  - Wrap around or posterior attachment
  - Mesh kit or inlay mesh
- Suture hysteropexy
  - Laparoscopic or open
- Colpocleisis
- Vault (vaginal, post-hysterectomy)
  - Posterior IVS
  - Sacrospinous fixation
  - Sacrocolpopexy with mesh
    - Laparoscopic or open
    - Mesh kit or inlay mesh
  - Colpocleisis
  - Uterosacral plication
    - Vaginal or laparoscopic

#### Posterior

- Rectocele repair or posterior repair or colporrhaphy
  - Transvaginal or transanal or transperineal
  - With or without mesh, synthetic or biological
  - Mesh kit or inlay mesh
- Perineorrhaphy
- Enterocoele repair
  - Vaginal or laparoscopic

NOTE: interventions and implants not approved in the UK or not used in clinical practice will not be included in this review.

However studies including this interventions may be included in the NMA if they provide data to inform the network.

Please see NMA protocol for details.

These surgical treatments will complement the following IPGs:

- IPG577 – Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse:  
<https://www.nice.org.uk/guidance/ipg577/documents/overview-2>
- IPG581 – Infracoccyeal sacropexy using mesh to repair vaginal vault prolapse:  
<https://www.nice.org.uk/guidance/ipg581/evidence/overview-final-pdf-4489810525>

	<ul style="list-style-type: none"><li>• IPG582 – Infracoccygeal sacrocepsy using mesh to repair uterine prolapse: <a href="https://www.nice.org.uk/guidance/ipg582/evidence/overview-final-pdf-4489846813">https://www.nice.org.uk/guidance/ipg582/evidence/overview-final-pdf-4489846813</a></li><li>• IPG583 – Sacrocolpopexy using mesh to repair vaginal vault prolapse: <a href="https://www.nice.org.uk/guidance/ipg583/evidence/overview-final-pdf-44898092">https://www.nice.org.uk/guidance/ipg583/evidence/overview-final-pdf-44898092</a></li><li>• IPG584 – Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse: <a href="https://www.nice.org.uk/guidance/ipg584/evidence/overview-final-pdf-4489848109">https://www.nice.org.uk/guidance/ipg584/evidence/overview-final-pdf-4489848109</a></li><li>• IPG599 – Transvaginal mesh repair of anterior or posterior vaginal wall prolapse: <a href="https://www.nice.org.uk/guidance/ipg599/evidence/overview-final-pdf-4669764013">https://www.nice.org.uk/guidance/ipg599/evidence/overview-final-pdf-4669764013</a></li><li>• IPG10060 – Laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina <a href="https://www.nice.org.uk/guidance/ipg608/documents/interventional-procedure-consultation-docu">https://www.nice.org.uk/guidance/ipg608/documents/interventional-procedure-consultation-docu</a></li></ul>
Eligibility criteria – comparator(s)/control or reference (gold) standard	<p><b>Specified comparisons:</b></p> <p><u>Anterior</u></p> <ul style="list-style-type: none"><li>• Mesh versus no mesh use</li></ul> <p>If mesh is superior in treatment effect then perform:</p> <ul style="list-style-type: none"><li>◦ Mesh (synthetic) versus mesh (biologic)</li><li>◦ Anterior combined with apical versus anterior alone for women with anterior prolapse</li></ul> <p><u>Apical- Uterus</u></p> <ul style="list-style-type: none"><li>• Hysterectomy versus vaginal hysteropexy</li><li>• Hysterectomy versus mesh hysteropexy (open or laparoscopic)</li><li>• Open versus laparoscopic hysteropexy</li></ul> <p><u>Apical- Vault</u></p> <ul style="list-style-type: none"><li>• Open or laparoscopic sacrocolpopexy (SCP) versus vaginal sacrospinous fixation</li><li>• Open versus laparoscopic sacrocolpopexy</li></ul> <p><u>Posterior</u></p> <ul style="list-style-type: none"><li>• Mesh versus no mesh use</li></ul>

	<p>If mesh is superior in treatment effect then perform</p> <ul style="list-style-type: none"> <li>• Mesh (synthetic) versus mesh (biologic)</li> </ul>
Outcomes and prioritisation	<p><b>Critical outcomes:</b></p> <ol style="list-style-type: none"> <li>1. Health related quality of life (measured through validated scales only)</li> <li>2. Adverse events <ul style="list-style-type: none"> <li>○ Severe bleeding requiring a blood transfusion</li> <li>○ Internal organ injury (to bladder or bowel)</li> </ul> </li> <li>3. Complications <ul style="list-style-type: none"> <li>○ Pain</li> <li>○ Mesh erosion or extrusion (bladder, vagina, bowel, urethra)</li> <li>○ Fistula</li> <li>○ Bladder function <ul style="list-style-type: none"> <li>- Stress UI</li> <li>- Urge incontinence</li> <li>- Voiding difficulty</li> </ul> </li> <li>○ Bowel function <ul style="list-style-type: none"> <li>- Faecal incontinence</li> <li>- Obstructed defecation</li> <li>- Constipation</li> </ul> </li> <li>○ Sexual function <ul style="list-style-type: none"> <li>- De novo dyspareunia</li> <li>- Apareunia</li> <li>- Prolapse and incontinence sexual questionnaire</li> </ul> </li> <li>○ Recurrence of any POP <ul style="list-style-type: none"> <li>- Same compartment</li> <li>- Different compartment</li> </ul> </li> </ul> </li> </ol> <p>Complications will be stratified as follows:</p> <ul style="list-style-type: none"> <li>• Short-term: complications occurring up to 1 year (i.e., ≤ 1 year);</li> <li>• Medium-term: complications occurring after 1 year, and up to 5 years (i.e., &gt; 1 year and ≤ 5 years); and</li> <li>• Long-term: complications occurring after 5 years (i.e., &gt; 5 years)</li> </ul> <p><b>Important outcomes:</b></p> <ol style="list-style-type: none"> <li>4. Cure/Prolapse <ul style="list-style-type: none"> <li>○ Subjective report or affirmation</li> </ul> </li> </ol>

	<ul style="list-style-type: none"> <li>○ Objective examination (POP-Q staging)</li> <li>5. Patient satisfaction</li> <li>6. Repeat surgery (for UI or POP, mesh complications)</li> </ul>
Eligibility criteria – study design	<p>For all outcomes except complications, systematic reviews of RCT and RCT with <math>\geq 75</math> participants will be considered. In the absence of full text published RCT, conference abstracts will be considered. In the absence of RCT, prospective and retrospective studies will be considered.</p> <p>For complications, the following types of study designs will be considered:</p> <ul style="list-style-type: none"> <li>• RCT for short- and medium-term complications;</li> <li>• In the absence of RCT data for short- and medium-term complications, and for long-term complications, prospective and retrospective studies; and</li> </ul> <p>In the absence of prospective and retrospective studies for any type of complication, case series.</p>
Other inclusion exclusion criteria	<p>Cohort studies/case series with <math>&lt;75</math> participants will not be included</p> <p>Women with co-existing POP and UI (this will be covered in a separate review).</p>
Proposed sensitivity/sub-group analysis, or meta-regression	<p>Special consideration will be given to the following groups for which data will be reviewed and analysed separately if available:</p> <ul style="list-style-type: none"> <li>• older women</li> <li>• women with physical disabilities</li> <li>• women with cognitive impairment</li> <li>• women who are considering future pregnancy</li> <li>• women who have no concurrent SUI surgery</li> <li>• women who have concurrent SUI surgery</li> </ul> <p>Planned subgroup analysis will be conducted by:</p> <p>Population subgroups</p> <ul style="list-style-type: none"> <li>• Type of prolapse <ul style="list-style-type: none"> <li>○ Anterior</li> <li>○ Posterior</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Apical</li> </ul> <p>In the presence of serious heterogeneity</p> <ul style="list-style-type: none"> <li>• Grade of prolapse (preoperative POP-Q grade)</li> </ul>
Selection process – duplicate screening/selection/analysis	<p>Duplicate screening will be performed using STAR - minimum sample size is 10% of the total for &lt;1000 titles and abstracts, and 5% of the total for ≥1000 titles and abstracts. All discrepancies are discussed and resolved between 2 screeners. Any disputes will be resolved in discussion with the Senior Systematic Reviewer. Data extraction will be supervised by a senior reviewer. Draft excluded studies and evidence tables will be discussed with the Topic Advisor, prior to circulation to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.</p>
Data management (software)	<p>Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists (AMSTAR – Systematic reviews, Cochrane RoB – RCTs, NOS – Cohort studies).</p>
Information sources – databases and dates	<p>Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase. Limits (e.g. date, study design): All study designs. Apply standard animal/non-English language filters. Supplementary search techniques: No supplementary search techniques were used. For details please see appendix B.</p>
Identify if an update	This is a new topic in the guideline.
Author contacts	<p>Developer: The National Guideline Alliance  <a href="https://www.nice.org.uk/guidance/indevelopment/gid-ng10035">https://www.nice.org.uk/guidance/indevelopment/gid-ng10035</a>.</p>
Highlight if amendment to previous protocol	For details please see section 4.5 of <a href="#">Developing NICE guidelines: the manual 2014</a> .
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).

## DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of <a href="#">Developing NICE guidelines: the manual 2014</a> . The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group <a href="http://www.gradeworkinggroup.org/">http://www.gradeworkinggroup.org/</a>
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of <a href="#">Developing NICE guidelines: the manual 2014</a> .
Methods for analysis – combining studies and exploring (in)consistency	For details of the methods please see supplementary material C. NMA is planned looking at the effectiveness of surgical interventions. For more detail please see NMA protocol.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of <a href="#">Developing NICE guidelines: the manual 2014</a> . If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots.  Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of <a href="#">Developing NICE guidelines: the manual 2014</a> .
Rationale/context – Current management	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of <a href="#">Developing NICE guidelines: the manual 2014</a> .  Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details of the methods please see supplementary material C.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.

PROSPERO registration  
number

Not registered with PROSPERO.

**Review protocol for review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Table 29: Review protocol for the role of surgery to prevent postoperative urinary incontinence in women having surgery for POP**

Field (based on PRISMA-P)	Content
Review question	What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?
Type of review question	Intervention
Objective of the review	Post-operative urinary incontinence is a recognised complication after surgery for pelvic organ prolapse. This review aims to address the uncertainty as to the role of preventative concomitant surgery for stress incontinence surgery.
Eligibility criteria – population/disease/condition/issue/domain	<p>Women (aged 18 years and over) undergoing surgery for anterior or apical pelvic organ prolapse.          Women having repeat surgery or those who are on treatment naïve will be included.          We will exclude women undergoing surgery for posterior pelvic organ prolapse.</p>
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	<p>Any surgery for anterior or apical pelvic organ prolapse plus concurrent preventative surgery for stress urinary incontinence.          Surgery for posterior pelvic organ prolapse will be excluded.          The following surgical treatments for the management of pelvic organ prolapse will be considered, as long as they are performed concurrently with any surgical option for the prevention of stress urinary incontinence:</p> <p><b>Anterior prolapse</b></p> <ul style="list-style-type: none"> <li>• Anterior repair or colporrhaphy or cystocele repair                     <ul style="list-style-type: none"> <li>◦ With or without mesh, biological or synthetic</li> <li>◦ Mesh kit or inlay mesh</li> </ul> </li> <li>• Paravaginal repair (open or laparoscopic)</li> </ul> <p><b>Apical prolapse</b></p> <ul style="list-style-type: none"> <li>• Vaginal hysterectomy</li> <li>• Vaginal sacrospinous hysteropexy</li> <li>• Manchester repair</li> <li>• Hysteropexy with mesh</li> <li>• Laparoscopic or open                     <ul style="list-style-type: none"> <li>◦ Wrap around or posterior attachment</li> </ul> </li> <li>• Suture hysteropexy</li> </ul>

Field (based on PRISMA-P)	Content
	<ul style="list-style-type: none"><li>○ Laparoscopic or open</li> <b>Vault prolapse</b><ul style="list-style-type: none"><li>• Posterior IVS</li><li>• Sacrospinous fixation</li><li>• Sacrocolpopexy with mesh<ul style="list-style-type: none"><li>○ Laparoscopic or open</li></ul></li><li>• Mesh kit or inlay mesh</li><li>• Colpocleisis</li><li>• Uterosacral plication<ul style="list-style-type: none"><li>○ Vaginal or laparoscopic</li></ul></li></ul></ul> <p>The following surgical treatments for stress urinary incontinence were deemed appropriate for the prevention of urinary incontinence in conjunction with POP repair, and will be considered in this review:</p> <p><b>Suburethral slings (synthetic mesh)</b></p> <ul style="list-style-type: none"><li>• Retropubic bottom up</li><li>• Retropubic top down</li><li>• Transobturator outside out</li><li>• Transobturator outside in</li><li>• Single incision<ul style="list-style-type: none"><li>○ Mini-sling or single-incision sling</li></ul></li><li>• Adjustable slings<ul style="list-style-type: none"><li>○ Retropubic</li><li>○ Transobturator</li></ul></li><li>• Colposuspension<ul style="list-style-type: none"><li>○ Open abdominal retropubic suspension</li><li>○ Laparoscopic retropubic suspension</li></ul></li><li>• Fascial slings (autologous/pubovaginal sling)/sling on a string/rectus sling/ fascia lata sling</li><li>• Para or transurethral injections (bulking agents)</li><li>• Artificial urinary sphincters</li></ul>

<b>Field (based on PRISMA-P)</b>	<b>Content</b>
Eligibility criteria – comparator(s)/control or reference (gold) standard	<p>Any surgery for pelvic organ prolapse alone (that is, with no concurrent preventative surgery for stress urinary incontinence).</p> <p>Surgery for posterior pelvic organ prolapse will be excluded.</p>
Outcomes and prioritisation	<p><b>Critical</b></p> <ul style="list-style-type: none"> <li>• Change in continence status <ul style="list-style-type: none"> <li>◦ Self-reported symptoms</li> <li>◦ Objective cure rate</li> <li>◦ Negative stress (cough) test</li> <li>◦ Number of incontinence episodes per day</li> </ul> </li> <li>• Long-term complications (&gt; 12 months) <ul style="list-style-type: none"> <li>◦ Pain</li> <li>◦ Mesh erosion or extrusion (vaginal, bladder, urethra)</li> <li>◦ Fistula</li> <li>◦ Need for catheterisation</li> <li>◦ Infection (recurrent UTI, wound)</li> <li>◦ De novo overactive bladder symptoms</li> <li>◦ Occurrence of POP</li> <li>◦ Wound complications (hernia)</li> </ul> </li> <li>• Repeated surgery for UI, POP or mesh complications</li> </ul> <p>Justification: there is an increased risk of developing incontinence after surgery for POP and the critical outcomes therefore relate to continence and need for further surgery.</p> <p><b>Important</b></p> <ul style="list-style-type: none"> <li>• Continence specific health-related quality of life (ICIQ, BFLUTS, I-QOL, SUIQQ, UISS, SEAPI-QMM, ISI, KHQ and E-PAQ)</li> <li>• Adverse events (immediate post-op or perioperative) <ul style="list-style-type: none"> <li>◦ Severe bleeding requiring a blood transfusion</li> <li>◦ Internal organ injury (to bladder or bowel)</li> </ul> </li> <li>• Patient satisfaction <ul style="list-style-type: none"> <li>◦ Patient reported improvement</li> <li>◦ Patient global impression of improvement (PGI)</li> </ul> </li> </ul> <p>Justification: These are all patient reported symptoms and adverse events, and as such they are important for decision making.</p>

<b>Field (based on PRISMA-P)</b>	<b>Content</b>
Eligibility criteria – study design	Systematic reviews of randomised controlled trials (RCTs) RCT Comparative cohort studies in the absence of other studies for critical outcomes only
Other inclusion exclusion criteria	Prospective observational studies for long-term outcomes (complications) if no long-term RCT available (>24 months follow-up) English language only.
Proposed sensitivity/sub-group analysis, or meta-regression	<b>Population Subgroups:</b> Type of POP: anterior or apical Severity/Grade of POP  Type of UI <ul style="list-style-type: none"> <li>• Pure stress</li> <li>• Mixed UI</li> </ul> Surgical status <ul style="list-style-type: none"> <li>• Repeat or recurrent surgery</li> <li>• Treatment naïve.</li> </ul>
Selection process – duplicate screening/selection/analysis	Dual sifting will be undertaken for this question using NGA STAR software. Sifting, data extraction, appraisal of methodological quality and GRADE assessment will be performed by the systematic reviewer. Dual weeding will be performed by a second systematic reviewer on 5% or 10% of records (depending on database size), with resolution of discrepancies in discussion with the senior reviewer if necessary. Quality control will be performed by the senior systematic reviewer. Dual data extraction will not be performed for this question.
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5).  'GRADEpro' will be used to assess the quality of evidence for each outcome.  NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits (e.g. date, study design): Apply standard animal/non-English language exclusion Limit to RCTs and systematic reviews in first instance but download all results

Field (based on PRISMA-P)	Content
Identify if an update	<p>This review question is not an update. However previous recommendations relating to surgery for UI include:</p> <p>1.10 Surgical approaches for SUI</p> <p>1.10.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence. [new 2013]</p> <p>1.10.2 If conservative management for SUI has failed, offer:</p> <ul style="list-style-type: none"> <li>• synthetic mid-urethral tape (see recommendations 1.10.3–8), or</li> <li>• open colposuspension (see also recommendation 1.10.9), or</li> <li>• autologous rectus fascial sling (see also recommendation 1.10.10). [new 2013]</li> </ul> <p><b>Synthetic tapes</b></p> <p>1.10.3 When offering a synthetic mid-urethral tape procedure, surgeons should:</p> <ul style="list-style-type: none"> <li>• use procedures and devices for which there is current high quality evidence of efficacy and safety[10]</li> <li>• only use a device that they have been trained to use (see recommendations in section 1.11)</li> <li>• use a device manufactured from type 1 macroporous polypropylene tape</li> <li>• consider using a tape coloured for high visibility, for ease of insertion and revision. [new 2013]</li> </ul> <p>1.10.4 If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. [new 2013]</p> <p>1.10.5 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. [new 2013]</p> <p>1.10.6 Use 'top-down' retropubic tape approach only as part of a clinical trial. [new 2013]</p> <p>1.10.7 Refer to single-incision sub-urethral short tape insertion for stress urinary incontinence (NICE interventional procedure guidance 262) for guidance on single-incision procedures. [new 2013]</p> <p>1.10.8 Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery. [new 2013]</p> <p><b>Colposuspension</b></p> <p>1.10.9 Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women. Only an experienced laparoscopic surgeon working in an MDT with expertise in the assessment and treatment of UI should perform the procedure. [2006]</p> <p><b>Biological slings</b></p> <p>1.10.10 Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI. [2006]</p>

Field (based on PRISMA-P)	Content
	<p>Intramural bulking agents</p> <p>1.10.11 Consider intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that:</p> <ul style="list-style-type: none"> <li>•repeat injections may be needed to achieve efficacy</li> <li>•efficacy diminishes with time</li> <li>•efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings. [2006, amended 2013]</li> </ul> <p>1.10.12 Do not offer autologous fat and polytetrafluoroethylene used as intramural bulking agents for the treatment of stress UI. [2006]</p> <p>Artificial urinary sphincter</p> <p>1.10.13 In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended. [2006]</p>
Author contacts	<p>Developer: NGA</p> <p><a href="https://www.nice.org.uk/guidance/indevelopment/gid-ng10035">https://www.nice.org.uk/guidance/indevelopment/gid-ng10035</a></p>
Highlight if amendment to previous protocol	For details please see section 4.5 of <a href="#">Developing NICE guidelines: the manual 2014</a>
Search strategy – for one database	For details please see appendix B of the full guideline
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables) of the full guideline.
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables) of the full guideline.
Methods for assessing bias at outcome/study level	<p>Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of <a href="#">Developing NICE guidelines: the manual 2014</a></p> <p>The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group <a href="http://www.gradeworkinggroup.org/">http://www.gradeworkinggroup.org/</a>.</p>
Criteria for quantitative synthesis	For details please see section 6.4 of <a href="#">Developing NICE guidelines: the manual 2014</a>
Methods for quantitative analysis – combining studies and exploring (in)consistency	For details please see the methods chapter of the full guideline

<b>Field (based on PRISMA-P)</b>	<b>Content</b>
Meta-bias assessment – publication bias, selective reporting bias	<p>For details please see section 6.2 of <a href="#">Developing NICE guidelines: the manual 2014</a>.</p> <p>If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots.</p>
	Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of <a href="#">Developing NICE guidelines: the manual 2014</a>
Rationale/context – what is known	For details please see the introduction to the evidence review in the full guideline.
Describe contributions of authors and guarantor	<p>A multidisciplinary committee developed the guideline.</p> <p><a href="https://www.nice.org.uk/guidance/indevelopment/gid-ng10035">https://www.nice.org.uk/guidance/indevelopment/gid-ng10035</a></p> <p>The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of <a href="#">Developing NICE guidelines: the manual 2014</a>.</p> <p>Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the methods chapter of the full guideline.</p>
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England
PROSPERO registration number	Not registered with PROSPERO

**Review protocol for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Table 30: Review protocol for surgical options for pelvic organ prolapse, compared to pessaries**

Field (based on <a href="#">PRISMA-P</a> )	Content
Review question	What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?
Type of review question	Intervention
Objective of the review	The objective of this review is to compare the effectiveness of surgical options for the management of pelvic organ prolapse in women, compared to that of pessaries.
Eligibility criteria – population/disease/condition/issue/domain	Women (aged 18 and over) with diagnosed pelvic organ prolapse. Women having repeat surgery or those that are treatment naïve will be included.
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	Surgical treatments: <u>Anterior</u> <ul style="list-style-type: none"><li>• Anterior repair or colporrhaphy or cystocele repair</li><li>• With or without mesh, biological or synthetic</li><li>• Mesh kit or inlay mesh</li><li>• Paravaginal repair</li><li>• Open or laparoscopic</li></ul> <u>Apical</u> <ul style="list-style-type: none"><li>• Uterus</li><li>• Vaginal hysterectomy</li><li>• Vaginal sacrospinous hysteropexy</li><li>• Manchester repair</li><li>• Hysteropexy with mesh</li><li>• Laparoscopic or open</li><li>• Wrap around or posterior attachment</li><li>• Mesh kit or inlay mesh</li><li>• Suture hysteropexy</li><li>• Laparoscopic or open</li></ul> <ul style="list-style-type: none"><li>• Colpocleisis</li><li>• Vault (vaginal, post-hysterectomy)</li></ul>

	<ul style="list-style-type: none"> <li>• Posterior IVS</li> <li>• Sacrospinous fixation</li> <li>• Sacrocolpopexy with mesh</li> <li>• Laparoscopic or open</li> <li>• Mesh kit or inlay mesh</li> <li>• Colpocleisis</li> <li>• Uterosacral plication</li> <li>• Vaginal or laparoscopic</li> </ul> <p><u>Posterior</u></p> <ul style="list-style-type: none"> <li>• Rectocele repair or posterior repair or colporrhaphy</li> <li>• Transvaginal or transanal or transperineal</li> <li>• With or without mesh, synthetic or biological</li> <li>• Mesh kit or inlay mesh</li> <li>• Perineorrhaphy</li> <li>• Enterocèle repair</li> <li>• Vaginal or laparoscopic</li> </ul> <p>NOTE: interventions and implants not approved in the UK or not used in clinical practice will not be included in this review. However studies including this interventions may be included in the NMA if they provide data to inform the network. Please see NMA protocol for details.</p>
Eligibility criteria – comparator(s)/control or reference (gold) standard	Any type of surgery against pessary
Outcomes and prioritisation	<p><b>Critical</b> Health related quality of life (measured through validated scales only)</p> <ul style="list-style-type: none"> <li>• Adverse events             <ul style="list-style-type: none"> <li>◦ Severe bleeding requiring a blood transfusion</li> <li>◦ Internal organ injury (to bladder or bowel)</li> </ul> </li> <li>• Long-term adverse events             <ul style="list-style-type: none"> <li>◦ Pain</li> <li>◦ Mesh erosion or extrusion (bladder, vagina, bowel, urethra)</li> <li>◦ Fistula</li> <li>◦ Bladder function                     <ul style="list-style-type: none"> <li>- Stress UI</li> </ul> </li> </ul> </li> </ul>

	<ul style="list-style-type: none"><li>- Urge incontinence</li><li>- Voiding difficulty</li><li>o Bowel function<ul style="list-style-type: none"><li>- Faecal incontinence</li><li>- Obstructed defecation</li><li>- Constipation</li></ul></li><li>o Sexual function<ul style="list-style-type: none"><li>- De novo dyspareunia</li><li>- Apareunia</li><li>- Prolapse and incontinence sexual questionnaire</li></ul></li><li>o Recurrence of any POP<ul style="list-style-type: none"><li>- Same compartment</li><li>- Different compartment</li></ul></li></ul> <p><b>Important</b></p> <ul style="list-style-type: none"><li>• Cure/Prolapse<ul style="list-style-type: none"><li>◦ Subjective report or affirmation</li><li>◦ Objective examination (POP-Q staging)</li></ul></li><li>• Patient satisfaction</li><li>• Need for subsequent surgery (for UI or POP, mesh complications)</li></ul>
Eligibility criteria – study design	Systematic reviews of RCTs RCTs In absence of full text published RCTs, conference abstracts will be considered. Prospective observational studies for assessing long-term complications
Other inclusion exclusion criteria	No restriction on size of study Women with co-existing POP and UI as this will be covered in a separate review
Proposed sensitivity/sub-group analysis, or meta-regression	Stratified analysis based on the following subgroups: <ul style="list-style-type: none"><li>• older women</li></ul> women considering future pregnancy.  Planned subgroup analysis will be conducted by: Population subgroups

	<ul style="list-style-type: none"> <li>• Type of prolapse           <ul style="list-style-type: none"> <li>◦ Anterior</li> <li>◦ Posterior</li> <li>◦ Apical</li> </ul> </li> </ul> <p>In the presence of serious heterogeneity</p> <ul style="list-style-type: none"> <li>• Grade of prolapse (preoperative POP-Q grade)</li> </ul> <p>Special consideration will be given to the following groups for which data will be reviewed and analysed separately if available:</p> <ul style="list-style-type: none"> <li>• older women</li> <li>• women with physical disabilities</li> <li>• women with cognitive impairment</li> <li>• women who are considering future pregnancy</li> </ul>
Selection process – duplicate screening/selection/analysis	Duplicate screening will be performed using STAR - minimum sample size is 10% of the total for <1000 titles and abstracts, and 5% of the total for ≥1000 titles and abstracts. All discrepancies are discussed and resolved between 2 screeners. Any disputes will be resolved in discussion with the Senior Systematic Reviewer. Data extraction will be supervised by a senior reviewer. Draft excluded studies and evidence tables will be discussed with the Topic Advisor, prior to circulation to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists (ROBIS for – Systematic reviews, Cochrane RoB – RCTs, NOS – Cohort studies).
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase. Limits (e.g. date, study design): All study designs. Apply standard animal/non-English language filters. Supplementary search techniques: No supplementary search techniques were used. See appendix B for full strategies.
Identify if an update	This is a new topic in the guideline.
Author contacts	Developer: NGA <a href="https://www.nice.org.uk/guidance/indevelopment/gid-ng10035">https://www.nice.org.uk/guidance/indevelopment/gid-ng10035</a>
Highlight if amendment to previous protocol	For details please see section 4.5 of <a href="#">Developing NICE guidelines: the manual 2014</a> .

Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	<p>Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual.</p> <p>The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group <a href="http://www.gradeworkinggroup.org/">http://www.gradeworkinggroup.org/</a></p> <p><b>Quality Assessment</b></p> <p>Appraisal of methodological quality will be conducted using the appropriate tool:          ROBIS (systematic reviews and meta-analyses),          Cochrane risk of bias tool (RCTs or comparative cohort studies).          Cochrane ROBINS-I (Non-randomised studies)</p>
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of <a href="#">Developing NICE guidelines: the manual 2014</a> .
Methods for analysis – combining studies and exploring (in)consistency	For details of the methods please see supplementary material C.
Meta-bias assessment – publication bias, selective reporting bias	<p>For details please see section 6.2 of f <a href="#">Developing NICE guidelines: the manual 2014</a></p> <p>If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots.</p> <p>Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.</p>
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of <a href="#">Developing NICE guidelines: the manual</a>
Rationale/context – Current management	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	<p>A multidisciplinary committee developed the guideline. <a href="https://www.nice.org.uk/guidance/indevelopment/gid-nq10035">https://www.nice.org.uk/guidance/indevelopment/gid-nq10035</a></p> <p>The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of Developing NICE guidelines: the manual.</p>

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	Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details of the methods please see supplementary material C.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	Not registered with PROSPERO.

*GRADE: grading of recommendations assessment, development and evaluation, IVS: intravaginal slingplasty, NMA, network meta –analysis, POP: pelvic organ prolapse, POP-Q: pelvic organ prolapse quantification system, RCT, randomised controlled trial, ROBINS-I: risk of bias in non-randomized studies - of interventions UI: urinary incontinence*

## Appendix B – Literature search strategies

**Literature search strategies for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

**Database: Medline & Embase (Multifile)**

Last searched on Embase Classic+Embase 1974 to 2018 June 01, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Date of last search: 4<sup>th</sup> June 2018.

#	Searches
1	exp Pelvic Organ Prolapse/ use ppez
2	exp pelvic organ prolapse/ use emczd
3	(pelvic\$ adj3 organ\$ adj3 prolaps\$).tw.
4	(urinary adj3 bladder adj3 prolaps\$).tw.
5	((vagin\$ or urogenital\$ or genit\$ or uter\$ or viscer\$ or anterior\$ or posterior\$ or apical or pelvi\$ or vault\$ or urethr\$ or bladder\$) adj3 prolaps\$).tw.
6	(splanchnoptos\$ or visceroptos\$).tw.
7	Rectocele/ use ppez
8	rectocele/ use emczd
9	(hernia\$ adj3 (pelvi\$ or vagin\$ or urogenital\$ or uter\$ or bladder\$ or urethr\$ or viscer\$)).tw.
10	(urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$).tw.
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	Surgical Mesh/ use ppez
13	exp surgical mesh/ use emczd
14	(mesh\$ or non-mesh\$ or nonmesh\$).tw.
15	Hysterectomy, Vaginal/ use ppez
16	vaginal hysterectomy/ use emczd
17	abdominal hysterectomy/ use emczd
18	((vagin\$ or abdom\$) adj3 hysterectom\$).tw.
19	(total adj laparoscopic\$ adj hysterectom\$).tw.
20	(hysteropex\$ or sacro-hysteropex\$ or sacrohysteropex\$ or colpopex\$ or sacro-colpopex\$ or sacrocolpopex\$ or sacropex\$ or cervicopex\$ or sacro-cervicopex\$ or sacrocervicopex\$).tw.
21	(colporrhaph\$ or perineorrhaph\$ or perineoplast\$ or culd?plast\$).tw.
22	(manchester\$ adj3 (repair\$ or operation\$ or procedure\$ or method\$ or surger\$)).tw.
23	colpocl\$.tw.
24	IVS.tw.
25	((intravagin\$ or intra-vagin\$) adj3 slingplast\$).tw.
26	(TSST or STST or TSTS).tw.
27	(transfix\$ adj3 (stitch\$ or sutur\$)).tw.
28	polypropylene/ use emczd
29	Polypropylenes/ use ppez
30	polypropylen\$.tw.
31	scaffold\$.tw.
32	((urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$ or vault\$ or anter\$ or poster\$ or apical\$ or vagin\$ or para-vagin\$ or paravagin\$ or utero-vagin\$ or uterovagin\$ or recto-vagin\$ or rectovagin\$ or utero-sacral\$ or uterosacral\$ or sacrospin\$ or sacro-spin\$ or prolaps\$ or POP) adj3 (repair\$ or suspen\$ or fix\$ or plicat\$)).tw.
33	((POP or prolaps\$) adj (surg\$ or operat\$)).tw.

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#	Searches
34	((vagin\$ or pelvi\$) adj3 reconstruct\$).tw.
35	or/12-34
36	11 and 35
37	*Pelvic Organ Prolapse/su use ppez
38	*pelvic organ prolapse/su use emczd
39	36 or 37 or 38
40	remove duplicates from 39
41	limit 40 to english language
42	limit 41 to RCTs and SRs, and general exclusions filter applied

**Database: Cochrane Library via Wiley Online**

Date of last search: 4<sup>th</sup> June 2018.

#	Searches
#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#2	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#3	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#4	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#5	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#6	MeSH descriptor: [Rectocele] explode all trees
#7	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#8	(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctococele* or rectocele* or rectocoelle* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocoole* or cystourethrocele* or cystourethrococle*):ti,ab,kw (Word variations have been searched)
#9	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10	MeSH descriptor: [Surgical Mesh] explode all trees
#11	(mesh* or non-mesh* or nonmesh*):ti,ab,kw (Word variations have been searched)
#12	MeSH descriptor: [Hysterectomy, Vaginal] explode all trees
#13	((vagin* or abdom*) near/3 hysterectom*):ti,ab,kw (Word variations have been searched)
#14	(total next laparoscopic* next hysterectom*):ti,ab,kw (Word variations have been searched)
#15	(hysteropex* or sacro-hysteropex* or sacrohysteropex* or colpopex* or sacro-colpopex* or sacrocolpopex* or sacropex* or cervicopex* or sacro-cervicopex* or sacrocervicopex*):ti,ab,kw (Word variations have been searched)
#16	(colporrhaph* or perineorrhaph* or perineoplast* or culdoplast* or culdeplast\$):ti,ab,kw (Word variations have been searched)
#17	(manchester* near/3 (repair* or operation* or procedure* or method* or surger*)):ti,ab,kw (Word variations have been searched)
#18	colpocl*:ti,ab,kw (Word variations have been searched)
#19	IVS:ti,ab,kw (Word variations have been searched)
#20	((intravagin* or intra-vagin*) near/3 slingplast*):ti,ab,kw (Word variations have been searched)
#21	(TSST or STST or TSTS):ti,ab,kw (Word variations have been searched)
#22	(transfix* near/3 (stitch* or sutur*)):ti,ab,kw (Word variations have been searched)
#23	MeSH descriptor: [Polypropylenes] explode all trees
#24	polypropylen*:ti,ab,kw (Word variations have been searched)
#25	scaffold*:ti,ab,kw (Word variations have been searched)
#26	((urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctococele* or rectocele* or rectocoelle* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocoole* or cystourethrocele* or cystourethrococle* or vault* or anter* or poster* or apical* or vagin* or para-vagin* or paravagin* or utero-vagin* or uterovagin* or recto-vagin* or rectovagin* or utero-sacral* or uterosacral* or sacrospin* or prolaps* or POP) near/3 (repair* or suspen* or fix* or plicat*)):ti,ab,kw (Word variations have been searched)
#27	((POP or prolaps*) next (surg* or operat*)):ti,ab,kw (Word variations have been searched)

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#	Searches
#28	((vagin* or pelvi*) near/3 reconstruct*):ti,ab,kw (Word variations have been searched)
#29	#10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28
#30	#9 and #29
#31	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees and with qualifier(s): [Surgery - SU]
#32	#30 or #31

**Literature search strategies for review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Database: Medline & Embase (Multifile)**

**Last searched on Embase Classic+Embase 1947 to 2017 October 25, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present**

Date of last search: 26<sup>th</sup> October 2017.

#	Searches
1	Urinary Incontinence, Stress/ use ppez
2	Stress Incontinence/ use emczd
3	Mixed Incontinence/ use emczd
4	(urine adj2 (loss or leak\$)).tw.
5	((stress\$ or mix\$ or effort\$) adj5 incontinen\$).tw.
6	SUI.tw.
7	exp Pelvic Organ Prolapse/ use ppez
8	exp pelvic organ prolapse/ use emczd
9	(pelvic\$ adj3 organ\$ adj3 prolaps\$).tw.
10	(urinary adj3 bladder adj3 prolaps\$).tw.
11	((vagin\$ or urogenital\$ or genit\$ or uter\$ or viscer\$ or anterior\$ or posterior\$ or apical or pelvi\$ or vault\$ or urethr\$ or bladder\$) adj3 prolaps\$).tw.
12	(splanchnoptos\$ or visceroptos\$).tw.
13	Rectocele/ use ppez
14	rectocele/ use emczd
15	(hernia\$ adj3 (pelvi\$ or vagin\$ or urogenital\$ or uter\$ or bladder\$ or urethr\$ or viscer\$)).tw.
16	(urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$).tw.
17	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18	Suburethral Slings/ use ppez
19	Urinary Sphincter, Artificial/ use ppez
20	exp suburethral sling/ use emczd
21	colposuspension/ use emczd
22	bladder sphincter prosthesis/ use emczd
23	retropubic\$.ti,ab.
24	"bottom up".ti,ab.
25	"top down".ti,ab.
26	(tension\$ adj3 (tape\$ or vagina\$)).ti,ab.
27	TVT\$.ti,ab.
28	((transvagin\$ or trans-vagin\$) adj3 tape\$).ti,ab.

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#	Searches
29	(transobturator\$ or trans-obturator\$).ti,ab.
30	"outside in".ti,ab.
31	"inside out".ti,ab.
32	(single adj incision).ti,ab.
33	(minisling\$ or mini-sling\$).ti,ab.
34	((sling\$ or tape\$ or hammock\$) adj3 (procedure\$ or operat\$ or surg\$)).ti,ab.
35	((fascia\$ or subfascia\$ or sub-fascia\$ or autologous\$ or adjust\$ or pubovagin\$ or rectus) adj3 (sling\$ or tape\$ or hammock\$)).ti,ab.
36	((midurethra\$ or mid-urethra\$ or suburethra\$ or sub-urethra\$ or synthetic\$) adj3 (sling\$ or tape\$ or hammock\$)).ti,ab.
37	MUS.ti,ab.
38	(colposuspen\$ or colpo-suspen\$ or cystopex\$ or urethropex\$).ti,ab.
39	((retro-pubis or retropubis or abdominis or open or laparoscopic\$ or bladder neck) adj3 suspension\$).ti,ab.
40	(miniarc or monarc or SPARC).ti,ab.
41	((artificial or prosthes\$) adj3 sphincter\$).ti,ab.
42	((transurethra\$ or trans-urethra\$ or paraurethra\$ or para-urethra\$ or periurethra\$ or peri-urethra\$) adj3 inject\$).ti,ab.
43	(bulk\$ adj3 agent\$).ti,ab.
44	MMK.ti,ab.
45	(Marshall\$ adj Marchett\$ adj Krantz\$).ti,ab.
46	(anterior adj3 repair).ti,ab.
47	Hysterectomy, Vaginal/ use ppez
48	vaginal hysterectomy/ use emczd
49	abdominal hysterectomy/ use emczd
50	((vagin\$ or abdom\$) adj3 hysterectom\$).tw.
51	(total adj laparoscopic\$ adj hysterectom\$).tw.
52	(hysteropex\$ or sacro-hysteropex\$ or sacrohysteropex\$ or colpopex\$ or sacro-colpopex\$ or sacrocolpopex\$ or sacropex\$ or cervicopex\$ or sacro-cervicopex\$ or sacrocervicopex\$).tw.
53	(colporrhaph\$ or perineorrhaph\$ or perineoplast\$ or culd?plast\$).tw.
54	(manchester\$ adj3 (repair\$ or operation\$ or procedure\$ or method\$ or surger\$)).tw.
55	colpocl\$.tw.
56	IVS.tw.
57	((intravagin\$ or intra-vagin\$) adj3 slingplast\$).tw.
58	(TSST or STST or TSTS).tw.
59	(transfix\$ adj3 (stitch\$ or sutur\$)).tw.
60	scaffold\$.tw.
61	((urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$ or vault\$ or anter\$ or poster\$ or apical\$ or vagin\$ or para-vagin\$ or paravagin\$ or utero-vagin\$ or uterovagin\$ or recto-vagin\$ or rectovagin\$ or utero-sacral\$ or uterosacral\$ or sacrospin\$ or sacro-spin\$ or pubourethral or Kelly or Stamey or prolaps\$ or POP) adj3 (repair\$ or suspen\$ or fix\$ or plicat\$)).tw.

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#	Searches
62	((POP or prolaps\$ or prolaps\$ reduc\$) adj (surg\$ or operat\$)).tw.
63	((vagin\$ or pelvi\$) adj3 reconstruct\$).tw.
64	*Pelvic Organ Prolapse/su use ppez
65	*pelvic organ prolapse/su use emczd
66	*Urinary Incontinence, Stress/su use ppez
67	*Stress Incontinence/su use emczd
68	64 or 65
69	66 or 67
70	68 and 69
71	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46
72	47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63
73	17 and 71 and 72
74	70 or 73
75	Surgical Mesh/ use ppez
76	exp surgical mesh/ use emczd
77	(mesh\$ or non-mesh\$ or nonmesh\$).tw.
78	Polypropylenes/ use ppez
79	polypropylene/ use emczd
80	polypropylen\$.tw.
81	75 or 76 or 77 or 78 or 79 or 80
82	1 or 2 or 3 or 4 or 5 or 6
83	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
84	81 and 82
85	81 and 83
86	84 and 85
87	74 or 86
88	limit 87 to english language
89	Limit 88 to RCTs and SRs, and general exclusions filter applied

**Database: Cochrane Library via Wiley Online**

Date of last search: 26th October 2017.

#	Searches
#1	MeSH descriptor: [Urinary Incontinence, Stress] explode all trees
#2	(urine near/2 (loss or leak*)):ti,ab,kw (Word variations have been searched)
#3	((stress* or mix* or effort*) near/5 incontinent*):ti,ab,kw (Word variations have been searched)
#4	SUI:ti,ab,kw (Word variations have been searched)

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#	Searches
#5	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#6	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#7	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#8	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#9	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#10	MeSH descriptor: [Rectocele] explode all trees
#11	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#12	(urethrocele* or urethrococle* or enterocele* or enterococle* or sigmoidococle* or sigmoidocele* or proctocele* or proctococle* or rectocele* or rectococle* or cystocele* or cystococle* or rectoenterocele* or rectoenterococle* or cystourethrocele* or cystourethrococle*):ti,ab,kw (Word variations have been searched)
#13	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12
#14	MeSH descriptor: [Suburethral Slings] explode all trees
#15	MeSH descriptor: [Urinary Sphincter, Artificial] this term only
#16	retropubic*:ti,ab,kw (Word variations have been searched)
#17	"bottom up":ti,ab,kw (Word variations have been searched)
#18	"top down":ti,ab,kw (Word variations have been searched)
#19	(tension* near/3 (tape* or vagina*)):ti,ab,kw (Word variations have been searched)
#20	TVT*:ti,ab,kw (Word variations have been searched)
#21	((transvagin* or trans-vagin*) near/3 tape*):ti,ab,kw (Word variations have been searched)
#22	(transobturator* or trans-obturator*):ti,ab,kw (Word variations have been searched)
#23	"outside in":ti,ab,kw (Word variations have been searched)
#24	"inside out":ti,ab,kw (Word variations have been searched)
#25	(single next incision):ti,ab,kw (Word variations have been searched)
#26	(minisling* or mini-sling*):ti,ab,kw (Word variations have been searched)
#27	((sling* or tape* or hammock*) near/3 (procedure* or operat* or surg*)):ti,ab,kw (Word variations have been searched)
#28	((fascia* or subfascia* or sub-fascia* or autologous* or adjust* or pubovagin* or rectus) near/3 (sling* or tape* or hammock*)):ti,ab,kw (Word variations have been searched)
#29	((midurethra* or mid-urethra* or suburethra* or sub-urethra* or synthetic*):ti,ab,kw (Word variations have been searched)
#30	MUS:ti,ab,kw (Word variations have been searched)
#31	(colposuspen* or colpo-suspen* or cystopex* or urethropex*):ti,ab,kw (Word variations have been searched)
#32	((retro-pub* or retropub* or abdomin* or open or laparoscopic* or bladder neck) near/3 suspension*):ti,ab,kw (Word variations have been searched)
#33	(miniarc or monarc or SPARC):ti,ab,kw (Word variations have been searched)
#34	((artificial or prosthes*) near/3 sphincter*):ti,ab,kw (Word variations have been searched)
#35	((transurethra* or trans-urethra* or paraurethra* or para-urethra* or periurethra* or peri-urethra*) near/3 inject*):ti,ab,kw (Word variations have been searched)
#36	(bulk* near/3 agent*):ti,ab,kw (Word variations have been searched)

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#	Searches
#37	MMK:ti,ab,kw (Word variations have been searched)
#38	(Marshall* next Marchett*:ti,ab,kw (Word variations have been searched)
#39	(anterior near/3 repair):ti,ab,kw (Word variations have been searched)
#40	#14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39
#41	MeSH descriptor: [Hysterectomy, Vaginal] this term only
#42	((vagin* or abdom*) near/3 hysterectom*:ti,ab,kw (Word variations have been searched)
#43	(total next laparoscopic* next hysterectom*:ti,ab,kw (Word variations have been searched)
#44	(hysteropex* or sacro-hysteropex* or sacrohysteropex* or colpopex* or sacro-colpopex* or sacrocolpopex* or sacropex* or cervicopex* or sacro-cervicopex* or sacrocervicopex*):ti,ab,kw (Word variations have been searched)
#45	(colporrhaph* or perineorrhaph* or perineoplast* or culdoplast* or culdeplast\$):ti,ab,kw (Word variations have been searched)
#46	(manchester* near/3 (repair* or operation* or procedure* or method* or surger*)):ti,ab,kw (Word variations have been searched)
#47	colpocl*:ti,ab,kw (Word variations have been searched)
#48	IVS:ti,ab,kw (Word variations have been searched)
#49	((intravagin* or intra-vagin*) near/3 slingplast*:ti,ab,kw (Word variations have been searched)
#50	(TSST or STST or TSTS):ti,ab,kw (Word variations have been searched)
#51	(transfix* near/3 (stitch* or sutur*)):ti,ab,kw (Word variations have been searched)
#52	scaffold*:ti,ab,kw (Word variations have been searched)
#53	((urethrocele* or urethrococle* or enterocele* or enterococle* or sigmoidococle* or sigmoidocele* or proctocele* or proctococele* or rectocele* or rectococele* or cystocele* or cystococele* or rectoenterocele* or rectoenterococele* or cystourethrocele* or cystourethrococle* or vault* or anter* or poster* or apical* or vagin* or para-vagin* or paravagin* or utero-vagin* or uterovagin* or recto-vagin* or rectovagin* or utero-sacral* or uterosacral* or sacrospin* or sacro-spin* or pubourethral or Kelly or Stamey or prolaps* or POP) near/3 (repair* or suspen* or fix* or plicat*):ti,ab,kw (Word variations have been searched)
#54	((POP or prolaps* or prolaps* reduc*) next (surg* or operat*)):ti,ab,kw (Word variations have been searched)
#55	((vagin* or pelvi*) near/3 reconstruct*):ti,ab,kw (Word variations have been searched)
#56	#41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55
#57	MeSH descriptor: [Pelvic Organ Prolapse] this term only and with qualifier(s): [Surgery - SU]
#58	MeSH descriptor: [Urinary Incontinence, Stress] this term only and with qualifier(s): [Surgery - SU]
#59	#57 and #58
#60	#13 and #40 and #56
#61	#59 or #60
#62	MeSH descriptor: [Surgical Mesh] explode all trees
#63	(mesh* or non-mesh* or nonmesh*):ti,ab,kw (Word variations have been searched)
#64	MeSH descriptor: [Polypropylenes] explode all trees
#65	polypropylen*:ti,ab,kw (Word variations have been searched)
#66	#62 or #63 or #64 or #65
#67	#1 or #2 or #3 or #4
#68	#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12

#	Searches
#69	#66 and #67
#70	#66 and #68
#71	#69 and #70
#72	#61 or #71

**Literature search strategies for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessary?**

**Database: Medline & Embase (Multifile)**

**Last searched on Embase Classic+Embase 1947 to 2017 December 11, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present**

Date of last search: 12<sup>th</sup> December 2017.

#	Searches
1	exp Pelvic Organ Prolapse/ use ppez
2	exp pelvic organ prolapse/ use emczd
3	(pelvic\$ adj3 organ\$ adj3 prolaps\$).tw.
4	(urinary adj3 bladder adj3 prolaps\$).tw.
5	((vagin\$ or urogenital\$ or genit\$ or uter\$ or viscer\$ or anterior\$ or posterior\$ or apical or pelvi\$ or vault\$ or urethr\$ or bladder\$) adj3 prolaps\$).tw.
6	(splanchnoptos\$ or visceroptos\$).tw.
7	Rectocele/ use ppez
8	rectocele/ use emczd
9	(hernia\$ adj3 (pelvi\$ or vagin\$ or urogenital\$ or uter\$ or bladder\$ or urethr\$ or viscer\$)).tw.
10	(urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$).tw.
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	Surgical Mesh/ use ppez
13	exp surgical mesh/ use emczd
14	(mesh\$ or non-mesh\$ or nonmesh\$).tw.
15	Hysterectomy, Vaginal/ use ppez
16	vaginal hysterectomy/ use emczd
17	abdominal hysterectomy/ use emczd
18	((vagin\$ or abdom\$) adj3 hysterectom\$).tw.
19	(total adj laparoscopic\$ adj hysterectom\$).tw.
20	(hysteropex\$ or sacro-hysteropex\$ or sacrohysteropex\$ or colpopex\$ or sacro-colpopex\$ or sacrocolpopex\$ or sacropex\$ or cervicopex\$ or sacro-cervicopex\$ or sacrocervicopex\$).tw.
21	(colporrhaph\$ or perineorrhaph\$ or perineoplast\$ or culd?plast\$).tw.
22	(manchester\$ adj3 (repair\$ or operation\$ or procedure\$ or method\$ or surger\$)).tw.
23	colpocl\$.tw.
24	IVS.tw.
25	((intravagin\$ or intra-vagin\$) adj3 slingplast\$).tw.
26	(TSST or STST or TSTS).tw.
27	(transfix\$ adj3 (stitch\$ or sutur\$)).tw.
28	polypropylene/ use emczd

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#	Searches
29	Polypropylenes/ use ppez
30	polypropylen\$.tw.
31	scaffold\$.tw.
32	((urethroc?ele\$ or enteroc?ele\$ or sigmoidoc?ele\$ or proctoc?ele\$ or rectoc?ele\$ or cystoc?ele\$ or rectoenteroc?ele\$ or cystourethroc?ele\$ or vault\$ or anter\$ or poster\$ or apical\$ or vagin\$ or para-vagin\$ or paravagin\$ or utero-vagin\$ or uterovagin\$ or recto-vagin\$ or rectovagin\$ or utero-sacral\$ or uterosacral\$ or sacrospin\$ or sacro-spin\$ or prolaps\$ or POP) adj3 (repair\$ or suspen\$ or fix\$ or plicat\$)).tw.
33	((POP or prolaps\$) adj (surg\$ or operat\$)).tw.
34	((vagin\$ or pelvi\$) adj3 reconstruct\$).tw.
35	or/12-34
36	11 and 35
37	*Pelvic Organ Prolapse/su use ppez
38	*pelvic organ prolapse/su use emczd
39	36 or 37 or 38
40	surg\$.m_titl.
41	11 and 40
42	Pessaries/ use ppez
43	vagina pessary/ use emczd
44	pessar\$.tw.
45	42 or 43 or 44
46	39 and 45
47	41 and 45
48	46 or 47
49	remove duplicates from 48
50	limit 49 to english language
51	letter/
52	editorial/
53	news/
54	exp historical article/
55	Anecdotes as Topic/
56	comment/
57	case report/
58	(letter or comment*).ti.
59	51 or 52 or 53 or 54 or 55 or 56 or 57 or 58
60	randomized controlled trial/ or random*.ti,ab.
61	59 not 60
62	animals/ not humans/
63	exp Animals, Laboratory/

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#	Searches
64	exp Animal Experimentation/
65	exp Models, Animal/
66	exp Rodentia/
67	(rat or rats or mouse or mice).ti.
68	61 or 62 or 63 or 64 or 65 or 66 or 67
69	letter.pt. or letter/
70	note.pt.
71	editorial.pt.
72	case report/ or case study/
73	(letter or comment*).ti.
74	69 or 70 or 71 or 72 or 73
75	randomized controlled trial/ or random*.ti,ab.
76	74 not 75
77	animal/ not human/
78	nonhuman/
79	exp Animal Experiment/
80	exp Experimental Animal/
81	animal model/
82	exp Rodent/
83	(rat or rats or mouse or mice).ti.
84	76 or 77 or 78 or 79 or 80 or 81 or 82 or 83
85	68 use ppez
86	84 use emczd
87	85 or 86
88	50 and 87
89	50 not 88

**Database: Cochrane Library via Wiley Online**

Date of last search: 12<sup>th</sup> December 2017.

#	Searches
#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#2	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#3	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#4	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#5	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)

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#	Searches
#6	MeSH descriptor: [Rectocele] explode all trees
#7	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#8	(urethrocele* or urethrococle* or enterocele* or enterococle* or sigmoidococle* or sigmoidocele* or proctocele* or proctococle* or rectocele* or rectococle* or cystocele* or cystococle* or rectoenterocele* or rectoenterococle* or cystourethrocele* or cystourethrococle*):ti,ab,kw (Word variations have been searched)
#9	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10	MeSH descriptor: [Surgical Mesh] explode all trees
#11	(mesh* or non-mesh* or nonmesh*):ti,ab,kw (Word variations have been searched)
#12	MeSH descriptor: [Hysterectomy, Vaginal] explode all trees
#13	((vagin* or abdom*) near/3 hysterectom*):ti,ab,kw (Word variations have been searched)
#14	(total next laparoscopic* next hysterectom*):ti,ab,kw (Word variations have been searched)
#15	(hysteropex* or sacro-hysteropex* or sacrohysteropex* or colpopex* or sacro-colpopex* or sacrocolpopex* or sacropex* or cervicopex* or sacro-cervicopex* or sacrocervicopex*):ti,ab,kw (Word variations have been searched)
#16	(colporrhaph* or perineorrhaph* or perineoplast* or culdoplast* or culdeplast\$):ti,ab,kw (Word variations have been searched)
#17	(manchester* near/3 (repair* or operation* or procedure* or method* or surger*)):ti,ab,kw (Word variations have been searched)
#18	colpocl*:ti,ab,kw (Word variations have been searched)
#19	IVS:ti,ab,kw (Word variations have been searched)
#20	((intravagin* or intra-vagin*) near/3 slingplast*):ti,ab,kw (Word variations have been searched)
#21	(TSST or STST or TSTS):ti,ab,kw (Word variations have been searched)
#22	(transfix* near/3 (stitch* or sutur*)):ti,ab,kw (Word variations have been searched)
#23	MeSH descriptor: [Polypropylenes] explode all trees
#24	polypropylen*:ti,ab,kw (Word variations have been searched)
#25	scaffold*:ti,ab,kw (Word variations have been searched)
#26	((urethrocele* or urethrococle* or enterocele* or enterococle* or sigmoidococle* or sigmoidocele* or proctocele* or proctococle* or rectocele* or rectococle* or cystocele* or cystococle* or rectoenterocele* or rectoenterococle* or cystourethrocele* or cystourethrococle* or vault* or anter* or poster* or apical* or vagin* or para-vagin* or paravagin* or utero-vagin* or uterovagin* or recto-vagin* or rectovagin* or utero-sacral* or uterosacral* or prolaps* or POP) near/3 (repair* or suspen* or fix* or plicat*)):ti,ab,kw (Word variations have been searched)
#27	((POP or prolaps*) next (surg* or operat*)):ti,ab,kw (Word variations have been searched)
#28	((vagin* or pelvi*) near/3 reconstruct*):ti,ab,kw (Word variations have been searched)
#29	#10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28
#30	#9 and #29
#31	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees and with qualifier(s): [Surgery - SU]
#32	#30 or #31
#33	MeSH descriptor: [Pessaries] explode all trees
#34	pessar*:ti,ab,kw (Word variations have been searched)
#35	#33 or #34
#36	#32 and #35

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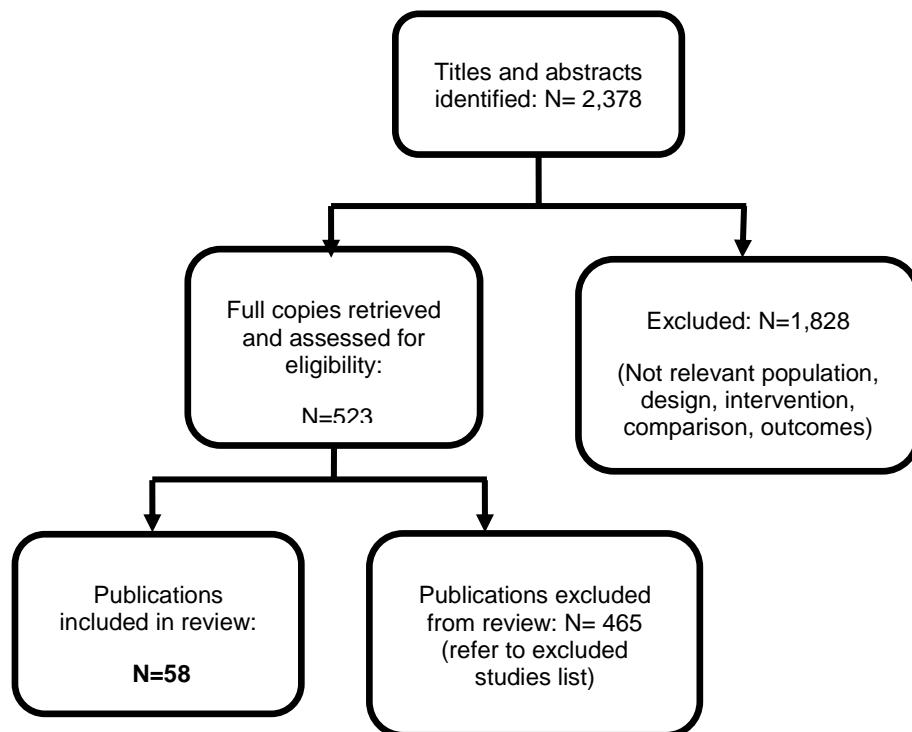
---

#	Searches
#37	surg*:ti (Word variations have been searched)
#38	#9 and #35 and #37
#39	#36 or #38

## Appendix C – Clinical evidence study selection

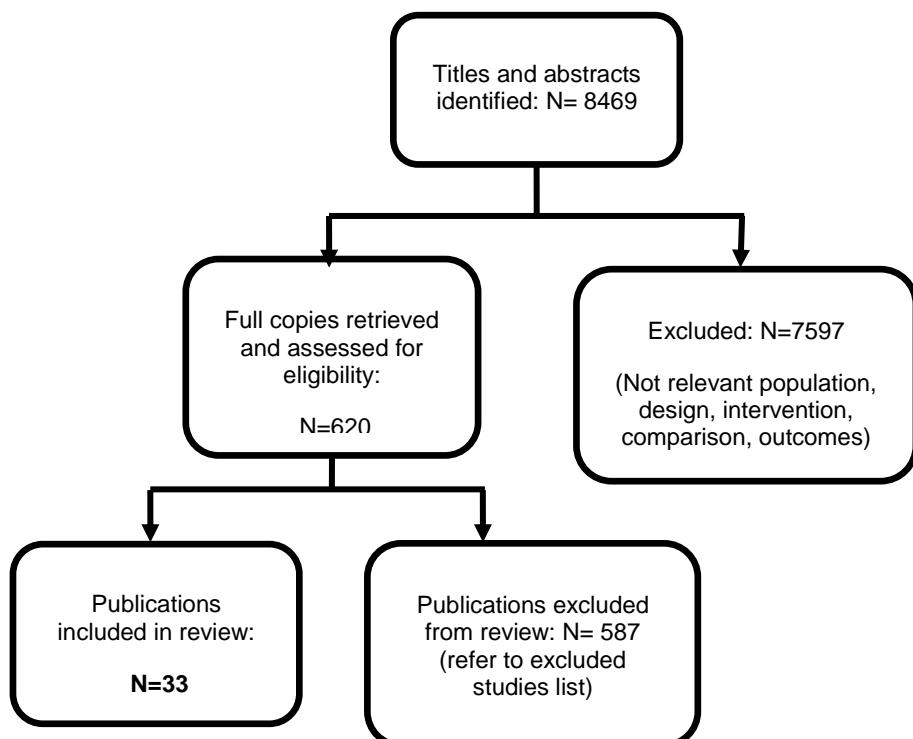
**Clinical evidence study selection for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse? RCT data.**

**Figure 4: PRISMA flow chart for effective surgical management options for POP; RCT data**



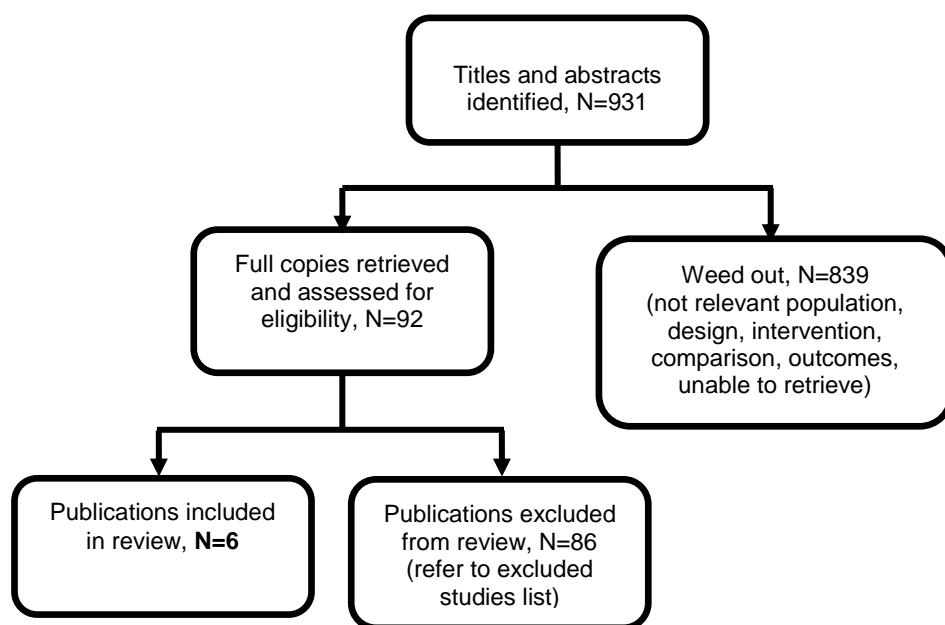
**Clinical evidence study selection for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse? Non-RCT**

**Figure 5: PRISMA flow chart for effective surgical management options for POP; non-RCT data**



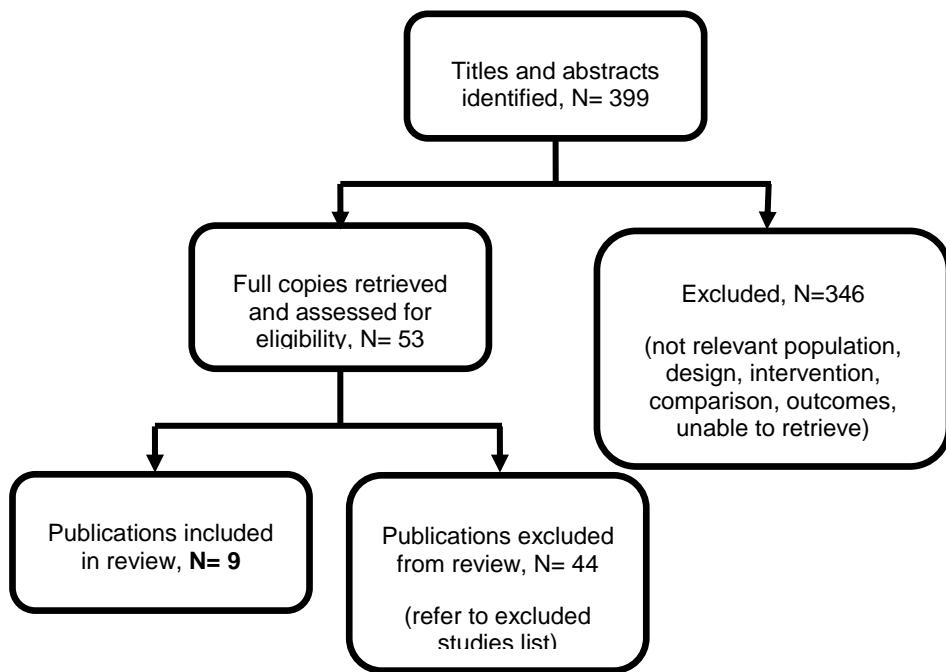
**Clinical evidence study selection for review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Figure 6 PRISMA flow chart for review question: what is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**



**Clinical evidence study selection for review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Figure 7: PRISMA diagram of clinical article selection for the effectiveness of surgical options for pelvic organ prolapse, compared to pessary review**



## Appendix D – Clinical evidence tables

**Clinical evidence tables for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse? RCT data**

**Table 31: Evidence tables for effectiveness studies**

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Full citation  Iyer, S., Seitz, M., Tran, A., Scalabrin Reis, R., Botros, C., Lozo, S., Botros, S., Sand, P., Tomezko, J., Wang, C., Gafni-Kane, A., Anterior Colporrhaphy With and Without Dermal Allograft: A Randomized Control Trial With Long-Term Follow-Up, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 03, 03, 2018	Sample size  Total Number = 114	Interventions  Anterior colporrhaphy (AC): N = 70 Anterior colporrhaphy plus dermal graft (graft): N = 44  Characteristics  Mean age AC: 60.3 years Graft: 59.6 years	Details  Anterior colporrhaphy: Participants underwent the midline colporrhaphy plication technique.  Anterior colporrhaphy plus insertion of an arcus tendineus fasia pelvis anchored dermal allograft (Repliform, Boston Scientific , Natick Mass,	Results  Surgery was performed by one of three fellowship trained urogynecologists and their fellows.  Recurrence (Aa or Ba ≥-1) 1 year AC:22/70 Graft: 8/44  7-10 years AC:24/70 Graft: 10/44	Limitations  No data on complications or cure provided Small study sample  Other information  Allocation bias: Low risk - Block randomised by computer programme, no significant differences between groups at baseline

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### Surgical management of pelvic organ prolapse

Ref Id 826576	Mean BMI AC: 27.8kg/m <sup>2</sup> Graft: 26.3kg/m <sup>2</sup>	USA): Participants underwent the same initial dissection followed by a bilateral, anterior approach to the sacrospinous ligaments			Allocation concealment: Low risk - opaque sealed envelopes Performance bias: High risk - surgeons aware of intervention. P articipants were told of intervention if asked Detection bias: Unclear risk - unclear if assessors were aware of intervention. T he primary outcome was the objective asses ment of prolapse Attrition bias: High risk, 61 out of 114 participants lost to follow up over the 10 year period. 21 out of 114 lost to follow up by 1 year (18%) Reporting bias: Low risk.
Country/ies where the study was carried out USA	Parity (range) AC: 2.5 (1-7) Graft: 2.5 (1- 5)	Inclusion criteria			
Study type Non-blinded randomised controlled trial		The woman was required to meet all of the following criteria:			
Aim of the study To compare cystocele recurrence following surgery with native tissue anterior colporrhaphy or anterior colporrhaphy with fascia pelvis anchored dermal allograft		<ul style="list-style-type: none"> <li>• Experienced bother from an anterior prolapse</li> <li>• planned surgical correction with a vaginal approach</li> <li>• English speaking</li> <li>• Willing to commit to the study requirement s</li> </ul>			
Study dates January 2005 to December 2007					

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

Source of funding  Boston Scientific supplied the Repliform allograft products	Exclusion criteria  <ul style="list-style-type: none"> <li>• A history of pelvic irradiation</li> <li>• Were pregnant, or planned to become pregnant in 12 months after surgery</li> <li>• Had undergone previous radical hysterectomy</li> <li>• Were non-English speakers</li> </ul>				Other risk:  Boston Scientific supplied the Repliform allograft products
Full citation  Lucot, J. P., Cosson, M., Bader, G., Debodinance, P., Akladios, C., Salet-Lizee, D., Delporte, P., Savary, D., Ferry, P., Deffieux, X., Campagne-Loiseau, S., de	Sample size  Total number: 262	Interventions  Laparoscopic Mesh sacropexy (LS) The mesh was anchored to the prevertebral ligament in front of the acral	Details  Both procedures were standardised across centres using a Delphi process Surgeons must have conducted over 30 procedures	Results  12 months data  Cure (POP stage 0-1) n/N LS: 59/130 TVM: 59/132  Vaginal bulge n/N LS: 118/130 TVM: 122/132  Repeat surgery for POP n/N	Limitations  Other information  Allocation bias: Unclear risk, computer generated central allocation. Report states groups were

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

Tayrac, R., Blanc, S., Fournet, S., Wattiez, A., Villet, R., Ravit, M., Jacquetin, B., Fritel, X., Fauconnier, A., Safety of Vaginal Mesh Surgery Versus Laparoscopic Mesh Sacropectomy for Cystocele Repair: Results of the Prosthetic Pelvic Floor Repair Randomized Controlled Trial, European Urology., 2018 Ref Id 826583	Characteristic s  Mean age (SD) LS: 62.6 years (6.0) TVM: 63.9 years (6.5)  Percentage with $\geq 3$ deliveries LS: 47% TVM: 39%  Mean BMI (SD) LS: 25.3kg/m <sup>2</sup> (3.6) TVM: 25.6kg/m <sup>2</sup> (3.6)	promontory with nonabsorbable sutures Length of operation: 119 minutes (SD 46) Length of stay in hospital: 3.3 days (SD 1.3)  Transvaginal Mesh Repair (TVM) Mesh was suspended by four arms Length of operation: 59 minutes (SD 34) Length of stay in hospital: 3.3 days (SD 2.0)	before the start of the study  LS: 1/130 TVM: 2/132  Dyspareunia n/N LS: 10/78 TVM: 18/67	comparable at baseline; however, no T-test was conducted and no data presented to confirm this Allocation concealment: Low risk, allocation revealed after baseline data taken Performance bias: High risk, Investigator and participants aware of allocation Detection bias: Low risk, independent assessors graded outcomes Attrition bias: Unclear risk, low drop out but differences between arms Reporting bias: Unclear risk, no tests between
Country/ies where the study was carried out	Inclusion criteria			
France				
Study type				
Multicentre randomized controlled trial	<ul style="list-style-type: none"><li>• Women aged 45 to 75 years</li><li>• Primary prolapse of anterior vaginal wall stage 2 or greater</li></ul>			

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Surgical management of pelvic organ prolapse

Aim of the study  To compare Laparoscopic sacrocepsy to Transvaginal mesh repair for cystocele repair	Exclusion criteria  <ul style="list-style-type: none"> <li>• Previous POP repair</li> <li>• Contraindication to either surgical route</li> <li>• Pelvic organ cancer</li> <li>• Contraindication to the use of mesh</li> <li>• Inability to read French</li> <li>• No social insurance</li> <li>• Pregnant, or a desire for future pregnancy</li> </ul>				groups at baseline Other risk:
Study dates  October 2012 to October 2014					
Source of funding  The study was supported by The French Ministry of Health (PHRC 2011/1921)					
Full citation  Altman, D., Vayrynen, T., Engh, M. E., Axelsen, S., Falconer, C., Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse, New	Sample size  N = 389 Transvaginal mesh repair group: N = 200  Traditional colporrhaphy group: N = 189	Interventions  Trocar-guided transvaginal mesh repair: Women underwent general anaesthesia (83/200; 41.5%), regional anaesthesia	Details  All surgeons were qualified to perform both interventions. Surgical procedures were standardised before initiation of the study and performed in an identical manner	Results  Prolapse stage 0 or 1 (n) At 2 months follow up Mesh repair: 170/200 Colporrhaphy: 113/189 Treatment effect 26.8 (17.9 to 35.8)  At 1 year follow up Mesh repair: 153/200 Colporrhaphy: 87/189 Treatment effect: 34.8 (25.1 to 44.3)  Recurrent Anterior prolapse at 12 months after surgery (n)	Limitations  Allocation bias: Unclear risk of bias - assigned in a ratio of 1:1 using balanced blocks of four; however no analysis to determine differences

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

England Journal of Medicine, 364, 1826-1836, 2011	Characteristic s	(115/200, 57.5%), or local anaesthesia (11/200, 5.5%).	across participating centres.	Mesh: 14/200 Colporrhaphy: 5/189 Adjusted Odds Ratio (95%CI): 5.9 (1.6 to 26.8)	between groups.
Ref Id 631148	Age - mean ± SD (years) Mesh repair: 64.3 (9.8) Colporrhaphy: 65.1 (9.8)	Mean (SD) operation time: 52.6 (16.5) mins	Postmenopausal women received pre-operative and post-operative topical oestrogen treatment.	UDI Summary score - mean (95% CI) - SD not reported At 2 months follow-up Mesh repair: 51.2 (44.1 to 58.2) Colporrhaphy: 41.2 (34.1 to 48.3) Treatment effect (95% CI): 10.0 (-0.01 to 20.0); p=0.05 At 1 year follow-up Mesh repair: 53.6 (45.9 to 61.2) Colporrhaphy: 53.6 (45.9 to 61.2) Treatment effect (95% CI): 0.03 (-10.8 to 10.8); p=0.99	Allocation concealment: Low risk of bias - allocated according to a sequentially numbered randomisation list at a co-ordinating centre
Country/ies where the study was carried out Sweden, Norway, Finland, and Denmark	Parity - median (range) - mean ± SD not reported Mesh repair: 2 (0-6) Colporrhaphy: 2 (0-7)	Traditional anterior colporrhaphy: Women underwent general anaesthesia (58/189, 30.7%), regional anaesthesia (98/189, 51.8%), or local anaesthesia (31/189, 16.4%).	Patients randomly assigned in a 1:1 ratio using balanced blocks of four.	PISQ-12 summary score - mean (95% CI) At 1 year follow-up Mesh repair: 35.0 (33.7 to 36.4) Colporrhaphy: 35.1 (33.7 to 36.4) Treatment effect (95% CI): -0.01 (-1.9 to 1.9); p=0.99	Performance bias: Unclear risk - patients unaware of allocation assignment until 1-year follow-up visit completed. Surgeons aware of participants group
Study type Multicentre, parallel-group, randomised trial	BMI - mean ± SD Mesh repair: 26.2 (3.4) Colporrhaphy: 25.0 (3.0)	Previous surgery for cystocele - n (%) Mesh repair: 33 (16.5) Colporrhaphy: 28 (14.8)	Mean (SD) operation time: 33.5 (10.5) mins	Statistical analysis Continuous outcomes (means ± SD) analysed using analysis of covariance (ANCOVA), with group and baseline values for the dependent variable entered as independent variables in a model. Categorical outcomes	Detection bias: Unclear risk - assessor may have been aware of treatment due to incisions. Self-report measures were
Aim of the study To compare the efficacy and safety of trocar-guided, transvaginal polypropylene-mesh repair kit with traditional colporrhaphy in women with prolapse of the anterior vaginal wall (cystocele).					

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### Surgical management of pelvic organ prolapse

Study dates	Prior pelvic surgery - n (%)		analysed using Fisher's exact test and univariate logistic regression, with treatment group as the only independent variable.		also used; however participants were blind to treatment.
Patients screened between December 2007 and December 2008, with follow-up at 2 and 12 months after surgery.	Posterior prolapse repair Mesh repair: 16 (8.0) Colporrhaphy: 24 (12.7)  Hysterectomy Mesh repair: 46 (23.0) Colporrhaphy: 36 (19.0) For incontinence Mesh repair: 5 (2.5) Colporrhaphy: 3 (1.6) Salpingo-oophorectomy Mesh repair: 3 (1.5) Colporrhaphy: 4 (2.1) Cervix amputation Mesh repair: 3 (1.5) Colporrhaphy: 1 (0.5) Sacrospinal fixation Mesh repair: 1 (0.5)		Additional multivariate logistic-regression analysis performed with adjustments for baseline covariates (BMI, parity, and presence or absence of a history of surgery for anterior-wall prolapse). Post-hoc analysis adjusted for the effects of descensus of the vaginal apex by adding numerical value of baseline position of POP-Q (position of vaginal apex before surgery) to covariates. Results of logistic-		Attrition bias: Low risk - only 10% lost to follow up, no differences between groups.
Source of funding	Swedish Society of Medicine, the Karolinska Institutet research foundations, the regional agreement on clinical research (ALF) between the Stockholm County Council and the Karolinska Institutet, and Ethicon.				Reporting bias: Unclear risk of bias.  Other information  Of 389 patients, 61 (15.7%) underwent surgery as a secondary procedure because of prolapse recurrence.  The 58 surgeons performed a median of 3 of each of the two types of

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### Surgical management of pelvic organ prolapse

	Colporrhaphy: 1 (0.5)		regression analyses presented as odds ratios with 95% confidence intervals.		procedures (Mesh repair: range 1 to 8; colporrhaphy: 1 to 9).
	UDI - mean ± SD Mesh repair: 86.9 (48.2)		Conservative sensitivity analysis of primary outcome assumed worst-case scenario for the mesh-repair group.		
	Colporrhaphy: 91.5 (52.5)				
	UDI-I - mean ± SD Mesh repair: 34.0 (20.5)				
	Colporrhaphy: 34.0 (22.0)				
	UDI-S - mean ± SD Mesh repair: 23.4 (23.5)		Power calculation At least 149 patients required for 90% power to detect a 20% difference in the primary outcome.		
	Colporrhaphy: 26.5 (25.9)				
	UDI-O - mean ± SD Mesh repair: 32.0 (18.5)				
	Colporrhaphy: 31.6 (18.3)				
	Symptom of vaginal bulging - n (%) Mesh repair: 169 (84.5)		Intention-to-treat Primary analysis used full data set based on observed outcomes without imputation of missing data.		
	Colporrhaphy: 158 (83.6)		Subsequent analysis included a per-protocol analysis.		
	POP-Q stage - n (%)				

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Stage 2 Mesh repair: 99 (50.0) Colporrhaphy: 103 (54.5) Stage 3 Mesh repair: 99 (50.0) Colporrhaphy: 83.43.9)					
PISQ-12 - mean $\pm$ SD Mesh repair: 32.2 (7.2) Colporrhaphy: 33.1 (6.7)					
Inclusion criteria  1] Women aged $\geq$ 18 years. 2] Primary or recurrent prolapse of the anterior vaginal wall at stage $\geq$ 2 (according to the Pelvic Organ Prolapse quantification (POP-Q))					

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	questionnaire)  3] Symptoms of vaginal bulging or pelvic heaviness.					
Full citation	Sample size  de Tayrac, R., Cornille, A., Eglin, G., Guilbaud, O., Mansoor, A., Alonso, S., N = 147 At 12 month follow-up N = 133	Interventions  AC: Performed using patient native tissues (vesico-vaginal fascia)	Details  All patients operated by the vaginal route. Prepared under strict aseptic	Results  Anatomical success Ba<- (n) AC: 43/82 MESH: 59/80  Quality of Life Scores - Improvement - mean ± SD	Limitations  Allocation bias: Low risk of bias - Balanced blocks method	

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Fernandez, H., Comparison between trans-obturator trans-vaginal mesh and traditional anterior colporrhaphy in the treatment of anterior vaginal wall prolapse: results of a French RCT, International Urogynecology Journal, 24, 1651-61, 2013	Anterior colporrhaphy (AC): N = 72 Trans-vaginal mesh repair (MESH): N = 75	and absorbable sutures (2/0 polyglactin): transverse plication and/or overlapping repair of the vaginal fascia.	conditions in the dorsal lithotomy position. A Foley catheter was used and cefazolin (antibiotic prophylaxis) was administered before incision).	PFIQ-UIQ AC: -66.1 (89.9) MESH: -54.8 (89.4); p=0.92  PFIQ-CRAIQ AC: -24.4 (51.2) MESH: -46.1 (81.6); p=0.12  PFIQ-POPIQ AC: -61.6 (70.2) MESH: -72.5 (115); p=0.68  PFDI-UDI AC: -51.3 (50.9) MESH: -51.7 (51.2); p=0.64  PFDI-CRADI AC: -36.4 (46.1) MESH: -35.8 (75); p=0.89  PFDI-POPDI AC: -75.8 (59.4) MESH: -76.4 (69.4); p=0.83	used and stratified by centre. No differences between groups at baseline
Ref Id	Characteristic s		A vasoconstricting solution was administered and a vertical anterior vaginal incision made from the apex to 2 cm short of the external urethral meatus. The fibromuscular layer of the anterior vaginal wall was dissected laterally to the inferior pubic ramus, and the bladder was completely dissected from the apex and up to 4 to 6 cm short of the pubic ramus.	Repeat surgery - n For mesh erosion AC: 0/82 MESH: 4/80  For haematoma AC: 1/82 MESH: 0/80  For dyspareunia AC: 0/82 MESH: 1/80  For prolapse recurrence AC: 3/82 MESH: 2/80  For SUI recurrence AC: 3/82 MESH: 1/80  For urinary retention AC: 1/82 MESH: 0/80	Allocation concealment: Low risk of bias - lots drawn in a centralised independent research department.
541354	Parity - N (range)	fixation of uterosacral ligaments using 2/0 polyglactin sutures)		Repeat surgery - n For mesh erosion AC: 0/82 MESH: 4/80  For haematoma AC: 1/82 MESH: 0/80  For dyspareunia AC: 0/82 MESH: 1/80  For prolapse recurrence AC: 3/82 MESH: 2/80  For SUI recurrence AC: 3/82 MESH: 1/80  For urinary retention AC: 1/82 MESH: 0/80	Performance bias: High risk of bias - participants not blinded, unclear if care staff were blind
Country/ies where the study was carried out	AC: 2 (0-6) MESH: 2 (1-10)				
France	BMI - mean ± SD (kg/m <sup>2</sup> )	permitted with associated hysterectomy. Paravaginal repair not permitted.			
Study type	AC: 25.4 (3.6) MESH: 25.5 (3.5)				
Prospective, randomised, multicentre trial					
Aim of the study	Previous surgery - N (%)	MESH: Ugytex® (highly porous polypropylene monofilament mesh) implanted into			
To compare the efficacy of Ugytex® (a collagen-coated	AC: 4 (5.6) MESH: 4 (5.3)				
	Anterior repair				

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polypropylene mesh) to anterior colporrhaphy (native tissue) in the treatment of ≥stage II (POP-Q) anterior vaginal wall prolapse.	AC: 0 MESH: 0 Hysterectomy AC: 12 (16.7) MESH: 10 (13.3) Incontinence surgery AC: 3 (4.2) MESH: 3 (4.0)	the obturator foramen in a tension-free manner, attached to the uterine isthmus. Surgeons were advised not to excise excess vaginal skin.	Randomisation Balanced blocks method (4 blocks), stratified by centre.	Patient satisfaction - very satisfied or satisfied -N AC: 46/82 MESH: 50/80  Long-term adverse events Pain reported during interview - n At 6 months AC: 3/82 MESH: 6/80 At 1 year AC: 4/82 MESH: 5/80		rates between groups  Selective reporting: Low risk of bias (All outcomes reported).
Study dates  April 2005 to December 2009	Anterior compartment POP-Q (cm) - N (%) [-1; +1] AC: 30 (41.7) MESH: 38 (50.7) > +1 AC: 38 (52.8) MESH: 34 (45.3) Total eversion AC: 4 (5.6) MESH: 3 (4.0) Ba point AC: 1.86 (1.96) MESH: 1.67 (1.89)		Statistical analysis Main outcome (anatomical recurrence of anterior vaginal wall prolapse) compared between two treatment groups using Chi-squared test. Relative risk and 95% confidence intervals (CIs) adjusted by centre and pre-operative measurement of anterior wall prolapse to evaluate association between type of surgery and anatomical recurrence.	At 6 months AC: 5/82 MESH: 9/80 At 1 year AC: 6/82 MESH: 12/80	Pain during examination - n At 6 months AC: 5/82 MESH: 9/80 At 1 year AC: 6/82 MESH: 12/80	Other bias: High risk of bias -The number of patients required for 80% power was not achieved.
Source of funding  The Department of Clinical Research of Paris-Ile-de-France.				Mesh exposure - n AC: 0 MESH: 7	MHU scores - mean ± SD SUI AC:-1.5 (2.5) MESH: -0.6 (3.1); p=0.14 Overactive bladder AC: -0.5 (2.6) MESH: -1.1 (2.8); p=0.42 Frequency AC: -0.3 (1.6) MESH: -0.5 (0.9); p=0.53 Voiding difficulties AC: -0.3 (1.2)	Other information
Partial funding from Safradim coproation for meshes, data management, and data analysis.	Urinary stress incontinence - N (%) AC: 27 (37.5) MESH: 25 (33.3)	Unconditional multivariate logistic regression used to estimate				*Any patients seen after 18 months with successful treatment were considered as treatment successes. Patients seen only before 9 months were not included in the results. The authors acknowledged

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			adjusted odds ratios and 95% CIs for relationship between variables and mesh shrinkage.	MESH: -0.9 (1.4); p=0.055  Obstructed defecation - n (%) AC: 9 (12.5) MESH: 8 (10.7); p=0.8 Obstructed defecation - De novo - n (%) AC: 4 (5.6) MESH: 4 (5.3)	that no conclusions could be drawn for the quality of life questionnaire data as a great deal of data were missing.
			Power calculation For power of 80% and a 10% dropout rate, 194 patients required.	Anal incontinence - De novo - n AC: 1/82 MESH: 1/80	
			Intention to treat analysis (ITT) ITT for main outcome (anatomical recurrence of anterior vaginal wall prolapse).	Sexual function - mean ± SD PISQ-12 AC: 5.3 (5.3) MESH: 6.6 (5.3); p=0.81	
				De novo dyspareunia - n AC: 1/82 MESH: 3/80	
				Anatomical and functional recurrence AC: 7/82 MESH: 3/80	

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	PFIQ - N (%) UIQ AC: 106.2 (95.2) MESH: 78.1 (77.0) CRAIQ AC: 72.9 (89.9) MESH: 33.7 (56.0) POPIQ AC: 82.0 (107.0) MESH: 59.7 (69.7)				
	PFID - N (%) UDI AC: 81.5 (57.1) MESH: 73.9 (44.7) CRADI AC: 86.8 (78.5) MESH: 70.9 (61.4) POPDI AC: 107.1 (67.6) MESH: 102.6 (67.6)				
	Inclusion criteria				

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1] Women aged ≥60 years. 2] Symptomatic stage II or more (POP-Q classification) anterior vaginal wall prolapse.				
Exclusion criteria  1] Stage 0 or I vaginal wall support. 2] Systemic corticosteroid treatment. 3] Uncontrolled diabetes. 4] Previous pelvic irradiation. 5] Untreated vaginal or urinary tract infection. 6] Cirrhotic ascites. 7] Inability to read French text.				

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	8] <60 years of age. Other exclusion criteria during the procedure included stage I anterior vaginal wall support and bladder injury.					
Full citation  Delroy, C. A., De, A. Castro R., Dias, M. M., Feldner Jr, P. C., Bortolini, M. A. T., Girao, M. J. B. C., Sartori, M. G. F., The use of transvaginal synthetic mesh for anterior vaginal wall prolapse repair: A randomized controlled trial, International Urogynecology Journal, 24, 1899-1907, 2013  Ref Id 631437	Sample size  N = 79  Trocar-guided transvaginal polypropylene mesh insertion (MESH): N = 40 (50.6%)  Anterior colporrhaphy: N = 39 (49.4%)  Characteristic s  Age - mean ± SD (years) MESH: 62.1 (8.3) Colporrhaphy: 59.6 (10.0)	Interventions  MESH Type I monofilament and macroporous polypropylene mesh (Nazca TCTM).  Anterior colporrhaphy: Vaginal infiltration with lidocaine and vasoconstrictor solution, two 5 mm suprapubic incisions made 3 cm apart. Full thickness vaginal incision from midurethra towards uterine cervix	Details  All procedures conducted under spinal anaesthesia.  Cystoscopy performed in operating room at surgeon's discretion.  All patients received cefazolin (2 g) and metronidazole (500 mg) antibiotics.	Results  Anatomical success (Ba<-1) - % (95% CI) of patients meeting cure criteria at 1 year follow-up MESH: 82.5% Colporrhaphy: 56.4% (95% CI 0.068-0.54; p=0.018); NNT: 4  Anatomical objective measurements (POP-Q) at 1 year follow-up - mean ± SD Point A Anterior - pre-operative MESH (N=40): 2.0 (0.8) Colporrhaphy: 1.7 (1.0); p=0.769 Anterior Point A - post-operative MESH: -1.9 (1.0) Colporrhaphy: -1.7 (0.9) Anterior Point B - pre-operative MESH: 2.8 (1.3) Colporrhaphy: 2.3 (1.5); p=0.072 Anterior Point B - post-operative MESH: -1.9 (1.1) Colporrhaphy: -1.4 (1.0); p=0.018  Intra-operative adverse events - n (%) Blood transfusion MESH: 2 (5) Colporrhaphy: 1 (5.1); p=1.00 Bladder perforation	Limitations  Allocation bias: Low risk of bias - Block randomisation based on 1:1 ratio using computerised random number generator. Allocation concealment: Low risk of bias - Envelopes containing allocation attached to patients' files by blinded secretary. Performance bias: High risk of bias, Surgeon aware of allocation in	

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Country/ies where the study was carried out	BMI - mean ± SD (kg/m <sup>2</sup> ) MESH: 27.6 (4.7) Colporrhaphy: 27.3 (3.7)	or vault made allowing proper vaginal dissection extended towards ascending branch of ischium and inferior aspect of the pubic bone.	postoperative day.  Randomisation Block randomisation based on 1:1 ratio using computerised random number generator.	MESH: 0 Colporrhaphy: 0 Urethral perforation MESH: 1 (2.5) Colporrhaphy: 0; p=0.99	Post-operative adverse events - n (%)  Tape exposure MESH: 2 (5%) Colporrhaphy: 0; p=0.76  Wound infection MESH: 0 Colporrhaphy: 0  Urinary retention MESH: 1 (2.5) Colporrhaphy: 2 (5.1); p=0.88	operating room, unclear if participants were blind.  Detection bias: Unclear risk - no mention of blinding of assessor  Attrition bias: Low risk of bias, all participants completed follow up  Reporting: Low risk of bias, all anticipated outcomes reported  Other bias: Low risk of bias
Study type	Non-inferiority randomised controlled trial (RCT)					
Aim of the study	To assess the efficacy and safety of transvaginal synthetic mesh (Nazca TCTM) compared to anterior colporrhaphy to repair advanced anterior vaginal wall prolapse.	Previous POP surgery - n (%) MESH: 8 (20) Colporrhaphy: 13 (33.3)	Sutures placed on body of mesh to remnants of cardinal ligament or the pericervical ring using polypropylene sutures to avoid apical cystocele recurrence.	Statistical analysis Student's t and Mann-Whitney tests used to compare continuous outcome data (means and SDs) between treatment groups. Chi-square and Fisher's tests used to evaluate nominal outcome data.	Voiding dysfunction MESH: 1 (2.5) Colporrhaphy: 0; p=0.99  UTI MESH: 8 (20) Colporrhaphy: 5 (13.8); p=0.34	
Study dates	January 2007 to January 2009	Previous hysterectomy - n (%) MESH: 1 (2.5) Colporrhaphy: 3 (7.6)	Vaginal wall closed using Montgomery overlapping technique to avoid superposition of the suture line on the mesh with interrupted	analysis of variance (ANOVA) performed to compare OPP measurements between treatment groups at pre-	Dyspareunia, of those sexually active, n/N (%) MESH: 2/23 (8.7) Colporrhaphy: 4/19 (21)	Other information  Women also had Posterior and/or apical POP: Posterior POP-Q stage - n (%) 0/I: MESH (18, 45%); Colporrhaphy (9, 23%)
Source of funding	The Federal University of Sao Paulo	Menopausal status - n (%)				

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Paulo and Hospital Sao Paulo.	<p>Pre-menopausal MESH: 2 (5.0) Colporrhaphy: 7 (17.9) Post-menopausal MESH: 38 (95) Colporrhaphy: 32 (82.1)</p> <p>Anterior POP-Q stage - n (%) Stage II MESH: 8 (20) Colporrhaphy: 16 (41.0) Stage III MESH: 26 (65.0) Colporrhaphy: 20 (51.3) Stage IV MESH: 6 (15.0) Colporrhaphy: 3 (7.7)</p> <p>Inclusion criteria Consecutive women presenting with:</p>	<p>sutures using Vicryl® 2-0. Anterior colporrhaphy Vaginal infiltration with lidocaine and 2% epinephrine solution diluted 1:1 in total of 40 ml. Longitudinal midline incision of the vaginal mucosa from 2 cm of the urethral meatus to uterine cervix or vaginal vault performed and dissected away from pubocervical fascia laterally and bilaterally.</p> <p>Purse string sutures used to plicate the fascia with Vicryl® 0, followed by</p>	<p>and post-operative time points. Power calculation For 80% power, anticipating 10% loss to follow-up and/or dropout rate over study period, 35 participants per treatment group required. Intention-to-treat (ITT) Per protocol, ITT, and number needed to treat analyses planned.</p>	<p>II: MESH (20, 50%); Colporrhaphy (28, 71.8%) III: MESH (2, 5%); Colporrhaphy (2, 5.1%) Apical POP-Q stage - n (%) 0/I: MESH (28, 70%); Colporrhaphy (31, 79%) II: MESH (9, 22.5%); Colporrhaphy (3, 7.7%) III: MESH (3, 7.5%); Colporrhaphy (5, 12.8%)</p> <p>Mean operative time significantly longer in MESH group (99.1 mins) compared with colporrhaphy group (46 mins); p&lt;0.001.</p>
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1] Anterior POP at least stage II beyond the hymen with point Ba $\geq +1$ according to the POP-Q classification. 2] Primary or recurrent POP.	vaginal mucosa trimming and midline closure with interrupted suture using Vicryl® 2-0).				

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	ns to a surgical procedure.					
Full citation	Sample size	Interventions	Details	Results	Limitations	
Dias, M. M., De, A. Castro R., Bortolini, M. A. T., Delroy, C. A., Martins, P. C. F., Girao, M. J. B. C., Sartori, M. G. F., Two-years results of native tissue versus vaginal mesh repair in the treatment of anterior prolapse according to different success criteria: A randomized controlled trial, Neurourology and Urodynamics, 35, 509-514, 2016	N = 88	AC: Anterior vaginal mucosa dissected from the pubovesicocervical fascia bilaterally. Synthetic mesh augmentation (MESH): N = 43	Postmenopausal women received pre- and post-operative local oestrogen treatment. All patients received spinal anaesthesia and intravenous cefazolin (2 g) and metronidazole (500 mg) as antibiotic prophylaxis.	Change in mean Ba point measures at 24 months (cm) AC: Pre-operative (2.3); Post-operative (-1.2) MESH: Pre-operative (2.7); Post-operative (-1.3); p=0.000 for both; interaction p=0.206  Objective success rates (Ba < -1) at 24 months - n/N AC: 17/45 MESH: 17/43  P-QoL scores at 24 months - mean (SD not reported) AC: pre-operative (46); post-operative (22.64) MESH: pre-operative (43.9); post-operative (20.89) Mean difference: 1.74, 95% CI: -0.28 to 3.77; p=0.09	Allocation bias: Low risk of bias - 1:1 ratio using computerised randomisation table. No significant differences at baseline between groups	
Ref Id	Characteristic s			Patient satisfaction at 24 months AC: 81.8% MESH: 97.3% Difference: 15.5%, 95% CI 1 to 29%; p=0.032		Allocation concealment: Low risk of bias - Envelopes prepared by secretary blinded to information; surgeon received envelope in operating room.
631452	Age - mean ± SD (years) AC: 59.4 (10.2) MESH: 61.7 (8.3)	Characteristic s	Cystoscopy performed when bladder injury suspected in the presence of intraoperative haematuria.	Symptoms of vaginal bulge at 24 months - n/N AC: 3/45 MESH: 2/43		
Country/ies where the study was carried out	BMI - mean ± SD (Kg/m) AC: 27.1 (3.6) MESH: 27.4 (4.8)			Adverse events during operation - n (% calculated) Bladder perforation AC: 0 MESH: 1 (2.33)		Performance bias: High risk of bias, participants and care staff aware of
Brazil	Parity - mean ± SD AC: 3.5 (2.0)		Randomisation 1:1 ratio using computerised randomisation table.	Long-term adverse events Mesh exposure - n/N AC: 0 MESH: 5/43 Urinary retention - n/N		

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Study type	MESH: 4.2 (3.2)	vical fascia, extending towards the ascending branch of the ischium and inferior edge of the pubic bone.	Student's t test and Mann-Whitney test used to compare quantitative variables between groups. X2 test and Fisher's test used for qualitative variables, and analysis of variance used to compare POP measurements and questionnaire scores between treatment groups at pre- and post-operative timepoints. 95% confidence intervals (CIs) calculated for primary outcome and patient satisfaction.	AC: 3/45 MESH: 1/43 New onset SUI - n/N AC: 2/45 MESH: 0/43 New onset dyspareunia - n/N AC: 4/45 MESH: 2/43 Pain - n/N AC: 4/45 MESH: 4/43	treatment allocation Detection bias: Unclear, no details of blinding of assessors
Randomised controlled trial	Menopausal status - n (%) AC: 34 (81.4) MESH: 41 (95.3)				Attrition bias: High risk of bias - 21% of patients lost to follow-up at 2 years
Aim of the study	SUI - n (%) AC: 21 (48.8) MESH: 23 (53.5)				Reporting bias: Low risk of bias - All outcomes anticipated reported
To compare the safety and efficacy of traditional colporrhaphy with transvaginal synthetic mesh to repair advanced anterior vaginal wall prolapse at 2 year follow-up.	Previous POP surgery - n (%) AC: 13 (30.2) MESH: 8 (18.6)				
Study dates	January 2007 to February 2010				Other bias: Unclear risk of bias - Insufficient sample size to make assumptions for all outcomes assessed.
Source of funding	Previous SUI surgery - n (%) AC: 12 (27.9) MESH: 8 (18.6)				
Federal University of São Paulo and Hospital São Paulo.	Previous hysterectomy - n (%) AC: 3 (7.0) MESH: 3 (7.0)		Power calculation For 80% power, 35 patients per group required.		Other information
	POP-Q Stage II - n (%) AC: 16 (37.2)				

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	MESH: 9 (20.9) (Ba Point) Stage III AC: 21 (48.8) MESH: 28 (65.1) Stage IV AC: 6 (13.9) MESH: 6 (13.9)	Intention to treat (ITT) analysis ITT for primary outcomes, with imputation of 'unsuccessful for missing data'. Secondary outcomes evaluated using per protocol analysis.		
	Symptoms of vaginal bulge - n (%) AC: 41 (95.3) MESH: 41 (95.3)			
	Pain - n (%) AC: 25 (58.1) MESH: 22 (51.1)			

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<p>anterior vaginal wall prolapse (Ba point <math>\geq +1</math> according to the POP-Q). 3] Primary or recurrent POP, with or without concomitant stress urinary incontinence (SUI).</p> <p>Exclusion criteria</p> <p>Women with:</p> <ul style="list-style-type: none"><li>1] Concomitant uterine prolapse.</li><li>2] Vaginal vault prolapse post hysterectomy.</li><li>3] Malignant urogenital disease.</li><li>4] Previous pelvic radiotherapy.</li><li>5] Clinical contraindications to a</li></ul>				
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	surgical procedure. 6] Connective tissue disorders. 7] Systemic glucocorticoid treatment. 8] Acute genitourinary infection.				
Full citation	Sample size	Interventions	Details	Results	Limitations
Feldner Jr, P. C., Castro, R. A., Cipolotti, L. A., Delroy, C. A., Sartori, M. G. F., Girao, M. J. B. C., Anterior vaginal wall prolapse: A randomized controlled trial of SIS graft versus traditional colporrhaphy, International Urogynecology Journal, 21, 1057-1063, 2010	Small intestine submucosa (SIS) graft: N = 29  Traditional anterior colporrhaphy (AC): N = 27	AC: Patients catheterised with Foley. Midline incision made. If cervix stage II POP-Q prolapse, vaginal hysterectomy was performed at the same time. Vaginal epithelium dissected off the underlying fibromuscular layer laterally to the lateral vaginal sulcus and up to the vaginal apex, cuff, or cervix, if present.	Randomisation Computer-generated list prepared by Biostatistics Centre of the Federal University of São Paulo.	Anatomic failure (POP-Q Stage II-IV) at 12 months follow-up - n AC: 4 recurrent prolapse; 7 primary repair.  SIS: 1 recurrent prolapse; 3 primary prolapse.  Anatomic cure (POP-Q Stage 0-I) at 12 months follow-up - n/N (%) AC: 16/27 (59.3)  SIS: 25/29 (86.2)  POP-Q scores (Ba) at 12 months follow-up - mean ± SD  Preoperatively AC: 2.22 (1.6) SIS: 2.07 (0.9); p=0.66  Postoperatively AC: -1.37 (1.0) SIS: -1.93 (0.8); p=0.02  Interaction for pre- and post-operative scores; p<0.001	Allocation bias: Low risk of bias - Computer-generated list prepared by the Biostatistics Centre, and maintained centrally. No differences between groups at baseline
Ref Id	631536	Characteristic s  Age - mean ± SD (years) AC: 56.3 (13.0) SIS: 53.8 (9.7); p=0.42  Parity - mean ± SD AC: 4.0 (2.1) SIS: 4.3 (1.8); p=0.68	Statistical analysis  Mann-Whitney U test used for continuous outcomes, and Chi-squared test used for categorical outcomes. Data were normally distributed, and independent samples t test was used to	Adverse events during surgery - n  Transfusion AC: 0 SIS: 0  Bladder perforation AC: 0 SIS: 0  Urethral perforation	Allocation concealment: Low risk of bias - Centrally co-ordinated so no investigators knew the treatment allocation of any patient

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Country/ies where the study was carried out	BMI - mean ± SD (Kg/m <sup>2</sup> ) AC: 27.5 (4.5) SIS: 27.3 (4.9); p=0.89	Dissection continued until entire length and width of anterior wall defect had been dissected off the underlying bladder.  Epithelium trimmed and closed with a separated 2/0 Vicryl suture.	assess difference between treatment groups or paired Student's t test for assessment of same treatment groups before and after surgery.	AC: 0 SIS: 1 Urinary retention AC: 2 SIS: 2   Long term adverse events at 12 months follow-up - n Mesh extrusion AC: 0 SIS: 0 Voiding difficulty AC: 0 SIS: 1 Dyspareunia AC: 4 SIS: 5	before randomisation.
Study type	Postmenopausal - n (%) AC: 13 (48.15) SIS: 19 (65.52)  Premenopausal - n (%) AC: 14 (51.85) SIS: 10 (34.48); p=0.44				Performance bias: High risk, participants not blinded, unclear if care staff were blind
Aim of the study		SIS graft: Traditional anterior repair	Power calculation For 80% power and based on a 25% difference in cure rates between treatment groups with a 10% loss to follow-up, 60 women were required.		Detection bias: Low risk - Outcome assessors blinded to treatment intervention
To compare the effects of small intestine submucosa (SIS) graft with traditional repair for the surgical treatment of anterior vaginal prolapse on anatomic cure rate, impact on quality of life and possible complications.	POP-Q stage - n (%) Stage II AC: 13 (48.15) SIS: 9 (31.03)  Stage III AC: 12 (44.44) SIS: 19 (65.12)  Stage IV AC: 2 (7.41) SIS: 1 (3.45); p=0.27	dissection, but underlying fibromuscular layer dissected further laterally, extending under the subpubic arch to the pelvic side wall. Graft cut to extend from bladder neck to vaginal apex and from one vaginal sulcus to the	Intention to treat (ITT) analysis ITT analysis used.		Attrition bias: Low risk of bias -No patients lost to follow-up.
Study dates	December 2006 to December 2008	Prior POP surgery - n (%) AC: 7 (25.93)			Reporting bias: Low risk of bias -All outcomes reported.
Source of funding					Other information

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No external financial support.	<p>SIS: 7 (24.14); p=0.87</p> <p>Prior SUI surgery - n (%) AC: 3 (11.11) SIS: 5 (17.24)</p> <p>Prior hysterectomy - n (%) AC: 1 (3.70) SIS: 3 (10.34)</p>	<p>other vaginal sulcus without tension. Traditional AC was not used prior to SIS insertion. Vaginal epithelium was trimmed and closed as with traditional AC.</p>		
	<p>Inclusion criteria</p> <p>1] Pre- and post-menopausal women referred for vaginal surgery. 2] Anterior vaginal wall prolapse <math>\geq</math> Stage II with point Ba <math>\geq+1</math>.</p> <p>Exclusion criteria</p> <p>1] Diabetes. 2] Pelvic radiotherapy.</p>			

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### Surgical management of pelvic organ prolapse

	3] Pelvic sepsis. 4] Gynaecologic cancer. 5] Vulvovaginal infections. 6] Current history of smoking, alcoholism, chronic disabling diseases, or hypertension.					
Full citation	Sample size  Gandhi, S., Goldberg, R. P., Kwon, C., Koduri, S., Beaumont, J. L., Abramov, Y., Sand, P. K., A prospective randomized trial using solvent dehydrated fascia lata for the prevention of recurrent anterior vaginal wall prolapse, American Journal of Obstetrics & Gynecology, 192, 1649-54, 2005	Interventions  N = 154; 134 (87%) returned for long-term evaluation, and 153 (99%) returned for at least 1 follow-up visit.	Details  AC: Patients in the dorsal lithotomy position, and midline anterior vaginal wall incision made from apex to level of the urethrovesical junction. Incision preceded by vaginal hysterectomy and McCall culdoplasty in women with uterine	Results  All procedures were supervised by a single doctor. All women received pre-operative antibiotic prophylaxis and a dilute vasopressin solution was given before vaginal incision.	Recurrent stage II or greater anterior vaginal wall prolapse - n/N (%) AC: 23/78 (29) AC + patch: 16/76 (21) OR: 0.77; p=0.541*  Symptoms of vaginal bulging - persistent - n/N AC: 6/78 AC + patch: 6/76  New onset symptoms at 12 months - n/N Pelvic pain AC: 8/78 AC + patch: 2/76  Abdominal pain AC: 5/78 AC + patch: 3/76  Slow urine stream AC: 5/78	Limitations  Allocation bias: Low risk of bias - Computer-generated random numbers table, no differences between groups at baseline.  Allocation concealment: Low risk of bias - concealed by sealed opaque envelopes until randomisation

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Ref Id 541417	Characteristic s	prolapse. Women who had undergone previous hysterectomy, had transverse incision through the vaginal epithelium distal to the cuff.	random numbers table.	AC + patch: 2/76  Post void fullness AC: 6/78 AC + patch: 3/76	in the operating room.
Country/ies where the study was carried out USA	Age - mean ± SD (years) AC: 65.5 (11.6) AC + patch: 64.9 (11.7)	Statistical analysis Multiple logistic regression was used to analyse associations between recurrent prolapse and the presence of a fascial patch, accounting for possible confounding variables such as age and concomitant surgeries.			Performance bias: High risk of bias, both surgeons, care staff and participants aware of treatment
Study type Prospective, randomised trial	Parity - n (range) AC: 3 (1-7) AC + patch: 3 (1-10)	Traditional colporrhaphy involved wide plication of the endopelvic connective tissue in the midline. All cases of vaginal vault prolapse to the midvagina or beyond were treated with a sacrospinous vaginal vault suspension.			Detection bias: High risk - self-report measures, participants not blind to treatment
Aim of the study To assess whether anterior colporrhaphy (AC) with cadaveric fascia patch compared to AC alone reduces recurrent prolapse rates in women with anterior vaginal wall prolapse to the hymen and beyond.	Previous hysterectomy or reconstructive surgery - n (%) AC: 42 (54) AC + patch: 38 (50)	Due to differences in follow-up time for the primary outcome, recurrent prolapse rates were described using Kaplan-Meier survival estimates.			Attrition bias: Low risk of bias -Less than 15% of patients lost to follow-up.
Study dates July 1999 to November 2002	Previous incontinence surgery - n (%) AC: 9 (12) AC + patch: 7 (9)	AC with mesh: AC as above with the addition of allograft,	Power calculation To detect a 20% difference in recurrent of		Reporting bias: Low risk of bias - All outcomes reported Other bias: Unclear risk of bias - use of non-validated questionnaire to assess prolapse symptoms

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Source of funding  Support from Mentor Corporation.	<p>Stage II AC: 36 (46) AC + patch: 40 (53)</p> <p>Stage III AC: 39 (50) AC + patch: 33 (43)</p> <p>Stage IV AC: 3 (4) AC + patch: 3 (4)</p> <p>Inclusion criteria             1] Women aged at least 18 years of age.            2] Women with anterior vaginal wall prolapse to the hymen or beyond while straining and planning on undergoing reconstructive pelvic surgery.            3] No plans for pregnancy.            A history of previous surgery and other planned procedures for</p>	<p>anchored at the lateral limits of the colporrhaphy dissection with interrupted 0 polyglactin sutures.</p> <p>stage II prolapse, with 80% power and 15% loss to follow-up, 81 women were required for each treatment group.</p> <p>Intention to treat (ITT) analysis All women were analysed in their allocation group.</p>		<p>Other information             *The presence of a transvaginal sling was associated with a decrease in recurrent stage II anterior vaginal wall prolapse (OR: 0.105; p&lt;0.0001). Subanalysis by the presence of a transvaginal Cooper's ligament sling showed that of patients without a sling, 49% of AC patients and 48% of patients with AC + patch experienced recurrent prolapse (<math>p&gt;0.2</math>); the rate of recurrent prolapse in patients receiving a</p>
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	concurrent prolapse or urinary incontinence did not preclude participation.				sling was 12% in AC group and 6% in patch group.
	Exclusion criteria				Of the 14 patients with a new onset of voiding symptoms, 13 (93%) had undergone sling ( $p=0.012$ ).
Full citation	Sample size	Interventions	Details	Results	Limitations
Guerette, N. L., Peterson, T. V., Aguirre, O. A., Vandrie, D. M., Biller, D. H., Davila, G. W., Anterior repair with or without collagen matrix reinforcement: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 114, 59-65, 2009	N = 94  AC: N = 47 AC + graft: N = 47	AC: Vaginal epithelium incised vertically and dissected off the underlying endopelvic fascia (fibromuscular layer) up to the lateral vaginal sulcus and urogenital diaphragm.  Characteristics Age - mean (range) - SD not reported (years) AC: 61.4 (36-80)  AC + graft: 60.9 (34-80)	Women showing a degree of vaginal atrophy were treated with local oestrogen cream for at least 4 weeks pre-operatively.  AC + graft: Graft cut to extend from bladder neck to vaginal apex and from	Successful anterior vaginal support ( $B_a > -1$ ) - n/N  At 1 year follow-up AC: 29/47 AC + graft: 30/47  At 2 year follow-up AC: 17/47 AC + graft: 13/47  Long-term adverse events at 24 months follow-up - n (%)  Graft erosion/exposure AC: 0 AC + graft: 0  Recurrence of POP at 12 months follow-up - n (%) AC: 8 (21.6) AC + graft: 5 (14.3)  Recurrence of POP at 24 months - n (%) AC: 10 (37) AC + graft: 4 (23.5)  Dyspareunia - de novo - n	Allocation bias: Low risk of bias - computer generated randomisation, no differences between groups at baseline.  Allocation concealment: Low risk of bias - Sealed envelopes which remained sealed until surgery
Ref Id 541436	Weight - mean (range) - SD				

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Country/ies where the study was carried out	not reported (kg) AC: 74.3 (45.0-105.0) AC + graft: 71.6 (52.3-134.1)	the vaginal sulcus to vaginal sulcus without tension. Bilaterally anchored to the obturator internus fascia at lateral-most aspect of the dissection distally and proximally, and to bladder neck and vaginal apex in the midline.	All women received postoperative vaginal packing for 24 hours.	AC: 1 AC + graft: 0	Performance bias: High risk: surgeons and care staff aware of treatment. No details of participant blinding Detection bias: High risk, same care team as operated conducted assessments, not blind to treatment Attrition bias: High risk of bias - >15% of patients lost to follow-up. Reporting bias: Low risk of bias -All outcomes reported. Other bias: Low risk of bias (no other potential source of bias identified).  Other information
USA					
Study type	Prospective randomised trial.		Randomisation Computer-generated randomisation.		
Aim of the study	Parity - mean (range) - SD not reported AC: 2.8 (0-5) AC + graft: 2.7 (1-7)		Statistical analysis Baseline and follow-up QoL data compared between treatment groups using Wilcoxon matched pairs signed rank test.		
To compare the efficacy of anterior colporrhaphy alone to anterior colporrhaphy with overlap of a xenograft (Veritas-bovine pericardium) in women with anterior vaginal wall prolapse.	Postmenopausal - n (% calculated) AC: 5 (10.64) AC + graft: 4 (8.51)		Power calculation For 80% power, 80 patients were required.		
Study dates	Urogenital atrophy - n (%) Absent AC: 10 (21.28) AC + graft: 9 (19.15)		Intention to treat (ITT) analysis Not mentioned in text.		
January 2004 to June 2005	Mild AC: 27 (57.45) AC + graft: 28 (59.57)				
Source of funding	Moderate AC: 9 (19.5) AC + graft: 10 (21.28)				
Data collection funded in part by	Severe				

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Synovis Life Technologies.	AC: 1 (2.13) AC + graft: 0  Previous cystocele repair - n (%) AC: 4 (8.5) AC + graft: 7 (14.9)  Previous vault suspension - n (%) AC: 0 AC + graft: 1 (2.1)  Previous enterocele repair - n (%) AC: 1 (2.1) AC + graft: 1 (2.1)  Previous Rectocele repair - n (%) AC: 5 (10.6) AC + graft: 7 (14.9)  Previous hysterectomy - n (%) AC: 11 (23.4) AC + graft: 14 (29.8)				Both treatment groups showed decline in UDI-6 scores at each follow-up period compared to baseline ( $p<0.001$ ). PISQ-12 scores decreased significantly at all follow-up timepoints within both groups with no statistically significant differences between groups. However, high rates of incomplete questionnaires resulted in invalidation.
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<p>Previous suburethral sling - n (%) AC: 0 AC + graft: 2 (4.3)</p> <p>QoL - UDI-6 - mean (SD not reported) AC: 41.8 AC + graft: 45.7; p=0.314</p> <p>Sexual function - PISQ-12 - mean (SD not reported) AC: 13.9 AC + graft: 16.0; p=0.118</p> <p>Inclusion criteria</p> <p>1] Women aged <math>\geq 18</math> years of age. 2] <math>\geq</math> Stage II cystocoele (POP-Q point Ba <math>&gt; -1\text{cm}</math>) and wish for surgical correction.</p>				
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	<p><b>Exclusion criteria</b></p> <p>1] Presence of a vaginal epithelial ulceration or infection.</p> <p>2] Previous POP surgery using an implant.</p> <p>3] Known allergy to bovine material.</p> <p>4] Severe vaginal atrophy (defined by dryness, pallor, and loss of rugation).</p> <p>5] Previously shortened vaginal length (total length &lt;6 cm).</p> <p>6] Future plans for pregnancy.</p> <p>7] Isolated paravaginal defect.</p>				
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Full citation	Sample size	Interventions	Details	Results	Limitations
Gupta, B., Vaid, N. B., Suneja, A., Guleria, K., Jain, S., Anterior vaginal prolapse repair: A randomised trial of traditional anterior colporrhaphy and self-tailored mesh repair, South African journal of obstetrics and gynaecology, 20, 47-50, 2014	N = 106 AC: N = 54 (n=41 completed 1 year follow-up) MESH: N = 52 (n=44 completed 1 year follow-up)	AC: Sagittal anterior vaginal wall incision made extending from urethrovesical junction to vaginal apex. Mucosa separated from the underlying fibromuscular layer and dissected up to the lateral sulcus. Midline plication of the fibromuscular layer performed, and vaginal wall closed.	Acriflavine-glycerine packing was used 1 week prior to surgery, if required. All women received preoperative antibiotics (IV cefotaxime, metronidazole). Regional anaesthesia was used for procedures. All patients received similar IV antibiotics for 48 hours postoperatively, and the vaginal pack was removed after 24 hours and catheter after 24 to 72 hours.	Optimal outcome - n (calculated) (%) AC: 29 (55) MESH: 34 (65)  Satisfactory outcome - n (calculated) (%) AC: 24 (45) MESH: 18 (35)  Ba measurements - median (cm) At 6 months follow-up AC: -1 MESH: -2  At 1 year follow-up AC: -2 MESH: -2	Allocation bias: Unclear risk of bias - Computer-generated random number table; however no analysis between groups at baseline to determine potential differences
Ref Id 631633	Characteristics			Symptoms of vaginal bulge - n (% calculated) AC: 4 (9.76) MESH: 0	Allocation concealment: Unclear risk of bias -not mentioned in text
Country/ies where the study was carried out India	Age - mean ± SD (years) AC: 51.5 (12) MESH: 49.6 (10)			Patient satisfaction with procedure - n/N (%) AC: 50/54 (92.5) MESH: 48/52 (92)	
Study type Prospective, randomised controlled trial	Parity - median (range AD: 4 (2-6) MESH: 4 (2-7)	MESH: Tailored non-absorbable, low-weight, monofilament, macroporous, vicryl-polypropylene mesh used. Fibromuscular	Randomisation Computer-generated random number table.	Adverse events during surgery: blood transfusion - n/N AC: 12/54 MESH: 19/52	Performance bias: Unclear risk - no details provided Detection bias - Unclear risk - no details provided as to blinding of assessors
Aim of the study To compare the safety and efficacy	Postmenopausal - n (%) AC: 40 (74.1) MESH: 36 (69.2)			Long term adverse events at 1 year follow-up - n (%) Recurrent cystocele (stage II POP-Q) AC: 2 (3.7) MESH: 0	Attrition bias: High risk of bias - > 15% of
			Statistical analysis Univariate analysis	Mesh erosion - n (%) AC: 0 MESH: 4 (7.6)	

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of traditional anterior colporrhaphy (AC) with anterior self-tailored mesh repair for the treatment of women with anterior vaginal prolapse.	Duration of prolapse - median (range) (years) AC: 4 (3-7) MESH: 4 (2-7)	layer separated from the mucosa of the anterior vaginal wall. Anterior tunnels made by dissection along the inside of the inferior rami of the pubic bone,	conducted using Fisher's exact test for categorical outcomes and Mann-Whitney U test for continuous outcomes. The Wilcoxon signed-rank test was used to compare POP-Q measures pre- and post-operatively.	
Study dates	Prior hysterectomy - n (%) AC: 1 (1.9) MESH: 1 (1.9)			patients lost to follow-up. Reporting bias: High risk of bias. Most outcomes reported, no baseline assessment of participants
May 2009 to May 2012				Other information
Source of funding	Pre-operative measurements and staging - median Ba (cm) AC: +4 MESH: +5	dissecting the fibromuscular layer towards the obturator foramina, not extending to the obturator membrane.	Power calculation For power of 80%, 106 women were required, taking into account patients who would be lost to follow-up.	
Not mentioned in text.	POP-Q stage AC: IIIBa MESH: IIIBa	The mesh was attached to the underlying bladder fascia and the vagina closed.	Intention to treat (ITT) analysis Not mentioned in text.	
	Inclusion criteria  1] Women with symptomatic anterior vaginal prolapse to the hymen or beyond.			

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	Exclusion criteria  1] Concomitant stress urinary incontinence. 2] Dominant symptomatic posterior vaginal prolapse. 3] Active vaginal infections. 4] Presence of any gynaecological malignancy.					
Full citation  Hiltunen,R., Nieminen,K., Takala,T., Heiskanen,E., Merikari,M., Niemi,K., Heinonen,P.K., Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized	Sample size  N = 202	Interventions  Traditional anterior colporrhaphy (AC): N = 97; at 12 months follow-up N = 96  AC with self-tailored low-weight	Details  AC: Patients placed in dorsal lithotomy position, and vaginal hysterectomy and bilateral salpingo-oophorectomy, resection of enterocele, and	Results  Women not receiving oestrogen treatment were prescribed topical oestrogen.  All patients received pre-operative intravenous antibiotics and	POP-Q values (preoperation; 12 months follow-up) - mean ± SD  Ba (cm) AC: 2.3 (1.7); -1.6 (1.5) AC + MESH: 2.1 (1.8); -2.4 (0.8); p<0.001*  Reoperation at 12 months follow-up - n (%) AC: 6 (6.2) AC + MESH: 5 (4.8)  Prolapse stage (POP-Q) (preoperative; 12 months follow-up) - n/N (%) Stage 0 AC: 0/97 (0); 28/96 (29) AC + MESH: 0/105 (0); 63/104 (61); p<0.001	Limitations  Allocation bias: Low risk of bias - Computer-generated randomisation list, no differences between groups at baseline

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controlled trial, Obstetrics and Gynecology, 110, 455-462, 2007	Ref Id 100634	Characteristic s	culoplasty were performed when required. Sagittal anterior vaginal wall incision made extending from the urethrovesical junction to the vaginal apex or anterior fornix. Mucosa separated from underlying fibromuscular layer and dissected up to the lateral sulci. Midline plication of the fibromuscular layer performed, and vaginal mucosa sparsely trimmed if necessary.	low-molecular-weight heparin. A diluted local anaesthetic was used on the vaginal wall before vaginal incision performed. 90% of procedures were performed using spinal block.	Stage I AC: 0/97 (0); 31/96 (32) AC + MESH: 0/105 (0); 34/104 (33); p=0.9  Stage II AC: 32/97 (33); 35/96 (36) AC + MESH: 41/105 (39); 7/104 (7); p<0.001*  Stage III AC: 64/97 (66); 2/96 (2) AC + MESH: 64/105 (61); 0/104 (0); p=0.1*  Stage IV AC: 1/97 (1); 0/96 (0) AC + MESH: 0/105 (0); 0/104 (0); p=0.3  Symptoms of vaginal bulging - n/N (%) Postoperative AC: 6/93 (6) AC + MESH: 7/104 (7); p=0.9 New onset and Persistent AC: 5 AC + MESH: 7  Long-term adverse effects at 12 months follow-up - n (%) Mesh exposure AC: 0 AC + MESH: 18 (17); 95% CI 9.8-24.4 Postoperative stress urinary incontinence - n/N (%) AC: 9/96 (10) AC + MESH: 23/104 (23); p=0.02 De novo stress incontinence - n/N (%) AC: 9/96 (9) AC + MESH: 15/104 (14); p=0.2 Postoperative voiding difficulties - n/N (%) AC: 8/96 (8) AC + MESH: 9/104 (9); p=1.0 New onset and persistent voiding difficulties - n/N (%) AC: 8 AC + MESH: 8	Allocation concealment: Low risk of bias - Performed blindly using cards from an opaque envelope
Country/ies where the study was carried out	Finland	Study type	Prospective, multicentre, randomised controlled trial.			Performance bias: Unclear risk - not details provided regarding blinding of care staff or participants
Aim of the study	To compare the effectiveness of traditional anterior colporrhaphy with and without self-tailored low-weight polypropylene mesh on recurrence of prolapse in postmenopausal women with anterior vaginal wall prolapse to	BMI - mean ± SD (kg/m <sup>2</sup> ) AC: 27.2 (4.1) AC + MESH: 26.5 (3.5)	Parity - n (range) AC: 2 (1-10) AC + MESH: 3 (0-11)	Randomisation Computer-generated randomisation list produced by the statistician.		Detection bias: Unclear risk - no details provided regarding blinding of assessors
		Previous hysterectomy - n (%) AC: 27 (28) AC + MESH: 23 (22)	Previous hysterectomy - n (%) AC: 27 (28) AC + MESH: 23 (22)	Statistical analysis To determine differences between study groups and 95% confidence intervals (95% CIs), independent samples t test were used for continuous outcomes and X <sup>2</sup> test for nominal or AC + MESH: As above, plus non-absorbable		Attrition bias: Low risk of bias -Less than 15% of patients lost to follow-up.
		Previous prolapse or				Reporting bias: Low risk of bias -all

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the hymen or beyond.	incontinence surgery - n (%) AC: 26 (27) AC + MESH: 19 (18)	low-weight monofilament polypropylene mesh for reinforcement.	ordinal outcomes. Power calculation For 80% power, with estimated recurrence rate of 20% with AC and 5% with mesh, 88 women were required for each treatment group. Assuming 15% loss to follow-up, a total of 202 women were required. Intention to treat (ITT) analysis Not mentioned in text.	Symptomatic recurrence of anterior vaginal wall prolapse AC: 14 (15) AC + MESH: 4 (4); p=0.005  *Postoperative difference between 2 treatment groups  24 months follow up data, from Nieminen et al. 2008 Objective cure (prolapse stage 0 or I) at 24 months n/N (%) AC: 57/97 (58.7) AC + MESH: 92/105 (87.6)  Recurrence of prolapse (stage II or III) at 24 months n/N (%) AC: 39/97 (40.2) AC + MESH: 12/105 (11.4)  Symptoms of prolapse at 24 months n/N (%) AC: 35/97 (36.1) AC + MESH: 27/105 (25.7)  36 months follow up data, from Nieminen et al., 2010 Anterior compartment recurrence at 36 months, n/N (%) AC: 40/97 (41.2) AC + MESH: 14/105 (13.3)  Posterior/apical compartment recurrence at 36 months, n/N (%) AC: 9/97 (9.3) AC + MESH: 16/105 (15.2)  Symptoms of prolapse at 36 months n/N (%) AC: 40/97 (41.2) AC + MESH: 29/105 (27.6)  Stress incontinence at 36 months, n/n (%) AC: 15/97 (15.5) AC + MESH: 15/105 (14.3)  Mesh erosion by 36 months, n/n (%) AC: 0/97 (0)	outcomes reported  Other bias: Low risk of bias (no other potential source of bias identified).  Other information
Study dates	April 2003 to May 2005				
Source of funding	Supported by grants from the Medical Research Funds of the Central Hospital of South Ostrobothnia and Tampere University Hospital.				

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<p>with symptomatic anterior vaginal wall prolapse to the hymen or beyond when straining.</p> <p>2] Referred for reconstructive pelvic surgery to one of 5 hospitals in Finland.</p> <p><b>Exclusion criteria</b></p> <p>1] Apical defect indicating concomitant vaginal fixation or stress urinary incontinence requiring surgery.</p> <p>2] Main symptomatic prolapse in the posterior vaginal wall.</p> <p>3] Women with gynaecologic tumour or</p>		<p>AC + MESH: 20/105 (19.0)</p> <p>Repeat surgery for prolapse by 36 months, n/N (%) AC: 9/97 (9.3) AC + MESH: 6/105 (5.7)</p> <p>Repeat surgery for incontinence by 36 months, n/N (%) AC: 9/97 (9.3) AC + MESH: 5/105 (4.8)</p>		
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	malignancy requiring laparotomy or laparoscopy. 4] Women with untreated vaginal infection.				
Full citation	Sample size	Interventions	Details	Results	Limitations
Hviid, U., Hviid, T. V. F., Rudnicki, M., Porcine skin collagen implants for anterior vaginal wall prolapse: A randomised prospective controlled study, International Urogynecology Journal, 21, 529-534, 2010	N = 61  Standard anterior colporrhaphy (AC): N = 31; N = 26 at 12 months follow-up  Pelvicol® graft (Graft): N = 30; N = 28 patients at 12 months follow-up	AC: Longitudinal incision made in the vaginal mucosa and dissected from the pubocervical fascia.  Plication of the pubocervical fascie performed and vaginal mucosa trimmed and closed.	All patients received a single dose of Cefuroxim preoperatively.  Randomisation based on computer-generated random list without block randomisation.	POP-Q Ba measurements at 12 months follow-up - median (range (cm) AC: -3.0 (-3.0 to +2.0) Graft: -3.0 (-3.0 to -1.0); p=NS  Stage of prolapse at point Ba (cm) - n (% calculated) Stage 0 AC (n=26): 15 (57.69) Graft (n=28): 21 (75.0) Stage I AC: 7 (26.92) Graft: 5 (17.86) Stage II AC: 2 (7.69) Graft: 2 (7.14) Stage III AC: 2 (7.69) Graft: 0	Allocation bias: Low risk of bias -Computer-generated random list without block randomisation, no differences between groups at baseline
Ref Id 632131			Statistical analysis Between group comparisons performed using Fisher's exact test, X <sup>2</sup> test, Mann-Whitney, Wilcoxon signed rank test, of Student's t test. Perioperative bleeding was	Recurrence of POP (Ba>-1.0) at 12 months follow-up - n (%) AC: 4 (15) Graft: 2 (7)  Subjective recurrence (prolapse symptoms of vaginal bulging, something falling out of vagina or as lumps feelings) - n (%) AC: 1 (3) Graft: 1 (3)	Allocation concealment: Low risk of bias sealed non-transparent envelopes used and opened just before patient entered the operating theatre
Country/ies where the study was carried out Denmark	Characteristic s Age - mean ± SD (years) AC: 61 (10.2) Graft: 60 (9.8)	Graft: Similar incision in vaginal mucosa and vaginal mucosa dissected from pubocervical fascia.		Reoperation for prolapse (anterior or posterior) at 12 months follow up - n/N (%)	Performance bias: Unclear ri

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Prospective, randomised controlled trial.	Parity - median (range) AC: 2 (0-3) Graft: 2 (0-5)	Pelvicol® graft implanted in patients.	compared using an unpaired t test (with log-transformed data).  Power calculation Assuming dropout rate of 10%, and based on 80% power, 25 patients required for each treatment group.  Intention to treat (ITT) analysis Not mentioned in text.	AC: 2/26 (7.7) Graft: 3/28 (10.7)  Long-term adverse events at 12 months follow-up - n (% calculated) Incontinence AC: 5 (19.23) Graft: 4 (14.29); p=NS  Mesh erosion - n (% calculated) AC: 0 Graft: 1 (3.57)  The QoL (King's Health) questionnaire showed no significant differences between the treatment groups at 12 months follow-up; showing improvement in all domains (general health perception, prolapse impact, physical limitation, personal relationship, emotions and sleep/energy (data only presented in a graph).	sk - no information regarding blinding of care staff or participants  Detection bias: Unclear risk - no information about blinding of assessor  Attrition bias: low risk of bias -less than 15% of patients lost to follow-up.  Reporting bias: Unclear risk, outcomes reported, but presented in graphical format without data  Other information
Aim of the study	To compare the effectiveness of a Pelvicol® graft with conventional anterior vaginal repair in women with a stage II or higher prolapse.	Abdominal hysterectomy - n (% calculated) AC: 2 (6.67) Graft: 0			
Study dates	2003 to 2005	BMI - mean ± SD (kg/m <sup>2</sup> ) AC: 25.2 (3.4) Graft: 26.4 (4.2)			
Source of funding	Not mentioned in the text.	Incontinence before surgery - n (% calculated) AC: 7 (24.24) Graft: 12 (41.38)			
		POP-Q Baseline measurement s - median (range (cm)) AC: +4.0 (+2.0 to +8.0) Graft: +4.0 (-1.0 to + 8.0)			*1 patient in each group had a sling procedure performed
		Stage of prolapse at			

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	<p>point Ba (cm)            - n (%)            calculated)</p> <p>Stage 0            AC: 0            Graft: 0</p> <p>Stage I            AC: 0            Graft: 0</p> <p>Stage II            AC: 4 (13.79)            Graft: 1 (3.57)</p> <p>Stage III            AC: 25 (86.21)            Graft: 27            (96.43)</p> <p><b>Inclusion criteria</b></p> <p>1] Women aged <math>\geq 18</math> years of age.            2] Women with <math>\geq</math>stage II (POP-Q; point Ba<math>\geq -1</math>) anterior wall prolapse.</p> <p><b>Exclusion criteria</b></p> <p>1] Defects in the posterior or apical compartment</p>			(Tension-free vaginal tape) 6 months after the primary procedure.
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	or decent of the uterus. 2] Previous pelvic surgery (i.e. vaginal, abdominal or incontinence surgery). 3] History of collagen diseases. 4] History of endocrine disorders.				
Full citation  Lunardelli, J. L., Auge, A. P., Lemos, N. L., Carramao Sda, S., de Oliveira, A. L., Duarte, E., Aoki, T., Polypropylene mesh vs. site-specific repair in the treatment of anterior vaginal wall prolapse: preliminary results of a randomized clinical trial, Revista do Colegio Brasileiro de Cirurgioes, 36, 210-6, 2009  Ref Id	Sample size  N = 32  Site-specific surgical repair of the anterior vaginal prolapse (AC): N = 16  AC + mesh (MESH): N = 16  Characteristics  Age - means (SD not reported) (years) AC: 62.3	Interventions  AC: Placed in lithotomy position and given bladder catheterisation . Saline and adrenaline introduced to the vaginal wall to aid dissection and haemostasis. Median incision made on the anterior vaginal wall below the meatus at the level of the pubourethral ligament insertion down	Details  All patients received antibiotic prophylaxis on anaesthetic induction. Bladder catheter was removed after 24 hours. Patients instructed to avoid physical strain for 30 days and refrain from sexual activity for 60 days post procedure. Concurrent surgical procedures were performed as required,	Results  No intraoperative complications occurred.  Mean follow-up (months) AC: 7.9 MESH: 9 POP-Q - point Ba (preoperatively; follow-up) AC: 0.631; 0.227 MESH: 0.548; 0.079; p=0.152 (preoperatively) p=0.027 (postoperatively)  Long term adverse events - n (%) calculated De novo stress urinary incontinence AC: 1 (6.25) MESH: 1 (6.25) Mesh erosion - n (%) AC: 0 MESH: 1 (6.25)  From Lunardelli et al., 2009 conference abstract Quality of life (measured with Kings Health Questionnaire) at 12 months, mean (SD) AC: 5.06 (7.9) MESH: 4 (6.0)	Limitations  Allocation bias: Low risk of bias -Group allocation performed using randomisation table by a third party not involved in the study. No differences between groups at baseline  Allocation concealment: Low risk of bias - Sealed envelopes,

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541524	MESH: 64.4	to the uterine cervix. Dissection extended to ischio-pubic ramus, bilaterally.	depending on the preoperative findings.		opened upon patients' admission.
Country/ies where the study was carried out	BMI - mean (SD not reported) (kg/m <sup>2</sup> ) AC: 26.5 MESH: 26.2	Patients with preoperative SUI received a suburethral transobturator sling through same incision made for AC	Randomisation Treatment allocation performed through a randomisation table by a third party not involved in the study.		Performance bias: Unclear risk - no details regarding blinding of care staff or participants
Study type	Parity - mean (SD not reported) AC: 4.1 MESH: 4.4				Detection bias: Unclear risk - no details about blinding of assessors
Prospective, randomised controlled trial.					
Aim of the study	Previous surgical procedures - n (%) AC: 9 (47.4) MESH: 10 (52.6)	Mesh: AC repair plus synthetic monofilament polypropylene mesh.	Statistical analysis Mann-Whitney test used to compare differences between treatment groups.		Attrition bias: Low risk of bias -Less than 15% of patients lost to follow-up
To compare the effects of polypropylene mesh versus site-specific repair for the treatment of anterior vaginal wall prolapse.					
Study dates	Preoperative stress urinary incontinence - n (%) calculated) AC: 7 (43.75) MESH: 2 (12.5)		Power calculation Sample size calculated on the basis of standard deviation for point Ba of 0.7 cm. Calculations based on ideal sample size of Student's t-test, considering a=5%, a 2-way		Reporting bias: Low risk of bias -All outcomes reported
June 2006 to May 2008.					
Source of funding	Inclusion criteria				Other bias: Low risk of bias (no other potential source of bias identified).
Not mentioned in the text.	1] Women with newly				

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				Other information
diagnosed or recurrent anterior vaginal wall prolapse stage II or IV.	Exclusion criteria  1] Pregnant women, mothers in the puerperal period and up to 6 months post partum. 3] Women with a history of use of implants in reconstructive or anti-incontinence pelvic procedures. 4] Women with blood coagulation disorders, kidney failure, and/or upper urinary tract obstruction, urethral diverticulum or a history of	analysis, 90% statistical power to detect a 1 cm difference between treatment group, and non-compliance rate of 30%.  Intention to treat (ITT) analysis Not mentioned in text.		

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	pelvic irradiation.					
Full citation	Sample size	Interventions	Details	Results		Limitations
Menefee, S. A., Dyer, K. Y., Lukacz, E. S., Simsiman, A. J., Luber, K. M., Nguyen, J. N., Colporrhaphy compared with mesh or graft-reinforced vaginal paravaginal repair for anterior vaginal wall prolapse: a randomized controlled trial, Obstetrics & Gynecology, 118, 1337-44, 2011	N = 99  Standard anterior colporrhaphy through midline plication (AC): N = 32; n=24 at follow-up	AC: Midline plication performed with interrupted delayed absorbable sutures, the epithelium was reapproximated with 2-0 polyglactin, and a vaginal packing placed.  Graft: As AC. Base of graft attached at level of the ischial spines, narrowing as graft approached bladder neck. Epithelium reapproximated with 2-0 polyglactin suture and vaginal packing placed.	Concomitant procedures were permitted and performed as required.  Antibiotic prophylaxis administered prior to incision and compression stockings provided before induction of anaesthesia. Vasoconstricting solution injected along the anterior vaginal wall in appropriate patients. Epithelium incised longitudinally and dissected off the underlying superficial fibromuscular layer.	Anatomic failure at 2-year follow-up (Ba>-2) - n (%) AC: 14 (58) (vs mesh, p=0.004; vs graft, p=0.0430) Graft: 12 (46) (vs MESH, p=0.015) MESH: 5 (18)  Anatomic failure (POP-Q Ba $\geq$ 0 at or beyond hymen) - n/N AC: 9/32 Graft: 8/3 MESH: 2/36  Anatomic failure (POP-Q point Ba >0 beyond the hymen) - n/N AC: 1/32 Graft: 2/31 MESH: 0/36  Composite failure rate (objective and subjective measure) - n/N AC: 3/32 (vs graft, p=0.623; vs MESH, p=0.284) Graft: 3/31 (vs MESH, p=0.284) MESH: 1/36 (4)		Attrition bias: Low risk of bias -Computer-generated randomisation, no differences between groups at baseline.
Ref Id	Paravaginal repair with polypropylene mesh (MESH): N = 36; n=28 at follow-up			Change in QoL scores - median (range)  POPDI AC: -33 (-87 to -8) Graft: -35 (-100 to 17) MESH: -38 (-100 to 8)  UDI AC: -25 (-86 to -36) Graft: -42 (-83 to 46) MESH: -25 (-75 to 13)  POPIQ AC: -14 (-85 to 0) Graft: -24 (-95 to 3) MESH: -33 (-100 to 0)  UIQ		Allocation concealment: Low risk of bias - Sealed opaque envelopes opened on day of surgery in operating room
Country/ies where the study was carried out	USA	Characteristics				Performance bias: Unclear risk of bias - Reported as double-blind, however, unclear if surgeons/care staff were blind. To prevent unblinding of patients, the operative report
Study type	Randomised double-blind clinical trial.	Age - mean $\pm$ SD (years) AC: 61 (11)	Randomisation			

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Aim of the study	Graft: 60 (10) MESH: 65 (7.0)	MESH: As per graft.	Computer-generated randomisation.	AC: -19 (-86 to 10) Graft: -31 (-91 to 10) MESH: -24 (-100 to 10)	listed the procedure as cystocele repair per protocol and nursing staff instructed not to discuss details with patients.
To compare the effects of traditional anterior colporrhaphy with vaginal paravaginal repairs using porcine dermis graft or permanent synthetic polypropylene mesh in the treatment of women with vaginal wall prolapse.	Parity - n (range) AC: 3 (1-8) Graft: 3 (1-8) MESH: 3 (1-7)	BMI - mean ± SD (kg/m <sup>2</sup> ) AC: 31 (10) Graft: 30 (5.0) MESH: 28 (4.0)	Statistical analysis X <sup>2</sup> test used to compare proportion of patients with anatomic success. Median QoL compared using Mann-Whitney U test. Student's t test used for continuous variables and X <sup>2</sup> or Fisher's exact tests for categorical variables.	Repeat surgery - n (% calculated) AC: 0 Graft: 2 (7.69) MESH: 0	Detection bias: Low risk - assessors blind to treatment allocation
Study dates	Prior procedures - n (%) Anterior repair AC: 1 (4) Graft: 2 (8) MESH: 1 (4)	Power calculation Based on 80% power, 25 patients per group were required to detect an absolute difference of 40% or more in anatomic success rates between	No blood transfusions were required. No intraoperative bladder or urethra injuries.	Adverse events No long term adverse events at 2 years follow-up Mesh erosion - n (%) AC: 0 Graft: 1 (4) MESH: 4 (14); p=0.413	Attrition bias: High risk of bias (More than 15% of patients lost to follow-up at 2 years).
January 2006 to September 2008.	Incontinence AC: 2 (8) Graft: 1 (4) MESH: 2 (7)			Change in PISQ-12 - median (range) AC: 0 (-32 to 16) Graft: 1 (-35 to 24) MESH: 0 (-28 to 36)	Reporting bias: Low risk of bias -All outcomes reported
Source of funding	Unrestricted educational grant from Boston Scientific.	Stress urinary incontinence - n (%) AC: 12 (50) Graft: 14 (54) MESH: 15 (54)		De novo dyspareunia - n (%) AC: 3 (12.5) Graft: 2 (7.69) MESH: 2 (7.14)	Other bias: Low risk of bias (no other potential source of bias identified).

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	<p>Overactive bladder - n (%) AC: 2 (8) Graft: 0 MESH: 1 (4)</p> <p><b>Inclusion criteria</b></p> <p>1] Women aged&gt;18 years of age. 2] At least stage II anterior vaginal wall prolapse, were symptomatic, and sought surgical correction.</p> <p><b>Exclusion criteria</b></p> <p>1] Pregnant women, or plans for future pregnancy. 2] Foreshortened vagina (total vaginal length</p>	<p>treatment groups. Assuming 25% dropout rate, a total of 99 patients were required, 33 in each group.</p> <p>Intention to treat (ITT) analysis ITT analysis and per protocol.</p>		Other information
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	<p>of 5 cm or less).</p> <p>3] History of vaginal cancer.</p> <p>4] Previous pelvic irradiation.</p> <p>5] Adverse reaction to porcine or synthetic materials.</p> <p>6] History of graft-reinforced or mesh-reinforced anterior repair.</p> <p>7] Plans to move outside study are within next 24 months.</p>				
Full citation	Sample size	Interventions	Details	Results	Limitations
Meschia, M., Pifarotti, P., Bernasconi, F., Magatti, F., Riva, D., Kocjancic, E., Porcine skin collagen implants to prevent anterior vaginal wall prolapse recurrence: a multicenter,	N = 206	AC: Anterior colporrhaphy performed, then pubocervical fascia dissected from vaginal epithelium and plication of pubocervical	Randomisation Computer-generated random list.	<p>Point Ba anatomy - n/N</p> <p>0</p> <p>AC: 62/106</p> <p>Implant: 66/100; p=0.22</p> <p>&gt;0 &lt;1</p> <p>AC: 21/106</p> <p>Implant: 25/100; p=0.48</p> <p>≥1</p> <p>AC: 20/106</p> <p>Implant: 7/100; p=0.019</p>	Allocation bias: Unclear risk of bias - Computer-generated random list). Participants had different mean values in

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randomized study, Journal of Urology, 177, 192-5, 2007  Ref Id 541549	AC with Pelvicol implant reinforcement (Implant): N = 100; n=98 at 1 year follow-up	fascia performed. Implant: As AC, then implant positioned over fascia and anchored to the endopelvic fascia and distal to the uterosacral-cardinal stumps or the cervical ring when the uterus was present.	standard deviations. Categorical data were analysed using X <sup>2</sup> test with Yates correction or the Fisher's exact test.  Power calculation For 80% power, 90 patients per treatment group required to detect a 15% decrease in recurrent cystoceles when implants were used. Assuming a dropout rate of 15%, 207 were required.  Intention to treat (ITT) analysis Not mentioned in the text.	AC: 20/106 Implant: 7/100 OR: 3.13 (95% CI 1.26 to 7.78; p=0.019)  Prolapse sensation - n/N AC: 13/106 Implant: 9/100; p=0.57  No intraoperative complications occurred.  Long term adverse events at 1 year follow-up VAS score for prolapse sensation - mean ± SD AC: 1.5 (1.6) Implant: 1.5 (1.7); p=1.0, vs preoperatively p<0.001  Stress incontinence - n/N AC: 14/106 Implant: 10/100 Overactive bladder - n/N AC: 18/106 Implant: 15/100  Mesh extrusion - n/N AC: 0/106 Implant: 1/100  Dyspareunia (unclear whether De novo) - n/N AC: 5/106 Implant: 7/100	dyspareunia at baseline  Allocation concealment: Low risk of bias - Allocation via telephone system which allocated treatment group.  Performance bias: Unclear risk of bias - no details about blinding of care staff or participants  Detection bias: Unclear risk - no details regarding blinding of assessors  Attrition bias: Low risk of bias -Less than 15% of patients lost to follow-up.  Reporting bias: Low risk of bias
Country/ies where the study was carried out  Italy  Study type  Prospective, multicentre, randomised controlled trial.  Aim of the study  To assess the efficacy of anterior vaginal prolapse repair with or without Pelvicol™ implant for preventing recurrent anterior vaginal wall prolapse in women.	Characteristic s  Age - mean ± SD (years) AC: 65 (9.0) Implant: 65 (8.0)  Years since menopause - mean ± SD AC: 14 (9.0) Implant: 14 (9.0)  Parity - median (range) AC: 2 (0-5) Implant: 2 (0-6)  BMI - mean ± SD (kg/m <sup>2</sup> ) AC: 25.1 (3.0) Implant: 25.8 (4.0)				

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Study dates	Stress urinary incontinence symptoms - n (%) AC: 18 (17) Implant: 22 (22)				-all outcomes reported
March 2003 to June 2004.					Other bias: Low risk of bias (no other potential source of bias identified).
Source of funding					Other information
No financial support from the mesh manufacturer.	Overactive bladder - n (%) AC: 35 (33) Implant: 44 (44)				
	Urge incontinence - n (%) AC: 13 (12) Implant: 21 (21)				
	Preoperative anterior prolapse stage (POP-Q) - % Stage 0 AC: 0 Implant: 0 Stage I AC: 0 Implant: 0 Stage II AC: 35 Implant: 21 Stage III AC: 58				

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	Implant: 69 Stage IV AC: 7 Implant: 14				
	<p>Inclusion criteria</p> <p>1] Women with <math>\geq</math>stage II anterior vaginal wall prolapse (point Ba <math>\geq</math>-1) planning to undergo primary pelvic reconstructive surgery.</p> <p>Exclusion criteria</p> <p>1] Women aged <math>&gt;80</math> years. 2] Previous pelvic surgery. 3] Diabetes and collagen disease.</p>				
Full citation	Sample size  N = 90	Interventions	Details	Results  POP-Q (point Ba) at 12 months follow-up - mean	Limitations

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Sivaslioglu,A.A., Unlubilgin,E., Dolen,I., A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocoele, International Urogynecology Journal, 19, 467-471, 2008  Ref Id 100757  Country/ies where the study was carried out Turkey  Study type Randomised controlled trial.  Aim of the study To compare the safety and efficacy of polypropylene mesh surgery with site-specific	Site-specific cystocoele repair (CR): N = 45  Polypropylene mesh surgery (MESH): N = 45  Characteristic s Age - mean ± SD (years) CR: 50.1 (9.9) MESH: 57.7 (9.4)  BMI - mean ± SD (kg/m <sup>2</sup> ) CR: 3.3 (5.6) MESH: 29.4 (4.1)  Parity - mean ± SD CR: 3.7 (1.9) MESH: 3.1 (1.4)  POP-Q (point Ba) - mean CR: 2.8 MESH: 2.7	CR: Women underwent anterior colporrhaphy, paravaginal defect repair, or anterior colporrhaphy + paravaginal defect repair. Vertical incision extending below the urethral meatus to above the anterior lip of the cervix. Pubocervical fascia separated from the vaginal mucosa. Excess vaginal mucosa was not trimmed.  MESH: Operated by vaginal route using low weight mesh. Mesh positioned in in a tension-	Menopausal women were given vaginal oestrogen treatment 2 weeks prior to surgery. All patients were given antibiotic treatment for 3 days after surgery and patients were instructed to rest for 2 week postoperatively. They were allowed to return to work after 4 weeks, and return to sexual activity after 12 weeks.  Randomisation Computer-generated.  Statistical analysis Wilcoxon test used to test differences within treatment groups and, X <sup>2</sup> used to test differences between	CR: 0 (vs preoperative value, p=0.008) MESH: -2.4 (vs preoperative value, p=0.001); Between group comparison, p=0.003  Efficacy of anatomical reconstruction (stage I prolapse or less) - n/N (%) CR: 30/45 (72) MESH: 39/45 (91); p=0.0044  P-QoL score at 12 months follow-up - mean ± SD CR: 7.5 (6.2) MESH: 6.2 (5.5); p<0.05  Symptoms at 12 months follow-up - n Pelvic pain CR: 4 MESH: 1; p>0.05 Abnormal emptying CR: 2 MESH: 0; p>0.05 Frequency CR: 3 MESH: 3; p>0.05 Urgency CR: 1 MESH: 1; p>0.05 De novo stress urinary incontinence - n (%) CR: 3 (7) MESH: 0  Mesh erosion - n/N (%) CR: 0 MESH: 3/45 (6.9)  De novo dyspareunia - n (%) CR: 0 MESH: 2 (4.6)  Overall recurrence rate was 9%.	Allocation bias: Unclear risk of bias, no details about method of randomisation.  Allocation concealment: Unclear risk of bias (not mentioned in text).  Performance bias: Unclear risk of bias - no details of blinding in methods  Detection bias: Unclear risk - no details of blinding in text  Attrition bias: Low risk of bias -Less than 15% of patients lost to follow-up  Reporting bias: Low risk of bias (All

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surgery in the treatment of vaginal wall prolapse.	P-QoL score - mean $\pm$ SD CR: 32.4 (28.5) MESH: 29.5 (26.1)	free manner under the bladder and the lower part of the mesh was fixed to the cervix.	treatment groups.  Power calculation For 80% power, 40 patients were required for each treatment group. Assuming a 10% dropout rate, 90 patients were required (45 in each group).  Intention-to-treat (ITT) analysis Not mentioned in the text.		outcomes reported).
Study dates	January 2006 to January 2007.				Other bias: Unclear risk of bias - limited details in methods
Source of funding	Not funded by an organisation.				Other information

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	Exclusion criteria				
	1] Women with stress urinary incontinence. 2] Concomitant rectocoele or enterocoele or recurrent cystocoele.				
Full citation	Sample size	Interventions	Details	Results	Limitations
Tamanini, J. T. N., Tamanini, M. M. M., Castro, R. C. O. S., Feldner Jr, P. C., Castro, R. A., Sartori, M. G. F., Girao, M. J. B. C., Treatment of anterior vaginal wall prolapse with and without polypropylene mesh: A prospective, randomized and controlled trial- Part I, International Braz J Urol, 39, 519-530, 2013  Ref Id	N = 100  Anterior colporrhaphy (AC): N = 55; n=54 at 1 year follow-up.  Propylene mesh kit (MESH): N = 45; n=43 at 1 year follow-up.  Characteristic s  Age - mean ± SD (years) AC: 63.4 (9.5) MESH: 66.8 (9.2)	AC: Women placed in the lithotomy position and midline incision made on the anterior vaginal wall, from the midurethra to the uterine cervix. Anterior vaginal wall separated from the vesicovaginal fascia and bladder. In the event of central defect, corrected using plication	All procedures performed under spinal anaesthesia and all patients received intravenous cephazolin for prophylaxis.  Catheter inserted into the bladder at the beginning of surgery and removed on the first day post surgery.	Cured (POP-Q stage 0-1) at 12 months follow-up - n/N (%) AC: 30/55 (55.5) MESH: 36/45 (83.7); p=0.006 Absolute risk reduction: 28%, number needed to treat: 4  POP-Q (Ba point - cm) at 12 months follow-up - mean ± SD AC: -1.57 (1.04) MESH: -2.46 (0.70); p<0.0001  Quality of life (score 0-10) at 12 months follow-up - mean ± SD AC: 1.13 (2.9) MESH: 0.14 (0.67); p=0.03  Vaginal symptom score (VSS) (0-53) at 12 months follow-up - mean ± SD AC: 4.02 (4.4) MESH: 3.24 (4.7); p=0.40  Long term adverse events at 12 months follow-up - n (%) Slight inguinal pain AC: 0 MESH: 0 Urinary retention with relaxation of the suburethral PM - n (%)	Allocation bias: Unclear risk of bias (Simple raffle system).  Allocation concealment: Unclear risk of bias (not mentioned in text).  Performance bias: High risk of bias, patients masked to procedure but not care staff.

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632435						Detection bias: Unclear risk of bias - no details
Country/ies where the study was carried out	Parity - n (%) Nulliparous AC: 3 (5.5) MESH: 0 Multiparous AC: 52 (94.5) MESH: 45 (100)	of the fascia along the midline using separated sutures of Vycril 2-0. Lateral defects treated using localised sutures with Vycril 2-0.	Randomisation using simple raffle system.  Statistical analysis Paired t-test used to calculate differences between pre- and post-operative means and standard deviations.	AC: 0 MESH: 0 Dyspareunia - n (%) AC: 0 MESH: 1 (2.3) Mesh exposition - n (%) AC: 0 MESH: 4 (9.3)	24 months follow up data from Tamanini 2015  Objective cure ( $B_a \leq -1$ ) at 24 months, n/N (%) AC: 43/55 (78.2) MESH: 40/45 (88.9)	Attrition bias: Low risk of bias (Less than 15% of patients lost to follow-up).
Study type	Prospective, randomised, single-blinded, controlled trial.	BMI - mean $\pm$ SD (kg/m <sup>2</sup> ) AC: 27.8 (4.9) MESH: 27.5 (5.4)	Women with urodynamic diagnosis of stress urinary incontinence were also treated with retropubic synthetic sling.	Power calculation For power of 80%, 42 women required for each treatment group. Assuming 10% loss to follow-up, a total of 92 women required.	Objective cure ( $B_a \leq -2$ ) at 24 months, n/N (%) AC: 32/55 (58.2) MESH: 32/45 (71.1)	Reporting bias: Low risk of bias (All outcomes reported).
Aim of the study	To assess the effectiveness of polypropylene mesh compared with traditional anterior vaginal wall colporrhaphy in the treatment of women with anterior vaginal wall prolapse.	Post-menopausal - n (%) AC: 54 (99.8) MESH: 43 (95.6)  Previous hysterectomy - n (%) AC: 6 (10.9) 3 (6.7)	MESH: Patient placed in the lithotomy position, and midline incision made in anterior vaginal wall, from midurethra to uterine cervix.  Dissection continued to	Subjective cure (VSS score of 0 for vaginal symptoms) AC: 17/55 (30.9) MESH: 20/45 (44.4)	Quality of life at 24 months follow up, mean (SD) range 0-10 AC: 1.1 (2.7) MESH: 0.4 (1.3)	Other bias: Low risk of bias (no other potential source of bias identified).
Study dates	February 2008 to December 2010.	POP Stage (POP-Q) - n (%) Stage II AC: 19 (34.5) MESH: 10 (22.2) Stage III AC: 31 (56.4)		Mesh exposure by 24 months, n/N (%) AC: 0/55 MESH: 7/45 (15.6)		Other information
Source of funding				Intention to treat (ITT) analysis Not mentioned in the text.		

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No funds were received from mesh manufacturers.	MESH: 28 (62.2) Stage IV AC: 5 (9.1) MESH: 7 (15.6)  POP-Q (Ba point - cm) - mean $\pm$ SD AC: 2.55 (2.50) MESH: 3.38 (2.50)  Quality of life (score 0-10) - mean $\pm$ SD AC: 8.45 (2.56) MESH: 8.51 (2.32)  Vaginal symptom score (VSS) (0-53) - mean $\pm$ SD AC: 23.6 (10.4) MESH: 25.05 (9.5)  Inclusion criteria	the ischial-pubic branch and inferior edge of the pubic symphysis. MESH connected and body of mesh fixed in the region of the cardinal ligaments and cervical ring.			
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<p>1] Women aged ≥45 years. 2] Anterior vaginal wall prolapse ≥Stage II (POP-Q). 3] Without previous surgical correction or with previous surgical treatment of anterior vaginal wall prolapse without the use of mesh.</p> <p>Exclusion criteria</p> <p>1] Women who were previously treated (due to anterior vaginal wall prolapse or stress urinary incontinence) using mesh. 2] Receiving oncological treatment.</p>				
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	3] Altered Papanicolaou smear exam or with uterine bleeding. 4] Genital or acute urinary infection. 5] Patients who would not to ambulatory follow-up or refused written informed consent.					
Full citation	Sample size  Tamanini, J. T. N., Castro, R. C. O. S., Tamanini, J. M., Feldner Jr, P. C., Castro, R. A., Sartori, M. G. F., Girao, M. J. B. C., Treatment of anterior vaginal wall prolapse with and without polypropylene mesh: A prospective, randomized and controlled trial - Part II, International Braz	Interventions  See Tamanini (2013) Part I  Characteristics  See Tamanini (2013) Part I  International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF) - mean ± SD  See Tamanini (2013) Part I	Details  See Tamanini (2013) Part I	Results  International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF) - mean ± SD AC: 4.6 (6.3); (pre vs postoperative, p<0.0001) MESH: 3.5 (5.1); (pre vs postoperative, p<0.0003); (AC vs Control, p=0.36)  Overactive Bladder Questionnaire - V8 (OAB-V8) at 12 months follow-up - mean ± SD AC: 6.2 (8.8); (pre vs postoperative, p<0.0001) MESH: 3.3 (6.2); (pre vs postoperative, p<0.0001); (AC vs MESH, p=0.07)  Long term adverse events at 12 months follow-up - n (%) De novo frequency AC: 3 (5.5) MESH: 2 (4.6); p=0.7933 De novo voiding difficulty AC: 0 MESH: 0 De novo urge-urinary incontinence	Limitations  See Tamanini (2013) Part I  Other information	

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J Urol, 39, 531-541, 2013	AC: 11.2 (7.6) MESH: 9.2 (8.4)			AC: 4 (7.4) MESH: 1 (2.3); p=0.5078 De novo stress urinary incontinence AC: 3 (5.5) MESH: 2 (4.6); p=0.7723	
Ref Id  632434	Overactive Bladder Questionnaire - V8 (OAB-V8) - mean ± SD AC: 20.38 (12.56) MESH: 14.95 (12.37)				
Country/ies where the study was carried out  Brazil					
Study type  See Tamanini (2013) Part I	Inclusion criteria  See Tamanini (2013) Part I				
Aim of the study  See Tamanini (2013) Part I	Exclusion criteria  See Tamanini (2013) Part I				
Study dates  See Tamanini (2013) Part I					
Source of funding  See Tamanini (2013) Part I					
Full citation  Turgal, M., Sivaslioglu, A.,	Sample size  N = 40	Interventions  AC: Patients positioned in	Details  Randomisation	Results  Anatomical cure (POP-Q stage 1; Ba <-1 cm) at 1 year follow-up - n (% calculated)	Limitations  Allocation bias: Low risk

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### Surgical management of pelvic organ prolapse

Yildiz, A., Dolen, I., Anatomical and functional assessment of anterior colporrhaphy versus polypropylene mesh surgery in cystocele treatment, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 170, 555-8, 2013	Anterior colporrhaphy (AC): N = 20 Polypropylene mesh (MESH): N = 20	lithotomy position and Foley catheter inserted into bladder. Vertical incision extending below the urethral meatus to above the anterior lip of the cervix. Pubocervical fascia separated from the vaginal mucosa, then anterior vaginal wall incised longitudinally. Vaginal epithelium then separated from pubocervical fascia. Dissection continued laterally to the vaginal sulci and proximally. Fascial	Allocation performed using computer programme. Statistical analysis Pearson X <sup>2</sup> test used to compare anatomic cure rates between treatment groups. Power calculation Not mentioned in the text.	AC: 15 (75) MESH: 19 (95); p=0.04  Symptoms of vaginal bulge at 1 year follow-up - n (%) AC: 5 (25) MESH: 1 (5); p=0.04  Long term adverse events at 1 year follow-up - n (%) Abnormal emptying AC: 1 (5) MESH: 1 (5); p=1.0 Frequency AC: 1 (5) MESH: 0; p=1.0 Urgency AC: 1 (5) MESH: 0; p=1.0  Pelvic pain AC: 1 (5) MESH: 0; p=1.0  Faecal incontinence AC: 0 MESH: 0  De novo urinary incontinence AC: 2 (10) MESH: 0; p=1.0  Mesh erosion AC: 0 MESH: 3 (15)	of bias - Allocated using computer programme, no differences between groups at baseline  Allocation concealment: Unclear risk of bias (not mentioned in text).  Performance bias: Unclear risk - no mention of blinding in text  Detection bias: Unclear risk - no mention of blinding of assessors  Attrition bias: Low risk of bias -all participants followed up at 12 months  Reporting bias: Low risk of bias (All)
Ref Id 541736	Country/ies where the study was carried out Turkey	Study type Prospective, randomised controlled trial.	Aim of the study To compare the outcome for		

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traditional anterior colporrhaphy and polypropylene mesh surgery for the treatment of cystocoele.	Inclusion criteria  1] Women with Stage II or III cystocoele according to POP-Q.	plication performed. Excess vaginal mucosa was not trimmed and vaginal incision closed.  MESH: Full-thickness vertical incision made, extending below the urethral meatus to above the anterior lip of the cervix.  The four arms of the mesh were brought out to the perineal skin. Mesh positioned in a tension-free manner under the bladder. The distal part of the mesh was laid under the proximal urethra, and the lower part of the mesh			outcomes reported).  Other bias: Low risk of bias (no other potential source of bias identified).
Study dates					Other information
June 2006 to February 2007.					
Source of funding					
Not reported.					

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		was fixed to the cervix.			
Full citation	Sample size	Interventions	Details	Results	Limitations
Weber, A. M., Walters, M. D., Piedmonte, M. R., Ballard, L. A., Anterior colporrhaphy: a randomized trial of three surgical techniques, American Journal of Obstetrics & Gynecology, 185, 1299-304; discussion 1304-6, 2001	N = 109  Standard anterior colporrhaphy (AC): N = 39; n=33 at follow-up.  Ultralateral anterior colporrhaphy (UAC): N = 35; n=24 at follow-up.	AC: Midline incision made in anterior vaginal wall, and vaginal epithelium separated from the underlying muscularis. After suburethral plication, the muscularis was plicated without tension in the midline, and stitched.  UAC: Midline anterior vaginal incision made and dissection performed laterally to edges of pubic rami on each side. After suburethral plication,	All women received preoperative antibiotic prophylaxis. Vagina infiltrated using dilute solution of epinephrine. Other procedures were performed before or after anterior vaginal prolapse repair, as appropriate.  UAC: Midline anterior vaginal incision made and dissection performed laterally to edges of pubic rami on each side. After suburethral plication,	Satisfactory (Ba Stage I; -2 cm) or optimal (Ba Stage 0; -3 cm) anatomic outcome, n/N  AC: 10/37 UAC: 11/39 MESH: 11/38  Adverse events - n (% calculated) Haemorrhage requiring transfusion AC: 1 (3.03) UAC: 0 MESH: 0  Long term adverse events at median 23.3 months follow-up - n (% calculated) Mesh erosion AC: 0 UAC: 0 MESH: 1 (3.85)	Allocation bias: Low risk of bias -Computer-generated random numbers table, no differences at baseline between groups  Allocation concealment: Low risk of bias - Sealed opaque envelopes
Ref Id  541762	Standard AC plus mesh (MESH): N = 35; n=26 at follow-up.	Characteristic s	Randomisation Computer-generated random numbers table.	Reanalysis of data with different outcome definitions: Chmielewski et al. 2011  Cure of prolapse (no prolapse beyond the hymen), n/N (%) AC: 25/39 (64.1) UAC: 20/35 (57.1) MESH: 22/35 (62.9)	Performance bias: High risk of bias, care staff and participants aware of treatment allocation - non-blinded study
Country/ies where the study was carried out  USA	Age - mean ± SD (years) AC: 65.6 (11.2) UAC: 62.4 (13.3)	Statistical analysis  Due to different follow-up time in the primary outcome measure, Kaplan-Meier was used to	Subjective cure of prolapse, n/N (%)  AC: 32/39 (82.1) UAC: 27/35 (77.1) MESH: 21/35 (60)	Detection bias - Unclear risk, Assessors	

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Aim of the study	MESH: 66.0 (11.2)	paravaginal connective tissue was plicated under tension in the midline, and stitched.	estimate the proportion of successes at follow-up, and the log-rank test for comparing success rates. McNemar's test used to calculate within-group change in symptoms. Sign tests used to assess improvements within treatment groups, and Kruskal-Wallis tests used to compare between group improvements.	were unaware of treatment. Self-report measures used by non-blinded participants
To compare the effects of anterior colporrhaphy with and without mesh and versus ultralateral anterior colporrhaphy on outcomes in women with anterior vaginal prolapse.	Postmenopausal - n (%) With oestrogen AC: 15 (40) UAC: 13 (37) MESH: 19 (56) Without oestrogen AC: 19 (50) UAC: 15 (43) MESH: 12 (35)		MESH: Standard AC performed. After midline plication of the vaginal muscularis, mesh anchored at the lateral limits of the dissection, stitched, and the vaginal epithelium closed over the mesh.	Attrition bias: High risk of bias (>15% of patients lost to follow-up).
Study dates	June 1996 to May 1999.			Reporting bias: Unclear risk of bias, data presented in graphical format without numbers
Source of funding	Previous hysterectomy - n (%) AC: 19 (50) UAC: 16 (46) MESH: 14 (41)			Other bias: Unclear risk of bias (Number of required patients for each treatment group was not achieved).
American College of Obstetricians and Gynaecologists/Ethicon Research Award for Innovations in Gynaecologic Surgery, and by the Department of Gynaecology and Obstetrics at the Cleveland Clinic Foundation.	Previous prolapse/incontinence surgery - n (%) AC: 4 (10) UAC: 2 (6) MESH: 3 (9)		Power calculation For 80% power, 31 patients were required per treatment group. Assuming 15% loss to follow-up, a total of 114 patients were required.	Other information
	Stage of prolapse at		Intention to treat (ITT) analysis	The authors acknowledged

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	<p>point Ba - n (%)          Stage 0          AC: 0          UAC: 0          MESH: 0          Stage I          AC: 3 (9)          UAC: 2 (7)          MESH: 2 (6)          Stage II          AC: 12 (34)          UAC: 10 (34)          MESH: 13 (42)          Stage III          AC: 19 (54)          UAC: 16 (55)          MESH: 16 (52)          Stage IV          AC: 1 (3)          UAC: 1 (3)          MESH: 0</p> <p>Inclusion criteria          1] Women with anterior vaginal prolapse.</p> <p>Exclusion criteria</p>	All outcome data based on operations performed (ITT).		that although procedures were agreed to be standardised across the 5 surgeons, variations in technique by surgeon may have occurred.
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	1] Women with planned concomitant incontinence procedure, other than suburethral plication (i.e. Burch colposuspension , sling, or needle suspension).				
Full citation	Sample size	Interventions	Details	Results	Limitations
Paraiso, M. F. R., Barber, M. D., Muir, T. W., Walters, M. D., Rectocele repair: A randomized trial of three surgical techniques including graft augmentation, American Journal of Obstetrics and Gynecology, 195, 1762-1771, 2006  Ref Id 632281  Country/ies where the study was carried out	N = 106	All participants were administered preoperative antibiotic prophylaxis (1g of cefazolin, or 100mg vibramycin if penicillin-allergic). The vaginal epithelium was opened transversely at the posterior fourchette. The posterior vaginal incision was made in the midline and	The investigation was approved by the Institutional Review Board at the Cleveland Clinic, and all patient provided written informed consent for participation.	Health related quality of life Change in scores compared to baseline measure was assessed. Pelvic Floor Distress Inventory-20 At 12 months: Group 1 (posterior colporrhaphy): $39 \pm 30$ Group 2 (site specific repair): $46 \pm 53$ Group 3 (site specific repair with mesh): $34 \pm 37$ At 24 months: Group 1: $44 \pm 32$ Group 2: $53 \pm 46$ Group 3: $32 \pm 33$  The Pelvic Floor Distress Inventory-20 (PFDI-20) has a range of 0-300 with higher scores indicating greater distress. It has 3 subscales: the Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), the Colorectal-anal Distress Inventory-8 (CRADI-8) and the Urinary Distress Inventory-6 (UDI-6), each of which has a range of 0-100. Pelvic Floor Impact Questionnaire-7 At 12 months: Group 1: $10 \pm 18$ Group 2: $22 \pm 38$ Group 3: $10 \pm 23$ At 24 months: Group 1: $16 \pm 32$	Random sequence generation: low risk of bias (computer generated randomisation schedule) Allocation concealment: low risk of bias (consecutively numbered, opaque, sealed envelopes) Blinding: unclear risk of bias (initially double blinded, but participants were able to find out their group)

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USA		ed to defect - specific rectocoele repair with graft	extended 1cm above the superior aspect of the posterior wall defect. Dissection of the vaginal epithelium away from the underlying fibromuscularis extended superiorly to identify the edge of the fibromuscularis, laterally to the medial aspect of the levator ani muscles, and inferiorly to the perineal body.	extended beyond the hymen.	Group 2: 16 ± 31 Group 3: 5 ± 13  The Pelvic Floor Impact Questionnaire-7 (PFIQ-7) has a range of 0-300 with higher scores indicating greater adverse impact on quality of life. It has 3 subscales: the Pelvic Organ Prolapse Impact Questionnaire-7 (POPIQ-7), the Colorectal-anal Impact Questionnaire-7 (CRAIQ-7) and Urinary Impact Questionnaire-7 (UIQ-7) each of which has a range of 0-100.  Absolute scores at 1 and 2 years were compared to baseline measures. Significant changes in scores were seen in each group for every outcome measure over time. However, no significant differences were identified between the different treatment groups at any time point, for all subscales as well as total scores.	allocation at the postoperative visit if they wished. However, outcome assessors for POP-Q scores remained blinded) Incomplete outcome data: unclear risk of bias (data for the primary outcome measure is available for 81 participants [76.4%]). 7 participants [6.6%] were reported to have withdrawn from the trial pre-operatively, but no data is presented regarding loss-to-follow-up for the remaining 18 participants. Selective reporting: low risk of bias (all outcomes reported)
Study type		Characteristics	Age, years (SD) Group 1 (posterior colporrhaphy): 61 (12) Group 2 (site specific rectocoele repair): 62 (9) Group 3 (site specific rectocoele repair with graft): 60 (11)	Each participant completed two condition-specific quality of life questionnaires (the Pelvic Floor Distress Inventory short form-20 [PFDI-20], the Pelvic Floor Impact Questionnaire short form 7 [PFIQ-7]) and a condition-specific sexual function questionnaire, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form (PISQ-12)	Repeat surgery during 2 year follow up, n/N (%) Re-operation for prolapse (any compartment) was reported. Group 1: 1/33 (3) Group 2: 2/37 (5) Group 3: 3/29 (10)	
Aim of the study			Parity Group 1: median 3 (range 1-6) Group 2: median 3 (range 1-8)	Follow up Participants were evaluated at 6 weeks, 6 months, 1 and 2 years following their surgery. Randomisation A computer-generated randomisation	Adverse events (early) Blood transfusion, n/N (%) Group 1: 1/37 (3) Group 2: 0/37 (0) Group 3: 1/31 (3)  Internal organ damage, n/N (%) Group 1: 0/37 (0) Group 2: 2/37 (5) [both bladder injuries] Group 3: 1/31 (3) [ureteric injury]	
To compare the anatomic and functional outcomes of three different techniques used in the repair of posterior vaginal wall prolapse: posterior colporrhaphy, site-specific rectocoele repair and site-specific repair augmented with a porcine graft.					Adverse events (late) Mesh erosion/extrusion No events in any group	
Study dates	June 2002 until December 2004.				Constipation, n/N (%) - positive answer to the question "Do you feel you have to strain too hard to have a bowel movement?" Group 1: 11/31 (35)	
Source of funding	Funded by an unrestricted research grant					

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<p>from Organogenesis, Inc (Canton, MA). The article states that Organogenesis had no involvement in the design, implementation, analysis or writing of the manuscript.</p>	<p>Group 3: median 3 (range 1-6) Menopausal status Group 1: 5 (14%) premenopausal; 13 (35%) postmenopausal with HRT; 19 (51%) postmenopausal without HRT Group 2: 2 (5%) premenopausal; 15 (40%) postmenopausal with HRT; 20 (54%) postmenopausal without HRT Group 3: 5 (16%) premenopausal; 12 (39%) postmenopausal with HRT; 14 (45%) postmenopausal without HRT Race</p>	<p>Somerville, NJ) in interrupted mattress stitches to plicate the rectovaginal muscularis across the midline. Unlike traditional posterior colporrhaphy, the levator muscles were not plicated in the midline.</p> <ul style="list-style-type: none"> <li>• The site-specific posterior repair was performed using the techniques described by Cundiff et al. Interrupted stitches of No. 2-0 braided polyester suture (Ethibond, Ethicon Inc) were placed</li> </ul>	<p>schedule was used to randomly assign participants to one of three groups. Groups assignments were concealed in consecutively numbered, sealed, opaque envelopes. Participants were blinded to treatment allocation in the immediate postoperative period. If they requested, they were informed of their treatment allocations at their 6-week postoperative visit. All postoperative assessments and examinations were performed by a nurse who was blinded to treatment assignment. Statistical analysis</p>	<p>Group 2: 14/33 (42) Group 3: 12/29 (41)</p> <p>Obstructed defecation, n/N (%)            - positive response to the question "Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?" or "Do you feel you have to strain too hard to have a bowel movement?" or "Do you feel you have not completely emptied your bowels at the end of a bowel movement?"            Group 1: 9/28 (32)            Group 2: 10/29 (35)            Group 3: 5/24 (21)</p> <p>Prolapse and Incontinence Sexual Questionnaire PISQ-12 score, mean (SD)            Group 1: 36 (5)            Group 2: 36 (7)            Group 3: 37 (5)</p> <p>Recurrence of prolapse in same compartment, n/N (%)            - defined as posterior vaginal wall prolapse to or beyond the hymen (<math>Bp \geq 0</math>) one year after surgery            Group 1: 2/28 (7.1)            Group 2: 2/27 (7.4)            Group 3: 5/25 (20)</p> <p>Objective cure of prolapse, n/N (%)            Definition: POP-Q point <math>Bp</math> less than or equal to -2 at the 12 month visit            Group 1: 24/28 (86)            Group 2: 21/27 (78)            Group 3: 14/26 (54)</p>	<p>Other risk of bias: low risk of bias (no other potential source of bias identified) Other information</p> <p>The authors acknowledge the following limitations:</p> <ul style="list-style-type: none"> <li>• small number of subjects in each group</li> <li>• medium term duration of follow up</li> <li>• use of a graft that is not currently commercially available</li> <li>• majority of participants underwent concurrent procedures in addition to posterior repair</li> </ul>
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Group 1: 35 (95%) white; 2 (5%) black Group 2: 34 (92%) white; 1 (3%) black; 2 (5%) other Group 3: 30 (97%) white; 1 (3%) black Current smoker Group 1: 3 (8%) Group 2: 3 (8%) Group 3: 1 (3%) Previous hysterectomy Group 1: 22 (59%) Group 2: 20 (54%) Group 3: 15 (48%) Pelvic Organ Prolapse Stage Stage II Group 1: 15 (41%) Group 2: 12 (32%) Group 3: 16 (53%) Stage III	to reapproxima te the broken edges of the fibromuscula ris and correct all defects.  • The site- specific posterior repair with graft implant was identical to the above procedure, but was augmented with a 4x8cm Fortagen graft (Organogen esis, Inc.). The graft was perforated with a scalpel 1cm medial from its borders in 3 to 4 rows of 3- mm incision points as recommend	Pearson's X <sup>2</sup> test was used to assess the primary endpoint (anatomic cure of the posterior vaginal wall, 12 months after surgery).  Secondary outcomes were analysed with Pearson's X <sup>2</sup> test or Fisher exact test for categorical data, and analysis of variance (ANOVA) or Kruskall-Wallis test for continuous data.  Changes in scales of QOL measures were analysed using repeated measures ANOVA.  Power calculation Alpha of 0.5 was assumed, therefore a sample size of 32 subjects in each group gave 80% power to	

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Group 1: 20 (54%) Group 2: 24 (64%) Group 3: 12 (38%) Stage IV Group 1: 2 (5%) Group 2: 1 (4%) Group 3: 3 (9%) POPQ measurement, cm, median (range) Point Bp Group 1: 0 (-1 to +8) Group 2: 0 (-1 to +8) Group 3: 0 (-1 to +10) Point C Group 1: -2.5 (-8 to +8) Group 2: -2 (-8 to +8) Group 3: -4 (-8 to +10) Genital hiatus Group 1: 4 (2 to 6) Group 2: 4 (2 to 7) Group 3: 2 (2 to 6)	ed by the manufacturer. The graft was secured superiorly to the posterior vaginal fibromuscularis and epithelium with No. 2-0 delayed absorbable polydioxanone suture (PDS, Ethicon, Inc). Laterally, the mesh was attached to the levator ani fascia with interrupted stitches of No. 2-0 braided polyester suture (Ethibond, Ethicon, Inc). In cases in which a concomitant	detect a variance of proportions of 14%, and an average failure rate of 17%. The authors aimed to enroll 106 subjects, to account for 10% loss to follow up. Intention to treat analysis The methods state that the study was conducted under the principle of intent-to-treat.		

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	Perineal body	uterosacral vaginal vault suspension or iliococcygeus fascia suspension was performed, the graft was secured superiorly with the respective suspension sutures.		
	Group 1: 3.5 (3 to 7)			
	Group 2: 3 (2 to 5)			
	Group 3: 3 (2 to 6)			
	Total vaginal length			
	Group 1: 8 (5 to 12)			
	Group 2: 8 (6 to 10)			
	Group 3: 8 (6 to 11)			
	Data presented as number (%) unless otherwise stated	Concomitant perineorrhaphy was performed if a patient reported splinting her perineum to defecate and/or a perineal		
	Concomitant prolapse procedures were permitted within the scope of the trial. The table			

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below shows the number (%) of women in each group who underwent additional procedures.	Vaginal vault suspension* Group 1: 22 (59) Group 2: 26 (70) Group 3: 19 (61) Anterior colporrhaphy Group 1: 20 (54) Group 2: 26 (70) Group 3: 19 (61) TVT or TOT Group 1: 15 (41) Group 2: 16 (46) Group 3: 12 (38) Hysterectomy Group 1: 12 (32) Group 2: 14 (38)	defect was noted at the time of surgery. No. 0 polyglycolic acid sutures (Vicryl, Ethicon, Inc) were used to reapproximate the deep and superficial transverse perineus muscles and bulbocavernosus muscles. The vaginal epithelium was trimmed and closed with No. 2-0 polyglycolic acid sutures in a running interlocking stitch continuing with a subcuticular stitch to close the perineum.	

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	<p>Group 3: 13 (42)</p> <p>Sacral colpopexy</p> <p>Group 1: 3 (8)</p> <p>Group 2: 3 (8)</p> <p>Group 3: 1 (3)</p> <p>Burch colposuspension</p> <p>Group 1: 2 (5)</p> <p>Group 2: 1 (3)</p> <p>Group 3: 3 (10)</p> <p>Oophorectomy</p> <p>Group 1: 2 (5)</p> <p>Group 2: 1 (3)</p> <p>Group 3: 1 (3)</p> <p>Paravaginal repair</p> <p>Group 1: 0</p> <p>Group 2: 1 (3)</p> <p>Group 3: 1 (3)</p> <p>Trachelectomy</p> <p>Group 1: 0</p> <p>Group 2: 1 (3)</p> <p>Group 3: 1 (3)</p> <p>Inguinal hernia repair</p> <p>Group 1: 0</p> <p>Group 2: 1 (3)</p> <p>Group 3: 1 (3)</p>				

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<p>Sigmoid resection/rect opexy Group 1: 1 (3) Group 2: 0 Group 3: 0</p> <p>* includes uterosacral vaginal vault suspensions, iliococcygeus suspensions and sacrospinous ligament fixation.</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"><li>• Age <math>\geq 21</math> years</li><li>• Stage II or greater posterior vaginal wall prolapse</li><li>• No desire for future vaginal delivery</li></ul>				
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	<p><b>Exclusion criteria</b></p> <ul style="list-style-type: none"> <li>• Undergoing additional colorectal procedures</li> <li>• Allergy to pork</li> <li>• Unwilling to accept porcine product implantation</li> </ul> <p>Participants who were undergoing concomitant procedures for prolapse and/or urinary incontinence were included.</p>				
Full citation	Sample size  Sung, V. W., Rardin, C. R., Raker, C. A., Lasala, C. A., Myers, D. L., Porcine  • n = 80 native tissue	Interventions  All participants received perioperative antibiotic prophylaxis. A posterior	Details  At baseline, women underwent a complete history and physical examination,	Results  Adverse events (early) Blood transfusion, n/N (%) Control (no graft): 0/80 (0) Graft group: 0/80 (0)  Internal organ damage, n/N (%)	Limitations  Randomisation: low risk of bias (computer generated randomisation schedule)

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subintestinal submucosal graft augmentation for rectocele repair: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 119, 125-33, 2012	<ul style="list-style-type: none"> <li>• rectocoele repair</li> <li>graft augmented rectocoele repair (using porcine subintestinal submucosal graft)</li> </ul>	vaginal incision was made in the midline and extended to the superior aspect of the rectocoele. The vaginal epithelium was dissected away from underlying connective tissue, lateral to the levator ani muscles. Women were randomised to one of two groups:	including the Pelvic Organ Prolapse Quantification (POP-Q) examination. Preoperative multichannel urodynamics were performed as clinically indicated. Participants were asked to return for routine visits at 2 weeks, 6 weeks, 6 months and 12 months. All women were placed on stool softeners during the first 4 weeks, and laxatives if needed during the first week. Strenuous activity was discouraged for 6 weeks.	Control (no graft): 1/80 (1.3) [bladder injury] Graft group: 1/80 (1.3) [rectal injury]	Allocation concealment: low risk of bias (consecutively numbered sealed envelopes) Blinding: low risk of bias (participants and investigators blinded to group allocation for follow up period of 12 months) Incomplete outcome data: unclear risk of bias (Data for the primary outcome measure is available for 137 of 180 participants [85.6%], with overall loss to follow up for 22 participants [13.8%]) Selective reporting: low risk of bias (all outcomes reported)
Ref Id 541709			Adverse events (late) Pain, mean (SD) - as reported at 6 weeks post-operative on 10 point Visual Analog Scale Control (no graft): 0.4 (1.2) Graft group: 0.4 (0.9)		
Country/ies where the study was carried out USA			Mesh erosion/extrusion, n/N (%) Control (no graft): 0/80 (0) Graft group: 0/80 (0)		
Study type Randomised controlled trial.			Constipation, n/N (%) - positive response to the question "Do you feel you have to strain too hard to have a bowel movement?" Control (no graft): 28/64 (43.8) Graft group: 27/68 (39.7)		
Aim of the study  To assess the effect of subintestinal submucosal graft augmentation of rectocoele repair compared with native tissue repair.	Characteristic s  Age in years, mean (SD) Control (no graft): 54.8 (11.2) Graft group: 54.5 (11.0)  Race, n/N (%) Control (no graft): 77 (97.5%) white; 2 (2.5%) non-white Graft group: 79 (100%) white	All women were placed on stool softeners during the first 4 weeks, and laxatives if needed during the first week. Strenuous activity was discouraged for 6 weeks.  Randomisation A computer generated randomisation schedule was used to assign participants to groups in a 1:1 allocation, in	Obstructed defecation, n/N (%) - positive response to the question "Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?" or "Do you feel you have to strain too hard to have a bowel movement" or "Do you feel you have not completely emptied your bowels at the end of a bowel movement?" Control (no graft): 26/58 (44.8) Graft group: 28/64 (43.8)  Recurrence of prolapse in same compartment, n/N (%) Definition: point Ap or Bp on POP-Q score -1 or greater at 12 months follow up Control (no graft): 6/70 (8.6) Graft group: 8/67 (12)  Subjective cure of prolapse, n/N (%) Definition: article reports "subjective failure of treatment", which is defined as women who report no improvement of vaginal bulge symptoms, worsening of bother or de novo vaginal bulge symptoms at		

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Study dates	Previous urogynaecologic procedure, n/N (%) Control (no graft): 18/80 (22)	operating surgeon. Graft: midline plication or site-specific repair was conducted as in the control group (at the discretion of the surgeon). This was then followed by augmenting the repair with a 4x7cm subintestinal submucosal graft. The graft was trimmed to the appropriate size, secured over the native tissue repair and sutured laterally to the levator ani fascia using interrupted No. 2-0 polyglycolic acid sutures bilaterally. The graft was secured superiorly to	random blocks ranging from 5 to 10 assignment blocks and stratified by site. Allocation concealment was ensured with sequentially numbered, opaque, sealed envelopes. Except for surgeons and operating room staff, patients, investigators and office and research staff were kept blind to group assignment. Statistics Student's T tests and paired T tests were used to compare means between and within groups. Chi square was used to compare proportions and McNemars test was used to compare ordinal data. All statistical	12 months. Women who did not report this are presumed to be "subjectively cured" for this analysis Control (no graft): 54/58 (93) Graft group: 62/64 (97)  Objective cure of prolapse, n/N (%) Definition: Points Ap and Bp less than -1 on POP-Q at 12 month follow up Control (no graft): 64/70 (91) Graft group: 59/67 (88)	Other risk of bias: low risk of bias (no other potential sources of bias identified)
Source of funding	The Eunice Kennedy Shriver National Institute of Child Health and Human Development. No funding or support was provided by the manufacturer of the graft for any part of the study.				<p>Other information</p> <p>The authors acknowledge the following limitations:</p> <ul style="list-style-type: none"> <li>participants underwent concomitant procedures, in addition to a rectocele repair</li> <li>follow up was only for 12 months</li> <li>the failure rate in the native tissue group was lower than anticipated (9%), making it</li> </ul>

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	Pre-operative splinting with bowel movements, n/N (%) Control (no graft): 42/73 (57.5) Graft group: 38/74 (51.4)	the rectovaginal connective tissue, and inferiorly to the perineal body using No. 2-0 polyglycolic acid sutures. For both groups, excess vaginal tissue was trimmed and the posterior vaginal incision was closed using running No. 2-0 polyglycolic acid sutures, taking care to close tension-free. Deep and superficial transverse perineal muscles were reapproximated with No. 0 polyglycolic acid sutures. Concomitant perineorrhaphy was	analyses were performed using SAS 8.2. Power calculation Based on a previous study assuming a 93% anatomic success rate with grafts, 63 women per group were needed to detect a 20% difference with $\alpha=0.05$ and $\beta = 0.20$ . The authors aimed to recruit 160 women to account for dropout. Intention to treat analysis Authors state that analysis was conducted on the basis of intention to treat (only one participant did not receive the allocated intervention).		<ul style="list-style-type: none"> <li>difficult to detect differences between the groups</li> <li>sexual function was not fully assessed using a validated questionnaire</li> <li>a single type of graft was used, making it difficult to compare with other grafts available</li> <li>fellowship-trained urogynaecologists conducted the surgery, therefore efficacy and safety rates may reflect subspecialty training,</li> </ul>
	Inclusion criteria				

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	<ul style="list-style-type: none"> <li>• women with stage II or greater symptomatic rectocele (defined as vaginal bulge, defecatory symptoms, or both) electing for surgical repair</li> </ul> <p><b>Exclusion criteria</b></p> <ul style="list-style-type: none"> <li>• age &lt; 18 years</li> <li>• women undergoing concomitant sacrocolpopexy or colorectal procedures</li> <li>• history of porcine allergy</li> </ul>	performed in all women.			the referral population, or both.
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Surgical management of pelvic organ prolapse

	<ul style="list-style-type: none"> <li>• connective tissues disease</li> <li>• pelvic malignancy</li> <li>• pelvic radiation</li> <li>• inability to understand English</li> <li>• unable or unwilling to consent, or comply with follow-up</li> </ul> <p>Previous rectocoele repair was not an exclusion criterion.</p>				
Full citation	Sample size  Rudnicki, M., Laurikainen, E., Pogosean, R., Kinne, I., Jakobsson, U., Teleman, P., A 3-year follow-up after anterior colporrhaphy compared with collagen-coated	Interventions  N = 169 Anterior colporrhaphy (AC): N = 82 Mesh: N = 79  Characteristics	Details  All surgeons had joint training in both procedures before the study to ensure optimal technique. Performed using a midline incision, intermittent Vicryl sutures (Ethicon, Edinburgh, UK) (or	Results  POP-Q stage 1 or below at 1 year follow up (n/N) AC: 31/82 Mesh: 67/79  POP-Q stage 1 or below at 3 years follow up (n/N) AC: 28/82 Mesh: 64/79  POP-Q stage 2 or above at 1 year follow up (n/N) AC: 42/82 Mesh: 9/79	Limitations  Allocation Bias: Unclear Participants were randomised using a generated randomisation list. Unclear if differences existed at

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					baseline between groups, analysis not shown Allocation concealment: Low risk: sealed envelopes Performance bias: Unclear risk -No details provided if participants or care staff were blind to their treatment. Detection bias: High risk, - those who evaluated outcomes were not blind to treatment allocation, other outcomes were self-report and participants were not blind to their treatment allocation. On ly the data analyst was reported to be blind to
transvaginal mesh for anterior vaginal wall prolapse: a randomised controlled trial, BJOG: An International Journal of Obstetrics & Gynaecology, 123, 136-42, 2016	Mean age in years (SD) AC: 65 (6.6) Mesh: 65 (6.4)	similar) in the pubocervical fascia. Women underwent spinal (35.4%), local (28%) or general (36.6%) anaesthesia	1500 mg and/or 1500mg metronidazole Women were advised to start local estrogen treatment at the start of the study and to continue application for 3 months post surgery.	POP-Q stage 2 or above at 3 years follow up (n/N) AC: 40/82 Mesh: 6/79	Vaginal mesh exposure occurred in 10 patients at 1 year follow up and 10 patients at 3 years follow up. Five patients had mesh revision surgery
Ref Id 541661	Parity (%) <3 - AC: 67.1% / Mesh: 61.5%	Mean operation time was 31.6 minutes (SD 17.6)	Randomisation Participants were randomised using a generated randomisation list	Vaginal bulge at 3 years (n/N) AC: 26/82 Mesh: 13/79	De Novo dyspareunia at 1 year (n/N) AC: 0/82 Mesh: 2/79 (None reported at 3years)
Country/ies where the study was carried out  Norway, Sweden, Finland, and Denmark	Stress urinary incontinence AC: 39.4% Mesh: 17.9%	Anterior Biosynthetic Mesh (Mesh) The mesh product used for surgery was Avaulta Plus, a monofilament, polypropylene mesh. The central section of the mesh is coated with an absorbable hydrophilic film of porcine collagen. The surgery was performed in accordance	Data Analysis Intention to treat analysis was conducted, imputation was performed using multiple imputation on the main outcome for participants who were lost to follow up. Fischers exact, chi- square, Mann- Whitney U-test or Friedmans test	Voiding difficulties at 1 year (n/N) AC: 0/82 Mesh: 2/79	Voiding difficulties at 1 year (n/N) AC: 0/82 Mesh: 2/79
Study type  Randomised controlled study	Urinary incontinence AC: 40.2% Mesh: 35.9%			Stress UI at 1 year (n/N) AC: 0/82 Mesh: 4/79	Bladder perforation during surgery (n/N) AC: 0/82 Mesh: 2/79
Aim of the study  To estimate the three year outcomes, and to compare complication rates of anterior colporrhaphy to a	Urge urinary incontinence AC: 27.3% Mesh: 32.1%			Blood transfusion during surgery (n/N) AC: 0/82 Mesh: 1/79	Repeat surgery for Anterior prolapse at 3 years (n/N) AC: 3/82 Mesh: 0/79

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collagen-coated mesh repair system.	Inclusion criteria  Women aged 55 years or older Anterior wall prolapse of stage 2 or above (POP-Q classification)	with the protocol provided by the company  Women underwent spinal (37.2%), local (0%), or general (62.8%) anaesthesia Mean operation time was 74.1 minutes (SD 23.6)	were used for outcome variables. Multiple linear regression was used to estimate impact of surgery procedure on POP-Q outcomes.  All analysis were conducted by an independent statistician		treatment groups.
Study dates					Attrition Bias: High risk of bias - greater than 15% lost to follow up
April 2008 to December 2010					Reporting Bias: Unclear risk:
Source of funding	The study was supported by the Region Zealand Health Research Fund	Exclusion criteria  History of major pelvic surgery (except hysterectomy for reasons other than genital prolapse, vaginal surgery or for POP) Additional prolapse of the uterus, or enterocele stage 1 or above Previous incontinence sling surgery (performed via			Primary outcomes provided, but not all outcomes, such as vaginal bulge are presented at 3 years (only at 1 year). Data is not always clearly presented in the paper

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	obturator membrane) Currently prescribed corticosteroids History of genital or abdominal cancer				r colporrhaphy compared to collagen coated transvaginal mesh for anterior vaginal wall prolapse: a randomised controlled trial. BJOG 2013; 121: 102-111.
Full citation  Lo, T. S., Wang, A. C., Abdominal colposacropexy and sacrospinous ligament suspension for severe uterovaginal prolapse: A comparison, Journal of gynecologic surgery, 14, 59-64, 1998  Ref Id  631597	Sample size  Total: N = 118 Abdominal colposacropexy (AbC): 52 Sacrospinous ligament suspension (SLS): 66  Characteristic s  Mean age Total: 61 years (SD 9.65) AbC: 63 years (SD 9.05) / SLS: 60 years (SD 9.95)	Interventions  Abdominal colposacropexy Performed according to Iosif 1993 Mersilene mesh was used to bridge the vaginal cuff and the sacral promontory  Mean operative time: 2.63 hours (SD 0.59) Mean length of hospital stay: 7.24	Details  All women were given oestrogen replacement therapy post surgery 36.5% of women undergoing Abdominal colposacropexy also underwent posterior colporrhaphy 96.6% of women undergoing sacrospinous ligament suspension also underwent anterior and posterior colporrhaphy	Results  24 months follow up  Cure (defined as no protrusion greater than stage II, ICS grading system) n/N AbC: 49/52 SLS: 53/66  Dyspareunia n/N AbC: 1/52 SLS: 7/66	Limitations  138 women were randomised, but numbers are not provided per group; therefore 118 with data are included  Other information  Allocation bias: Unclear risk - Randomisation occurred using a random number table; however,

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Country/ies where the study was carried out	Parity (n) Total: 4.83 (SD 3.71) AbC: 5.57 (SD 5.07) SLS: 4.24 (SD 1.94)	days (SD 2.07) sacrospinous ligament suspension Performed according to Nichols 1982			although baseline characteristics are presented, there is no analysis to determine differences.
China					Allocation concealment: Unclear risk - no information provided
Study type					Performance bias: Unclear risk - no information provided
Prospective randomised study Conducted at the Chang Gung Medial Centre, Linkou, Taiwan	Previous pelvic floor surgery n/N AbC: 19/52 SLS: 22/66	Nylon was used to fix the vaginal cuff or uterine cervix to the sacrospinous ligament			regarding the blinding of care staff or participants
Aim of the study	Inclusion criteria	Mean operative time: 2.36 hours (SD 0.61) Mean length of hospital stay: 8.77 days (SD 3.78)			Detection bias: Unclear risk - no information provided
To compare abdominal colposacropexy to sacrospinous ligament suspension for vaginal vault prolapse	• Women with a history of severe cervical prolapse or vaginal vault erosion (stage $\geq$ III on ICS grading system)				Attrition bias: Unclear risk - overall 15% were lost to follow up; however there is no detail of which intervention
Study dates					
January 1991 to January 1996					
Source of funding	Exclusion criteria				
Not stated	• Women with				

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	<ul style="list-style-type: none"> <li>• voiding problems</li> <li>• Women of advanced age (no definition provided)</li> <li>• Women with disability (not defined)</li> </ul>					these participants were originally allocated, so it is not possible to determine if differences exist between the two groups in drop out rates Selective reporting: High risk, no baseline analysis between groups.
Full citation	Sample size	Interventions	Details	Results		Limitations
Maher, C. F., Qatawneh, A. M., Dwyer, P. L., Carey, M. P., Cornish, A., Schluter, P. J., Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective	Total: N = 95 Abdominal sacral colpopexy (ASC): N = 47 Vaginal sacrospinous colpopexy (VSC): N = 48	Abdominal sacral colpopexy (ASC) A sacral colposuspension was performed with prolene mesh. The mesh suspended the vaginal vault to the	Women in both groups with SUI or occult SUI underwent Burch colposuspension All procedures were undertaken under supervision of a consultant urogynaecologist All women were given preoperative	24 months Cure (POP-Q <2) n/N ASC:35/47 VSC: 29/48  Dyspareunia n/N ASC: 2/47 VSC: 3/48  SUI n/N ASC: 2/47 VSC: 8/48		The authors state a sample size of 250 would be required to detect a difference between the groups with the outcomes used in the study 10% of women did not

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					complete the full review
randomized study, American Journal of Obstetrics & Gynecology, 190, 20-6, 2004	Mean age Total: 63 years (SD 10.25) ASC: 63 years (SD 10.3) / VSC: 63 years (SD 10.3) p = 0.80	sacral promontory Mean operative time: 106 minutes (SD 37) Mean length of hospital stay: 5.4 days (SD 2.2)	vaginal oestrogen therapy and postoperative antithrombotic and antibiotic therapy		Other information
Ref Id 541531					Allocation bias: Low risk, computer generated stratified randomisation. No differences between groups at baseline Allocation concealment: Unclear risk, randomisatoin lists held by non-surgical co-author Performance bias: Unclear risk, no information on blinding of care staff or participants Detection bias: Unclear risk, no information on blinding of assessors Attrition bias: Unclear risk,
Country/ies where the study was carried out Australia	Mean BMI Total: 26.6kg/m <sup>2</sup> (SD 4.87) ASC: 26.7kg/m <sup>2</sup> (SD 4.9) / VSC: 26.6kg/m <sup>2</sup> (SD 4.9) p = 0.97	Vaginal sacrospinous colpopexy (V SC) A unilateral sacrospinous colpopexy was undertaken			
Study type Prospective randomised study					
Aim of the study To test the hypothesis that sacrospinous and sacral colpopexy are equally effective	Parity n/N Total: 3.10 (SD 1.33) ASC: 3.0 (SD 1.6) / VSC: 3.2 (SD 1.0) p = 0.31	Mean operative time: 76 minutes (SD 42) Mean length of hospital stay: 4.8 days (SD 1.4)			
Study dates September 1997 to December 2000	Inclusion criteria <ul style="list-style-type: none"><li>• Women who required surgical</li></ul>				

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<p>Source of funding</p> <p>The study was supported by the Arthur Wilson Scholarship, Royal Australian and New Zealand College of Obstetrics and Gynecology</p>	<p>treatment for vaginal vault prolapse</p> <ul style="list-style-type: none"> <li>• Women with symptomatic post-hysterectomy vaginal vault prolapse, that extended to or beyond the introitus</li> </ul> <p>Exclusion criteria</p> <ul style="list-style-type: none"> <li>• Women who had previous sacral colpopexy</li> <li>• Women with a significantly foreshortened vagina</li> </ul>	<p>overall less than 15% lost to follow up; however, potential differences in drop out rates between the two groups.</p> <p>Reporting bias: Low risk, expected outcomes presented.</p>
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Full citation	Sample size	Interventions	Details	Results	Limitations
Robert, M., Girard, I., Brennand, E., Tang, S., Birch, C., Murphy, M., Ross, S., Absorbable mesh augmentation compared with no mesh for anterior prolapse: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 123, 288-94, 2014	Total: N = 57 Anterior repair: (AR): n = 29 Anterior repair with mesh (Mesh): = 29	Anterior repair (AR) A midline incision was undertaken and lateral dissection . Vicryl sutures were used	Concomitant procedures were also conducted in 79% of the population	12 months Cure (Ba stage 2 or less) n/N AR: 26/29 Mesh: 28/28  In surgery events Blood transfusion n/N AR: 1/29 Mesh: 0/28	Allocation bias: Low risk - block randomisation, no differences between groups at baseline Allocation concealment: Low risk, central allocation system Performance bias: Low risk - participants blind to treatment, surgeons blind to "next treatment" Detection bias: Low risk - assessors blind to treatment Attrition bias: Low risk - less than 10% lost to follow up, no difference in follow up between groups Reporting bias: Low risk - all expected
Ref Id	541644				
Country/ies where the study was carried out	Mean age Total: 58 years (SD 12.30) AR: 57 years (SD 12.9) / Mesh: 59 years (SD 11.8)	Mesh repair The procedure was the same as for standard repair but augmented mesh was used.			
Study type	Mean BMI Total: 27.56kg /m <sup>2</sup> (SD 3.98) AR: 27.9kg/m <sup>2</sup> (SD 3.9) / Mesh: 27.2kg/m <sup>2</sup> (SD 4.1)				
Aim of the study	Parity, greater than 1 n/N AR: 27/29				

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repair with mesh-augmented anterior repair	Mesh: 28/28  Previous pelvic surgery n/N AR: 19/29 Mesh: 19/28			outcomes reported
Study dates  September 2009 to June 2010	Inclusion criteria  <ul style="list-style-type: none"><li>• Women who had elected for surgical management of prolapse</li><li>• Prolapse greater than Ba &gt; 0</li><li>• Provided written consent</li></ul>			Other information
Source of funding  The study was supported by a Cook medical Grant	Exclusion criteria  <ul style="list-style-type: none"><li>• Women who preferred to have an obliterative procedure</li></ul>			

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	<ul style="list-style-type: none"> <li>• Women with and allergy to graft material</li> <li>• Women who were immunocompromised</li> <li>• Women who had previous anterior prolapse repair</li> <li>• Unable to understand English</li> <li>• Women who were unavailable for follow up</li> </ul>					
Full citation	Sample size	Interventions	Details	Results		Limitations
Rudnicki, M., Laurikainen, E., Pogosean, R., Kinne, I., Jakobsson, U., Teleman, P., Anterior colporrhaphy compared with collagen-coated	See Rudnicki 2016	See Rudnicki 2016	See Rudnicki 2016	See Rudnicki 2016		See Rudnicki 2016
	Characteristics					Other information
	See Rudnicki 2016					See details in Rudnicki 2016

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transvaginal mesh for anterior vaginal wall prolapse: a randomised controlled trial, BJOG: An International Journal of Obstetrics & Gynaecology, 121, 102-10; discussion 110-1, 2014	Inclusion criteria  See Rudnicki 2016				
Ref Id	Exclusion criteria  See Rudnicki 2016				
541660					
Country/ies where the study was carried out					
Norway, Sweden, Finland, and Denmark					
Study type					
See Rudnicki 2016					
Aim of the study					
See Rudnicki 2016					
Study dates					

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See Rudnicki 2016					
Source of funding					
See Rudnicki 2016					
Full citation	Sample size	Interventions	Details	Results	Limitations
El-Nazer, M. A., Gomaa, I. A., Ismail Madkour, W. A., Swidan, K. H., El-Etriby, M. A., Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study, Archives of Gynecology & Obstetrics, 286, 965-72, 2012	N = 54 Anterior colporrhaphy (AC): N = 23 Mesh repair (Mesh): N= 21	Anterior colporrhaphy (AC) Women underwent either regional (70%) or general (30%) anaesthesia. Mean operative time was 76 minutes (SD 12.6)	The same surgical team operated on both groups of participants. All participants received antibiotic prophylaxis, were placed in the lithotomy position and given a diluted solution of epinephrine (1:200,000) for vaginal infiltration. Only Kelly's sutures, and/or perineal body reinforcement was added when clinically required.	POP-Q outcome at 2 years Optimal (points Aa, Ba, Ap and Bb at stage 0) (n/N) AC: 7/23 Mesh: 16/21 Satisfactory (points Aa, Ba, Ap, Bb at stage 1) (n/N) AC: 7/23 Mesh: 3/21  Recurrence (POP-Q stage II or greater) (n/N) at 2 years AC: 3/23 Mesh: 1/21  There was one reported case of mesh erosion at 2 years follow up De Novo dyspareunia (n/N) at 2 years AC: 1/23 Mesh: 0/21  Stress incontinence (persistent and new onset) at 2 years (n/N) AC: 4/23 Mesh: 1/21  Vaginal bulge (persistent and new onset) at 2 years (n/N) AC: 6/23 Mesh: 1/21  Voiding difficulty (persistent and new onset) at 2 years (n/N) AC: 6/23 Mesh: 1/21	Allocation bias: Low risk - participants were randomised via a computer generated list. No baseline differences between the two groups.  Allocation concealment: Low risk: participants were assigned to the treatment groups using sealed envelopes, opened just prior to surgery.  Performance bias: Unclear risk: The surgical team was described
Ref Id	Mean Parity AC: 5 (2.2) Mesh: 5 (2.0)	Mesh repair (mesh) The mesh used was designed for the vaginal route, it was a synthetic non-absorbable mono-filamentous polypropylene, macroporous,	Randomisation		
Country/ies where the study was carried out	Mean BMI, kg/m <sup>2</sup> (SD) AC: 31.7 (6.6) Mesh: 33.4 (7.01)				
Egypt					

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Study type		lightweight material - GYMEMESH (PS, Gynecare, Ethicon, France).	Participants were randomly assigned using a computer generated number table, and assigned intervention group using sealed envelopes. Evaluations were carried out by blinded personnel		as blinded, It is unclear if participants were blind to their treatment group.
Aim of the study	Stress incontinence AC: 50% Mesh: 25%	Dyspareunia AC: 44.4% Mesh: 41.4%			Detection bias: Low risk - the team who conducted the assessments and those who carried out data analysis were blinded.
To compare the clinical effectiveness of anterior colporrhaphy to mesh repair.	Voiding difficulty AC: 75% Mesh: 75%	Women underwent either regional (60%) or general (40%) anaesthesia Mean operation time was 75 minutes (SD 8.4)			Attrition bias 93% completed follow up assessments at 2 years Selective reporting Unclear risk: Outcomes are reported, but data is not clearly presented in the paper
Study dates	Vaginal bulge/pressure AC: 95% Mesh: 90%		Sample size Based on lifetime risk of surgical intervention for prolapse (11%) and a probability of perimenopausal prolapse incidence (44%) a sample size of 20 participants for each group was calculated, providing 85.02% power.		Other bias Unclear risk
Source of funding	Mean POP-Q Ba (SD) AC: +0.45 (0.7) Mesh: +0.45 (0.9)	POP-Q stage (%) Stage II - AC: 60% / Mesh: 55% Stage III - AC: 40% / Mesh: 45%	Data analysis An independent analyst conducted the data		Other information

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	Inclusion criteria  Cystocele grade II or above according to POP-Q system No plans for pregnancy within 12 months	analysis. Students t test was used for quantitative parametric data, and Mann-Whitney U test, and likelihood ratio for quantitative non-parametric data. Chi-Square and Fisher exact tests were used for qualitative data.		
	Exclusion criteria  Contemplating pregnancy Paravaginal defects or in need of anti-incontinence procedure other than sub-urethral plication Women with previous Burch colposuspension or vaginal surgery Immunocompromised Participants with diabetes			

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	Participants with symptoms mostly due to urinary tract infection Those who do not provide consent					
Full citation	Sample size  Glazener, C., Breeman, S., Elders, A., Hemming, C., Cooper, K., Freeman, R., Smith, A., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., McDonald, A., McPherson, G., MacLennan, G., Norrie, J., Clinical effectiveness and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study -	Interventions  See details in Glazener 2017	Details  See details in Glazener 2017	Results  See details in Glazener 2017	Limitations  See details in Glazener 2017  Other information  See details in Glazener 2017	

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results from the PROSPECT Study, Health Technology Assessment (Winchester, England)Health Technol Assess, 20, 1-452, 2016					
Ref Id					
619275					
Country/ies where the study was carried out					
UK					
Study type					
See details in Glazener 2017					
Aim of the study					
See details in Glazener 2017					
Study dates					
See details in Glazener 2017					

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Source of funding						
See details in Glazener 2017						
Full citation	Sample size	Interventions	Details	Results		Limitations
Svabik, K., Martan, A., Masata, J., El-Haddad, R., Hubka, P., Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial, Ultrasound in Obstetrics & Gynecology, 43, 365-71, 2014	Total: N = 70 Sacrospinous vaginal colpopexy (Prolift): N = 36 Sacrospinous fixation (SSF): N = 34	Sacrospinous vaginal colpopexy with mesh Prolift Total mesh kit used (Prolift totalTM, Gynecare Ethicon, Sommerville USA). The kit was fitted according to the recommended technique The mesh was inserted and spread anteriorly from the bladder next and fixed using vicryl plus sutures	Preoperative levator assessment and avulsion diagnosis was performed POP-Q classification of prolapse was used to assess patients, examination was undertaken by two physicians experienced in pelvic floor ultrasound examination At three month assessment those with SUI were offered vaginal tape-obturator procedure	12 months Cure (POP-Q <2) n/N Prolift: 30/36 SSF: 4/34  Recurrence n/N Prolift: 0/36 SSF: 3/34  Mesh exposure n/N Prolift: 3/36 SSF: 0/34  Dyspareunia n/N Prolift: 2/36 SSF: 1/34		Prolift mesh now removed from market - data may be relevant for other polypropylene meshes Small study size
Ref Id	Mean BMI Total: 27.69kg/m <sup>2</sup> (SD 3.72) Prolift: 27.2kg/m <sup>2</sup> (SD 3.231) /	Sacrospinous vaginal colpopexy Using native tissue				Other information
541711						Allocation bias: Low risk, computer generated randomisation list. No differences between groups at baseline Allocation concealment: Unclear risk, no details provided Performance bias: High risk, both care staff

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Country/ies where the study was carried out	SSF: 28.2kg/m <sup>2</sup> (SD 4.18) p = 0.27	Performed without the dissection of fascia. Conventional anterior repair and posterior high levatorplasty were conducted in all cases.			and participants aware of treatment allocation
Czech Republic	Mean parity Total: 2.15 (SD 0.75)				Detection bias: Low risk, examination at 12 months conducted by an assessor unaware of treatment at the start of the examination.
Study type	Prolift: 2.1 (SD 0.83) / SSF: 2.2 (SD 0.67) p = 0.83				Attrition bias: Low risk, less than 15% loss to follow up at 12 months
Single centred randomised controlled trial	Inclusion criteria	SSF was conducted unilaterally on the right using two permanent sutures of Nurolon inserted and attached to the vaginal apex.			Reporting bias: Low risk, all expected outcomes reported
Aim of the study					
To compare sacrospinous vaginal colpopexy using Prolift total to sacrospinous fixation using native tissue					
Study dates					
2008 to 2011					
Source of funding					
The study was supported by a grant from the Ministry of Health of the Czech Republic (NT 12147-4) and by Charles					

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University, Prague (UNCE 204024)	floor surgery					
	• Women diagnosed with a complete unilateral or bilateral avulsion					
	Exclusion criteria					
	<ul style="list-style-type: none"> <li>• Women with prolapse and uterus in place</li> <li>• Women without levator ani avulsion</li> <li>• Women not requesting pelvic floor surgery</li> </ul>					
Full citation	Sample size	Interventions	Details	Results		Limitations
Damiani, G. R., Riva, D., Pellegrino, A., Gaetani, M., Tafuri, S., Turoli, D., Croce, P.,	Total: N = 58 Pelvisoft: 28 Avaulta: 30	Pelvisoft Porcine dermal acellular collagen matrix	All procedures were conducted by a single surgeon. All women received	12 months Cure (POP-Q stage 0-1) n/N Pelvisoft: 24/28 Avaulta: 28/30  24 months		No clear which women had anterior, posterior or both.

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Loverro, G., Conventional fascial technique versus mesh repair for advanced pelvic organ prolapse: Analysis of recurrences in treated and untreated compartments, Journal of Obstetrics & Gynaecology, 36, 410-5, 2016  Ref Id 541349	Characteristics  Mean age 57 years (SD 5.58) Pelisoft: 57 years (SD 4.4) / Avaulta: 58 years (SD 6.5)	BioMesh (Pelvisoft BioMesh CR Bard, Cranston, R.I. USA) The implant was anchored using polydioxanone monofilament delayed absorbable sutures Mean operative time: 57 minutes (SD 23.5)	preoperative antibiotic prophylaxis Patients were instructed to avoid physical activity for the following 2 months	Cure (POP-Q Stage 0-1) n/N Pelvisoft: 23/28 Avaulta: 24/30  Recurrence n/N Pelvisoft: 4/28 Avaulta: 5/30	Other information  Allocation bias: Low risk: randomisation conducted using a computer generated list Allocation concealment: Unclear risk, no details provided Performance bias: Unclear risk, no information regarding the blinding of care staff or participants Detection bias: Follow up assessments conducted by assessors blind to the intervention Attrition bias: Low risk, all participants followed up at 24 months Reporting bias: Low risk, all
Country/ies where the study was carried out	Mean Vaginal Parity Total: 2 (SD 1.10)	Avaulta Solo(R)			
Italy	Pelvisoft: 2 (SD 1.0) / Avaulta 2 (SD 1.2)	Polypropylene vaginal mesh delivery system (CR Bard Incs, Covington, GA)			
Study type	Inclusion criteria	Postoperative vaginal oestrogens were prescribed			
Randomised controlled trial					
Aim of the study					
To compare the outcomes of POP surgery conducted	• Women with vaginal or uterine				

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with facial repair as compared to polypropylene or biological implants	pelvic organ prolapse (POP-Q >2)	twice a week for one month to postmenopausal women			expected outcomes presented Other bias: Units in the tables were not always clear. Analysis is not always between the two groups (may be between mesh and no mesh, with the two mesh arms combined)
Study dates		<ul style="list-style-type: none"> <li>• Symptoms specific to POP</li> </ul>	The mesh was fixed to the cervical ring or to the vaginal apex using 1 prolene suture on each side.		
January 2008 to January 2010		<ul style="list-style-type: none"> <li>• Ability to complete 24 month follow up</li> </ul>	Mean operative time: 58.5 minutes (SD 23.7) Mean length of hospital stay: 4.5 days (SD 1.0)		
Source of funding		Exclusion criteria			
Not stated		<ul style="list-style-type: none"> <li>• Women contemplating future pregnancies</li> <li>• Presence of active/latent systemic infections</li> <li>• Women with a compromised immune function</li> <li>• Women with connectiv</li> </ul>			

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	e tissue disorders • Women with uncontroll ed diabetes or previous cancer				
Full citation	Sample size	Interventions	Details	Results	Limitations
Vollebregt, A., Fischer, K., Gietelink, D., van der Vaart, C. H., Effects of vaginal prolapse surgery on sexuality in women and men; results from a RCT on repair with and without mesh, Journal of Sexual Medicine, 9, 1200-11, 2012	See details in Vollebregt 2011	See details in Vollebregt 2011	See details in Vollebregt 2011	See details in Vollebregt 2011	Allocation bias: Unclear risk - Computerised randomisation table, difference in use of anti-depressive drugs between groups at baseline Allocation concealment Unclear risk - no details Performance bias: High risk - unclear if participants were blind. Surgical teams were not blind
Ref Id 541754	Characteristic s See details in Vollebregt 2011				
Country/ies where the study was carried out Netherlands	Inclusion criteria See details in Vollebregt 2011  Exclusion criteria				

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Study type	See details in Vollebregt 2011					Detection bias: Unclear: Assessors were blind to the treatment, the groin was bandaged to blind assessors.how ever for self-report measures the risk of bias is increased as participants were not blind to treatment.
Aim of the study	See details in Vollebregt 2011					Attrition bias: Low risk, less than 15% drop out
Study dates	See details in Vollebregt 2011					Reporting bias: Low risk, all expected outcomes presented
Source of funding	See details in Vollebregt 2011					Other information
Full citation	Sample size	Interventions	Details	Results		Limitations See details in Vollebregt 2011

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Natale, F., La Penna, C., Padoa, A., Agostini, M., Paneli, M., Cervigni, M., High levator myorrhaphy versus uterosacral ligament suspension for vaginal vault fixation: a prospective, randomized study, International Urogynecology Journal, 21, 515-22, 2010	Total: N = 229 High levator myorrhaphy (HLM): 116 Uterosacral ligament suspension (USLS): 113	High levator myorrhaphy Midline posterior colpotomy extending from the vault to the perineum is performed. The prerectal fascia is dissected, to the ischiorectal fossa. The vaginal cuff is attached to the puborectalis sheath on both the left and right side. Mean length of hospital stay: 4.2 days	Three surgeons performed all operations	12 months Cure (Stage 0-1 Ba) n / N HL: 82/116 USLS: 73/113  Dyspareunia n/N HLM: 7/116 USLS: 9/113  Mesh erosion n/N HLM: 12/116 USLS: 16/113  Vaginal erosion n/N HLM: 4/116 USLS: 5/113  SUI n/N HLM: 7/116 USLS: 11/113	No standard deviations presented
Ref Id	541574	Mean BMI Total: Country/ies where the study was carried out	Characteristics Mean age Total: 65 years HLM: 65 years / USLS: 64 years p = 0.34		Other information
Italy	25.86kg/m2 HLM: 26.8kg/m2 / USLS: 24.9kg/m2 p = 0.26				Allocation bias: Unclear risk, no details are provided. No significant differences exist between the two groups at baseline
Study type	Prospective randomised study	Median parity HLM: 2 USLS: 2			Allocation concealment: Unclear risk, no details provided
Aim of the study	To compare high levator myorrhaphy to	Sexually active n/N HLM: 57/116 USLS: 59/113			Performance bias: Unclear risk, no details provided, it is unclear if participants and/or care staff are aware of allocation Detection bias: Unclear risk, no details provided. No information as to who conducted the assessment, or

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uterosacral ligament suspension for anatomical cure of apical prolapse	[No standard deviations presented]	fascia. the suture also fixes the anterior and posterior vaginal epithelium. The procedure was conducted intraperitoneally. Mean length of hospital stay: 5.2 days				if they were aware of the treatment allocation Attrition bias: Low risk, all participants were followed up at 12 months Reporting bias: Unclear risk, very limited methods therefore unclear if data is as expected Other bias: Unclear risk, poorly reported methods
Study dates	Inclusion criteria					
September 2005 to December 2007	<ul style="list-style-type: none"> <li>Women with symptomatic stage ≥2 apical prolapse</li> </ul>					
Source of funding	Exclusion criteria					
Non stated	<ul style="list-style-type: none"> <li>Women with concomitant stress urinary incontinence</li> <li>Women who had previously undergone hysterectomy, POP or SUI surgery</li> </ul>					
Full citation	Sample size	Interventions	Details	Results		Limitations

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Rondini, C., Braun, H., Alvarez, J., Urzua, M. J., Villegas, R., Wenzel, C., Descouvieres, C., High uterosacral vault suspension vs Sacrocolpopexy for treating apical defects: a randomized controlled trial with twelve months follow-up, International Urogynecology Journal, 26, 1131-8, 2015	Total: N = 124 Abdominal sacrocolpopexy (SCP): N = 63 High uterosacral vault suspension (HUVS): N = 61	Abdominal sacrocolpopexy (SCP) Performed through a Pfannenstiel incision (unless the patient had a previous midline laparotomy)	All procedures were performed or supervised by the senior authors	12 months Cure (POP-Q stage <2) n/N SCP: 54/63 HUVS: 45/61  Repeat surgery for POP n/N SCP: 3/63 HUVS: 10/61  Mesh exposure n/N SCP: 2/63 HUVS: 0/61	Data generally reporting poorly, making interpretation difficult  Other information  Allocation bias: Unclear risk, limited details provided regarding generation of randomisation. No differences at baseline between groups were shown Allocation concealment: Low risk, allocation conducted by a gynaecologist not involved with the study Performance Bias: High risk, care staff aware of allocation, unclear if participants
Ref Id	541648	Characteristic s			
Country/ies where the study was carried out	Chile	Mean age Total: 57 years (SD 10.2) SCP: 57 years (SD 10.1) / HUVS: 57 years (SD 10.4) p=0.60	Mean BMI Total: 29.98kg/m <sup>2</sup> (SD 5.16) SCP: 29.0kg/m <sup>2</sup> (SD 4.4) / HUVS: 31.0kg/m <sup>2</sup> (SD 5.7) p =0.07	The dissection went through the retroperitoneum to the vaginal vault or cervical stump, and continued posteriorly to the level of the levator plate and anteriorly Prolene mesh was fixed to the anterior and posterior vagina	
Study type	Parallel randomised study	Mean parity	High uterosacral vault suspension (HUVS) Performed as described by		
Aim of the study					

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To compare hihg uterosacral vault suspension (HUVS) to abdominal sacrocolpopexy for apical prolapse	Total: 3.90 (SD 1.89) SCP: 3.8 (SD 1.8) / HUVS: 4.0 (SD 2.0) p = 0.60	Shull et al 2000 A standard vaginal hysterectomy was performed, the vaginal cuff was suspended and anchored to the USL bilaterally at or above the level of the sacral spine. In patients with a previous hysterectomy the vaginal cuff was opened at the level of the scar and an intraperitoneal suspension performed.		were aware of treatment Detection bias: Unclear risk, no information provided Attrition bias: Low risk, no loss of follow up Reporting bias: Unclear risk, data presented in graphical format without numbers for clarification.
Study dates	Inclusion criteria			
October 2006 to October 2010	<ul style="list-style-type: none"> <li>• Aged over 18 years</li> <li>• Required reconstructive surgery</li> <li>• Sexually active</li> <li>• Women with symptomatic stage 2-4 prolapse (POP-Q)</li> </ul>			
Source of funding	Exclusion criteria			
Not stated	<ul style="list-style-type: none"> <li>• A history of previous apical reconstruction</li> </ul>			

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	tive surgery					
Full citation	Sample size	Interventions	Details	Results	Limitations	
de Tayrac, R., Mathe, M. L., Bader, G., Deffieux, X., Fazel, A., Fernandez, H., Infracoccygeal sacropexy or sacrospinous suspension for uterine or vaginal vault prolapse, International Journal of Gynaecology & Obstetrics, 100, 154-9, 2008	Total: 49 Infracoccygeal sacropexy (IS): 24 Sacrospinous suspension (SS): 25	Infracoccygeal sacropexy (IS) A polypropylene intravaginal sling is placed between the vaginal vault and the perineal body. Skin incisions are made sideways and backwards from the anus, the mesh is fixed with non-absorbable thread to the vaginal vault or uterosacral ligament.	Antibiotic prophylaxis were given intraoperatively only. Concomitant surgery for cystocele, hysterectomy, suburethral tape and posterior repair were undertaken if required	16.8 months follow up Cure (POP-Q stage 0-1) n/N IS: 20/24 SS: 24/25  Repeat surgery for uterine prolapse N/N IS: 1/24 SS: 0/25  Voiding difficulties n/N IS: 5/24 SS: 12/25  Constipation n/N IS: 1/24 SS: 11/25  Quality of Life (Number who improved their score by 50%) POPDI n/N IS: 16/24 SS: 16/25 POPIQ n/N IS: 15/24 SS: 10/25  Sexual function - PSIQ 12 (change from baseline) IS: 3.1 (SD 6.2) SS: 0 (SD 6.4)	Small study size Limited methods in article No conflict of interest statement  Other information  Risk of Bias Allocation Bias: High risk - centralised telephone block randomisation. Participants in the IS group had a significantly greater BMI at baseline than those in the SS group. Allocation concealment: Unclear risk - No information provided	
Ref Id						
541356						
Country/ies where the study was carried out	Mean BMI Total: 26.36kg/m <sup>2</sup> (SD 3.98) IS: 27.9kg/m <sup>2</sup> (SD 4.0) SS: 25.0kg/m <sup>2</sup> (SD 3.5)	Mean operative time: 13.2 minutes (SD 5.2) Mean length of stay in hospital: 4.9 days (SD 1.8)				
Study type	Mean Parity					
Multi-centred randomised controlled trial.						

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The study was conducted across four University hospitals	Total: 2.2 (SD 0.89) IS: 2.2 (SD 0.9) SS: 2.2 (SD 0.9)	Sacrospinous suspension (SS)  A unilateral procedure. The vaginal vault, uterosacral ligaments or a vaginal flap are fixed to one sacrospinous ligament with 2 monofilament, non-absorbable threads.  Mean operative time: 20 minutes (SD 8.1)  Mean length of hospital stay: 3.9 days (SD 1.2)			Performance Bias: Unclear risk - No information provided  Detection Bias: Unclear risk - No information provided  Attrition Bias: Low risk, No differences between the interventions groups in drop out rates, overall low drop out rates  Reporting Bias: Low risk - Expected outcomes reported  Other bias: Very limited methods section
Aim of the study	Previous prolapse repair n/N Total: 5/49 IS: 3/24 SS: 2/25				
To compare infracoccygeal sacropexy and sacrospinous suspension for uterine or vaginal vault prolapse	Sexually active n/N Total: 20/49 IS: 8/24 SS: 12/25				
Study dates					
March 2003 to December 2005					
Source of funding	Inclusion criteria				
Not stated	<ul style="list-style-type: none"> <li>• Women with symptomatic uterine or vaginal vault prolapse (stage ≥2)</li> </ul>				
	Exclusion criteria				

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	<ul style="list-style-type: none"> <li>• Women isolated cystocele</li> <li>• Women with stage 1 prolapse</li> <li>• Women with rectal prolapse</li> <li>• Women with intestinal inflammatory disease</li> </ul>				
Full citation	Sample size  Rahmanou, P., Price, N., Jackson, S. R., Laparoscopic hysteropexy versus vaginal hysterectomy for the treatment of uterovaginal prolapse: a prospective randomized pilot study, International Urogynecology Journal, 26, 1687-94, 2015	Interventions  Total: N = 101 Laparoscopic hysteropexy (LH): N = 51 Vaginal hysterectomy (VH): N = 50  Characteristics  Mean age Total: 65 years LH: 64 years / VH: 66years p =0.14	Details  Laparoscopic hysteropexy (LH) The uterus was suspended from the sacral promontory using bifurcated polypropylene type 1 monofilament macroporous non-absorbable mesh	Results  Surgery was performed under general anesthesia All surgeons had extensive experience of both operations If required the surgery was combined with anterior and/or posterior repair  12 months Repeat surgery for apical prolapse n/N LH: 3/51 VH: 7/50  Repeat surgery for POP - any compartment n/N LH: 8/51 VH: 7/50	Limitations  No standard deviations presented No cure data  Other information  Allocation bias: Unclear risk, no significant differences between the two groups at baseline; however, no details of

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Ref Id 541625	Mea BMI Total: 26.70kg/m2 LH: 25.9kg/m2 / 27.5kg/m2 p = 0.07	Mean operative time: 39.5 minutes  Mean length of hospital stay : 2.1 days			randomisation process are given. The text states "simple randomisation" Allocation concealment: low risk, sealed envelopes were used  Performance bias: Unclear risk, no details are provided. it is unclear if the participants and/or care staff are aware of treatment allocation  Detection bias: Unclear risk, no information is given as to blinding of assessors.  Attrition bias: High risk, over 15% loss to follow up  Reporting bias: Low risk, expected data is presented
Country/ies where the study was carried out	UK	Median parity (range) LH: 2 (1-5) VH: 2 (1-6)	Vaginal hysterectomy (VH)  The uterosacral ligaments were reattached using reabsorbable sutures to the vaginal vault. In cases of complete procidentia, additional vault support was added by sacrospinous fixation.		
Study type	Prospective randomised, single centre pilot study	[No standard deviations presented]			
Aim of the study	To compare rates of recurrence of uterovaginal prolapse following laparoscopic hysteropexy or vaginal hysterectomy	Inclusion criteria	<ul style="list-style-type: none"><li>• Women requesting surgical treatment for symptoma tic uterine prolapse (stage 2- 4)</li><li>• Aged 18 years or above</li><li>• No desire to</li></ul>		
Study dates	May 2009 to September 2012		<ul style="list-style-type: none"><li>• Mean operative time: 28.1 minutes</li><li>• Mean length of hospital stay: 2.5 days</li></ul>		
Source of funding	No funding				

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	preserve fertility					
	Exclusion criteria					
	<ul style="list-style-type: none"> <li>• Women with significantly enlarged fibroid uterus</li> <li>• Women with concomitant medical conditions precluding general anesthesia</li> <li>• Women with a concomitant medical conditions precluding the use of a steep Trendelenberg position</li> </ul>					
Full citation	Sample size	Interventions	Details	Results		Limitations
Maher, C. F., Feiner, B.,	Total number: 108		All women with SUI underwent	24 months Cure (POP-Q <2) (n/N)		As reported: Single site

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DeCuyper, E. M., Nichlos, C. J., Hickey, K. V., O'Rourke, P., Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial, American Journal of Obstetrics & Gynecology, 204, 360.e1-7, 2011	Laparoscopic sacral colpopexy (LSC): n = 53 Total Vaginal mesh kit (TVM): n = 55	laparoscopic sacral colpoxy (LSC) the retroperitoneum was opened using monopolar diathermy from sacral promontory to vault. A self-styled Y-shaped monofilament polypropylene large pore mesh was secured to the anterior and posterior vagina. Median operating time: 97 minutes Median length of hospital stay: 2 days	colposuspension, those with significant anterior prolapse underwent paravaginal repair  The study was approved by the institutional review boards at the Royal Women's, Wesley, and Mater hospitals The study was registered at the ANZCTR clinical trials registry	LSC: 41/53 TVM: 23/55  Repeat surgery for POP (n/N) LSC: 0/53 TVM: 23/55	study with only two surgeons. Vaginal surgery is performed twice as frequently in the institution as compared to laparoscopic surgery, therefore the expertise across procedures may not have been equal.
Ref Id					Small study No total scores for P-QoL presented No data on complications at 24 months (only 6 months)
541530					
Country/ies where the study was carried out					
Australia					
Study type	Characteristics				Other information
Randomised trial	Mean age LSC: 63 years (SD 8.1) TVM: 63 years (SD 8.8)				Allocation bias: Low risk, computer generated randomisation list. No significant
Aim of the study	Mean BMI LSC: 28kg/m <sup>2</sup> (SD 3.3)	Total vaginal mesh kit (TVM) A total Prolift (Gynecare, Ethicon) was performed as described by			
To compare Laparoscopic sacral colpopexy to total vaginal mesh for vault prolapse					

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Study dates 2005 to 2007	TVM: 28kg/m <sup>2</sup> (SD 4.2)  Median Parity (range) LSC: 2 (0-6) TVM: 2 (0-7)	Fatton, with the addition of polyglactin absorbable sutures at the distal anterior and posterior tails to the vaginal fascia without breaching the mucosa  Median operating time: 50 minutes  Median length of hospital stay: 3 days			differences were obsereved between the two groups at baseline  Allocation concealment: Low risk, randomisation was centralised through a telephone system  Performance bias: Unclear risk, no details as to blinding of participants or care staff  Detection bias: Low risk, assessments undertaken by staff unaware of treatment allocation  Attrition bias: High risk, more than 15% loss of follow up  Reporting bias: Low risk, all expected outcomes presented.
Source of funding  The study was supported by competitive research grants from the Australian Gynaecological Endoscopy Society 2007 and 2008, Sydney, Australia	Inclusion criteria  • Women with symptoma tic stage 2 or greater vaginal vault prolapse (POP-Q)				
	Exclusion criteria  • Women younger than 18 years of age • Unable to give				

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	<ul style="list-style-type: none"> <li>informed consent</li> <li>• unable to return for review</li> <li>• Unable to undergo general anaesthesia</li> <li>• BMI &gt;35</li> <li>• ≥5 previous laparotomies</li> <li>• Prior sacral colpopexy or vaginal vault prolapse procedure</li> <li>• Vaginal length less than 6cm</li> </ul>				
Full citation	Sample size	Interventions	Details	Results	Limitations
Coolen, A. L. W. M., van Oudheusden, A. M. J., Mol, B. W. J., van Eijndhoven, H. W. F., Roovers, J. P. W. R., Bongers,	N=74  Laparoscopic sacrocolpopexy (LSC): 37  Abdominal sacrocolpopexy (ASC): 37	Laparoscopic sacrocolpopexy (LSC)  The vaginal vault was elevated with a probe. The peritoneum	All gynaecologists had to have performed at least 50 procedures before the start of the study	12 months follow up  Cure (POP-Q stage 0-1) n/N  LSC: 29/37 ASC: 29/37  SUI n/N  LSC: 5/37 ASC: 4/37	Only 58 out of 74 participants completed follow up examination  Patients and staff not blinded

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M. Y., Laparoscopic sacrocolpopexy compared with open abdominal sacrocolpopexy for vault prolapse repair: a randomised controlled trial, International Urogynecology Journal, 1-11, 2017	Ref Id  631387	Characteristic s	was incised laparoscopically to expose rectovaginal and vesiovaginal fascia. Polypropylene mesh was attached anteriorly and posteriorly.  Mean BMI Total: 25.60kg/m <sup>2</sup> (LSC: 25.3kg/m <sup>2</sup> / ASC: 25.9kg/m <sup>2</sup> )	All participants received a bowel preparations the day before surgery  All surgery was performed with women under general anaesthesia.  Participants received prophylactic antibiotics after surgery	Dyspareunia n/N LSC: 4/37 ASC: 3/37  Repeat surgery for POP n/N LSC: 4/37 ASC: 1/37  Adverse events in surgery  Bladder lesion n/N LSC: 1/37 ASC: 0/37	Other information  Study registered in the Dutch Trial Register (NTR3267) Risk of Bias Allocation Bias: Unclear risk - Randomisation on a 1:1 ratio, however, baseline data between groups is not analysed, and differences are likely. Allocation concealment: Low risk - Randomisation conducted using sealed opaque envelopes Performance Bias: High risk - Participants, care staff and researchers all aware of intervention
Country/ies where the study was carried out	The Netherlands	Study type	Presence of Stress UI Total: 6.8% (LSC: 5.4% / ASC: 8.1%)	If stress incontinence surgery was performed a tension-free vaginal tape was used.		
Multi-centre randomised controlled trial. Conducted across four teaching and two university hospitals, all of which are part of the Dutch consortium for women's health.		Inclusion criteria	Sexually active Total: 45.6% (LSC: 54% / ASC: 37.8%)	Abdominal sacrocolpopexy (ASC) The peritoneum was incised to expose the rectovaginal and vesicovaginal fascia from the vault to the sacral promontory. Polypropylene mesh was used and		

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Aim of the study  To compare Laparoscopic sacrocolpopexy to Abdominal sacrocolpopexy.	<ul style="list-style-type: none"> <li>Women with vault prolapse- defined as a post-hysterectomy prolapse of the apical compartment attached anteriorly and posteriorly. Mean operative time was 115minutes (IQR: 94-129) Median time in hospital was 4 days (IQR: 3-5)</li> </ul>			Detection Bias: Unclear risk - high risk for self-report measures; however objective measures unlikely to be at risk of bias  Attrition Bias: High risk  Reporting Bias: High risk - Data not presented clearly. No baseline comparision
Study dates  2007 to 2012	<ul style="list-style-type: none"> <li>Women presenting with symptomatic vaginal vault prolapse (with or without concomitant cystocele and rectocele)</li> </ul>			
Source of funding  No funding stated	<ul style="list-style-type: none"> <li>Women who chose surgery</li> </ul> <p>Exclusion criteria</p> <ul style="list-style-type: none"> <li>Women who had undergone</li> </ul>			

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	e previous surgery for vault prolapse • Women with a contra-indication for surgery					
Full citation  Costantini, E., Mearini, L., Lazzeri, M., Bini, V., Nunzi, E., di Biase, M., Porena, M., Laparoscopic Versus Abdominal Sacrocolpopexy: A Randomized, Controlled Trial, Journal of Urology, 196, 159-65, 2016  Ref Id 541333  Country/ies where the study was carried out Italy	Sample size  Total = 121 Laparoscopic sacrocolpopexy (LSC): 61 Abdominal sacrocolpopexy (ASC): 60  Characteristic s  Mean age Total: 61 years (LSC: 61years / ASC: 61 years)  Mean BMI Total: 24.80kg/m <sup>2</sup> (LSC: 24.7kg/m <sup>2</sup> /	Interventions  Abdominal sacrocolpopexy (ASC) The anterior vaginal wall was excised to expose a wide vaginal wall area, polypropylene mesh was attached. The posterior wall was prepared to the levator ani and the mesh was attached. The meshes were placed on the sacral periosteum and the peritoneum	Details  No concomitant anti-incontinence surgery was undertaken Surgery was conducted by two senior surgeons Procedures were as standardised as possible	Results  41.7 month follow up  Cure (not defined) n/N LSC: 61/61 ASC: 60/60  Recurrence of Anterior POP LSC: 11/61 ASC: 1/60  Recurrence of Posterior POP LSC: 3/61 ASC: 5/60  Voiding symptoms n/N LSC: 1/61 ASC: 0/60  Constipation n/N LSC: 16/61 ASC: 18/60  Mesh exposure n/N LSC: 3/61 ASC: 1/60	Limitations  Single site study Limited methods and poorly presented results section  Other information  Study registered with www.ClinicalTrials.gov (NCT01182090) Risk of Bias Allocation Bias: Low risk - Randomisation conducted using computer generated permuted	

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Study type  Single site randomised controlled trial Conducted in a tertiary department for Urology	ASC: 24.9kg/m <sup>2</sup> )  Previous prolapse surgery n/N LSC:15/61 / ASC: 12/60	was closed over the meshes  Laparoscopic sacrocolpopexy (LSC) The same preparation of vaginal walls ad mesh attachment was conducted as for ASC.	Adverse events in surgery  Blood transfusion n/N LSC: 1/61 ASC: 7/60	blocks. No significant differences reported between groups at baseline Allocation concealment: Unclear risk - No details provided Performance Bias: High risk - Participants and investigators aware of intervention Detection Bias: Low risk - Postoperative examinations conducted by examiners blind to the procedure. Attrition Bias: Low risk Reporting Bias: Unclear risk - Data not presented clearly, and methods very limited
Aim of the study  To compare Laparoscopic sacrocolpopexy (LSC) to abdominal sacrocolpopexy (ASC)	Sexually active n/N LSC: 33/61 / ASC: 27/60	Inclusion criteria  <ul style="list-style-type: none"> <li>• Women aged 18 to 75 years</li> <li>• Women with symptomatic POP (POP-Q <math>\geq 2</math>)</li> </ul>		
Study dates  2010 to 2013				
Source of funding  No funding stated		Exclusion criteria  <ul style="list-style-type: none"> <li>• Women with a contraindication for surgery and/or</li> </ul>		

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	general anaesthesia <ul style="list-style-type: none"><li>• Women with a BMI <math>\geq 40\text{kg/m}^2</math></li><li>• Women with suspected malignant uterus lesions</li><li>• Women with known sensitivity to synthetic materials</li><li>• Pregnant or lactating women</li><li>• Women with significant cardiovascular, renal, hepatic or respiratory disease</li><li>• Women who were unable to give written</li></ul>				
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	informed consent					
Full citation	Sample size	Interventions	Details	Results	Limitations	
Farthmann, J., Watermann, D., Niesel, A., Funfgeld, C., Kraus, A., Lenz, F., Augenstein, H. J., Graf, E., Gabriel, B., Lower exposure rates of partially absorbable mesh compared to nonabsorbable mesh for cystocele treatment: 3-year follow-up of a prospective randomized trial, International Urogynecology Journal, 24, 749-58, 2013	Total N = 200 Partially absorbable mesh (PA): 98 Non-absorbable mesh (PP): 102	PP: Polypropylene monofilament mesh. Non-absorbable, macroporous material, which allows fibroblasts and leukocytes to presad into the mesh. The mesh has constant tensile stability  PA: Mesh made of six polypropylene filaments, with an absorbable coating made from polyglycolic acid and caprolactone. The mesh is absorbed over approximately 120 days.	The surgery was performed in the same way for both groups. Both groups had mesh with six identical arms All patients had preoperative oestrogen application, and an antibiotic prophylaxis For women who also had apical pelvic floor prolapse simultaneous sacrospinous fixation was condcuted	Mesh exposure n/N 3 months - PP: 11/102 / PA: 3/98 12 months - PP: 6/102 / PA: 6/98 36 months - PP: 6/102 / PA: 3/98  Recurrent POP (any compartment) n/N 3 months - PP: 10/102 / PA: 7/98 12 months - PP: 16/102 / PA: 13/98 36 months - PP: 15/102 / PA: 12/98  Organ injury during surgery n/N PP: 4/102 PA: 1/98	Limited methods section  Other information  Allocation bias: Unclear risk - Block randomisation, stratified by centre. No reported differences at baseline, but no data to demonstrate statement Allocation concealment: Low risk, Computer generated list Performance Bias: Unclear, no mention of blinding of care staff, or participants Detection bias: Unclear	
Ref Id	541404					
Country/ies where the study was carried out	Germany	Concomitant sacrospinous				

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Study type	fixation (apical surgery) n/N PP: 62/102 PA: 58/98				risk, no mention of blinding of assessors Reporting bias: Unclear risk, Outcomes expected are reported. No analysis of between groups at baseline reported
Two-arm, prospective open-label randomized multi-centre study	Inclusion criteria				
Aim of the study					
To compare mesh exposure rates following cystocele surgery with either a partially absorbable mesh or a non-absorbable mesh	<ul style="list-style-type: none"> <li>• Women with symptomatic cystocele (&gt;stage II or stage III) in combination with lateral defect and risk factors for recurrent POP (chronic obstructive pulmonary disease, chronic constipation, overweight)</li> </ul>				
Study dates					
2007 to 2008					
Source of funding					
The study was supported by Serag Wiessner KG, Naila, Germany					

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### Surgical management of pelvic organ prolapse

Exclusion criteria <ul style="list-style-type: none"><li>• Women under the age of 18 years</li><li>• Women who had incomplete family planning</li><li>• Women with allergy to polypropylene</li><li>• Women with previous malignancy of the lower urinary tract, genital organs or rectosigmoid</li><li>• Previous mesh implantation</li><li>• Unable to provide</li></ul>				
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### Surgical management of pelvic organ prolapse

	<ul style="list-style-type: none"> <li>• informed consent</li> <li>• Life expectancy less than 3 years</li> <li>• Unable to agree to 3 year follow up</li> </ul>					
Full citation	Sample size	Interventions	Details	Results		Limitations
Glazener, C. M., Breeman, S., Elders, A., Hemming, C., Cooper, K. G., Freeman, R. M., Smith, A. R., Reid, F., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., McDonald, A., McPherson, G., MacLennan, G., Norrie, J., Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery:	Total population: N = 45 Primary trial N = 365 Mesh trial: 371 (AC: 184 / SM: 187) Graft trial: 264 : (AC: 132 /BG: 132)	Anterior repair (AC) Considered standard repair, used native tissue only	Surgery may have also included concomitant uterine, vault, or continence surgery	Primary trial Mesh trial Cure (POP-Q stage 0-1) at 12 months n/N AC: 67/184 / SM: 73/187  Graft trial Cure (POP-Q stage 0-1) at 12 months n/N AC: 50/132 / Graft: 31/132		Characteristics not available for secondary trial Small numbers in secondary trial  Other information  Version:1.0 StartHTML:0000274 EndHTML:000001998 StartFragment:000001349 EndFragment:00001966 StartSelection:000001349

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### Surgical management of pelvic organ prolapse

two parallel-group, multicentre, randomised, controlled trials (PROSPECT), The Lancet, 389, 381-392, 2017	Characteristics	Porcine acellular collagen matrix, porcine small intestinal submucosa or bovine dermal grafts			EndSelection:0 00001966 SourceURL: <a href="https://star.ncc-wch.org.uk/AssignedStudyData/EditRowBased?questionId=1808&amp;page=2&amp;next=prevpage&amp;search=Glazener">https://star.ncc-wch.org.uk/AssignedStudyData/EditRowBased?questionId=1808&amp;page=2&amp;next=prevpage&amp;search=Glazener</a>
Ref Id 631584	Primary trial Mesh trial Mean age AC: 60 years (SD 10.1) / SM: 60 years (SD 10.4)	Median Parity AC: 2 (0 to 8) / SM: 2 (0 to 9)			
Country/ies where the study was carried out UK	Graft trial Mean age AC: 60 years (SD 10.4) / Graft: 59 years (SD 10.5)				Allocation bias: Low risk - Web based stratified allocation.Â No differences between groups at baseline were observed
Study type Multi-centred randomised controlled trial	Median parity (range) AC: 2 (0-8) / Graft: 2 (1-7)				Allocation concealment: Low risk - central allocation system
Aim of the study To compare prolapse repair using synthetic mesh or biological grafts to standard repair	No details provided for secondary trial				Performance bias: Unclear risk - surgeons not blind, care staff and participants were blind to allocation
Study dates January 2008 to August 2013	Inclusion criteria <ul style="list-style-type: none"><li>• All women awaiting surgery</li></ul>				Detection bias: Assessors were blind to

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### Surgical management of pelvic organ prolapse

Source of funding  The study was supported by the National Institute for Health Research Health Technology Assessment Programme (project: 07-60-18)	for pelvic organ prolapse					allocation of treatment Attrition bias: High risk - more than 15% lost to follow up at 2 years Reporting bias: Low risk, all expected outcomes presented
	<ul style="list-style-type: none"> <li>Primary surgery was for anterior or posterior prolapse surgery</li> </ul> <p>Exclusion criteria</p> <ul style="list-style-type: none"> <li>Women who were unable to give informed consent</li> <li>Women who were unable to complete study questionnaires</li> </ul>					
Full citation	Sample size	Interventions	Details	Results		Limitations
Halaska,M., Maxova,K., Sottner,O., Svabik,K., Micoch,M., Kolarik,D., Mala,I., Krofta,L.,	Total number: 168 Sacrospinous fixation (SF): n = 83 Prolift mesh (PF): n = 85	Sacrosinou s fixation (SF) Anterior and posterior median colpotomy and dissection of	The study was approved by the ethical committee of Charles University in Prague and	12 months Recurrence (n/N) SF: 28/83 PM: 13/85  Pelvic Pain (n/N) SF: 3/83		Authors note a 9.52% drop out at 3 months, and that the response rate for sexual function

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Halaska,M.J., A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse, American Journal of Obstetrics and Gynecology, 207, 301-301, 2012	A sample size of 70 participants per group were required (70% power), to detect a 20% difference between procedures	urethrovesical/ rectovaginal spaces were arried out. Anterior repair was followed by visualisation of a right sacrospinous ligament. Suturing of the colpotomy and knotting of SF stitches elevated the vagina into its final position.	registered with the FDA Prophylactic application of second generation cephalosporin and vaginal packing with oestrogen cream was applied for 48 hours in both groups	PM: 6/85 De novo SUI (n/N) SF: 18/83 PM: 27/85  Mesh exposure (n/N) PM: 16/85	decreased over time Methods and results not clearly reported  Other information
Ref Id 215743	Characteristic s				
Country/ies where the study was carried out Czech Republic	Mean age SF: 66.41 years (SD 9.62) PM: 63.37 years (SD 10.12) p = 0.48	Prolift Mesh An idioform gauze wick was inserted into the anus and rectum until the end of surgery. Hydrodissection of the vaginal wall was followed by preparation of the arcus tendineus fasciae pelvis and sacrospinous	All participating surgeons were experienced in pelvic surgery and performed at least 20 of each of the procedures before the start of the study		
Study type Multi-centre, prospective, randomised comparative study Conducted in five tertiary, accredited urogynaecological centres	Mean BMI SF: 27.62kg/m <sup>2</sup> (SD 3.8) PM: 26.81kg/m <sup>2</sup> (SD 3.7) p = 0.15				Allocation bias: Unclear risk - Randomisation was conducted using a computer generated sequence, unclear if this was concealed. Unclear how comparable participants were at baseline, some p values were provided, but not for all demographic variables assessed. Performance Bias: Unclear risk - unclear if participants, surgeons or care providers were blind to

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### Surgical management of pelvic organ prolapse

Aim of the study  To compare the clinical efficacy and complication rates between Prolene surgical mesh kit and sacrospinous fixation in women with central posthysterectomy vaginal vault prolapse	Mean Parity SF: 2.32 (SD 0.68) PM: 2.08 (SD 0.71)	ligament. Prolift cannulas were inserted, anterior and posterior dissections were performed preserving the integrity of the vaginal cuff apex.		treatment allocation Detection bias: Unclear risk - unclear if those assessing outcomes were blind to treatment. Attrition bias: Low risk. Less than 10% drop out at 12 months Reporting bias: Unclear risk. T-test results not presented for all demographic variables assessed. No details on surgery length, or number of days spent in hospital, despite this being discussed in the text, Other bias: Unclear - generally the methods were poorly reported, and data not
Study dates	January 2007			
Source of funding	The study was supported by the Ministry of Health Care of the Czech Republic (NS 10453-3/2009)			

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	<ul style="list-style-type: none"> <li>• History of radiotherapy of the pelvis</li> <li>• Women requiring hysterectomy</li> </ul>					clearly presented.
Full citation	Sample size	Interventions	Details	Results	Limitations	
Dietz, V., van der Vaart, C. H., van der Graaf, Y., Heintz, P., Schraffordt Koops, S. E., One-year follow-up after sacrospinous hysteropexy and vaginal hysterectomy for uterine descent: a randomized study, International Urogynecology Journal, 21, 209-16, 2010	Total N = 71 Vaginal hysterectomy (VH): 34 Sacrospinous hysteropexy (SH): 37  The sample size was 61 women per group (Total N = 122), calculated for an expected difference of 25% between groups, at 80% power, alpha of 0.05.	Vaginal hysterectomy The uterosacral ligaments were reattached with resorbable sutures to the vaginal cuff after removal of the uterus Median length of hospital stay (range): 4 days (3 -14)	Experienced gynaecologist from the six hospitals performed all vaginal hysterectomy procedures, sacrospinous hysteropexy was performed by those with special skills in pelvic floor surgery, and had performed at least 20 operations before the study started.	12 months Cure (POP-Q 0-1) (n/N) VH: 30/34 SH: 27/37  Recurrence (n/N) VH: 9/34 SH: 3/37  Repeat surgery for POP (n/N) VH: 2/34 SH: 4/37	The sample size was not reached Unclear numbers having SUI surgery, anterior and or posterior colporrhaphy that had recurrence/cure /repeat surgery  Other information	
Ref Id 541377	Characteristics Mean age	Sacrospinous hysterectomy Performed unilaterally to the right ligament. A midline incision in the	Both procedures were combined with anterior or posterior		Allocation bias: High risk, randomisation occurred by drawing sealed envelopes. The participants in the vaginal hysterectomy	

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Netherlands	VH: 63.7 years (SD 9.0) SH: 61.5 years (SD 9.6)	posterior vaginal wall was extended to the posterior part of the cervix. Non-absorbable sutures were placed through the right sacrospinous ligament and then placed through the posterior side of the cervix in the midline. The cervix was placed in close contact with the ligament.	colporrhaphy when required  If SUI also existed, tension free vaginal tape was inserted.  All women received perioperative thrombosis prophylaxis and a single dose of intravenous prophylactic antibiotic before surgery.		group were significantly older than the sacrospinous hysteropexy group.  Allocation concealment: Low risk, sealed, opaque envelopes were used  Performance bias: High risk, care staff and participants aware of allocation  Detection bias: Unclear risk, no details of blinding of assessors  Attrition bias: Low risk, less than 15% loss to follow up  Reporting bias: Low risk, expected outcomes presented in tables and text.
Study type					
Non-blinded randomised study. Conducted across six hospitals	Mean BMI VH: 25.9kg/m <sup>2</sup> (SD 2.9) SH: 26.3kg/m <sup>2</sup> (SD 3.2)				
Aim of the study	Median Parity (range) VH: 2 (1-7) SH: 2 (0-5)				
To compare vaginal hysterectomy with sacrospinous hysteropexy for uterine descent (stage 2-4)	Inclusion criteria				
Study dates					
February 2004 to December 2006	• Women with uterine descent stage 2-4 according to the International conference Society classification system	Median length of hospital stay (range): 3 days (3 -7)			
Source of funding					
None stated. No conflicts of interest stated	• Normal uterus and				

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### Surgical management of pelvic organ prolapse

	<ul style="list-style-type: none"> <li>ovaries on ultrasound examination</li> <li>• Normal menstrual bleeding pattern (if pre-menopausal)</li> <li>• Normal cervical cytology</li> </ul> <p><b>Exclusion criteria</b></p> <ul style="list-style-type: none"> <li>• Women with Insulin dependent diabetes</li> <li>• Medical history of pelvic surgery</li> </ul>					
Full citation	Sample size	Interventions	Details	Results		Limitations
Nguyen, J. N., Burchette, R. J., Outcome after anterior vaginal prolapse repair: a randomized controlled trial,	N = 76 Anterior colporrhaphy (AC): N = 38 Polypropylene mesh (mesh): N= 38	Anterior colporrhaphy Performed through a midline anterior	A single surgeon conducted all procedures. All participants received perioperative intravenous	Optimal or satisfactory surgery at 1 year (optimal = both Aa and Bb at stage 0. Satisfactory = both Aa and Bb = stage 1) (n/N) AC: 21/38 Mesh: 33/38  De novo dyspareunia at 1 year (n/N) AC: 4/38		Allocation method Low risk: A computer generated schedule was used to

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Obstetrics & Gynecology, 111, 891-8, 2008		vaginal incision. Median, and range operation time was 120 minutes (60 to 150 minutes)	antibiotic prophylaxis and vaginal infiltration with 0.25% bupivacaine and 1:200,000 epinephrine solution. Menopausal women were advised to use estrogen vaginal cream for 6 weeks before and 2 weeks after surgery	Mesh: 2/38  Mean PFIQ-7 at 1 year (SD) AC: 23 (31) Mesh: 14 (23)  Mean PFDI-20 at 1 year (SD) AC: 45 (32) Mesh: 34 (31)	randomise participants. No observable differences occurred between groups at baseline
Ref Id	Characteristics	Mean Age in years (SD) AC: 59 (9.5) Mesh: 61 (10.5)	Polypropylene Mesh		
541578			Performed through an anterior midline vaginal incision. Mesh used was The Perigee Transbturator Prolapse Repair System (polypropylene mesh repair, American Medical Systems, Minnetonka, MN).		
Country/ies where the study was carried out	Median vaginal parity (range) AC: 3 (0 to 6) Mesh: 3 (0 to 5)		Post operative assessments were conducted at 8 weeks, 6 months, 1 year and annually for three years.		Allocation concealment Low risk: Assignment was concealed using sealed, opaque envelopes.
USA	Mean BMI kgm <sup>2</sup> (SD) AC: 27 (4) Mesh: 28 (3)		Previous prolapse surgery AC: 16% Mesh: 22%	Sample size Based on previously published success rates, 50% for AC and 85% for mesh repair, and assuming a two-tailed hypothesis, 5% type 1 error at 80% power, 33 participants per group were	Performance bias Unclear risk: The surgeon was blinded until the day of surgery. The participant, research nurse and medical assistants were blind to treatment assignment.
Study type		Urodynamic stress incontinence AC: 64% Mesh: 54%	Median and range operation time was 135 minutes(65 to 210 minutes).		
Randomized controlled trial	POP-Q Stage				
Aim of the study					
To compare the anatomic success rates, effect on quality of life, sexual symptom scores and rates of adverse events between polypropylene mesh and anterior colporrhaphy.					
Study dates					
Participants were recruited from					

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January 2005 to April 2006.	Stage II - AC: 61% / Mesh: 49% Stage III - AC: 37% / Mesh: 43% Stage IV - AC: 2% / Mesh: 8%		required to detect a difference of 35% or greater in recurrent stage II prolapse		out by a research nurse and medical assistant blinded to the participants group assignment.
Source of funding	Mean PFIQ-7 (SD) AC: 82 (54) Mesh: 77 (54)	Data Analysis Continuous variables were compared using two-tailed t tests or Wilcoxon rank sum tests. And categorical variables were compared using X <sup>2</sup> or Fisher exact test. Recurrent prolapse was analysed using an intention to treat analysis.			Attrition bias Low risk: 97% of participants received 1 year follow up assessments
The study was supported by an unrestricted grant from American Medical Systems (Minnetonka, Minnesota).	Mean PFDI-20 (SD) AC: 109 (58) Mesh: 108 (45)				Selective reporting Unclear risk: Primary outcomes are reported, but data is not clearly presented
Inclusion criteria	Women 21 years or above Stage II or greater anterior vaginal prolapse requiring				Other bias High risk The majority of participants also underwent concurrent pelvic reconstruction and anti-incontinence procedures in surgery.

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	surgical correction				The study was funded by the manufacturers of the mesh used within the study.
	Exclusion criteria				Other information

Women with stage 0 or 1 anterior vaginal support  
Were Pregnant or planning a pregnancy  
Prior anterior vaginal prolapse repair with biological or synthetic graft  
Active or latent systemic inflammation or comprised immune system  
Uncontrolled type 2 diabetes, previous pelvic irradiation or cancer known hypersensitivity

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	y to polypropylene Unwilling or unable to give informed consent, declined participation, unwilling or unable to comply with the protocol Scheduled for concomitant Burch colposuspension or pubovaginal sling				
Full citation	Sample size  Culligan, P. J., Salamon, C., Priestley, J. L., Shariati, A., Porcine dermis compared with polypropylene mesh for laparoscopic sacrocolpopexy: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 121, 143-51, 2013	Interventions  Total: N = 120 Porcine group (porcine) : N = 58 Mesh group (PP): N = 62  Characteristics  Mean age Total: 57 years (SD 8.4) Porcine: 58 years (SD 8.3) / PP: 56 years	Details  Porcine graft PelviSoft acellular collagen matrix  Mesh (PP) Polypropylene mesh, Pelvitex	Results  12 months Cure (POP-Q stage 0-1) n/N Porcine:46/58 PP: 50/62  Mesh exposure n/N Porcine: 1/58 PP: 0/62  Dyspareunia n/N Porcine: 2/58 PP: 3/62  Clinical cure (both objective and subjective) n/N Porcine: 48/58 PP: 52/62	Limitations  Unclear which surgeries were conducted with robotic assistance  Other information  Allocation bias: Low risk, computer generated block randomisation. No differences

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Ref Id 541339	(SD 8.5) p = 0.32		were conducted using the straight stick laparoscopic approach		were shown between the groups at baseline Allocation concealment: Low risk, the statistician created the sequentially, sealed opaque envelopes to ensure allocation concealment Performance bias: low risk, care staff and participants blind to treatment (only surgeons aware of treatment allocation) Detection bias: Low risk, assessors blind to treatment
Country/ies where the study was carried out	Mean BMI Total: 25.2 kg/m <sup>2</sup> (SD 3.3) Porcine: 24.8kg/m <sup>2</sup> (3.0) / PP: 25.6kg/m <sup>2</sup>				
USA					
Study type					
Double blind randomised controlled trial	(SD 3.6) p = 0.21				
Aim of the study	Vaginal Parity Total: 2.5 (SD 1.26) Porcine: 2.6 (SD 1.1) PP: 2.4 (SD 1.4)				
To compare an organic porcine graft to a synthetic polypropylene graft for laparoscopic sacrocolpopexy	Inclusion criteria				
	<ul style="list-style-type: none"> <li>• Women scheduled to undergo laparoscopic sacrocolpopexy for apical POP</li> </ul>				
Study dates					
2006 to 2008					
Source of funding					
The study was supported by CR Bard through an					

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### Surgical management of pelvic organ prolapse

unrestricted educational grant	(stage II or above)					Reporting bias: Unclear risk, all outcomes expected reported; however some data is presented in graphical format making interpretation difficult
	Exclusion criteria					
	<ul style="list-style-type: none"> <li>• Pregnant women, or those planning pregnancy in the future</li> <li>• Prior sacrocolpopexy</li> <li>• Any previous POP surgery with mesh material</li> </ul>					
Full citation	Sample size	Interventions	Details	Results	Limitations	
Vollebregt, A., Fischer, K., Gietelink, D., van der Vaart, C. H., Primary surgical repair of anterior vaginal prolapse: a randomised trial comparing anatomical and functional outcome between	N = 125 Anterior colporrhaphy (AC): N= 64 Trocar-guided transbturtor mesh (mesh): N = 61	Anterior colporrhaphy (AC) A midline incision of the vaginal epithelium was performed and the bladder dissected from	Six gynaecologists, whom had all performed over 20 trocar-guided transbturtor mesh procedures carried out the surgery	POP-Q stage less than 2 at 1 year follow up (n/N) AC: 23/64 Mesh: 53/61  POP-Q stage II or above at 1 year follow up (n/N) AC: 33/63 Mesh:5/61  12 months mesh exposure was observed in 2 participants (1 underwent re-operation)  De novo dyspareunia (n/N)	Allocation method Unclear risk: A computer randomisation table was used to allocate participants on a 1:1 basis. randomisation was stratified based	

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anterior colporrhaphy and trocar-guided transobturator anterior mesh, BJOG: An International Journal of Obstetrics & Gynaecology, 118, 1518-27, 2011	Characteristics Mean age in years (SD) AC: 59 (8.6) Mesh: 60 (9.1)	the vaginal wall. Women underwent either total (37%) or locoregional (63%) anaesthesia Mean surgery time was 41 minutes (ranging from 20 to 80minutes)	prophylactic antibiotics and thrombosis prophylaxis treatment inline with the study protocol	AC: 2/64 Mesh: 3/59  Reoperation with anterior mesh (n/N) AC: 3/64 Mesh: 0/61  Reoperation with posterior mesh (n/N) AC: 0/64 Mesh: 2/61	on the requirement to perform a sacrospinous hysteropexy. At baseline the use of depressive medication was higher in the mesh group.
Ref Id 541753	Mean parity (SD) AC: 2.7 (1.9) Mesh: 2.4 (0.9)	Trocar-guided transobturator mesh (Mesh)	Sample size calculation Sample size was based on anatomical failure rate of 35% in the AC group at 1 year. To enable detection of a difference at a significance level of 0.05, with a power of 0.80, 50 women were required per treatment arm. the authors initially estimated a 15% dropout rate, but extended this to 25% due to an intended increase in the follow up period to 5 years; therefore 125 women were		Allocation concealment Unclear risk: No details are provided as to concealment of the randomisation procedure.
Country/ies where the study was carried out The Netherlands	POP-Q Stage Stage < II - AC: 0% / Mesh: 0%	The Avaulta anterior mesh system was used (Bard, Covington, LA, USA). Mesh was placed according to the product guidelines			
Study type Randomised controlled trial	Stage II - AC: 23% / Mesh: 25% Stage III - AC: 77% / Mesh: 75%	Women underwent total (39%) or locoregional (61%) anaesthesia Mean surgery time was 48			
Aim of the study To compare anterior colporrhaphy to a trocar-guided transobturator mesh procedure for cystocele repair	Inclusion criteria Women aged 40 to 80 years Diagnosed with bothersome				Blinding Unclear risk: The participants and surgeons were aware of treatment allocation; however those undertaking assessments were not.
					Detection Bias Unclear risk: Assessors

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Study dates	pelvic organ prolapse (cytotocele stage II or above, on POP-Q criteria)	minutes (ranging from 25 to 90 minutes)	required for the study.		were blind to treatment allocation; however for self-report measures the risk of bias is increased as participants were not blind to treatment.
June 2007 to May 2009	Indication for surgical correction		Data analysis Analyses were conducted using Intention-to-treat. Unpaired student t tests and Mann-Whitney U-tests were used appropriately for normal and skewed data. Relative risks and absolute risk reduction numbers were both calculated. Postmenopausal women in the mesh group were advised to use topical estrogens twice a week post operatively		Attrition bias Low risk: 88% completed 1 year follow up
No funding is stated	Exclusion criteria  Women of child bearing age who had not completed their planned family, or who had inadequate birth control History of urogynaecological surgery for pelvic organ prolapse Urinary stress urinary incontinence with an indication for surgical correction				Selective reporting Low risk: Outcomes presented  Other information

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	History of cancer of chronic obstructive pulmonary disease Recurrent urinary tract infections (more than 3 cases per year) Maximum bladder capacity of less than 300ml Indication for hysterectomy					
Full citation	Sample size  Natale, F., La Penna, C., Padoa, A., Agostini, M., De Simone, E., Cervigni, M., A prospective, randomized, controlled study comparing Gynemesh, a synthetic mesh, and Pelvicol, a biologic graft, in the surgical treatment of recurrent cystocele,	Interventions  Total = 190 Pelvicol: 94 Gynemesh: 96  Characteristics  Mean age Total: 65 years (SD 8.6) Pelvicol: 67 years (SD 8.1) / Gynemesh: 63 years (SD 8.5)	Details  Pelvicol (R) : Derived from porcine dermis. The implant is made from dermal collagen and elastin fibres. The collagen is stabilised by diisocyanate cross-linking, and it is resistant to breakdown.	Results  All participants underwent cystocele repair surgery, implants were trimmed and shaped in the same way for both interventions Three different surgeons conducted the operations All women underwent regional aesthetics and	24 months  Cure (ba stage 0-1) n/N Gynemesh: 69/96 / Pelvicol: 53/94  Recurrence (of anterior POP) n/N Gynemesh: 27/96 / Pelvicol: 41/94  Dyspareunia n/N Gynemesh: 10/96 / Pelvicol: 12/94  Constipation n/N Gynemesh: 8/96 / Pelvicol: 6/94  6 months  Mesh erosion n/N Gynemesh: 6/96 / Pelvicol: 0/94	Limitations  Other information  Allocation bias: Unclear risk - No details provided; however groups do not show any differences at baseline Allocation concealment: Unclear risk - no details provided

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International Urogynecology Journal, 20, 75-81, 2009	Mean BMI Total: 25.31kgm <sup>2</sup> (SD 5.1) Pelvicol: 24.7kg/m <sup>2</sup> (SD 4.5) / Gynemesh: 25.9kg/m <sup>2</sup> (SD 5.5)	Gynemesh PS (R): A monofilament, large pore polypropylene, non-absorbable mesh. It is made of knitted fibres, and is specifically designed for pelvic floor surgery	received antibiotics before and after surgery. Women also underwent high levator myorrhaphy of the vaginal apex		Performance bias: Unclear risk - no details of blinding of surgeons, care administrators, or subjects Detection bias: Unclear risk - no details of blinding of assessors Attrition bias: Low risk - All patients completed the 2 year follow up Reporting bias: Low risk - all expected outcomes reported
Ref Id 541573					
Country/ies where the study was carried out Italy	Sexually active n/N Total: 104/190 Pelvicol: 48/94 / Gynemesh: 56/96				
Study type Prospective randomised study	Inclusion criteria				
Aim of the study To determine incidence of vaginal mesh erosion between Pelvicol and Gynemesh in women with recurrent cystocele	<ul style="list-style-type: none"> <li>• Women with recurrent, symptomatic anterior prolapse (stage 2 or greater, point Ba≥-1)</li> <li>• Women planning to have surgery for POP</li> </ul>				
Study dates September 2003 to November 2005					

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Source of funding	Exclusion criteria				
No financial support was provided for the study	<ul style="list-style-type: none"> <li>• Women requiring concomitant anti-incontinence surgery</li> <li>• Women with diabetes mellitus</li> <li>• women with collagen disease</li> </ul>				
Full citation	Sample size	Interventions	Details	Results	Limitations
Roovers, J. P. W. R., Van Der Vaart, C. H., Van Der Bom, J. G., Schagen Van Leeuwen, J. H., Scholten, P. C., Heintz, A. P. M., A randomised controlled trial comparing abdominal and vaginal prolapse surgery: Effects on urogenital function, BJOG: An International	Total: N = 82 Abdominal surgery (AS): N = 41 Vaginal surgery (VS): N = 41  Characteristics Mean age Total: 58 years (SD 9.01)	Abdominal surgery A sacro-colpopexy conducted with preservation of the uterus. The vaginal was dissected from the bladder anteriorly and from the rectum posteriorly, providing a multi-	A colposuspension was conducted at the same time for women who also had stress incontinence All surgeries were performed by experienced gynaecologists, who were experienced with both techniques, (performing at least 50 of each	12 months Repeat surgery for POP n/N AS: 5/41 VS: 0/41  In surgery adverse events Blood transfusion n/N AS: 1/41 VS: 2/41  Bowel injury n/N AS: 0/41 VS: 1/41	Limited inclusion criteria stated  Other information  Allocation bias: Low risk, randomisation was conducted using a computer generated list. No differences

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Journal of Obstetrics and Gynaecology, 111, 50-56, 2004	AS: 58 years (SD 8.8) / VS: 56 years (SD 10.9)	compartment approach. Mean operative time: 97 minutes (SE 3.6)	before the study began) All women received peri-operative deep vein thrombosis prophylaxis.		were reported between groups at baseline
Ref Id 632217	Mean BMI Total: 25.18kg/m <sup>2</sup> (SD 3.07)	Mean length of hospital stay: 7.7 days (SE 0.2)	All women received a single dose of intravenous prophylactic antibiotic during the surgery		Allocation concealment: Low risk, randomisation codes were kept in sealed envelopes and were unknown to any participating gynecologists
Country/ies where the study was carried out	AS: 25.1kg/m <sup>2</sup> (SD 3.0) / VS: 26.0kg/m <sup>2</sup> (SD 3.6)	Vaginal surgery A vaginal hysterectomy combined with anterior and or posterior colporraphy if required			Performance bias: Unclear risk, it is unclear if participants and or care staff are blind to treatment allocation
Netherlands	Study type Multi-centre randomised trial	Mean parity Total: 2.86 (SD 1.11) AS: 2.9 (SD 1.1) / VS: 25. (SD 1.2)	The vaginal vault position was fixed with absorbable sutures to the cardinal-uterosacral ligaments Mean operative time: 107 minutes (SE 4.7)		Detection bias: Unclear risk, no details are provided in relation to blinding of assessors
Aim of the study To compare functional and anatomical outcomes following abdominal or vaginal surgery for uterine prolapse	Inclusion criteria <ul style="list-style-type: none"><li>• Women with intact uteri</li></ul> Exclusion criteria <ul style="list-style-type: none"><li>• Presence of an adnexal mass</li></ul>	Mean length of stay in hospital: 7.6 days (SE 0.3)			Attrition bias: Low risk, less than 15% lost to follow up Reporting bias: Unclear risk, mean and SD
Study dates January 1998 to July 2000					

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Source of funding Not stated	<ul style="list-style-type: none"> <li>• A history of more than two pelvic floor surgeries</li> <li>• BMI greater than 35kg/m<sup>2</sup></li> <li>• Women with prior inflammatory bowel or pelvic disease</li> <li>• Faecal incontinence due to an internal or external sphincter defect</li> </ul>				are not presented in text, only OR.
Full citation  Freeman, R. M., Pantazis, K., Thomson, A., Frappell, J., Bombieri, L., Moran, P., Slack, M., Scott, P., Waterfield, M., A randomised controlled trial of abdominal versus	Sample size  Total = 54 Laparoscopic sacrocolpopexy (LSC): 26 Abdominal sacrocolpopexy (ASC): 28	Interventions  Limited information provided: Procedures were performed in a standardised manner, following training of surgeons	Details  Prophylactic antibiotics were given Anti-embolism stockings were used as prophylaxis, and low dose heparin for thromboembolism	Results  12 month follow up data Mesh exposure n/N LSC: 0/28 ASC: 0/26  SUI n/N LSC: 4/28 ASC: 0/26  Prolapse quality of life (P-QOL) (change from baseline)_ LSC: -51.4 (SD 26.04)	Limitations  Small number of participants Limited methods provided.  Other information  Risk of Bias

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Laparoscopic sacrocolpopexy for the treatment of post-hysterectomy vaginal vault prolapse: LAS study, International Urogynecology Journal, 24, 377-84, 2013	Characteristics Mean age Total: 62 years LSC: 63 years (SD 6.6) / ASC: 61 years (SD 8.1)	Polypropylene mesh was attached anteriorly and as far down the posterior wall as possible. The mesh was attached to the sacral promontory and was covered with the peritoneum.	ASC: -46.1 (SD 19.73)	Allocation Bias: Unclear risk - Computer generated block randomisation, participants were randomised to a particular surgeon. Differences in baseline data between groups is not provided, and differences are likely.
Ref Id 541413	Mean BMI Total: 27.36kg/m <sup>2</sup> (SD 4.07) LSC: 27.26kg/m <sup>2</sup> (SD 3.46) / ASC: 27.46kg/m <sup>2</sup> (SD 4.65)			
Country/ies where the study was carried out UK	Laparoscopic sacrocolpopexy (LSC) Mean operating time: 144 minutes (SD 28)			Allocation concealment: Unclear risk - No information provided
Study type Prospective multi-centre equivalence trial	Previous POP surgery n/N Total: 22/54 LSC: 12/26 / ASC: 10/28	Mean length of stay in hospital: 3.2 days (SD 1.1)		Performance Bias: Unclear risk - Participants not blind; however care staff were blinded
Aim of the study To test the clinical equivalence of open (abdominal) and laparoscopic sacrocolpopexy	Inclusion criteria <ul style="list-style-type: none"><li>• Women with symptomatic and "bothersome" vault prolapse</li></ul>	Abdominal sacrocolpopexy (ASC) Mean operating time: 131 minutes (SD 44)		Detection Bias: Low risk - Assessors were blind to allocation
				Attrition Bias: Low risk, < 15% dropout, no differences

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Study dates 2006 to 2008	<ul style="list-style-type: none"> <li>Prolapse greater or equal to POP-Q stage 2 Women with or without concomitant cystocele and rectocele</li> </ul>	Mean length of stay in hospital: 4.1 days (SD 1.6)				between the interventions in drop out rates Reporting Bias: Unclear risk - No baseline comparison of groups provided
Source of funding  The study was supported by a competitive grant from the Plymouth Surgical Services Trust	<p>Exclusion criteria</p> <ul style="list-style-type: none"> <li>Women who were considered medically unfit for sacrocolpopexy</li> <li>Women in need of concomitant pelvic or stress urinary incontinence surgery</li> <li>Women with a BMI <math>\geq 35\text{kg}/\text{m}^2</math></li> </ul>					

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	<ul style="list-style-type: none"> <li>• Women who had previously undergone abdominal or vaginal vault prolapse surgery</li> </ul>				
Full citation	Sample size	Interventions	Details	Results	Limitations
Roovers, J. P. W. R., Van Der Bom, J. G., Van Der Vaart, C. H., Schagen Van Leeuwen, J. H., Scholten, P. C., Heintz, A. P. M., A randomized comparison of post-operative pain, quality of life, and physical performance during the first six weeks after abdominal or vaginal surgical correction of descensus uteri, <i>Neurourology and Urodynamics</i> , 24, 334-340, 2005	See details in Roovers 2004	See details in Roovers 2004	See details in Roovers 2004	See details in Roovers 2004	See details in Roovers 2004

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Ref Id						
632235						
Country/ies where the study was carried out						
Netherlands						
Study type						
See details in Roovers 2004						
Aim of the study						
See details in Roovers 2004						
Study dates						
See details in Roovers 2004						
Source of funding						
See details in Roovers 2004						
Full citation	Sample size	Interventions	Details	Results		Limitations
Lamblin,G., Van-Nieuwenhuyse,A., Chabert,P., Lebail-Carval,K., Moret,S.,	N=68 Vaginal colposuspension (VC): N= 35	Vaginal colposuspension (VC) A nonresorbable	Surgery was performed by surgeons experienced in pelvic floor	Asymptomatic stage 1 cystocele at 1 year (n/N) VC: 6/35 Mesh: 5/33 Asymptomatic stage 1 cystocele at 2 years (n/N) VC: 11/35		Allocation bias: Low risk: Assigned by the co-ordination

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Mellier,G., A randomized controlled trial comparing anatomical and functional outcome between vaginal colposuspension and transvaginal mesh, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 961-970, 2014	Vaginal mesh (mesh): N= 33  Characteristic s  Mean age: years (SD) VC: 65 (1.3) Mesh: 65 (1.3)	suture is anchored to the internal side of the vagina on the pubovesical fasica. Colpo suspension is bilateral, suspending the entire anterior vaginal wall. Mean operation time was 74.6 (3.8) minutes.  Parity: Mean (SD) VC: 2.7 (0.2) Mesh: 3 (0.3)	surgery and mesh repair. In menopausal patients (97% VC and 100% Mesh), local estrogen therapy (two Colpotrophine capsules per week for three months) was initiated at the end of the surgery to help tissue regeneration. Sexual relations, sporting activities, baths and vaginal douches were advised against for 6 weeks. Patients were advised to return to work after 4 weeks. Anticholinergics were proscribed to all participants.	Mesh: 10/33  Recurrence of POP-Q stage 2 or above at 1 year VC: 4/35 Mesh: 0/33  Recurrence of POP-Q stage 2 or above at 2 years VC: 5/35 Mesh: 0/33  Revision of surgery (n/N) VC: 0/35 Mesh: 1/33  Mesh exposure occurred in two patients at 3 months and 2 years.  De novo dyspareunia (n/N) VC: 1/35 Mesh: 1/33	centre in a block design. No significant differences observed between the groups at baseline.  Allocation concealment Low risk: Central allocation centre
Ref Id  328104	Mean BMI: kg/m <sup>2</sup> (SD) VC: 26.4 (0.7) Mesh: 26.3 (0.5)	Women underwent either regional (23%) or general (77%) anaesthesia.		Mean score PFIQ-7 at 1 year (SD) VC: 20 (5) Mesh: 27 (9)  Mean score PFIQ-7 at 2 years (SD) VC: 23 (9) Mesh 28 (10)	Performance bias  High risk: Patients and surgeons were aware of allocation prior to surgery
Country/ies where the study was carried out  France	Previous prolapse repair (Abdominal) VC: 6% Mesh: 3%  Previous prolapse repair (Vaginal) VC: 11% Mesh: 15%	Transvaginal mesh (Mesh)  The Perigee transbturator anterior compartment repair system (AMS) is a medium-weight, highly porous polypropylene monofilament mesh. The		Mean PFDI-20 score at 1 year (SD) VC: 42 (7) Mesh: 50 (7)  Mean PFDI-20 at 2 years (SD) VC: 40 (7) Mesh: 49 (9)	Detection bias  High risk: No detail as to who assessed the POP-Q stage at follow up, unclear if this was a blinded clinician or the surgeon who completed the surgery. Self
Aim of the study  To compare native-tissue vaginal			Randomisation An independent study centre conducted randomisation		

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colposuspension to transobturator vaginal mesh. Secondary aims were to compare the functional outcomes relating to morbidity and onset of UI, using validated questionnaires.	Previous incontinence surgery VC: 6% Mesh: 3%	mesh is inserted into the obturator foramen and attached with polypropylene stiches to either the uterine isthmus or apical vaginal wall.	using preformed six-blocks, unblended randomisation on SAS statistical software.			report for secondary outcomes.  Attrition bias Low risk: 93% completed 24 month follow up data.
Study dates  September 2008 to June 2011, with follow up until July 2013.	Stress urinary incontinence VC: 26% Mesh: 45%	Overactive bladder VC: 11% Mesh: 3%	Sample size The study anticipated a 20% failure rate for the VC surgery and 5% for mesh surgery, demonstrating clinically significant benefit of the mesh technique. Using a bilateral hypothesis with an alpha risk of 5%, a difference of 15% and 80% power, the sample required 88 participants per group (176 in total). This number was not reached, despite an additional one year inclusion period.			Selective reporting Unclear risk. Data not always clearly presented in the paper.
Source of funding  The study was supported by Claude Bernard University financing and Hospices Civils de Lyon	Ba point (cm) Stage III VC: 91% Mesh: 100%	Ba point (cm) Stage IV VC: 9% Mesh: 0%				Other Bias The study did not meet the planned sample size, only 68 participants were randomised.
	PFIQ-7 score: Mean (SD) VC: 76.1 (9.8) Mesh: 73.0 (10.7)	PFDI-20 score: Mean (SD) VC: 102.8 (8.1)			Data analysis	Other information

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	Mesh: 120.2 (9.7)	Categorical variables were compared by X <sup>2</sup> or Fishers exact test, if n equalled 5 or greater. Continuous variables were compared using student t-test.		
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	Uncontrolled type 2 diabetes Polypropylene hypersensitivity Receiving treatment which affects the immune response (either ongoing or received within the previous month) Pathology with complication risks, such as coagulation disorder, malignancy, immunologic disease)					
Full citation	Sample size	Interventions	Details	Results	Limitations	Other information
Culligan, P. J., Blackwell, L., Goldsmith, L. J., Graham, C. A., Rogers, A., Heit, M. H., A randomized controlled trial comparing fascia	Total number: 100  Fascia group: 50  Mesh group: 50  Authors state a sample size	In the mesh group, Polypropylene (Trelex, Boston Sceintific, MA) mesh was used.	All patients underwent a urogynecology assessment. Each woman was individually assessed as to whether she needed	12 months Cure (POP-Q stage 0-1) Fascia: 30/50 Mesh: 41/50  60 months Cure (POP-Q stage 0-1) Fascia: 18/50 Mesh: 27/50	Study funded by producers of the fasica graft material	

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lata and synthetic mesh for sacral colpopexy, Obstetrics & Gynecology, 106, 29-37, 2005	of 100 was adequate for generalised estimating equation for POP stage	In the fascia group, solvent dehydrated cadaveric fascia lata (Tutoplast, Suspend fascia lata, Mentor Corporation, Santa Barbara, CA) was used.	concomitant continence surgery	mesh erosion (n/N) Fascia: 1/50 Mesh: 2/50	Allocation bias: High risk - Computer random number generation, however, significant differences exist between groups at baseline Allocation concealment: Low risk - Opaque sealed envelopes used, randomisation list held by statistician Performance bias: High risk - Participants blind to treatment, but care administrators aware of allocation Detection bias: Low risk - Assessors not aware of treatment allocation Attrition bias: Low risk - less
Ref Id  541336	Characteristic s				
Country/ies where the study was carried out	Mean age Fascia: 57.5 years (SD 10.8) Mesh: 60.4 years (SD 10.1)				
USA					
Study type					
Double blind randomized controlled trial	Mean BMI Fascia: 27.3kg/m <sup>2</sup> (SD 3.9) Mesh: 28.4kg/m <sup>2</sup> (SD 4.7)				
Aim of the study					
To compare cadaveric fascia lata and polypropylene mesh for sacral colpopexy	Median Vaginal Parity Fascia: 2 Mesh: 3				
Study dates	Inclusion criteria				
July 2001 and June 2003	Women with vaginal vault prolapse,				

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Source of funding  The study was supported by the Mentor Corporation, Santa Barbara, California	scheduled for sacral colpopexy					than 15% drop out at 12 months  Reporting bias: Low risk - Data from outcomes expected reported  Other bias: Study funded by producers of the fasica graft material  Results are from Tate 2011 (Culligan 2005 paper only gives failure rates)
	Exclusion criteria					
Full citation  Minassian, V. A., Parekh, M., Poplawsky, D., Gorman, J., Litzky, L., Randomized controlled trial comparing two procedures for anterior vaginal wall prolapse, Neurourology & Urodynamics, 33, 72-7, 2014  Ref Id	Sample size  Total: N= 70 Anterior colporrhaphy with mesh (AC): N = 35 Paravaginal repair (PVR): N = 35  Ref Id	Interventions  Anterior colporrhaphy (AC) Conducted in the traditional manner and used polyglactin 910 (vicryl) mesh Mean operative time: 283 minutes (SD 84)	Details  Women may also have undergone hysterectomy, sacropcolpopexy , midurethral slings or rectocele  Characteristics  Mean age	Results  12 months Cure (POP-Q stage 0-1) n/N AC: 29/35 PVR: 28/35  Mean change in sexual function score (PSIQ-12) AC: -6 (SD 9) PVR: -4 (SD 6)  24 months Cure (POP-Q stage 0-1) n/N AC: 27/35 PVR: 25/35	Limitations  Allocation bias: Low risk, computer generated randomisation. No differences between groups at baseline Allocation concealment: Low risk - sealed enveloped were used to	

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541553	Total: 54 years (SD 11.62) Country/ies where the study was carried out USA	Median length of hospital stay: 3 days AC: 54 years (SD 10.6) / PVR: 53 years (SD 12.7) p = 0.74			conceal allocation Performance Bias: High risk - participants and care staff aware of treatment allocation non-blind study Detection bias: High risk - assessors aware of treatment Attrition bias: High risk- greater than 15% loss to follow up at 2 years Reporting bias: Low risk - all expected outcomes presented
Study type	Prospective randomised controlled trial	Mean BMI Total: 28.50kg/m <sup>2</sup> (SD 4.53) AC: 27.8kg/m <sup>2</sup> (SD 4.3) / PVR: 29.2kg/m <sup>2</sup> (SD 12.7) p = 0.19	Paravaginal Repair (PVR) Followed the technique by Schull et al 1989 mean operative time: 267 minutes (SD 85)		
Aim of the study	To compare anterior vaginal colporrhaphy surgery carried out with polyglactin 910 mesh to abdominal paravaginal repair	Median length of hospital stay: 2 days Median Parity AC: 2 (IQR 2,3) / PVR: 3 (IQR 2, 3) p = 0.13			
Study dates	January 2006 to February 2010	Sexually active n/N Total: 47/70 AC: 22/35 / PVR: 25/35 p = 0.82			Other information
Source of funding	Not stated	Inclusion criteria			

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<ul style="list-style-type: none"><li>• women with primary or recurrent anterior vaginal wall prolapse</li><li>• Women over the age of 18 years</li><li>• women with symptomatic anterior prolapse scheduled for surgery</li></ul> <p>Exclusion criteria</p> <ul style="list-style-type: none"><li>• Women who were pregnant or lactating</li><li>• Women who were not willing to provide informed consent</li><li>• Women who had</li></ul>			
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	more than one previous failed anterior prolapse repair					
Full citation	Sample size	Interventions	Details	Results		Limitations
Tate,S.B., Blackwell,L., Lorenz,D.J., Steptoe,M.M., Culligan,P.J., Randomized trial of fascia lata and polypropylene mesh for abdominal sacrocolpopexy: 5-year follow-up, International urogynecology journal and pelvic floor dysfunction, 22, 137-143, 2011	See Culligan 2013 for details	See Culligan 2013 for details	See Culligan 2013 for details	See Culligan 2013 for details		See Culligan 2013 for details
Ref Id	Characteristics					Other information
135600	See Culligan 2013 for details					Allocation bias: Computer generated block randomisation. Those allocated to the Fascia intervention had significantly higher vaginal parity than those in the mesh group
Country/ies where the study was carried out	Inclusion criteria					Allocation concealment: Low risk, the statistician held the
USA	Exclusion criteria					
	See Culligan 2013 for details					

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Study type					randomisation list, which was contained in sealed opaque envelopes
See Culligan 2013 for details					Performance bias: High risk, the care team were aware of treatment allocation. Participants were blinded
Aim of the study					Detection bias: Low risk, the assessors were blind to treatment allocation
See Culligan 2013 for details					Attrition bias: Unclear risk, less than 15% loss to follow up at 12 months follow up overall; however, difference in drop out rates were seen between the two groups.
Study dates					Reporting bias: Low risk, expected outcomes were reported.
See Culligan 2013 for details					
Source of funding					
See Culligan 2013 for details					

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Full citation	Sample size	Interventions	Details	Results	Limitations
Detollenaere, R. J., den Boon, J., Stekelenburg, J., IntHout, J., Vierhout, M. E., Kluivers, K. B., van Eijndhoven, H. W., Sacrospinous hysteropexy versus vaginal hysterectomy with suspension of the uterosacral ligaments in women with uterine prolapse stage 2 or higher: multicentre randomised non-inferiority trial, BMJ, 351, h3717, 2015	Total number = 208	Sacrospinous hysteropexy (SH) Sacrospinous hysteropexy (SH): n = 103 Vaginal hysterectomy (VH): n = 105	All women received perioperative antibiotics, prophylaxis against thrombosis and a bladder catheter the posterior vaginal wall was incised and the sacrospinous ligament accessed through the pararectal space Mean operating time: 59 minutes (SD 13)	Data at 12 months Recurrence of apical prolapse (POP stage $\geq 2$ ) SH: 6/103 VH: 10/105  Cure (POP stage 0-2, calculated from failure rates) SH: 52/103 VH: 61/105  Repeat surgery (any compartment) SH: 1/103 VH: 4/105	limitation stated in paper: Residents were allowed to perform the interventions under supervision of a gynaecologist, which may have led to variation in procedures.
Ref Id		Characteristic s			Other information
541367		Median age (range) SH: 61.7 years (45-85) VH: 61.9 years (33-82)			Allocation bias: Low risk, stratified randomisation conducted using a web-based system. No differences in baseline characteristics were shown between the groups.
Country/ies where the study was carried out	Mean number of vaginal birth deliveries (range) SH: 2 (0-7) VH: 3 (0-7)	Median number of vaginal birth deliveries (range) SH: 2 (0-7) VH: 3 (0-7)	Mean length of hospital stay: 3 days (SD 1)		Allocation concealment: Low risk, web-based
Netherlands	Mean BMI (SD) SH: 26.0kg/m <sup>2</sup> (3.3)	Vaginal hysterectomy (VH) The vaginal wall around the cervix was circumcised. The uterus			
Study type					

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Multi-centred randomised, non-blinded, non-inferiority trial All centres were large Dutch non-university teaching hospitals	VH: 25.9kg/m <sup>2</sup> (3.5)	was released in several steps using clamps and sutures. The uterus was removed and peritoneum closed using a delayed absorbable suture. Additional vault support was provided by attachment of the uterosacral ligaments to the vaginal vault.			allocation system Performance Bias: High risk, both care staff and participants aware of treatment allocation Detection bias: Low risk, an independent doctor conducted the 12 month assessment Attrition bias: Low risk, less than 15% lost to follow up Reporting bias: Unclear risk, all expected outcomes presented; however, mean and SD not always presented, therefore data could not always be included in the meta-analysis
Aim of the study		Inclusion criteria	<ul style="list-style-type: none"> <li>• Women with uterine prolapse stage 2 or greater</li> </ul>		
To determine if sacrospinous hysteropexy was non-inferior to vaginal hysterectomy with suspension of the uterosacral ligaments for uterine prolapse		Exclusion criteria	<ul style="list-style-type: none"> <li>• Women with previous pelvic floor or prolapse surgery</li> <li>• Women with known malignancy or an abnormal cervical smear</li> <li>• A desire to preserve fertility</li> </ul>		
Study dates	November 2009 to March 2012				
Source of funding  the study was supported by an unrestricted grant from the Isala research foundation.					

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	<ul style="list-style-type: none"> <li>• Women with language barriers</li> <li>• Women with immunological or haematological disorders</li> <li>• Women with abnormal ultrasound findings of the uterus or ovaries</li> <li>• Women with abnormal bleeding</li> <li>• Unwilling to return for follow - up</li> </ul>				
Full citation	Sample size	Interventions	Details	Results	Limitations
Salamon, C. G., Lewis, C. M., Priestley, J., Culligan, P. J., Sexual function before and 1 year after laparoscopic sacrocolpopexy,	See Culligan 2005 for details	See Culligan 2005 for details	See Culligan 2005 for details	See Culligan 2005 for details	See Culligan 2005 for details
	Characteristics				Other information

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Female Pelvic Medicine & Reconstructive Surgery, 20, 44-7, 2014	See Culligan 2005 for details				See Culligan 2005 for details
Ref Id	Inclusion criteria				
541662	See Culligan 2005 for details				
Country/ies where the study was carried out					
USA	Exclusion criteria				
Study type	See Culligan 2005 for details				
See Culligan 2005 for details					
Aim of the study					
See Culligan 2005 for details					
Study dates					
See Culligan 2005 for details					
Source of funding					
See Culligan 2005 for details					

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Full citation	Sample size	Interventions	Details	Results	Limitations
Lopes, E. D., De Barros Moreira Lemos, N. L., Da Silva Carramao, S., Lunardelli, J. L., Ruano, J. M. C., Aoki, T., Auge, A. P. F., Transvaginal polypropylene mesh versus sacrospinous ligament fixation for the treatment of uterine prolapse: 1-year follow-up of a randomized controlled trial, International Urogynecology Journal, 21, 389-394, 2010  Ref Id 632426	Total: 32 Synthetic mesh (SM): 16 sacrospinous ligament fixation (SSLF): 16  Characteristic s Mean age Total: 64 years SM: 66 years / SSLF: 63 years  Mean BMI Total: 25.75kg/m <sup>2</sup> SM: 25.7kg/m <sup>2</sup> / SSLF: 25.8kg/m <sup>2</sup>	Synthetic mesh (SM) Correction of apical prolapse with a synthetic, monofilament polypropylene mesh kit - Nazca R(R) Sacrospinous ligament fixation (SSLF) Unilateral SSLF with non-absorbable polyester sutures  Parity (n) SM: 4 / SSLF: 3.3	Women had vaginal hysterectomy plus anterior and posterior reconstruction  Mean operative time: 117.14 minutes (SD 33.14)	12 months follow up Recurrence (Ba >1) n/N SM: 8/16 SSLF: 7/16  Mesh erosion n/N SM: 5/16 SSLF: 0/16  De novo urgency SM: 1/16 SSLF: 1/16	Limited methods Small study sample  Other information  Allocation bias: Low risk - Participants were randomised using computer generated tables. No differences were shown between groups at baseline Allocation concealment: Unclear risk - no details provided Performance bias: Unclear risk - no details regarding the blinding of care personnel or participants Detection bias: Unclear risk -
Country/ies where the study was carried out	Inclusion criteria				
Brazil					
Study type					

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Randomised controlled trial Conducted at two university urogynecology centres in Sao Paulo	<ul style="list-style-type: none"> <li>• Women aged 50 to 75 years</li> <li>• Women with uterine prolapse (POP-Q stage III and IV)</li> </ul>			
Aim of the study	Exclusion criteria			
To compare the use of posterior polypropylene mesh kit to sacrospinous ligament fixation for uterine prolapse surgery	<ul style="list-style-type: none"> <li>• Women with a history of implants for pelvic floor surgery</li> <li>• A diagnosis of coagulation disorder</li> </ul>			
Study dates  June 2006 to May 2008	<ul style="list-style-type: none"> <li>• Women with renal failure</li> <li>• Women with a history of pelvic irradiation</li> <li>• Cognitive limitation which</li> </ul>			
Source of funding  Not stated				

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		could potentially limit the woman's ability to provide informed consent or complete quality of life questionnaires				
Full citation  Unlubilgin, E., Sivaslioglu, A. A., Ilhan, T. T., Kumtepe, Y., Dolen, I., Which one is the appropriate approach for uterine prolapse: Manchester procedure or vaginal hysterectomy?, Turkiye Klinikleri Journal of Medical Sciences, 33, 321-325, 2013  Ref Id 632517	Sample size  Total N = 94 VH: 49 MR: 45	Interventions  Characteristic s  Mean age Total: 51 years (SD 10.51) VH: 52 years (SD 11.04) / MR: 50 years (SD 10.02)	Details  All surgical procedures were performed by the same team  Mean operation time: 77.8 minutes (SD 13.6) Mean hospital stay: 2.88 days (SD 0.56)	Results  6 months follow up Recurrence n/N VH: 3/45 MR: 1/49  Quality of life (Q-POP) mean change VH-22.78 (SD 7.4) MR: -24.57 (SD 7.74)  SUI n/N VH: 4/45 MR: 0/49		Limitations  Other information  Allocation bias: Low risk - Randomisation by computer programme, no significant differences between groups at baseline Allocation concealment: Unclear risk - no details provided Performance bias: Unclear

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Country/ies where the study was carried out	VH: 26kg/m <sup>2</sup> (SD 4.6) / MR: 27kg/m <sup>2</sup> (SD 4.2)	colporrhaphy with cervical amputation Mean operative time: 62.4 minutes (SD 10.5) VH: 2.81 (SD 1.07) / MR: 3.01 (SD 1.05) Mean length of hospital stay: 2.58 days (0.56)			risk - no details provided regarding blinding of participants or care staff
Study type	Mean Parity Total: 2.9 (SD 1.06)				Detection bias: Unclear risk - no details regarding blinding of assessors
Randomised controlled trial Conducted in the Urogynecology Clinics of Ankara Etilik Zubeyde Hanim Women's Health Teaching and Research Hospital		Inclusion criteria <ul style="list-style-type: none"><li>• Women with uterine prolapse</li></ul>			Attrition bias: Low risk - all participants followed up
Aim of the study					Reporting bias: Low risk - all expected outcomes presented in article
To compare vaginal hysterectomy (VH) and Manchester repair (MR)	Exclusion criteria <ul style="list-style-type: none"><li>• Women with urinary incontinence</li></ul>				
Study dates					
July 2002 to March 2006					
Source of funding					
Not stated					



**Clinical evidence tables for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse? Non-RCT data**

**Table 32: Evidence tables for effectiveness studies; non-RCT data**

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Full citation Balci, O., Capar, M., Acar, A., Colakoglu, M. C., Balci technique for suspending vaginal vault at vaginal hysterectomy with reduced risk of vaginal vault prolapse, Journal of Obstetrics & Gynaecology Research, 37, 762-9, 2011 Ref Id 541257	Sample size Vaginal hysterectomy (IP) N= 65 Control group (USP) N=110 .  Characteristics <u>Age – mean ± SD</u> IP: 52.6 (4.9) USL: 53.3 (4.7) <u>Parity - mean ± SD</u> IP: 5.3 (1.9) USL: 5.1 (1.6)  <u>BMI -- mean ± SD</u> IP: 25.2 (3.4) USP:25.8 (3.6)	Interventions VH -IP (n=65) versus VH USL (n=110) Mean (SD) operation time: IP 57.(5) min vs USL 76 (9) min	Details Surgery The new surgery was explained to patients, and those who accepted the new operation were assigned to the study group. The surgery was performed by three surgeons.  Follow-up Follow-up measures at 4 years were assessed using questionnaires	Results  <u>At 52 months</u>  <u>Dyspareunia</u> VH-IP 13/65 or 24/175 VH USL 11/110  <u>Recurrence</u> VH-IP 1/65 or 13/174 VH USL 12/110	Limitations <u>Paper reported limitations</u> Short period of follow up  Other information Confounding bias: high risk of bias – Participants could choose whether to opt for the new or standard surgery  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
Country/ies where the study was carried out Turkey	Inclusion criteria Patients with total uterine prolapse (stage IV POPQ)				Classification of interventions bias: high risk of bias – participants could self-select to the intervention
Study type Prospective two arm non-randomised study	Exclusion criteria				

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Aim of the study To evaluate the new technique of suspending the vaginal vault at the infundibulo-pelvic (IP) ligament, compared to the traditional sacrospinous ligament (USL).</p> <p>Study dates Surgery performed between January 2003 and June 2005 with follow-up at 4 years.</p> <p>Source of funding None received</p>	Those with previous uterine surgery or malignant conditions				<p>Deviations from intended interventions bias: low risk of bias – once surgery performed, deviation not possible</p> <p>Missing data bias: moderate risk of bias – not all participants completed 4 years follow-up, reasons were not given for dropout</p> <p>Measurement of outcomes bias: low risk of bias – all outcomes were assessed using the same methods study</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data does not include all participants originally recruited</p>
Full citation	Sample size Original surgery, n=213 (97%) N = 223. N=140	Interventions women had an	Details Operations were performed by two	Results <u>Follow up</u> Median 5.2 years (range 1 to 12 years), mean 7 years	<p>Limitations</p> <p>Other information</p>

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Bedford, N. D., Seman, E. I., O'Shea R, T., Keirse, M. J., Long-term outcomes of laparoscopic repair of cystocoele, Australian & New Zealand Journal of Obstetrics & GynaecologyAust N Z J Obstet Gynaecol, 55, 588-92, 2015	contributed to the 5-year data. Follow-up was in person.	apical compartment repair (either laparoscopic uterosacral colpopexy in the case of previous or concurrent hysterectomy or uterosacral hysteropexy if the woman requested uterine conservation). n=47 (21%) women also underwent a laparoscopic posterior repair. n=91 (41%) Burch colposuspension was most common for stress incontinence.	surgeons or fellows under their direct supervision. Technique was based on Miklos and Kohli with some modifications.	<u>Recurrence (ba&gt;0) over entire follow-up period</u> 54/223  <u>Repeat surgery for POP over entire follow-up period</u> 38/223	Confounding bias: not applicable – single arm study
Ref Id	<u>Characteristics</u> <u>Age - median ± range (years)</u> 62 (35-89)				Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
636970	<u>Parity - median (range) - mean ± SD not reported</u> 3 (0-6)				Classification of interventions bias: not applicable - single arm study
Country/ies where the study was carried out	<u>Weight - median ± range (kg)</u> 68 (45-120)				Deviations from intended interventions bias: not applicable - single arm study
Australia					
Study type	<u>Prior pelvic surgery - n (%)</u>				
Prospective single arm	<u>Anterior repair</u> 39 (17.5)				
Aim of the study	<u>Hysterectomy</u> 108 (48.4)				Missing data bias: moderate risk of bias – not all participants had reached 5 year follow-up for the long-term data analysis
To present long-term outcome data for women following laparoscopic repair for anterior compartment prolapse	<u>Compartments involved - n (%)</u> <u>Anterior</u> 93 (41.7) <u>Anterior + Apical</u> 49 (22.0)				
Study dates	<u>Apical</u> 7 (3.1) <u>Anterior + Posterior</u>				Measurement of outcomes bias: serious risk of bias – as single arm design, study
Surgery performed between January					

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
1999 to December 2005 and followed up at 6 weeks, 6 months, 12 months and then yearly or biannually as required.  Source of funding Not stated	40 (17.9) <u>Global</u> 34 (15.2)	Inclusion criteria Women following laparoscopic paravaginal repair and associated procedures  Exclusion criteria Not stated			outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those originally recruited.
Full citation  Cervigni, M., Natale, F., La Penna, C., Panei, M., Mako, A., Transvaginal cystocele repair with polypropylene mesh using a tension-free technique, International Urogynecology Journal, 19, 489-96, 2008  Ref Id 637303	Sample size Initial surgeries N= 357.  Follow up data only for n=218 patients who had the TCR procedure and associated with high levator myorraphy to suspend the upper vaginal segment.	Interventions Tension free mesh cystocele repair. Type 1 polypropylene mesh for the correction of anterior vaginal wall prolapse	Details Surgery Using a tension-free way to apply a type 1 polypropylene mesh (Marlex®, Bard®, Billerica, MA, USA)—for the correction of medium/high-degree defects of the anterior vaginal compartment – ‘Tension-free cystocele repair’ The surgery was performed by three surgeons	Results <u>Follow up 38 months</u> Urge incontinence 58/218 Dyspareunia 39/218 Perineal pain 5/218 Pelvic pain 9/218 Constipation 49/218	Limitations  Other information Confounding bias: not applicable – single arm study  Selection of participant’s bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Country/ies where the study was carried out Italy	<u>Age - median ± (SD; range)</u> years 6 62.5 (8.82; 39-79)		Follow-up Follow-up measures at a mean follow up of 38 months, (median 35.8 months, range 12-82 months) were performed by an independent examiner.		Deviations from intended interventions bias: not applicable - single arm study
Study type Prospective single arm	<u>Parity - median ± range</u> 2 (0-10)				Missing data bias: moderate risk of bias – not all participants data used for the follow-up, only focused on one sub-group.
Aim of the study The use of prosthetic materials (tension free techniques) to reinforce pubocervical fascia	<u>BMI -- mean ± median, SD, range</u> 25.99 (25.49, 3.34, 17.63-37.02)				Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods
Study dates Surgery performed between January 2000 and January 2005 with follow-up at .3 years.	<u>Associated procedures with TCR</u> Bladder neck suspension n=41 TVT n=32 TOT n=13 Pubo-vaginal sling n=5 Infracoccigeal sling n=20 Rectocele repair with mesh n=16 High levator myorraphy n=218 <u>Previous Surgery: n (%)</u> Total abdominal hysterectomy				Selection of the reported results bias: serious risk of bias – long term outcome data comes from only one sub-group of patients and not all patients treated with this surgery.

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## Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>n=19 (8.7) Vaginal hysterectomy n=6 (2.8) Anterior colporraphy n=6 (2.8) Posterior colporraphy n=5 (2.3) Burch n=5 (2.3) Marshall Marchetti Krantz n=2 (0.9) Bladder neck suspension n=1 (0.5) Bologna n=1 (0.5) Burch n=1 (0.5) TVT n=1 (0.5)</p> <p>Inclusion criteria Only included the largest subgroup (n=218) of patients who had TCR procedure</p> <p>Exclusion criteria Patients who showed objective stress urinary incontinence and so needed anti-</p>					

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	incontinence procedures				
Full citation  Chen, Z., Wong, V., Wang, A., Moore, K. H., Nine-year objective and subjective follow-up of the ultra-lateral anterior repair for cystocele, International Urogynecology Journal, 25, 387-92, 2014	Sample size n=241 patients identified  n=225 sent questionnaire, 135/225 (60%) completed questionnaire, 53/135 were examined.	Interventions Ultra-lateral anterior repair (n=241)	Details QoL questionnaire, Pelvic floor distress inventory (PFDI) and POP-Q examination.  Examinations were performed by a clinician who had not been involved in any of the procedures.	Results <u>Follow Up</u> Mean duration 9.25yrs ( $\pm 3.2$ , range 5.5 to 18yrs); median 7.9yrs (IQR 7 -11)  <u>Recurrence (symptomatic) at 96mo</u> 35/135  <u>Recurrence POP-Q&gt;2 (96mo)</u> 24/53  <u>Repeat surgery at 48mo</u> 10-135	Limitations <u>Paper reported limitations:</u> There are limitations associated with using PFDI, since it is not 100% specific for cystoceles.  Other information Confounding bias: not applicable – single arm study
Ref Id  637366	Characteristics <u>Age - median <math>\pm</math> range (years, at time of follow-up)</u> 70 (63-78)				Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
Country/ies where the study was carried out  Australia	<u>Parity - median (range) - mean <math>\pm</math> SD not reported</u> 3 (2-3)				Classification of interventions bias: not applicable - single arm study
Study type  Prospective data collection of a retrospective procedure	<u>BMI - median <math>\pm</math> range</u> 24.6 (22.6-28.2)				Deviations from intended interventions bias: not applicable - single arm study
Aim of the study  To present long-term outcome data for women following	<u>Prior pelvic surgery - n (%)</u> Prolapse surgery (not				

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
standardised primary native tissue ultra-lateral anterior repair	anterior compartment) 5 (3.7) Hysterectomy 51 (37.8)				Missing data bias: moderate risk of bias – not all participants eligible to take part responded, some reasons were given for those who did not complete follow-up (e.g. death or advanced dementia).
Study dates Surgery performed between January 1994 to December 2006	Surgical procedures included various combinations of: Isolated ultra-lateral anterior repair, posterior repair, tension-free tape, vaginal hysterectomy, abdominal hysterectomy, sacrospinous fixation and Manchester				Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods
Source of funding Col - none to declare	Inclusion criteria Grade 2-4 cystocele  Exclusion criteria  Any previous cystocele repair (with or without mesh) and inability to answer the questionnaire (i.e because of dementia)				Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those eligible.

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Full citation  Darai, E., Coutant, C., Rouzier, R., Ballester, M., David-Montefiore, E., Apfelbaum, D., Genital prolapse repair using porcine skin implant and bilateral sacrospinous fixation: midterm functional outcome and quality-of-life assessment, Urology, 73, 245-50, 2009  Ref Id  637692	Sample size Initial surgeries N=101 . Follow up data for N=89  Characteristics Age - mean ± SD; range (years) 67 (9; 46-84)  <u>Parity - mean ± SD; range</u> 2.9 (2, 0-12)  <u>BMI -- mean ± SD ; range</u> 25.7 (4.03; 19-38)	Interventions <u>Porcine implant for sacrospinous fixation:</u>	Details Surgery The surgery (augmentation of the genital prolapse with a total hammock of porcine skin collagen implant (Pelvicol)). Surgery lasted a median duration of 112 minutes (range 40-310)  Follow-up Follow-up measures at 1 and 6 months postoperative and then yearly via clinical exam and the following questionnaires: PFDI-20, POPDI-6, CRADI-8 and UDI-6.	Results <u>Follow-up 38 months</u> Recurrence 13/89 Dyspareunia 2/89 POPSI-6, UDI-6, CRADI-8, PFID-20, PFIQ-7	Limitations  <u>Paper reported limitations:</u>  Small sample size. Unable to draw definitive long-term conclusions for Pelvicol implantation and bilateral sacrospinous fixation to treat genital prolapse.  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions
Country/ies where the study was carried out  France	<u>Previous hysterectomy, N (%)</u> Benign tumor n=10 (9.9) Prolapse surgery n=3 (3)				
Study type Prospective single arm	<u>Previous surgery for genital prolapse, N (%)</u> Anterior vaginal wall prolapse n=3 (3) Anterior vaginal wall prolapse n=3 (3)				
Aim of the study Evaluate the mid-term anatomic, functional outcomes and QoL following					

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
genital repair of high-grade (Stage III-IV) vaginal prolapse using a porcine skin collagen implant and bilateral sacrospinour fixation.  Study dates Surgery performed between May 2001 and June 2006 with follow-up at a mean of 38 months (18mo).  Source of funding Not reported	Previous abdominal surgery n=34 (33.7) Cardiovascular disorders n=64 (63.4)  Inclusion criteria Women with Stage III or IV genital prolapse  Exclusion criteria Patients who underwent laparoscopic surgery				bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all participants completed follow-up – some reasons for dropout given (e.g. death).  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated.
Full citation	Sample size Initial surgeries N= 150.	Interventions <u>laparoscopic sacrocolpopexywi</u>	Details Follow-up Follow-up	Results	Limitations  Other information

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Deprest,J., Ridder,D.D., Roovers,J.P., Werbrouck,E., Coremans,G., Claerhout,F., Medium Term Outcome of Laparoscopic Sacrocolpopexy With Xenografts Compared to Synthetic Grafts, Journal of Urology, 182, 2362-2368, 2009  Ref Id 143907  Country/ies where the study was carried out  Belgium  Study type Prospective two arm non-randomised study  Aim of the study Assess outcomes and complication rates following sacrocolpopexy with xenografts compared	Follow up data for functional evaluation N=104 at mean 32.6months  <u>th porcine or polypropylene mesh:</u>  Characteristics <u>Age - mean ±SD (years)</u> Xenografts 67.8 (9.9) Polypropylene 63.1 (9.1)  <u>Parity - mean ± SD</u> Xenografts 3.34 (2.5) Polypropylene 2.76 (1.1)  <u>BMI -- mean ± SD</u> Xenografts 25.5 (2.4) Polypropylene 26.3 (4.0)  <u>No. previous prolapse surgery</u> Xenografts n=50 (100) Polypropylene n=92 (92)	<u>th porcine or polypropylene mesh:</u>  measures for xenograft group was a mean of 32.6 months ( median 35, range 20 to 68 months) and for polypropylene repair was 33.5 months (median 23.9 months, range 6 to 93 months).  Follow-up was physical exam and where not possible, telephone interview and questionnaire.	<u>Follow up 33 months</u> Mesh erosion 8/104 Pain 2/104		Confounding bias: high risk of bias – unclear how participants assigned group, possible based on time of presentation  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: high risk of bias – unclear how participants assigned to groups  Deviations from intended interventions bias: low risk of bias – once surgery performed, deviation not possible  Missing data bias: moderate risk of bias – not all participants eligible to take part completed follow-

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>to polypropylene repair.</p> <p>Study dates Surgery performed between April 1998 and February 2005 with follow-up until December 2006.</p> <p>Source of funding No funding declared, but conflicts with Ethicon, Bard, AMS, Covidien, Astellas, and Pohl Boskamp declared by authors.</p>	<p>No. <u>hysterectomy</u> Xenografts n=46 (92) Polypropylene n=89 (89)</p> <p>Inclusion criteria Symptomatic vault or uterine prolapse, with minimum of stage II apical prolapse.</p> <p>Exclusion criteria None stated</p>				<p>up, reasons were not given for dropout.</p> <p>Measurement of outcomes bias: low risk of bias – all outcomes were assessed using the same methods study</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller group of those initially treated.</p>
<p>Full citation Granese,R., Candiani,M., Perino,A., Romano,F., Cucinella,G., Laparoscopic sacrocolpopexy in the treatment of vaginal vault prolapse: 8 years experience, European Journal of Obstetrics, Gynecology, and Reproductive</p>	<p>Sample size Initial surgeries N=165 .</p> <p>Follow up data for N=138</p>	<p>Interventions <u>laparoscopic sacrocolpopexy with polypropylene mesh:</u></p> <p>Characteristics <u>Age - mean ± SD, range (years)</u> 67 (19.22, 58-76)</p>	<p>Details Surgery The surgery was performed by one surgeon and lasted a duration of 55 minutes (range 40 to 120 for sacrocolpopexy – extra time if additional repairs)</p> <p>Follow-up Follow-up measures at 43 months (range 6-96months) were</p>	<p>Results <u>Follow up 43 months</u> Vaginal Bulge 10/138 Lower abdominal pain 6/138 SUI 11/138 Voiding dysfunction 9/138 Urge incontinence 25/138 Constipation 18/138 Obstructed defecation 8/138</p>	<p>Limitations</p> <p>Other information Confounding bias: not applicable – single arm study</p> <p>Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable</p> <p>Classification of</p>

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Biology, 146, 227-231, 2009  Ref Id 124310  Country/ies where the study was carried out  Italy  Study type Prospective single arm	<u>Parity - mean ± range</u> 3 (2-5)  <u>BMI -- mean ± range</u> 28 (24-30)  <u>Previous abdominal hysterectomy, n (%)</u> N=94 (57)  <u>Previous vaginal hysterectomy</u> N=71 (43)		both questionnaire and physical exam. Postmenopausal women received pre-operative and post-operative topical oestrogen treatment.		interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all participants eligible to take part completed follow up, some reasons were given for dropout.
Aim of the study Evaluate long-term results of laparoscopic sacrocolpopexy using polypropylene mesh of vaginal vault prolapse	<u>Surgery</u> Sacrocolpopexy n=88  Sacrocolpopexy with posterior repair and vaginal perineorraphy n=77				Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods
Study dates Surgery performed between January 1999 and January 2007 with follow-up at a median of 43 months (range 6-96months)	Sacrocolpopexy with paravaginal repair and Burch colposuspension n=63  Sacrocolpopexy with anterior colporraphy and urethropessy n=24				Selection of the reported results bias: serious risk of bias – long term outcome data
Source of funding Not reported	Inclusion criteria				

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	Diagnosed vaginal vault prolapse between 2nd and 4th degree according to the half way system classification.  Exclusion criteria None stated				comes from a smaller -group of those initially treated.
Full citation  Hefni, M. A., El-Toukhy, T. A., Long-term outcome of vaginal sacrospinous colpopexy for marked uterovaginal and vault prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 127, 257-263, 2006	Sample size Initial surgeries N=305 . Follow up data for N=293	Interventions <u>Transvaginal sacrospinous colpopexy:</u>	Details Follow-up Follow-up measures at 57 months (range 24-84) via physical exam.	Results <u>At 57 months</u> Recurrence (vault prolapse) 12/293 Recurrence (anterior prolapse) 26/200 SUI 11/51 De novo dyspareunia 2/293	Limitations <u>Paper reported limitations</u> Lack of validated sexual function questionnaire
Ref Id  638748	Characteristics <u>Age - mean ± SD; range (years)</u> 59.9 (10.4; 22-80)				Other information Confounding bias: not applicable – single arm study
Country/ies where the study was carried out	<u>Parity - mean ± SD; range</u> 2.3 (0.9; 0-6)				Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
UK	<u>BMI -- mean ± SD ; range</u> 28.1 (4.1; 21-34)				Classification of interventions bias: not applicable - single arm study
Study type	<u>Previous pelvic operations N</u>				

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Prospective single arm</p> <p>Aim of the study Evaluate the efficacy (safety and long-term outcomes) of sacrospinous colpopexy in patients with marked uterovaginal and vault prolapse over 7 years.</p> <p>Study dates Surgery performed between September 1993 and May 2000 with follow-up at mean 57 months.</p> <p>Source of funding Not reported</p>	<p>(%)</p> <p>Abdominal hysterectomy n=84</p> <p>Vaginal hysterectomy n=49</p> <p>Anterior colporrhaphy n=61</p> <p>Posterior colporrhaphy n=24</p> <p>Colposuspension n=14</p> <p>Sacral colpopexy n=3</p> <p>Manchester repair n=2</p> <p>Stanley's urethropexy n=1</p> <p>Inclusion criteria Symptomatic genital prolapse – symptoms included pressure into vagina, feeling a lump in the introitus, dragging or falling-out sensation and chronic pelvic discomfort.</p> <p>Exclusion criteria Not stated</p>				<p>Deviations from intended interventions bias: not applicable - single arm study</p> <p>Missing data bias: moderate risk of bias – not all participants eligible to take part completed follow-up, reasons were given for dropout.</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sample than those initially treated.</p>

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Full citation  Jacquetin, B., Hinoul, P., Gauld, J., Fatton, B., Rosenthal, C., Clave, H., Garbin, O., Berrocal, J., Villet, R., Salet-Lizee, D., Debodinance, P., Cosson, M., Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study, International Urogynecology Journal, 24, 1679-86, 2013	Sample size  Surgery of n=90. Follow-up data for n=82	Interventions  Transvaginal Mesh surgery.	Details  Follow-up care was at 6 weeks, 6 months, 1, 3 and 5 years. All patients with a uterus had a concurrent hysterectomy. POP-Q assessment was used.  A sample size of 90 subjects to obtain at least 82 evaluable was selected as this would provide 80% power to detect if the proportion of treatment failures was less than 20%.	Results  Recurrence (at 60 months) 13/82  Mesh Exposure (at 60 months) 14/82  De novo dyspareunia (at 60 months) 3/61  Pelvic pain (at 60 months) 1/82	Limitations  <u>Paper reported limitations:</u> The use of the PSI-QOL questionnaire is limited, since it lacks a published minimally important difference.  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study
Ref Id  638985					
Country/ies where the study was carried out  France	Previous surgery for prolapse repair - n (%) 4/90 (4.4) Previous surgery for incontinence - n (%) 5/90 (5.6)				
Study type Prospective sing-arm					
Aim of the study To report long-term (5-year) follow-up of					

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
transvaginal mesh procedures  Study dates January to December 2004  Source of funding Ethicon	Prior hysterectomy - n (%) 18/90 (20.0) Concomitant hysterectomy - n (%) 72/90 (80.0)  Inclusion criteria Eligible for anterior and posterior surgical repair with symptomatic prolapse and the most dependent part of the vaginal wall was at least 1 cm beyond the hymenal ring.  Older than 21 yrs of age and had completed their family  Exclusion criteria Uncontrolled diabetes or coagulation disorders				Missing data bias: moderate risk of bias – not all participants eligible to take part were able to. Reasons given for those who were unable e.g. with-drawl of consent, death, too frail to take part. Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those eligible.
Full citation	Sample size	Interventions	Details	Results <u>Tape erosion at 60 months</u>	Limitations

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Joshi, V. M., Otiv, S. R., Dagade, V. B., Borse, M., Majumder, R. N., Shrivastava, M., Shelomohkar, R., Bijwe, S., Pectineal ligament suspension of prolapsed vaginal vault, International Journal of Gynaecology & Obstetrics Int J Gynaecol Obstet, 123, 29-32, 2013  Ref Id  639079  Country/ies where the study was carried out  India  Study type Prospective single arm  Aim of the study Long-term follow-up of pectineal ligament suspension of the prolapsed vaginal vault	Surgery performed on N = 119. Followup at 5 years included N=110.  Characteristics <u>Age - mean ± range (years)</u> Open surgery (n=104): 42 (30-60) Laparoscopic surgery (n=15): 45 (30-65)  <u>Parity - median (range) - mean ± SD not reported</u> Open surgery (n=104): 3.5 (2-6) Laparoscopic surgery (n=15): 3 (2-5)  <u>BMI - mean ± SD</u> Open surgery (n=104): 23.8 (20-29) Laparoscopic surgery (n=15): 26 (25-30)	Pectineal ligament suspension procedure either open or laparoscopic	Postoperative followups after 1 month, 6 months and then annually where symptoms noted and examination occurred. Mean operating time was 90 minutes (60-150 minutes)	2/110	<p><u>Study reported limitations:</u> Follow-up assessments did not use the POP quantification system. Single arm study.</p> <p>Other information Confounding bias: not applicable – single arm study</p> <p>Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable</p> <p>Classification of interventions bias: not applicable - single arm study</p> <p>Deviations from intended interventions bias: not applicable - single arm study</p> <p>Missing data bias: moderate risk of bias – not all participants eligible</p>

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Study dates January 2000 to December 2011  Source of funding Col - none to declare	<u>Prior abdominal hysterectomy - n (%)</u> Open surgery: 79/104  <u>Laparoscopic surgery: 9/15</u>  <u>Prior abdominal hysterectomy - n (%)</u> Open surgery: 25/104 Laparoscopic surgery: 6/15  <u>Vault descent - complete eversion - n (%)</u> Open surgery: 96/104 Laparoscopic surgery: 12/15  <u>Vault descent - to the introitus - n (%)</u> Open surgery: 8/104 Laparoscopic surgery: 3/15				to take part responded, reasons were not given for dropout.  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated.

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p><u>Previous transvaginal repair - n (%)</u></p> <p>Open surgery: 4/104 Laparoscopic surgery: 0/15</p> <p><u>Moderate to severe stress urinary incontinence - n (%)</u></p> <p>Open surgery: 10/104 Laparoscopic surgery: 0/15</p> <p><u>Cystocele - n (%)</u></p> <p>Open surgery: 20/104 Laparoscopic surgery: 4/15</p> <p><u>Rectocele - n (%)</u></p> <p>Open surgery: 26/104 Laparoscopic surgery: 6/15</p> <p>Inclusion criteria Women presenting with vaginal vault</p>					

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	prolapse (apex at or below the introitus) following hysterectomy.  Exclusion criteria Major contraindications for surgery				
Full citation  Kdous, M., Zhioua, F., 3-year results of transvaginal cystocele repair with transobturator four-arm mesh: A prospective study of 105 patients, Arab Journal of Urology PrintArab J, 12, 275-84, 2014	Sample size Initial surgeries N=105.  Follow up data for N=105  Characteristics Age - mean ± SD, range (years) 63.4 (4.2, 52-73)	Interventions <u>Transobturator 4 arm mesh for cystocele :</u>	Details Surgery The surgery was performed by one surgeon and lasted a duration of 27 minutes (2.3; range 25-45). Concomitant procedures included 67 hysterectomies, 10 sacro-spinofixations, 12 rectocele repairs, 14 pre-rectus fascia plications, 75 perineal plastics associated with posterior levator myorrhaphy and 19 SUI treatments.	Results <u>Follow-up 36 months</u> Pelvic pain 3/105 SUI 2/105 Urinary urge 12/105 Dyspareunia 12/105 Fecal incontinence 2/105 Constipation 28/105 Mesh extrusion 8/105 Mesh retraction (erosion) 6/105 PSIQ-12, POPSI	Limitations <u>Paper reported limitations</u> No control arm, limited sample size. Imprecise data about severity of SUI before surgery and the outcome of patients with mixed urinary incontinence after cystocele repair.
Ref Id  639212	Parity - mean ± SD, range 3.2 (1.2, 1-8)				Other information Confounding bias: not applicable – single arm study
Country/ies where the study was carried out  Tunisia	BMI -- mean ± SD, range 25.2 (4.18, 18.1-35.9)				Selection of participant's bias: moderate risk of bias – inclusion/exclusion details given, of
Study type Prospective single arm	Previous hysterectomy N(%) N=18 (17%)		Follow-up Follow-up measures at 36		

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Aim of the study Evaluate long-term safety and efficacy of cystocele treatment using transobturator four-arm polypropylene mesh</p> <p>Study dates Surgery performed between January 2004 and December 2008 with follow-up at 4 weeks, 3 and 6 months then annually.</p> <p>Follow up data at 36 months.</p> <p>Source of funding None</p>	<p><u>Previous three compartment prolapse repair</u> N(%) N=16 (15); (abdominal route n=4; vaginal route n=12)</p> <p>Previous: Anterior vaginal wall repair only N=4 (4) Posterior colporrhaphy only n=7 (7) Anterior + posterior repair n=2 (2) SUI procedure n=7 (7) Burch colposuspension n=4 (4) TVT n=3 (3)</p> <p>Inclusion criteria &gt;50yrs, had cystocele of grade II (Baden and Walker), isolated or associated with prolapse of other stages, either initial or recurrent, functional</p>		<p>months by physical exam.</p>		<p>those given criteria are reasonable</p> <p>Classification of interventions bias: not applicable - single arm study</p> <p>Deviations from intended interventions bias: not applicable - single arm study</p> <p>Missing data bias: low risk of bias – all participants eligible to take part reported follow-up data.</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: low risk of bias – long term</p>

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	discomfort warranting surgery.  Exclusion criteria Medical contraindications against the surgery, urinary or genital recurrent infection, history of pelvic irradiation or malignant neoplasm of lower urinary tract, long term corticosteroid therapy or other immune deficiency, adnexal mass, neurological disorder affecting the stability of the bladder (MS, spinal cord injury) or indications for laparotomy for other causes.				outcome data comes from same participants of those initially treated.
Full citation  Kowalik, C. R., Lakeman, M. M. E.,	Sample size Initial surgeries N= 188. Follow	Interventions <u>Trocar-guided transvaginal mesh repair:</u>	Details Follow-up Follow-up measures at a	Results <u>Follow up at 40 months</u> Mesh erosion 23/188	Limitations  Other information

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Oryszczyn, J. E., Roovers, J. P. W. R., Reviewing Patients Following Mesh Repair; The Benefits, Gynecologic and Obstetric Investigation., 29, 2016  Ref Id  639406  Country/ies where the study was carried out  Netherlands  Study type Prospective data collection of a retrospective procedure  Aim of the study Explore prevalence of mesh specific complications following surgery  Study dates Surgery performed between 2007 and 2012 with follow-up	up data for N=188  Characteristics <u>Age - mean ± SD (years)</u> 60.2 (11.4)  <u>BMI -- mean ± SD</u> 26.4 (3.6)  <u>Mesh performed due to recurrence N (%)</u> n=147 (78.3)  <u>Surgical history</u> Hysterectomy abdominal n=19 Hysterectomy vaginal n=82 Hysterectomy laparoscopic n=1 vaginal prolapse surgery n=110 Abdominal prolapse surgery n=13 Stress incontinence surgery n=17 Previous mesh surgery n=10  Inclusion criteria		median of 40 months (range 12 to 76 months) from chart review.	Pain 23/188	Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: high risk of bias – not all participants eligible to take part consented, reasons were given for those not consenting.  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
at median 40 months.  Source of funding Conflicts of interest- none declared Funding not reported	Vaginal synthetic mesh surgery  Exclusion criteria None stated				be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sample than those initially identified.
Full citation  Laso-Garcia, I. M., Rodriguez-Cabello, M. A., Jimenez-Cidre, M. A., Orosa-Andrade, A., Carracedo-Calvo, D., Lopez-Fando, L., Burgos-Revilla, F. J., Prospective long-term results, complications and risk factors in pelvic organ prolapse treatment with vaginal mesh, European Journal of Obstetrics Gynecology and Reproductive	Sample size N = 75  Characteristics <u>Age - median ± range (years)</u> 67.6 (45.4-85.1) <u>BMI - median ± range</u> 26.8 (20.3-43) <u>Previous abdominal surgery - n (%)</u> 23/75 (30.3) <u>Previous vaginal surgery (hysterectomy) - n (%)</u> 20/75 (26.3)	Interventions Repair for POP with tension free transvaginal mesh Prolift. An isolated anterior Prolift mesh was inserted in 4 patients (5.3%), an isolated posterior mesh in 1 patient (1.3%) and anterior and posterior in 70 patients (93.3%). 44/75 (58.7) also had concomitant treatment for stress urinary incontinence.	Details All surgeries were carried out by the same surgeon. followup was at 1, 3, 6 and 12 months post surgery then annually or by request. Median follow-up 5.3yrs (IQR 4.4 to 6.3yrs)	Results <u>Mesh Extrusion at 60mo - n/N</u> 9/75  <u>De Novo pain at 60mo - n/N</u> 4/75  <u>Dyspareunia at 60mo - n/N</u> 13/75  <u>Constipation at 60mo - n/N</u> 29/75  <u>SUI at 60mo - n/N</u> 22/75  <u>Urge Incontinence at 60mo - n/N</u> 20/75	Limitations <u>Study reported limitations:</u> Small sample size and limitation to the availability of a validated questionnaire.  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Biology, 211, 62-67, 2017					details given, of those given criteria are reasonable
Ref Id 639544	Inclusion criteria Symptomatic and significant prolapse, POP grade $\geq 2$ in any compartment.				Classification of interventions bias: not applicable - single arm study
Country/ies where the study was carried out Spain					Deviations from intended interventions bias: not applicable - single arm study
Study type Prospective single arm	Exclusion criteria NR				Missing data bias: moderate risk of bias – not all participants included in all analysis.
Aim of the study Long-term results, complications and effects on functional features following treatment of POP with tension-free vaginal mesh					Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods
Study dates November 2005 to December 2008					Selection of the reported results bias: moderate risk of bias – long term
Source of funding None received					

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
					outcome data comes predominately from the original sample group.
Full citation  Long, C. Y., Hsu, C. S., Wu, C. H., Liu, C. M., Wang, C. L., Tsai, E. M., Three-year outcome of transvaginal mesh repair for the treatment of pelvic organ prolapse, European Journal of Obstetrics, Gynecology, & Reproductive Biology Eur J Obstet Gynecol Reprod Biol, 161, 105-8, 2012	Sample size  Surgeries performed on N=162 but enrolled only N= 124.  Follow-up time points were 1, 2 3 and 6 months then semi-annually.	Interventions  <u>TVM: Apogee and Prolift (and concomitant midurethral sling operations for women with current or occult urodynamic stress incontinence)</u>	Details  Follow-up measures at a mean of 36.4 months (12.8 SD) were from questionnaire and physical exam.	Results  <u>Follow up at 36 months</u> Mesh erosion 14/124	Limitations  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all participants eligible to take consented to, reasons for no
Ref Id  639817					
Country/ies where the study was carried out  Taiwan					
Study type  Prospective single arm					
Aim of the study					

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Evaluate clinical and urodynamic outcomes of transvaginal mesh repair for treatment of POP  Study dates Surgery performed between June 2004 and January 2010 with follow-up at a mean of 36.4 months (SD 12.8)  Source of funding Grant from Kaohsiug Municipal Hsiao Kang Hospital.	<u>Procedures in the study, n (%):</u> Anterior mesh repair n=67 (54.0) Anterior and posterior mesh repair n=57 (46) Posterior repair n=4 (3.2) Vaginal hysterectomy n=8 (6.5) Suburethral sling n=72 (58.1)				consent were not given.  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods
Full citation  Miedel, A., Tegerstedt, G., Morlin, B., Hammarstrom, M., A 5-year prospective follow-up study of vaginal surgery for pelvic organ prolapse, International	Sample size Surgery performed on N=248. Follow-up was completed by N = 185  Characteristics <u>Age - mean ± SD [range] (years)</u>	Interventions Surgery for symptomatic pelvic organ prolapse:  • Manchester procedure (n=74) • Vaginal hysterectomy	Details Participants were followed-up at 6-8 weeks post surgery and also at 1, 3 and 5 years.	Results <u>Vaginal bulge at 60mo - n/N</u> 28/143  <u>Urge incontinence at 60mo - n/N</u> 30/143  <u>SUI at 60mo - n/N</u> 13/143  <u>Constipation at 60mo - n/N</u> 41/143	Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller group compared to those eligible.  Limitations <u>Paper reported limitations:</u> Inconsistent system of classification due to policy changes during study period with the introduction of POPQ. Language barriers, as no questionnaires were

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Urogynecology Journal, 19, 1593-1601, 2008	65.4 (13.3) [32-89]	with anterior and posterior colporrhaphy (n=30)		<u>Faecal incontinence at 60mo - n/N</u> 16/143	presented in Swedish. QoL using SF36 was only used at the 5 year time point, therefore changes over time could not be assessed.
Ref Id 640152	<u>Parity - median (range) - mean ± SD not reported</u> 2.4 (0-15)	<ul style="list-style-type: none"> <li>Vaginal hysterectomy with posterior or anterior colporrhaphy (n=5)</li> </ul>		<u>Dyspareunia at 60mo - n/N</u> 19/143	Other information Confounding bias: not applicable – single arm study
Country/ies where the study was carried out Sweden	<u>BMI - mean ± range</u> 25.5 (19-38)	<ul style="list-style-type: none"> <li>Anterior-Posterior Colporrhaphy (n=25)</li> <li>Anterior colporrhaphy (n=7)</li> </ul>			Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
Study type Prospective, single arm	<u>Previous surgery for hysterectomy - n (%)</u> 27/185 (14.6)	<ul style="list-style-type: none"> <li>Posterior colporrhaphy (n=36)</li> <li>Colpocleisis (n=4)</li> <li>Cervix amputation (n=2)</li> <li>TVT (n=32)</li> </ul>			Classification of interventions bias: not applicable - single arm study
Aim of the study Long-term functional outcomes, recurrence rate and side effects following vaginal prolapse reconstructive surgery	<u>Previous surgery for incontinence - n (%)</u> 21/185 (11.4)				Deviations from intended interventions bias: not applicable - single arm study
Study dates Surgery between January 1998 to January 2001	<u>Previous surgery for prolapse - n (%)</u> 24/185 (13.0)				Missing data bias: moderate risk of bias – not all participants eligible
Source of funding Col - none declared	Inclusion criteria All patients planned for surgical treatment of symptomatic pelvic organ prolapse (including those				

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	with recurrent prolapse)  Exclusion criteria Inability to answer questionnaire, dementia or other severe illness.				<p>to take part chose to. No reasons give as to why women did not wish to take part, but age compared between those who did and did not take part and deemed similar.</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated.</p>
Full citation  Miller, D., Lucente, V., Babin, E., Beach,	Sample size Surgery originally on N=85. Followup	Interventions TVM (AC and PC)	Details Assessments at 6 weeks, 6 months, 1,	Results <u>Recurrence at 60 months</u> 15/66	Limitations <u>Study reported limitations:</u>

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
P., Jones, P., Robinson, D., Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse-5-year results, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 17, 139-43, 2011	at 6 years for N=66.		3 and 5 years after surgery.	<u>Dyspareunia at 60 months</u> 3/66  <u>Mesh Exposure at 60 months</u> 16/66  <u>Vaginal Pain at 60 months</u> 1/66	No control group with conventional POP surgery, and dropout rate at 5 years. Limited use of PSI and QoL questionnaires with no published minimally important difference
Ref Id		<u>Surgical history</u>			Other information Confounding bias: not applicable – single arm study
640193		Prior hysterectomy n=57 (67)			
Country/ies where the study was carried out		Previous POP repair n=22 (26)			
USA		Previous incontinence surgery n=15 (18)			
Study type		Inclusion criteria			Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
Prospective single-arm		Candidates for anterior, posterior, or total surgical repair with a symptomatic prolapse			
Aim of the study		deemed at least ICS POP-Q stage 2. Women were older than			Classification of interventions bias: not applicable - single arm study
Assess effectiveness (anatomic and subjective) and complications for the TVM technique for POP repair					
Study dates					Deviations from intended interventions bias: not applicable - single arm study

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Surgery from January 2004 to December 2004	21 yrs and had completed their family.				Missing data bias: moderate risk of bias – not all participants were available for follow up, reasons were given for dropout
Source of funding None reported	Exclusion criteria Uncontrolled diabetes or coagulation disorders				Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods
					Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sample than of those initially treated
Full citation  Mourtialon, P., Letouzey, V., Eglin, G., De Tayrac, R.,	Sample size Initial surgeries N= 230. Follow up data for N=78	Interventions <u>Infracoccygeal sacropexy and posterior mesh</u>	Details Surgery The surgery was performed by 18 surgeons from 13	Results <u>Follow-up 36 months</u> Mesh erosion 9/78 Dyspareunia 1/78	Limitations <u>Paper reported limitations:</u> Other surgical procedures were done during

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Transischioanal trans-sacrospinous ligament rectocele repair with polypropylene mesh: A prospective study with assessment of rectoanal function, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, 81-89, 2013	Characteristics Age - mean $\pm$ SD; [median, range] (years) N=78: 62.7 (12.10) [63, 33-91]	<u>repair (possible anterior repair):</u>	departments and lasted a duration of 95.7 mins (38.8 SD, Range 30-180 mins)		the same rectocele repair which would affect pelvic floor dynamics and may change anatomical and symptom improvements. Different techniques were used for the cystocele repair with mesh which may alter results. Each surgeon did the followup to their own surgery. 33% of patients were lost to follow-up. No questionnaire on sexual activity was used. The POP-Q, PFIQ and PFDI were not completed by all participants.
Ref Id 640333	Parity - mean $\pm$ SD N=72: 2.40 (1.17) [2, 0-5]		Follow-up Follow-up measures at 6 weeks, 6 months, 1 year, 2 years and 3 years after surgery. Mean followup was 36 months (8.1 SD) and patients were followed up both from questionnaire and physical exam.		
Country/ies where the study was carried out France	BMI -- mean $\pm$ SD N=75: 25.3 (3.38) [24.8, 19.5-37.1]				Other information Confounding bias: not applicable – single arm study
Study type Prospective single arm	Previous surgeries Previous prolapse repair n=14/78				Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given unclear why some data was excluded given the
Aim of the study To assess midterm (24 month) anatomical success rates, rectoanal function and complications following rectocele mesh repair.	Previous surgery for incontinence n=10/56 Prior hysterectomy n=24/78 (30.8)				
Study dates	<u>Surgery type</u> Posterior repair only N=23 Anterior and posterior repair N=142				

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Surgery performed between March 2003 and June 2004 with follow-up at 24 months..</p> <p>Source of funding Funded by Sofradim-Covidien</p>	<p>Anterior repair only N=65</p> <p>Inclusion criteria Symptomatic anterior and/or posterior vaginal wall prolapse</p> <p>Exclusion criteria Those with Posterior repair with plication and mesh fixed to the sacrospinous ligament were excluded</p>				<p>mix of surgeries performed.</p> <p>Classification of interventions bias: not applicable - single arm study</p> <p>Deviations from intended interventions bias: not applicable - single arm study</p> <p>Missing data bias: moderate risk of bias – not all participants eligible to take part completed follow up, reasons were not given for dropout</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the</p>

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
					reported results bias: serious risk of bias – long term outcome data comes from a smaller sample than that originally treated.
Full citation  Natale, F., La Penna, C., Padoa, A., Panei, M., Cervigni, M., High levator myorrhaphy for transvaginal suspension of the vaginal apex: long-term results, Journal of Urology, 180, 2047-52; discussion 2052, 2008	Sample size  Original sample of N=286 had surgery.  Follow up was on N=272	Interventions  Suspension of the vaginal apex to the suburethral bundle of the levator ani for symptomatic vaginal prolapse	Details  All surgeries were performed by one surgeon or under his supervision.  Follow-up visits were planned at 6 months and then annually for all patients. These visits included symptoms questionnaire, urogynecologic examination according to the POP-Q system, a supine stress test, a cotton swab test, conventional urodynamic studies and P-QoL	Results  <u>SUI at 60 months</u> 12/272  <u>Urge incontinence at 60 months</u> 84/272  <u>Pelvic Pain at 60 months</u> 22/272  <u>Constipation at 60 months</u> 54/272  <u>Dyspareunia at 60 months</u> 51/272  <u>Recurrence at 60 months</u> 8/272	Limitations  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all
Ref Id  541905	<u>Median parity</u> 2				
Country/ies where the study was carried out  Italy	<u>Mean BMI (SD [range])</u> 26.4 (3.5 [19.8-43.4])				
Study type Prospective single-arm	<u>Previous surgery for prolapse</u> 64 (23.5%)				
Aim of the study	<u>Associated</u>				

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Long-term experience with high levator myorrhaphy for correcting and preventing vaginal apical defects including anatomical outcomes, incidence and type of complications and impact of surgery on anorectal function, sexuality and QoL</p> <p>Study dates Surgery from May 2000 to November 2004</p> <p>Source of funding Not reported</p>	<p><u>pelvic surgery</u> TCR n=247 (90.8) Vaginal hysterectomy n=132 (48.5) Tension free vaginal tape procedure n=46 (16.9) Urethrolysis n=3 (1.1)</p> <p>Inclusion criteria Stage 2 or greater according to POP-Q</p> <p>Exclusion criteria None stated</p>				<p>participants eligible to take part responded, reasons were not given for dropout</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sample than of those initially treated</p>
<p>Full citation Ramanah, R., Ballester, M., Chereau, E., Bui, C., Rouzier, R., Darai, E., Anorectal symptoms before and after</p>	<p>Sample size Initial surgeries N=200</p> <p>Follow up data for laparoscopic sacrocolpopexy N=87 vs Vaginal sacrospinous</p>	<p>Interventions <u>Laparoscopic sacrocolpopexy</u> versus <u>vaginal sacrospinous ligament fixation</u></p>	<p>Details Surgery Being assigned to the sacrospinous ligament suspension were for women with comorbidities which contraindicated</p>	<p>Results <u>Follow-up 32 months</u></p> <p><u>Urge Incontinence</u> Laparoscopic sacrocolpopexy 1/87 Vaginal sacrospinous ligament fixation 3/64</p>	<p>Limitations <u>Paper reported limitations:</u> Study not randomised. Use of short version of QoL questionnaires.</p> <p>Other information</p>

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
laparoscopic sacrocolpopexy for pelvic organ prolapse, International Urogynecology Journal, 23, 779-783, 2012 Ref Id 640985	ligament fixation N=64  Characteristics Age - mean $\pm$ SD (years, at time of follow-up) Laparoscopic sacrocolpopexy 53.29 (9.49) Vaginal sacrospinous ligament fixation 68.05 (8.80)  Parity - median $\pm$ range Laparoscopic sacrocolpopexy 2 (1-7) Vaginal sacrospinous ligament fixation 2 (0-12)  BMI - mean kg/m <sup>2</sup> $\pm$ SD Laparoscopic sacrocolpopexy 23.75 (2.59) Vaginal sacrospinous ligament fixation 25.48 (3.79)  History of hysterectomy N (%) Laparoscopic		laparoscopic approach e.g. severe heart failure, respiratory failure, morbid obesity and adhesions in the abdomen.  Follow-up Follow-up measures at 4-6 weeks, then yearly, median follow-up was 32.4 months (range 7-101 months). Follow-up was from questionnaire and physical exam.	<u>SUI</u> Laparoscopic sacrocolpopexy 11/87 Vaginal sacrospinous ligament fixation 15/64  <u>Voiding difficulties</u> Laparoscopic sacrocolpopexy 3/87 Vaginal sacrospinous ligament fixation 3/64  <u>Recurrence</u> Laparoscopic sacrocolpopexy 2/87 Vaginal sacrospinous ligament fixation 15/64	Confounding bias: high risk of bias – Participants with poorer health were offered Vaginal sacrospinous ligament fixation over laparoscopic sacrocolpopexy.  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: high risk of bias – participants not fairly distributed between each surgery  Deviations from intended interventions bias: low risk of bias – once surgery performed, deviation not possible  Missing data bias: moderate risk

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
with follow-up at 32 months  Source of funding Not reported	sacrocolpopexy 10 (11.49) Vaginal sacrospinous ligament fixation 10 (15.62)  <u>History of prolapse repair</u> N (%) Laparoscopic sacrocolpopexy 10 (11.49) Vaginal sacrospinous ligament fixation 4 (6.25)  Inclusion criteria Patients requiring POP repair.  Exclusion criteria Individuals with urinary tract infection or who had previously been treated for SUI or undergone concomitant surgery for SUI				of bias – not all participants completed follow-up, reasons were not given for dropout  Measurement of outcomes bias: low risk of bias – all outcomes were assessed using the same methods study  Selection of the reported results bias: serious risk of bias – long term outcome data does not include all participants originally recruited.
Full citation  Sarlos, D., Kots, L., Ryu, G., Schaer, G.,	Sample size Original surgeries N=99	Interventions Laparoscopic Sacrocolpopexy	Details The German version of the Kings Health	Results <u>Recurrence at 60 months</u> 11/68	Limitations  Other information

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Long-term follow-up of laparoscopic sacrocolpopexy, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 1207-1212, 2014  Ref Id 641344  Country/ies where the study was carried out  Switzerland  Study type Prospective single-arm  Aim of the study Report long-term follow-up of laparoscopic sacrocolpopexy for anatomical results, recurrence rates, and postoperative quality of life after 60 months mean follow up  Study dates Follow up exams between July and September 2011.	N=68 attended follow-up exam  Characteristics Age range: 36 - 81 years  Parity range: 0-6  Median BMI 26kg/m <sup>2</sup>  Inclusion criteria Women undergoing laparoscopic sacrocolpopexy  Exclusion criteria None stated		Questionnaire and the validated German version of the pelvic floor prolapse questionnaire were used at 5 years (mean) post surgery. In addition a follow-exam was also performed (or if patient unavailable a questionnaire sent).	<u>Mesh extrusion at 60 months</u> 2/68  <u>de novo SUI at 60 months</u> 32/85  <u>Constipation at 60 months</u> 4/85  <u>Voiding dysfunction at 60 months</u> 11/85  <u>Dyspareunia at 60 months</u> 10/85	Confounding bias: not applicable – single arm study  Selection of participant's bias: high risk of bias – no inclusion/exclusion details given  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all participants eligible to take part were able, reasons were given for dropout and adaptions to data collection for those able to complete questionnaires remotely  Measurement of outcomes bias: serious risk of bias – as single arm

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Surgeries started in the clinic in 2003</p> <p>Source of funding None reported</p> <p>No conflicts of interest stated</p>					<p>design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods or grouped accordingly to different measures</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sample than of those initially</p>
<p>Full citation</p> <p>Sayer, T., Lim, J., Gauld, J. M., Hinoul, P., Jones, P., Franco, N., Van Drie, D., Slack, M., Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device, International Urogynecology Journal, 23, 487-493, 2012</p>	<p>Sample size Initial surgeries N=136.</p> <p>Follow up data (those who re-consented for extended follow-up) N=110.</p> <p>Characteristics <u>Age - mean ± SD (years)</u> 64.6 (10)</p> <p><u>BMI -- mean kg/m<sup>2</sup> ±</u></p>	<p>Interventions <u>Polypropylene mesh:</u></p>	<p>Details Follow-up Follow-up measures at 29 months via questionnaire and physical exam.</p>	<p>Results <u>Follow-up 29 months</u> Mesh exposure 11/110 Dyspareunia 4/110 SUI 6/110</p>	<p>Limitations</p> <p>Other information Confounding bias: not applicable – single arm study</p> <p>Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable</p> <p>Classification of</p>

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Ref Id 641361  Country/ies where the study was carried out UK, USA, Germany and Australia  Study type Prospective single arm  Aim of the study Mid-term outcomes (anatomical and functional outcomes and complications) to assess the durability of the repair using non-anchored placement of pre-cut polypropylene mesh and vaginal support device.  Study dates Surgery performed between August 2009 and May 2010 with follow-up at median 29 months (range 24-34).  Source of funding Conflicts of interest and author	SD 28.5 (5.1)  Prior POP repair n=29 (26.4%) Anterior mesh repair n=21 Posterior mesh repair n=27 Combined mesh repair n=62  Inclusion criteria POP-Q stage II or III women who were planning augmented vaginal prolapse repair in anterior, posterior, or both compartments  Exclusion criteria Additional prolapse procedures, previous prolapse mesh repair, hysterectomy within 6 months of index surgery, diseases known to affect bladder				interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all participants eligible to take part responded, reasons were given for dropout  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Employment with Ethicon	or bowel function.				smaller sample than of those initially treated.
Full citation  Schiavi, M. C., Perniola, G., Di Donato, V., Visentin, V. S., Vena, F., Di Pinto, A., Zullo, M. A., Monti, M., Benedetti Panici, P., Severe pelvic organ prolapse treated by vaginal native tissue repair: long-term analysis of outcomes in 146 patients, Archives of Gynecology and Obstetrics, 295, 917-922, 2017	Sample size Initial patients affected N=208, surgery performed on n=146 .  Follow up data for N=146  Characteristics <u>Age - mean ± SD (years)</u> 61.61 (8.83)  <u>Parity - median ± parity</u> 2 (1-5)  <u>BMI -- mean kg/m<sup>2</sup> ± SD</u> 27.34 (3.82)  <u>Previous hysterectomy</u> N=52 (35.6%)  <u>Previous POP surgery and/or continence surgery</u> N=16 (11)  <u>Concomitant</u>	Interventions <u>Native tissue for AC, apical and Posterior POP:</u>	Details Surgery The surgery lasted a duration of median 85 mins (range 37-154)  Follow-up Follow-up measures at a median of 48 months from clinical records on database.	Results <u>At 48 months</u> SUI 5/146 Dyspareunia 4/146 Urge incontinence 6/146 Voiding difficulties 5/146 Constipation 4/146 Gluteal pain 4/146 Recurrence 13/146	Limitations  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all participants eligible to take part did, also participants retrospectively identified.
Ref Id  619074					
Country/ies where the study was carried out  Italy					
Study type Retrospective data collection from prospective data collection database					

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Aim of the study Evaluate follow a median of 48-months, the efficacy, safety complication rate and impact on sexual function of native tissue repair for POP surgical treatment in patients with one or more vaginal defects.</p> <p>Study dates Surgery performed between January 2008 and January 2013 with follow-up at a median of 48 months (range, 36-63).</p> <p>Source of funding No Conflicts of interest declared</p>	<p><u>stress urinary incontinence</u> N=32 (22)</p> <p><u>Surgical procedures N (%)</u>: Vaginal hysterectomy n=91 (62.3) Bilateral adnexectomy n=82 (56.1) Shull Suspension n=109 (69.2) Anterior colporraphy n=135 (92.5) Posterior colporraphy n=98(67.1) TOT insertion n=32 (22)</p> <p>Inclusion criteria Patients with genitourinary prolapse Stage III of greater according to POP-Q with or without coexisting clinical or latent SUI</p> <p>Exclusion criteria</p>				<p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of bias – participants retrospectively identified.</p>

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	Poor performance status (ECOG>2)				
Full citation  Sargent,F., Resch,B., Al-Khattabi,M., Ricbourg,A., Schaal,J.P., Marpeau,L., Transvaginal mesh repair of pelvic organ prolapse by the transobturator-infracoccygeal hammock technique: Long-term anatomical and functional outcomes, <i>Neurourology and Urodynamics</i> , 30, 384-389, 2011	Sample size  N=114	Interventions  <u>Transobturator Infracoccygeal hammock:</u>	Details  Surgery - performed by four surgeons	Results  <u>Follow-up 58 months</u> Mesh erosion 6/101 Vaginal pain 10/101 Dyspareunia 9/101	Limitations  <u>Paper reported limitation</u> Population was advanced in age and had reduced sexual activity
Ref Id  135949	Characteristics  <u>Age - mean (SD [median, range])(years)</u> 66 (10) [66, 49-85]  <u>Parity - mean (SD [median, range])</u> 3.5 (20) [1-14]  <u>BMI kg/m<sup>2</sup> - mean (SD [median, range])</u> 28 (5) [14-44]		Follow-up Follow-up measures at 6 weeks, 6 months and yearly, with final follow-up reported at a mean of 58 months (median 57, range 24-84) and were by a physical exam and questionnaire.		Other information  Ref: Sargent 2011a Confounding bias: not applicable – single arm study
Country/ies where the study was carried out  France	Previous hysterectomy n=50 (44) Including supracervical hysterectomy n=9 (18)				Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
Study type Prospective single arm	Previous prolapse repair, n=34 (30)				Classification of interventions bias: not applicable - single arm study
Aim of the study	Previous at				Deviations from intended interventions bias: not applicable - single arm study

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Assess them anatomical and functional outcomes and complications of the TOICH technique beyond 2 years using the new protected implanted polypropylene mesh.  Study dates Surgery performed between July 2003 and July 2007 with follow-up at mean 58 months.  Source of funding No Conflicts of interest declared	least two prolapse repairs, n=13 (11) Previous stress urinary incontinence cure, n=26 (23)  Inclusion criteria TOICH indications with high-risk of recurrence - advanced Stages (Stage ≥III pelvic organ prolapse quantification system staging—POPQ-S), recurrent, or posthysterectomy vaginal vault prolapse.  Exclusion criteria None reported				Missing data bias: moderate risk of bias – not all participants eligible to take part responded, reasons were not given for dropout  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated
Full citation  Sargent, F., Resch, B., Loisel, C., Bisson, V., Schaal, J. P.,	Sample size Initial surgeries N=124  Characteristics	Interventions <u>Laparoscopic sacral colpopexy</u>	Details Surgery The surgery lasted a duration of 185	Results <u>At 34 months</u> Mesh Erosion 4/116 SUI 35/116 Urge incontinence 17/116	Limitations -  Other information Ref: Sargent 2011b

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Marpeau, L., Mid-term outcome of laparoscopic sacrocolpopexy with anterior and posterior polyester mesh for treatment of genito-urinary prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 156, 217-222, 2011	<u>Age - mean ± SD, range (years)</u> 52.2 (9.5, 30-70)  <u>Parity - mean ± SD</u> 2.0 (1.2, 1-8)  <u>BMI - mean kg/m<sup>2</sup> ± SD</u> 25.8 (5, 17.9-37.6)		mins (24 SD, range 90-235)  Follow-up Follow-up measures at a mean of 34.2 months (20.5 SD; median 30, range 12 to 72 months) and were assessed by both questionnaire and physical exam.	Constipation 23/116 Fecal Incontinence 1/116 Dyspareunia 7/116 Voiding dysfunction 2/116  PSIQ-12	Confounding bias: not applicable – single arm study
Ref Id	<u>Prior hysterectomy n (%)</u> N=6 (4.8)				Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
641446	<u>Prior prolapse repair n(%)</u> 9 (7.2)				Classification of interventions bias: not applicable - single arm study
Country/ies where the study was carried out	<u>Prior stress urinary incontinence procedure n (%)</u> 15 (12.0)				Deviations from intended interventions bias: not applicable - single arm study
France	<u>Inclusion criteria</u> Symptomatic upper vaginal prolapse, with at least stage II prolapse of the apex – associated with anterior or posterior vaginal wall prolapse.				Missing data bias: moderate risk of bias – not all participants eligible to take part completed follow-up.
Study type					Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to
Prospective single arm					
Aim of the study					
To assess postoperative anatomic and functional outcomes following Laparoscopic sacral colpopexy using anterior and posterior mesh in all pelvic compartments.					

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Study dates Surgery performed between October 2003 and March 2009 with a mean follow-up at 34 months.  Source of funding None reported	Exclusion criteria None reported				other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sample than of those initially treated.
Full citation  Silva, W. A., Pauls, R. N., Segal, J. L., Rooney, C. M., Kleeman, S. D., Karram, M. M., Uterosacral ligament vault suspension: Five-year outcomes, <i>Obstetrics and Gynecology</i> , 108, 255-263, 2006  Ref Id 641588  Country/ies where the study was carried out USA	Sample size N=72 from eligible N=110 who had had surgery.  Characteristics <u>Mean age (years)</u> 64.0 <u>Parity</u> 3.0 <u>BMI kg/m<sup>2</sup></u> 27.0  Inclusion criteria Women with prolapse of the	Interventions Uterosacral vault suspension	Details All surgeries were performed or under direct supervision of one surgeon. Postoperative evaluations included, urinary function, sexual function and defecatory function from standardised questionnaires (IIQ, UDI and FSFI)	Results <u>Recurrence at 60 months</u> 11/72  <u>Abnormal Sexual Function at 60 months</u> 54.8%  <u>de novo dyspareunia at 60 mo</u> 7/72  <u>Constipation at 60 months</u> 15/72  <u>Faecal Incontinence at 60 months</u> 9/72	Limitations <u>Paper reported limitations:</u> No validated bowel questionnaire for POP. FSFI was not collected preoperatively, only post.  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Study type Prospective single arm	apex to the level of the hymen who had uterosacral vault suspension				details given, of those given criteria are reasonable
Aim of the study 5 year anatomic and functional outcomes of uterosacral vault suspension surgery	Exclusion criteria If the surgery was performed at three other outlying hospitals where hospital privileges were no longer in place for the senior author				Classification of interventions bias: not applicable - single arm study
Study dates Surgery from January 1997 to January 2000  follow up between July 2003 and April 2005					Deviations from intended interventions bias: not applicable - single arm study
Source of funding None reported					Missing data bias: moderate risk of bias – not all participants eligible to take part consented, reason for no consent were not given.
					Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods
					Selection of the reported results

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
					bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated.
Full citation  Souviat, C., Bricou, A., Porcher, R., Demaria, F., Fritel, X., Benifla, J. L., Pigne, A., Long-term functional stability of sacrospinous ligament-fixation repair of pelvic organ prolapse, Journal of Obstetrics & GynaecologyJ Obstet Gynaecol, 32, 781-5, 2012	Sample size  Surgery completed on N=178.  Followup on N=79.	Interventions  Sacrospinous ligament fixation  Characteristics <u>Median Age (IQR) years</u> 67 (61-72)  <u>Parity Median (IQR)</u> 2 (2-3)	Details  PFDI-20 questionnaire sent, in addition a satisfaction, QoL and sexual function questionnaire also sent	Results  <u>Dysparenia at 115 mo</u> 10/79	Limitations  <u>Paper reported limitations:</u> The SLF surgery was not in isolation for 93.4% of patients who were also treated for other POP compartments or SUI. Loss to follow-up was 27.8% which could be considered poor  Other information Confounding bias: not applicable – single arm study
Ref Id  631966	<u>BMI kg/m<sup>2</sup> (range)</u> 23 (21-26)				Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable
Country/ies where the study was carried out  France	<u>Priory hysterectomy</u> no n=56 (71) total hysterectomy n=4 (5) subtotal hysterectomy n=19 (24)				
Study type Prospective single arm					
Aim of the study					

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Changes of functional discomfort associated with POP over 5 years after sacrospinous ligament fixation	Prior surgery for UI n=11 (14)				Classification of interventions bias: not applicable - single arm study
Study dates Surgery between 1993 and 2001	Prior POP repair No n=59 (75) Vaginal approach n=11 (14) Abdominal approach n=8 (10) Vaginal and abdominal approaches n=1 (1) <u>Prolapse stage</u> Stage 2 n=12 (15) Stage 3 n=67 (85)				Deviations from intended interventions bias: not applicable - single arm study
Source of funding None reported	Inclusion criteria Stage 2 or 3 POP  Exclusion criteria None stated				Missing data bias: moderate risk of bias – not all participants eligible to take part responded, reasons were given for dropout

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
					comes from a smaller group of those initially treated.
Full citation  Thompson, P. K., Pugmire, J. E., Sangi-Haghpeykar, H., Abdominal sacrocolpopexy utilizing Gore-Tex in genital prolapse: Unresolved issues, Journal of Pelvic Medicine and Surgery, 10, 311- 317, 2004	Sample size Initial surgeries N=168  Follow up data for N=135	Interventions <u>Abdominal sacrocolpopexy</u>	Details Surgery The surgery was performed by the same surgeon  Follow-up Follow-up measures at an average of 43 months (range 7-154 months) and were either by annual questionnaire or physical exam.	Results <u>Follow up 43 months</u> Mesh erosion 4/135	Limitations  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – no inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: moderate risk of bias – not all participants eligible to take part completed follow up
Ref Id  641940					
Country/ies where the study was carried out  USA					
Study type  Prospective data collection of a retrospective procedure					
Aim of the study  To assess the safety (risk of graft erosion) of abdominal					

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
sacrocolpopexy with concomitant hysterectomy using Gore-Tex.  Study dates Surgery performed from 1988 to 2003 with follow-up at a mean of 43 months..  Source of funding No Conflicts of interest declared					as their data was too immature.  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller group of those initially treated.
Full citation  Ubachs, J. M. H., Van Sante, T. J., Schellekens, L. A., Partial colpocleisis by a modification of LeFort's operation, <i>Obstetrics and Gynecology</i> , 42, 415-420, 1973	Sample size N=141 originally had surgery.  N=93 followed up.	Interventions Partial colpocleisis plus high levator plasty  Characteristics <u>Age, mean (range)</u> 65.9 (46-85)	Details Patients examined at least 3 years after operation	Results <u>Recurrence at 60 months n/N</u> 5/93  <u>SUI at 60 months n/N</u> 15/93  <u>Urge incontinence at 60 months n/N</u> 4/93	Limitations  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: high risk of bias – no

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Ref Id 642054  Country/ies where the study was carried out Netherlands  Study type Prospective single arm  Aim of the study Long-term followup of partial colpocleisis surgery  Study dates Surgery between 1959 and 1968  Source of funding None reported	<u>Indications for operation</u> Cystocele n=9 Rectocele n=1 Cystocele with rectocele n=39 Cystocele and rectocele with descensus uteri n=38  Total prolapse of uterus n=54  Inclusion criteria None reported  Exclusion criteria None reported				<p>inclusion/exclusion details given</p> <p>Classification of interventions bias: not applicable - single arm study</p> <p>Deviations from intended interventions bias: not applicable - single arm study</p> <p>Missing data bias: moderate risk of bias – not all participants eligible to take part responded, reasons were given for dropout.</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of</p>

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
					bias – long term outcome data comes from a smaller group of those initially treated.
Full citation Wang, F. M., He, C. N., Song, Y. F., Prospective study of transobturator mesh kit (ProliftTM) in pelvic reconstructive surgery with vaginal hysterectomy after 3 years' follow-up, Archives of Gynecology & Obstetrics, 288, 355-9, 2013	Sample size Initial surgeries N=80  Follow up data for N=75	Interventions <u>Mesh for Vaginal hysterectomy</u>	Details Surgery The surgery was performed by one surgeon and lasted a duration of 98 min (range 80-120). N=79 had total Prolift mesh repair and n=1 had anterior mesh repair (because of an inadvertent rectal injury during dissection).	Results <u>Follow-up 36 months n/N</u> Mesh erosion 5/75	Limitations <u>Paper reported limitations</u> Not all POP-Q measurements were performed at every follow-up.  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study
Ref Id 543140	<u>Parity - median ± range</u> 2 (1-7)		Follow-up Follow-up measures at 1 and 6 months and then every 6 to 12 months and were either in person or via telephone (depending on symptoms). Follow up time point 3 years.		
Country/ies where the study was carried out China	<u>BMI - mean kg/m<sup>2</sup> ± SD</u> 23.2 (3.5)				
Study type Prospective single arm	<u>Previous prolapse repair n (%)</u> 3 (3.75) <u>Previous surgery for incontinence n</u>				
Aim of the study To assess long-term anatomic and					

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### Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
functional outcomes of transvaginal pelvic reconstructive surgery using Prolift with one continuous piece of mesh concomitant vaginal hysterectomy for POP women  Study dates Surgery performed from March 2008 with follow-up at 3 years.  Source of funding None reported	(%) 5 (6.25)  Inclusion criteria Women with uterus prolapse stage 2 or more  Exclusion criteria Genital malignancies diagnosed prior to or after surgery, also neurogenic bladder dysfunction, uncontrolled diabetes, severe pelvic trauma.				Missing data bias: moderate risk of bias – not all participants eligible to take part responded, reasons were given for dropout  Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller group than of those initially treated.
Full citation  Webb, M. J., Aronson, M. P., Ferguson, L. K., Lee,	Sample size Surgery of initial N=810	Interventions Vaginal vault prolapse repair	Details Questionnaires asking about symptoms, satisfaction and	Results <u>Vaginal Bulge at median 7.4yrs n/N</u> 80/657	Limitations  Other information

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Surgical management of pelvic organ prolapse

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
R. A., Posthysterectomy vaginal vault prolapse: Primary repair in 693 patients, <i>Obstetrics and Gynecology</i> , 92, 281-285, 1998	Follow up of N=693		complications were sent to patients	<u>Dyspareunia at median 7.4 yrs n/N</u> 42/189	Confounding bias: not applicable – single arm study
Ref Id 642313	Characteristics <u>Age Median (range) years</u> 66 (31-88)				Selection of participant's bias: high risk of bias – no inclusion/exclusion details given
Country/ies where the study was carried out	<u>Abdominal hysterectomy</u> 343 (49.5%)				Classification of interventions bias: not applicable - single arm study
USA	<u>Vaginal hysterectomy without repair</u> 77 (11.1%)				Deviations from intended interventions bias: not applicable - single arm study
Study type Retrospectively identified, prospectively followed-up	<u>Vaginal hysterectomy with vaginal repair</u> 224 (32.3%)				Missing data bias: moderate risk of bias – not all participants eligible to take part responded, reasons were not given for dropout
Aim of the study Longterm follow-up following vaginal vault prolapse repair	<u>Hysterectomy unknown</u> 49 (7.1%)				Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions,
Study dates Surgery January 1976 to December 1987	<u>Median years from hysterectomy to vault prolapse repair</u> 15.8 (range 0.4–48.4 years).				
Source of funding None reported	Inclusion criteria Patients with vaginal vault prolapse repairs				

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	at the Mayo Clinic  Exclusion criteria None reported				however all outcomes for the participants were measured using the same methods  Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated.
Full citation  Weintraub, A. Y., Friedman, T., Baumfeld, Y., Neymeyer, J., Neuman, M., Krissi, H., Long-term functional outcomes following mesh-augmented posterior vaginal prolapse repair, International Journal of Gynecology and Obstetrics, 135, 107-111, 2016  Ref Id 642344	Sample size Eligible population N=102.  Data reported on N = 80.  Characteristics <u>Mean Age (SD)</u> 61.53 (11.41)  <u>Median Parity</u> 3 (2-3)  <u>Previous hysterectomy</u> 39/80 (49)  <u>Previous POP surgery</u> 23/80 (30)	Interventions Mesh-augmented posterior vaginal wall prolapse repair	Details Indications for primary surgery were symptomatic posterior wall prolapse. All surgery was performed by one surgeon and clinically assessed 1-3 months after surgery. Followup continued with primary care physician.	Results <u>Recurrence (at 70 mo, range 61-83) n/N</u> 14/80  <u>Mesh Complications n/N</u> 6/80  <u>Dyspareunia n/N</u> 6/80	Limitations <u>Paper reported limitations:</u> Lack of validated QoL questionnaires administered pre-operatively.  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – very few inclusion/exclusion details given, of those given criteria are reasonable

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Country/ies where the study was carried out Israel</p> <p>Study type Prospective telephone interview study</p> <p>Aim of the study Long-term functional outcomes of patients who had had mesh-augmented posterior vaginal wall prolapse repair</p> <p>Study dates January 2015</p> <p>Source of funding No conflicts of interest to declare</p>	<p>Inclusion criteria Patients who had undergone posterior vaginal wall mesh augmentation for symptomatic posterior vaginal wall prolapse between January 1st 2006 and February 28th 2009</p> <p>Exclusion criteria None reported</p>				<p>Classification of interventions bias: not applicable - single arm study</p> <p>Deviations from intended interventions bias: not applicable - single arm study</p> <p>Missing data bias: moderate risk of bias – not all participants eligible to take part responded, reasons were not given for dropout.</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data</p>

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
					comes from a smaller sub-group of those initially treated.
Full citation  Rahkola-Soisalo, P., Mikkola, T. S., Altman, D., Falconer, C., for Nordic, T. V. M. Group, Pelvic Organ Prolapse Repair Using the Uphold Vaginal Support System: 5-Year Follow-up, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 11, 11, 2017	Sample size 207 women had the operation A total of 164 attended the five year follow up  Characteristics Mean age: 70 years (SD 9.7), range 41 to 89  Mean BMI: 26.4kg/m <sup>2</sup> (SD 4), range 17.6 to 40.3	Interventions The uphold Lite Vaginal Support System was used in all women, a monofilament, macroporous, polypropylene, lightweight mesh. This was attached to the anterior part of the sacrospinous ligaments and to suspend the apex	Details Anterior colporraphy was undertaken at the surgeons discretion	Results 60 months follow up  Pain (n/N):3/207 Mesh erosion (n/N): 2/207  <u>PFDI</u> Pre op: 102.9 (SD 44.9) Post op: 46.0 (SD 39.6)  <u>PSIQ</u> Pre op: 15.7 (SD 7.7) Post op: 33.3 (SD 8.2)	Limitations Study authors have received funding from potentially conflicting parties, Johnson & Johnson, Astellas and Contura, Pfizer, Ivent Medic, Gynecare and Boston Scientific  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – very few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias:
Ref Id  826834	Inclusion criteria				
Country/ies where the study was carried out  Sweden, Finland, Denmark and Norway	<ul style="list-style-type: none"> <li>• Women with uterine or vaginal vault prolapse</li> <li>• With or without anterior wall prolapse</li> </ul>				
Study type Prospective multicentre cohort study	Exclusion criteria				

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Aim of the study To assess the long term outcomes of the Uphold Vaginal Support System for apical prolapse (with or without anterior colporraphy)</p> <p>Study dates February to June 2012</p> <p>Source of funding The study was supported by an investigator-initiated grant from Boston Scientific and the Swedish Scientific Council</p>	<ul style="list-style-type: none"> <li>Cervical elongation</li> <li>Previous or current pelvic organ cancer</li> <li>Severe Rheumatic disease</li> <li>Insulin treated diabetes mellitus</li> <li>Connective tissue disorder</li> <li>Current systemic steroid treatment</li> </ul>				<p>not applicable - single arm study</p> <p>Missing data bias: low risk of bias – all missing participants accounted for.</p> <p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated.</p>
<p>Full citation Funfgeld, C., Stehle, M., Henne, B., Kaufhold, J., Watermann, D., Grebe, M., Mengel,</p>	<p>Sample size Total number: 292</p> <p>Characteristics Mean age: 67 years (SD 8),</p>	<p>Interventions Cystocele was carried out using the vaginal approach with implantation of a titanized</p>	<p>Details Vaginal estrogenization and a single dose antibiotic were prescribed</p>	<p>Results 36 months data  Recurrence (n/N): 5/292  mesh erosion (n/N): 7/292</p>	<p>Limitations Authors state no conflicts of interest; however authors have received fees from potentially interested</p>

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
M., Quality of Life, Sexuality, Anatomical Results and Side-effects of Implantation of an Alloplastic Mesh for Cystocele Correction at Follow-up after 36 Months, Geburtshilfe und Frauenheilkunde Geburtshilfe Frauenheilkd, 77, 993-1001, 2017  Ref Id 826927  Country/ies where the study was carried out Germany  Study type Prospective cohort study, conducted across nine hospitals  Aim of the study To investigate anatomical outcomes and impact on quality of life following Alloplastic mesh insertion for Cystocele  Study dates	range 43 to 87 years  Mean BMI: 27kg/m <sup>2</sup> (SD 4), range 17 to 37kg/m <sup>2</sup>  Mean number of children: 2.3 (SD 1.2)  Inclusion criteria Women with cystocele or pelvic organ prolapse requiring surgical intervention  Exclusion criteria <ul style="list-style-type: none"> <li>• Women with previous pelvic radiation</li> <li>• Women with mesh implantation in the anterior compartment</li> <li>• Women with previous</li> </ul>	polypropylene mesh (TiLOOP <sup>(R)</sup> ) Total 6, pfm medical. Longitudinal incision of the anterior vaginal wall was carried out, and the 6-armed mesh inserted using a tunneler for a transobturator and ischiorectal approach. Apical fixation was done at the sacrospinal ligament.	Some women also underwent additional procedures, for example posterior repair, or suburethral sling.	Dyspareunia (n/N): 12/292	commercial parties: pfm medical, Serag Wiessner, BARD, AMD, AMI, Astellas, Recordati, Promedon, Johnson and Johnson.  Other information Confounding bias: not applicable – single arm study  Selection of participant's bias: moderate risk of bias – very few inclusion/exclusion details given, of those given criteria are reasonable  Classification of interventions bias: not applicable - single arm study  Deviations from intended interventions bias: not applicable - single arm study  Missing data bias: low risk of bias – all missing participants accounted for.

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Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
2010 and 2012  Source of funding Not stated	systemic steroid therapy				<p>Measurement of outcomes bias: serious risk of bias – as single arm design, study outcomes cannot be compared to other interventions, however all outcomes for the participants were measured using the same methods</p> <p>Selection of the reported results bias: serious risk of bias – long term outcome data comes from a smaller sub-group of those initially treated.</p>

**Clinical evidence tables for review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Table 33: Evidence tables for effectiveness studies**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation  Brubaker,L., Nygaard,I., Richter,H.E., Visco,A., Weber,A.M., Cundiff,G.W., Fine,P., Ghetti,C., Brown,M.B., Two-year outcomes after sacrocolpopexy with and without burch to prevent stress urinary incontinence, <i>Obstetrics and Gynecology</i> , 112, 49-55, 2008	Sample size  N=322 women randomised  Intervention: n=157  Control: n=165  Characteristics  See entry for Burgio et al. 2007 for details.	Interventions  Intervention: Sacrocolpopexy plus Burch Colposuspension (SAC+BURCH)  Control group: Sacrocolpopexy only (SAC)	Details  See entry for Burgio et al. 2007 for details.	Results  See entry for Burgio et al. 2007 for details.	Limitations  See entry for Burgio et al. 2007 for details.  Other information  CARE trial, article reports 3-mo and 12-mo data originally published in Brubaker et al. 2006 and Burgio et al. 2007; results published in Table 1 of Brubaker et al. 2008 were erroneous, corrections printed in <i>Obstetrics &amp; Gynecology</i> , May 2016, 127(5), p. 968-969.
Ref Id  100568	Inclusion criteria  See entry for Burgio et al. 2007 for details.				
Country/ies where the study was carried out					
USA					
Study type	Exclusion criteria  See entry for Burgio et al. 2007 for details.				
Multicentre RCT					
Aim of the study  To evaluate if Burch colposuspension performed at the time of abdominal					

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<b>Study details</b>	<b>Participants</b>	<b>Interventions</b>	<b>Methods</b>	<b>Outcomes and Results</b>	<b>Comments</b>
sacrocolpopexy for prolapse reduces postoperative incontinence symptoms in continent women at 3-mo, 12-mo and 24-mo follow up					
Study dates					
March 2002 to February 2005					
Source of funding					
Study supported by grants from the National Institute of Child Health and Human Development (U01 HD41249, U10 HD41268, U10 HD41248, U10 HD41250, U10 HD41261, U10 HD41263, U10 HD41269, and U10 HD41267). Some co-authors reported having received research funding/speaker fees/consultant fees from Eli Lilly, Cook OB/GYN, Novartis, Pfizer, Q-Med, CR Bard, Astellas, Life-Tech and Allergan					
Full citation	Sample size	Interventions	Details	Results	Limitations
	N=322 women randomised				

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Burgio, K. L., Nygaard, I. E., Richter, H. E., Brubaker, L., Gutman, R. E., Leng, W., Wei, J., Weber, A. M., Pelvic Floor Disorders Network, Bladder symptoms 1 year after abdominal sacrocolpopexy with and without Burch colposuspension in women without preoperative stress incontinence symptoms, American Journal of Obstetrics & Gynecology, 197, 647.e1-6, 2007	Intervention: n=157  Control: n=165  Characteristics  Data for SAC+BURCH, n=157; SAC, n=165  Mean age in years (SD)  SAC+Burch: 62.4 (9.7); SAC: 60.3 (10.6)  Mean BMI, kg/m <sup>2</sup>  SAC+BURCH: 27.0 (4.3); SAC: 27.1 (4.8)  Obese [BMI>35]  Country/ies where the study was carried out  USA  Study type  Multicentre RCT  Aim of the study  To evaluate if Burch colposuspension performed at the time of abdominal sacrocolpopexy for prolapse reduces postoperative incontinence symptoms	Intervention: Sacrocolpopexy plus Burch Colposuspension (SAC+BURCH)  Control group: Sacrocolpopexy only (SAC)	Participants were randomly allocated to sacrocolpopexy with or without Burch colposuspension through the use of a computer-generated random sequence in blocks of various sizes.  Preoperative urodynamics were completed with and without prolapse reduction.  Participants completed the Hunskaar measure, Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) at baseline and at 3-month follow-up (by telephone interviews). Follow up: 3 months, 12 months, 24 months.	Note: all data from Brubaker et al. 2008 unless otherwise stated.  Change of continence status  Objective/composite SUI at 3-mo: SAC+BURCH: 49/157; SAC: 89/165 (# women who (i) answer yes to any PFDI-stress subscale question, (ii) have a positive cough stress test, or (iii) have SUI treatment subsequent to study surgery)  Objective/composite SUI at 12-mo: SAC+BURCH: 54/157; SAC: 80/165  Objective/composite SUI at 24-mo: SAC+BURCH: 51/157; SAC: 81/165  Subjective SUI at 3-mo: SAC+BURCH: 29/157; SAC: 60/165 (response of 'yes' to any of 3 PFDI-stress [UDI] incontinence questions)  Subjective SUI at 12-mo: SAC+BURCH: 33/157; SAC: 63/165  Subjective SUI at 24-mo: SAC+BURCH: 38/157; SAC: 63/165  Any irritative symptoms at 12-mo: SAC+BURCH: 118/157; SAC: 118/165 (response of 'yes' to any UDI-irritative symptom subscale, inc. urge incontinence, urgency, frequency, nocturia, and enuresis) (data from Burgio et al. 2007)  Any obstructive symptoms at 12-mo: SAC+BURCH: 63/157; SAC: 66/165 (response of 'yes' to any UDI-obstructive symptom subscale, inc. difficulty emptying bladder, feeling of	Random sequence generation: Low risk (computer-generated random numbers with variable block size, stratified by surgeon and intention to perform paravaginal repair)  Allocation concealment: Unclear risk (sealed opaque envelopes opened in operating room but no further details)  Blinding of participants/personnel: Low risk (participants, research staff and telephone interviewers blinded, to be maintained up to 2 years after surgery)  Blinding of outcome assessment: Low risk (assessors blinded to group assignment)  Incomplete outcome data: Unclear risk (missing data imputed but no details of method used provided)  Selective reporting: Low risk (protocol available, all relevant outcomes reported)

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
in continent women at 12-mo and 24-mo follow up	Previous hysterectomy: 70.1%			incomplete bladder emptying, feeling of unusually weak stream or that it takes too long to empty bladder; start and stop urination; having to assume an unusual position or change positions to start or complete urination; having to push up on a bulge in the vaginal area with fingers to start or complete urination; having to push on the lower abdomen to start or complete urination; dribbling urine as standing up or beginning to walk immediately after finishing urination.) (data from Burgio et al. 2007)	Other bias: Low risk (appears free from other sources of bias)
Study dates	Inclusion criteria			Positive cough stress test at 3-mo: SAC+BURCH: 30/157; SAC: 65/165	Other information
March 2002 to February 2005	Women with stage II, III, or IV prolapse (as assessed with the use of the POP-Q system) undergoing abdominal sacrocolpopexy			Positive cough stress test at 12-mo: SAC+BURCH: 26/157; SAC: 41/165	CARE trial, 24-mo follow up data reported in Brubaker et al. 2008; results published in Table 1 of Brubaker et al. 2008 were erroneous, corrections printed in Obstetrics & Gynecology, May 2016, 127(5), p. 968-969.
Source of funding	Women without stress incontinence (defined as answering Never or Rarely to 6 stress incontinence questions on the Medical, Epidemiological and Social Aspects of Aging (MESA) questionnaire			Positive cough stress test at 24-mo: SAC+BURCH: 24/157; SAC: 39/165	
Study supported by grants from the National Institute of Child Health and Human Development (U01 HD41249, U10 HD41268, U10 HD41248, U10 HD41250, U10 HD41261, U10 HD41263, U10 HD41269, and U10 HD41267). Some co-authors reported having received research funding/speaker fees/consultant fees from Eli Lilly, Cook OB/GYN, Novartis, Pfizer, Q-Med, CR Bard, Astellas, Life-Tech and Allergan	Exclusion criteria			Composite urge incontinence outcome at 3-mo: SAC+BURCH: 50/157; SAC: 59/165 (urge incontinence, urgency, frequency, nocturia, or enuresis acc. to PFDI or subsequent treatment after study surgery for these)	
	Symptoms of stress incontinence (prior undergoing sacrocolpopexy)			Composite urge incontinence outcome at 12-mo: SAC+BURCH: 51/157; SAC: 66/165	
	Unable to undergo Burch colposuspension based on the assessment of the mobility of the urethrovesical junction			Composite urge incontinence outcome at 24-mo: SAC+BURCH: 47/157; SAC: 69/165	
				Complications	

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Mesh or suture erosion at <math>\leq</math>12-mo:          SAC+BURCH: 4/157 ; SAC: 10/162</p> <p>Mesh or suture erosion at &gt;1 year for POPto 2 years          : SAC+BURCH: 4/153 ; SAC: 2/158</p> <p>Wound complications (inc. hernia) at <math>\leq</math>12-mo : 6/157 ; SAC: 8/162</p> <p>Wound complications (inc. hernia) at &gt;1 year to 2 years: 2/157 ; SAC: 2/162</p> <p>Repeat surgery</p> <p>Repeat surgery for POP at 12-mo:          SAC+BURCH: 1/157; SAC: 4/162</p> <p>Repeat surgery for POP at &gt;1 year to 2 years:          SAC+BURCH: 1/153; SAC: 2/158</p> <p>Repeat surgery for other surgery-related complications at 12-mo:          SAC+BURCH: 2/157; SAC: 1/162</p> <p>Repeat surgery for other surgery-related complications at &gt;1 year to 2 years: SAC+BURCH: 2/157; SAC: 1/162</p> <p>Continence-specific health-related quality of life</p> <p>Mean Incontinence Severity Index at 3-mo: SAC+BURCH: 1.9 (sd 2.5), n=153; SAC: 2.9 (sd 3.1), n=152</p> <p>Mean Incontinence Severity Index at 12-mo: SAC+BURCH: 1.9 (sd 2.5), n=155; SAC: 2.9 (sd 3.1), n=158</p>	

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Mean Incontinence Severity Index at 24-mo: SAC+BURCH: 2.0 (2.5), n=147; SAC: 2.8 (3.1), n=155</p> <p>Mean PISQ-12 score at 12-mo: SAC+BURCH: 37.3 (sd 5.3), n=96; SAC: 37.4 (5.1), n=98</p> <p>Mean PISQ-12 score at 24-mo: SAC+BURCH: 37.2 (sd 5.0), n=98; SAC: 37.3 (5.5), n=96</p> <p>Adverse events</p> <p>Serious adverse events at 3-mo: SAC+BURCH: 23/157; SAC: 24/165 (number of women who had untoward life-threatening or fatal medical occurrences, required prolonged hospitalisation or readmission for the index surgery, any condition that resulted in persistent or clinically significant disability, or any other important medical condition).</p>	
<p>Full citation</p> <p>Costantini, E., Zucchi, A., Giannantoni, A., Mearini, L., Bini, V., Porena, M., Must colposuspension be associated with sacropectomy to prevent postoperative urinary incontinence?, European Urology, 51, 788-94, 2007</p> <p>Ref Id</p> <p>541334</p>	<p>Sample size</p> <p>N=66 randomised Intervention, n=34</p> <p>Control, n=32</p> <p>Characteristics</p> <p>Mean age, years (SD): SAC+BURCH: 63 (sd 9); SAC: 61 (sd 8)</p>	<p>Interventions</p> <p>Intervention: Sacrocolpopexy and Burch colposuspension (SAC+BURCH)</p> <p>Control: Sacrocolpopexy (SAC)</p>	<p>Details</p> <p>Evaluation of participants included history, Urogenital Distress Inventory, Impact Incontinence Quality of Life, voiding diary, urine culture, physical examination, pelvic ultrasound, and urodynamic assessment. POP was classified</p>	<p>Results</p> <p>Note: 8-year follow-up data from Costantini et al. 2011</p> <p>Change of continence status (as determined by bladder diary, number of daily pads and stress test with success defined as complete dryness with no leakage reported in the bladder diary, no pad use and a negative stress test)</p> <p>Any incontinence symptoms at 3-years: SAC+BURCH: 12/34; SAC: 3/32</p>	<p>Limitations</p> <p>Random sequence generation: Low risk (computer-generated block randomisation)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: High risk (no attempt made to blind participants and investigators)</p>

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out  Italy	Mean BMI, kg/m <sup>2</sup> (SD)  SAC+BURCH: 24 (sd 3); SAC 4 (sd 2)		according to the Halfway System and the International Continence Society system. Urinary incontinence was classified on the basis of the International Continence Society definition and the graded on the Ingelman Sunderberg scale. Stress test was conducted in the supine position at physiologic bladder capacity, before and after prolapse reposition both with the fingers and with a Sims speculum inserted in the anterior vaginal fornix. Urodynamic evaluation involved uroflowmetry, cystometry, pressure/flow study, urethral profilometry, and Valsalva leak point pressure.	Any incontinence symptoms at 8-years: SAC+BURCH: 9/34; SAC: 5/32  Any urge or mixed incontinence symptoms at 3-years: SAC+BURCH: 3/34; SAC: 2/32	Blinding of outcome assessment: Low risk (assessors blind to group assignment)
Study type  RCT	Median parity  SAC+BURCH: 2; SAC: 2			Any urge or mixed incontinence symptoms at 8-years: SAC+BURCH: 2/34; SAC: 3/32	Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates)
Aim of the study  To evaluate the impact of Burch colposuspension in preventing incontinence in continent patients undergoing abdominal surgery for severe prolapse	Menopausal, %  SAC+BURCH: 88; SAC: 81  Previous anti-incontinence or anti-prolapse surgery, %  SAC+BURCH: 24; SAC: 38			Any stress incontinence symptoms at 3-years: SAC+BURCH: 9/34; SAC: 1/32  Any stress incontinence symptoms at 8-years: SAC+BURCH: 7/34; SAC: 2/32  Complications	Selective reporting: Unclear risk (insufficient information)
Study dates  From 2000 to 2004	Inclusion criteria  Continent women with severe pelvic organ prolapse undergoing colposacropexy  Negative stress test before and after prolapse reduction			Need for catheterisation at 3-mo: 2/34; 0/32  De novo storage symptoms at 8-years: SAC+BURCH: 2/34; 0/32  Adverse events	Other bias: Low risk (appears free from other sources of bias)  Other information  8-year follow-up data reported in Costantini et al. 2011.
Source of funding  Not reported	No preoperative history of UI symptoms  Negative symptoms questionnaires  No leakage during urodynamic evaluation  Exclusion criteria		Sacrocolpopexy performed abdominally and according to standard practice, followed if assigned by	Severe bleeding requiring blood transfusion at 6-mo: SAC+BURCH: 3/34; SAC: 3/32	

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			<p>Standard Burch procedure using 4 sutures (2 each side). Follow-up assessments took place at 3, 6, and 9 months, and then annually.</p> <p>Median FU in Costantini et al. 2007</p> <p>Overall, mean 39.5-mo; SAC+BURCH=42 months (sd 18; range 12-74); SAC=38 months (sd 19; range 15-71).</p> <p>Median FU in Costantini et al. 2011</p> <p>Overall, 97 months (range 72-134); SAC+BURCH=110 months (range 72-134); SAC=96 months (range 75-125).</p>		
Full citation	<p>Sample size</p> <p>N=66 randomised</p> <p>Intervention, n=34</p> <p>Control, n=32</p>	<p>Interventions</p> <p>Intervention: Sacrocolpopexy and Burch colposuspension (SAC+BURCH)</p> <p>Control: Sacrocolpopexy (SAC)</p>	<p>Details</p> <p>See entry for Costantini et al. 2007 for details.</p>	<p>Results</p> <p>See entry for Costantini et al. 2007 for details.</p>	<p>Limitations</p> <p>See entry for Costantini et al. 2007 for details.</p> <p>Other information</p>

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
continent women: a randomized, controlled trial with 8-year followup, Journal of Urology, 185, 2236-40, 2011	Characteristics  See entry for Costantini et al. 2007 for details.				8-year follow-up article to Costantini et al. 2007
Ref Id					
541331	Inclusion criteria				
Country/ies where the study was carried out	See entry for Costantini et al. 2007 for details.				
Italy					
Study type	Exclusion criteria				
RCT	See entry for Costantini et al. 2007 for details.				
Aim of the study					
To evaluate long-term impact of Burch colposuspension in preventing incontinence in continent patients undergoing abdominal surgery for severe prolapse					
Study dates					
From 2000 to 2004					
Source of funding					
Not reported					
Full citation	Sample size	Interventions	Details	Results	Limitations

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Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
van der Ploeg, J. M., Oude Rengerink, K., van der Steen, A., van Leeuwen, J. H., van der Vaart, C. H., Roovers, J. P., Dutch Urogynaecology Consortium, Vaginal prolapse repair with or without a midurethral sling in women with genital prolapse and occult stress urinary incontinence: a randomized trial, International Urogynecology Journal, 27, 1029-38, 2016	N=91 randomised Intervention, n=43 Control, n=48	Intervention: Vaginal prolapse surgery + Transobturator synthetic mesh sling (VPRO+TMUS)  Control: Vaginal prolapse surgery (VPRO)	CUPIDO-2: Continent women underwent a stress test with POP reduction, followed by standardised urodynamic assessment. Women identified as having occult stress urinary incontinence were randomised into blocks of four in a 1:1 ratio. Women without occult stress urinary incontinence underwent prolapse repair alone and were followed up in a separate cohort. Follow up of 12 months. 88% of women in the synthetic mesh sling group received transobturator mesh sling; 12% received retropubic mesh sling.	Change of continence status at 12 months  Any sign of incontinence: VPRO+TMUS: 0/43; VPRO: 18/47 (bothersome incontinence symptoms on UDI, positive cough stress test, or any incontinence treatment)  Subjective urge urinary incontinence symptoms: VPRO+TMUS: 8/43; PRO: 16/47 (UDI assessed)  Subjective absence of urinary incontinence: VPRO+TMUS: 31/43; VPRO: 18/47 (absence of any incontinence symptoms, assessed by UDI)  Subjective absence of SUI: VPRO+TMUS: 36/43; VPRO: 22/47 (absence of SUI symptoms, assessed by UDI)  Positive positive cough stress test: VPRO+TMUS: 0/29; VPRO: 11/31 (>20% missing data)  Subjective Frequency symptoms: VPRO+TMUS: 10/43; VPRO: 10/47 (10 or more times a day, UDI)  Subjective Nocturia symptoms: VPRO+TMUS: 15/43; VPRO: 9/47 (2 or more times a night, UDI)  Complications  Mesh extrusion/exposure: VPRO+TMUS: 3/43; VPRO: 0/47	Random sequence generation: Low risk (computer-generated block randomisation stratified by centre and leading edge of POP)  Allocation concealment: Low risk (web-based central allocation)  Blinding of participants/personnel: High risk (blinding of participants and personnel not attempted)  Blinding of outcome assessment: High risk (assessors not blinded to group assignment)  Incomplete outcome data: Low risk (missing data not sufficient to induce clinically-relevant change to effect estimates)  Selective reporting: Low risk (protocol available, all relevant outcomes reported)  Other bias: Low risk (appears free from other sources of bias)  Other information
Ref Id	VPRO+TMUS: 26.7 (sd 3.4); VPRO: 26.3 (sd 3.3)				
541743					
Country/ies where the study was carried out	Mean number of vaginal deliveries				
The Netherlands	VPRO+TMUS: 2.7 (sd 1.2); VPRO: 2.7 (sd 1.3)				
Study type	Inclusion criteria				
RCT	Women with POP at least stage II according to the POP-Q system, scheduled for vaginal prolapse repair				
Aim of the study	Continent women defined as women who did not leak urine more than once a week and had a negative cough stress test without POP reduction				
To compare vaginal prolapse repair with or without midurethral sling (MUS) in women with pelvic organ prolapse and occult urinary incontinence					

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates  November 2007 to April 2014	Exclusion criteria  Women with postvoidal residuals > 300 ml  Previous incontinence surgery  Recent prolapse surgery  Women unable to give informed consent  Pregnant women  Women wishing to become pregnant  Women with a systemic disease that could influence bladder function (for example, multiple sclerosis or Parkinson's disease)  Women scheduled for/undergoing chemo- or radiotherapy			Infection (UTI): VPRO+TMUS: 5/43; VPRO: 1/47  Repeat surgery for SUI at 12 months  VPRO+TMUS: 0/43; VPRO: 6/47  Adverse events  Bladder injury: VPRO+TMUS: 0/43; VPRO: 0/47  Patient satisfaction at 12 months  PGII: VPRO+TMUS: 31/43; VPRO: 31/47 (response of 'much' or 'very much' improvement on Patient Global Impression of Improvement scale)	Included in the Vaginal POP repair + Transobturator synthetic mesh sling versus vaginal POP repair only comparison.
Source of funding  Unrestricted grant received from the Dutch Ohra Fund.					
Full citation  Wei, J. T., Nygaard, I., Richter, H. E., Nager, C. W., Barber, M. D., Kenton, K., Amundsen, C. L., Schaffer, J., Meikle, S. F., Spino, C., Pelvic Floor Disorders, Network, A midurethral sling to reduce incontinence after vaginal prolapse repair,	Sample size  N=337 randomised Intervention, n=165 Control, n=172 Characteristics	Interventions  Intervention: Vaginal prolapse repair + TVT retropubic mesh sling (VPRO+TVT)  Control: Vaginal prolapse repair (VPRO) + sham incisions	Details  OPUS trial, clinicalTrials.gov number, NCT00460434. Baseline assessment involved demographic and general health data, examination	Results  Change in continence status  Composite urinary incontinence outcome at 12-months: VPRO+TVT: 45/165; TVT: 74/172 (positive cough stress test, or response of 'moderately' or 'quite a bit' bothersome on 4 PFDI leakage items)	Limitations  Random sequence generation: Unclear risk (reports permuted block design stratified by surgeon and type of prolapse surgery but no further details)

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
New England Journal of Medicine, 366, 2358-67, 2012	Data for VPRO+TVT, n=165; VPRO, n=172		for prolapse, measurement of post-voiding residual volume, preoperative prolapse reduction stress test (at a bladder volume of 300 ml), scores on the Medical Outcomes Study 36-Item Short-Form Health Survey, the PFDI, PFIQ, Incontinence Severity Index, Pelvic Organ Prolapse/Urinary Incontinence Sexual Functioning Questionnaire Short Form, and a visual analogue pain scale adapted for suprapubic pain. Follow up took place at 3, 6 and 12 months and involved history taking, administration of the same surveys administered during the baseline assessment, and an assessment of prolapse severity. Cough stress test, urinalysis, and measurement of post-voiding residual volume were performed at	Positive cough stress test at 12-months: VPRO+TVT: 5/165; TVT: 31/172	Allocation concealment: Unclear risk (insufficient information)
Ref Id	Mean age, years (SD)			Continence-specific health-related quality of life	Blinding of participants/personnel: Low risk (sham incisions used for women in control group)
541765	VPRO+TVT: 63.4 (sd 10.8); VPRO: 62.2 (sd 10.2) in the control group			Mean change from baseline in Incontinence Severity Index score at 12-mo: VPRO+TVT: -0.9 (2.7), n=154; TVT: 0.1 (2.7), n=152	Blinding of outcome assessment: Low risk (all assessors blinded to group assignment)
Country/ies where the study was carried out	Mean BMI (SD), kg/m <sup>2</sup>			Complications at ≤1 year after surgery	Incomplete outcome data: Low risk (missing data not sufficient to induce clinically-relevant impact on effect estimates)
USA	VPRO+TVT: 27.8 (sd 4.9); VPRO: 28.1 (sd 5.5)			Mesh erosion/exposure: VPRO+TVT: 0/165; VPRO: 0/172	Selective reporting: Low risk (protocol available, all relevant outcomes reported)
Study type	POP-Q Stage 2/3/4, %			Infection (UTI): VPRO+TVT: 49/165; VPRO: 30/172	Other bias: Low risk (appears free from other bias)
Multicentre RCT	VPRO+TVT: 27/65/8; VPRO: 28/62/10			Adverse events	Other information
Aim of the study	Inclusion criteria			Bladder injury: VPRO+TVT: 11/164; VPRO: 0/172	
To determine if a concomitant midurethral sling affects the prevalence or urinary incontinence in continent women undergoing vaginal prolapse surgery	Women planning to undergo vaginal prolapse surgery after reporting a vaginal bulge but who reported no symptoms of stress urinary incontinence (as defined as a positive response to any of the 3 questions regarding stress incontinence on the PFDI)				
Study dates	On pelvic examination, the anterior vaginal wall prolapse had to be within 1 cm of the hymen with straining				
May 2007 - January 2011	Exclusion criteria				
Source of funding	Funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institutes of Health Office				

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<b>Study details</b>	<b>Participants</b>	<b>Interventions</b>	<b>Methods</b>	<b>Outcomes and Results</b>	<b>Comments</b>
of Research on Women's Health	<p>Previous sling placement</p> <p>Receiving treatment for stress urinary incontinence</p> <p>Contraindications for a midurethral sling</p> <p>Planning pregnancy in the first year after surgery</p> <p>History of two or more hospitalisations for medical illnesses in the previous year</p>		<p>3 and 12 months.</p> <p>All participants had vaginal prolapse repair with either TVT (Gynecare) retropubic synthetic mesh sling or 2 x 1-cm suprapubic, superficial sham incisions.</p>		

**Clinical evidence tables for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Table 34: Clinical evidence tables**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<b>Full citation</b>	<b>Sample size</b>	<b>Interventions</b>	<b>Details</b>	<b>Results</b>	<b>Limitations</b>
Abdool, Z., Thakar, R., Sultan, A., Oliver, R., Prospective evaluation of outcome of vaginal pessaries versus surgery in women with symptomatic pelvic organ prolapse, International Journal of Gynecology and Obstetrics, 107, S94, 2009	See Abdool et al. 2011  Characteristics See Abdool et al. 2011	See Abdool et al. 2011  Other information See Abdool et al. 2011			
Ref Id 636463	Inclusion criteria  See Abdool et al. 2011				
Country/ies where the study was carried out					
See Abdool et al. 2011	Exclusion criteria  See Abdool et al. 2011				
Study type See Abdool et al. 2011					
Aim of the study See Abdool et al. 2011					

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates See Abdool et al. 2011					
Source of funding See Abdool et al. 2011					
<b>Full citation</b>  Abdool, Z., Thakar, R., Sultan, A. H., Oliver, R. S., Prospective evaluation of outcome of vaginal pessaries versus surgery in women with symptomatic pelvic organ prolapse, International Urogynecology Journal, 22, 273-278, 2011	<b>Sample size</b>  N=554 Pessary group N=359 Surgery group N=195	<b>Interventions</b>  Pessary Interventions: N=296 ring pessary N=50 gellhorn pessary N=8 cube pessary N=5 donut pessary	<b>Details</b>  Postal questionnaires of the SPS-Q were sent after 1 year, a second was sent if no response after 2-3 months	<b>Results</b>  At follow up of 1 year (more specifically: Surgery, 14 months (6.14) vs Pessary, 12 months (3.1)), n=164 (68%) from the pessary group and n=107 (55%) from the surgery group completed the SPS-Q  Change of symptoms  General symptoms  Awareness of a lump  Pessary: Better n=85 (65.3); Worse n=7 (5.3); No change n=38 (29.2)  Surgery: Better n=74 (69.8); Worse n=6 (5.6); No change n=26 (24.5)  Prolapse coming out of vagina  Pessary: Better n=75 (59.5); Worse n=7 (5.6); No change n=44 (35)	<b>Limitations</b>  Bias due to confounding – high, participant ages vary between groups  Bias in selection of participants into the study – high, self-selection  Bias in classification of interventions – low, intervention groups clearly defined a priori  Bias due to deviations from intended interventions – low, those who crossed from pessary to surgery group were excluded from analysis.  Bias due to missing data – moderate, not all outcome data
Ref Id 636464	Characteristics  Age - mean ± SD (years) Pessary: 68.4 (13.08) Surgery: 60.4 (12.25)	Surgery interventions: N=30 posterior colporrhaphy N=44 anterior colporrhaphy N=15 anterior and posterior colporrhaphy N=59 vaginal hysterectomy and anterior colporrhaphy N=27 vaginal hysterectomy, Mc Call's culoplasty and posterior colporrhaphy N=10 sacrocolpopexy N=6 vaginal hysterectomy and Mc Call's culoplasty N=4 sacrospinous fixation			
Country/ies where the study was carried out England	Between groups, there were no statistically significant differences for vaginal parity, previous prolapse repairs or hysterectomy				
Study type Prospective observational study					
Aim of the study					

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Using the Sheffield validated Pelvic Organ Prolapse quality of life questionnaire (SPS-Q), to evaluate and compare the effectiveness of pessaries and surgery in women with symptomatic POP after 1 year	From abstract: between pessary and surgery group respectively - vaginal parity (mean 2.4 vs. 2.6, $p = 0.196$ ) previous repairs (9% vs. 13.6%, $p = 0.196$ ) and hysterectomy (32% vs. 24%; $p = 0.05$ )			Surgery: Better n=57 (54.8); Worse n=10 (9.6); No change n=37 (35.6)  Vaginal Soreness  Pessary: Better n=32 (23.7); Worse n=14 (10.4); No change n=89 (66)	available for all who enrolled  Bias in measurement of outcomes – high, outcome measure could have been influenced by knowledge of intervention. Outcome measures were self-reported by participants
Study dates				Surgery: Better n=36 (34); Worse n=12 (11.3); No change n=58 (54.7)	
Women were referred between June 2002 and May 2007. Follow up was 1 year later	Inclusion criteria  Symptomatic POP patients who chose pessary or surgery			Draggling pain in lower abdomen  Pessary: Better n=52 (38.5); Worse n=14 (10.4); No change n=69 (51.1)	Bias in selection of the reported results – low, data reported appropriately
Source of funding				Surgery: Better n=52 (50); Worse n=7 (6.7); No change n=45 (43.3)	Other information
IUGA granted primary author an International Fellowship award	Exclusion criteria  Women with pessaries fitted for UI and those who had concomitant UI surgery (e.g. TVT) were excluded  Women who started in pessary group but went on to have surgery were excluded from analysis			Low back pain  Pessary: Better n=50 (36.8); Worse n=20 (14.7); No change n=66 (48.5)	
				Surgery: Better n=40 (37.7); Worse n=15 (14.2); No change n=51 (48.1)  Urinary Symptoms  Difficulty in emptying bladder	

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Pessary: Better n=37 (27.6); Worse n=20 (15); No change n=77 (57.5)</p> <p>Surgery: Better n=50 (46.7); Worse n=15 (14); No change n=43 (39.3)</p> <p>Push prolapse to void</p> <p>Pessary: Better n=36 (27.5); Worse n=10 (7.6); No change n=85 (64.9)</p> <p>Surgery: Better n=25 (23.6); Worse n=7 (6.6); No change n=74 (69.8)</p> <p>Urinary urgency</p> <p>Pessary: Better n=46 (34.3); Worse n=17 (12.7); No change n=71 (53)</p> <p>Surgery: Better n=36 (33.6); Worse n=17 (15.9); No change n=54 (50.5)</p> <p>Urge urinary incontinence</p> <p>Pessary: Better n=28 (21); Worse n=24 (18); No change n=82 (61.2)</p> <p>Surgery: Better n=27 (25.2); Worse n=14 (13.1); No change n=66 (61.7)</p> <p>Stress incontinence</p>	

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Pessary: Better n=28 (21); Worse n=22 (16); No change n=85 (63)</p> <p>Surgery: Better n=22 (21); Worse n=16 (15); No change n=67 (64)</p> <p>Defecatory symptoms</p> <p>Incomplete emptying of the bowel</p> <p>Pessary: Better n=32 (24.4); Worse n=23 (17.6); No change n=76 (58)</p> <p>Surgery: Better n=38 (35.5); Worse n=18 (16.8); No change n=51 (47.7)</p> <p>Fecal urgency</p> <p>Pessary: Better n=25 (18.4); Worse n=12 (8.8); No change n=99 (72.8)</p> <p>Surgery: Better n=23 (22); Worse n=12(11.4); No change n=70 (66.6)</p> <p>Sexual activity</p> <p>Satisfaction</p> <p>Pessary: Better n=15 (47); Worse n=4 (12); No change n=13 (41)</p>	

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<b>Study details</b>	<b>Participants</b>	<b>Interventions</b>	<b>Methods</b>	<b>Outcomes and Results</b>	<b>Comments</b>
				<p>Surgery: Better n=39 (67); Worse n=5 (9); No change n=14 (24)</p> <p>Frequency</p> <p>Pessary: Better n=15 (45); Worse n=5 (15); No change n=13 (40)</p> <p>Surgery: Better n=14 (25); Worse n=15 (26); No change n=28 (49)</p> <p>Interference with physical activity</p> <p>Pessary: Better n=51 (39.2); Worse n=10 (7.7); No change n=69 (53.1)</p> <p>Surgery: Better n=57 (55.3); Worse n=11 (10.7); No change n=35 (34)</p> <p>Interference with enjoyment of life</p> <p>Pessary: Better n=62 (47.3); Worse n=12 (9.2); No change n=57 (43.5)</p> <p>Surgery: Better n=64 (62); Worse n=11 (10.7); No change n=28 (27.3)</p>	
<b>Full citation</b>	<b>Sample size</b>	<b>Interventions</b>	<b>Details</b>	<b>Results</b>	<b>Limitations</b>
Barber, M. D., Walters, M. D., Cundiff, G. W., Pessri Trial Group,	N=108 Pessary group N=42	Surgery interventions: N= 27 Vaginal hysterectomy	Surgery: questionnaires administered at baseline and 6 months after surgery	Mean change in score (SD)	Bias due to confounding – high, participant ages vary

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Responsiveness of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) in women undergoing vaginal surgery and pessary treatment for pelvic organ prolapse, American Journal of Obstetrics & Gynecology, 194, 1492-8, 2006	Surgery group N=64  Characteristics  Age - mean (SD) (years) Pessary: 62 (15) Surgery: 58 (13)	N=48 Anterior colporrhaphy N=35 Posterior colporrhaphy N=43 Vaginal vault suspension N=26 Sling procedure N=2 Anal sphincteroplasty N=7 Colpocleisis N=5 Other (laparoscopic cholecystectomy n=2, urethrolysis n=1, transperineal rectopexy n=1 and cervical trachelectomy n=1)	Pessary: participants had the gelhorn pessary or ring pessary randomly for 3 months before switching to other pessary. Questionnaires administered at baseline and after 3 months (after switch to other pessary data not used)	POPIQ: Pelvic organ prolapse impact questionnaire (range 0-300); UDI: urinary distress inventory (range 0-300); CRADI: colo-rectal-anal distress inventory (range 0-400)  Pessary group:  PFDI Scales  POPDI: -46 (67) p<0.001  UDI: -30 (53) p=0.0007  CRADI: -12 (48) p=0.14	between groups and stage of POP is higher for surgery group  Bias in selection of participants into the study – high, self-selection  Bias in classification of interventions – low, intervention groups clearly defined a priori
Ref Id  541268	BMI - mean (SD) (kg/m <sup>2</sup> )  Pessary: 27 (6) Surgery: 26 (8)				Bias due to deviations from intended interventions – unclear whether any participants deviated
Country/ies where the study was carried out  USA				PFIQ Scales  POPIQ: -30 (100) p=0.08  UIQ: -14 (100) p=0.88  CRADI: -12 (48) p=0.80	Bias due to missing data – unclear, not clear whether all who enrolled completed the study
Study type  Prospective observational study	Parity - median (range)  Pessary: 2 (1-7) Surgery: 3 (0-6)				Bias in measurement of outcomes – high, outcome measure could have been influenced by knowledge of intervention. Outcome measures were self-reported by participants
Aim of the study  Evaluate responsiveness of the Pelvic floor distress inventory (PFDI) and the Pelvic floor impact questionnaire (PFIQ) for women with advanced POP receiving surgical or nonsurgical treatment	Previous hysterectomy - (%)  Pessary: 29% Surgery 20%  Previous pelvic reconstructive surgery - (%)  Pessary: 12% Surgery 20%			Surgery group:  PFDI Scales  POPDI: -89 (74) p<0.0001  UDI: -63 (60) p<0.0001  CRADI: -44 (72) p<0.0001	Bias in selection of the reported results – low, data reported appropriately
Study dates				PFIQ Scales	

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Not reported	Stage of POP Pessary: Stage II 35%, stage III 57%, stage IV 7% Surgery: Stage II 0%, stage III 81%, stage IV 19%			POPIQ: -59 (92) p<0.0001  UIQ: -60 (86) p<0.0001  CRADI: -35 (69) p<0.006	Other information
Source of funding  Pessaries were donated by Milex Products, Inc, Chicago IL		Inclusion criteria  For surgery group: stage III or IV prolapse, over 18 years, scheduled for surgery			Pessary group recruited from PESSRI trial (population might overlap with pessary guideline data)
		None specifically reported for pessary group			
		Exclusion criteria  Those mentally or physically incapable of completing self- administered questionnaires.			
		For Pessary group: if pregnant, currently using a pessary, had vaginal agglutination			

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	that precluded pessary insertion				
<b>Full citation</b>	<b>Sample size</b>	<b>Interventions</b>	<b>Details</b>	<b>Results</b>	<b>Limitations</b>
Chan, S. S. C., Cheung, R. Y. K., Lai, B. P. Y., Lee, L. L., Choy, K. W., Chung, T. K. H., Responsiveness of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire in women undergoing treatment for pelvic floor disorders, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, 213-221, 2013	N=128  Pessary group N=27 (n=20 POP only, n=7 POP and USI)  Pelvic floor surgery group N=62 (n=60 POP only, n=2 POP and USI)  Pelvic floor and continence surgery group N=39 (n=39 POP and USI)	Surgery included: Vaginal hysterectomy and anterior and or posterior colporrhaphy - VHPFR (generally for stage I-II uterine prolapse) VHPFR with sacrospinous ligament fixation or vaginal mesh repair surgery (generally for stage III-IV uterine prolapse) Vaginal mesh repair surgery / laparoscopic sacrocolpopexy (generally for vaginal vault prolapse) Transobturator tension free transvaginal tape surgery - TVT-O (generally for those with concomitant USI)  Pessary included: (for those with POP only or POP and USI) Vaginal ring pessary	Women completed the PFDI and PFIQ on their own, or if illiterate, with help of an experienced research assistant. Higher scores equal worse symptoms.  Urinary, prolapse and bowel symptoms were evaluated by the attending gynaecologist following standardised data sheets.	Mean change in score (SD)  UDI: urinary distress inventory; POPIQ: Pelvic organ prolapse impact questionnaire; CRADI: colorectal-anal distress inventory; UIQ Urinary impact questionnaire; POPIQ: pelvic organ prolapse impact questionnaire; CRAIQ: colorectal-anal impact questionnaire  Pessary group (n=27): UDI: -24.4 (43.5) p=0.008 POPDI: -38.2 (58.0) p=0.047 CRADI: -8.8 (52.8) p=0.07 UIQ: -30.7 (75.4) p=0.05 POPIQ: 46.9 (86.1) p=0.01 CRAIQ: -18.3 (46.5) p=0.02	Allocation bias: High risk of bias - self selection  Allocation concealment: Not applicable  Performance bias: High risk of bias - patients and physicians were not blinded
Ref Id  637330	(N=28 with urinary stress incontinence who received continence surgery only were not extracted as not relevant)		Women with USI and not responsive to pelvic floor exercise were offered continence surgery. Women with POP with or without concomitant USI were offered vaginal ring pessary or pelvic floor repair (PFR) surgery appropriate for their condition/preference	Pelvic floor surgery group (n=62): UDI: -55.9 (52.4) p<0.005 POPDI: -77.6 (68.6) p=0.004	Detection bias: High risk - assessor may have been aware of treatment, measures were primarily self-reported
Country/ies where the study was carried out  Hong Kong	Characteristics		Following surgery, women were followed up 3-4 months post surgery and then annually		Attrition bias: High risk - 290 women recruited but only 156 completed, some reasons given for loss, but do not account for all women
Study type  Prospective observational study					
Aim of the study  Evaluate responsiveness of the Chinese pelvic floor distress inventory (PFDI) and the pelvic floor impact questionnaire (PFIQ) in	Age - mean (SD) (years)  Pessary: 60.7 (11.0) PF Surgery: 60.3 (8.1) PF and continence surgery: 61.1 (9.7)				

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women with POP and/or urodynamic stress incontinence (USI) who were undergoing treatment.	BMI - mean (SD) kg/m <sup>2</sup> Pessary: 24.6 (3.7) PF Surgery: 25.6 (3.3) PF and continence surgery: 26.0 (3.5)		Following pessary, women were followed up every 6 months	CRADI: -34.1 (61.2) p<0.005  UIQ: -52.5 (59.6) p<0.005  POPIQ: -59.7 (68.9) p<0.005	Reporting bias: Unclear risk of bias
Study dates			Follow up: mean (SD), median [range]	CRAIQ: -38.9 (48.4) p<0.005	Other information
April 2009 to September 2009			Pessary group: 12.3 (6.5), 12 [3-25]		
Source of funding	Parity - mean (SD) Pessary: 3.0 (1.5) PF Surgery: 3.0 (1.3) PF and continence surgery: 3.3 (1.5)		Pelvic floor surgery: 7.6 (4.0), 4 [4-24]	Pelvic floor and concomitant continence surgery group (n=39):  UDI: -71.2 (61.8) p=0.002  POPDI: -73.6 (64.3) p=0.001	
Grant from the Health and Health Service Research Fund (HHSRF) from the Food and Health Bureau of Hong Kong SAR	Previous hysterectomy - (%) Pessary: 3/27, 11.1% PF Surgery: 8/62, 12.9% PF and continence surgery: 2, 5.1%		Pelvic floor and continence surgery: 8.5 (4.6), 4 [4-24]	CRADI: -40.3 (63.1) p=0.001  UIQ: -69.6 (89.7) p<0.005  POPIQ: -79.5 (79.6) p<0.005  CRAIQ: -44.7 (65.6) p<0.005	
	Stage of POP Pessary: Stage I/II 19/27, 70.4%; Stage III IV 8/27, 29.6% PF Surgery: Stage I/II 37/62, 59.7%; Stage III IV 25/62, 40.3% PF and continence surgery: Stage I/II 25/39, 64.1%; Stage III IV 14/39, 35.9%				

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>Inclusion criteria</p> <p>Women presenting with pelvic floor disorders with urodynamic stress incontinence requiring continence surgery who received treatment for POP with or without concomitant USI</p> <p>Exclusion criteria</p> <p>None given, women who elected for conservative management were excluded in the analysis</p>				
<b>Full citation</b> Coolen, A. W. M., Troost, S., Mol, B. W. J., Roovers, Jpwr, Bongers, M. Y., Primary treatment of pelvic organ prolapse: pessary use versus prolapse surgery, International urogynecology journal, 09, 09, 2017 <b>Ref Id</b>	<b>Sample size</b> N = 113 Pessary group: N=74 (n=2 randomised to pessary and n=72 chose) Surgery group: N=39 (n=4 randomised to surgery and 35 chose)	<b>Interventions</b> Pessary Either a shelf (Falk, n=10) (primarily for those with apical descent, extensive prolapse or lack of support from ring pessary) or ring pessary (n=64, with or without central support, preferred option and for those with apical descent).	<b>Details</b> Women were treated by one of three urogynaecologists. Randomisation Performed using opaque sealed envelopes, allocated 1:1.	<b>Results</b> Pessary (n=74) Side effects: Vaginal discharge n=15, vaginal pain n=10, Urinary incontinence n=7, Erosion n=3, Bleeding n=1 Continuation rates: 4 weeks n=60, 3 months n=60, 6 months n=47, 1 year n=44 Reason for discontinuation: Pessary expulsion n=7, Urinary	<b>Limitations</b> Bias due to confounding – high, participant ages vary between groups and POP staging Bias in selection of participants into the study – high, self-selection for n=107 (n=6 were randomised 1:1)

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### Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
651189	Country/ies where the study was carried out	Characteristics	Power calculation	incontinence n=6, Vaginal pain n=6, Vaginal discharge n=5, No symptom reduction n=5, Urinary retention n=1	Bias in classification of interventions – low, intervention groups clearly defined a priori
The Netherlands	Age - mean ± range (years)	Surgery	Assuming a standard deviation of 15 points for the UDI questionnaire, 72 patients would be needed to show a statistical significant difference. With a 10% attrition rate, 80 patients would be needed (40 in each arm).	Second intervention performed: 23/74 (31%) within 3.0 (1.0-7.0) months, including POP surgery n=21, IR surgery n=1, physiotherapy n=1	Bias due to deviations from intended interventions – high, participants deviated
Study type	Pessary: 63.2 (60.4-65.9)	Correction of all compartments that required surgery (at discretion of gynaecologist). All performed under general or spinal anaesthesia. Prophylactic antibiotics were given peroperatively and prophylaxis for thromboembolism, low molecular weight heparin peroperatively and postoperatively	Statistical analysis	Surgery (n=39)	Bias due to missing data – moderate, not all outcome data available for all who enrolled
Randomised Controlled Trial. However, since women had a strong preference for one or other of the treatments, the RCT was ended prematurely and the study was changed to a prospective cohort group. (6 women consented to randomisation and 107 were treated according to preference)	Surgery: 57.6 (53.8-61.4)	Parity - n/N (%)	Domain scores were calculated for UDI, DDI and IIQ at baseline and after 12 months in both groups (scores between 0 to 100).	Complications during surgery: bleeding n=2	Bias in measurement of outcomes – high, outcome measure could have been influenced by knowledge of intervention. Outcome measures were self-reported by participants
Aim of the study	0: Pessary 0/74 (0), Surgery 0/39 (0)	Anterior colporrhaphy n=15, Laparoscopic hysteropexy n=1,	Differences between groups were examined using an unpaired t test or the Mann-Whitney test for continuous variables, or the chi-squared test was used for dichotomous variables. The Wilcoxon signed-ranks test was used to compare the domain scores before and after treatment in both groups separately.	Complications during admission: UTI n=4, bladder retention n=8, bleeding (reoperation) n=1	
To compare quality of life after 12 months in women treated for POP with either pessary or surgery	1: Pessary 9/74 (12), Surgery 4/39 (10)	Sacrospinous fixation and anterior colporrhaphy n=9, Sacrospinous fixation, anterior colporrhaphy and posterior colporrhaphy n=1,		Second intervention performed: 4/39 (10%) within 10.0 (3.0-11.8) months , including pessary n=1, pessary + physiotherapy n=2 and surgery for recurrent POP with physiotherapy n=1	
≥4: Pessary 35/74 (47), Surgery 22/39 (56)	2: Pessary 35/74 (47), Surgery 22/39 (56)	Anterior colporrhaphy and posterior colporrhaphy n=7 Manchester Fothergill procedure and anterior colporrhaphy n=1		Overactive bladder: median (10-90th percentile)	
≥4: Pessary 19/74 (27), Surgery 8/39 (21)	3: Pessary 19/74 (27), Surgery 8/39 (21)	Manchester Fothergill procedure, anterior colporrhaphy and posterior colporrhaphy n=1			
≥4: Pessary 11/74 (15), Surgery 5/39 (13)	≥4: Pessary 11/74 (15), Surgery 5/39 (13)	Manchester Fothergill procedure and anterior colporrhaphy n=1			
Study dates	BMI - median ± IQR	Transvaginal hysterectomy n=2			
Women were invited to participate between June 2009 and July 2014.	Follow-up was 6 weeks after pessary	Pessary: 25.8 (25.0-26.6)	Two-sided significance tests were used, and p values <0.05 were considered to indicate statistical significance. For dichotomous	Pessary: Baseline 11.1 (0-44), 12 months 0.0 (0-33); Surgery: Baseline 22.2 (0-58), 12 months 5.6 (0-56)	Other information

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### Surgical management of pelvic organ prolapse

<b>Study details</b>	<b>Participants</b>	<b>Interventions</b>	<b>Methods</b>	<b>Outcomes and Results</b>	<b>Comments</b>
placement/surgery and every 3 to 6 months and 12 months after treatment.	Surgery: 24.6 (23.5-25.7)	Transvaginal hysterectomy and anterior colporrhaphy n=1 Manchester Fothergill procedure, anterior colporrhaphy and posterior colporrhaphy n=1	outcomes, relative risks and 95% confidence intervals were calculated.	Incontinence: median (10-90th percentile)  Pessary: Baseline 16.1 (0-44), 12 months 16.7 (0-35); Surgery: Baseline 24.2 (0-73), 12 months 33.3 (0-50)	
Source of funding	POP-Q Stage (Anterior Compartment) - n/N (%)	Operative time mean (95%CI): 64 (54-75) mins	Intention-to-treat	Obstruction micturition: median (10-90th percentile)	
Not reported - no conflicts declared.	0: Pessary (0), Surgery (3)  I: Pessary (13), Surgery (8)  II: Pessary (28), Surgery (72)  III: Pessary (54), Surgery (18)  IV: Pessary (6), Surgery (0)	Complications during surgery: bleeding n=2  Complications during admission: UTI n=4, bladder retention n=8, bleeding (reoperation) n=1  Additional interventions:  Pessary Group - could include physiotherapy and incontinence surgery	ITT principles were used to analyse the data.	Pessary: Baseline 0.0 (0-65), 12 months 0.0 (0-35); Surgery: Baseline 16.7 (0-70), 12 months 5.6 (0-33)  Pain/discomfort: median (10-90th percentile)  Pessary: Baseline 16.4 (0-63), 12 months 0.0 (0-33); Surgery: Baseline 33.1 (0-70), 12 months 5.6 (0-33)  Prolapse: median (10-90th percentile)	
	POP-Q Stage (Apical Compartment) - n/N (%)  0: Pessary (1), Surgery (0)  I: Pessary (43), Surgery (62)  II: Pessary (36), Surgery (26)	Surgery group - could include physiotherapy, incontinence surgery or surgery for recurrent prolapse		Pessary: Baseline 33.3 (0-98), 12 months 0.0 (0-33); Surgery: Baseline 33.3 (0-86), 12 months 5.6 (0-0)  Recurrent bladder infections: N (%)  NEVER: Pessary: Baseline 29 (41), 12 months 24 (40); Surgery, Baseline 12 (36), 12 months 12 (46)	

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Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>III: Pessary (17), Surgery (13)</p> <p>IV: Pessary (3), Surgery (0)</p> <p>POP-Q Stage (Posterior Compartment) - n/N (%)</p> <p>0: Pessary (29), Surgery (61)</p> <p>I: Pessary (39), Surgery (18)</p> <p>II: Pessary (25), Surgery (16)</p> <p>III: Pessary (3), Surgery (5)</p> <p>IV: Pessary (4), Surgery (0)</p> <p>Inclusion criteria</p> <p>Women with Symptomatic POP (POP-Q stage II or higher) with bothersome urogenital symptoms</p> <p>Exclusion criteria</p>			<p>ONCE: Pessary: Baseline 4 (6), 12 months 2 (3); Surgery, Baseline 7 (21), 12 months 3 (12)</p> <p>2 to 4 TIMES: Pessary: Baseline 4 (6), 12 months 5 (8); Surgery, Baseline 3 (9), 12 months 1 (4)</p> <p>&gt;4 TIMES: Pessary: Baseline 1 (1), 12 months 1 (2); Surgery, Baseline 0 (0), 12 months 0 (0)</p> <p>Incontinence impact questionnaire, median (10-90th percentile)</p> <p>PHYSICAL: Pessary: Baseline 0.0 (0-48), 12 months 0.0 (0-33); Surgery, Baseline 0.0 (0-50), 12 months 0.0 (0-13)</p> <p>MOBILITY: Pessary: Baseline 11.1 (0-44), 12 months 0.0 (0-33); Surgery, Baseline 16.7 (0-56), 12 months 0.0 (0-31)</p> <p>SOCIAL: Pessary: Baseline 0.0 (0-22), 12 months 0.0 (0-11); Surgery, Baseline 11.1 (0-44), 12 months 0.0 (0-9)</p> <p>SHAME: Pessary: Baseline 0.0 (0-32), 12 months 0.0 (0-22); Surgery, Baseline 0.0 (0-33), 12 months 0.0 (0-17)</p>	

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### Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>Previous surgery for POP or UI correction</p> <p>Previously treated with a pessary</p> <p>Contraindication to surgical intervention</p> <p>Isolated rectocele without prolapse of any other compartment (as there may be insufficient support for a pessary)</p>			<p><b>EMOTIONAL:</b> Pessary: Baseline 5.5 (0-43), 12 months 0.0 (0-37); Surgery, Baseline 11.1 (0-67), 12 months 0.0 (0-11)</p> <p><b>SEXUAL INTERCOURSE, n/N (%):</b></p> <p>Pessary: Baseline 42/64 (66), 12 months 35/53 (68); Surgery, Baseline 25/32 (78), 12 months 21/27 (82)</p>	
<b>Full citation</b>  Lone, F., Thakar, R., Sultan, A. H., One-year prospective comparison of vaginal pessaries and surgery for pelvic organ prolapse using the validated ICIQ-VS and ICIQ-UI (SF) questionnaires, International Urogynecology Journal, 26, 1305-12, 2015  <b>Ref Id</b> 632039  <b>Country/ies where the study was carried out</b> UK  <b>Study type</b>	<b>Sample size</b>  N=287 Pessary group N=133 Surgery group N=154  <b>Characteristics</b>  Pessary N= 191 Surgery N=266  Age - mean (SD) (years) Pessary: 67 (14.1) Surgery: 59 (11.9)	<b>Interventions</b>  Pessary:  The ring pessary was the pessary of choice (n=101, 21%), if unsuccessful then the cube pessary (if sexually active, n=2, 1.5%) or the Gellhorn (n=28, 21%) or doughnut pessary (if not sexually active, n=2, 1.5%) was fitted. Women were seen at 6 monthly intervals for a change in pessary.  Surgery:  49 (32 %) anterior colporrhaphy,	<b>Details</b>  Women referred were offered the choice of pessary or surgery. Women completed the International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS) and the International Consultation on Incontinence Questionnaire-Urinary incontinence (ICIQ-UI) to assess vaginal, sexual, urinary and quality of life symptoms at baseline and after 1 year - at their 1 year visit if in pessary group or via return of postal questionnaire if in surgery group.	<b>Results</b>  Pessary group: N=133. Questionnaires completed at baseline N=116. Questionnaires completed at 12 months (SD 3.2) N=80  Surgery group: N=154. Questionnaires completed at baseline N=153. Questionnaires completed at 14 months (SD 5.9) N=103  Changes in score (n=80 pessary, n=103 surgery):  Dragging  Pessary: -2.08  Surgery: -6	<b>Limitations</b>  Bias due to confounding – high, participant ages vary between groups and POP staging  Bias in selection of participants into the study – high, self-selection  Bias in classification of interventions – low, intervention groups clearly defined a priori  Bias due to deviations from intended interventions – unclear whether any participants deviated

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### Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Prospective observational study	BMI - mean (SD) (kg/m <sup>2</sup> ) Pessary: 30.5 (7.2) Surgery: 26.5 (6.5)	18 (12 %) posterior colporrhaphy,  8 (5 %) anterior and posterior colporrhaphy,  42 (27 %) vaginal hysterectomy and anterior colporrhaphy,  18 (12 %) vaginal hysterectomy,  9 (6 %) sacrocolpopexy  8 (5 %) sacrospinous fixation.		p value 0.769  Soreness  Pessary: -0.4  Surgery: -5.1  p value 0.997  Sensation  Pessary: -1.2  Surgery: -2.4  p value 0.785  Loose vagina  Pessary: -1.9  Surgery: -5.2  p value 0.113  Lump felt  Pessary: -6.9  Surgery: -8  p value 0.156  Lump seen  Pessary: -5.2  Surgery: -7.2  p value 0.493	Bias due to missing data – moderate, not all outcome data available for all who enrolled
Aim of the study					Bias in measurement of outcomes – high, outcome measure could have been influenced by knowledge of intervention. Outcome measures were self-reported by participants
To assess outcomes after 1 year for women with symptomatic POP, who have received treatment either with pessary or surgery	Parity - median (range) Pessary: 2 (0-8) Surgery: 2 (0-6)				
Study dates	Previous hysterectomy - (%) Pessary: 23.5% Surgery 24.8%				
Women were referred between August 2009 and December 2010	Previous POP surgery - (%) Pessary: 6.28% Surgery 14.2%				Bias in selection of the reported results – low, data reported appropriately
Source of funding					Other information
None for the study.					
The following author declarations were made: Ranee Thakar: Secretary IUGA, Honorarium and Astellas speaker; Abdul H. Sultan: Pfizer and Astellas speaker.	Stage of POP Pessary: Stage I n=2 (1.5%), Stage II n=111 (83%), stage III n=21 (15.8%) Surgery: Stage I n=0 (0%), Stage II n=87 (56.5%), stage III n=60 (39%), stage IV n=7 (4.8%)				

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Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>Inclusion criteria Women with symptomatic POP</p> <p>Exclusion criteria Women who were fitted for pessaries solely for urinary incontinence surgery Women who started in the pessary group but subsequently opted for surgery were excluded from analysis</p>			<p>Dry vagina Pessary: -1.4 Surgery: -4.4 p value 0.122</p> <p>Tight vagina Pessary: -3.7 Surgery: -1.2 p value 0.382</p> <p>Faecal evacuation Pessary: -4.6 Surgery: -6.1 p value 0.441</p> <p>Interfered with sex life Pessary: -1.4 Surgery: -2.89 p value 0.930</p> <p>Affected relationship Pessary: -1.2 Surgery: -2.45 p value 0.345</p> <p>Sex life spoilt</p>	

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## Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Pessary: -1.3 Surgery: -2.6 p value 0.342 Interfered with daily life Pessary: -5.5 Surgery: -6.8 p value 0.629 Vaginal score Pessary: -7 Surgery: -3.6 p value 0.118 Sex score Pessary: -1 Surgery: -8 p value 0.245 QoL Score Pessary: -5.5 Surgery: -12.7 p value 0.362 Frequency of urine leak	

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### Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Pessary: -2.68 Surgery: -6 p value 0.423 Amount of urine leak Pessary: -0.5 Surgery: -1.5 p value 0.997 Leaking interfering with everyday life Pessary: -1.4 Surgery: -3.6 p value 0.535	
<b>Full citation</b>	<b>Sample size</b> Lowenstein, L., Gamble, T., Sanses, T. V., van Raalte, H., Carberry, C., Jakus, S., Pham, T., Nguyen, A., Hoskey, K., Kenton, K., Fellow's Pelvic Research, Network, Changes in sexual function after treatment for prolapse are related to the improvement in body image perception, Journal of Sexual Medicine, 7, 1023-8, 2010  <b>Ref Id</b>	<b>Interventions</b> N=239 (from an original sample of N=384) Pessary: N=33 Surgery: N=206  <b>Characteristics</b> Not reported - characteristics given for women lost to follow-up (n=145) and women who returned for followup (n=239)	<b>Details</b> Surgery (n=206): Sacrocolpopexy N=112 (54%) Apical Suspension N=67 (32%) Hysterectomy N=69 (33%) Colpocleisis N=52 (25%) Site specific repair N=131 (64%) Vaginal Mesh N=59 (29%) Sling N=84 (41%) Burch N=52 (25%)	<b>Results</b> Participants completed three questionnaires, i) relating to symptoms of POP (PFDI-20), ii) sexual function (PISQ-12), iii) body image (MBIS). Questionnaires were completed at baseline and at the 6 month follow-up visit. For those who did not return for a follow-up visit, questionnaires were mailed. Higher numbers on the scale indicates greater distress. Sexual function, change in mean score Pessary: -2.5 (5.5) Surgery: 11.5 (1) P<0.0001	<b>Limitations</b> Bias due to confounding - unclear, most characteristics not reported  Bias in selection of participants into the study – high, self-selection  Bias in classification of interventions – low, intervention groups clearly defined a priori

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### Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
639842					Bias due to deviations from intended interventions – unclear whether any participants deviated
Country/ies where the study was carried out	Inclusion criteria				
USA	Over 18 years old				
Study type	Stage II or greater POP measured by the POP-Q				Bias due to missing data – moderate, not all outcome data available for all who enrolled
Prospective observational study	completed questionnaires at baseline and 6 months after treatment				
Aim of the study					Bias in measurement of outcomes – high, outcome measure could have been influenced by knowledge of intervention. Outcome measures were self-reported by participants
Following treatment of POP with either pessary or surgery, to assess self-reported outcomes of POP symptoms, sexual function, self-perceived body image	Exclusion criteria				
	Women with recurrent urinary tract infections				
	History of peripheral neuropathy				
Study dates	Using pessary at time of initial presentation,				Bias in selection of the reported results – moderate, data reported appropriately, however number of participants in each group not balanced
June 2007 through to April 2008	Had pelvic surgery in last 6 months				
Source of funding					Other information
None reported, no conflicts of interest either					Additional linked paper, not identified through searches, provided some additional details for this study. Lowenstein, L.,

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Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Gamble, T., Deniseiko Sanses, T. V., Van Raalte, H., Carberry, C., Jakus, S., ... & Hoskey, K. (2009). Sexual function is related to body image perception in women with pelvic organ prolapse. <i>The journal of sexual medicine</i> , 6(8), 2286-2291.
Full citation  Madsen, A. M., Raker, C. A., Sung, V., Patient-reported functioning outcomes after surgery compared to pessary for the treatment of pelvic organ prolapse using the patient reported outcomes measurement system, American Journal of Obstetrics and Gynecology, 1), S457, 2016	Sample size  See Sung et al 2016	Interventions  See Sung et al 2016	Details  See Sung et al 2016	Results  See Sung et al 2016	Limitations  See Sung et al 2016
Ref Id  639917	Characteristics  See Sung et al 2016	Inclusion criteria  See Sung et al 2016			Other information  See Sung et al 2016
Country/ies where the study was carried out  See Sung et al 2016	Exclusion criteria  See Sung et al 2016				
Study type  See Sung et al 2016					

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### Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study See Sung et al 2016					
Study dates See Sung et al 2016					
Source of funding See Sung et al 2016					
Full citation  Sung, V. W., Wohlrab, K. J., Madsen, A., Raker, C., Patient-reported goal attainment and comprehensive functioning outcomes after surgery compared with pessary for pelvic organ prolapse, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 215, 659.e1-659.e7, 2016	Sample size  N=160 recruited Pessary group: N=64 completed from N=80 recruited Surgery group: N=72 completed from N=80 recruited	Interventions  Surgery group: 44% hysterectomy 74% apical suspension 37% anterior vaginal repair 52% posterior vaginal repair 52% concomitant anti-incontinence procedure  Pessary group: n=31 discontinued pessary use or crossed to surgery - of these 14 who discontinued and 8 who crossed to surgery provided follow-up data	Details  Women chose whether to have surgery or a pessary following POP quantification examination. The following questionnaires were completed at baseline and after 6 and 12 months for the surgery group and 3, 6 and 12 months for the pessary group.  Goals from treatment (max 10 in rank order) Patient-reported outcomes measurement information system (PROMIS) survey for physical function, satisfaction with social roles, satisfaction with participation in discretionary social activities, anxiety and depression Pelvic floor distress inventory-20 short form Pelvic floor impact	Results  P value between groups  PROMIS physical function - change in mean score (SD) Pessary: 3.5 (6.9) Surgery: 8.7 (8.8) P = 0.0004  PROMIS social roles - change in mean score (SD) Pessary: 2.8 (9.3) Surgery: 6.3 (10.5) P = 0.049  PROMIS social discretionary - change in mean score (SD) Pessary: 2.4 (7.7) Surgery: 5.1 (8.9) P = 0.07  PROMIS anxiety - change in mean score (SD) Pessary: -3.2 (9.1) Surgery: -5.0 (10.3) P = 0.30	Limitations  Limitations Bias due to confounding – high, participant ages vary between groups  Bias in selection of participants into the study – high, self-selection  Bias in classification of interventions – low, intervention groups clearly defined a priori  Bias due to deviations from intended interventions – high, participants who switched from pessary to surgery group provided data as surgery participants  Bias due to missing data – moderate, not all outcome data
Ref Id 632080	Age - mean (SD) Pessary: 64.2 (13.0) Surgery: 59.0 (10.0)				
Country/ies where the study was carried out USA	POPQ stage - median (range) Pessary: 3 (1-4) Surgery: 2 (1-4)				
Study type Prospective observational study					

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### Surgical management of pelvic organ prolapse

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study  For women treated for POP with surgery or pessary: to compare goal attainment and comprehensive, physical, social and emotional function	Inclusion criteria  Women over 18 years  Confirmed stage 2 or greater POP		questionnaire-7 short form Patient global impression of improvement Pelvic organ prolapse / Urinary incontinence sexual function questionnaire-12 Body Image scale	PROMIS depression - change in mean score (SD) Pessary: -0.6 (7.1) Surgery: -4.0 (9.4) P = 0.02	available for all who enrolled  Bias in measurement of outcomes – high, outcome measure could have been influenced by knowledge of intervention. Outcome measures were self-reported by participants
Study dates  Participants were recruited between September 2012 and October 2014	Exclusion criteria  Women without symptomatic or documented POP  Women unable to complete questionnaires because of cognitive or language barriers		Crossover was allowed from pessary to surgery group and new 6 and 12 month data was captured following surgery	Data from Abstract Madsen et al 2016 gives pessary results for n=42 women, where those that crossed to surgery (n=8) and those that discontinued (n=14) were excluded.	Bias in selection of the reported results – low, data reported appropriately
Source of funding  Supported by grant K23HD050108 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.	Women who planned on short term pessary use			PROMIS physical function - change in mean score (SD)  Pessary: 2.4 (4.6) - n=37 Surgery: 5.1 (6.3) - n=71 P = 0.02	Other information
				PROMIS social roles - change in mean score (SD)  Pessary: 2.9 (6.4) - n=41 Surgery: 4.4 (7.9) - n=68 P = 0.3	
				PROMIS social discretionary - change in mean score (SD)	
				Pessary: 2.1 (6.4) - n=41 Surgery: 3.8 (6.9) - n=70 P = 0.2	
				PROMIS anxiety - change in mean score (SD)	
				Pessary: -2.1 (5.2) - n=41 Surgery: -3.1 (6.4) - n=70 P = 0.4	

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## Surgical management of pelvic organ prolapse

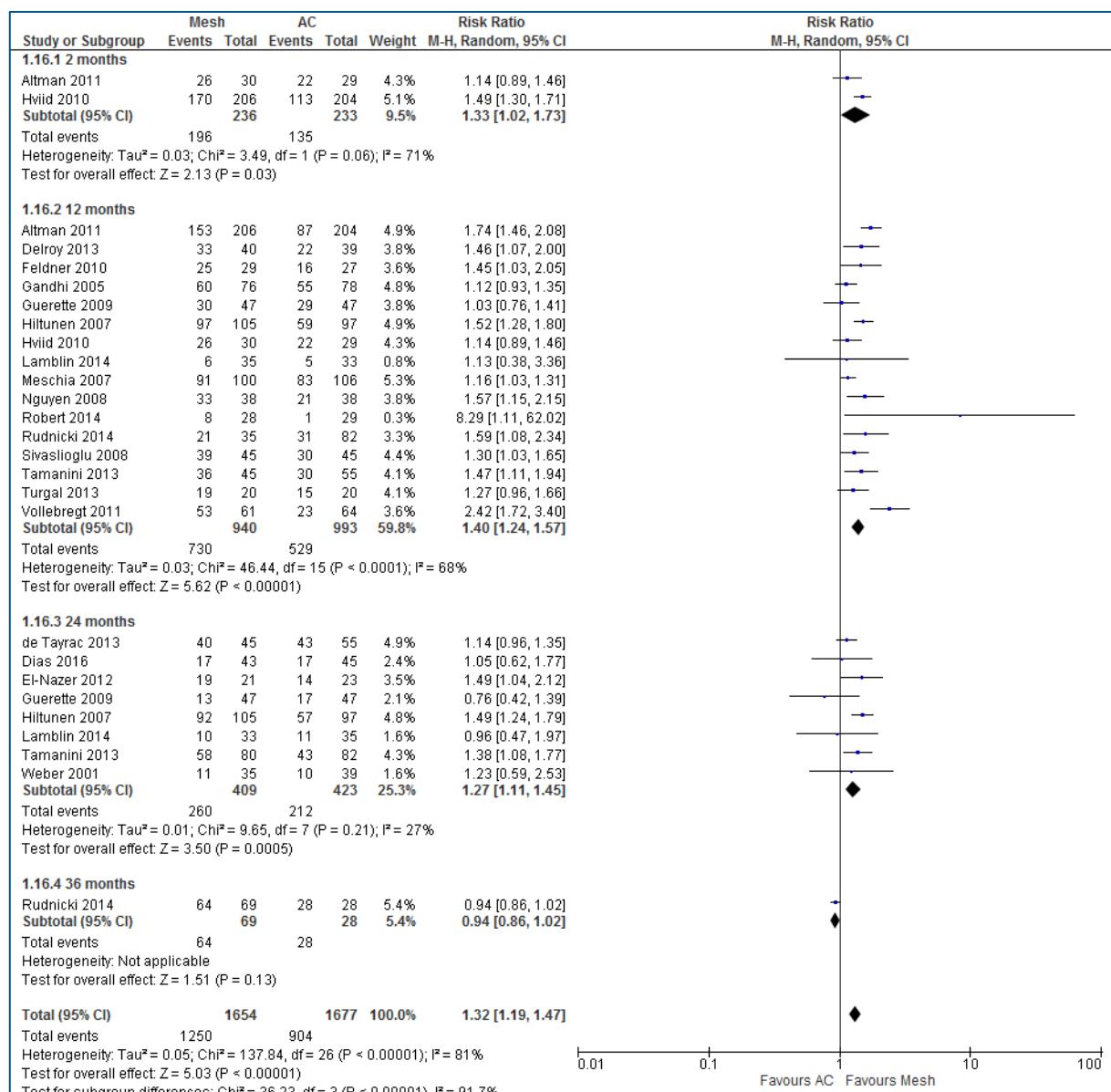
Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				PROMIS depression - change in mean score (SD) Pessary: -0.03 (3.0) - n=39 Surgery: -2.4 (6.7) - n=71 P = 0.01	

## Appendix E – Forest plots

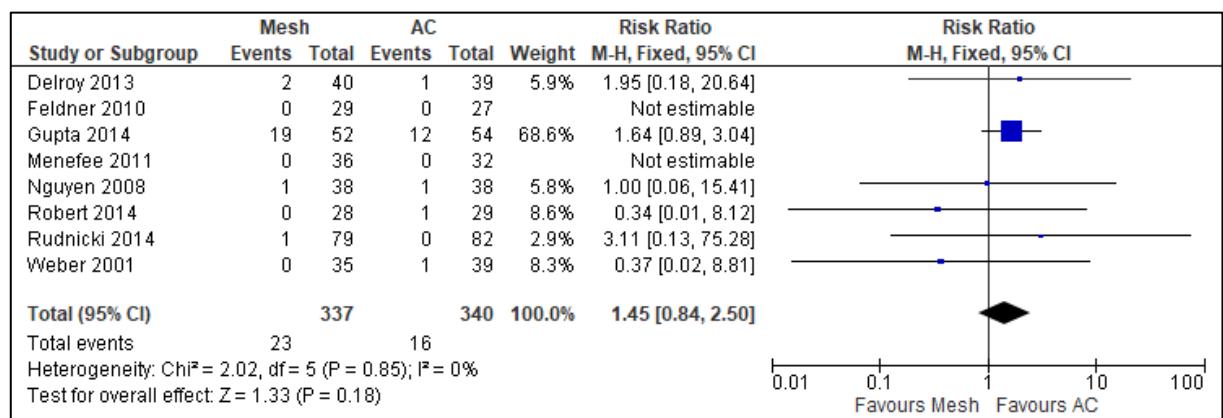
**Forest plots for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

### Anterior Surgery: Effectiveness

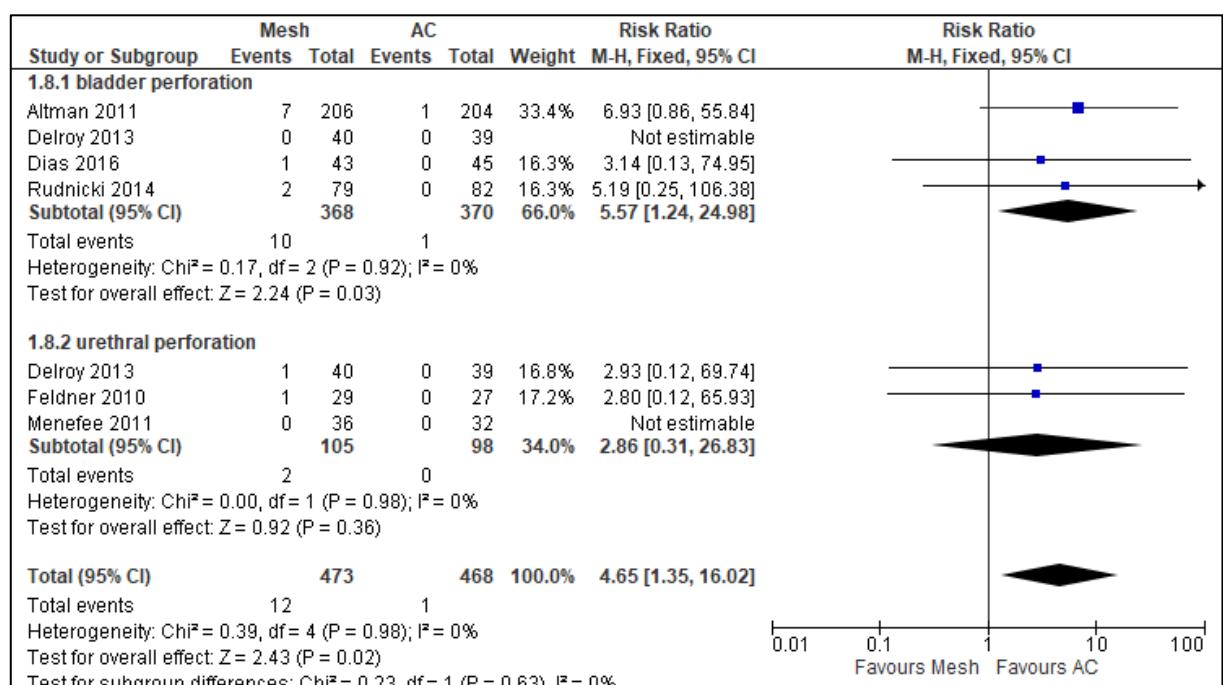
**Figure 8: Forest plot for comparison mesh surgery versus anterior colporrhaphy; cure of anterior prolapse (POP-Q stage 0-1 / Ba <1)**



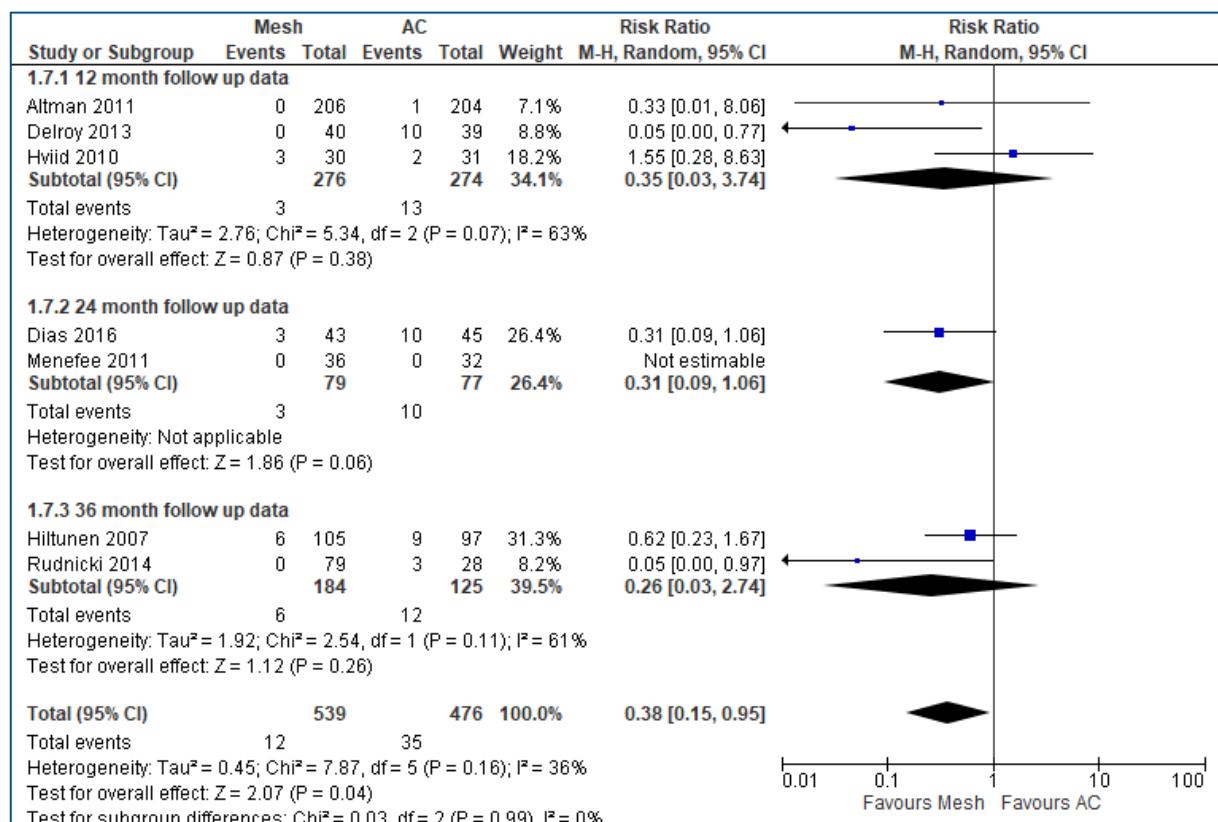
**Figure 9: Forest plot for comparison mesh surgery versus anterior colporrhaphy; blood transfusion during surgery**



**Figure 10: Forest plot for comparison mesh surgery versus anterior colporrhaphy; internal organ injury during surgery**

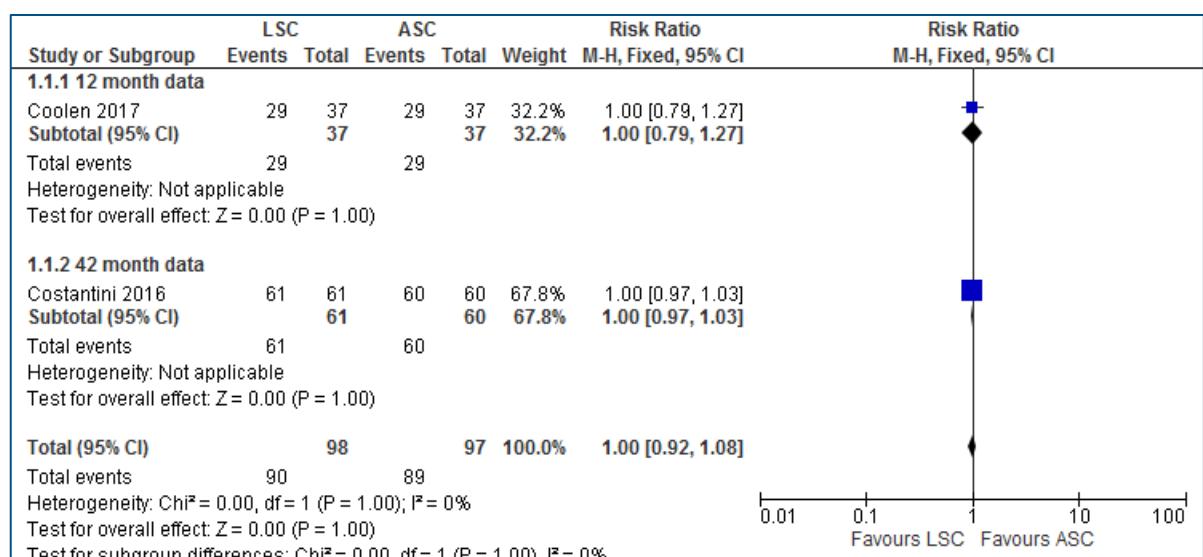


**Figure 11: Forest plot for comparison mesh surgery versus anterior colporrhaphy; repeat surgery for POP**

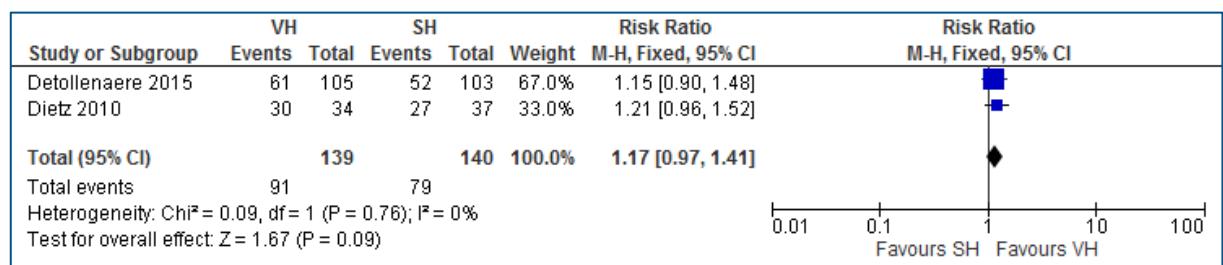


## Apical Surgery: Effectiveness

**Figure 12: Forest plot for comparison laparoscopic sacrocolpopexy versus abdominal sacrocolpopexy; cure (POP-Q stage 0-1)**



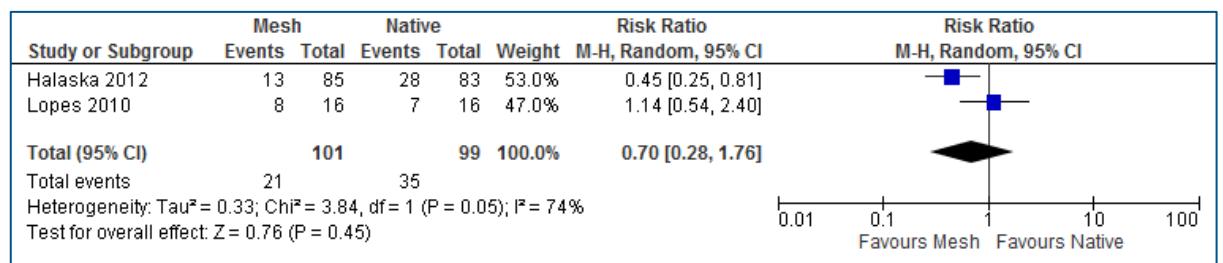
**Figure 13: Forest plot for comparison vaginal hysterectomy versus sacrospinous hysteropexy; cure (POP-Q stage 0-1)**



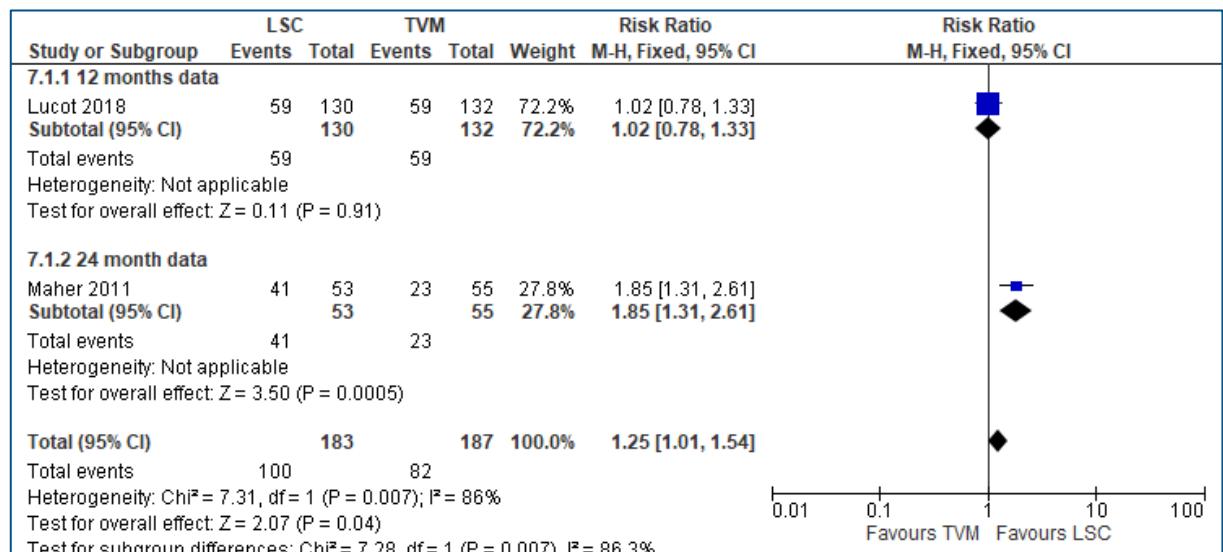
**Figure 14: Forest plot for comparison vaginal hysterectomy versus sacrospinous hysteropexy; recurrence of POP**



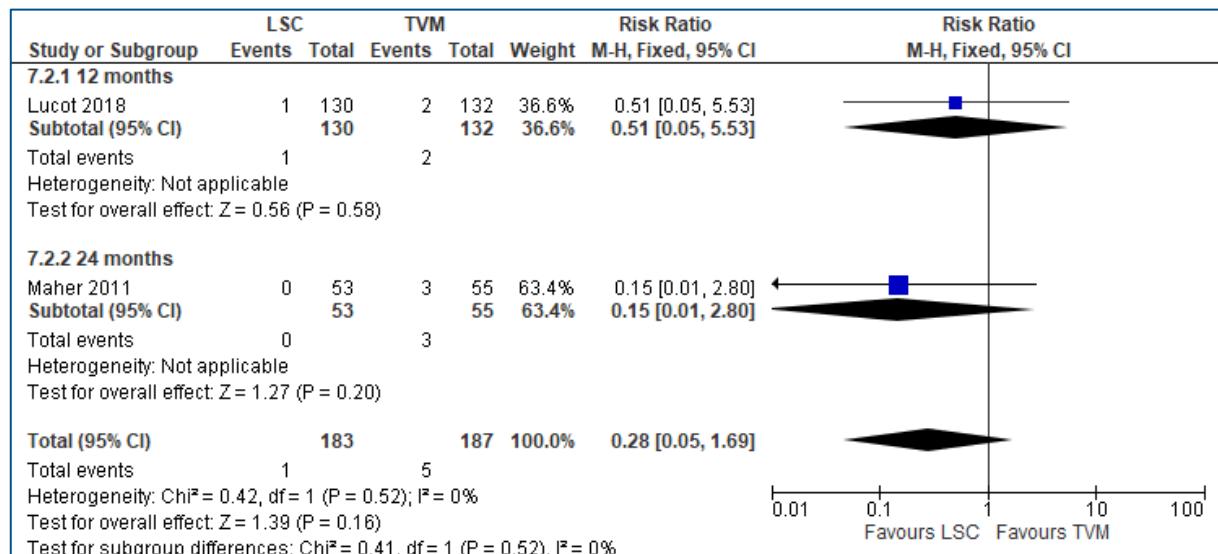
**Figure 15: Forest plot for comparison sacrospinous ligament fixation with native tissue versus mesh surgery; recurrence of POP**



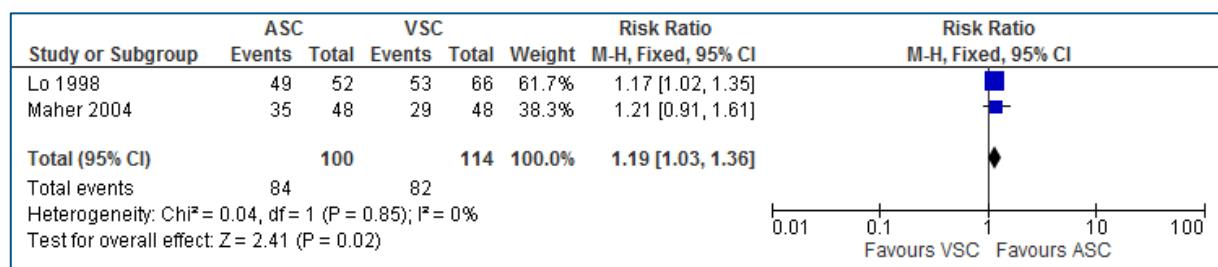
**Figure 16: Forest plot for comparison laparoscopic sacral colpopexy versus vaginal mesh kit; cure (POP-Q stage 0-1):**



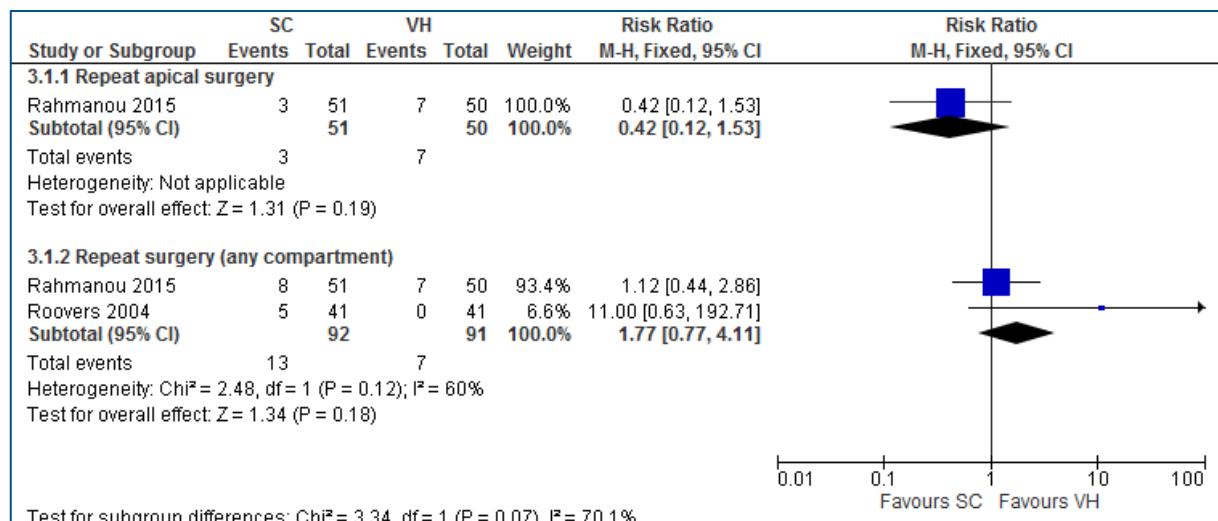
**Figure 17: Forest plots for comparison laparoscopic sacral colpopexy versus vaginal mesh kit; repeat surgery for POP**



**Figure 18: Forest plot for comparison abdominal sacral colpopexy versus vaginal sacrospinous colpopexy; cure (POP-Q stage 0-1)**

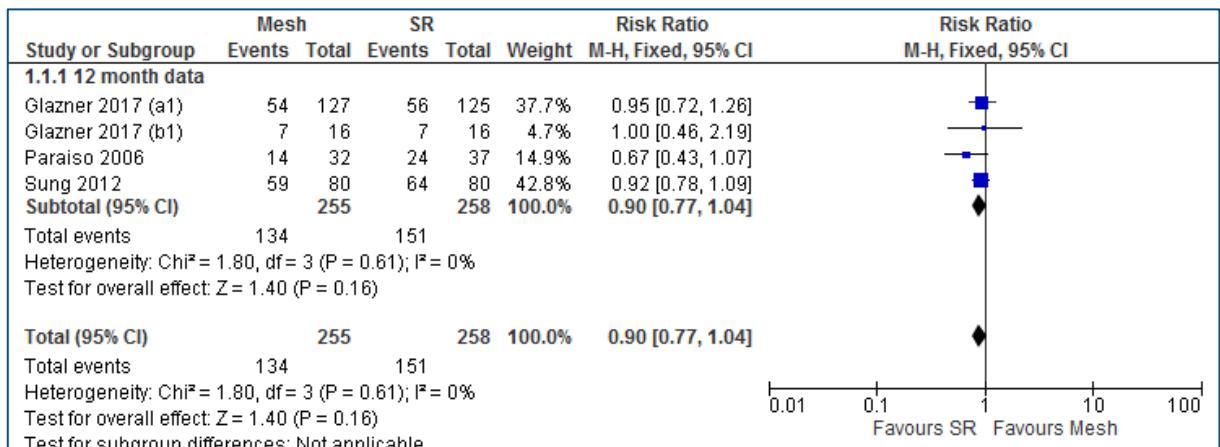


**Figure 19: Forest plot for comparison sacral colpopexy versus vaginal hysterectomy; repeat surgery for POP**

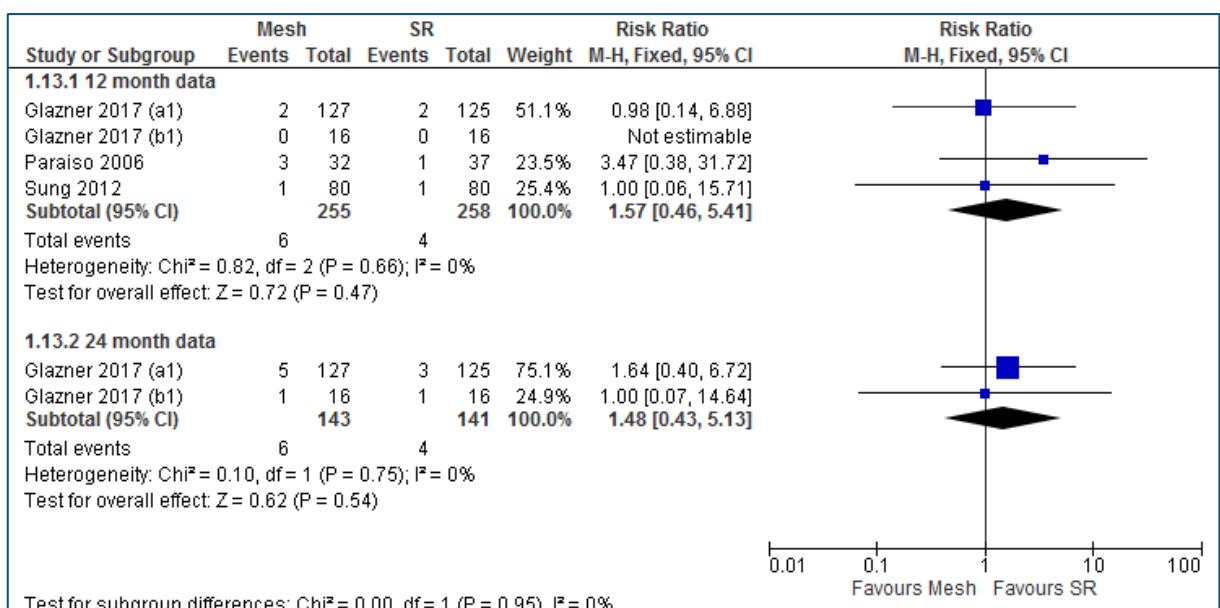


## Posterior surgery: Effectiveness

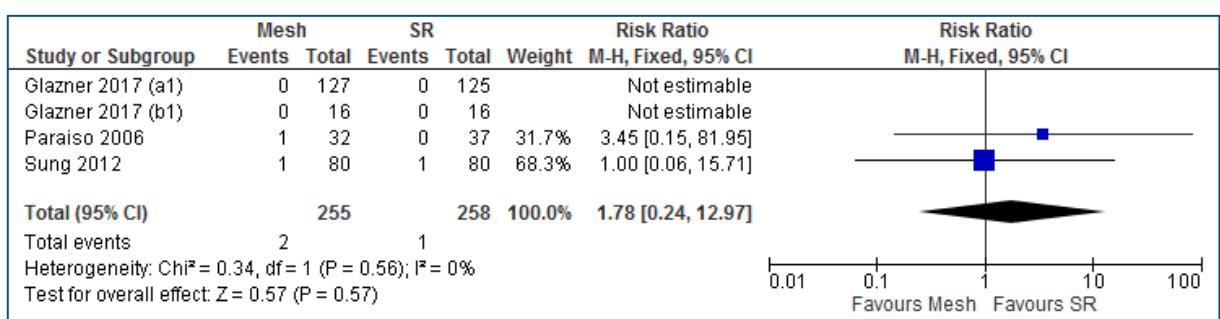
**Figure 20: Forest plot for comparison mesh surgery versus standard repair; cure of posterior prolapse (POP-Q stage 0-1)**



**Figure 21: Forest plot of comparison mesh surgery versus standard repair; repeat surgery for POP**

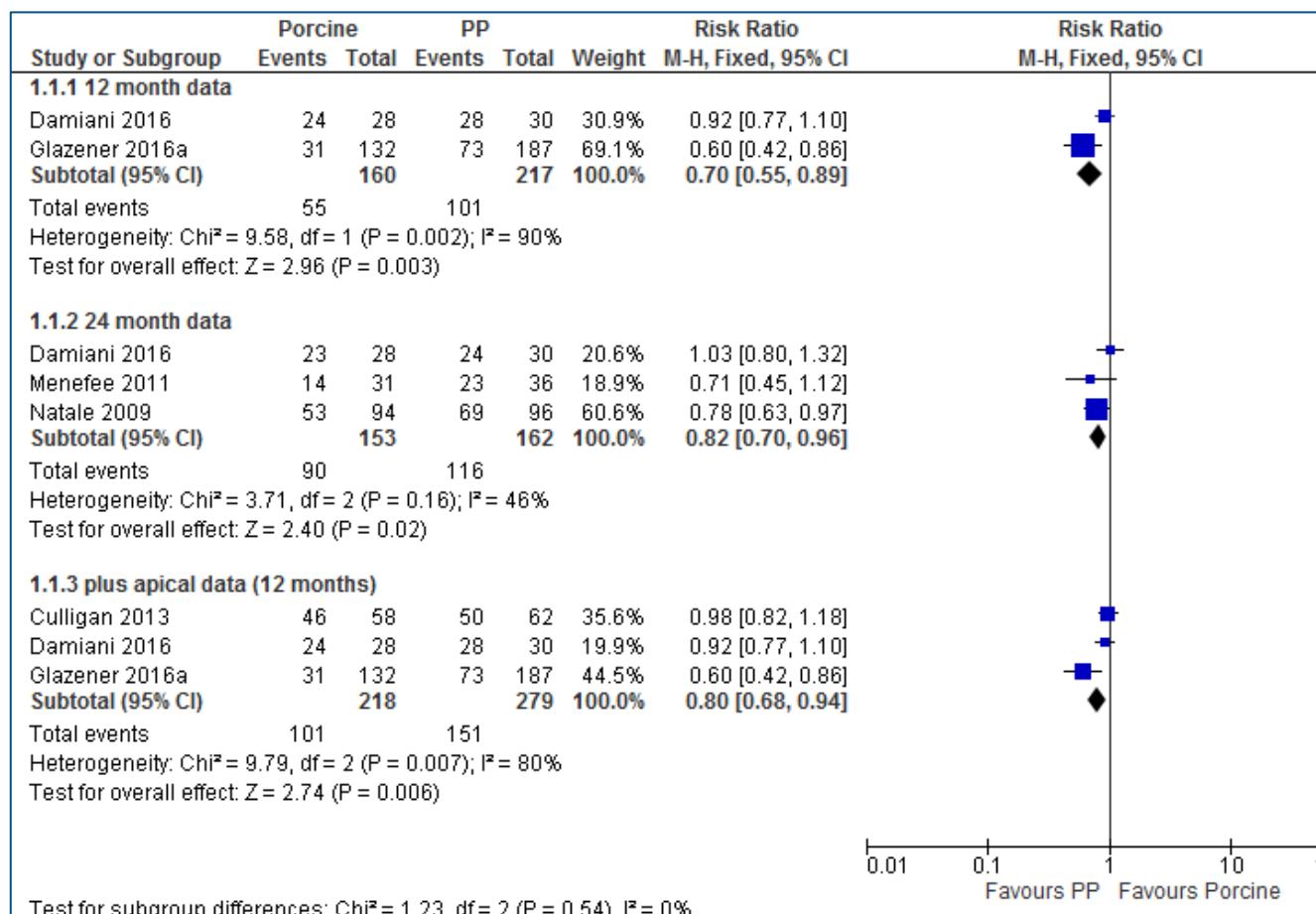


**Figure 22: Forest plot for comparison mesh surgery versus standard repair; internal organ injury during surgery**



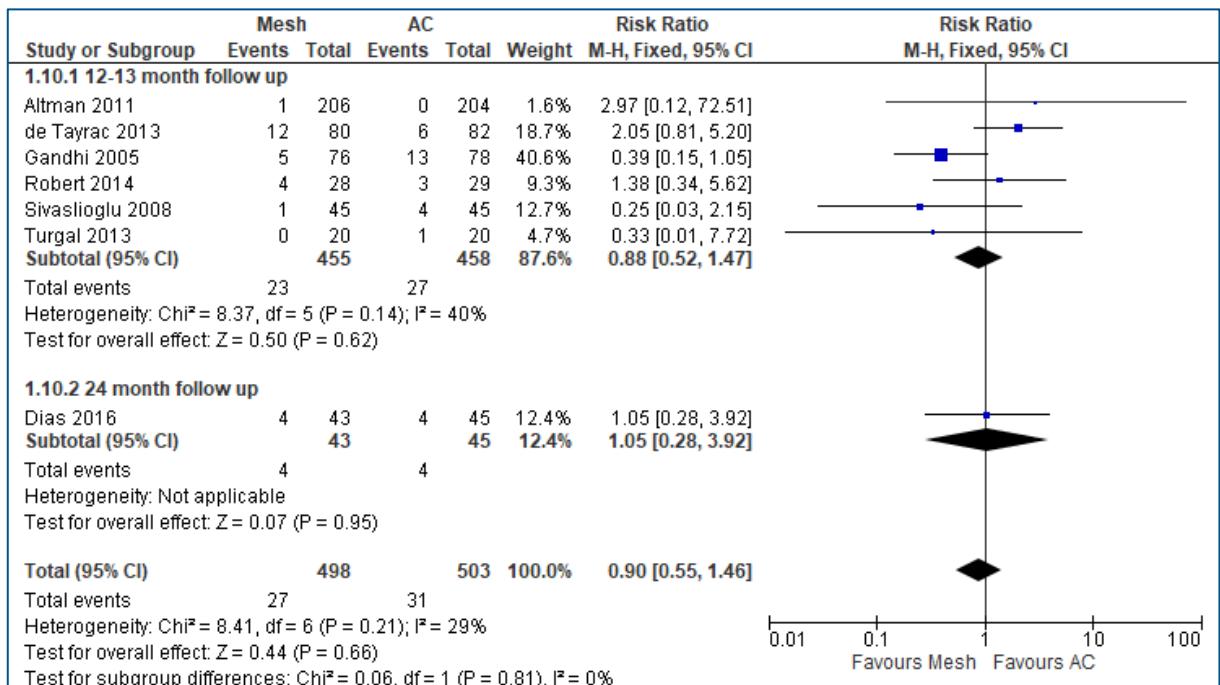
### Comparison of mesh types for POP surgery

**Figure 23: Forest plot for comparison porcine graft versus polypropylene mesh; cure of prolapse (POP-Q stage 0-1)**

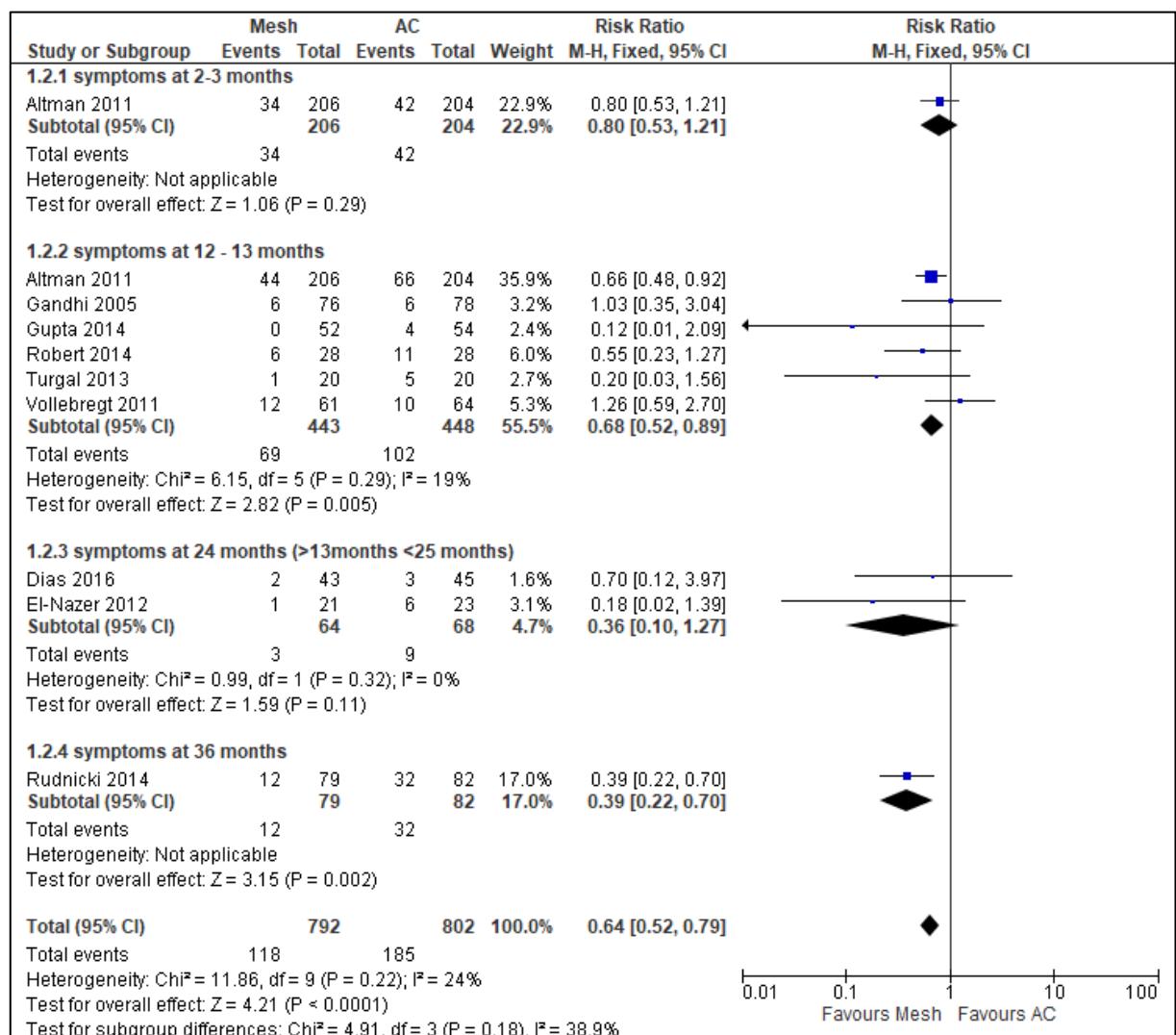


### Short-term complications: Anterior surgery

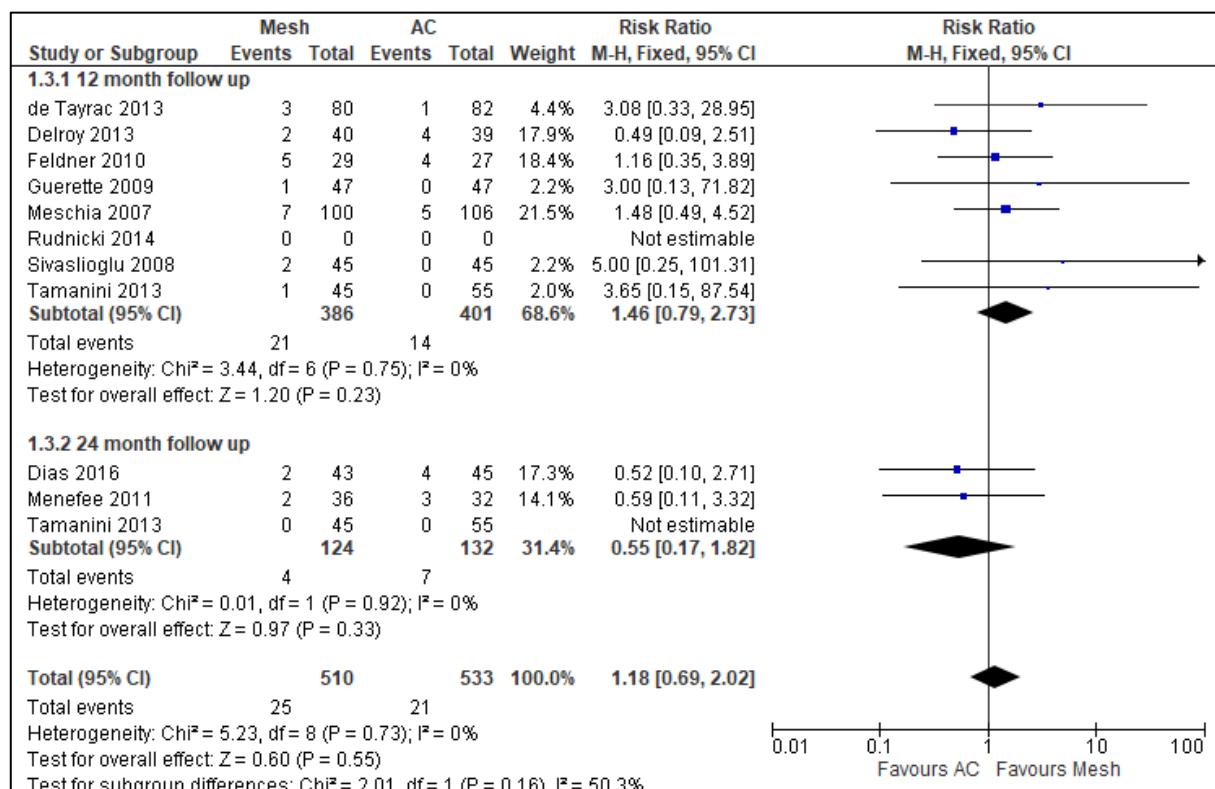
**Figure 24: Forest plot of comparison mesh surgery versus anterior colporrhaphy; reported pain**



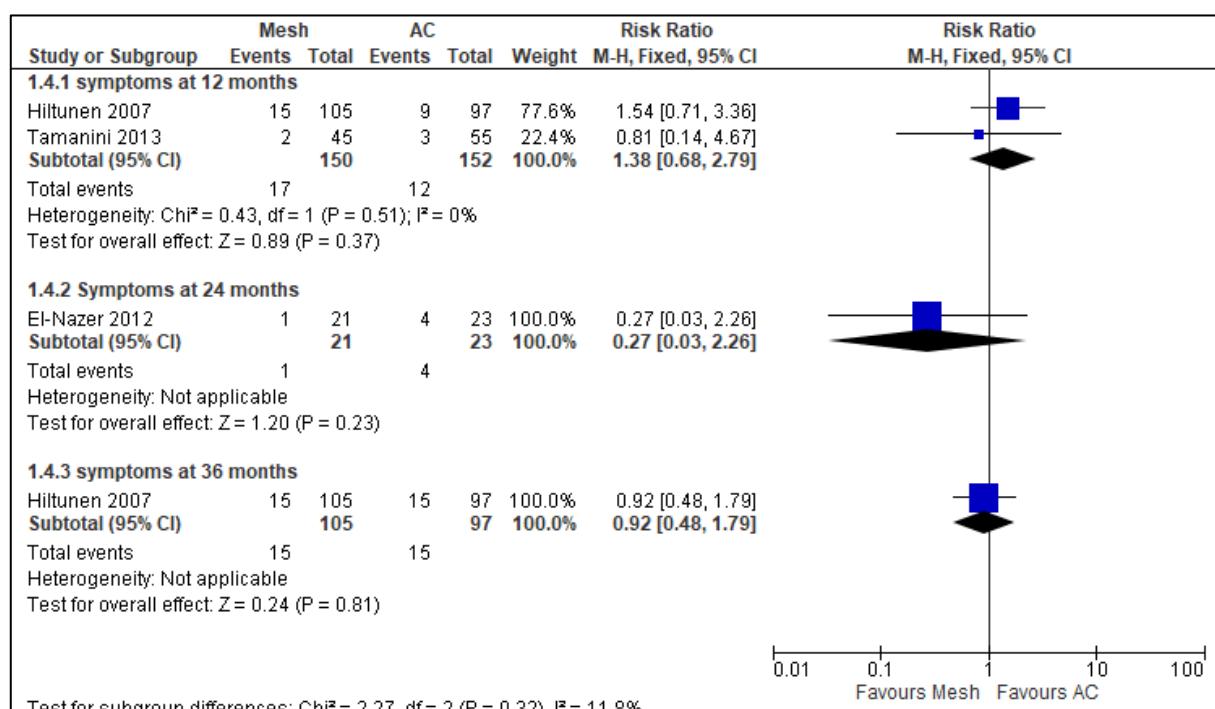
**Figure 25: Forest plot of comparison mesh surgery versus anterior colporrhaphy; vaginal bulge**



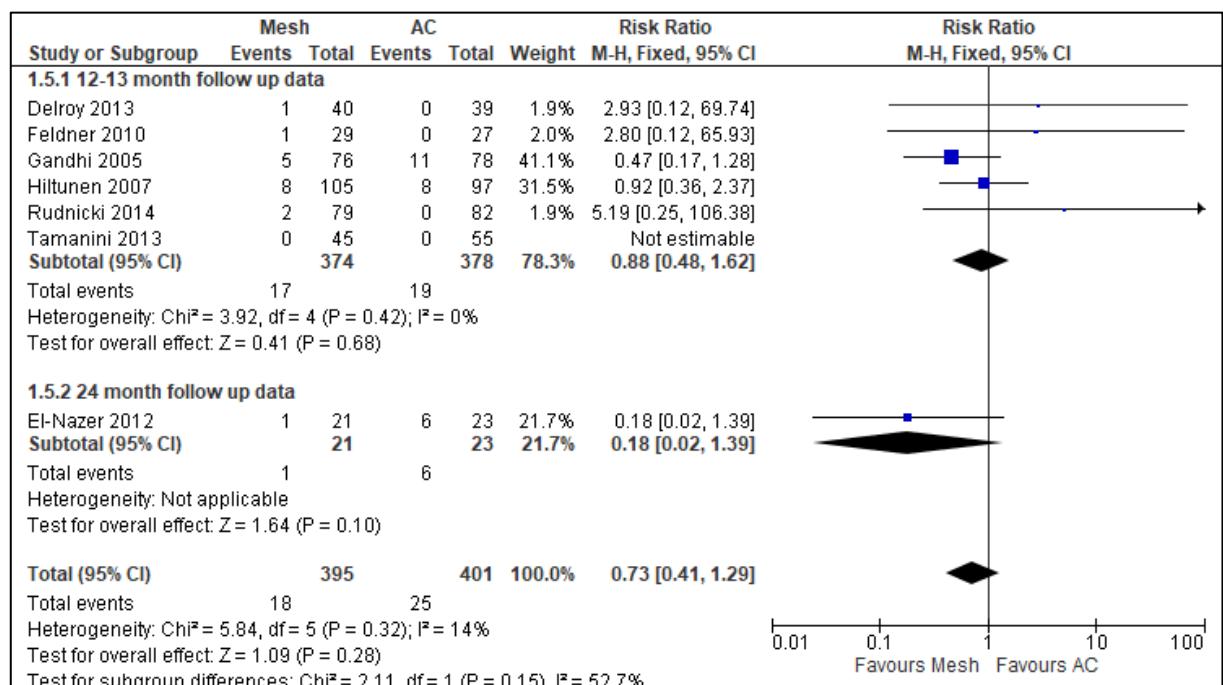
**Figure 26: Forest plot of comparison mesh surgery versus anterior colporrhaphy; de novo dyspareunia**



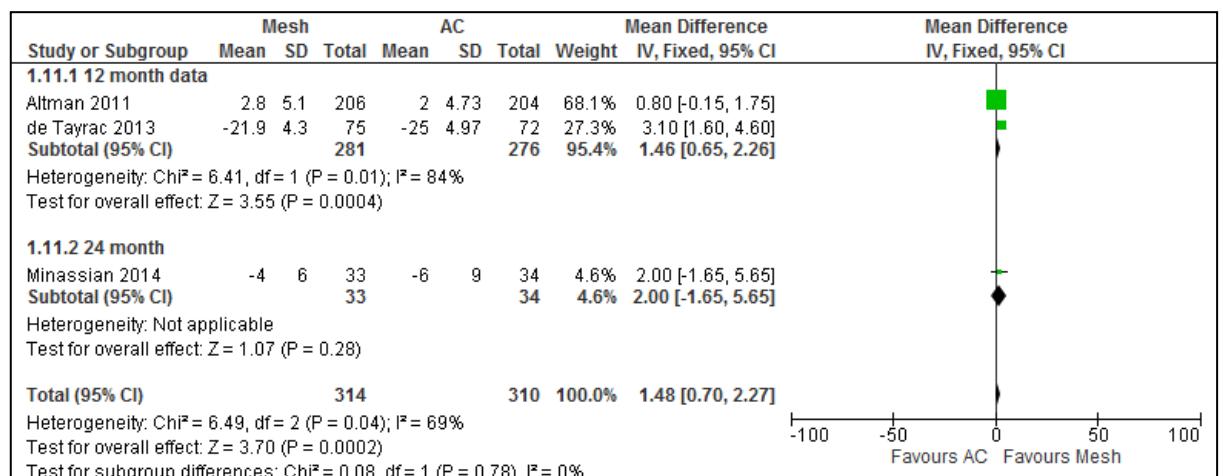
**Figure 27: Forest plot of comparison mesh surgery versus anterior colporrhaphy; stress UI**



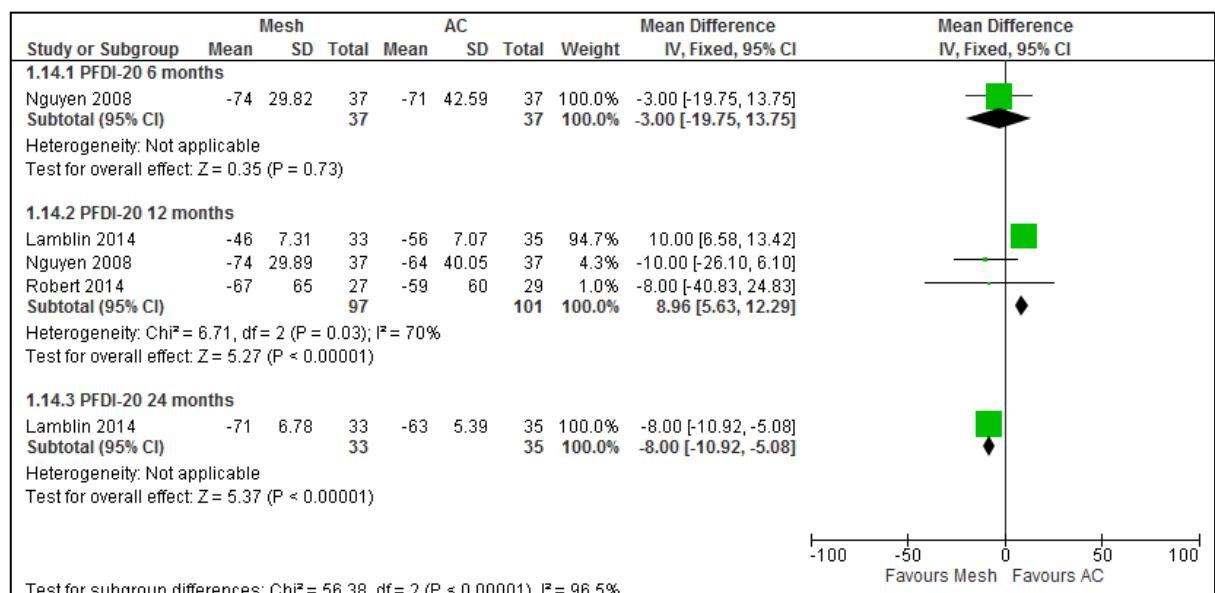
**Figure 28: Forest plot of comparison mesh surgery versus anterior colporrhaphy; voiding difficulties**



**Figure 29: Forest plot of comparison mesh surgery versus anterior colporrhaphy; sexual function (PSIQ-12)**

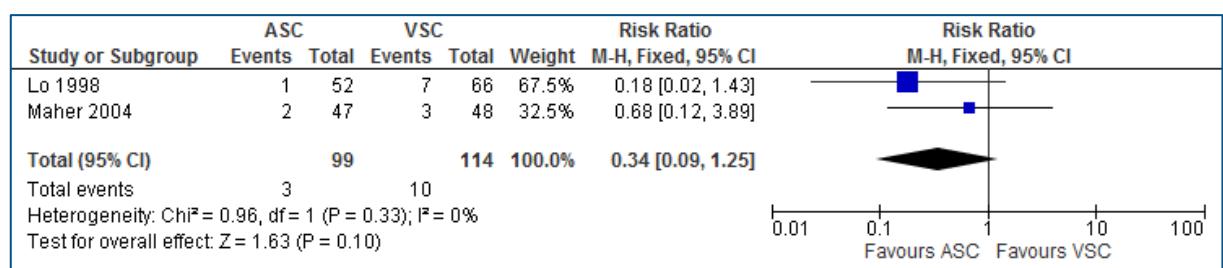


**Figure 30: Forest plot of comparison mesh surgery versus anterior colporrhaphy; quality of Life: PFDI-20**



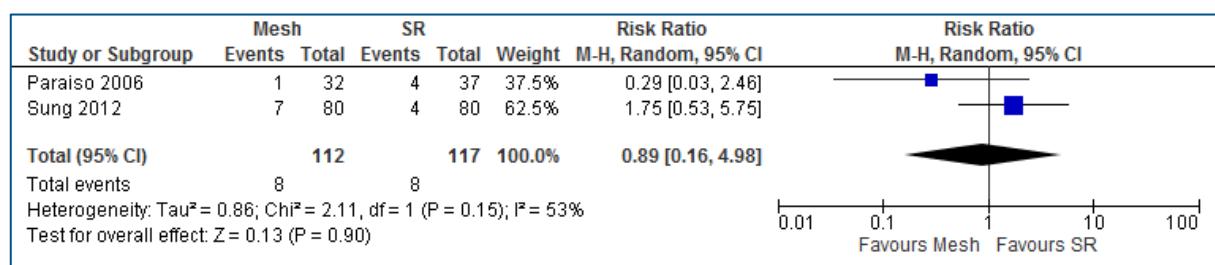
#### **Short-term complications: Apical**

**Figure 31: Forest plot of comparison abdominal sacral colpopexy versus vaginal sacrospinous colpopexy; dyspareunia**

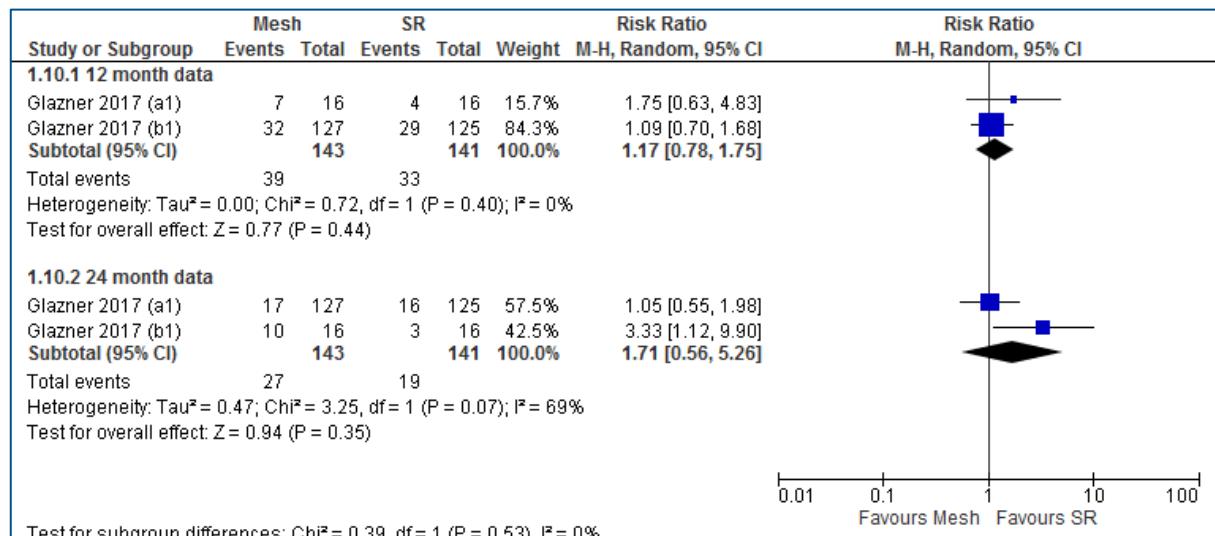


#### **Short-term complications: Posterior surgery**

**Figure 32: Forest plot for comparison mesh surgery versus standard repair; dyspareunia**

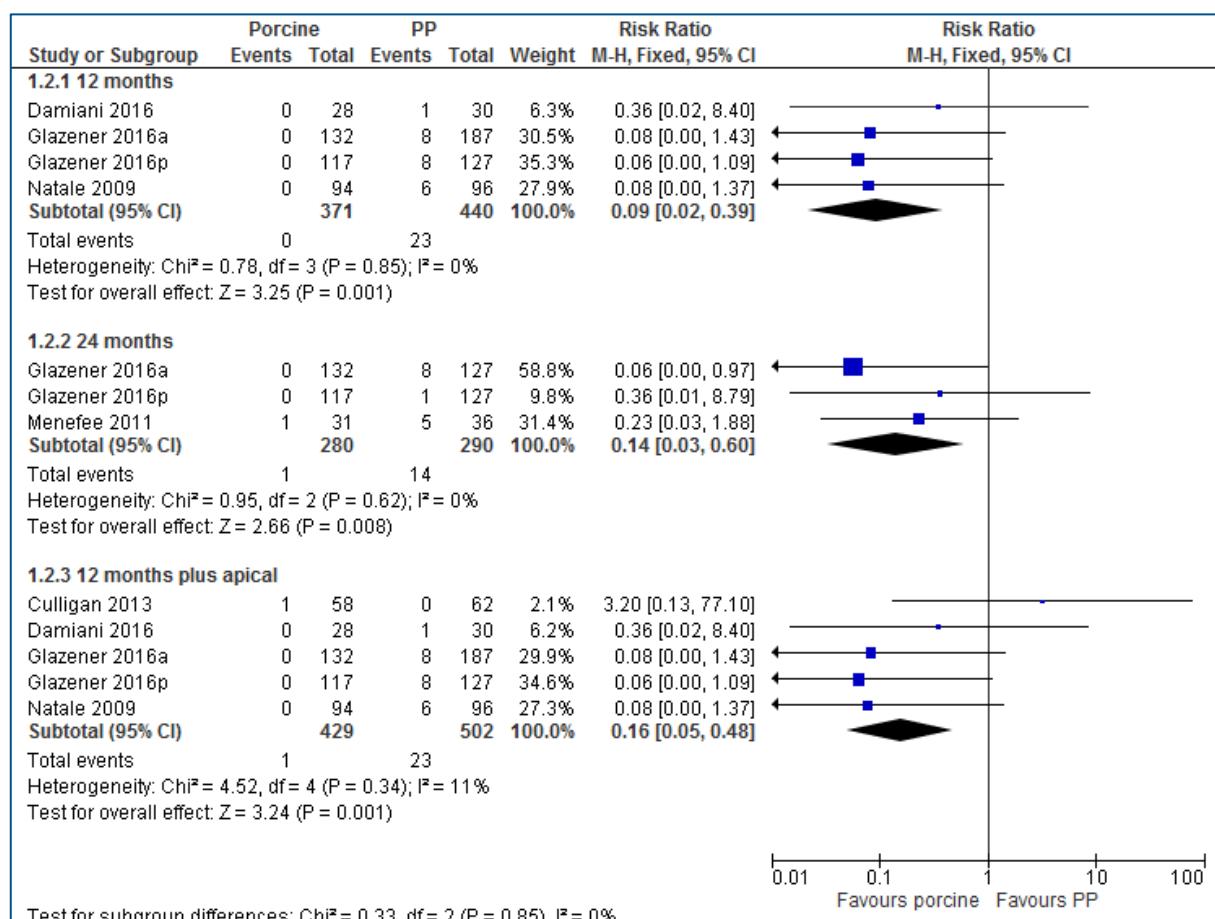


**Figure 33: Forest plot for comparison mesh surgery versus standard repair; faecal incontinence**

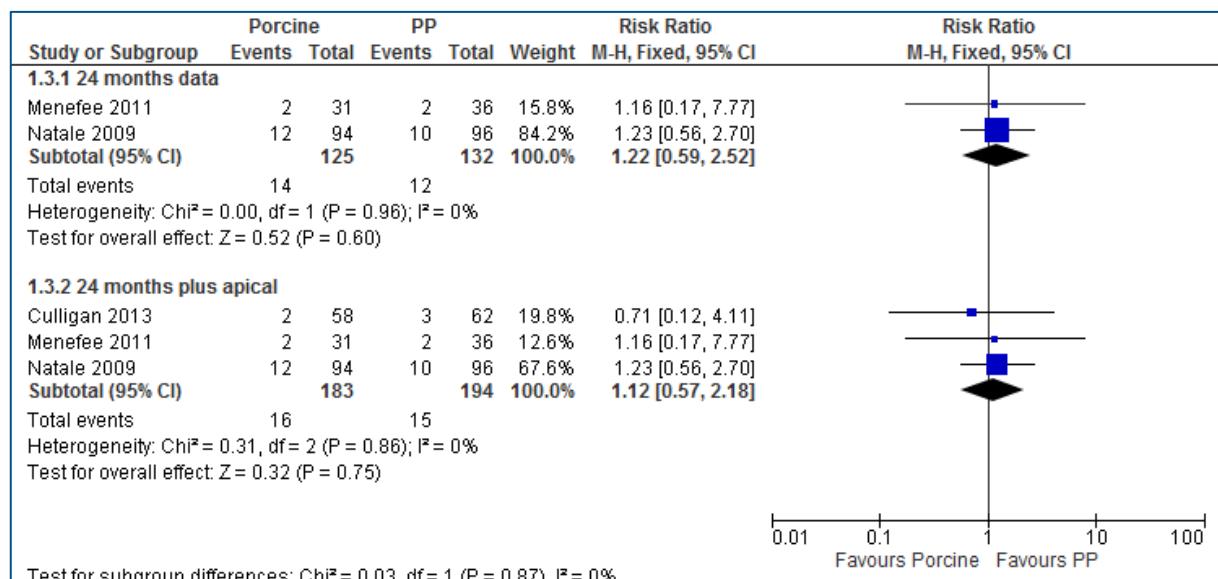


### Short-term complications: Comparison of mesh types for POP surgery

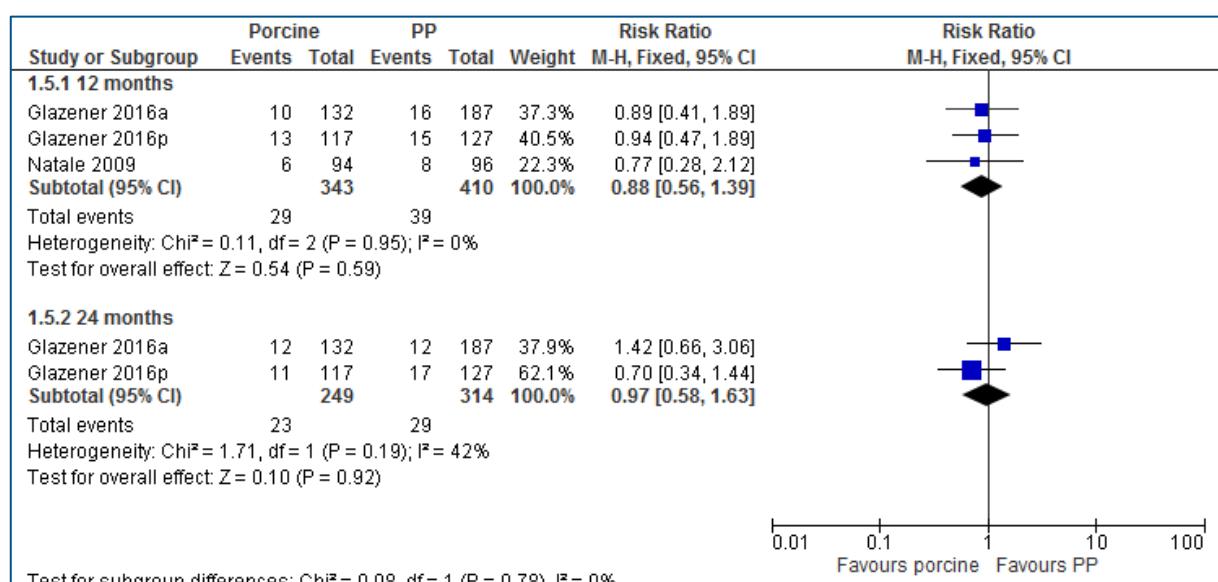
**Figure 34: Forest plot of Porcine mesh versus polypropylene mesh: Mesh exposure**



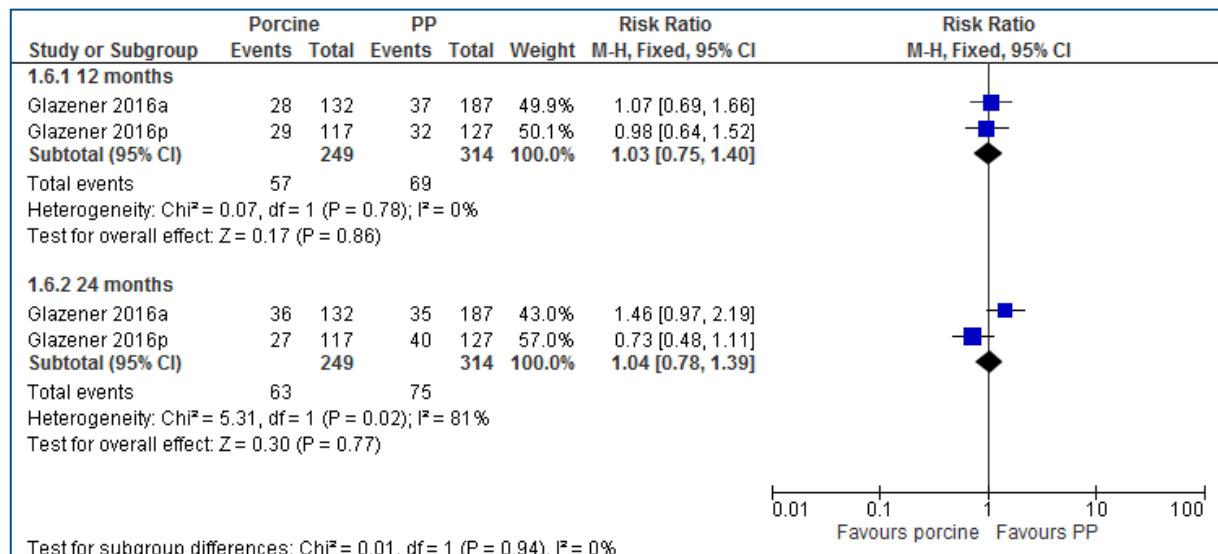
**Figure 35: Forest plot of porcine mesh versus polypropylene mesh: Dyspareunia**



**Figure 36: Forest plot for comparison porcine mesh versus polypropylene mesh; Constipation**



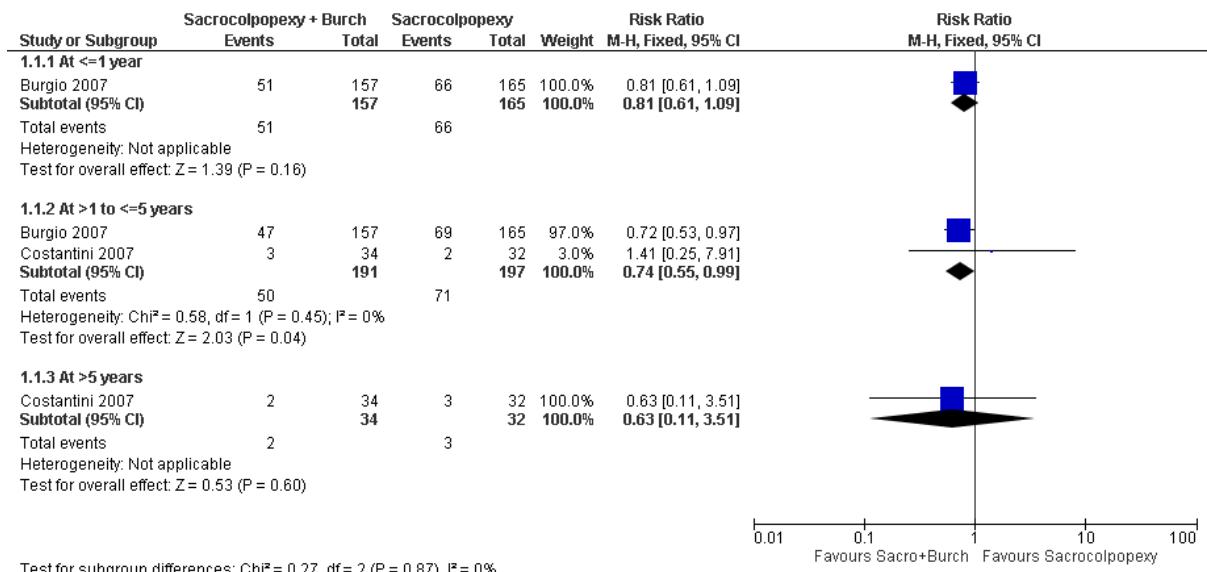
**Figure 37: Forest plot for comparison porcine mesh versus polypropylene mesh; faecal incontinence**



**Forest plots for the review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

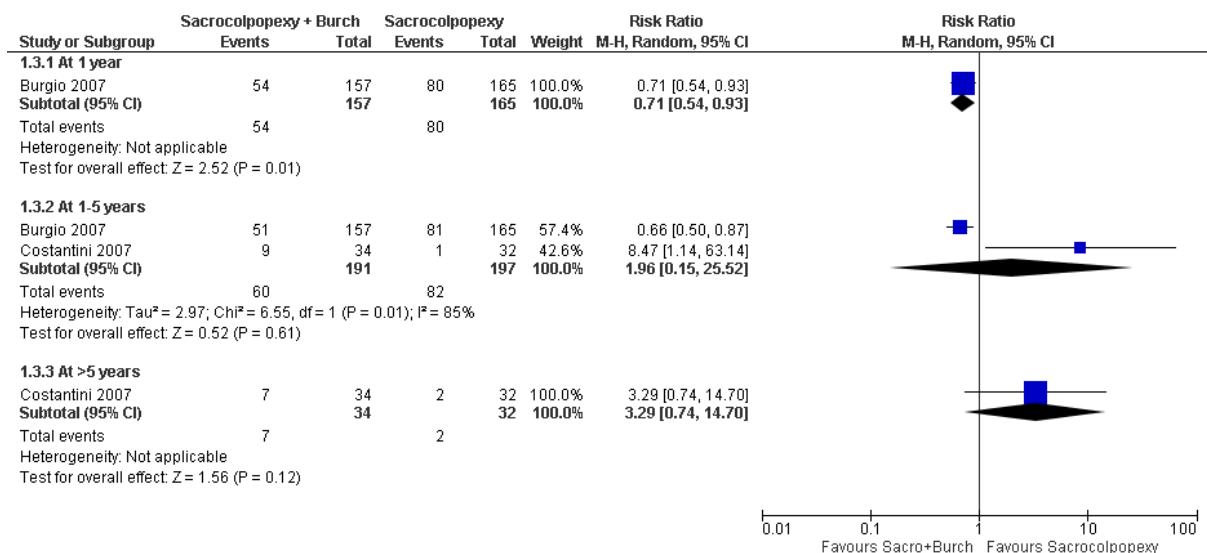
**Sacrocolpopexy and Burch colposuspension versus sacrocolpopexy**

**Figure 38: Any sign of urge or mixed urinary incontinence**



Abbreviations: *Sacro*, sacrocolpopexy; *Burch*, Burch colposuspension.

**Figure 39: Any sign of stress urinary incontinence**



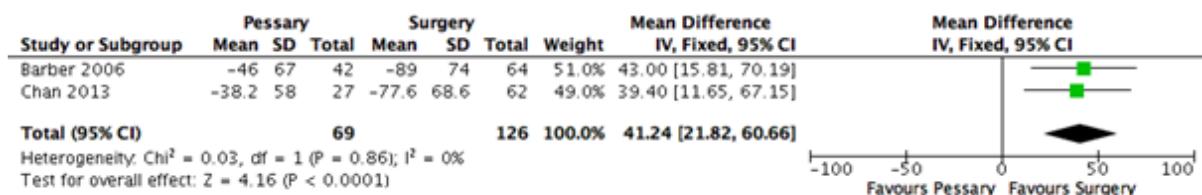
Abbreviations: *Sacro*, sacrocolpopexy; *Burch*, Burch colposuspension

### Vaginal POP repair and TVT versus vaginal POP repair

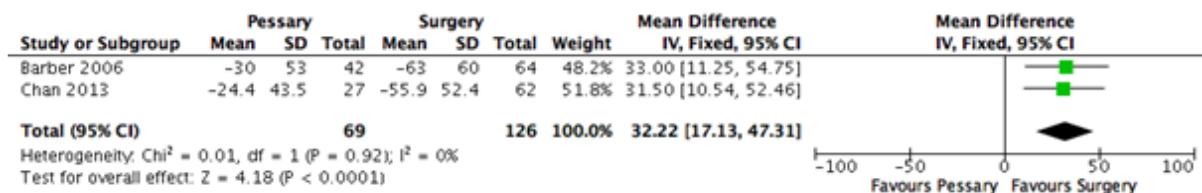
No forest plots are presented for this comparison.

**Forest plots for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

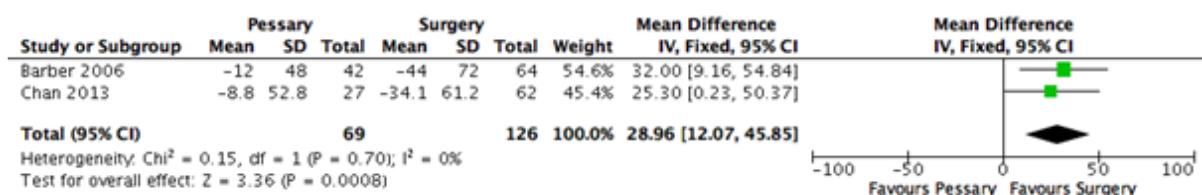
**Figure 40: POPDI - Pelvic organ prolapse distress inventory**



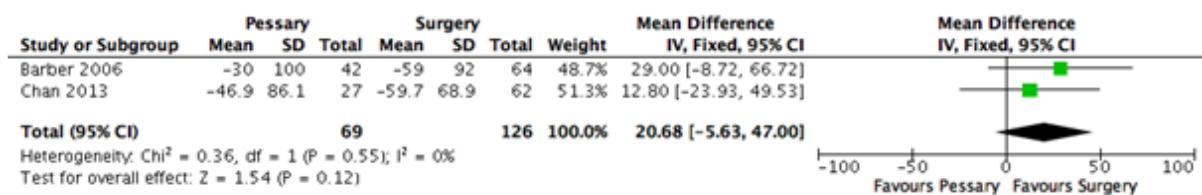
**Figure 41: UDI - Urogenital distress inventory**



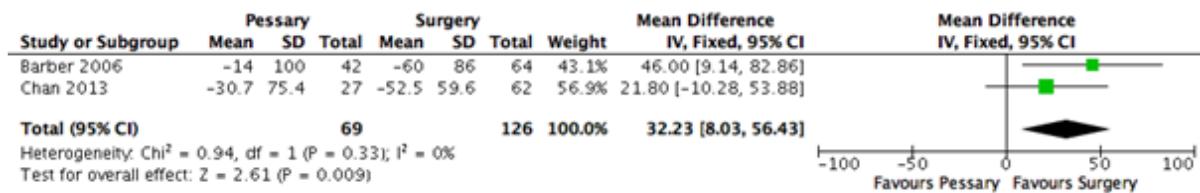
**Figure 42: CRADI - Colorectal-anal distress inventory**



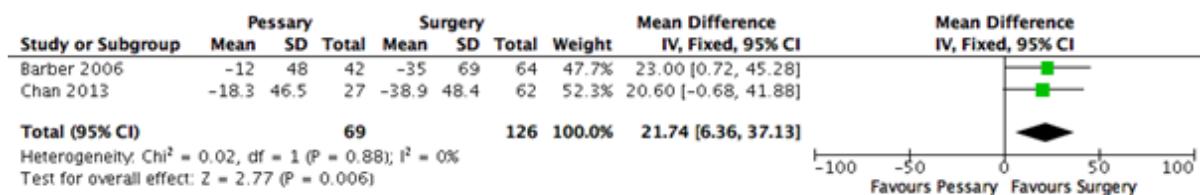
**Figure 43: POPIQ - Pelvic organ prolapse impact questionnaire**



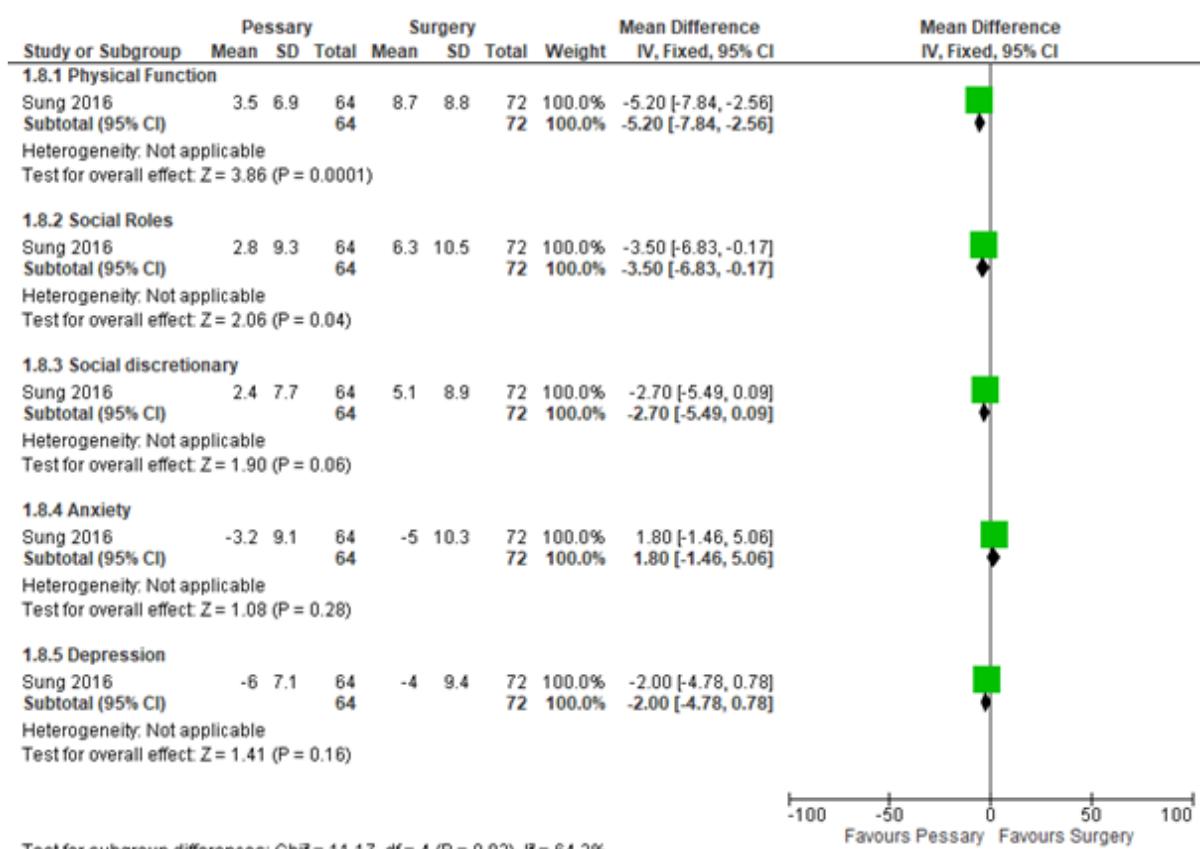
**Figure 44:** UIQ - Urinary impact questionnaire



**Figure 45:** CRAIQ - Colorectal-anal impact questionnaire



**Figure 46:** PROMIS - Patient reported outcomes measurement information system



## Appendix F – GRADE tables

**GRADE tables for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

**GRADE: Anterior surgery for POP**

**Table 35: Clinical evidence profile for comparison mesh surgery versus anterior colporrhaphy**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh surgery	AC	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Prolapse Cure (follow-up mean 3 months; assessed with: POPQ-Q stage 0-1 )</b>														
2	randomised trials	serious <sup>1</sup>	no serious inconsistency <sup>2</sup>	no serious indirectness	no serious imprecision	none	196/236 (83.1%)	135/233 (57.9%)	RR 1.33 (1.02 to 1.73)	191 more per 1000 (from 12 more to 423 more)	⊕⊕⊕O MODERATE	IMPORTANT		
<b>Prolapse Cure (follow-up mean 12 months; assessed with: POPQ-Q stage 0-1 )</b>														
17	randomised trials	serious <sup>3</sup>	serious	no serious indirectness	serious <sup>4</sup>	none	730/940 (77.7%)	529/993 (53.3%)	RR 1.44 (1.24 to 1.57)	213 more per 1000 (from 128 more to 304 more)	⊕⊖⊖O VERY LOW	IMPORTANT		
<b>Prolapse Cure (follow-up mean 24 months; assessed with: POPQ-Q stage 0-1 )</b>														
9	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	285/444 (64.2%)	239/458 (52.2%)	RR 1.2 (1.04 to 1.39)	104 more per 1000 (from 21 more to 204 more)	⊕⊕O O LOW	IMPORTANT		
<b>Prolapse Cure (follow-up mean 36 months; assessed with: POPQ-Q stage 0-1 )</b>														
1	randomised trials	very serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	64/69 (92.8%)	28/28 (100%)	RR 0.94 (0.86 to 1.02)	60 fewer per 1000 (from 140 fewer to 20 more)	⊕⊕O O LOW	IMPORTANT		

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

Repeat surgery for prolapse (follow-up 12-36 months)												
7	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	12/539 (2.2%)	35/476 (7.4%)	RR 0.38 (0.15 to 0.95)	46 fewer per 1000 (from 4 fewer to 62 fewer)	⊕⊕OO LOW	IMPORTANT
Repeat surgery for prolapse (follow-up mean 12 months)												
3	randomised trials	very serious <sup>6</sup>	serious <sup>2</sup>	no serious indirectness	serious <sup>4</sup>	none	3/276 (1.1%)	13/274 (4.7%)	RR 0.35 (0.03 to 3.74)	31 fewer per 1000 (from 46 fewer to 130 more)	⊕OOO VERY LOW	IMPORTANT
Repeat surgery for prolapse (follow-up mean 24 months)												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/79 (3.8%)	10/77 (13%)	RR 0.31 (0.09 to 1.06)	90 fewer per 1000 (from 118 fewer to 8 more)	⊕⊕⊕O MODERATE	IMPORTANT
Repeat surgery for prolapse (follow-up mean 36 months)												
2	randomised trials	very serious <sup>7</sup>	serious <sup>2</sup>	no serious indirectness	serious <sup>4</sup>	none	6/184 (3.3%)	12/125 (9.6%)	RR 0.26 (0.03 to 2.74)	71 fewer per 1000 (from 93 fewer to 167 more)	⊕OOO VERY LOW	IMPORTANT
Blood transfusion required during surgery												
8	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	23/337 (6.8%)	16/340 (4.7%)	RR 1.45 (0.84 to 2.5)	21 more per 1000 (from 8 fewer to 71 more)	⊕OOO VERY LOW	CRITICAL
Internal organ injury during surgery - urethral perforation												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	2/105 (1.9%)	0/98 (0%)	RR 2.86 (0.31 to 26.83)	-	⊕⊕OO LOW	CRITICAL
Internal organ injury during surgery - bladder perforation												
4	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	very serious <sup>8</sup>	none	10/368 (2.7%)	1/370 (0.27%)	RR 5.57 (1.24 to 24.98)	12 more per 1000 (from 1 more to 65 more)	⊕OOO VERY LOW	CRITICAL
Complications												
Vaginal bulge (follow-up mean 2 months; assessed with: Self-reported symptoms)												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	34/206 (16.5%)	42/204 (20.6%)	RR 0.8 (0.53 to 1.21)	41 fewer per 1000 (from 97 fewer to 43 more)	⊕⊕⊕O MODERATE	CRITICAL

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

Vaginal bulge (follow-up mean 12 months; assessed with: Self-reported symptoms)												
6	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	69/443 (15.6%)	102/448 (22.8%)	RR 0.68 (0.52 to 0.89)	73 fewer per 1000 (from 25 fewer to 109 fewer)	⊕⊕⊕O MODERATE	CRITICAL
Vaginal bulge (follow-up mean 24 months; assessed with: Self-reported symptoms)												
2	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	3/64 (4.7%)	9/68 (13.2%)	RR 0.36 (0.1 to 1.27)	85 fewer per 1000 (from 119 fewer to 36 more)	⊕⊕OO LOW	CRITICAL
Vaginal bulge (follow-up mean 36 months; assessed with: Self-reported symptoms)												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	12/79 (15.2%)	32/82 (39%)	RR 0.39 (0.22 to 0.7)	238 fewer per 1000 (from 117 fewer to 304 fewer)	⊕⊕⊕O MODERATE	CRITICAL
De novo dyspareunia (follow-up 12-24 months)												
10	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	25/510 (4.9%)	21/533 (3.9%)	RR 1.18 (0.69 to 2.02)	7 more per 1000 (from 12 fewer to 40 more)	⊕⊕OO LOW	CRITICAL
De novo dyspareunia (follow-up mean 12 months)												
8	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	21/386 (5.4%)	14/401 (3.5%)	RR 1.46 (0.79 to 2.73)	16 more per 1000 (from 7 fewer to 60 more)	⊕⊕OO LOW	CRITICAL
De novo dyspareunia (follow-up mean 24 months)												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	4/124 (3.2%)	7/132 (5.3%)	RR 0.55 (0.17 to 1.82)	24 fewer per 1000 (from 44 fewer to 43 more)	⊕⊕OO LOW	CRITICAL
Stress UI (follow-up mean 12 months)												
2	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	17/150 (11.3%)	12/152 (7.9%)	RR 1.38 (0.68 to 2.79)	30 more per 1000 (from 25 fewer to 141 more)	⊕OOOO VERY LOW	CRITICAL
Stress UI (follow-up mean 24 months)												
1	randomised trials	serious	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	1/21 (4.8%)	4/23 (17.4%)	RR 0.27 (0.03 to 2.26)	127 fewer per 1000 (from 169 fewer to 219 more)	⊕⊕OO LOW	CRITICAL
Stress UI (follow-up mean 36 months)												

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	15/105 (14.3%)	15/97 (15.5%)	RR 0.92 (0.48 to 1.79)	12 fewer per 1000 (from 80 fewer to 122 more)	⊕⊕OO LOW	CRITICAL
<b>Voiding difficulties (follow-up 12-24 months)</b>												
7	randomised trials	very serious <sup>7</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	18/395 (4.6%)	25/401 (6.2%)	RR 0.73 (0.41 to 1.29)	17 fewer per 1000 (from 37 fewer to 18 more)	⊕⊖OO VERY LOW	CRITICAL
<b>Voiding difficulties (follow-up mean 12 months)</b>												
6	randomised trials	serious <sup>7</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	17/374 (4.5%)	19/378 (5%)	RR 0.88 (0.48 to 1.62)	6 fewer per 1000 (from 26 fewer to 31 more)	⊕⊕OO LOW	CRITICAL
<b>Voiding difficulties (follow-up mean 24 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	1/21 (4.8%)	6/23 (26.1%)	RR 0.18 (0.02 to 1.39)	214 fewer per 1000 (from 256 fewer to 102 more)	⊕⊕OO LOW	CRITICAL
<b>Reported pain (pelvic/abdominal/not specified) (follow-up 12-24 months)</b>												
7	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	27/498 (5.4%)	31/503 (6.2%)	RR 0.9 (0.55 to 1.46)	6 fewer per 1000 (from 28 fewer to 28 more)	⊕⊖OO VERY LOW	CRITICAL
<b>Reported pain (pelvic/abdominal/not specified) (follow-up mean 12 months)</b>												
6	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	23/455 (5.1%)	27/458 (5.9%)	RR 0.88 (0.52 to 1.47)	7 fewer per 1000 (from 28 fewer to 28 more)	⊕⊖OO VERY LOW	CRITICAL
<b>Reported pain (pelvic/abdominal/not specified) - 24 month follow up</b>												
1	randomised trials	very serious <sup>9</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	4/43 (9.3%)	4/45 (8.9%)	RR 1.05 (0.28 to 3.92)	4 more per 1000 (from 64 fewer to 260 more)	⊕⊖OO VERY LOW	
<b>Sexual function (follow-up 12-24 months; measured with: PISQ-12; Better indicated by higher values)</b>												
3	randomised trials	very serious <sup>6</sup>	serious <sup>2</sup>	no serious indirectness	no serious imprecision	none	314	310	-	MD 1.48 higher (0.7 to 2.27 higher)	⊕⊖OO VERY LOW	CRITICAL
<b>Sexual function (follow-up 12 months; measured with: PISQ-12; Better indicated by higher values)</b>												
2	randomised trials	very serious <sup>6</sup>	very serious <sup>10</sup>	no serious indirectness	no serious imprecision	none	281	276	-	MD 1.46 higher (0.65 to 2.26 higher)	⊕⊖OO VERY LOW	CRITICAL

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

Sexual function (follow-up mean 24 months; measured with: PISQ-12; Better indicated by higher values)												
1	randomised trials	very serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	33	34	-	MD 2 higher (1.65 lower to 5.65 higher)	⊕⊕OO LOW	CRITICAL
Quality of life (follow-up mean 12 months; measured with: P-QoL; Better indicated by higher values)												
1	randomised trials	very serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	45	45	-	MD 1.6 higher (6.38 lower to 9.58 higher)	⊕⊕OO LOW	CRITICAL
Quality of Life (follow-up mean 12 months; measured with: ICIQ-VS; Better indicated by lower values)												
1	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	45	55	-	MD 1.05 lower (1.73 to 0.37 lower)	⊕⊕OO LOW	CRITICAL
Quality of Life (follow-up median 24 months; measured with: ICIQ-VS ; Better indicated by lower values)												
1	randomised trials	very serious <sup>6</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	45	55	-	MD 0.7 lower (1.38 to 0.02 lower)	⊕⊕OO LOW	CRITICAL
Quality of Life (follow-up mean 6 months; measured with: PFDI-20; Better indicated by lower values)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	37	37	-	MD 3 lower (19.75 lower to 13.75 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life (follow-up mean 12 months; measured with: PFDI-20 ; Better indicated by lower values)												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	97	101	-	MD 8.96 higher (5.63 to 12.29 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life (follow-up mean 24 months; measured with: PFDI-20 ; Better indicated by lower values)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	33	35	-	MD 8 lower (10.92 to 5.08 lower)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life (follow-up mean 6 months; measured with: PFIQ-7; Better indicated by lower values)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	37	37	-	MD 5 higher (12.4 lower to 22.4 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life (follow-up mean 12 months; measured with: PFIQ-7; Better indicated by lower values)												

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### Surgical management of pelvic organ prolapse

3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	97	101	-	MD 9.55 higher (6.2 to 12.89 higher)	$\oplus\oplus\ominus\ominus$ MODERATE	CRITICAL
<b>Quality of Life (follow-up mean 24 months; measured with: PFIQ-7; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	33	35	-	MD 8 higher (4.6 to 11.4 higher)	$\oplus\oplus\ominus\ominus$ MODERATE	CRITICAL

<sup>1</sup> Serious risk of bias: evidence downgraded by 1 as unclear risk of performance bias; unclear if participants, care staff and/or assessors blind to treatment allocation.

<sup>2</sup> Evidence is downgraded by 1 due to serious inconsistency; heterogeneity across studies greater than 50%  $I^2$ . This heterogeneity remains despite conducting random effects analysis.

<sup>3</sup> Serious risk of bias, evidence downgraded by 1; risk of performance bias as participants aware of treatment allocation, and outcome based on self-report

<sup>4</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>5</sup> Very serious risk of bias; evidence downgraded by 2 due to high attrition rates and high risk of detection bias, assessors aware of treatment allocation

<sup>6</sup> Very serious risk of bias. Unclear performance bias, as it is unclear if care staff and participants aware of treatment allocation. In addition, high risk bias due to unclear allocation methods in one or more study.

<sup>7</sup> Serious risk of bias due to high risk of performance bias, participants and care staff aware of allocation treatment and high risk of detection bias due to self-reported measures

<sup>8</sup> Evidence downgraded by 2 due to very serious imprecision; 95% confidence intervals cross both default MID for dichotomous outcomes (0.8 and 1.25)

<sup>9</sup> Very serious risk of bias; evidence downgraded by 2 due to performance bias as unclear if participants and care staff aware of allocation bias. High risk of attrition bias as dropout rates greater than 20%

<sup>10</sup> Evidence is downgraded by 2 due to very serious inconsistency; heterogeneity across studies greater than 80%  $I^2$ . This heterogeneity remains despite conducting random effects analysis.

AC: Anterior colporrhaphy; MD: mean difference; MID: minimally important difference; ICIQ-VS: international consultation incontinence questionnaire- vaginal symptoms: MD: mean difference; PISQ-12: pelvic organ prolapse/incontinence sexual questionnaire; PFDI-20: pelvic floor dysfunction index- short form; PFIQ-7: pelvic floor impact questionnaire-short form; POP: pelvic organ prolapse; POPQ-Q; pelvic organ prolapse quantification system; P-QOL: perceived quality of life scale; RR: relative risk; UI: urinary incontinence;

**Table 36: Clinical evidence profile for mesh surgery versus PVR for anterior pelvic organ prolapse**

Quality assessment							No of patients		Effect			Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	PVR	Relative (95% CI)	Absolute			
<b>Cure 12 months (follow-up mean 12 months; assessed with: POP-Q stage 0-1)</b>													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	29/35 (82.9%)	28/35 (80%)	RR 1.04 (0.83 to 1.3)	32 more per 1000 (from 136 fewer to 240 more)	⊕000 VERY LOW	CRITICAL	
<b>Cure 12 months (follow-up mean 24 months; assessed with: POP-Q stage 0-1)</b>													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	27/35 (77.1%)	25/35 (71.4%)	RR 1.08 (0.82 to 1.42)	57 more per 1000 (from 129 fewer to 300 more)	⊕000 VERY LOW	CRITICAL	

<sup>1</sup> Very serious risk of bias; evidence downgraded by 2 due risk of performance and detection bias as participants, care staff and assessors being aware of intervention allocation. In addition, high risk of attrition bias as greater than 20% of population lost to follow up

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

POP: pelvic organ prolapse; POP-Q: pelvic organ prolapse quantification system; PVR: paravaginal repair; RR: relative risk

**GRADE - Apical surgery for POP****Table 37: Clinical evidence profile for comparison laparoscopic sacrocolpopexy versus abdominal sacrocolpopexy**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopic sacrocolpopexy	Abdominal sacrocolpopexy	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Cure (follow-up 12-42 months; assessed with: POP-Q stage 0-1)</b>														
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	90/98 (91.8%)	89/97 (91.8%)	RR 1 (0.92 to 1.08)	0 fewer per 1000 (from 73 fewer to 73 more)	⊕⊕OO LOW	IMPORTANT		
<b>Cure (follow-up mean 12 months; assessed with: POP-Q stag 0-1)</b>														
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	29/37 (78.4%)	29/37 (78.4%)	RR 1 (0.79 to 1.27)	0 fewer per 1000 (from 165 fewer to 212 more)	⊕OOOO VERY LOW	IMPORTANT		
<b>Cure (follow-up mean 42 months; assessed with: POP-Q stage 0-1)</b>														
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	61/61 (100%)	60/60 (100%)	RR 1 (0.97 to 1.03)	0 fewer per 1000 (from 30 fewer to 30 more)	⊕⊕OO LOW	IMPORTANT		
<b>Repeat surgery for POP (follow-up mean 12 months)</b>														
1	randomised trials	very serious <sup>4</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	4/37 (10.8%)	1/37 (2.7%)	RR 4 (0.47 to 34.11)	81 more per 1000 (from 14 fewer to 895 more)	⊕OOOO VERY LOW	IMPORTANT		
<b>Recurrence of POP - Anterior (follow-up mean 42 months; assessed with: POP-Q stage 0-1)</b>														

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1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	11/61 (18%)	1/60 (1.7%)	RR 10.82 (1.44 to 81.23)	164 more per 1000 (from 7 more to 1000 more)	$\oplus\ominus\ominus$ VERY LOW	CRITICAL
<b>Recurrence of POP - Posterior (follow-up mean 42 months; assessed with: POP-Q stage 0-1)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	3/61 (4.9%)	5/60 (8.3%)	RR 0.59 (0.15 to 2.36)	34 fewer per 1000 (from 71 fewer to 113 more)	$\oplus\ominus\ominus$ VERY LOW	CRITICAL
<b>Blood transfusion</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/61 (1.6%)	7/60 (11.7%)	RR 0.14 (0.02 to 1.11)	100 fewer per 1000 (from 114 fewer to 13 more)	$\oplus\ominus\ominus$ LOW	CRITICAL
<b>Complications</b>												
<b>SUI (follow-up mean 12 months)</b>												
2	randomised trials	very serious <sup>4</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	9/65 (13.8%)	4/63 (6.3%)	RR 2.07 (0.7 to 6.07)	68 more per 1000 (from 19 fewer to 322 more)	$\oplus\ominus\ominus$ VERY LOW	CRITICAL
<b>Dyspareunia (follow-up mean 12 months)</b>												
1	randomised trials	very serious <sup>4</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	4/37 (10.8%)	3/37 (8.1%)	RR 1.33 (0.32 to 5.55)	27 more per 1000 (from 55 fewer to 369 more)	$\oplus\ominus\ominus$ VERY LOW	CRITICAL
<b>Mesh exposure (follow-up mean 42 months)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	3/61 (4.9%)	1/60 (1.7%)	RR 2.95 (0.32 to 27.58)	33 more per 1000 (from 11 fewer to 443 more)	$\oplus\ominus\ominus$ VERY LOW	CRITICAL
<b>Quality of Life P-QOL (follow-up mean 12 months; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	28	26	-	MD 5.3 lower (17.57 lower to 6.97 higher)	$\oplus\ominus\ominus$ MODERATE	CRITICAL

<sup>1</sup> Very serious risk of bias, risk of allocation bias due to unclear allocation methods and unclear allocation concealment. Risk of performance bias as participants and care staff aware of treatment allocation. Potential risk of reporting bias in studies

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### Surgical management of pelvic organ prolapse

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>3</sup> Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes (0.8 and 1.25)

<sup>4</sup> Very serious risk of bias, risk of allocation bias due to unclear allocation methods and unclear allocation concealment methods. Risk of performance and detection bias as participants, care staff and/or assessors aware of treatment allocation.

<sup>5</sup> Serious risk of bias, risk of allocation bias due to unclear allocation methods

MD: mean difference; MID: minimally important difference; POP: pelvic organ prolapse; POP-Q: pelvic organ prolapse quantification system; P-QOL: perceived quality of life score; RR: relative risk; SUI: stress urinary incontinence.

**Table 38: Clinical evidence profile for comparison vaginal hysterectomy versus sacrospinous hysteropexy**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal hysterectomy	Sacrospinous hysteropexy	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Cure (follow-up mean 12 months; assessed with: POP-Q stage 0-1)</b>														
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	91/139 (65.5%)	79/140 (56.4%)	RR 1.17 (0.97 to 1.41)	96 more per 1000 (from 17 fewer to 231 more)	⊕000 VERY LOW	IMPORTANT		
<b>Repeat surgery for POP (follow-up mean 12 months)</b>														
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	2/34 (5.9%)	4/37 (10.8%)	RR 0.54 (0.11 to 2.78)	50 fewer per 1000 (from 96 fewer to 192 more)	⊕000 VERY LOW	IMPORTANT		
<b>Recurrence of POP (follow-up mean 12 months)</b>														
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	13/139 (9.4%)	3/140 (2.1%)	RR 4.1 (1.33 to 12.62)	66 more per 1000 (from 7 more to 249 more)	⊕000 VERY LOW	CRITICAL		
<b>Complications</b>														
<b>Sexual function (follow-up mean 12 months; measured with: PSIQ-12; Better indicated by higher values)</b>														

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### Surgical management of pelvic organ prolapse

1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	56	49	-	MD 2 lower (3.41 to 0.59 lower)	$\oplus\ominus\ominus$ LOW	CRITICAL
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<sup>1</sup> Very serious risk of bias; risk of allocation bias as significant differences in participants at baseline were observed. Risk of performance and detection bias as participants, care staff and assessors aware of treatment allocation

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>3</sup> Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes (0.8 and 1.25)

**Table 39: Clinical evidence profile for comparison vaginal hysterectomy versus sacrocolpopexy/hysteropexy**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal hysterectomy	Sacrocolpopexy/hysteropexy	Relative (95% CI)	Absolute		
<b>Repeat surgery for POP - Repeat apical surgery (follow-up mean 12 months)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	3/51 (5.9%)	7/50 (14%)	RR 0.42 (0.12 to 1.53)	81 fewer per 1000 (from 123 fewer to 74 more)	$\ominus\ominus\ominus$	VERY LOW
<b>Repeat surgery for POP - any compartment (follow-up mean 12 months)</b>												
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	13/92 (14.1%)	7/91 (7.7%)	RR 1.77 (0.77 to 4.11)	59 more per 1000 (from 18 fewer to 239 more)	$\ominus\ominus\ominus$	VERY LOW
<b>Blood transfusion</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	1/41 (2.4%)	2/41 (4.9%)	RR 0.5 (0.05 to 5.3)	24 fewer per 1000 (from 46 fewer to 210 more)	$\ominus\ominus\ominus$	VERY LOW
<b>Bowel injury</b>												

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### Surgical management of pelvic organ prolapse

1	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	0/41 (0%)	1/41 (2.4%)	RR 0.33 (0.01 to 7.95)	16 fewer per 1000 (from 24 fewer to 170 more)	$\oplus\ominus\ominus$ O LOW	CRITICAL
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<sup>1</sup> Very serious risk of bias due to high attrition bias, dropout rates greater than 20% and performance and detection bias as participants, care staff and assessors aware of treatment allocation.

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>3</sup> Serious risk of bias; risk of performance and detection bias as participants, care staff and assessors aware of treatment allocation

MID: minimally important difference; POP: pelvic organ prolapse; RR: relative risk

**Table 40: Clinical evidence profile for comparison Infracoccygeal sacropexy versus sacrospinous suspension**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Infracoccygeal sacropexy	Sacrospinous suspension	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Cure (follow-up mean 16.8 months; assessed with: POP-Q stage 0-1)</b>														
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	20/24 (83.3%)	24/25 (96%)	RR 0.87 (0.71 to 1.06)	125 fewer per 1000 (from 278 fewer to 58 more)	$\oplus\ominus\ominus$ O MODERATE	IMPORTANT		
<b>Repeat surgery for uterine prolapse (follow-up mean 16.8 months)</b>														
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	1/24 (4.2%)	0/25 (0%)	RR 3.12 (0.13 to 73.04)	-	$\oplus\ominus\ominus$ O LOW	IMPORTANT		
<b>Complications</b>														
<b>SUI (follow-up mean 16.8 months)</b>														
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	0/24 (0%)	3/25 (12%)	RR 0.15 (0.01 to 2.73)	102 fewer per 1000 (from 119 fewer to 208 more)	$\oplus\ominus\ominus$ O LOW	CRITICAL		

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### Surgical management of pelvic organ prolapse

Voiding difficulties (follow-up mean 16.8 months)													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	5/24 (20.8%)	12/25 (48%)	RR 0.43 (0.18 to 1.05)	274 fewer per 1000 (from 394 fewer to 24 more)	⊕⊕⊕○ MODERATE	CRITICAL	
Constipation (follow-up mean 16.8 months)													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/24 (4.2%)	11/25 (44%)	RR 0.09 (0.01 to 0.68)	400 fewer per 1000 (from 141 fewer to 436 fewer)	⊕⊕⊕○ MODERATE	CRITICAL	
Sexual function (follow-up mean 16.8 months; measured with: PISQ-12; Better indicated by higher values)													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	24	25	-	MD 3.1 higher (0.43 lower to 6.63 higher)	⊕⊕○○ LOW	CRITICAL	

<sup>1</sup> Serious risk of bias, risk of selection bias as allocation methods and allocation concealment methods were inadequate

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>3</sup> Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes (0.8 and 1.25)

<sup>4</sup> Evidence downgraded due to serious imprecision; 95% confidence interval crosses 1 MID for PISQ-12, established MID equals 6 points

MD: mean difference; MID: minimally important difference; POP: pelvic organ prolapse; PISQ-12: pelvic organ prolapse/incontinence sexual questionnaire:

**Table 41: Clinical evidence profile for comparison sacrospinous ligament fixation with mesh versus sacrospinous ligament fixation with native tissue**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh for sacrospinous fixation	Native tissue for sacrospinous fixation	Relative (95% CI)	Absolute				
Effectiveness outcomes														
Cure (follow-up mean 12 months; assessed with: Ba <1)														

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### Surgical management of pelvic organ prolapse

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	30/36 (83.3%)	4/34 (11.8%)	RR 7.08 (2.79 to 17.99)	715 more per 1000 (from 211 more to 1000 more)	⊕OOO VERY LOW	IMPORTANT
<b>Recurrence (follow-up mean 12 months; assessed with: Ba&gt;1)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	21/101 (20.8%)	35/99 (35.4%)	RR 0.7 (0.28 to 1.76)	106 fewer per 1000 (from 255 fewer to 269 more)	⊕⊕OO LOW	CRITICAL
<b>Complications</b>												
<b>SUI (follow-up mean 12 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	43/121 (35.5%)	28/117 (23.9%)	RR 1.48 (0.99 to 2.21)	115 more per 1000 (from 2 fewer to 290 more)	⊕⊕OO LOW	CRITICAL
<b>Dyspareunia (follow-up mean 12 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	8/121 (6.6%)	3/117 (2.6%)	RR 2.58 (0.7 to 9.48)	41 more per 1000 (from 8 fewer to 217 more)	⊕⊕OO LOW	CRITICAL
<b>Quality of life (follow-up mean 12 months; measured with: POP-DI; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	36	34	-	MD 10.5 lower (24.41 lower to 3.41 higher)	⊕⊕OO LOW	CRITICAL
<b>Sexual function (follow-up mean 12 months; measured with: PSIQ-12; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	36	34	-	MD 0.2 lower (2.72 lower to 2.32 higher)	⊕⊕⊕O MODERATE	CRITICAL
<b>Mesh erosion (follow-up mean 12 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	21/101 (20.8%)	0/99 (0%)	RR 21.68 (2.98 to 157.67)	-	⊕OOO VERY LOW	CRITICAL
<b>Pelvic pain (follow-up mean 12 months)</b>												

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### Surgical management of pelvic organ prolapse

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	6/85 (7.1%)	3/83 (3.6%)	RR 1.95 (0.51 to 7.55)	34 more per 1000 (from 18 fewer to 237 more)	⊕⊕OO LOW	CRITICAL
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<sup>1</sup> Serious risk of bias; risk of performance and detection bias as participants, care staff and assessors aware of treatment allocation.

<sup>2</sup> Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes (0.8 and 1.25)

<sup>3</sup> Evidence downgraded by 1 due to very serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>4</sup> Evidence downgraded by 1 due to serious inconsistency, 95% confidence intervals cross the default MID for continuous variables, calculated as 0.5 +/- of SD native tissue (+/- 11.78).

**Table 42: Clinical evidence profile for comparison fascia lata versus synthetic mesh for sacral colpopexy**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fascia lata sacral colpopexy	Synthetic mesh sacral colpopexy	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Objective Cure (follow-up mean 12 months; assessed with: POP-Q stage 0-1)</b>														
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	30/50 (60%)	41/50 (82%)	RR 0.73 (0.56 to 0.95)	221 fewer per 1000 (from 41 fewer to 361 fewer)	⊕⊕OO LOW	IMPORTANT		
<b>Objective Cure (follow-up mean 60 months; assessed with: POP-Q stage 0-1)</b>														
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	18/50 (36%)	27/50 (54%)	RR 0.67 (0.43 to 1.04)	178 fewer per 1000 (from 308 fewer to 22 more)	⊕⊕OO LOW	IMPORTANT		
<b>Subjective cure (follow-up mean 60 months)</b>														
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	26/50 (52%)	28/50 (56%)	RR 0.93 (0.65 to 1.33)	39 fewer per 1000 (from 196 fewer to 185 more)	⊕OOOO VERY LOW	IMPORTANT		
<b>Complications</b>														

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### Surgical management of pelvic organ prolapse

Mesh erosion (follow-up mean 12 months)													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	1/50 (2%)	1/50 (2%)	RR 1 (0.06 to 15.55)	0 fewer per 1000 (from 19 fewer to 291 more)	⊕000 VERY LOW	CRITICAL	
Mesh erosion (follow-up mean 60 months)													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	1/50 (2%)	2/50 (4%)	RR 0.5 (0.05 to 5.34)	20 fewer per 1000 (from 38 fewer to 174 more)	⊕000 VERY LOW	CRITICAL	

<sup>1</sup> Very serious risk of bias; high risk of selection bias as significant differences between groups were apparent at baseline. Risk of detection and performance bias as assessors and care staff aware of treatment allocation

<sup>2</sup> Very serious risk of bias, high risk of selection bias as significant differences were observed between groups at baseline. Risk of detection bias as participants were aware of treatment allocation, and outcome is self-reported

<sup>3</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

MID: minimally important difference; POP-Q: pelvic organ prolapse quantification system; RR: relative risk

**Table 43: Clinical evidence profile for comparison abdominal sacral colpopexy versus vaginal sacrospinous colpopexy**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Abdominal sacral colpopexy	Vaginal sacrospinous colpopexy	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Cure (follow-up mean 24 months; assessed with: POP-Q &lt;2)</b>														
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	84/100 (84%)	82/114 (71.9%)	RR 1.19 (1.03 to 1.36)	137 more per 1000 (from 22 more to 259 more)	⊕000 VERY LOW	IMPORTANT		
<b>Complications</b>														
<b>Dyspareunia (follow-up mean 24 months)</b>														

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	3/99 (3%)	10/114 (8.8%)	RR 0.34 (0.09 to 1.25)	58 fewer per 1000 (from 80 fewer to 22 more)	⊕⊕OO LOW	CRITICAL
<b>SUI (follow-up mean 24 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/47 (4.3%)	8/48 (16.7%)	RR 0.26 (0.06 to 1.14)	123 fewer per 1000 (from 157 fewer to 23 more)	⊕⊕OO MODERATE	CRITICAL
<b>Voiding dysfunction (follow-up mean 24 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	1/47 (2.1%)	1/48 (2.1%)	RR 1.02 (0.07 to 15.86)	0 more per 1000 (from 19 fewer to 310 more)	⊕⊕OO LOW	CRITICAL
<b>Constipation (follow-up mean 24 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	12/47 (25.5%)	8/48 (16.7%)	RR 1.53 (0.69 to 3.41)	88 more per 1000 (from 52 fewer to 402 more)	⊕⊕OO LOW	CRITICAL
<b>UDI- short form (follow-up mean 24 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	46	43	-	MD 5 lower (12.48 lower to 2.48 higher)	⊕⊕OO MODERATE	

<sup>1</sup> Serious risk of bias; risk of performance bias as unclear if care staff were and participants were aware of treatment allocation

<sup>2</sup> Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes (0.8 and 1.25)

<sup>3</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses one default MID for dichotomous outcomes (0.8 or 1.25)

MD: mean difference; MID: minimally important difference; POP-Q: pelvic organ prolapse quantification system; SUI: stress urinary incontinence; RR: relative risk; UDI: urogenital distress inventory/

**Table 44: Clinical evidence profile for comparison vaginal hysterectomy versus Manchester repair**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal hysterectomy	Manchester repair	Relative (95% CI)	Absolute		

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

Effectiveness outcomes													
Repeat surgery (follow-up mean 61 months)													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	1/49 (2%)	3/45 (6.7%)	RR 0.31 (0.03 to 2.84)	46 fewer per 1000 (from 65 fewer to 123 more)	⊕000 VERY LOW	IMPORTANT	
Complications													
P-QOL (follow-up mean 61 months; Better indicated by higher values)													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	49	45	-	MD 1.79 lower (4.85 lower to 1.27 higher)	⊕000 VERY LOW	CRITICAL	

<sup>1</sup> Very serious risk of bias; high risk of allocation bias as unclear if allocation was concealed. Risk of performance and detection bias as unclear if participants, care staff or assessors were blind to treatment allocation

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>3</sup> Evidence downgraded due to serious imprecision; 95% confidence intervals crosses 1 default MID, calculated as 0.5 +/- SD of vaginal hysterectomy (+/- 3.5)

MD: mean difference; MID: minimally important difference; P-QOL: perceived quality of life score; RR: relative risk

**Table 45: Clinical evidence profile for comparison abdominal sacrocolpopexy versus high uterosacral vault suspension**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Abdominal sacrocolpopexy	High uterosacral vault suspension	Relative (95% CI)	Absolute		
Cure (follow-up mean 12 months; assessed with: POP-Q 0-1)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	54/64 (84.4%)	45/61 (73.8%)	RR 1.14 (0.95 to 1.37)	103 more per 1000 (from 37 fewer to 273 more)	⊕⊕00 LOW	IMPORTANT
Repeat surgery (follow-up mean 12 months)												

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/63 (4.8%)	10/61 (16.4%)	RR 0.29 (0.08 to 1.01)	116 fewer per 1000 (from 151 fewer to 2 more)	⊕⊕⊕O MODERATE	IMPORTANT
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<sup>1</sup> Serious risk of bias, risk of performance bias as unclear if participants and care staff aware of treatment allocation

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

MID: minimally important difference; POP-Q: pelvic organ prolapse quantification system; RR: relative risk

**Table 46: Clinical evidence profile for comparison high levator myorrhaphy versus uterosacral ligament suspension**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	High levator myorrhaphy	Uterosacral ligament suspension	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Cure (follow-up mean 12 months; assessed with: POP-Q)</b>														
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	82/116 (70.7%)	73/113 (64.6%)	RR 1.09 (0.91 to 1.31)	58 more per 1000 (from 58 fewer to 200 more)	⊕⊕OO LOW			
<b>Rectal injury during surgery</b>														
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	0/116 (0%)	1/113 (0.88%)	RR 0.32 (0.01 to 7.89)	6 fewer per 1000 (from 9 fewer to 61 more)	⊕⊕OO LOW	CRITICAL		
<b>Complications</b>														
<b>Mesh erosion (follow-up mean 12 months)</b>														
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	12/116 (10.3%)	16/113 (14.2%)	RR 0.73 (0.36 to 1.47)	38 fewer per 1000 (from 91 fewer to 67 more)	⊕⊕OO LOW	CRITICAL		
<b>Vaginal erosion (follow-up mean 12 months)</b>														

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### Surgical management of pelvic organ prolapse

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	4/116 (3.4%)	5/113 (4.4%)	RR 0.78 (0.21 to 2.83)	10 fewer per 1000 (from 35 fewer to 81 more)	$\oplus\ominus O$ LOW	CRITICAL
<b>Dyspareunia (follow-up mean 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	7/116 (6%)	9/113 (8%)	RR 0.76 (0.29 to 1.97)	19 fewer per 1000 (from 57 fewer to 77 more)	$\oplus\ominus O$ LOW	CRITICAL
<b>Constipation (follow-up mean 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	29/116 (25%)	21/113 (18.6%)	RR 1.35 (0.82 to 2.21)	65 more per 1000 (from 33 fewer to 225 more)	$\ominus O O O$ VERY LOW	CRITICAL
<b>SUI (follow-up mean 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	7/116 (6%)	11/113 (9.7%)	RR 0.62 (0.25 to 1.54)	37 fewer per 1000 (from 73 fewer to 53 more)	$\oplus\ominus O$ LOW	CRITICAL

<sup>1</sup> Serious risk of bias: risk of allocation bias as methods of allocation unclear

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>3</sup> Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals cross both default MIDs for dichotomous outcomes (0.8 and 1.25)

MID: minimally important difference; POP-Q: pelvic organ prolapse quantification system; RR: relative risk

**Table 47: Clinical evidence profiles for comparison porcine dermis versus polypropylene mesh for sacrocolpopexy**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Porcine dermis for sacrocolpopexy	Polypropylene mesh for sacrocolpopexy	Relative (95% CI)	Absolute				
<b>Effectiveness outcomes</b>														
<b>Cure (follow-up mean 12 months; assessed with: Objective cure (POP-Q 0-1))</b>														

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	46/58 (79.3%)	50/62 (80.6%)	RR 0.98 (0.82 to 1.18)	16 fewer per 1000 (from 145 fewer to 145 more)	⊕⊕⊕ HIGH	IMPORTANT
<b>Cure (follow-up mean 12 months; assessed with: Clinical cure (subjective and objective))</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	48/58 (82.8%)	52/62 (83.9%)	RR 0.99 (0.84 to 1.16)	8 fewer per 1000 (from 134 fewer to 134 more)	⊕⊕⊕ HIGH	IMPORTANT
<b>Complications</b>												
<b>Mesh exposure (follow-up mean 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	1/58 (1.7%)	0/62 (0%)	RR 3.2 (0.13 to 77.1)	-	⊕⊕⊕ MODERATE	CRITICAL
<b>Dyspareunia (follow-up mean 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	2/58 (3.4%)	3/62 (4.8%)	RR 0.71 (0.12 to 4.11)	14 fewer per 1000 (from 43 fewer to 150 more)	⊕⊕⊕ MODERATE	CRITICAL
<b>Quality of life (follow-up mean 12 months; measured with: PFDI-20; Better indicated by lower values)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	57	58	-	MD 5.9 lower (20.2 lower to 8.4 higher)	⊕⊕⊕ HIGH	CRITICAL
<b>Quality of life (follow-up mean 12 months; measured with: PFIQ-7; Better indicated by lower values)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	37	58	-	MD 6.2 lower (24.4 lower to 12 higher)	⊕⊕⊕ HIGH	CRITICAL
<b>Sexual function (follow-up mean 12 months; measured with: PISQ-12; Better indicated by higher values)</b>												

## DRAFT FOR CONSULTATION

### Surgical management of pelvic organ prolapse

1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	37	39	-	MD 1.8 lower (3.67 lower to 0.07 higher)	⊕⊕⊕ HIGH	
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<sup>1</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

MD: mean difference; MID: minimally important difference; PISQ-12: pelvic organ prolapse/incontinence sexual questionnaire; PFDI-20: pelvic floor dysfunction index- short form; PFIQ-7: pelvic floor impact questionnaire-short form; POPQ-Q: pelvic organ prolapse quantification system; P-QOL: perceived quality of life scale; RR: relative risk.

**Table 48: Clinical evidence profile for comparison mesh versus native tissue repair for sacrospinous fixation**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh for sacrospinous fixation	Native tissue for sacrospinous fixation	Relative (95% CI)	Absolute				
<b>Effectiveness</b>														
<b>Cure (follow-up mean 12 months; assessed with: POP-Q)</b>														
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	30/36 (83.3%)	4/34 (11.8%)	RR 7.08 (2.79 to 17.99)	715 more per 1000 (from 211 more to 1000 more)	⊕OOO VERY LOW	IMPORTANT		
<b>Recurrence (follow-up mean 12 months)</b>														
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	21/101 (20.8%)	35/99 (35.4%)	RR 0.7 (0.28 to 1.76)	106 fewer per 1000 (from 255 fewer to 269 more)	⊕⊕OO LOW	CRITICAL		
<b>Complications</b>														
<b>SUI (follow-up mean 12 months)</b>														

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### Surgical management of pelvic organ prolapse

2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	43/121 (35.5%)	28/117 (23.9%)	RR 1.48 (0.99 to 2.21)	115 more per 1000 (from 2 fewer to 290 more)	⊕⊕OO LOW	CRITICAL
<b>Dyspareunia (follow-up mean 12 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	8/121 (6.6%)	3/117 (2.6%)	RR 2.58 (0.7 to 9.48)	41 more per 1000 (from 8 fewer to 217 more)	⊕⊕OO LOW	CRITICAL
<b>Quality of life (follow-up mean 12 months; measured with: PFDI; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	36	34	-	MD 10.5 lower (24.41 lower to 3.41 higher)	⊕⊕OO LOW	CRITICAL
<b>Sexual function (follow-up mean 12 months; measured with: PISQ-12; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	36	34	-	MD 0.2 lower (2.72 lower to 2.32 higher)	⊕⊕⊕O MODERATE	CRITICAL
<b>Mesh erosion (follow-up mean 12 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	21/101 (20.8%)	0/99 (0%)	RR 21.68 (2.98 to 157.67)	-	⊕OOO VERY LOW	CRITICAL
<b>Pelvic pain (follow-up mean 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	6/85 (7.1%)	3/83 (3.6%)	RR 1.95 (0.51 to 7.55)	34 more per 1000 (from 18 fewer to 237 more)	⊕⊕OO LOW	CRITICAL

<sup>1</sup> Serious risk of bias; risk of performance and detection bias as participants, care staff and assessors aware of treatment allocation.

<sup>2</sup> Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes (0.8 and 1.25)

<sup>3</sup> Evidence downgraded by 1 due to very serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>4</sup> Evidence downgraded by 1 due to serious inconsistency, 95% confidence intervals cross the default MID for continuous variables, calculated as 0.5 +/- of SD native tissue (+/- 11.78).

MD: mean difference; MID: minimally important difference; PISQ-12: pelvic organ prolapse/incontinence sexual questionnaire; PFDI: pelvic floor dysfunction index; POPQ-Q: pelvic organ prolapse quantification system; RR: relative risk; UI: urinary incontinence;

**comparison laparoscopic sacral colpopexy versus total vaginal mesh kit****Table 49: Clinical evidence profile for**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopic sacral colpopexy	total vaginal mesh	Relative (95% CI)	Absolute				
<b>Effectiveness</b>														
<b>Cure (follow-up 12-24 months; assessed with: POP-Q stage 0-1)</b>														
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	100/183 (54.6%)	82/187 (43.9%)	RR 1.25 (1.01 to 1.54)	110 more per 1000 (from 4 more to 237 more)	⊕OOO VERY LOW	IMPORTANT		
<b>Cure (follow-up mean 12 months; assessed with: POP-Q stage 0-1)</b>														
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	59/130 (45.4%)	59/132 (44.7%)	RR 1.02 (0.78 to 1.33)	9 more per 1000 (from 98 fewer to 148 more)	⊕OOO VERY LOW	IMPORTANT		
<b>Cure (follow-up mean 24 months; assessed with: POP-Q stage 0-1)</b>														
1	randomised trials	serious <sup>4</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	41/53 (77.4%)	23/55 (41.8%)	RR 1.85 (1.31 to 2.61)	355 more per 1000 (from 130 more to 673 more)	⊕OOO VERY LOW	IMPORTANT		
<b>Repeat surgery for POP (follow-up mean 12 months)</b>														
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	1/130 (0.77%)	2/132 (1.5%)	RR 0.51 (0.05 to 5.53)	7 fewer per 1000 (from 14 fewer to 69 more)	⊕OOO VERY LOW	IMPORTANT		
<b>Repeat surgery for POP (follow-up mean 24 months)</b>														
1	randomised trials	serious <sup>4</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	0/53 (0%)	3/55 (5.5%)	RR 0.15 (0.01 to 2.8)	46 fewer per 1000 (from 54 fewer to 98 more)	⊕⊕OO LOW	IMPORTANT		

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### Surgical management of pelvic organ prolapse

Organ injury - Bladder injury													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	3/130 (2.3%)	3/132 (2.3%)	RR 1.02 (0.21 to 4.94)	0 more per 1000 (from 18 fewer to 90 more)	⊕OOO VERY LOW	CRITICAL	
Organ injury - Rectal injury													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	1/130 (0.77%)	1/132 (0.76%)	RR 1.02 (0.06 to 16.06)	0 more per 1000 (from 7 fewer to 114 more)	⊕OOO VERY LOW	CRITICAL	
Complications													
Vaginal bulge (follow-up mean 12 months)													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	118/130 (90.8%)	122/132 (92.4%)	RR 0.98 (0.91 to 1.06)	18 fewer per 1000 (from 83 fewer to 55 more)	⊕⊕OO LOW	CRITICAL	
Dyspareunia (follow-up mean 12 months)													
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	10/78 (12.8%)	18/67 (26.9%)	RR 0.48 (0.24 to 0.96)	140 fewer per 1000 (from 11 fewer to 204 fewer)	⊕⊕OO LOW	CRITICAL	

<sup>1</sup> Very serious risk of bias; unclear allocation bias, unclear if differences were apparent between groups at baseline. Risk of performance bias as unclear if care staff were aware of treatment allocation

<sup>2</sup> Evidence downgraded by 2 due to serious imprecision, 95% confidence intervals crosses both default MID for dichotomous outcomes (0.8 and 1.25)

<sup>3</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

<sup>4</sup> Serious risk of bias, risk of performance bias as unclear if care staff aware of treatment allocation

MID: minimally important difference; POP: pelvic organ prolapse; POPQ-Q: pelvic organ prolapse quantification system; RR: relative risk.

## GRADE - Posterior surgery for POP

Table 50: Clinical evidence profile for comparison posterior mesh surgery versus standard repair

Quality assessment	No of patients	Effect	Quality	Importance

# DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh surgery	Standard repair	Relative (95% CI)	Absolute		
<b>Effectiveness</b>												
<b>Prolapse Cure (follow-up mean 12 months)</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	134/255 (52.5%)	151/258 (58.5%)	RR 0.9 (0.77 to 1.04)	59 fewer per 1000 (from 135 fewer to 23 more)	⊕⊕⊕O MODERATE	IMPORTANT
<b>Repeat surgery for POP (follow-up mean 12 months)</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	6/255 (2.4%)	4/258 (1.6%)	RR 1.57 (0.46 to 5.41)	9 more per 1000 (from 8 fewer to 68 more)	⊕⊕OO LOW	CRITICAL
<b>Repeat surgery for POP (follow-up mean 24 months)</b>												
2	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	6/143 (4.2%)	4/141 (2.8%)	RR 1.48 (0.43 to 5.13)	14 more per 1000 (from 16 fewer to 117 more)	⊕⊕OO LOW	CRITICAL
<b>Blood transfusion</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>4</sup>	none	1/255 (0.39%)	1/258 (0.39%)	not pooled	not pooled	⊕OOOO VERY LOW	CRITICAL
<b>Internal organ injury</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	2/255 (0.78%)	1/258 (0.39%)	RR 1.78 (0.24 to 12.97)	3 more per 1000 (from 3 fewer to 46 more)	⊕⊕OO LOW	CRITICAL
<b>Complications</b>												
<b>Sexual function (follow-up mean 12 months; measured with: PISQ-12; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	32	37	-	MD 3 lower (5.55 to 0.45 lower)	⊕⊕⊕O MODERATE	CRITICAL
<b>Dyspareunia (follow-up mean 12 months)</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	8/112 (7.1%)	8/117 (6.8%)	RR 1.05 (0.40 to 2.74)	3 more per 1000 (from 41 fewer to 107 more)	⊕⊕OO LOW	CRITICAL

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### Surgical management of pelvic organ prolapse

Quality of Life: PFDI-20 (follow-up mean 12 months; measured with: PFDI-20; Better indicated by lower values)												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	28	-	MD 7 lower (31.31 lower to 17.31 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life: PFDI-20 (follow-up mean 24 months; measured with: PFDI-20; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	serious <sup>5</sup>	no serious indirectness	no serious imprecision	none	13	15	-	MD 14 lower (42.07 lower to 14.07 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life: PFIQ-7 (follow-up mean 12 months; measured with: PFIQ-7; Better indicated by lower values)												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	28	-	MD 2 higher (26.79 lower to 30.79 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life: PFIQ-7 (follow-up median 24 months; measured with: PFIQ-7; Better indicated by lower values)												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>4,6</sup>	none	13	15	-	MD 9 lower (48.05 lower to 30.05 higher)	⊕⊕OO LOW	CRITICAL
Quality of Life: POP-SS (follow-up mean 12 months; measured with: POP-SS; Better indicated by lower values)												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	129	130	-	MD 0.4 lower (1.45 lower to 0.65 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life: POP-SS (follow-up mean 24 months; measured with: POP-SS; Better indicated by lower values)												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>7</sup>	none	130	110	-	MD 0.59 higher (0.49 lower to 1.67 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life: ICIQ-UI (follow-up mean 12 months; measured with: ICIQ-UI; Better indicated by lower values)												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	117	117	-	MD 0.75 higher (0.22 lower to 1.71 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life: ICIQ-UI (follow-up mean 24 months; measured with: ICIQ-UI; Better indicated by lower values)												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	108	110		MD 0.48 higher (0.52 lower to 1.47 higher)	⊕⊕⊕O MODERATE	
Quality of Life: ICIQ-VS (follow-up mean 12 months; measured with: ICIQ-VS; Better indicated by lower values)												

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2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	110	108	-	MD 1.1 lower (2.8 lower to 0.59 higher)	$\oplus\oplus\ominus$ O MODERATE	CRITICAL
<b>Quality of Life: ICIQ-VS (follow-up mean 24 months; measured with: ICIQ-VS; Better indicated by lower values)</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	101	99	-	MD 0.64 lower (2.44 lower to 1.17 higher)	$\oplus\oplus\ominus$ O MODERATE	CRITICAL
<b>Faecal incontinence (follow-up mean 12 months)</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	39/143 (27.3%)	33/141 (23.4%)	RR 1.17 (0.78 to 1.74)	40 more per 1000 (from 51 fewer to 173 more)	$\oplus\oplus\ominus$ O LOW	CRITICAL
<b>Faecal incontinence (follow-up mean 24 months)</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	27/143 (18.9%)	19/141 (13.5%)	RR 1.4 (0.82 to 2.39)	54 more per 1000 (from 24 fewer to 187 more)	$\oplus\oplus\ominus$ O LOW	CRITICAL
<b>Constipation (follow-up mean 12 months)</b>												
4	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious	none	50/255 (19.6%)	53/258 (20.5%)	RR 0.97 (0.69 to 1.36)	6 fewer per 1000 (from 64 fewer to 74 more)	$\oplus\oplus\ominus$ O LOW	CRITICAL
<b>Constipation (follow-up mean 24 months)</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	19/143 (13.3%)	18/141 (12.8%)	RR 1.04 (0.57 to 1.9)	5 more per 1000 (from 55 fewer to 115 more)	$\oplus\oplus\ominus$ O LOW	CRITICAL

1 Serious risk of bias; unclear if care staff were aware of treatment allocation

2 Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

3 No explanation was provided

4 Evidence downgraded by 2 due to very serious imprecision, 95% confidence intervals cross both default MIDs for dichotomous outcomes (0.8 and 1.25)

5 Unclear risk of bias; self-reported measures - participants potentially influenced by knowledge of treatment on reporting of outcomes

6 Evidence downgraded due to serious imprecision; 95% confidence interval crosses 1 default MID. MID for PFIQ-7 equals 36 points

7 Evidence downgraded due to serious imprecision; 95% confidence intervals crosses 1 default MID. MID for POP-SS equals 1.5 points

MD: mean difference; MID: minimally important difference; ICIQ-VS: international consultation incontinence questionnaire- vaginal symptoms; ICIQ-UI: international consultation incontinence questionnaire- urinary incontinence; PISQ-12: pelvic organ prolapse/incontinence sexual questionnaire; PFDI-20: pelvic floor dysfunction index- short form; PFIQ-7: pelvic floor impact questionnaire-short form; POP: pelvic organ prolapse; POP-Q: pelvic organ prolapse quantification system; P-QOL: perceived quality of life scale; POP-SS: pelvic organ prolapse symptom score; RR: relative risk.

**POP surgery**

**Table 51: Clinical evidence profile for comparison porcine mesh versus polypropylene mesh for POP**

Quality assessment							No of patients		Effect		Quality	Importance		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Porcine mesh	Polypropylene mesh	Relative (95% CI)	Absolute				
<b>Effectiveness</b>														
<b>Cure (follow-up mean 12 months; assessed with: POP-Q)</b>														
2	randomised trials	serious <sup>1</sup>	serious <sup>2</sup>	no serious indirectness	no serious imprecision	none	55/160 (34.4%)	101/217 (46.5%)	RR 0.7 (0.55 to 0.89)	140 fewer per 1000 (from 51 fewer to 209 fewer)	⊕⊕OO LOW	IMPORTANT		
<b>Cure (follow-up mean 24 months; assessed with: POP-Q)</b>														
3	randomised trials	very serious <sup>3</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	90/153 (58.8%)	116/162 (71.6%)	RR 0.82 (0.7 to 0.96)	129 fewer per 1000 (from 29 fewer to 215 fewer)	⊕⊕OO LOW	IMPORTANT		
<b>Cure -anterior plus apical data (follow-up mean 12 months; assessed with: POP-Q)</b>														
3	randomised trials	serious <sup>1</sup>	very serious <sup>2</sup>	no serious indirectness	no serious imprecision	none	101/218 (46.3%)	151/279 (54.1%)	RR 0.8 (0.68 to 0.94)	108 fewer per 1000 (from 32 fewer to 173 fewer)	⊕OOOO VERY LOW	IMPORTANT		
<b>Complications</b>														
<b>mesh complications (follow-up mean 12 months)</b>														
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/371 (0%)	23/440 (5.2%)	RR 0.09 (0.02 to 0.39)	48 fewer per 1000 (from 32 fewer to 51 fewer)	⊕⊕⊕O MODERATE	CRITICAL		
<b>mesh complications (follow-up mean 24 months)</b>														

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3	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/280 (0.36%)	14/290 (4.8%)	RR 0.14 (0.03 to 0.6)	42 fewer per 1000 (from 19 fewer to 47 fewer)	⊕⊕⊕ HIGH	CRITICAL
<b>mesh complications - anterior plus apical (follow-up mean 12 months)</b>												
5	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/429 (0.23%)	23/502 (4.6%)	RR 0.16 (0.05 to 0.48)	38 fewer per 1000 (from 24 fewer to 44 fewer)	⊕⊕⊕ MODERATE	CRITICAL
<b>Dyspareunia (follow-up mean 24 months)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	14/125 (11.2%)	12/132 (9.1%)	RR 1.22 (0.59 to 2.52)	20 more per 1000 (from 37 fewer to 138 more)	⊕⊕⊕ LOW	CRITICAL
<b>Dyspareunia - plus apical data (follow-up mean 24 months)</b>												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	16/183 (8.7%)	15/194 (7.7%)	RR 1.12 (0.57 to 2.18)	9 more per 1000 (from 33 fewer to 91 more)	⊕⊕⊕ LOW	CRITICAL
<b>Constipation (follow-up mean 12 months)</b>												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	29/343 (8.5%)	39/410 (9.5%)	RR 0.88 (0.56 to 1.39)	11 fewer per 1000 (from 42 fewer to 37 more)	⊕⊕⊕ LOW	CRITICAL
<b>Constipation (follow-up mean 24 months)</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	23/249 (9.2%)	29/314 (9.2%)	RR 0.97 (0.58 to 1.63)	3 fewer per 1000 (from 39 fewer to 58 more)	⊕⊕⊕ MODERATE	CRITICAL
<b>Faecal incontinence (follow-up mean 12 months)</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	57/249 (22.9%)	69/314 (22%)	RR 1.03 (0.75 to 1.4)	7 more per 1000 (from 55 fewer to 88 more)	⊕⊕⊕ MODERATE	CRITICAL
<b>Faecal incontinence (follow-up mean 24 months)</b>												

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2	randomised trials	no serious risk of bias	serious <sup>2</sup>	no serious indirectness	serious <sup>4</sup>	none	63/249 (25.3%)	75/314 (23.9%)	RR 1.04 (0.78 to 1.39)	10 more per 1000 (from 53 fewer to 93 more)	⊕⊕OO LOW	CRITICAL
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<sup>1</sup> Serious risk of bias, evidence downgraded by 1 due to unclear allocation concealment

<sup>2</sup> Evidence downgraded by 2 due to very high risk of inconsistency - I<sup>2</sup> greater than 80% despite conducting random effects analysis

<sup>3</sup> Very serious risk of bias; evidence downgraded by 2 due to allocation bias and performance bias, unclear if participants, and or care staff were aware of treatment allocation

<sup>4</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

MID: minimally important difference; POP-Q pelvic organ prolapse quantification system; RR: relative risk

**Table 52: Non-absorbable mesh versus partially absorbable for Anterior POP**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Non-absorbable mesh	partially absorbable	Relative (95% CI)	Absolute		
<b>Mesh exposure - 12 months (follow-up mean 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	6/102 (5.9%)	6/98 (6.1%)	RR 0.96 (0.32 to 2.88)	2 fewer per 1000 (from 42 fewer to 115 more)	⊕⊕OO LOW	CRITICAL
<b>Mesh exposure (follow-up mean 36 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	6/102 (5.9%)	3/98 (3.1%)	RR 1.92 (0.49 to 7.47)	28 more per 1000 (from 16 fewer to 198 more)	⊕⊕OO LOW	CRITICAL

<sup>1</sup> Serious risk of bias; risk of performance bias as unclear if care staff, participants and/or assessors were aware of treatment allocation

<sup>2</sup> Evidence downgraded by 1 due to serious imprecision, 95% confidence intervals crosses a default MID for dichotomous outcomes (0.8 or 1.25)

MID: minimally important difference; RR: relative risk

**GRADE tables for review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Table 53: Clinical evidence profile for sacrocolpopexy and Burch colposuspension versus sacrocolpopexy**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sacrocolpopexy + Burch colposuspension	Sacrocolpopexy	Relative (95% CI)	Absolute		
<b>Any sign of urge or mixed incontinence - At &lt;=1 year (follow-up 12 months; assessed with: Pelvic Floor Distress Inventory urge items or treatment for urge incontinence)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	51/157 (32.5%)	66/165 (40%)	RR 0.81 (0.61 to 1.09)	76 fewer per 1000 (from 156 fewer to 36 more)	⊕⊕⊕O	MODERATE
<b>Any sign of urge or mixed incontinence - At &gt;1 to &lt;=5 years (follow-up 2-3 years; assessed with: Bladder diary, daily pad use, or stress test; Pelvic Floor Distress Inventory urge items or treatment for UUI)</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	50/191 (26.2%)	71/197 (36%)	RR 0.74 (0.55 to 0.99)	94 fewer per 1000 (from 4 fewer to 162 fewer)	⊕⊕⊕O	MODERATE
<b>Any sign of urge or mixed incontinence - At &gt;5 years (follow-up 8 years; assessed with: Pelvic Floor Distress Inventory urge items or treatment for urge incontinence)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	2/34 (5.9%)	3/32 (9.4%)	RR 0.63 (0.11 to 3.51)	35 fewer per 1000 (from 83 fewer to 235 more)	⊕⊕OO	LOW
<b>Any sign of incontinence - At &gt;1 to &lt;=5 years (follow-up 3 years; assessed with: Bladder diary, daily pad use, or stress test)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	12/34 (35.3%)	3/32 (9.4%)	RR 3.76 (1.17 to 12.12)	259 more per 1000 (from 16 more to 1000 more)	⊕⊕⊕O	MODERATE
<b>Any sign of incontinence - At &gt;5 years (follow-up 8 years; assessed with: Bladder diary, daily pad use, or stress test)</b>												
1	randomised trials	no serious	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	9/34 (26.5%)	5/32 (15.6%)	RR 1.69 (0.64 to 4.52)	108 more per 1000 (from 56	⊕⊕OO	LOW
												CRITICAL

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Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sacrocolpopexy + Burch colposuspension	Sacrocolpopexy	Relative (95% CI)	Absolute		
		risk of bias								fewer to 550 more)		
Any sign of stress incontinence - At <=1 year (follow-up 12 months; assessed with: Pelvic Floor Distress Inventory urge items or treatment for stress incontinence)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	54/157 (34.4%)	80/165 (48.5%)	RR 0.71 (0.54 to 0.93)	141 fewer per 1000 (from 34 fewer to 223 fewer)	⊕⊕⊕○ MODERATE	CRITICAL
Any sign of stress incontinence - At 1-5 years (follow-up 2-3 years; assessed with: Bladder diary, daily pad use, or stress test; Pelvic Floor Distress Inventory stress items, cough stress test, or treatment for SUI)												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	60/191 (31.4%)	82/197 (41.6%)	RR 1.96 (0.15 to 25.52)	400 more per 1000 (from 354 fewer to 1000 more)	⊕⊕○○ LOW	CRITICAL
Any sign of stress incontinence - At >5 years (follow-up 8 years; assessed with: Bladder diary, daily pad use, or stress test)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	7/34 (20.6%)	2/32 (6.3%)	RR 3.29 (0.74 to 14.7)	143 more per 1000 (from 16 fewer to 856 more)	⊕⊕○○ LOW	CRITICAL
Subjective sign of SUI - At <=1 year (follow-up 12 months; assessed with: 'Yes' response to any UDI stress item)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	33/157 (21%)	63/165 (38.2%)	RR 0.55 (0.38 to 0.79)	172 fewer per 1000 (from 80 fewer to 237 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
Subjective sign of SUI - At >1 to <=5 years (follow-up 2 years; assessed with: 'Yes' response to any UDI stress item)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	38/157 (24.2%)	63/165 (38.2%)	RR 0.63 (0.45 to 0.89)	141 fewer per 1000 (from 42 fewer to 210 fewer)	⊕⊕⊕○ MODERATE	CRITICAL
Subjective sign of irritative symptoms - At <=1 year (follow-up 12 months; assessed with: 'Yes' response to any UDI irritative subscale item)												
1	randomised trials	no serious	no serious inconsistency	no serious indirectness	no serious imprecision	none	118/157 (75.2%)	118/165 (71.5%)	RR 1.05 (0.92 to 1.2)	36 more per 1000 (from 57 fewer to 143 more)	⊕⊕⊕⊕ HIGH	CRITICAL

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### Surgical management of pelvic organ prolapse

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sacrocolpopexy + Burch colposuspension	Sacrocolpopexy	Relative (95% CI)	Absolute		
		risk of bias										
Subjective sign of obstructive symptoms - At <=1 year (follow-up 12 months; assessed with: 'Yes' response to any UDI obstructive subscale item)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	63/157 (40.1%)	66/165 (40%)	RR 1 (0.77 to 1.31)	0 fewer per 1000 (from 92 fewer to 124 more)	⊕⊕OO LOW	CRITICAL
De novo storage symptoms – at >5 years (follow-up 8 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	2/34	0/32 (9%)32	RR 4.71 (0.23 to 94.58)	-	⊕⊕OO LOW	CRITICAL
Positive stress test - At <=1 year (follow-up 12 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	26/157 (16.6%)	41/165 (24.8%)	RR 0.67 (0.43 to 1.03)	82 fewer per 1000 (from 142 fewer to 7 more)	⊕⊕⊕O MODERATE	CRITICAL
Positive stress test - At >1 to <=5 years (follow-up 2 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	24/157 (15.3%)	39/165 (23.6%)	RR 0.65 (0.41 to 1.02)	83 fewer per 1000 (from 139 fewer to 5 more)	⊕⊕⊕O MODERATE	CRITICAL
Mesh erosion - At <=1 year (follow-up 12 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	4/157 (2.5%)	10/162 (6.2%)	RR 0.41 (0.13 to 1.29)	36 fewer per 1000 (from 54 fewer to 18 more)	⊕⊕OO LOW	CRITICAL
Mesh erosion - At >1 to <=5 years (follow-up 2 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	4/153 (2.6%)	2/158 (1.3%)	RR 2.07 (0.38 to 11.11)	14 more per 1000 (from 8 fewer to 128 more)	⊕⊕OO LOW	CRITICAL

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## Surgical management of pelvic organ prolapse

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sacrocolpopexy + Burch colposuspension	Sacrocolpopexy	Relative (95% CI)	Absolute		
Need for catheterisation at <=1 year (follow-up 3 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	2/34 (5.9%)	0/32 (0%)	RR 4.71 (0.23 to 94.58)	-	⊕⊕OO LOW	CRITICAL
Wound complications - At <=1 year (follow-up 6 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	6/157 (3.8%)	8/162 (4.9%)	RR 0.77 (0.27 to 2.18)	11 fewer per 1000 (from 36 fewer to 58 more)	⊕⊕OO LOW	CRITICAL
Wound complications - At >1 to <=5 years (follow-up 24 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	2/153 (1.3%)	2/158 (1.3%)	RR 1.03 (0.15 to 7.24)	0 more per 1000 (from 11 fewer to 79 more)	⊕⊕OO LOW	CRITICAL
Repeat surgery for POP - At <=1 year (follow-up 12 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	1/157 (0.64%)	1/162 (0.62%)	RR 1.03 (0.07 to 16.35)	0 more per 1000 (from 6 fewer to 95 more)	⊕⊕OO LOW	CRITICAL
Repeat surgery for POP - At >1 to <=5 years (follow-up 24 months)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	1/153 (0.65%)	2/158 (1.3%)	RR 0.52 (0.05 to 5.64)	6 fewer per 1000 (from 12 fewer to 59 more)	⊕⊕OO LOW	CRITICAL
Incontinence Severity Index - At <=1 year (follow-up 12 months; range of scores: 0-8; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	155	152	-	MD 1 lower (1.63 to 0.37 lower)	⊕⊕⊕O MODERATE	IMPORTANT
Incontinence Severity Index - At >1 year to <=5 years (follow-up 2 years; range of scores: 0-8; Better indicated by lower values)												

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### Surgical management of pelvic organ prolapse

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sacrocolpopexy + Burch colposuspension	Sacrolcopexy	Relative (95% CI)	Absolute		
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	147	155	-	MD 0.8 lower (1.43 to 0.17 lower)	⊕⊕⊕⊕ HIGH	IMPORTANT
PISQ-12 At <=1 year (follow-up 12 months; measured with: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire Short Form; range of scores: 0-48; Better indicated by higher values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision <sup>4</sup>	none	96	98	-	MD 0.1 lower (1.56 lower to 1.36 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT
PISQ-12 - At >1 year to <=5 years (follow-up 2 years; measured with: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire Short Form; range of scores: 0-48; Better indicated by higher values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision <sup>4</sup>	none	98	96	-	MD 0.1 lower (1.58 lower to 1.38 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT
Severe bleeding requiring blood transfusion												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	3/34 (8.8%)	3/32 (9.4%)	RR 0.94 (0.2 to 4.33)	6 fewer per 1000 (from 75 fewer to 312 more)	⊕⊕OO LOW	IMPORTANT

1 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

2 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

3 95% CI crosses 1 MID for this outcome (+/- 1.55), calculated as 0.5 times the SD of the control arm at follow up.

4 MID for this outcome is +/- 2.55 at 12 months follow-up, +/- 2.75 at 2 years follow up, calculated as 0.5 times the SD of the control arm at these time points.

**Table 54: Clinical evidence profile for vaginal POP repair and TVT versus vaginal POP repair**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal POP repair + TVT	Vaginal POP repair	Relative (95% CI)	Absolute		
<b>Any sign of urinary incontinence at 12 months (follow-up 12 months; assessed with: Positive cough stress test or 'moderate'/'quite a bit' response to PFDI leakage items)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	45/165 (27.3%)	74/172 (43%)	RR 0.63 (0.47 to 0.86)	159 fewer per 1000 (from 60 fewer to 228 fewer)	⊕⊕OO LOW	CRITICAL
<b>Positive cough stress test at 12 months (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	5/165 (3%)	31/172 (18%)	RR 0.17 (0.07 to 0.42)	150 fewer per 1000 (from 105 fewer to 168 fewer)	⊕⊕⊕O MODERATE	CRITICAL
<b>Mesh erosion/exposure at 12 months (non-event) (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/165 (0%)	0/172 (0%)	RR 1.0 (0.99 to 1.01)	-	⊕⊕⊕O MODERATE	CRITICAL
<b>Need for catheterisation at &lt;=1 year (follow-up 6 months)</b>												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	very serious <sup>4</sup>	none	4/47 (8.5%)	2/43 (4.7%)	RR 2.32 (0.45 to 11.98)	61 more per 1000 (from 26 fewer to 511 more)	⊕OOOO VERY LOW	CRITICAL
<b>Infection at 1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	49/165 (29.7%)	30/172 (17.4%)	RR 1.7 (1.14 to 2.54)	122 more per 1000 (from 24 more to 269 more)	⊕⊕OO LOW	CRITICAL
<b>Incontinence Severity Index - change from baseline at 1 year (follow-up 12 months; range of scores: 0-8; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>5</sup>	none	154	152	-	MD 1 lower (1.61 to 0.39 lower)	⊕⊕OO LOW	CRITICAL
<b>Bladder injury</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	11/164 (6.7%)	0/172 (0%)	RR 24.12 (1.43 to 405.95)	-	⊕⊕⊕O MODERATE	IMPORTANT

<sup>1</sup> Unclear risk of bias regarding random sequence generation and allocation concealment.<sup>2</sup> 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

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3 High risk of bias regarding outcome assessment; Unclear

risk of bias regarding allocation concealment, blinding of participants/personnel, and selective reporting.

4 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

5 95% CI crosses 1 MID for this outcome (+/- 1.35), calculated as 0.5 times the SD of the control arm at follow up.

**Table 55: Clinical evidence profile for vaginal POP repair and synthetic transobturator mesh sling versus vaginal POP repair**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal POP repair + transobturator mesh sling	Vaginal POP repair	Relative (95% CI)	Absolute		
<b>Any sign of incontinence at &lt;=1 year (follow-up 12 months; assessed with: Bothersome symptoms on UDI, positive cough stress test or any incontinence treatment)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	0/43 (0%)	18/47 (38.3%)	RR 0.03 (0 to 0.47)	371 fewer per 1000 (from 203 fewer to 383 fewer)	⊕⊕OO LOW	CRITICAL
<b>Subjective urge incontinence symptoms at &lt;=1 year (follow-up 12 months; assessed with: Urinary Distress Inventory)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	8/43 (18.6%)	16/47 (34%)	RR 0.55 (0.26 to 1.15)	153 fewer per 1000 (from 252 fewer to 51 more)	⊕OOO VERY LOW	CRITICAL
<b>No subjective urinary incontinence symptoms at &lt;=1 year (follow-up 12 months; assessed with: Urinary Distress Inventory)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	31/43 (72.1%)	18/47 (38.3%)	RR 1.88 (1.25 to 2.83)	337 more per 1000 (from 96 more to 701 more)	⊕⊕OO LOW	CRITICAL
<b>No subjective SUI symptoms at &lt;=1 year (follow-up 12 months; assessed with: Urinary Distress Inventory)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	36/43 (83.7%)	22/47 (46.8%)	RR 1.79 (1.28 to 2.49)	370 more per 1000 (from 131 more to 697 more)	⊕⊕OO LOW	CRITICAL
<b>Positive cough stress test at &lt;=1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	0/29 (0%)	11/31 (35.5%)	RR 0.05 (0 to 0.75)	337 fewer per 1000 (from 89 fewer to 355 fewer)	⊕⊕OO LOW	CRITICAL
<b>Subjective frequency symptoms at &lt;=1 year (follow-up 12 months; assessed with: Urinary Distress Inventory, &gt;10 times a day)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>4</sup>	none	10/43 (23.3%)	10/47 (21.3%)	RR 1.09 (0.5 to 2.37)	19 more per 1000 (from 106 fewer to 291 more)	⊕OOO VERY LOW	CRITICAL
<b>Subjective nocturia symptoms at &lt;=1 year (follow-up 12 months; assessed with: Urinary Distress Inventory, &gt;2 times a night)</b>												

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Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vaginal POP repair + transobturator mesh sling	Vaginal POP repair	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	15/43 (34.9%)	9/47 (19.1%)	RR 1.82 (0.89 to 3.73)	157 more per 1000 (from 21 fewer to 523 more)	⊕OOO VERY LOW	CRITICAL
Mesh extrusion/exposure at <=1 year (follow-up 12 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>4</sup>	none	3/43 (7%)	0/47 (0%)	RR 7.64 (0.41 to 143.7)	-	⊕OOO VERY LOW	CRITICAL
Infection at <=1 year (follow-up 12 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>4</sup>	none	5/43 (11.6%)	1/47 (2.1%)	RR 5.47 (0.66 to 44.93)	95 more per 1000 (from 7 fewer to 935 more)	⊕OOO VERY LOW	CRITICAL
Bladder injury (non-event)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	0/43 (0%)	0/47 (0%)	RR 1.0 (0.96 to 1.04)	-	⊕⊕OO LOW	IMPORTANT
Patient Global Impression of Improvement at <=1 year (follow-up 12 months; assessed with: Response of 'very much' or 'much' improved)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	31/43 (72.1%)	31/47 (66%)	RR 1.09 (0.83 to 1.44)	59 more per 1000 (from 112 fewer to 290 more)	⊕OOO VERY LOW	IMPORTANT

1 High risk of bias regarding blinding of outcome assessment; Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, and selective reporting.

2 12% of women in intervention arm received retropubic mesh sling.

3 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

4 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

**GRADE tables for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Table 56: Clinical evidence profile for surgery versus pessary**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	Surgery	Relative (95% CI)	Absolute		
UDI (follow-up median 12 months; Better indicated by lower values)												
2	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	126	-	MD 32.22 higher (17.13 to 47.31 higher)	⊕000 VERY LOW	CRITICAL
POPDI (follow-up median 12 months; Better indicated by lower values)												
2	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	126	-	MD 41.24 higher (21.82 to 60.66 higher)	⊕000 VERY LOW	CRITICAL
CRADI (follow-up median 12 months; Better indicated by lower values)												
2	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	126	-	MD 28.96 higher (12.07 to 45.85 higher)	⊕000 VERY LOW	CRITICAL
POPIQ (follow-up median 12 months; Better indicated by lower values)												
2	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	126	-	MD 20.68 higher (5.63 lower to 47 higher)	⊕000 VERY LOW	CRITICAL
UIQ (follow-up median 12 months; Better indicated by lower values)												
2	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	126	-	MD 32.23 higher (8.03 to 56.43 higher)	⊕000 VERY LOW	CRITICAL
CRAIQ (follow-up median 12 months; Better indicated by lower values)												
2	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	69	126	-	MD 21.74 higher (6.36 to 37.13 higher)	⊕000 VERY LOW	CRITICAL
PROMIS - Physical Function (follow-up mean 12 months; Better indicated by lower values)												

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Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pessary	Surgey	Relative (95% CI)	Absolute		
1	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	64	72	-	MD 5.2 lower (7.84 to 2.56 lower)	⊕000 VERY LOW	CRITICAL
PROMIS - Social Roles (follow-up mean 12 months; Better indicated by lower values)												
1	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	64	72	-	MD 3.5 lower (6.83 to 0.17 lower)	⊕000 VERY LOW	CRITICAL
PROMIS - Social discretionary (follow-up mean 12 months; Better indicated by lower values)												
1	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	64	72	-	MD 2.7 lower (5.49 lower to 0.09 higher)	⊕000 VERY LOW	CRITICAL
PROMIS - Anxiety (follow-up mean 12 months; Better indicated by lower values)												
1	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	64	72	-	MD 1.8 higher (1.46 lower to 5.06 higher)	⊕000 VERY LOW	CRITICAL
PROMIS - Depression (follow-up mean 12 months; Better indicated by lower values)												
1	observational studies	serious <sup>1,2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	64	72	-	MD 3.4 higher (0.62 to 6.18 higher)	⊕000 VERY LOW	CRITICAL
PSIQ (follow-up mean 6 months; Better indicated by lower values)												
1	observational studies	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	33	203	-	MD 14.0 lower (15.88 to 12.12lower)	⊕000 VERY LOW	CRITICAL

<sup>1</sup> High risk of bias due to unbalanced arms across the intervention groups

<sup>2</sup> High risk of bias due to unbalanced length of follow-up across the intervention groups

## Appendix G – Economic evidence study selection

**Economic evidence study selection for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

One global search was conducted for this review question. See supplementary material D for further information.

**Economic evidence study selection for review question: What is the role for surgery for preventing postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

One global search was conducted for this review question. See supplementary material D for further information.

**Economic evidence study selections for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

One global search was conducted for this review question. See supplementary material D for further information.

## Appendix H – Economic evidence tables

**Economic evidence tables for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

**Table 57: Economic evidence tables for anterior and/or posterior prolapse**

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Glazener, C., Breeman, S., Elders, A., Hemming, C., Cooper, K., Freeman, R., Smith, A., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., Clinical effectiveness and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study-results from the PROSPECT Study,	Interventions :  Standard repair, synthetic mesh, and biological graft	Adult women requiring primary anterior and/or posterior vaginal wall prolapse repair  Economic analysis alongside RCT and modelling (Markov model to explore long-term costs and outcomes)  Source of clinical effectiveness data: year 1 standard repair N=195, synthetic mesh N=195, biological graft N=191 year 2	Costs:  NHS perspective: intervention procedure (mesh, staff time in theatre, drugs in theatre, catheterisation, vaginal packing, theatre overheads), inpatient and follow-up secondary care costs (readmissions, reoperations, visits to ward, outpatient consultations) and costs to primary care services (GP, nurse, physiotherapist), other treatments (shelf pessary, ring pessary, incontinence drugs, oestrogen, intermittent catheters, permanent catheters, absorbent pads, other drug treatments)  Participant and indirect costs: time off work, participant and companion time and travel costs for both outpatient and inpatient appointments, self-purchased health care and medication		Perspective: NHS Currency: UK£ Cost year: 2013/14 prices  Time horizon: within trial 1 year, 2 years; modelling 5 years  Discounting: 3.5% for costs and outcomes  Applicability: directly applicable  Quality: minor limitations  Incremental analysis was adjusted for covariates (age group, type of prolapse, concomitant continence procedure and

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<b>Study Country Study type</b>	<b>Intervention details</b>	<b>Study population Study design Data sources</b>	<b>Costs: description and values Outcomes: description and values</b>	<b>Results: Cost-effectiveness</b>	<b>Comments</b>
Health technology assessment (Winchester, England), 2016 - primary repair	UK	standard repair N=165, synthetic mesh N=168; biological graft N=170)	Primary outcome measure: QALYs (EQ-5D-3L, UK general population norms)		concomitant upper compartment prolapse surgery), as well as surgeon and baseline EQ-5D-3L scores.
Cost-utility analysis		Source of resource use data: RCT (N is same as above)			
Conflict of interest: none.		Source of unit costs: national sources			
Funding: NIHR and HTA.					
			From NHS perspective using complete case data at 1 year: Mean cost per participant Standard repair: £3,216 (SD: £1,301) Synthetic mesh: £3,698 (SD: £1,387) Biological graft: £3,823 (SD: £1,500) The difference (synthetic mesh vs. standard repair): £429 (95% CI: £161; £697)  Mean QALYs per participant: Standard repair: 0.790 (SD 0.236) Synthetic mesh: 0.808 (SD 0.174)	From NHS perspective using complete case data at 1 year: Biological graft is dominated by synthetic mesh  ICER of synthetic mesh (vs. standard repair): £35,750/QALY  At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that: standard repair is cost effective is 0.70 and 0.57, respectively; synthetic mesh is cost effective is 0.29 and 0.40;	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
			<p>Biological graft: 0.781 (SD 0.231)</p> <p>The difference (synthetic mesh vs. standard repair): 0.012 (95% CI: -0.021; 0.044)</p>	<p>biological graft is cost effective is 0.02 and 0.04.</p>	
			<p>From NHS perspective using complete case data at 2 years:</p> <p>Mean cost per participant</p> <p>Standard repair: £3,664 (SD: £1,777)</p> <p>Synthetic mesh: £4,081 (SD: £1,762)</p> <p>Biological graft: £4,165 (SD: £1,691)</p> <p>The difference (synthetic mesh vs. standard repair): £337 (95% CI: -£73; £747)</p> <p>The difference (biological graft vs. standard repair): £555 (95% CI: £156; £954)</p> <p>Mean QALYs per participant:</p> <p>Standard repair: 1.569 (SD 0.502)</p> <p>Synthetic mesh: 1.643 (SD 0.304)</p> <p>Biological graft: 1.582 (SD 0.455)</p> <p>The difference (synthetic mesh vs. standard repair): 0.075 (95% CI: 0.000; 0.150)</p>	<p>From NHS perspective using complete case data at 2 years:</p> <p>Biological graft is dominated when compared with synthetic mesh</p> <p>ICER of synthetic mesh (vs. standard repair): £4,493/QALY</p> <p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that:</p> <p>standard repair is cost effective is 0.08 and 0.05, respectively;</p> <p>synthetic mesh is cost effective is 0.83 and 0.84;</p> <p>biological graft is cost effective is 0.10 and 0.12.</p> <p>Deterministic sensitivity analyses</p> <p>ICER of synthetic mesh (vs. standard repair) is:</p> <p>reduced to £4,351/QALY (from £4,493/QALY) when undiscounted costs and QALYs are used</p> <p>reduced to £4,451/QALY (from £4,493/QALY) when 6% discount</p>	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
				<p>rate for both costs and QALYs is used</p> <p>increased to £4,507/QALY (from £4,493/QALY) when gamma regression model for costs with a log link function is used</p> <p>increased to £8,944/QALY (from £4,493/QALY) when all primary trial women are used in the analysis<sup>a</sup></p>	
			<p>From NHS perspective using imputed data at 2 years:</p> <p>Mean cost per participant at 2 years (imputed data set):</p> <p>Standard repair: £3,570 (SD: £468)</p> <p>Synthetic mesh: £3,889 (SD: £468)</p> <p>Biological graft: £4,098 (SD: £468)</p> <p>The difference (synthetic mesh vs. standard repair): £319 (95% CI: - £56; £694)</p> <p>The difference (biological graft vs. standard repair): £527 (95% CI: £161; £893)</p> <p>Mean QALYs per participant at 2 years (imputed data set):</p>	<p>From NHS perspective using imputed data at 2 years:</p> <p>Standard repair is dominant when compared to both synthetic mesh and biological graft</p> <p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that:</p> <p>standard repair is cost effective is 0.57 and 0.52, respectively;</p> <p>synthetic mesh is cost effective is 0.28 and 0.29;</p> <p>biological graft is cost effective is 0.16 and 0.20.</p>	

<sup>a</sup> The trial was stratified into 3 sub-trials (RCT1A – women were randomised to standard repair, synthetic mesh, and biological graft; RCT1B – women were randomised to standard repair and synthetic mesh; RCT1C – women were randomised to standard repair and biological graft). The base-case health-economic analysis is presented for women who were randomised to the three-way comparison of standard repair, synthetic mesh and biological graft (i.e. all women randomised to RCT1A). Sensitivity analysis was conducted that included all women that were randomised to the primary repair that is RCT1A plus RCT1B and RCT1C.

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<b>Study Country Study type</b>	<b>Intervention details</b>	<b>Study population Study design Data sources</b>	<b>Costs: description and values Outcomes: description and values</b>	<b>Results: Cost-effectiveness</b>	<b>Comments</b>
			<p>Standard repair: 1.559 (SD: 0.297)</p> <p>Synthetic mesh: 1.555 (SD: 0.297)</p> <p>Biological graft: 1.554 (SD: 0.297)</p> <p>The difference (synthetic mesh vs. standard repair): -0.003 (95% CI: -0.068; 0.063)</p> <p>The difference (biological graft vs. standard repair): -0.004 (95% CI: -0.073; 0.065)</p>		
			<p>From NHS plus participant and indirect costs complete case data at 2 years:</p> <p>Mean cost per participant: Standard repair: £5,479 (SD: £6,026) Synthetic mesh: £5,740 (SD: £4,657) Biological graft: £5,813 (SD: £4,199)</p> <p>The difference (synthetic mesh vs. standard repair): -£26 (95% CI: -£1,302; £1,250)</p> <p>Mean QALYs per participant: Standard repair: 1.569 (SD: 0.502) Synthetic mesh: 1.643 (SD: 0.304) Biological graft: 1.582 (SD: 0.455)</p>	<p>From NHS plus participant and indirect costs complete case data at 2 years:</p> <p>Synthetic mesh is dominant when compared to standard repair and biological graft</p> <p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that: standard repair is cost effective is 0.07 and 0.04, respectively; synthetic mesh is cost effective is 0.82 and 0.84; biological graft is cost effective is 0.11 and 0.11.</p>	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
			<p>The difference (synthetic mesh vs. standard repair): 0.075 (95% CI: 0.000; 0.150)</p>		
			<p>Modelling results from NHS perspective at 5 years:</p> <p>Expected cost per participant:            Standard repair: £4,811            Synthetic mesh: £5,264            Biological graft: £5,304</p> <p>The difference (synthetic mesh vs. standard repair): £453</p> <p>The difference (biological graft vs. standard repair): £492</p> <p>Expected QALYs per participant:            Standard repair: 3.753            Synthetic mesh: 3.748            Biological graft: 3.749</p> <p>The difference (synthetic mesh vs. standard repair): -0.0047</p> <p>The difference (biological graft vs. standard repair): -0.0035</p>	<p>Modelling results from NHS perspective at 5 years:</p> <p>Standard repair is dominant when compared with synthetic mesh inlay and biological graft</p> <p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that:            standard repair is cost effective is 0.51 and 0.50, respectively;            synthetic mesh is cost effective is 0.23 and 0.23;            biological graft is cost effective is 0.27 and 0.27.</p> <p>Model results are robust to changes in:            the time horizon of the analysis (i.e. 10 and 30 years);            the use of 0% discount rate for costs and QALYs;            model start age;            changes in the utility values associated with failure;            the use of high/low estimates of mesh material costs.</p>	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
				<p>Secondary analysis When using treatment-specific utilities<sup>b</sup>: biological graft is dominated by synthetic mesh inlay; and the ICER of synthetic mesh inlay (vs. standard repair) was £5,933</p> <p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that: standard repair is cost effective is 0.26 and 0.23, respectively; the probability that synthetic mesh is cost effective is 0.53 and 0.57; and the probability that biological graft is cost effective is 0.22 and 0.21.</p>	
Glazener, C., Breeman, S., Elders, A., Hemming, C., Cooper, K., Freeman, R., Smith, A., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., Clinical	Interventions :  Standard repair, mesh inlay, mesh kits	Adult women requiring secondary anterior and/or posterior vaginal wall prolapse repair  Economic analysis alongside RCT and modelling (Markov model to explore)	Costs:  NHS perspective: intervention procedure (mesh, staff time in theatre, drugs in theatre, catheterisation, vaginal packing, theatre overheads), inpatient and follow-up secondary care costs (readmissions, reoperations, visits to ward, outpatient consultations) and costs to primary care services		<p>Perspective: NHS Currency: UK£ Cost year: 2013/14 prices Time horizon: 1 and 2 years Discounting: 3.5% for costs and outcomes</p>

<sup>b</sup> This analysis incorporates the coefficient of treatment effect on QALYs that are generated from GLM models, adjusting for health state in the trial-based analysis model. It essentially adds an additional utility to the synthetic mesh repair for all women in all of the health states, and is more directly comparable with the data seen in the complete case analysis of the trial. The treatment-specific additional utility gained from synthetic mesh across all of the health states.

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
effectiveness and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study-results from the PROSPECT Study, Health technology assessment (Winchester, England), 201, 2016 – secondary repair	UK  Cost-utility analysis  Conflict of interest: none. Funding: NIHR and HTA.	long-term costs and outcomes)  Source of clinical effectiveness data: RCT  year 1 standard repair N=44, mesh inlay N=42, biological graft N=38  year 2 standard repair N=165, synthetic mesh N=168; biological graft N=170)	(GP, nurse, physiotherapist), other treatments (shelf pessary, ring pessary, incontinence drugs, oestrogen, intermittent catheters, permanent catheters, absorbent pads, other drug treatments)  Participant and indirect costs: time off work, participant and companion time and travel costs for both outpatient and inpatient appointments, self-purchased health care and medication  Primary outcome measure: QALYs (EQ-5D-3L, UK general population norms)		Applicability: directly applicable Quality: minor limitations  Incremental analysis was adjusted for covariates (age group, type of prolapse, concomitant continence procedure and concomitant upper compartment prolapse surgery), as well as surgeon and baseline EQ-5D-3L scores.
			From NHS perspective using complete case data at 1 year:	From NHS perspective using complete case data at 1 year:	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
			<p>Mean cost per participant: Standard repair: £3,454 (SD: £1,639) Mesh inlay: £3,734 (SD: £1,808) Mesh kits: £4,165 (SD: £1,386) The difference (mesh inlay vs. standard repair): £471 (95% CI: - £404; £1,346)</p> <p>Mean QALYs per participant: Standard repair: 0.728 (SD 0.272) Synthetic mesh: 0.816 (SD 0.148) Biological graft: 0.764 (SD 0.191) The difference (mesh inlay vs. standard repair): 0.007 (95% CI: - 0.060; 0.074)</p>	<p>Mesh inlays dominant when compared with mesh kits</p> <p>ICER of mesh inlays (vs. standard repair): £67,286/QALY</p> <p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that: standard repair is cost effective is 0.64 and 0.55, respectively; mesh inlay is cost effective is 0.33 and 0.39; mesh kit is cost effective is 0.04 and 0.06.</p>	
			<p>From NHS perspective using complete case data at 1 year: Mean cost per participant: Standard repair: £3,454 (SD: £1,639) Mesh inlay: £3,734 (SD: £1,808) Mesh kits: £4,165 (SD: £1,386) The difference (mesh inlay vs. standard repair): £471 (95% CI: - £404; £1,346)</p> <p>Mean QALYs per participant: Standard repair: 0.728 (SD 0.272) Synthetic mesh: 0.816 (SD 0.148)</p>	<p>From NHS perspective using complete case data at 1 year: Mesh inlays dominant when compared with mesh kits</p> <p>ICER of mesh inlays (vs. standard repair): £67,286/QALY</p> <p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that: standard repair is cost effective is 0.64 and 0.55, respectively; mesh inlay is cost effective is 0.33 and 0.39;</p>	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
			Biological graft: 0.764 (SD 0.191) The difference (mesh inlay vs. standard repair): 0.007 (95% CI: –0.060; 0.074)	mesh kit is cost effective is 0.04 and 0.06.	
			From NHS perspective using complete case data at 2 years: Mean cost per participant: Standard repair: £3,883 (SD: £2,127) Mesh inlay: £4,133 (SD: £2,153) Mesh kit: £4,528 (SD: £1,721) The difference (mesh kit vs. standard repair): £642 (95% CI: -£309; £1,592)  Mean QALYs per participant: Standard repair: 1.486 (SD 0.493) Mesh inlay: 1.600 (SD 0.335) Mesh kit: 1.614 (SD 0.306) The difference (mesh kit vs. standard repair): 0.050 (95%: –0.085; 0.185)	From NHS perspective using complete case data at 2 years: Mesh inlay dominated by standard repair  ICER of mesh kits (vs. standard repair): £12,840/QALY  At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that: standard repair is cost effective is 0.36 and 0.32, respectively; mesh inlay is cost effective is 0.21 and 0.19; mesh kit is cost effective is 0.44 and 0.49.  Deterministic sensitivity analyses  ICER of mesh kits (vs. standard repair) was: reduced to £10,904/QALY (from £12,840/QALY) when using undiscounted costs and QALYs reduced to £6,768/QALY (from £12,840/QALY) when using 6%	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
				<p>discount rate for both costs and QALYs increased to £12,979/QALY (from £12,840/QALY) when using multiple imputation of missing costs and QALY data reduced to £12,260/QALY (from £12,840/QALY) when using gamma regression model for costs with a log link function</p> <p>In all of the above analyses mesh inlay remained dominated option</p> <p>When using data from three-way comparison (RCT2A) mesh kits are dominated by standard repair; and the ICER of mesh inlay (vs. standard repair) was £9,775 savings per QALY lostc</p>	
			<p>From NHS plus participant and indirect costs complete case data at 2 years:</p> <p>Mean cost per participant:</p> <p>Standard repair: £3,883 (SD: £2,127)</p> <p>Mesh inlay: £4,133 (SD: £2,153)</p> <p>Mesh kit: £4,528 (SD: £1,721)</p>	<p>From NHS plus participant and indirect costs complete case data at 2 years:</p> <p>Mesh inlay was dominated by standard repair</p> <p>ICER of mesh kit (vs. standard repair): £5,860/QALY</p>	

<sup>c</sup> The trial was stratified into 3 sub-trials (RCT2A – women were randomised to standard repair, mesh kits, and mesh inlays; RCT2B – women were randomised to mesh inlay and standard repair). The base-case health-economic analysis is presented for women who were randomised to both RCT2A and RCT2B. Sensitivity analysis was conducted that included only women that were randomised to the three way comparison that is RCT2A (standard repair, mesh inlay, and mesh kits).

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
			<p>The difference (mesh kit vs. standard repair): £293 (95% CI: -£1,839; £2,426)</p> <p>Mean QALYs per participant:</p> <ul style="list-style-type: none"> <li>Standard repair: 1.486 (SD: 0.493)</li> <li>Synthetic mesh: 1.600 (SD: 0.335)</li> <li>Biological graft: 1.614 (SD: 0.306)</li> </ul> <p>The difference (mesh kits vs. standard repair): 0.050 (95% CI: -0.085; 0.185)</p>	<p>At £20,000 and £30,000 threshold values of WTP for a QALY gain the probability that:</p> <ul style="list-style-type: none"> <li>standard repair is cost effective is 0.35 and 0.33, respectively;</li> <li>mesh inlay is cost effective is 0.11 and 0.11;</li> <li>mesh kit is cost effective is 0.54 and 0.56.</li> </ul>	
Jacklin, P. and Duckett, J., A decision-analytic Markov model to compare the cost–utility of anterior repair augmented with synthetic mesh compared with non-mesh repair in women with surgically treated prolapse, BJOG: An International Journal of Obstetrics & Gynaecology, 120, 217-223, 2013	Interventions: Mesh vs. no mesh	<p>Adult women with anterior pelvic organ prolapse</p> <p>Economic modelling (Markov model)</p> <p>Source of clinical effectiveness data: review of published literature and authors' assumptions</p> <p>Source of resource use data: NA</p>	<p>Costs:</p> <p>Mean cost per participant at 5 years:</p> <ul style="list-style-type: none"> <li>• Mesh: £4,146</li> <li>• No Mesh: £2,607</li> <li>• The difference: £1,539</li> </ul> <p>Primary outcome measure: QALYs</p> <p>Mean QALYs per participant:</p> <ul style="list-style-type: none"> <li>• Mesh: 0.27465</li> <li>• No mesh: 0.27455</li> </ul> <p>The difference: 0.0001</p>	<p>ICER of mesh (vs. no mesh): £15 million per QALY gained</p> <p>Sensitivity analyses:</p> <p>Time horizon 10 years and no recurrence in mesh group beyond 5 years 6% in the no mesh group by 10 years - the ICER of mesh (vs. no mesh): £13.4 million per QALY gained</p> <p>In a scenario analysis where all model inputs were set to favour mesh the ICER of mesh (vs. no mesh): £104,276 per QALY gained</p>	<p>Perspective: NHS</p> <p>Currency: UK£</p> <p>Cost year: 2008/09</p> <p>Time horizon: 5 years</p> <p>Discounting: 3.5% for both costs and outcomes</p> <p>Applicability: directly applicable</p> <p>Quality: minor limitations</p>

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
UK  Cost-utility analysis  Conflict of interest: none.  Funding: not reported.		Source of unit costs: NA  Cost data were obtained from published sources (NHS tariff) and manufacturers			
Murray, S., Haverkorn, R.M., Lotan, Y., Lemack, G. E., Mesh kits for anterior vaginal prolapse are not cost effective, International urogynecology journal, 22, 447-452, 2011  USA  Cost analysis  Conflict of interest: none. Funding: not reported.	Interventions:  Anterior colporrhaphy (AC), hand-cut mesh, and mesh kit	Adult women with anterior vaginal prolapse  Economic modelling  Source of resource use data: published sources, and authors' assumptions  Source of unit costs: national and local sources	Costs: costs associated with the initial procedure (surgeon, physician office visits, mesh, anterior repair kits, operating room time, recovery room costs, intravenous fluids, room and board), extrusion and recurrence costs.  Mean cost per participant: <ul style="list-style-type: none"> <li>• AC: \$3,461</li> <li>• Hand cut mesh: \$3,380</li> <li>• Mesh kit: \$4,678</li> <li>• The difference: \$81 (AC vs. hand cut mesh)</li> <li>• The difference: \$1,298 (mesh kit vs. AC)</li> </ul>	Hand cut mesh is cost saving  Sensitivity analysis: If the recurrence rate for AC is 28% (base case: 30%) it is cost-equivalent with non-kit mesh  Non-kit mesh supply cost must remain below \$480 (base case: \$400) for it to remain cost effective when compared with AC  Mesh kit repair does not reach cost-equivalence even at an operating time of 0 min (base case: 64 min)  If recurrence rate of traditional repair is below 20% (base case: 30%), AC is more cost effective even if extrusion rate for mesh repair is 0% (base case: 12%)	Perspective: health care payer  Currency: USD Cost year: likely 2010 Time horizon: 2 years Discounting: None Applicability: partially applicable Quality: potentially serious limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
				<p>When the recurrence rate for AC is at a base case rate of 30%, non-kit mesh repair is more cost effective if extrusion rate is less than 25% (base case: 12%).</p> <p>If recurrence rate is 50% for AC, then hand-cut mesh is more cost effective even with a 50% extrusion rate.</p>	

**Table 58: Economic evidence tables for apical pelvic organ prolapse**

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Judd, J. P., Siddiqui, N. Y., Barnett, J. C., Visco, A. G., Havrilesky, L. J., Wu, J. M., Cost-minimization analysis of robotic-assisted, laparoscopic, and abdominal sacrocolpopexy, Journal of minimally invasive	Interventions:  Robotic-assisted, laparoscopic, and abdominal sacrocolpopexy	Adult women with advanced apical pelvic organ prolapse  Modelling (Decision tree model)  Source of clinical effectiveness data: NA  Source of resource use data: published studies	Costs: anesthesia, physician, operating room, disposable equipment, postanesthesia care unit, and room and board for the duration of hospital stay, medication, and laboratory tests  Mean cost per participant (without robotic equipment acquisition costs): Abdominal: \$5,792 Robotic: \$8,508 Laparoscopic: \$7,353 Difference (robotic vs. abdominal): \$2,716 Difference (laparoscopic vs. abdominal): \$1,561 Difference (robotic vs. laparoscopic): \$1,155	Abdominal sacrocolpopexy is the least costly option  Sensitivity analysis: Without surgical equipment acquisition costs  The cost equivalence between the robotic and laparoscopic approaches achieved when mean operative time was 149 minutes (base case: 328 minutes) for robotic	Perspective: health care payer  Currency: USD Cost year: 2008  Time horizon: likely immediate postoperative period  Discounting: NA  Applicability: partially applicable  Quality: minor limitations

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<b>Study Country Study type</b>	<b>Intervention details</b>	<b>Study population Study design Data sources</b>	<b>Costs: description and values Outcomes: description and values</b>	<b>Results: Cost-effectiveness</b>	<b>Comments</b>
gynecology, 17, 493-499, 2010 USA  Cost-minimisation analysis  Conflict of interest: one of the authors has involvement with the manufacturer Funding: not reported		Source of unit costs: unclear (seems to be local and national sources)	Mean cost per participant (including robotic equipment acquisition costs): Abdominal: \$5,792 Robotic: \$9,962 Laparoscopic: \$7,353 Difference (robotic vs. abdominal): \$4,170 Difference (laparoscopic vs. abdominal): \$1,561 Difference (robotic vs. laparoscopic): \$2,609	and it remained at the base case for laparoscopic (269 minutes). Robotic procedure was less costly (versus laparoscopic) when robotic disposable costs were <\$2,132 (base-case: \$3,293) and laparoscopic disposable costs >\$3,413 (base-case: \$2,244). Varying other model inputs including the length of stay, the risk of switching, the risk of transfusion, anaesthesia costs, surgeon fees, post-anaesthesia costs, hospital room and board costs, medication costs, and laboratory costs failed to make the robotic approach less costly (versus laparoscopic approach).  In all sensitivity analysis laparoscopic approach remained more expensive when	

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<b>Study Country Study type</b>	<b>Intervention details</b>	<b>Study population Study design Data sources</b>	<b>Costs: description and values Outcomes: description and values</b>	<b>Results: Cost-effectiveness</b>	<b>Comments</b>
				<p>compared with the abdominal approach. The laparoscopic approach was less expensive only when (1) the mean length of stay for the abdominal approach &gt; 5.6 days (base case: 2.7 days) and laparoscopic approach remained at 1.8 days, (2) when the surgeon costs for the abdominal approach &gt;\$2,213 (base case: \$638), (3) and when disposable equipment costs for the laparoscopic procedure &lt;\$668 (base case: \$1,677 and \$2,244 for early and late switching). In all other scenarios the abdominal approach remained the least costly option.</p> <p>With surgical equipment acquisition costs</p> <p>Varying the number of procedures per month from 60 to 20 the robotic-assisted costs</p>	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
				increased by \$581-\$1,724 per procedure (base case cost: \$8,508). In no scenario the robotic approach was less costly when compared with the laparoscopic approach.	
Anger, J. T., Mueller, E. R., Tarnay, C., Smith, B., Stroupe, K., Rosenman, A., Brubaker, L., Bresee, C., Kenton, K., Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial, <i>Obstetrics and gynecology</i> , 123, 5-12, 2014	Interventions: Laparoscopic vs. robot-assisted sacrocolpopexy	Adult women with symptomatic stage POP II or greater, including significant apical support loss  RCT (Anger 2014)  Source of clinical effectiveness data: RCT (N=78)	Costs: hospital and physician services, costs of the robot and its maintenance, disposable instruments  Mean cost per participant: Laparoscopic: \$12,170 (SD: \$4,129) Robotic: \$20,898 (SD: \$3,386) Difference: \$8,728 ( $p < 0.001$ )  Primary measure of outcome: QALYs (EQ-5D-3L, USA general population norms)  Mean QALYs per participant: Laparoscopic: 0.101 (SD: 0.009) Robotic: 0.098 (SD: 0.011) Difference: -0.003 ( $p = 0.234$ )	Laparoscopic sacrocolpopexy is dominant  Sensitivity analysis: When the robot purchase and maintenance costs are excluded there is no difference in costs.  Sub-group analyses: Results remain unchanged when population is stratified by concomitant procedure status (that is, the costs remain higher in the robotic group).	Perspective: health care payer Currency: USD Cost year: likely 2013 Time horizon: 6 weeks Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Conflict of interest: none. Funding: the National Institute of Biomedical Imaging and Bioengineering Recovery Act Limited Competition Challenge Grant.					
Paraiso, M. F., Jelovsek, J. E., Frick, A., Chen, C. C., Barber, M. D., Laparoscopic compared with robotic sacrocolpopexy for vaginal prolapse: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 118, 1005-1013, 2011	Interventions: Laparoscopic versus robotic-sacrocolpopexy	Adult women with stage 2–4 post-hysterectomy vaginal apex prolapse  RCT (Paraiso 2011) that found no difference in effectiveness between the two interventions in terms of complications, anatomic outcome, and QoL	Costs: surgery, and surgery-related inpatient and outpatient care  Mean cost per participant: Robotic sacrocolpopexy: \$16,278 (SD: \$3,326) Laparoscopic sacrocolpopexy: \$14,342 (SD: \$2,941) The difference: \$1,936 (95% CI: \$417 to \$3,454); p=0.008	Laparoscopic sacrocolpopexy is cost saving  Sensitivity analyses: none	Perspective: health care payer Currency: USD Cost year: 2011  Time horizon: costs 6 weeks post-surgery Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

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<b>Study Country Study type</b>	<b>Intervention details</b>	<b>Study population Study design Data sources</b>	<b>Costs: description and values Outcomes: description and values</b>	<b>Results: Cost-effectiveness</b>	<b>Comments</b>
Cost-minimisation analysis  Conflict of interest: none Funding: not reported.		Source of resource use data: RCT (N=68)  Source of unit costs: unclear			
Elliott, C. S., Hsieh, M. H., Sokol, E. R., Comiter, C. V., Payne, C. K., Chen, B., Robot-assisted versus open sacrocolpopexy: a cost-minimization analysis, The Journal of urology, 187, 638-643, 2012  USA  Cost minimisation analysis	Interventions:  Abdominal open vs. robot-assisted sacrocolpopexy	Adult women with symptomatic stage POP II or greater, including significant apical support loss  Observational cohort study (N=59 procedures)  Source of resource use data: cohort study participants  Source of unit costs: local and national sources (published data, local county costs, and other local hospital data)	Costs: operating room costs, anaesthesia, robot system costs and disposable instruments, hospital stay, surgeon, and mesh  Mean cost per participant: Robotic: \$10,178 Open surgery: \$11,307 Difference: -\$1,129	Robot-assisted sacrocolpopexy is cost saving  Sensitivity analysis: The results are sensitive to robot cases per year, cost per day of hospital stay, length of hospital stay, operating room time and disposable costs	Perspective: health care payer Currency: USD Cost year: 2008 Time horizon: 30 days Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Conflict of interest: none. Funding: not reported.					
Hoyte, L., Rabbanifard, R., Mezzich, J., Bassaly, R., Downes, K., Cost analysis of open versus robotic-assisted sacrocolpopexy, Female pelvic medicine & reconstructive surgery, 18, 335-339, 2012  USA  Cost analysis  Conflict of interest: none reported. However, the main author is a paid surgical doctor for a manufacturer of da Vinci	Interventions: Robotic vs. open sacrocolpopexy	Adult women with a median preoperative prolapse stage III. Type of prolapse not specified.  Observational cohort study (N=164)  Source of resource use data: retrospective cohort study and associated administrative hospital databases  Source of unit costs: unclear, but likely local hospital sources	Costs: operating room, surgical supply (including mesh), supply distribution, pharmacy, anaesthesia, laboratory, radiology, hospital stay, robot and maintenance costs  Mean cost per participant (all participants): Robotic: \$9,725 Open: \$12,485 Difference: -\$2,760 (p < 0.001)  Mean cost per participant (excluding 2 outliers in the open surgery group): Robotic: \$9,725 Open: \$11,214 Difference: -\$1,489 (p = 0.001)	Robotic sacrocolpopexy is cost saving  Sensitivity analysis: Changing the assumptions pertaining to the residual value of robot (residual value changed from \$500,000 to \$0) and increasing the daily case count from 2 to 3 robotic approach results in the range of 10-15% of the cost savings	Perspective: health care payer Currency: USD Cost year: likely 2011 Time horizon: unclear but seems to be immediate postoperative period Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

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<b>Study Country Study type</b>	<b>Intervention details</b>	<b>Study population Study design Data sources</b>	<b>Costs: description and values Outcomes: description and values</b>	<b>Results: Cost-effectiveness</b>	<b>Comments</b>
Surgical System.  Funding: not reported.					
Lua, L. L., Vicente, E. D., Pathak, P., Lybbert, D., Dandolu, V., Comparative analysis of overall cost and rate of healthcare utilization among apical prolapse procedures, International Urogynecology Journal, 31, 1-8, 2017  USA  Cost analysis  Conflict of interest: none. Funding: not reported.	Interventions: sacrospinous ligament fixation (SSF), abdominal sacrocolpopexy (ASC), laparoscopic sacrocolpopexy (LSC)	Adult women with apical prolapse  Source of resource use data: retrospective observational cohort study, Commercial Claims and Encounter database (SSF [n=17,549]; ASC [n= 6,126]; LSC [n = 10,708])  Source of unit costs: unclear but seems to be national sources (national claims database)	Costs: intervention costs, inpatient readmissions, emergency room visits, outpatient visits  Mean cost per participant: SSF: \$13,916 ASC: \$15,716 LSC: \$16,838  The difference (ASC vs. SSF): \$1,800.69, (95% CI: \$1,476.50; \$2,124.88); p< 0.0001 The difference (LSC vs. SSF): \$2,922.03; (95% CI: \$2,648.56; \$3,195.50); p < 0.0001 The difference (LSC vs. ASC): \$1,122 (p-value not reported)	SSF is cost saving when compared with ASC and LSC  Sensitivity analyses: None conducted	Perspective: health care payer Currency: USD Cost year: likely 2016 Time horizon: 90 days Discounting: NA Applicability: partially applicable Quality: minor limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
<p>Ohno, M. S., Richardson, M. L., Sokol, E. R., Abdominal sacral colpopexy versus sacrospinous ligament fixation: a cost-effectiveness analysis, International urogynecology journal, 27, 233-237, 2016</p> <p>USA</p> <p>Cost-effectiveness analysis</p> <p>Conflict of interest: one author received research grants from various manufacturers, he is principal investigator with one manufacturer</p>	<p>Interventions: Abdominal sacral colpopexy (ASC) versus sacrospinous ligament fixation (SSLF)</p>	<p>Adult women with apical prolapse</p> <p>Economic modelling (decision tree model)</p> <p>Source of clinical effectiveness data: systematic review and published literature</p> <p>Source of resource use data: Medicare reimbursement data; published literature</p> <p>Source of unit costs: national sources (Medicare reimbursement data); unclear for other published cost estimates.</p>	<p>Costs: intervention costs including ASC, SSLF, mid-urethral sling (in outpatient setting); hospital stay, mesh</p> <p>Mean cost per participant: ASC: \$13,988 SSLF: \$11,950 The difference: \$2,038</p> <p>Primary outcome measure: QALYs (utility weights generated by a focus group)</p> <p>Mean QALYs per participant: ASC: 1.53 SSLF: 1.45 The difference: 0.08</p>	<p>ICER of ASC (versus SSLF): \$24,574/QALY</p> <p>Sensitivity analyses: The one-way sensitivity analysis of costs shows that ASC is no longer cost-effective if the cost of ASC is greater than \$15,620 (base case: \$13,460) or if the cost of SSLF is less than \$8,539 (base case: \$10,653).</p> <p>Results are also sensitive to the postoperative rates of SUI, MUS placement in the event of SUI, recurrent prolapse, and post-operative dyspareunia rates.</p> <p>ASC remains cost effective as long as post-operative rate of SUI is &lt;36% (base case: 30%) or if the rate of MUS placement for SUI is &lt;60% (base case 36%).</p>	<p>Perspective: health care payer</p> <p>Currency: USD</p> <p>Cost year: 2013</p> <p>Time horizon: 2 years (however only immediate costs were considered)</p> <p>Discounting: 3% QALYs</p> <p>Applicability: partially applicable</p> <p>Quality: potentially serious limitations</p>

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Study Country <b>Study type</b>	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
and received consulting fees. Funding: not reported.				<p>ASC remains cost effective if:</p> <p>rate of recurrent prolapse is &lt;5% (base case: 3.6%); or</p> <p>rate of post-operative dyspareunia is &lt;59% (base case: 16%).</p> <p>SSLF becomes cost-effective if:</p> <p>post-operative rate of SUI after SSLF is &lt;28% (base case: 35%);</p> <p>MUS placement after SUI is &lt;13% (base case: 60%);</p> <p>rate of recurrent prolapse is &lt;4% (base case: 15%);</p> <p>rate of post-operative dyspareunia is &lt;19% (base case: 36%).</p> <p>ASC remains cost-effective over reasonable ranges for the cost of MUS, the rate of re-operation for recurrent prolapse,</p>	

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
				and all of the utilities included in the model (recurrent prolapse, dyspareunia, and SUI).	
Carracedo, D., López-Fando, L., Sánchez, M. D., Jiménez, M. Á., Gómez, J. M., Laso, I., Rodríguez, M.Á., Burgos, F. J., Cost analysis of surgical treatment for pelvic organ prolapse by laparoscopic sacrocolpopexy or transvaginal mesh, Actas Urológicas Españolas (English Edition), 41, 117-122, 2017	Interventions: Laparoscopic sacrocolpopexy versus transvaginal mesh	Adult women with pelvic organ prolapse  Source of resource use data: retrospective cohort study (N=138 procedures) and associated administrative hospital databases  Source of unit costs: unclear but seems to be local hospital sources	Costs: personnel, pharmaceutical products, prosthesis and implants, functioning, operating room, anaesthesia and resuscitation, hospital meals, intermediate services, structure, TVT, TOT  Mean cost per participant: LS: €5,985.7 (95% CI: €5,613.1; €6,358.3) TVM: €6,534.3 (95% CI: €6,290.4; €6778.3) The difference: -€548.6, p = ns	LS is cost saving when compared with TVM  Sensitivity analyses: none undertaken	Perspective: health care payer Currency: Euros Cost year: likely 2016 Time horizon: unclear but likely immediate postoperative period Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Conflict of interest: none. Funding: not reported.					
Culligan, P. J., Salamon, C., Lewis, C., Abell, T. D., Cost-effectiveness analysis comparing robotic sacrocolpopexy to a vaginal mesh hysteropexy for treatment of uterovaginal prolapse, Open Journal of Obstetrics and Gynecology, 3, 613-629, 2013  USA  Cost-effectiveness analysis  Conflict of interest: two authors are	Interventions: Robotic sacrocolpopexy versus a vaginal mesh hysteropexy	Adult women with uterovaginal prolapse  Economic modelling (a decision tree model)  Source of clinical effectiveness data: published literature where possible systematic reviews; expert opinion  Source of resource use data: retrospective cohort study (N=16) and associated administrative hospital databases  Source of unit costs: local sources	Costs: surgical procedures including equipment and materials used during the surgery; payments to the surgeons and anaesthesiologists; and salary costs of the operating room personnel  Mean cost per participant: Robotic sacrocolpopexy: \$21,853 Vaginal mesh hysteropexy: \$14,890 The difference: \$6,963  Primary outcome measure: QALYs (utility weights derived from a panel of health care providers and lay-women)  Mean QALYs per participant: Robotic sacrocolpopexy: 0.9645 Vaginal mesh hysteropexy: 0.9309 The difference: 0.0366	ICER of robotic sacrocolpopexy (vs. vaginal mesh hysteropexy): \$207,232/QALY  Sensitivity analyses: The results are robust to changes in: estimates of surgical mortality, probabilities of complications (bleeding, cystotomy, surgical site infection, mesh exposure, de novo lower urinary tract symptoms, de novo chronic pain); probability of reoperation; utility weights; surgical costs; simultaneous changes in the probabilities of complications and surgical costs.	Perspective: health care payer Currency: USD Cost year: 2009 Time horizon: 12 months Discounting: NA Applicability: partially applicable Quality: minor limitations

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Study Country <b>Study type</b>	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
consultants and instructors for manufacturer. Funding: an unrestricted educational grant from Boston Scientific (manufacturer).					
Ehlert, M. J., Gupta, P., Park, J., Sirls, L. T., Detailed cost analysis of robotic sacrocolpopexy compared to transvaginal mesh repair, Urology, 97, 86-91, 2016  USA  Cost analysis  Conflict of interest: none. Funding: not reported.	Interventions: Robotic sacrocolpopexy vs. total transvaginal mesh (TVM)	Adult women with apical prolapse  Source of resource use data: observational cohort study (N=226)  Source of unit costs: unclear	Costs: hospital costs including recovery room costs, operating room, anesthesia, inpatient room and board, laboratory, surgical supplies and mesh.  Mean cost per participant with concomitant hysterectomy: Robotic sacrocolpopexy: \$12,483 TVM: \$9,820 (SE: \$358) Difference: \$2,663 (p < 0.001)  Mean cost per participant without concomitant hysterectomy: Robotic sacrocolpopexy: \$9,676 TVM: \$6,719 Difference: \$2,957 (p < 0.001)	Robotic sacrocolpopexy is cost saving when compared with TVM	Perspective: health care payer Currency: USD Cost year: 2015 Time horizon: not reported but seems to be immediate post-operative Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
<p>Maher, C. F., Connelly, L. B., Cost minimization analysis of laparoscopic sacral colpopexy and total vaginal mesh, American journal of obstetrics and gynecology, 206, 433-e1, 2012</p> <p>AUS</p> <p>Cost-minimisation analysis</p> <p>Conflict of interest: none. Funding: not reported.</p>	<p>Interventions:</p> <p>Laparoscopic sacral colpopexy (LSC) vs. total vaginal mesh (TVM)</p>	<p>Adult women with prolapse of the vaginal wall</p> <p>RCT (Maher 2012)</p> <p>Source of clinical effectiveness data: RCT (N=108)</p> <p>Source of resource use data: RCT (N=108)</p> <p>Source of unit costs: local hospital sources</p>	<p>Costs: operating room, labour costs (anaesthetist, surgeon, assistant, theatre nursing labour), inpatient costs, consumable costs (total vaginal mesh, sub urethral obturator tape, trocars, hernia tracker), and insurer expenditures, reoperation costs, and productivity losses</p> <p>Mean cost per participant: LSC: \$14,296 (SE \$279) TVM: \$18,289 (SE: \$358) Difference: -\$4,013 (p &lt; 0.001)</p> <p>Primary measure of outcome: objective success (POP-Q stage 0 or 1 prolapse at all vaginal sites), patient satisfaction on a scale (0-100), Australian Pelvic Floor Questionnaire (APFQ), pelvic organ prolapse quality of life (P-QoL)</p> <p>Objective success: LSC: 0.77 TVM: 0.43 Difference: 0.34; p &lt; 0.001</p> <p>Mean patient satisfaction: LSC: 87 (SD: 21) TVM: 79 (SD: 20) Difference: 8.09; p &lt; 0.002</p>	<p>LSC is dominant using objective success and mean patient satisfaction scores.</p> <p>LSC is dominant using APFQ as an outcome measure. However, it is based on non-significant differences.</p> <p>It is unclear which intervention is preferred when using P-QoL as an outcome measure since it does not provide a summary score.</p> <p>Sensitivity analysis: The cost equivalence is achieved when the following threshold values are reached for cost variables: consumable cost is reduced to \$0 in the TVM and increased by \$900 in the LSC group; operating time in the LSC is 130 min longer;</p>	<p>Perspective: societal perspective</p> <p>Currency: USD</p> <p>Cost year: 2008</p> <p>Time horizon: 2 years</p> <p>Discounting: None</p> <p>Applicability: partially applicable</p> <p>Quality: potentially serious limitations</p>

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
			<p>Mean APFQ scores (decrease from pre to post): LSC: 59% TVM: 53% Difference: 6%; p = ns</p> <p>Mean P-QoL scores: no summary scores, however there was no significant difference in the pre- and postoperative quality of life changes between the groups.</p>	<p>operating room labour cost increases from \$47 to \$128 per min; hospital stay is reduced to 0 in TVM group and increased from 2.93 to 4.8 days in the LSC arm; recovery time is reduced from the mean 24 days to 8 days in the TVM group or having no reoperations in the TVM group.</p>	
Husby, K. R., Tolstrup, C. K., Lose, G., Klarskov, N., Manchester–Fothergill procedure versus vaginal hysterectomy with uterosacral ligament suspension: an activity-based costing analysis, International urogynecology	<p>Interventions:</p> <p>Manchester–Fothergill procedure vs. uterosacral ligament suspension (with vaginal hysterectomy)</p>	<p>Adult women with apical prolapse</p> <p>Source of resource use data: retrospective cohort study (N=590)</p> <p>Source of unit costs: local hospital sources and expert opinion</p>	<p>Costs: primary operation (surgeon, surgical nurses, anesthetic nurse, post-anesthesia care nurse, operating theatre, overnight hospital stays, utensils, pathological evaluations, contacts, CT urography related to primary operation), complication management (postoperative bleeding, unacknowledged obstruction of ureter, and urinary retention), recurrences, uterus-dependant issues (pathological tests, contacts and procedures)</p> <p>Mean cost per participant (only primary operation costs): Uterosacral ligament suspension: €3,514 Manchester–Fothergill: €2,318 Difference: €898, 95% CI: €818; €982</p>	<p>Manchester–Fothergill procedure was cost saving when compared with uterosacral ligament suspension (with vaginal hysterectomy)</p> <p>Sensitivity analyses: The findings robust to changes in the costs associated with hospital stay, operating theater costs, and the percent of a health care professional's working</p>	<p>Perspective: health care payer</p> <p>Currency: Euro</p> <p>Cost year: likely 2017</p> <p>Time horizon: 20 months</p> <p>Discounting: NA</p> <p>Applicability: partially applicable</p> <p>Quality: minor limitations</p>

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
journal, 1-1, 2018  Denmark  Cost analysis  Conflict of interest: authors received various fees and travel grants for conference participation, and received consultation and personal fees  Funding: By the Program fro Clinical Research Infrastructure established by Lundbeck Foundation and Novo Nordisk Foundation.			Difference when considering health care costs over 20 months: €1,196, 95% CI: €927; €1,465; p < 0.0001	time involved in direct patient contact. Excluding patients costing more than 300% of the median costs, including the costs of sampling the pathological specimen irrespective of whether performed in the primary sector or at private gynecologists, or excluding women with missing information about duration of surgery and/or anesthesia and/or post-anesthesia care did not change the conclusions. In all of the above scenarios the cost difference between Manchester-Fothergill procedure and uterosacral ligament suspension (with vaginal hysterectomy) remained statistically significant.	

**Economic evidence tables for review question: What is the role for surgery for preventing postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Table 59: Economic evidence table**

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Richardson, M. L., Elliott, C. S., Shaw, J. G., Comiter, C. V., Chen, B., Sokol, E. R., To sling or not to sling at time of abdominal sacrocolpopexy: a cost-effectiveness analysis, <i>The Journal of Urology</i> , 190, 1306-1312, 2013  USA  Cost-utility analysis  Conflict of interest: not reported.	Interventions: Abdominal sacrocolpopexy (ASC) alone with deferred option for mid urethral sling (MUS), ASC with universal concomitant MUS, preoperative urodynamic study (UDS) for selective MUS.	Adult women with pelvic organ prolapse  Economic modelling (decision tree model)  Source of clinical effectiveness data: published studies mainly RCT (CARE trial, Brubaker 2008)  Source of resource use data: Medicare reimbursement data  Source of unit costs: national sources	Costs: inpatient surgical procedures, physician costs, UDS, outpatient care, complication management, medication  Mean costs per participant were not reported.  Primary outcome measure: QALYs (Health Utilities Index-Mark III [HUI-Mark III], Canadian general population norms)  Mean QALYs per participant were not reported.	UDS for selective MUS at the time of ASC is dominated by ASC with universal MUS  The ICER of ASC plus MUS vs. ASC alone (MUS as needed): \$2,867/QALY  Sensitivity analyses:  ICER of ASC plus MUS never exceeds \$20,000/QALY  The results robust to ±50% in cost estimates. Even if the cost of concomitant MUS is reduced to as little as \$1,000 (vs. \$13,090) the ICER of ASC plus MUS is \$20,761/QALY.	Perspective: health care payer  Currency: USD  Cost year: 2010  Time horizon: 1 year  Discounting: NA  Applicability: partially applicable  Quality: potentially serious limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Funding: not reported.				<p>If outpatient MUS was \$2,100 (vs. \$4,340), the ICER of ASC plus MUS is \$8,929/QALY.</p> <p>ASC alone is the least expensive option as long as 45% or more of women chose to pursue further SUI therapy following postoperative SUI (base-case 36%).</p> <p>The cost of UDS and anticholinergic medication has little impact on the overall cost effectiveness of the 3 strategies.</p> <p>UDS for selective MUS is dominated regardless of the postoperative urinary retention rate, rates of risk of mesh exposure removal.</p>	

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<b>Study Country Study type</b>	<b>Intervention details</b>	<b>Study population Study design Data sources</b>	<b>Costs: description and values Outcomes: description and values</b>	<b>Results: Cost-effectiveness</b>	<b>Comments</b>
				The conclusions are robust to changes in the utility values.	

**Economic evidence tables for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Table 60: Economic evidence table**

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
Hullfish, K. L., Trowbridge, E. R., Stukenborg, G. J., Treatment strategies for pelvic organ prolapse: a cost-effectiveness analysis. International urogynecology journal, 22, 507-515, 2011  USA  Cost-utility analysis  Conflict of interest: none. Funding: not reported.	Interventions:  Expectant management followed by vaginal reconstructive surgery (VRS), VRS, traditional open abdominal sacrocolpopexy (ASC), robotic assisted ASC, expectant management followed by laparoscopic traditional open ASC, expectant management followed by robotic-assisted ASC	Adult women with post-hysterectomy pelvic organ prolapse (POP) ( $\geq$ stage III apical prolapse of the vagina).  Economic modelling: Markov model  Source of clinical effectiveness data: published studies, expert opinion  Source of resource use data: national hospital discharge data, expert opinion  Source of unit costs: national sources	Costs: pessary use (charges for pessary, professional fees, outpatient visit, surgery costs, complication management; inpatient and outpatient care)  Mean cost per participant:  Pessary: \$10,287  Expectant management (followed by VRS): \$11,686  Expectant management followed by laparoscopic ASC: \$13,191  Expectant management followed by robotic-assisted ASC: \$14,366  VRS: \$15,040  Laparoscopic traditional/open ASC: \$16,993  Robotic assisted laparoscopic ASC: \$18,472	The ICER of VRS versus pessary: \$59,607/QALY  Expectant management followed by laparoscopic ASC and expectant management followed by robotic assisted ASC dominated by both pessary and expectant management followed by VRS  Laparoscopic traditional open ASC and robotic assisted laparoscopic ASC dominated by VRS  Expectant management followed by VRS is extendedly dominated by both pessary and VRS  The probabilistic sensitivity analysis demonstrated that pessary use is the optimal strategy below the \$5,600 (£4,480) willingness to pay threshold	Perspective: health care payer  Currency: USD  Cost year: likely 2010  Time horizon: 12 months  Discounting: NA  Applicability: partially applicable  Quality: minor limitations

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Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
			<p>Primary measure of outcome: QALYs (utility weights based on expert opinion)</p> <p>Mean QALYs per participant:</p> <p>Pessary: 0.867</p> <p>Expectant management (followed by VRS): 0.886</p> <p>Expectant management followed by laparoscopic ASC: 0.864</p> <p>Expectant management followed by robotic-assisted ASC: 0.864</p> <p>VRS: 0.947</p> <p>Laparoscopic traditional/open ASC: 0.907</p> <p>Robotic assisted laparoscopic ASC: 0.906</p>	<p>and that the VRS strategy is the optimal strategy above this threshold.</p> <p>Deterministic sensitivity analyses indicated that the model results were sensitive to the:</p> <ul style="list-style-type: none"> <li>probability of POP complication</li> <li>probability of surgery following pessary</li> <li>utility of pessary use</li> <li>probability of late complications for VRS</li> <li>cost estimate for robotic-assisted ASC as a proportion of the total hospitalisation charge for traditional ASC</li> </ul>	

## Appendix I – Economic evidence profiles

**Economic evidence profiles for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

**Table 61: Economic evidence profile, anterior and/or posterior prolapse: synthetic partially absorbable mesh, synthetic non-absorbable mesh, biological mesh, and anterior colporrhaphy**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Guideline economic analysis  UK	Minor limitations <sup>1</sup>	Directly applicable <sup>2</sup>	Cost-utility analysis  Time horizon: 15 years  Primary measure of outcome: QALYs	vs. anterior colporrhaphy with no mesh: £488.45 biological mesh £335.71 synthetic partially absorbable mesh £381.60 synthetic non-absorbable mesh	vs. anterior colporrhaphy with no mesh: -0.037 biological mesh -0.140 synthetic partially absorbable mesh -0.140 synthetic non-absorbable mesh	Anterior colporrhaphy with no mesh dominant	The findings were robust to changes in model inputs including effectiveness, the risk of mesh extrusion and pain complications, cost data, and utility values. The probability of anterior colporrhaphy with no mesh being cost effective was 0.69 at NICE lower cost effectiveness threshold of £20,000/QALY. The probability of other treatments being cost effective was <10%.

1. Some model inputs based on the committee expert opinion including resource use; mesh complication data based on a single study each with a short term follow-up

2. UK study, QALYs with EQ-5D weights, population norms

**Table 62: Economic evidence profile, anterior and/or posterior prolapse: synthetic mesh, biological mesh, and standard repair**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Glazener 2016 – primary repair	Minor limitations <sup>1</sup>	Directly applicable <sup>2</sup>	Cost-utility analysis	At 1 year, CCA, NHS perspective:			

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<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
UK			Time horizon: up to 5 years  Primary measure of outcome: QALYs	£429 (synthetic mesh vs. standard repair) £125 (biological mesh vs. synthetic mesh)	0.012 (synthetic mesh vs. standard repair) -0.027 (biological mesh vs. synthetic mesh)	Biological mesh dominated £35,750 (synthetic mesh vs. standard repair)	The probability cost effective at a WTP of £20,000 and £30,000 per QALY: 0.70-0.57 standard repair; 0.29-0.40 synthetic mesh; 0.02-0.04 biological graft
				At 2 years, CCA, NHS perspective: £337 (synthetic mesh vs. standard repair) £555 (biological mesh vs. synthetic mesh)	At 2 years, CCA, NHS perspective: 0.075 (synthetic mesh vs. standard repair) -0.061 (biological mesh vs. synthetic mesh)	At 2 years, CCA, NHS perspective: Biological mesh dominated £4,493 (synthetic mesh vs. standard repair)	At 2 years, CCA, NHS perspective: The probability cost effective at a WTP of £20,000 and £30,000 per QALY: 0.08-0.05 standard repair; 0.83-0.84 synthetic mesh; 0.10-0.12 biological graft  The findings were robust to changes in discount rate for cost and QALYs, modelling assumptions pertaining to costs, inclusion of women randomised to two way comparisons

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<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
				At 2 years, imputed data, NHS perspective: £319 (synthetic mesh vs. standard repair) £527 (biological mesh vs. synthetic mesh)	At 2 years, imputed data, NHS perspective: -0.003 (synthetic mesh vs. standard repair) -0.004 (biological mesh vs. synthetic mesh)	At 2 years, imputed data, NHS perspective: Standard repair is dominant	At 2 years, imputed data, NHS perspective The probability cost effective at a WTP of £20,000 and £30,000 per QALY: 0.57-0.52 standard repair; 0.28-0.29 synthetic mesh; 0.16-0.20 biological graft
				At 2 years, CCA, NHS perspective plus participant and indirect costs: -£26 (synthetic mesh vs. standard repair)	At 2 years, CCA, NHS perspective plus participant and indirect costs: 0.075 (synthetic mesh vs. standard repair)	At 2 years, CCA, NHS perspective plus participant and indirect costs: Synthetic mesh is dominant when compared with both standard care and biological mesh	The probability cost effective at a WTP of £20,000 and £30,000 per QALY: 0.07-0.04 standard repair; 0.82-0.84 synthetic mesh; 0.11-0.11 biological graft
				NHS perspective, 5 years £453 (synthetic mesh vs. standard repair) £492 (biological graft vs. standard repair)	NHS perspective, 5 years -0.0047 (synthetic mesh vs. standard repair) -0.0035 (biological graft vs. standard repair)	NHS perspective, 5 years Standard repair is dominant	NHS perspective, 5 years The probability cost effective at a WTP of £20,000 and £30,000 per QALY: 0.51-0.50 standard repair; 0.23-0.23

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<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
							synthetic mesh; 0.27-0.27 biological graft Model results robust to changes in the time horizon, discount rate, utility values, mesh material costs, When using treatment specific utilities synthetic mesh was cost effective (ICER of £5,933/QALY when compared with standard repair.
Glazener 2016 – secondary repair  UK	Minor limitations <sup>1</sup>	Directly applicable <sup>2</sup>	Cost-utility analysis  Time horizon: up to 2 years  Primary measure of outcome: QALYs	NHS perspective, CCA, 1 year £471 (mesh inlay vs. standard repair)	NHS perspective, CCA, 1 year 0.007 (mesh inlay vs. standard repair)	NHS perspective, CCA, 1 year Mesh inlay dominant when compared with mesh kits £67,286 (mesh inlay vs. standard care)	NHS perspective, CCA, 1 year The probability cost effective at a WTP of £20,000 and £30,000 per QALY: 0.64-0.55 standard repair; 0.33-0.39 synthetic mesh; 0.04-0.06 biological graft

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<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
				NHS perspective, CCA, 2 years £642 (mesh inlay vs. standard repair)	NHS perspective, CCA, 2 years 0.050 (mesh inlay vs. standard repair)	NHS perspective, CCA, 2 years  Mesh inlays dominated by standard repair  £12,480 (mesh kits vs. standard repair)	NHS perspective, CCA, 2 years  The probability cost effective at a WTP of £20,000 and £30,000 per QALY: 0.36-0.32 standard repair; 0.21-0.19 synthetic mesh; 0.44-0.49 biological graft  The findings were robust to discount rate, using imputed data, modelling assumptions pertaining to costs  When using data from a three-way comparisons standard repair was the preferred treatment option.
				NHS plus participant and indirect costs, CCA, 2 years £293 (mesh kits vs. standard repair)	NHS plus participant and indirect costs, CCA, 2 years 0.050 (mesh kits vs. standard repair)	NHS plus participant and indirect costs, CCA, 2 years  Mesh inlay dominated by standard repair	NHS plus participant and indirect costs, CCA, 2 years  The probability cost effective at a WTP of £20,000 and £30,000 per

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Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
						£5,860 (mesh kits vs. standard repair)	QALY: 0.35-0.33 standard repair; 0.11-0.11 synthetic mesh; 0.54-0.56 biological graft

1. Effectiveness from a single RCT

2. UK study, QALYs with EQ-5D weights

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Jacklin 2013 UK	Minor limitations <sup>1</sup>	Directly applicable <sup>2</sup>	Type of economic analysis: cost-utility  Time horizon: 5 years  Primary measure of outcome: QALYs	£1,539	0.0001	£15 million	Time horizon 10 years and no recurrence in mesh group beyond 5 years 6% in the no mesh group by 10 years - the ICER of mesh (vs. no mesh): £13.4 million per QALY gained  In a scenario analysis where all model inputs were set to favour mesh the ICER of mesh (vs. no mesh): £104,276 per QALY gained

1. Some key model inputs based on authors assumptions (informed by published literature)

2. UK study, QALYs

**Table 63: Economic evidence profile, anterior and/or posterior prolapse: anterior colporrhaphy, hand cut mesh, and mesh kit**

<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
Murray 2011  USA	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis  Time horizon: 2 years	\$81 (AC vs. hand cut mesh)  \$1,298 (mesh kit vs. AC)	NA	Hand cut mesh is cost saving	If the recurrence rate for AC is 28% (base case: 30%) it is cost-equivalent with non-kit mesh  Non-kit mesh supply cost must remain below \$480 (base case: \$400) for it to remain cost effective when compared with AC  Mesh kit repair does not reach cost-equivalence even at an operating time of 0 min (base case: 64 min)  If recurrence rate of traditional repair is below 20% (base case: 30%), AC is more cost effective even if extrusion rate for mesh repair is 0% (base case: 12%)  When the recurrence rate for AC is at a base case rate of 30%, non-kit mesh repair is more cost effective if extrusion rate is less than 25% (base case: 12%).

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Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
							If recurrence rate is 50% for AC, then hand-cut mesh is more cost effective even with a 50% extrusion rate.

1. Short time horizon; some of the resource use supplemented with expert opinion; national and local unit cost data

2. USA study

**Table 64: Economic evidence profile, apical surgery: laparoscopic, robot-assisted, and abdominal sacrocolpopexy**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Judd 2010 USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis Time horizon: 2 years	Excluding robot acquisition costs: \$2,716 (robotic vs. abdominal) \$1,155 (laparoscopic vs. abdominal):  Including robot acquisition costs: \$4,170 (robotic vs. abdominal) \$1,561 (laparoscopic vs. abdominal)	NA	Abdominal is cost saving	Without surgical equipment acquisition costs In all sensitivity analysis laparoscopic approach remained more expensive when compared with the abdominal approach. The laparoscopic approach was less expensive only when (1) the mean length of stay for the abdominal approach > 5.6 days (base case: 2.7 days) and laparoscopic approach remained at 1.8 days, (2) when the surgeon costs for the abdominal approach >\$2,213 (base case: \$638), (3) and when disposable equipment costs for the laparoscopic procedure < \$668 (base case \$1,677 and \$2,244 for early and late switching). In all other

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Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
							scenarios the abdominal approach remained the least costly option.

1. Short time horizon, mix of local and national unit cost data

2. USA study

**Table 65: Economic evidence profile, apical surgery: laparoscopic versus robot-assisted sacrocolpopexy**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Judd 2010 USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis Time horizon: immediate post-operative	-\$1,155 (excluding robot acquisition costs)  -\$2,609 (including robot acquisition costs)	NA	Laparoscopic is cost saving	Without surgical equipment acquisition costs  The cost equivalence between the robotic and laparoscopic approaches achieved when mean operative time was 149 minutes (base case: 328 minutes) for robotic and it remained at the base case value of 269 minutes for laparoscopic. Robotic procedure was less costly (versus laparoscopic) when robotic disposable costs were <\$2,132 (base-case: \$3,293) and laparoscopic disposable costs >\$3,413 (base-case: \$2,244). Varying other model inputs including the length of stay, the risk of switching, the risk of transfusion, anaesthesia costs, surgeon fees, post-anaesthesia costs, hospital room and board costs,

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<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
							<p>medication costs, and laboratory costs failed to make the robotic approach less costly (versus laparoscopic approach).</p> <p>The laparoscopic approach was less expensive only when the disposable equipment costs for the laparoscopic procedure were &lt;\$668 (base case \$1,677 and \$2,244 for early and late switching).</p> <p>With surgical equipment acquisition costs</p> <p>Varying the number of procedures per month from 60 to 20 the robotic-assisted costs increased by \$581-\$1,724 per procedure (base case: \$8,508). In no scenario the robotic approach was less costly when compared with the laparoscopic approach.</p>
Anger 2014 USA	Potentially serious limitations <sup>4</sup>	Partially applicable <sup>3</sup>	Type of economic analysis: cost-utility analysis Time horizon: 6 weeks Outcome: QALYs	\$8,728	-0.003	Laparoscopic sacrocolpopexy is dominant	<p>Difference in costs was statistically significant, p &lt; 0.001; difference in outcomes was not statistically significant, p=0.234</p> <p>When the robot purchase and maintenance costs are excluded there is no difference in costs.</p>

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<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
Paraiso 2011 USA	Potentially serious limitations <sup>6</sup>	Partially applicable <sup>5</sup>	Type of economic analysis: cost-minimization analysis Time horizon: 6 weeks	\$1,936	NA	Laparoscopic sacrocolpopexy is cost saving	The difference in costs 95% CI \$417 to \$3,454, p = 0.008

1. Short time horizon, mix of local and national unit cost data

2. USA study

3. Short time horizon, baseline and treatment effects from a single RCT, some of the unit costs were from local sources

4. USA study, QALY with EQ-5D utility weights based on USA general population norms

5. Short time horizon, unclear cost categories

6. USA study

**Table 66: Economic evidence profile, apical surgery: abdominal open versus robot-assisted sacrocolpopexy**

<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
Elliot 2012 USA	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-minimisation analysis Time horizon: 30 days	-\$1,129	NA	Robot-assisted sacrocolpopexy is cost saving	The results are sensitive to robot cases per year, cost per day of hospital stay, length of hospital stay, operating room time and disposable costs
Hoyte 2012 USA	Potentially serious limitations <sup>3</sup>	Partially applicable <sup>4</sup>	Type of economic analysis: cost analysis Time horizon: immediate postoperative	-\$2,760	NA	Robotic sacrocolpopexy is cost saving	The difference in costs was statistically significant (p<0.001)  Changing the assumptions pertaining to the residual value of robot (residual value changed from \$500,000 to \$0) and increasing the

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Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
							daily case count from 2 to 3 robotic approach results in the range of 10-15% of the cost savings

1. Short time horizon, resource use from a small retrospective cohort study, some of the unit costs were from local sources

2. USA study

3. Unclear source of unit cost data and time horizon

4. USA study

**Table 67: Economic evidence profile, apical surgery: abdominal sacrocolpopexy (ASC) versus sacrospinous ligament fixation (SSLF)**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Lua 2017 USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis Time horizon: 90 days	\$1,800.69	NA	SSLF is cost saving	The 95% CI around the difference in mean costs \$1,476.50 to \$2,124.88; p<0.0001
Ohno 2016 USA	Potentially serious limitations <sup>3</sup>	Partially applicable <sup>4</sup>	Type of economic analysis: cost-effectiveness analysis Time horizon: 2 years Outcome: QALYs	\$2,038	0.08	\$24,574	The one-way sensitivity analysis of costs shows that ASC is no longer cost-effective if the cost of ASC is greater than \$15,620 (base case: \$13,460) or if the cost of SSLF is less than \$8,539 (base case: \$10,653).  Results are also sensitive to the postoperative rates of SUI, MUS placement in the event of SUI, recurrent prolapse, and post-operative dyspareunia rates.

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Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
							<p>ASC remains cost effective as long as post-operative rate of SUI is &lt;36% (base case: 30%) or if the rate of MUS placement for SUI is &lt;60% (base case 36%).</p> <p>ASC remains cost effective if:</p> <ul style="list-style-type: none"> <li>• rate of recurrent prolapse is &lt;5% (base case: 3.6%); or</li> <li>• rate of post-operative dyspareunia is &lt;59% (base case: 16%).</li> </ul> <p>SSLF becomes cost-effective if:</p> <ul style="list-style-type: none"> <li>• post-operative rate of SUI after SSLF is &lt;28% (base case: 35%);</li> <li>• MUS placement after SUI is &lt;13% (base case: 60%);</li> <li>• rate of recurrent prolapse is &lt;4% (base case: 15%);</li> <li>• rate of post-operative dyspareunia is &lt;19% (base case: 36%).</li> </ul> <p>ASC remains cost-effective over reasonable ranges for the cost of MUS, the rate of re-operation for recurrent prolapse, and all of the utilities included in the model (recurrent prolapse, dyspareunia, and SUI).</p>

1. Short time horizon, unclear source of unit cost data (but seems to be national claims database)

2. USA study

3. Included only immediate postoperative costs, sources of unit cost data unclear

4. USA study, outcomes discounted at 3%, estimated QALYs however utility weights based on expert opinion

**Table 68: Economic evidence profile, apical surgery: laparoscopic sacrocolpopexy versus sacrospinous ligament fixation (SSLF)**

<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
Lua 2017 USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis Time horizon: 90 days	\$2,922.03	NA	Sacrospinous ligament fixation is cost saving	The 95% CI around the difference in mean costs \$2,648.56 to \$3,195.50, p < 0.0001

1. Short time horizon, unclear source of unit cost data (but seems to be national claims database)

2. USA study

**Table 69: Economic evidence profile, apical surgery: abdominal open sacrocolpopexy versus laparoscopic sacrocolpopexy**

<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
Lua 2017 USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis Time horizon: 2 years	\$1,122	NA	Abdominal open sacrocolpopexy is cost saving	None

1. Short time horizon, unclear source of unit cost data (but seems to be national claims database)

2. USA study

**Table 70: Economic evidence profile, apical surgery: laparoscopic sacrocolpopexy versus transvaginal mesh**

<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
Carracedo 2017 Spain	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis Time horizon: unclear (likely immediate postoperative period)	-€548.6	NA	Laparoscopic sacrocolpopexy	The difference in costs was not statistically significant

1. Unclear time horizon but seems immediate postoperative period, some cost categories are unclear, resource use based on small observational study, source of unit costs unclear

2. Spanish study

**Table 71: Economic evidence profile, apical surgery: robotic sacrocolpopexy versus vaginal mesh hysteropexy**

<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
Culligan 2013 USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-effectiveness analysis Time horizon: 12 months Outcome: QALYs	\$6,963	0.0366	\$207,232	The results are robust to changes in: <ul style="list-style-type: none"><li>estimates of surgical mortality, probabilities of complications (bleeding, cystotomy, surgical site infection, mesh exposure, de novo lower urinary tract symptoms, de novo chronic pain);</li><li>probability of reoperation;</li><li>utility weights;</li><li>surgical costs;</li><li>simultaneous changes in the probabilities of complications and surgical costs.</li></ul>

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1. Some estimate pertaining to treatment effectiveness supplemented with expert opinion, unit cost data from local sources
2. USA study, estimated QALYs however utility weights based on expert opinion

**Table 72: Economic evidence profile, apical surgery: robotic sacrocolpopexy versus transvaginal mesh repair**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Ehlert 2016 USA	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis  Time horizon: immediate postoperative	With concomitant hysterectomy: \$2,663  Without concomitant hysterectomy: \$2,957	NA	NA	The differences were statistically significant, p<0.001

1. Time horizon is not reported; source of unit costs unclear

2. USA study

**Table 73: Economic evidence profile, apical surgery: laparoscopic sacral colpopexy (LSC) versus total vaginal mesh (TVM)**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Maher 2012 AUS	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-minimisation analysis  Time horizon: 2 years  Outcomes: objective success (POP-Q stage 0 or 1 prolapse at all vaginal sites), patient satisfaction on a scale (0-100),	-\$4,013	0.34 (objective success)  8.09 (patient satisfaction)  6% greater reduction	Hand cut mesh is cost saving	If the recurrence rate for AC is 28% (base case:

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Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
			Australian Pelvic Floor Questionnaire (APFQ), pelvic organ prolapse quality of life (P-QoL)				

1. Baseline outcomes and treatment effectiveness from a single RCT, unit costs from local sources

2. Australian study, societal perspective, no QALYs

**Table 74: Economic evidence profile, apical surgery: Manchester–Fothergill procedure vs. uterosacral ligament suspension (with vaginal hysterectomy)**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Husby 2018 Denmark	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis Time horizon: 20 months	Surgery costs only: -€898  Surgery plus subsequent health care costs: -€1,196	NA	NA	The confidence interval around the difference in surgery costs was 95% CI: €818; €982 and between surgery and sub-sequent health care costs 95% CI: €927; €1,465.  The conclusions were robust to changes in the costs associated with hospital stay, operating theatre costs, and the percent of a health care professional's working time involved in direct patient contact. Excluding patients costing more than 300% of the median costs, including the costs of sampling the pathological specimen irrespective of whether performed in the primary sector or at private gynecologists, or excluding women with missing information about duration of surgery and/or anesthesia and/or post-

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<b>Study and country</b>	<b>Limitations</b>	<b>Applicability</b>	<b>Other comments</b>	<b>Incremental costs</b>	<b>Incremental effects</b>	<b>ICER</b>	<b>Uncertainty</b>
							anesthesia care did not change the conclusions.

1. Local unit cost data supplemented with expert opinion

2. Danish study

**Economic evidence profiles for review question: What is the role for surgery for preventing postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Table 75: Economic evidence profile for anterior colporrhaphy (AC) with a preventative concomitant retropubic mid-urethral sling (RMUS) versus AC with a deferred option of RMUS**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Guideline economic analysis  UK	Minor limitations <sup>1</sup>	Directly applicable <sup>2</sup>	Cost-utility analysis  Time horizon: 2 years with complications captured over the long term follow-up  Primary measure of outcome: QALYs	£774	-0.014	AC with a deferred option of RMUS dominant	The findings were robust to changes in model inputs including the risk ratio of SUI associated with AC with the preventative concomitant RMUS (versus AC with a deferred option for RMUS), the risk of RMUS-related complications (including, urge incontinence, mesh extrusion, pain, and infection); intervention costs (including, the cost of AC, combined AC and RMUS procedure, and RMUS procedure only); the costs associated with managing complications, and utility values.  The baseline risk of SUI would need to be <0.70 for AC with a preventative concomitant RMUS to be cost effective.  The probability of AC with preventative concomitant RMUS being cost-effective was below 0.01 when taking into account the uncertainty.

Notes: 1,Short time horizon, baseline and relative effects from a single RCT, hasn't considered long term complications, absolute costs and outcomes not reported; 2, USA study, QALYs with utility weights based on HUI-Mark-III and vignettes.

**Economic evidence profile for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Table 76: Economic evidence profile for surgery versus pessary**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Hullfish 2011 USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-utility analysis  Time horizon: 12 months	\$4,753 (vaginal reconstructive surgery versus pessary)	0.080 (vaginal reconstructive surgery versus expectant management followed by vaginal reconstructive surgery)	\$59,607 per QALY (vaginal reconstructive surgery versus pessary)  Expectant management followed by laparoscopic abdominal sacrocolpopexy and expectant management followed by robotic assisted abdominal sacrocolpopexy dominated by expectant management followed by vaginal reconstructive surgery  Laparoscopic traditional open abdominal sacrocolpopexy and robotic assisted laparoscopic abdominal sacrocolpopexy dominated by vaginal reconstructive surgery  Expectant management followed by vaginal reconstructive surgery extendedly dominated vaginal reconstructive surgery	Deterministic sensitivity analyses indicated that the model results were sensitive to the: <ul style="list-style-type: none"> <li>probability of POP complication</li> <li>probability of surgery following pessary</li> <li>utility of pessary use</li> <li>probability of late complications for vaginal reconstructive surgery</li> <li>cost estimate for robotic-assisted abdominal sacrocolpopexy as a proportion of the total hospitalisation charge for traditional abdominal sacrocolpopexy</li> </ul>

1. Some model inputs pertaining to treatment effectiveness and resource use supplemented with authors' expert opinion

2. USA study, estimated QALYs however utility weights based on expert opinion

## Appendix J – Economic analysis

### Economic analysis for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?

#### Economic model

The choice of surgical procedure in women with anterior pelvic organ prolapse (POP) was identified by the committee and the guideline health economist as an area with potentially major resource implications. Existing UK economic evidence in this area was limited and did not cover all relevant surgical procedures (that is, the committee wanted to explore the potential cost-effectiveness of different mesh products). The clinical evidence in the area of recurrence prevention was judged to be sufficient and adequate to inform primary economic modelling. Based on the above considerations, an economic model was developed to assess the relative cost-effectiveness of surgical procedures aiming at preventing recurrence in women with anterior POP.

#### Methods

##### *Population*

The study population of the economic model comprised adult women with primary anterior POP (POP-Q stage ≥2). The committee acknowledged the importance of other prolapse types. However, it was noted that anterior POP is the most common type of prolapse. Also, the clinical evidence for posterior and apical type prolapses was judged to be insufficient to inform primary de-novo economic modelling.

##### *Surgical procedures assessed*

Only effective surgical procedures when compared with standard care treatment for anterior colporrhaphy (AC) (as identified in the network meta-analysis utilising recurrence at the same site as an outcome measure) were assessed in the economic analysis and comprised of AC without mesh, AC with synthetic non-absorbable mesh, AC with synthetic partially absorbable mesh, and AC with biological mesh. Each surgical procedure was compared to a standard surgical procedure (that is, AC without mesh) and also to each other.

The network meta-analysis (NMA) included a range of other treatments including AC & synthetic absorbable mesh (n=73), paravaginal repair & synthetic non-absorbable mesh (n=36), paravaginal defect repair (abdominal) (n=35), and paravaginal repair & biological mesh (n=31). However, after reviewing the results the committee was uncomfortable making recommendations based on treatments with a total pooled number of participants (n) of less than 100 across all randomised controlled trials (RCTs) therefore these surgical procedures were excluded from further consideration in the economic analysis.

##### *Model structure*

A Markov model was constructed using Microsoft Office Excel 2013. The model estimated the total costs and benefits associated with the provision of each of the surgical procedures in women with primary anterior POP. The structure of the model, which aimed to simulate the course of anterior POP and relevant clinical practice in the UK, was also driven by the availability of clinical data.

According to the model structure, hypothetical cohorts of adult women with a primary anterior POP were initiated on a surgical procedure.

The model, which was run in yearly cycles, included the following health states: 'primary surgical repair', 'well' (that is, successfully managed POP), 'failure/recurrence', and 'complications'.

Within each year, women could remain in the same state or move from one state to another. The model considered only one further recurrence following the primary repair given that very few women have more than 2 repairs (Lowenstein 2017).

In the model after their initial surgical treatment, women then move into one of the health states. They may enter the 'well' health state (defined as women who are not experiencing complications or failure/recurrence). Women might stay in the 'well' state for the duration of the model. However, at the end of each yearly cycle women may also transition from 'well' state if they experience failure/recurrence or complications.

Women might experience a failure/recurrence which:

- May require further repeat POP surgery. According to Abdel-Fattah (2011) the median time interval between index and repeat POP surgery is approximately 3 years. Consequently, in the model women who failed initial anterior repair or experienced recurrence entered a tunnel health state for the duration of 3 cycles to reflect this.
- During the time between the initial anterior repair and subsequent anterior repair, women were assumed to be managed using conservative treatment options. Women requiring surgery for recurrent POP go through a similar model process as those following their first anterior repair.
- Some women might suffer a failure/recurrence and require conservative management. Women might stay in this recurrence health state for the duration of the model. However, at the end of each yearly cycle women may also transition from this state if they experience complications.
- Some women might suffer a failure/recurrence but POP may not be severe enough (asymptomatic) and requires no further treatment. Women might stay in this (asymptomatic) recurrence health state for the duration of the model. However, at the end of each yearly cycle women may also transition from this state if they experience mesh-related complications.

For the modelling purposes only recurrence at the same site was modelled. The risk of recurrent POP at a different site was assumed to be the same across all model arms. As a result, costs and consequences associated with recurrence at the other site than anterior was not considered.

At any point, women may experience complications following their surgery. If a woman experiences complications, she enters the 'complications' health state and receives treatment. It is not thought that surgical complications other than those associated with the mesh itself would vary much between the arms and were excluded from the analysis.

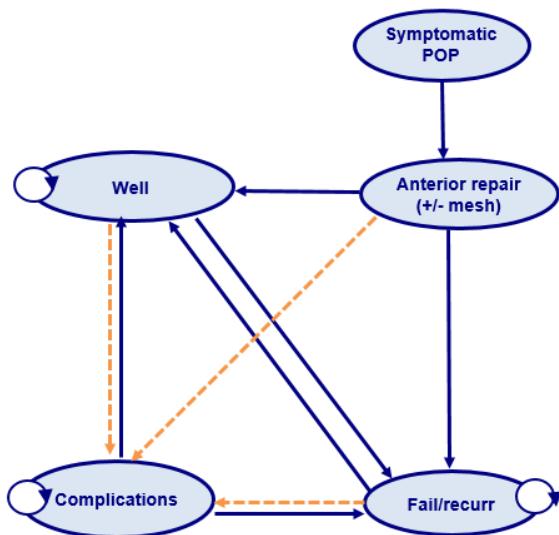
A woman who experiences complications might have these resolved during a single cycle or might remain in the 'complications' health state until the complications resolve. This allowed to capture the potential impact of persistent complications that require long-term management, and have important consequences in terms of health-related quality of life and health care costs.

The mortality rate from prolapse surgery is small at 37 per 100 000 cases, and therefore this would also only make a very small contribution to the health state utility loss (RCOG, 2009). As a result, this analysis has not considered this.

The time horizon of the analysis was determined by the availability of clinical data and was 15 years, which allowed assessment of longer-term costs and benefits associated with surgical management. A half-cycle correction was applied; this practically means that all events in the model occurred in the middle of each cycle.

The structure of the economic model is shown in Figure 47.

**Figure 47: Schematic diagram of the economic model structure.**



Abbreviations: POP, pelvic organ prolapse

#### **Costs and outcomes considered in the analysis**

The economic analysis adopted the perspective of the NHS, as recommended by NICE (NICE, 2014). Costs consisted of surgical procedure costs (mesh and non-mesh), conservative management, as well as other costs associated with revision surgery and complications. The cost year was 2017.

The measure of outcome was the Quality Adjusted Life Year (QALY), which incorporated utilities associated with the health states of being well (that is, resolved POP), recurrent POP, as well as utility decrements due to further revisions and mesh complications.

#### **Clinical input parameters and overview of methods employed for evidence synthesis**

The main clinical input parameter used in the economic analysis was the risk of recurrence (at the anterior compartment). To take all trial information into consideration, network (mixed treatment comparison) meta-analytic techniques were employed to synthesise evidence on recurrence (the methods used can be found in appendix O). NMA is a generalisation of standard pair-wise meta-analysis for A versus B trials to data structures that include, for example, A versus B, B versus C and A versus C trials (Lu and Ades, 2004). A basic assumption of NMA is that direct and indirect evidence estimate the same parameter; in other words, the relative effect between A and B measured directly from an A versus B trial is the same with the relative effect between A and B estimated indirectly from A versus C and B versus C trials. Network meta-analytic techniques strengthen inference concerning the relative effect of two treatments by including both direct and indirect comparisons between treatments and, at the same time, allow simultaneous inference on all treatments examined in the pair-wise trial comparisons while respecting randomisation (Lu and Ades, 2004; Caldwell 2005). Simultaneous inference on the relative effect of a number of treatments is possible provided that treatments participate in a single ‘network of evidence’, that is, every treatment is linked to at least one of the other treatments under assessment through direct or indirect comparisons. The NMA conducted within a Bayesian framework using Markov Chain Monte Carlo simulation techniques implemented in WinBUGS 1.4.3. (Lunn 2000; Spiegelhalter 2002).

Given the lack of naturalistic studies that reported anatomical (overall) recurrence (that is, the identified studies predominantly focused on surgically managed recurrence) the baseline risk

of recurrence was estimated by combining surgically managed recurrence that was derived from a long-term naturalistic study and anatomical (overall) recurrence that was derived from anterior repair arm of an RCT with the longest follow-up.

Lowenstein (2017) was a large population-based registry study of Danish women above the age of 18 years undergoing primary surgery for POP during the period 1996–2000. In this study, a total of 8,326 procedures were performed and after 20 years' follow-up, there were 777 reoperations. A 20-year cumulative rate of surgically managed recurrence reported in this study was used to estimate the annual probability of surgically managed recurrence, which was subsequently attached to the AC without mesh and was used in the economic analysis.

Rudnicki (2016) assessed the effectiveness of AC compared with collagen-coated transvaginal mesh for anterior vaginal wall prolapse in a total of 138 women, of 55 years of age or older with stage ≥2 anterior vaginal wall prolapse. A 3-year cumulative rate of anatomical (overall) recurrence in the anterior arm was used to estimate the annual probability of anatomical (overall) recurrence. Since the anatomical (overall) recurrence already includes women who experience recurrence that requires surgical management the annual risk of anatomical (overall) recurrence was adjusted for the risk of surgically managed recurrence estimated from a study by Lowenstein (2017). The resulting annual probability of recurrence not requiring surgical management was subsequently attached to the AC without mesh and was used in the economic analysis.

There are studies suggesting that recurrence varies with time and that the majority of the recurrences take place within the first few years. In contrast, the committee explained that they expect the risk of recurrence to be relatively high in the first few years, then to decline, and then again to increase during the long-term follow-up. Given the uncertainty in how the risk of recurrence varies with time, in consultation with the committee, a constant risk was assumed each year for the duration of the model.

The summary statistic of the NMA undertaken to inform the economic analysis included the hazard ratios (HRs) of all treatments considered in the economic analysis versus AC without mesh. Table 77 provides the results of the NMA of data on anatomical (overall) recurrence of each intervention versus AC without mesh that was included in the economic analysis.

**Table 77: Recurrence at the same site associated with interventions for anterior POP – findings of the NMA.**

Intervention	Posterior median HR for recurrence versus AC without mesh (95% Crls)
AC and synthetic non-absorbable mesh	0.38 (0.24, 0.59)
AC and synthetic partially absorbable mesh	0.27 (0.11, 0.62)
AC and biological mesh	0.44 (0.26, 0.73)

Abbreviations: AC, anterior colporrhaphy; Crl, Credible interval; HR, hazard ratio; NMA, network meta-analysis

The results of the NMA indicated that AC with synthetic partially absorbable mesh resulted in the greatest reduction in the risk of recurrence (posterior median HR 0.27), followed by AC with synthetic non-absorbable mesh (posterior median HR 0.38), and AC with biological mesh (posterior median HR 0.44). However, there was no evidence of differences between non-absorbable mesh, partially absorbable mesh, and biological mesh.

It was assumed that proportional hazards stand; therefore, the transition probabilities for recurrence for surgical procedures with mesh were estimated by multiplying on a natural scale associated hazard ratios of each surgical procedure (versus AC without mesh) with the baseline risk of surgically managed recurrence and anatomical (overall) recurrence (adjusted for the surgically managed recurrence) associated with AC without mesh.

In consultation with the committee and given that the follow-up time included RCT was clustered around 3 years the estimated HRs of mesh procedures (versus AC without mesh) were applied only during the first 3 years following the initial surgical repair with mesh. After the 3 years, the risk of recurrence in the mesh groups including synthetic non-absorbable mesh, partially absorbable mesh, and the biological mesh was modelled to be the same as for women receiving AC without mesh.

Details on the interventions, data and type of model use to synthesise the effectiveness data are shown in appendix O; model fit statistics (that is, fixed and random effects) are presented in appendix R.

### **Probability of other events**

According to Lowenstein (2017), only around 1% of women require a second reoperation and 0.1–0.2% require a third reoperation, which is the same for every compartment. Consequently, the economic analysis considered only the possibility of one further anterior repair following the failure of the initial surgical procedure. According to the committee expert opinion, any anterior repair could be used as a second line treatment (that is, mesh and non-mesh procedure). The risk of surgically managed recurrence following a secondary repair was based on the observational cohort study by Denman (2008). This was a prospective cohort study in 374 women who underwent surgery for POP and UI in a community population in the USA. In this study, the majority of women received POP repair using a vaginal approach. The rate of surgically managed recurrence at 12 years was annualised and was used to estimate the annual probability of surgically managed recurrence. The same risk was assumed irrespective of the initial anterior repair procedure (that is, with or without mesh). The study did not report the total anatomical (overall) recurrence. As a result, this was taken from a UK-based RCT (Glazener 2016). The risk of anatomical recurrence was modelled as the average of the recurrence rates for AC with synthetic mesh repairs in women who had a secondary repair in this trial. The rate was converted to the annual probability which was adjusted for the surgically managed recurrence (estimated from a cohort study) and was applied during each year for the duration of the model.

### **Probability of development of complications from mesh**

Surgical treatment with mesh is associated with the development of various mesh-related complications. These can be serious and may require surgical revision. Given the uncertainty as to the long-term incidence rate of complications the decision was made to focus only on complications with a greatest impact on health-related quality of life and costs including mesh extrusion and pain. The clinical review identified a number of prospective cohort studies reporting complication rates. However, their follow-up was limited. For the purposes of modelling a study with the longest follow-up was chosen for each complication.

For mesh extrusion, a study by Jacquetin (2013) was used. This was a prospective, observational, multi-centre study that evaluated the clinical effectiveness and complication rates at 5 years following the total transvaginal mesh technique to treat POP of stage 2 or higher. In the study, a total of 90 women were operated in centres across UK, France, and the USA. Over the 5 year follow-up period, a total of 14 women experienced mesh exposure for which 8 resections needed to be performed. The number of women developing mesh extrusion was stratified and reported in year 1, years 2-3, and years 4-5. For the purposes of modelling, a rate of mesh extrusion reported in this study during each time period was used to estimate the annual probability of mesh extrusion during each time period, which was subsequently attached to the synthetic mesh repairs and was used in the economic analysis. According to the committee expert opinion, women will continue developing mesh extrusion during the long-term follow-up. Consequently, the estimated annual probability of mesh extrusion in year 5 was applied at each year for the remaining duration of the model (that is, up to 15 years).

A similar approach was adopted to model pain complications. The study by Laso-García (2017) was a prospective study of women who underwent repair for POP with the tension-free transvaginal mesh in a major tertiary hospital in Spain. In the study, a total of 75 women were operated. An isolated anterior mesh was inserted in 4 patients, an isolated posterior mesh in 1 patient and anterior and posterior in 70 patients. At the median follow-up of 5.3 years, the de novo pain was observed in 4 women out of 75 giving a rate of 5.9%. For the purposes of modelling, a 5.3-year cumulative rate of pain reported in this study was used to estimate the annual probability of pain, which was subsequently attached to the mesh repairs and was used in the economic analysis. According to the committee expert opinion, women will continue developing pain complications during the long-term follow-up. Consequently, the estimated annual probability of pain was applied at each year for the duration of the model (that is, 15 years).

It is not known what proportion of mesh complications including mesh extrusion and pain resolve as time goes by. Following the consultation with the committee, it was assumed that most complications will resolve by year 2 and approximately 10% of complications (that is, mesh extrusion and pain) will persist for the duration of the model. The committee explained that such persistent mesh complications are poorly captured in the literature and it is crucial to account for the possibility that women may experience mesh-related complications for many years to come. In effect, the above assumption meant that out of 100 women in 90 women mesh complications (including, mesh extrusion and pain) will resolve by year 2. However, in a further 10 women mesh complications were assumed to persist for the duration of the model (that is, 15 years). It was further assumed those mesh complications (that is, mesh extrusion and pain) that resolve following appropriate treatment would do so within a year.

The complication data was insufficient to differentiate between different mesh types (that is, non-absorbable and partially absorbable). Consequently, following a consultation with the committee, the same complication rates for all synthetic mesh types were used.

The guideline systematic review indicated that the risk of mesh extrusion was reduced for biological mesh when compared with synthetic mesh. The risk ratio of 0.14 (95% CI: 0.03 to 0.60) was applied to the risk of mesh extrusion with synthetic mesh to estimate the annual risk of mesh extrusion associated with the biological mesh. However, given the lack of long-term clinical data reporting the pain complications associated with the biological mesh the same rate as for synthetic mesh was used in the analysis.

### ***Utility data and estimation of quality-adjusted life years***

In order to express outcomes in the form of QALYs, the health states of the economic model needed to be linked to appropriate utility scores. Utility scores represent the health-related quality of life (HRQoL) associated with specific health states on a scale from 0 (death) to 1 (perfect health); they are estimated using preference-based measures that capture people's preferences on the HRQoL experienced in the health states under consideration.

NICE recommends the EuroQol five dimensions questionnaire (EQ-5D) (Brooks, 1996) as the preferred measure of HRQoL in adults for use in cost-utility analysis. When EQ-5D scores are not available, NICE recommends that such data be estimated by mapping other health-related quality of life measures to EQ-5D (NICE, 2013).

Glazener (2016) used the EQ-5D-3L for the estimation of HRQoL in women with POP; thus the resulting utility values that were used in the economic analysis satisfy the NICE criteria for use of utility data in the cost-utility analysis. The HRQoL data reported in Glazener (2016) corresponds to the health states described in the economic model. An overview of the study characteristics, the methods used to define health states, and the health-state utility values reported by Glazener (2016) are provided in Table 78.

The HRQoL associated with 'stable post prolapse surgery' state was used to estimate utility scores for women in 'well' health state and also in women who experience an asymptomatic recurrence. The HRQoL associated with 'treatment failure' was used to estimate utility scores for women who do not respond to treatment following anterior repair.

The HRQoL associated with 'complications requiring surgery' was used to estimate utility scores for women who experience recurrence and require surgical management in the model. Women who experience recurrent prolapse, require surgical management and experience resolution of POP symptoms were assumed to experience a linear improvement in their symptoms during the year (that is, their utility increased from HRQoL associated with 'complications requiring surgery' to HRQoL associated with 'well' health state). Similarly, women who experience recurrence that requires surgical management but do not have their POP symptoms resolved were assumed to experience a linear decline in the HRQoL (that is, their utility decreased from HRQoL associated with 'complications requiring surgery' to HRQoL associated with 'treatment failure').

The HRQoL associated with women who experience recurrence and are managed using conservative treatment was used to estimate HRQoL in women who have recurrent symptomatic prolapse in the model and are managed using conservative treatment options in the model.

For mesh extrusion, a weighted HRQoL decrement was estimated using HRQoL decrements associated with 'complications requiring surgery' and 'other mesh complications not requiring surgery'. The HRQoL decrements associated with mesh complications were derived from Glazener (2016) and the weights (that is, the probability of a woman with mesh extrusion undergoing surgical revision) were derived from Jacquetin (2013). The similar approach was adopted to estimate HRQoL decrement associated with pain complications where the committee expert opinion was used to estimate the probability of pain complications that require surgical revision.

**Table 78: Summary of EQ-5D-3L derived health-state utility data for women with pelvic organ prolapse.**

Study	Definition of health states	Health state	Mean HRQoL scores
Glazener 2016	Analysis of EQ-5D-3L obtained from women (n=1348) participating in an RCT of primary anterior or posterior repair surgery including synthetic mesh, biological mesh, and standard anterior repair. In the trial, the mean HRQoL was estimated for various health events. UK general population norms were used.	Treatment failure Complications requiring surgery Stable post prolapse surgery Other mesh complications not requiring surgery Failure (conservative management)	0.609 0.646 0.831 0.739 0.797

Abbreviations: HRQoL, Health-related quality of life

### Cost data

Intervention costs, as well as other health care costs incurred by women with anterior POP, were heavily based on cost data reported in Glazener 2016. Intervention costs comprised of a standard AC cost plus mesh product as appropriate. AC was assigned a unit cost associated with intermediate open lower genital tract procedures with CC Score 0-2, elective inpatient procedure (DHSC, 2018). Manufacturers of various mesh products were contacted to provide unit cost data for mesh products but no response was received. As a result, unit costs for mesh products, including mesh kit, were obtained from (Glazener 2016). However,

Glazener (2016) did not differentiate between different mesh types (that is, non-absorbable and partially absorbable mesh). Given the lack of suitable data, the same unit cost for different synthetic mesh types was used (that is, synthetic non-absorbable mesh and synthetic partially absorbable mesh). The unit costs for all mesh types used in the analysis are reported in table 3.

According to the committee expert opinion, the repeat surgery (following a failure of initial anterior repair) could include anterior repair with or without mesh, and also an apical procedure as recurrent anterior vaginal wall prolapse could be associated with apical descent. For the modelling purposes, the average cost of mesh and non-mesh procedures was used including AC without mesh, AC with synthetic mesh, and AC with biological mesh, and also apical procedure. Apical procedure was assigned the unit cost associated with major open lower genital tract procedures with CC score 0-2 (DHSC, 2018).

The cost associated with conservative management was obtained from a UK-based RCT (Glazener 2016) and included treatment with pelvic floor exercises, oestrogens and pessaries. It was further assumed that only 50% of women experiencing recurrence would require treatment. The committee advised that in the remainder of the women symptoms were not severe enough to require treatment for their prolapse. This is in line with the published literature. For example, in the study by Miedel (2008) the anatomic recurrence rate was 41.1% following a vaginal prolapse reconstructive surgery but less than half of the women were symptomatic and required further management.

The economic analysis did not consider complementary tests, treatments and consultations that would typically be carried out in advance of, and following, each surgery since these were assumed to be the same irrespective of a surgical procedure received. Similarly, the cost of medication needed for pain relief post-surgery wasn't considered, since the duration of pain relief required was assumed to be similar.

The cost inputs also included costs associated with managing mesh extrusion and pain complications. Based on a prospective cohort study by Jacquetin (2013) it was modelled that 57% of women with a mesh extrusion would require surgical revision for mesh extrusion. The surgical management of mesh extrusion was assigned the unit cost associated with a minor lower genital tract procedure (MA22Z), elective inpatient with a unit costs obtained from NHS reference costs 2016/17 (DHSC, 2018). It was further modelled that women undergoing surgical revision for mesh extrusion would require one face-to-face consultation prior to the surgery and one post-surgery with a consultant in urogynaecology or gynaecology.

The management of the remainder of the women (43%) was modelled based on Laso-Garcia (2017) i.e. 50% of women will be successfully managed with topical oestrogens and in 50% of women symptoms are not severe enough and they will require only close surveillance. The management with topical oestrogen included the cost of topical oestrogen (that is, Estriol 0.01% cream) that was obtained from Drug Tariff, 2018. The dose of topical oestrogen was 0.5g at a time. One applicatorful was applied daily for 2–3 weeks, then reduced to 1 applicatorful twice weekly, with a break every 3 months for 4 weeks (BNF, 2018). It was also assumed that these women would require 2 face-to-face consultation with a consultant in urogynaecology or gynaecology.

The committee advised that women with persistent complications would require the same management as above. However, over the long duration. In the model, it was assumed that a small proportion of mesh complications will persist for the duration of the model (that is, 15 years). The cost associated with mesh extrusion management was apportioned over 15 years to approximate the annual cost associated with managing persistent mesh complications related to mesh extrusion.

Women for whom symptoms are not severe enough to require active treatment (that is are in a 'well' health state) following anterior repair with or without mesh would have one follow up

visit with a consultant in urogynaecology or gynaecology. The committee explained that further follow up visits do not happen unless the woman is referred back by her GP.

According to the committee, pain management could include pharmacological treatments, vaginal oestrogen, dilators, psychosexual counselling, physiotherapy, or mesh removal. For the purposes of modelling, it was assumed that 95% of women would receive pharmacological treatment, 50% of women would receive treatment with vaginal oestrogen, 10% with dilators, 20% would receive psychosexual counselling, 50% would receive physiotherapy, and 5% would require mesh removal.

Pain management was assumed to comprise of treatment with paracetamol (4g per day), codeine (240mg per day), co-codamol (120/4000 mg per day) and pregabalin (150 mg per day) (BNF, 2018). The unit cost of drugs were obtained from Drug Tariff, 2018. The average cost of the above pharmacological treatments was used.

The cost of vaginal oestrogen was estimated as described above for the management of mesh extrusion. The cost of the dilator (that is, Femmax, Medical Devices Technology) was obtained from Drug Tariff, 2018. According to the committee expert opinion, women receiving psychosexual counselling would receive a mean of 6 sessions each lasting approximately 50 minutes. The sessions would be facilitated by a Band 6 professional at a unit cost of £43 per hour (Curtis & Burns, 2017). Similarly, women receiving physiotherapy would receive a mean of 6 sessions facilitated by a Band 7 professional at a unit cost of £53 per hour (Curtis & Burns, 2017). The cost of mesh removal was estimated as described above for the management of mesh extrusion.

It was further modelled that on average these women would require 1 face-to-face consultation with a consultant in urogynaecology or gynaecology. For pain that is persistent an additional 2 consultations were added with a consultant in pain management.

The unit costs associated with face-to-face consultation with a consultant in urogynaecology or gynaecology and consultant in pain management was obtained from NHS reference costs 2016/17 (DHSC, 2018).

All costs were uplifted to 2016/2017 UK pounds and all future costs were discounted at a rate of 3.5% as recommended by NICE (2013).

Cost data used in the economic analysis are presented in Table 79 which reports the mean (deterministic) values of all input parameters used in the economic model and provides information on the distributions assigned to specific parameters in probabilistic sensitivity analysis.

**Table 79: Input parameters used in the economic model of surgical procedures for women with anterior pelvic organ prolapse.**

<b>Input parameter</b>	<b>Mean deterministic value</b>	<b>Probabilistic distribution</b>	<b>Source data - comments</b>
<b>HR of recurrence (vs. AC without mesh)</b> AC with synthetic non-absorbable mesh AC with synthetic partially absorbable mesh AC with biological mesh	0.392 0.291 0.456	NA	NMA of data included in the guideline systematic review; distributions based on 10,000 iterations. Given that the longest follow-up of RCTs included in the NMA was clustered around 12-36 months mesh treatment effect was applied for 3 years only.
<b>Baseline risk of recurrence – primary repair</b> Surgically managed recurrence – at 20 years Overall (anatomical) recurrence – at 3 years	0.090 0.490	Beta distribution alpha: 777, beta: 7549 alpha: 40, beta: 42	Lowenstein 2017. Rudnicki 2014. The reported rates were annualised and expressed as annual probabilities.
<b>Risk of surgically managed recurrence (secondary repair) - 12 years</b>	0.280	Beta distribution alpha: 31, beta: 80	Denman 2008. The reported rate was annualised and expressed as an annual probability.
<b>Risk of anatomical (overall) recurrence (secondary repair) – 1 year</b>	0.509	Beta distribution alpha: 54, beta: 52	Glazener 2016.
<b>Recurrence (less surgically managed recurrence) requiring conservative management</b>	0.500	Beta distribution SE: 20% of mean values (assumption)	Committee expert opinion.
<b>Risk of mesh extrusion with synthetic mesh</b> Year 1 Year 2-3 Year 4-5	0.13 0.03 0.03	Beta distribution alpha: 11, beta: 71 alpha: 2, beta: 69 alpha: 2, beta: 67	Jacquetin 2013. The rates were annualised and expressed as annual probabilities. The probability of mesh extrusion in year 5 was carried over and used in each year for the duration of the model.
<b>Risk ratio of mesh extrusion with biological mesh vs. synthetic mesh</b>	0.14	Log-normal distribution Fitted using 95% CI (0.03, 0.60)	Guideline systematic review.
<b>Risk of mesh-related pain - 5 years</b>	0.05	Beta distribution	Laso-Garcia 2017.

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## Surgical management of pelvic organ prolapse

<b>Input parameter</b>	<b>Mean deterministic value</b>	<b>Probabilistic distribution</b>	<b>Source data - comments</b>
		alpha: 4, beta 71	The rate was annualised and expressed as the annual probability. The annual probability was applied to each year for the duration of the model.
<b>Proportion of mesh complications that resolve by 2 years</b>	0.90	Beta distribution SE: 20% of mean value (assumption)	Committee expert opinion.
<b>Intervention costs</b> AC without mesh	£2,234	Normal distribution SE: £30.07 (estimated using lower and upper quartile ranges, and the number of submissions by NHS providers)	Intermediate open lower genital tract procedures with CC Score 0-2, elective inpatient procedure (MA04C/D), NHS reference costs 2016/17 (DHSC, 2018).
<b>Mesh costs</b> Synthetic non-absorbable mesh Synthetic partially absorbable mesh Biological mesh Mesh kits	£115 £115 £315 £666	Gamma distribution SE: 20% of mean values (assumption)	Glazener 2016. All costs uplifted to 2016/17 prices using the hospital & community health services (HCHS) inflation indexes (Curtis & Burns, 2017).
<b>Cost of revision surgery</b>	£2,451	NA (dependant on the above)	Estimated as the average cost of AC, AC & synthetic non-absorbable mesh, AC & synthetic partially absorbable mesh, AC & synthetic absorbable mesh, AC biological mesh, and also apical repair. For apical repair the unit cost associated with major open lower genital tract procedure with CC score 0-2, elective inpatient procedure (MA03D) was assigned, NHS reference costs 2016/17 (DHSC, 2018).
<b>Cost of conservative management (annual)</b>	£546	Gamma distribution alpha: 15.37; beta: 22.54 (taken from Glazener 2016)	Glazener 2016. The cost were uplifted to 2016/17 prices using the hospital & community health services (HCHS) inflation indexes (Curtis & Burns, 2017).

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Input parameter	Mean deterministic value	Probabilistic distribution	Source data - comments
<b>Cost of well (following mesh or non-mesh procedure)</b>	£130	Log-normal distribution SE: £4.12 (estimated using lower and upper quartile ranges, and the number of submissions by NHS providers)	One consultant-led non-admitted follow-up face-to-face attendance in gynaecology (WF01C), NHS reference costs 2016/17 (DHSC, 2018).
<b>Cost of managing mesh extrusion (annual)</b>	£1,207 £80 (persistent)	NA (dependant on distributions associated with treatment probabilities and treatment costs)	<p>Based on the assumption that 57% require surgical revision (Jacquetin 2017), 21% topical oestrogen, and 21% surveillance only.</p> <p>Surgical revision assigned the unit cost of £1,584 associated with minor lower genital tract procedures (MA22Z), elective inpatient, NHS reference costs 2016/17 (DHSC, 2018); plus 2 consultations with a urogynaecologist/gynaecologist.</p> <p>For topical oestrogen a unit cost of £24.98 associated with Estriol 0.01% cream 15g with applicator was used (Drug Tariff, 2018). The dose of 0.5g at a time applied daily for 2–3 weeks, then reduced to 1 applicator twice weekly, discontinued every 2–3 months for 4 weeks was used (BNF, 2018); plus 2 consultations with a urogynaecologist/gynaecologist.</p> <p>For surveillance six monthly consultations with a urogynaecologist/gynaecologist were modelled.</p> <p>For urogynaecologist/gynaecologist a consultant-led non-admitted follow-up face-to-face attendance in gynaecology was used, WF01C, NHS reference costs 2016/17 (DHSC, 2018).</p> <p>For persistent cases the committee advised that women would incur the same cost as above for mesh extrusion cases that resolve. However, since it was assumed that persistent mesh complications will last for the duration of the model the cost of mesh erosion was apportioned over 15 years to approximate the annual cost associated with managing persistent mesh complications.</p>
<b>Cost of managing pain complications (annual)</b>	£754	NA (dependant on distributions associated	Committee expert opinion: 95% will require pharmacological treatment, 50% topical oestrogen, 10% dilators, 20%

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## Surgical management of pelvic organ prolapse

Input parameter	Mean deterministic value	Probabilistic distribution	Source data - comments
	£69 (persistent)	with treatment probabilities and treatment costs)	<p>psychosexual counselling, 50% physiotherapy, and 5% mesh removal.</p> <p>Pharmacological treatment included paracetamol (4g per day), codeine (240mg per day), co-codamol (120/4000mg per day), and pregabalin (150mg per day) (BNF, 2018). The unit cost of paracetamol (500 mg, 32 tbs., £0.31), codeine (60mg, 28 tbs., £1.32), co-codamol (15/500 mg, 100 tbs., £4.93) and pregabalin (150 mg, 56 tbs., £5.88) (Drug Tariff, 2018). The average cost of all of the above pharmacological treatments was used.</p> <p>Vaginal oestrogen costs were estimated as above for the management of mesh extrusion.</p> <p>For dilators the Femmax device, Medical Devices Technology, was used at a cost of £26.66 (Drug Tariff, 2018).</p> <p>For psychosexual counselling six sessions each lasting 50 min delivered by Band 6 therapist at a unit cost of £43 per hour were used (Curtis &amp; Burns, 2017).</p> <p>For physiotherapy six sessions each lasting 50 min delivered by Band 7 therapist at a unit cost of £53 per hour was used (Curtis &amp; Burns, 2018).</p> <p>Plus all women were modelled to have one consultation with a consultant urogynaecologist/gynaecologist.</p> <p>For mesh removal a unit cost of £1,584 associated with minor lower genital tract procedures (MA22Z), elective inpatient, NHS reference costs 2016/17 (DHSC, 2018); plus 2 consultations with a urogynaecologist/gynaecologist was assigned.</p> <p>For urogynaecologist/gynaecologist a consultant-led non-admitted follow-up face-to-face attendance in gynaecology was used, WF01C, NHS reference costs 2016/17 (DHSC, 2018).</p> <p>For persistent pain 2 additional consultations with a pain consultant were modelled.</p>

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Input parameter	Mean deterministic value	Probabilistic distribution	Source data - comments
			For pain consultant a consultant-led non-admitted initial and follow-up face-to-face attendance for pain management was used, WF01B/A, NHS reference costs 2016/17 (DHSC, 2018). Since it was assumed that persistent mesh complications will last for the duration of the model the cost of pain was apportioned over 15 years to approximate the annual cost associated with managing persistent pain complications.
<b>Quality of life adjustments</b>			
Well	0.83	Beta distribution	Glazener 2016; EQ-5D-3L utility weights.
Reoperation	0.65	SE: 20% of mean values (assumption).	For mesh extrusion the proportion managed surgically (57%) was obtained from Jacquetin 2017.
Conservative management	0.80		For pain, the proportion requiring surgical removal of mesh (5%) was based on the committee expert opinion.
Symptomatic POP	0.71		
Utility decrement - surgically managed complications	0.19		
Utility decrement - non-surgically managed complications	0.09		
<b>Discount rate for costs and outcomes</b>	3.5%	NA	NICE (2013)

Abbreviations: AC, Anterior colporrhaphy; SE, standard error; HR, hazard ratio; NMA, network meta-analysis

## Data analysis and presentation of the results

Deterministic and probabilistic analysis were employed to analyse the input parameter data and present the results of the economic analysis.

A deterministic analysis was undertaken, where data are analysed as point estimates; results are presented as mean total costs and QALYs associated with each treatment option are assessed. Relative cost effectiveness between alternative treatments was estimated using incremental analysis: all options were ranked from most to least effective. Options that were dominated by absolute dominance (that is, they were less effective and more costly than one or more other options) or by extended dominance (that is, they were less effective and more costly than a linear combination of two alternative options) were excluded from further analysis. Subsequently, incremental cost-effectiveness ratios (ICERs) were calculated for all pairs of consecutive options remaining in the analysis.

ICERs expressed the additional cost per additional unit of benefit associated with one treatment option relative to its comparator. Estimation of such a ratio allowed consideration of whether the additional benefit were worth the additional cost when choosing one treatment option over another.

Negative ICERs may represent a situation where existing treatment is favoured (that is, new treatment results in lower QALYs and greater costs) and also where new treatment is favoured (that is, new treatment results in lower costs but higher QALYs) yet these will be grouped together in any rank ordering. To distinguish between these situations a net monetary benefit (NMB) for each intervention was derived. NMB was calculated by multiplying incremental QALYs by NICE threshold value of £20,000 per QALY and from this subtracting the incremental costs.

The treatment option with the highest ICER below the cost-effectiveness threshold was deemed to be the most cost-effective option. One-way sensitivity analyses explored impact of varying:

- mesh treatment effects (reduction in the recurrence at the same site) persist beyond 3 years
- the probabilities of surgically managed recurrence ( $\pm 20\%$  around the base-case values)
- the HR for recurrence (using upper and lower CrI)
- the utility values ( $\pm 10\%$  around the base-case values)
- the unit cost of synthetic mesh was replaced with the unit cost of mesh kit
- the intervention costs ( $\pm 50\%$  around the base-case value)
- the costs associated with conservative management ( $\pm 50\%$  around the base-case value)
- the cost of revision surgery ( $\pm 50\%$  around the base-case value)
- the costs of managing complications ( $\pm 50\%$  around the base-case value)
- the annual probabilities of surgically management recurrence and anatomical recurrence ( $\pm 20\%$  around the base-case value)
- the probabilities of mesh erosion and pain complications ( $\pm 20\%$  around the base-case value)
- proportion of mesh complications that persist during the long-term follow-up
- the time it takes for complications to resolve if they do so

One-way sensitivity analyses and the ranges used are summarised in appendix 1. Given the problems associated with negative ICERs (that is, inability to distinguish between negative ICERs which result due to new treatment resulting in lower QALYs and greater costs or

lower costs but higher QALYs) the sensitivity analyses were undertaken on the NMB using £20,000 per QALY threshold value to help to distinguish from situations where mesh procedures resulted in fewer QALYs and higher costs and where mesh procedures resulted in greater QALYs and lower costs.

In addition to deterministic analysis, a probabilistic analysis was also conducted. In this case, all model input parameters were assigned probability distributions (rather than being expressed as point estimates), to reflect the uncertainty characterising the available clinical and cost data. Subsequently, 10,000 iterations were performed, each drawing random values out of the distributions fitted on to the model input parameters. This exercise provided more accurate estimates of mean costs and benefits for each surgical intervention assessed (averaging results from the 10,000 iterations), by capturing the non-linearity characterising the economic model structure (Briggs 2006). Table 79 provides information on the distributions assigned to specific parameters in probabilistic sensitivity analysis

Results of probabilistic analysis were presented in the form of cost effectiveness acceptability curves (CEACs), which demonstrated the probability of each treatment option being the most cost effective among the strategies assessed at different levels of willingness-to-pay per unit QALY (that is, at different cost-effectiveness thresholds the decision maker may set).

## Economic modelling results

### **Results of deterministic analysis**

According to the deterministic analysis, AC without mesh was dominant when compared with AC utilising biological mesh, partially absorbable mesh or non-absorbable mesh (that is, AC without mesh resulted in lower costs and greater QALYs) (Table 80). It also resulted in the highest NMB. The cost effectiveness of AC without mesh can be attributed to a lower rate of complications (including, mesh extrusion and pain) and the associated costs.

Figure 48 provides the cost-effectiveness plane showing the incremental costs and QALYs of all interventions versus AC without mesh. It can be seen that AC with synthetic mesh (partially absorbable or non-absorbable mesh) results in higher costs and lower QALYs when compared with AC without mesh and also when compared with AC with biological mesh.

**Table 80: Mean costs and QALYs for each treatment option for women with anterior POP assessed in the economic analysis – results per women.**

Treatment option	Mean total costs	Mean total QALYs	Cost-effectiveness (cost/QALY)	Mean NMB
AC without mesh	£3,363	9.672	Dominant	£190,086
AC with biological mesh	£3,690	9.642	Dominated	£189,141
AC with synthetic partially absorbable mesh	£3,790	9.548	Dominated	£187,178
AC with synthetic non- absorbable mesh	£3,792	9.550	Dominated	£187,214

Abbreviations: AC, anterior colporrhaphy; NMB, Net monetary benefit; QALY, Quality-adjusted life year

Deterministic sensitivity analyses indicated that the findings were robust to changes in model inputs including HRs, the risk of mesh extrusion and pain complications, cost data, and utility

values (that is, in all scenarios explored AC without mesh remained the most cost-effective option with a highest NMB). Sensitivity analyses are summarised in appendix 1.

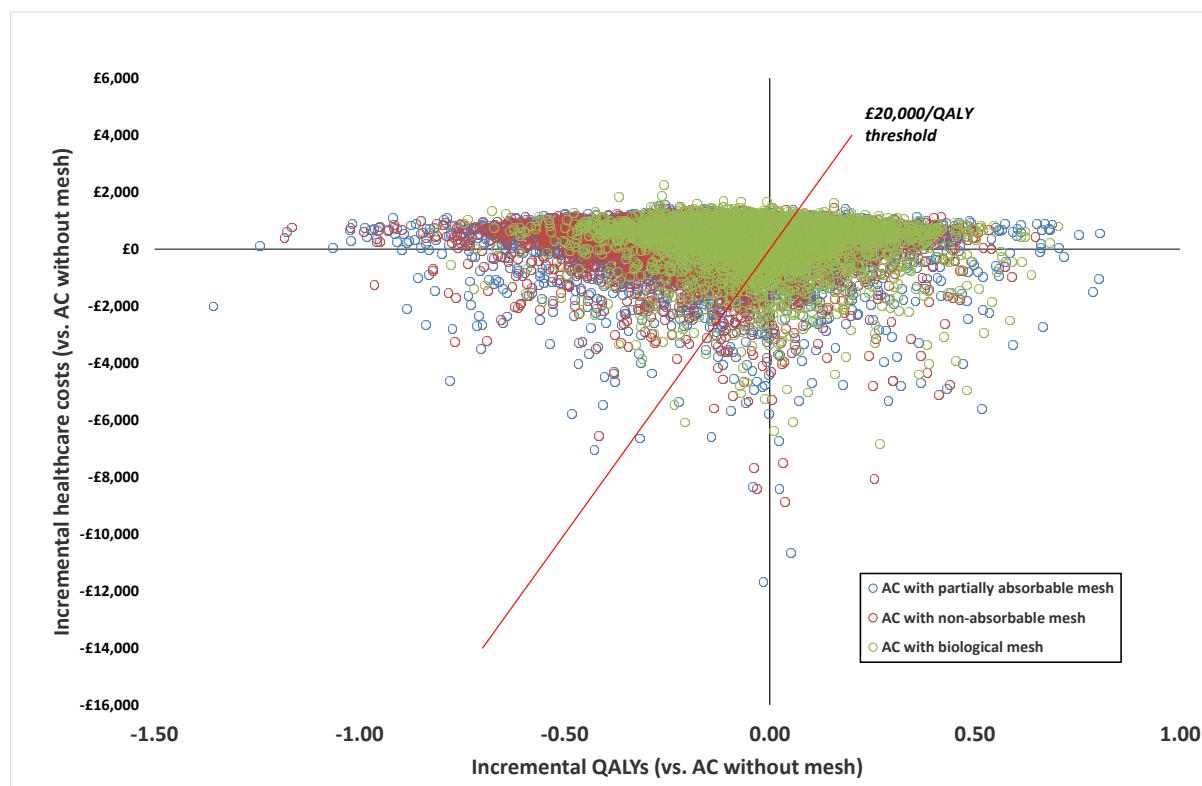
There was uncertainty pertaining to how long mesh treatment effectiveness (that is, reduction in recurrence) is sustained. Even assuming that mesh treatment effectiveness is sustained for the duration of the model (that is, 15 years) the AC without mesh remained the most cost-effective option (appendix 1). As expected, the NMBs of mesh procedures became more favourable. However, these were still below the NMB associated with non-mesh procedure. More favourable effectiveness associated with mesh is insufficient to outweigh the costs and consequences associated with mesh complications. Also, the probability of surgically managed recurrence is low and a large proportion of women are asymptomatic following the recurrence and do not require any further management limiting the potential for mesh being the cost effective treatment option.

There was a great uncertainty surrounding the risk of mesh complications including mesh extrusion and pain. In a sensitivity analysis where the risk of mesh complications was set to zero, partially absorbable mesh became dominant with the cost per woman reduced to £3,284 and QALYs increased to 9.687, which is expected since it has the most favourable effectiveness (that is, recurrence of anterior pelvic organ prolapse) when compared with other surgical procedures. However, this is an implausible scenario. As a result, a two way deterministic sensitivity analysis was undertaken where both the risk of mesh extrusion and the risk of pain complications were varied simultaneously. According to this two-way sensitivity analysis, synthetic partially absorbable mesh was cost effective (that is resulted in the highest NMB and ICER below of £20,000 per QALY gained) only when the risk of mesh extrusion and pain complications was approximately below 0.10 over 15 years which is well below to what the committee experts expect the risk of mesh complications to be associated with synthetic mesh in the clinical practice. Two way deterministic sensitivity analyses are summarised in appendix 2.

Also, using only the available risk rates for mesh complications (including mesh extrusion and pain) as reported in the observational studies (Jacquetin 2013 and Laso-Garcia 2017) over the 5 years and making no assumptions pertaining to the risk of long-term mesh complications beyond 5 years did not change the conclusions of the analysis (that is, the cost effectiveness of mesh procedures improved, however non-mesh still resulted in the highest NMB). Also, in the base case analysis it was assumed that 10% of mesh complications will persist for the duration of the model. In a scenario analysis where only the available mesh complication rates were used and assuming that all mesh complications will resolve by year 2 non-mesh still remained the dominant option.

Assuming the use of mesh kits reinforced the conclusions of the analysis since mesh kits are associated with substantially higher acquisition costs.

**Figure 48: Cost-effectiveness plane of all treatments assessed in the economic analysis plotted against AC (without mesh) – incremental costs and QALYs per women.**



Abbreviations: AC, Anterior colporrhaphy; QALY, Quality-adjusted life year

### Results of the probabilistic analysis

Conclusions of probabilistic analysis were the same to those of deterministic analysis: AC without mesh was the dominant option when compared with mesh procedures including synthetic and biological mesh with mean costs and QALYs derived from 10,000 iterations of the model (

Table 81). AC without mesh also resulted in the highest mean NMB and had the highest probability of being the most cost-effective treatment option. At the lower NICE cost-effectiveness threshold of £20,000 per QALY (NICE, 2008) the probability of AC without mesh being cost effective was 0.70 (Figure 49).

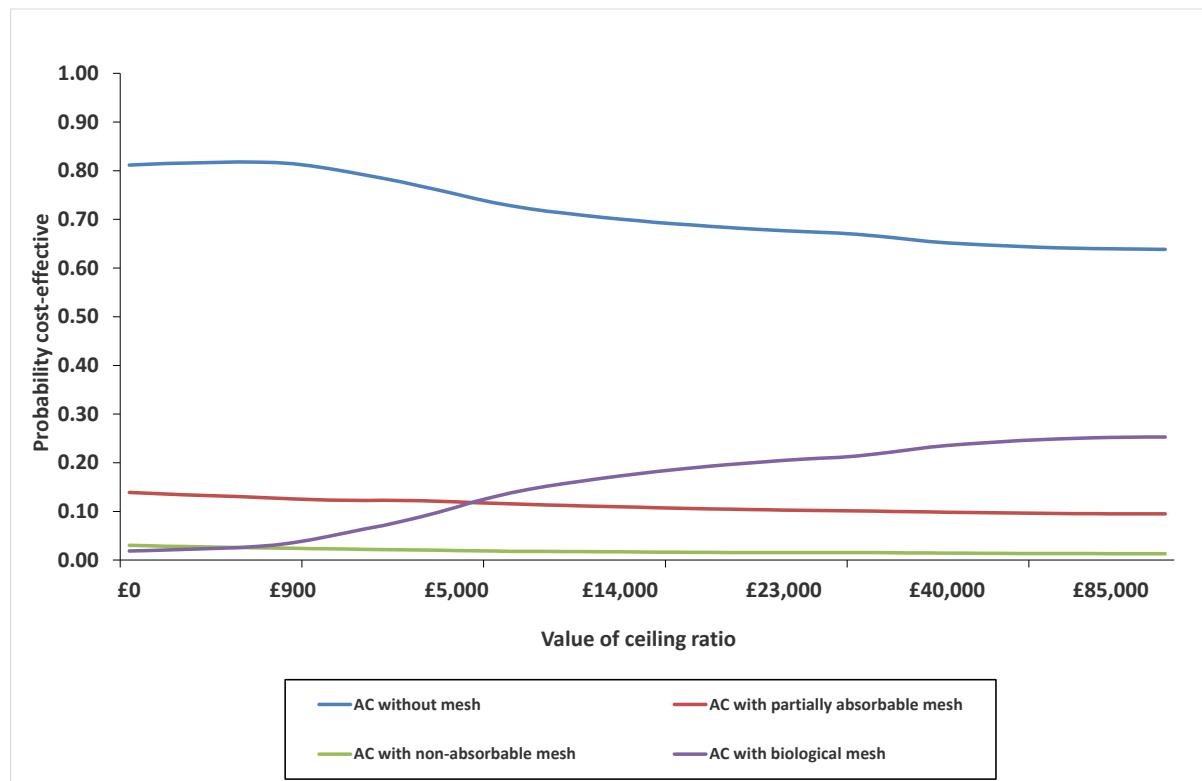
**Table 81: Mean costs and QALYs for each treatment option for women with anterior prolapse assessed in the economic analysis – results of probabilistic analysis per women.**

Treatment option	Mean total costs	Mean total QALYs	Cost-effectiveness (cost/QALY)	Mean NMB
AC without mesh	£3,833	9.642	Dominant	£188,999
AC with biological mesh	£4,348	9.614	Dominated	£187,931
AC with synthetic partially absorbable mesh	£4,211	9.527	Dominated	£186,337

Treatment option	Mean total costs	Mean total QALYs	Cost-effectiveness (cost/QALY)	Mean NMB
AC with synthetic non-absorbable mesh	£4,246	9.529	Dominated	£186,327

Abbreviations: AC, anterior colporrhaphy; NMB, Net monetary benefit; QALY, Quality-adjusted life year

**Figure 49: CEACs of all treatment options for women with anterior prolapse assessed in the economic analysis.**



Abbreviations: AC, Anterior colporrhaphy; CEAC, Cost-effectiveness acceptability curve

## Discussion - limitations of the analysis

The economic analysis suggested that AC without mesh was the dominant surgical treatment when compared with AC with biological and AC with synthetic mesh (non-absorbable and partially absorbable mesh) for women with anterior prolapse. The cost effectiveness of AC without mesh was attributed to a lower risk of mesh complications including mesh extrusion and pain, and the associated lower complication management costs. Even though mesh resulted in fewer women recurring at the same site the probability of surgically managed recurrence is low and a large proportion of women are asymptomatic following the recurrence of anterior prolapse and do not require any further management.

Clinical data on recurrence at the same site were synthesised using network meta-analytic techniques. Such methods enabled evidence synthesis from both direct and indirect comparisons between treatments and allowed simultaneous inference on all treatments examined in pair-wise trial comparisons while respecting randomisation (Lu and Ades, 2004; Caldwell 2005).

One of the limitations of the economic analysis was that the follow-up of RCTs informing the NMA was clustered around 12 to 36 months. Given the uncertainty surrounding the long-term effects associated with mesh procedures, the committee made a conservative assumption that treatment effectiveness at 4 years onwards for mesh procedures will be the same as for AC without mesh. This is in line with the review of prospective cohort and cross-sectional studies undertaken for this guideline which indicated that the long-term recurrence rates following vaginal mesh surgery and non-mesh surgery were nearly identical (that is, 9.49% and 9.13% in vaginal mesh surgery group and non-mesh surgery group, respectively). Also, according to the deterministic sensitivity analysis relaxing this assumption does not change the conclusions.

Another limitation of the economic analysis was that the rate of mesh complications including mesh extrusion and pain during the follow-up were based on a single prospective cohort study each with a limited follow-up. According to the prospective cohort study conducted by Jacquetin (2013) most mesh extrusion cases happened in the first year with the risk declining over time. The committee explained that this was a small study and there is little data to inform us about the frequency of mesh complications occurring after one year. Although, the committee are aware of women who experience mesh complications many years after mesh insertion. Nevertheless, the mesh was cost-ineffective even when using only the available rates of mesh complications (that is, no extrapolation was undertaken beyond the available follow-up in observational studies reporting complication rates).

Due to the lack of suitable studies, the risk of developing pain complications following mesh procedure was obtained from a study where only 4 women received anterior repair with mesh, with the remainder receiving anterior and/or posterior repair with mesh. The committee explained that they would expect posterior repair with mesh to be associated with more pain than anterior mesh but concluded that the rate was reasonable and that it was better to overestimate the risk given the lack of good data. Also, for mesh removal the unit cost associated with minor lower genital tract procedures was assigned which was the same as the unit cost for mesh extrusion. The committee explained that mesh removal is more major surgery than partial excision for extrusion. However, the codes for mesh removal don't map to an HRG code and there is no unique unit cost available. However, given that only a small proportion of women undergo complete mesh removal the impact of using the same unit cost for mesh removal and mesh erosion is likely to be negligible.

Given the uncertainty in the risk of long-term complications, the economic analysis considered only the most common mesh complications (that is, mesh extrusion and pain). The committee recognised that prolapse procedure may be associated with a number of other complications. For example, de novo SUI has been recognised as a potential

complication of anterior repair. However, complication review undertaken for this guideline indicated that the rate of SUI was similar following vaginal mesh surgery and also non-mesh surgery. Moreover, the clinical review could not estimate what proportion of SUI was accounted for de novo SUI due to the unclear reporting in the studies. The risk of urge incontinence was higher in the vaginal mesh group when compared with abdominal mesh surgery and non-mesh group. However, the majority of urge incontinence cases are likely to be successfully managed with anticholinergic drugs and only 20-30% of women with urge incontinence would require treatment with botulinum toxin injections. However, this represents <5% of women (that is, 20-30% out of 25% developing urge incontinence following vaginal mesh surgery) and this would have a negligible impact on the cost effectiveness. Similarly, constipation would be easily managed with laxatives in most cases. The committee noted that women who have obstructed defecation may require more intensive management (i.e. physiotherapy and biofeedback, and surgery). However, since the rate of constipation was higher following vaginal mesh surgery the exclusion of constipation from the analysis would have only underestimated the cost effectiveness of non-mesh surgery. The management of dyspareunia is similar to the management of pain and would have been partially reflected by considering pain complications. Again, given that the rate of dyspareunia was slightly higher in the vaginal mesh surgery the omission of it would have underestimated the cost effectiveness of non-mesh surgery. Overall, the omission of other complications would have a negligible impact on the cost effectiveness and only underestimated the cost effectiveness of non-mesh surgery.

The economic analysis has penalised mesh since some women who had received anterior colporrhaphy without mesh initially could receive surgery with mesh on recurrence and therefore potentially suffer mesh-related complications. However, the economic analysis has not accounted for this. Also, the ancillary costs of surgery were excluded. These are clearly irrelevant for the initial procedure since these costs are the same across all arms and cancel out. However, since the recurrence rates are different then these costs may be relevant for repeat surgical procedures. Although, the committee explained that the absolute numbers of women experiencing surgically managed recurrence are very small and the omission of the above would only have a negligible impact on the cost-effectiveness of mesh.

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## Appendix 1 – Results of deterministic sensitivity analyses

Results of deterministic sensitivity analyses on NMB using £20,000 per QALY threshold. (The results indicate that under most scenarios explored the NMB remains the highest for anterior repair without mesh, bolded light blue shaded cells. For example, when the probability of anatomical recurrence that requires further management is varied between 0.40 and 0.60, NMB for AC is between £252,847-251,752 which is more than NMB for biological mesh of £251,621-250,695; synthetic partially absorbable mesh £249,227-248,358; and synthetic non-absorbable mesh £249,270-248,366).

		AC		AC plus biological mesh		AC plus synthetic partially absorbable mesh		AC plus synthetic non-absorbable mesh	
Model input	Base case values, and upper and lower values explored in the sensitivity analyses	NMB using low estimate	NMB using high estimate	NMB using low estimate	NMB using high estimate	NMB using low estimate	NMB using high estimate	NMB using low estimate	NMB using high estimate
Anatomical recurrence requiring further management	0.50 (0.40, 0.60)	£190,515	£189,656	£189,496	£188,786	£187,509	£186,848	£187,560	£186,869
Cost mesh erosion (initial)	£1207 (£965, £1448)	£190,086	£190,086	£189,152	£189,130	£187,254	£187,103	£187,283	£187,146
Cost mesh erosion (persistent)	£80 (£0, £97)	£190,086	£190,086	£189,147	£189,140	£187,216	£187,171	£187,252	£187,207
Cost of biological mesh	£315 (£157, £472)	£190,086	£190,086	£189,293	£188,989	£187,178	£187,178	£187,214	£187,214
Cost of conservative management	£546 (£436, £655)	£190,277	£189,894	£189,299	£188,983	£187,325	£187,031	£187,368	£187,060
Cost of non-absorbable mesh	£115 (£57, £172)	£190,086	£190,086	£189,141	£189,141	£187,178	£187,178	£187,270	£187,159
Cost of pain management	£754 (£604, £905)	£190,086	£190,086	£189,157	£189,125	£187,194	£187,162	£187,231	£187,198
Cost of partially absorbable mesh	£115 (£57, £172)	£190,086	£190,086	£189,141	£189,141	£187,234	£187,123	£187,214	£187,214
Cost of persistent pain management	£69 (£55, £82)	£190,086	£190,086	£189,143	£189,139	£187,180	£187,176	£187,216	£187,212
Cost of revision surgery	£2451 (£1961, £2941)	£190,107	£190,065	£189,159	£189,123	£187,196	£187,161	£187,232	£187,196
Cost of well - mesh (one off cost)	£130 (£104, £156)	£190,114	£190,057	£189,179	£189,103	£187,217	£187,140	£187,253	£187,176
Cost of well - non-mesh (one-off cost)	£130 (£104, £156)	£190,086	£190,086	£189,141	£189,141	£187,178	£187,178	£187,214	£187,214
HR of biological mesh (vs. AC)	0.46 (0.26, 0.73)	£190,086	£190,086	£189,300	£188,923	£187,178	£187,178	£187,214	£187,214
HR of non-absorbable mesh (vs. AC)	0.39 (0.24, 0.59)	£190,086	£190,086	£189,141	£189,141	£187,178	£187,178	£187,340	£187,053
HR of partially absorbable mesh (vs. AC)	0.29 (0.11, 0.62)	£190,086	£190,086	£189,141	£189,141	£187,330	£186,909	£187,214	£187,214
Proportion of complications that resolve by year 2	0.90 (0.72, 1.00)	£190,086	£190,086	£188,670	£189,403	£185,501	£188,110	£185,512	£188,160
Rate of anatomical recurrence (secondary repair) at year 1	0.51 (0.41, 0.61)	£190,095	£190,076	£189,153	£189,130	£187,190	£187,168	£187,226	£187,204

DRAFT FOR CONSULTATION

Surgical management of pelvic organ prolapse

		AC		AC plus biological mesh		AC plus synthetic partially absorbable mesh		AC plus synthetic non-absorbable mesh	
Rate of surgically managed recurrence (secondary repair) over 12 years	0.28 (0.22, 0.34)	£190,087	£190,084	£189,142	£189,140	£187,179	£187,177	£187,216	£187,213
RR of mesh erosion with biological (vs. synthetic) mesh	0.14 (0.03, 0.6)	£190,086	£190,086	£189,457	£187,878	£187,178	£187,178	£187,214	£187,214
The rate of anatomical recurrence (primary repair) over 7 years	0.34 (0.27, 0.41)	£190,506	£189,675	£189,489	£188,797	£187,502	£186,858	£187,553	£186,880
The rate of mesh extrusion over 15 years	0.34 (0.27, 0.41)	£190,086	£190,086	£189,221	£189,062	£187,685	£186,687	£187,697	£186,747
The rate of pain complications over 15 years	0.15 (0.12, 0.18)	£190,086	£190,086	£189,254	£189,031	£187,291	£187,068	£187,327	£187,104
The risk of surgically managed recurrence (primary repair) over 20 years	0.09 (0.07, 0.11)	£190,111	£190,060	£189,172	£189,109	£187,214	£187,141	£187,251	£187,177
The time mesh extrusion resolves (if it does so) following the appropriate management (months)	12 (3, 12)	£190,086	£190,086	£189,439	£189,141	£189,169	£187,178	£189,116	£187,214
The time pain complications resolve (if they do so) following appropriate management (months)	12 (3, 12)	£190,086	£190,086	£189,577	£189,141	£187,614	£187,178	£187,650	£187,214
Treatment effect sustained (years)	3 (2, 15)	£190,086	£190,086	£189,141	£189,935	£187,178	£188,255	£187,214	£188,119
Utility associated with active POP	0.61 (0.55, 0.67)	£190,072	£190,099	£189,129	£189,153	£187,167	£187,189	£187,203	£187,226
Utility associated with conservative management	0.80 (0.72, 0.88)	£187,289	£192,882	£186,830	£191,452	£185,027	£189,329	£184,964	£189,464
Utility associated with reoperation	0.65 (0.58, 0.71)	£190,058	£190,113	£189,117	£189,165	£187,155	£187,201	£187,191	£187,238
Utility associated with well	0.83 (0.75, 0.91)	£173,578	£206,593	£172,121	£206,161	£169,989	£204,368	£170,129	£204,299
Utility decrement associated with complications that do not require surgical management	0.09 (0.08, 0.10)	£190,086	£190,086	£189,196	£189,087	£187,285	£187,071	£187,319	£187,110
Utility decrement associated with complications that require surgical management	0.19 (0.17, 0.20)	£190,086	£190,086	£189,171	£189,111	£187,349	£187,008	£187,379	£187,050

Abbreviations: AC, Anterior colporrhaphy; NMB, Net monetary benefit; POP, Pelvic organ prolapse; RR, Risk ratio

## Appendix 2 – Results of two-way deterministic sensitivity analyses

Two way deterministic sensitivity analysis showing the NMB associated with synthetic mesh procedures for different values of mesh extrusion and pain complications. (The shaded light blue cells indicate the combination of mesh extrusion and pain complication risks where NMB associated with mesh procedures is greater than with non-mesh procedure [NMB>£190,086], the bolded cells indicate which mesh type would be the most cost-effective at different risk combinations). The base-case values for mesh complications and pain are approximately 30% and 16% over the 15 years, respectively.

**Figure 50:** Findings from the two way deterministic sensitivity analysis

		0%	10%	20%	30%	40%
<b>Synthetic non-absorbable mesh</b>						
<b>Risk of pain complications (over 15 years)</b>	0%	£190,379	£189,574	£188,806	£188,073	£187,374
	5%	£190,176	£189,370	£188,602	£187,870	£187,170
	10%	£189,980	£189,174	£188,406	£187,674	£186,974
	15%	£189,791	£188,986	£188,218	£187,485	£186,786
	20%	£189,610	£188,804	£188,036	£187,304	£186,604
	25%	£189,435	£188,630	£187,862	£187,129	£186,429
	30%	£189,267	£188,462	£187,694	£186,961	£186,261
<b>Synthetic partially absorbable mesh</b>						
<b>Risk of pain complications (over 15 years)</b>	0%	<b>£190,461</b>	£189,621	£188,818	£188,050	£187,315
	5%	<b>£190,258</b>	£189,417	£188,614	£187,846	£187,112
	10%	£190,062	£189,221	£188,418	£187,651	£186,916
	15%	£189,873	£189,033	£188,230	£187,462	£186,727
	20%	£189,692	£188,852	£188,049	£187,281	£186,546
	25%	£189,518	£188,677	£187,874	£187,106	£186,372
	30%	£189,350	£188,509	£187,706	£186,938	£186,204

Source: *health economic analysis*

**Economic analysis for the review question: What is the role for surgery for preventing postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Economic model**

The cost-effectiveness of preventative concomitant surgery for stress urinary incontinence (SUI) surgery for women with anterior prolapse, but no SUI was considered by the committee as an area with likely significant resource implications. The committee discussed the potential cost savings associated with undertaking both procedures at the same time.

The committee acknowledged other prolapse types (that is, apical or a combination of anterior and apical prolapse). However, anterior prolapse was prioritised given its much higher prevalence. Also, the clinical data on other than anterior prolapse was very limited and insufficient to inform de-novo economic modelling.

Existing economic evidence on the cost-effectiveness of preventative concomitant surgery for SUI surgery was limited to 1 USA study. As a result, the committee were of a view that de novo economic modelling would be useful to inform recommendations in this area.

**Methods**

***Interventions assessed***

The economic analysis assessed the cost-effectiveness of 2 treatment approaches 1) anterior repair with preventative concomitant SUI procedure and 2) anterior repair with a deferred option for SUI procedure. The treatments assessed in the economic analysis was determined by the availability of respective clinical data included in the guideline systematic literature review.

The economic analysis considered effective treatments, as demonstrated by the systematic review of clinical evidence for review questions, “What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures for women with SUI” and “What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?”. The treatment modelled for POP was anterior colporrhaphy (AC) and for SUI retropubic mid-urethral sling (RMUS). The committee explained that women could also receive colposuspension and autologous rectus fascial sling for SUI. However, RMUS is the most common procedure for SUI and therefore it was prioritised for the economic modelling.

***Model structure***

A decision-analytic model in the form of a decision-tree was constructed using Microsoft Office Excel 2013. The structure of the model was determined by the availability of clinical data. According to the model structure, hypothetical cohorts of women with POP, but not SUI, were initiated on each of the 2 strategies assessed (AC with preventative concomitant RMUS or AC only with the deferred option for RMUS). During the follow-up, women either were treated successfully (that is, they experienced no SUI symptoms) or women developed de novo SUI symptoms. Women who developed de novo SUI symptoms following an initial surgical procedure had an option to undergo further treatment for their SUI symptoms or alternatively they could opt out for observation and choose not to undergo further surgical treatment. For the purposes of modelling all women were assumed to respond to repeat SUI repair or RMUS following AC only. Note, that only very few women were eligible for repeat SUI or RMUS post AC and the impact of considering these women would have been negligible on the cost-effectiveness.

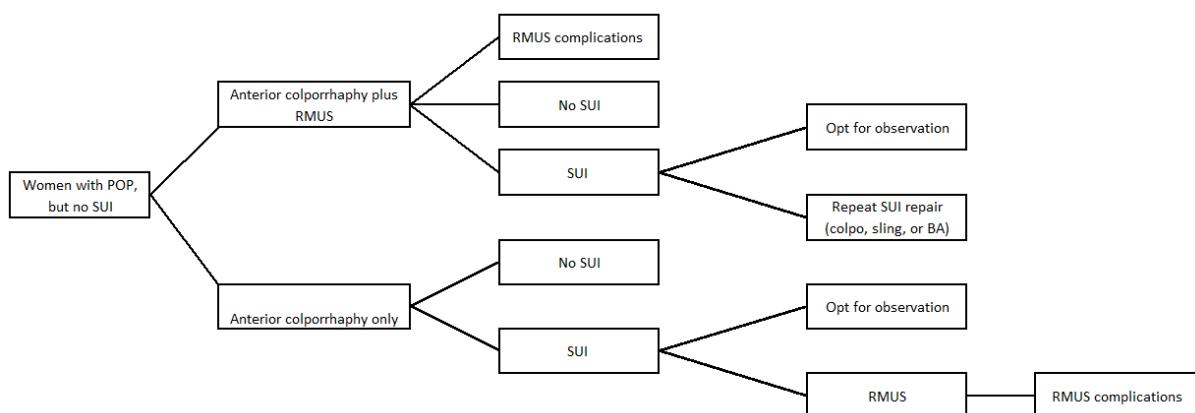
Women could also experience complications. Since in both groups women received AC and the aim of the economic analysis is to capture the incremental costs and outcomes only the complications associated with RMUS procedure were included in the analysis.

The study population comprised of women with POP, but no SUI. Since the aim was to capture the impact of preventative RMUS surgery the underlying assumption was that POP was successfully managed and only the costs and consequences associated with SUI was captured. Moreover, it was anticipated that performing preventative concomitant RMUS procedure will not have a detrimental impact on the outcome of the anterior repair.

The time horizon of the analysis was up to 2 years with complications associated with RMUS captured over the long-term follow-up (that is, 5 to 11 years depending on the complication considered). For more detail see, [Clinical input parameters and overview of methods employed for evidence](#).

A schematic diagram of the decision-tree is presented in Figure 51.

**Figure 51: Schematic diagram of the decision-tree constructed for the assessment of the relative cost-effectiveness of preventative concomitant surgery for stress urinary incontinence in women undergoing anterior pelvic organ prolapse repair**



Abbreviations: BA, bulking agents; COLPO, colposuspension; POP, Pelvic organ prolapse; RMUS, Retropubic mid-urethral mesh sling; SUI, Stress urinary incontinence

### Costs and outcomes considered in the analysis

The economic analysis adopted the perspective of the National Health Service (NHS), as recommended by NICE (NICE, 2014). Costs consisted of intervention costs including AC, RMUS, and also combined AC with RMUS undertaken at the same time; repeat SUI repair (following the failure of initial anterior repair with preventative RMUS); contacts with healthcare professionals, such as consultant urogynaecologist/gynaecologist, and other healthcare costs associated with managing complications including mesh extrusion, infection, de novo symptoms of urge incontinence, and pain. The measure of outcome was the quality-adjusted life year (QALY).

### Clinical input parameters and overview of methods employed for evidence

Clinical input parameters consisted of the risk ratio of developing SUI with AC and concomitant preventative SUI procedure (versus AC with a deferred option of RMUS), the baseline risk of developing SUI symptoms after AC, and the risk of RMUS-related complications.

Efficacy of preventative concomitant RMUS procedure was based on a 1-year follow-up data. The guideline systematic review identified only two RCTs assessing the effectiveness of preventative concomitant SUI surgery (that is, RMUS) versus AC (Van der Ploeg 2016, n=

90; Wei 2012, n= 337) that provided dichotomous efficacy data (that is, change in continence status - number of women with symptomatic incontinence after 12 months). In Van der Ploeg 2016 symptomatic continence was defined by the Dutch version of UDI and in the Wei 2012 symptomatic incontinence was defined as a response of 'moderately' or 'quite a bit' to any of the leakage items on the PFDI.

The baseline probability of SUI risk that was assigned to AC and utilised in the analysis in order to estimate the probability of SUI associated with anterior repair with preventative concomitant RMUS surgery was derived from a study conducted by Alas (2017). This was a retrospective database review of women who had surgery for POP from 2003 to 2013 in the US and developed de novo SUI postoperatively. In this study, a total number of 274 women underwent POP surgery. Out of all women, 157 underwent anterior repairs and out of these 11 developed de novo SUI postoperatively at a mean follow-up of 64 weeks (range 39 to 125 weeks). For the purposes of modelling the 64-week rate was assigned to the AC arm to approximate the risk of postoperative SUI at 1 year.

The risk of SUI post AC with preventative concomitant SUI procedure was estimated by multiplying the baseline risk of SUI associated with AC (estimated from the retrospective observational study, Alas 2017) by the risk ratio at 1 year which was obtained from the guideline systematic review.

The committee explained that if initial RMUS procedure fails only a proportion of women will pursue further SUI repair. The probability of a woman pursuing further SUI surgery after AC with or without preventative RMUS was based on the estimate reported in economic evaluation by Richardson (2013).

Surgical treatment with RMUS is associated with the development of various complications. The clinical review undertaken for this guideline identified a number of prospective cohort studies reporting complication rates. However, their follow-up was limited. For the purposes of modelling a prospective study (where available) with the longest follow-up was chosen for each complication in consultation with the committee. The complications modelled were de-novo urge incontinence, infection, mesh extrusion, and pain.

- For de novo symptoms of urge incontinence, a study by Reich (2011) was used. This was a prospective observational study that evaluated the long-term effectiveness and late complications after treatment of female SUI with tension-free vaginal tape (TVT) in Germany. Over the 9 year follow-up period, a total of 26 women out of 108 experienced de novo urge incontinence symptoms.
- For infection, a study by Kuuva (2006) was used. This prospective observational study was undertaken to examine the long-term effects and effectiveness of the TVT procedure in an unselected group of women with SUI in Finland. In this study 49 out of 129 women reported urinary tract infections over the 6 years.
- For mesh extrusion, a study by Svenningsen (2013) was used. In this study, the authors evaluated the long-term objective and subjective outcomes in a non-selected patient population after the retropubic TVT procedure In Norway. In this prospective observational study out of 327 women, 4 cases of vaginal mesh exposure were reported over 11 years.
- For pain, a study by Holmgreen (2007) was used. In this prospective observational study in Sweden out of 463 women, 66 cases of pain and/or dyspareunia were reported at the average follow-up of 5.2 years.

For the purposes of modelling, a rate of a complication reported in one of the above studies was used to estimate the annual probability of a complication, which was subsequently attached to the RMUS and was used in the economic analysis. No extrapolation of complication rates was undertaken (that is, complications were considered only over the available follow-up as reported in the above observational studies; so for example, the costs

and consequences associated with de novo urge incontinence were considered over 9 years, infection over 6 years, mesh extrusion over 11 years, and pain complications over 5 years).

### ***Utility data and estimation of quality-adjusted life years***

In order to express outcomes in the form of QALYs, the health states of the economic model needed to be linked to appropriate utility scores.

Utility scores represent the health-related quality of life (HRQoL) associated with specific health states on a scale from 0 (death) to 1 (perfect health); they are estimated using preference-based measures that capture people's preferences on the HRQoL experienced in the health states under consideration.

NICE recommends the EuroQol five dimensions questionnaire (EQ-5D) (Brooks 1996) as the preferred measure of HRQoL in adults for use in cost-utility analysis.

Haywood (2008) used EQ-5D-3L alongside a clinical trial of physiotherapy in women with clinical symptoms of urinary incontinence (n=174) in the UK. Participants completed the baseline questionnaires including EQ-5D-3L before randomisation. The mean EQ-5D-3L scores at baseline were stratified according to the number of episodes of incontinence per day including 'not at all', 'a few days', 'about half the week', 'most days', and 'every day'. The mean score for women who were rated 'not at all' for a number of incontinent episodes was used to approximate the utility score for women without SUI and the score for women who were rated 'every day' for a number of incontinent episodes was used to approximate the utility score for women with SUI.

There was a lack of HRQoL data for complications as a result utility weights were obtained from the economic evaluation conducted by Shepherd (2010). In this study values to various complications were assigned by an expert panel of six urogynecologists. Each physician was given articles with the list of utility values for a variety of common medical conditions including associated complications related to medical conditions and surgical procedure. Members of the expert panel were instructed to find a similar condition to each complication associated with SUI and surgical procedures. The published utility for the similar condition was then assigned to each complication in the model. The HRQoL decrements associated with urinary tract infection, pain, mesh exposure, and urge incontinence were estimated based on the utility values reported in the study. For the modelling purposes, it was assumed that infection will resolve within 2 weeks, pain within 24 weeks, de novo symptoms of urgency 12 weeks, and tape/mesh exposure within 24 weeks.

An overview of the study characteristics, the methods used to define health state, and the health-state utility values reported are provided in Table 82.

**Table 82: Summary of methods and utility scores for health states experienced by women with stress urinary incontinence**

<b>Study</b>	<b>Definition of health states</b>	<b>Valuation of method</b>	<b>Population valuing</b>	<b>Health states and corresponding health states</b>	
Haywood 2008	The EQ-5D-3L questionnaire was completed by women (n=174) taking part in a clinical trial of physiotherapy for urinary incontinence. All participants had clinical symptoms of stress and /or urge incontinence. Participants were aged over 18 years. The questionnaire was completed at baseline, 5 weeks, and 6 months follow-up. Mean scores were stratified according to the number of incontinence episodes at baseline i.e. 'not at all', 'a few days', 'about half the week', 'most days', 'every day'. The EQ-5D-3L scores were also stratified according to whether women perceived benefit from physiotherapy or not at 5 months.	Time trade-off	UK general population	No stress urinary incontinence (incontinence episodes, not at all, n=25) Stress urinary incontinence (incontinence episodes, every day, n=41)	0.85 (SD 0.24) 0.75 (SD 0.32)
Shepherd 2010	Utility values for outcomes and complications of surgical treatment including de novo urgency/frequency, urinary tract infection, pain, and mesh extrusion were assigned by an expert panel of six urogynecologists.	NA	NA	Stress urinary incontinence - dry Urinary tract infection Pain Mesh exposure De novo symptoms of urge incontinence	0.985 0.760 0.700 0.695 0.710

### **Cost data**

Intervention costs for the surgical procedures including AC and RMUS were obtained from the NHS reference costs 2016/17 (DHSC 2018):

- AC was assigned a unit cost associated with intermediate open lower genital tract procedures with CC Score 0-2, elective inpatient procedure (MA04C/D).
- RMUS was assigned the unit cost associated with vaginal tape operations for urinary incontinence, with CC Score 0-1, day case (LB51B).

The combination surgery of AC and RMUS was assigned a unit cost associated with major open lower genital tract procedures with CC Score 0-2 (MA03D).

In the analysis it was assumed that women who do not experience SUI symptoms following either AC with/out preventative concomitant SUI surgery will have 1 follow-up visit with consultant urogynaecologist/gynaecologist. The cost of a visit with urogynaecologist/gynaecologist was obtained from NHS reference costs 2016/17 (DHSC 2018). These women were assumed not to incur any other healthcare costs.

Women who experience SUI symptoms and who opt for observation were assumed to have one follow-up consultation with consultant urogynaecologist/gynaecologist and incur the cost associated with the treatment with incontinence pads. The weekly cost of incontinence pads was obtained from NICE 2013 Guideline CG171. The reported unit costs were uplifted to 2016/2017 UK pounds using inflation indexes for hospital and community health services (HCHS) (Curtis & Burns, 2017). Also, women who are managed using incontinence pads were assumed to have six-monthly visits with incontinence nurse specialist (Band 6 Agenda for Change professional) at a unit cost of £44 per hour (Curtis & Burns, 2017). Each consultation was assumed to last half an hour.

Women who experience SUI symptoms following AC and choose to undergo SUI repair (that is, RMUS) were assumed to have 1 follow-up visits with a consultant urogynaecologist/gynaecologist, and an appointment for a urodynamic test, before having surgery; and incur the costs associated with SUI procedure (that is RMUS).

Similarly, women who experience SUI symptoms following AC and RMUS, and choose to undergo further SUI repair were assumed to have 1 follow-up visits with a consultant urogynaecologist/gynaecologist, and an appointment for a urodynamic test, before having surgery; and incur the costs associated with SUI procedure. According to the committee, the SUI procedure could include colposuspension, sling, or bulking agents. For the purposes of modelling, the average cost of the 3 procedures was used.

In consultation with the committee it was assumed that the time between surgeries will be 1 year and in the meantime, women will be managed using incontinence pads.

The costs associated with managing complications were also included. Following RMUS procedure women could experience complications including infection, pain, de novo symptoms of urge incontinence, and mesh extrusion.

According to the committee expert opinion, the management of infection will involve treatment with an antibiotic such as co-amoxiclav 250/125mg every 8 hours for approximately 2 weeks (BNF 2018). The unit cost of co-amoxiclav was obtained from the Drug Tariff, 2018.

Pain management was assumed to comprise of treatment with paracetamol (4g per day), codeine (240mg per day), co-codamol (120/4000 mg per day) and pregabalin (150 mg per day) (BNF, 2018). The unit costs of drugs were obtained from the Drug Tariff, 2018. The average cost of the above pharmacological treatments was used.

In most cases, de novo symptoms of urgency will be successfully managed with a combination of anticholinergic drug and bladder training. The anticholinergic drug modelled was oxybutynin 5mg 2-3 times/day. The unit cost of oxybutynin was obtained from the Drug Tariff, 2018. The cost of bladder training was obtained from NICE 2013 Guideline CG171 and included six sessions with a physiotherapist with the initial session lasting one hour and all subsequent sessions lasting half an hour each. The cost estimate also included consumables such as gloves, KY Jelly, wipes and paper towels. The reported unit costs were uplifted to 2016/2017 UK pounds using inflation indexes for hospital and community health services (HCHC) (Curtis & Burns, 2017).

The management of mesh extrusion was assigned the unit cost associated with minor lower genital tract procedures, elective inpatient (MA22Z) and was obtained from NHS reference costs 2016/17 (DHSC, 2018).

In addition, all women experiencing RMUS-related complications were assumed to have 2 visits with a consultant urogynaecologist/gynaecologist. The unit cost of urogynaecologist/gynaecologist was obtained from NHS reference costs 2016/17 (DHSC, 2018).

All future costs and outcomes were discounted at 3.5% as recommended by NICE (2013).

Cost data are presented in Table 83 which also reports the mean (deterministic) values of all input parameters utilised in the economic model and provides information on the distributions assigned to specific parameters in probabilistic sensitivity analysis.

**Table 83: Input parameters utilised in the economic model of strategies to prevent postoperative stress urinary incontinence in women undergoing anterior pelvic organ prolapse repair**

Input parameter	Deterministic value	Probabilistic distribution	Source of data - comments
Probability of SUI post anterior repair only at 64 weeks	0.07	Beta distribution alpha = 11; beta = 146	Alas 2017
The risk ratio of SUI for combined POP and SUI procedure versus single POP procedure	0.510	Log-normal distribution Estimated using 95% CI: 0.34, 0.77	Guidelines systematic review
Probability of choosing to undergo SUI procedure after a failure of initial procedure	0.36	Beta distribution SE: 20% of mean value (assumption)	Richardson 2013
RMUS-related complications		Beta distribution	
De novo urge incontinence – 9 years	24%	alpha = 26; beta = 82	Reich 2011
Infection – 6 years	38%	alpha = 49; beta = 80	Kuova 2006
Mesh extrusion – 11 years	1%	alpha = 4; beta = 323	Svenningsen 2013
Pain – 5 years	14%	alpha = 66; beta = 397	Holmgreen 2007
Intervention costs – 2016/17 prices		Normal distribution	
AC	£2,234	Fitted using upper and lower range values and submissions. SD: £30.07	Intermediate Open Lower Genital Tract Procedures with CC Score 0-2, NHS reference costs 2016/17, elective inpatient, MA04C/D (DHSC, 2018).
Combined AC and RMUS procedure	£2,776	Normal distribution Fitted using upper and lower range values and submissions. SD: £34.21	Major Open Lower Genital Tract Procedures with CC Score 0-2, NHS reference costs 2016/17, elective inpatient, MA03D (DHSC, 2018).
RMUS	£1,404	Log-normal distribution Fitted using upper and lower range values and submissions. SD: £30.82	Vaginal tape operations for urinary Incontinence, with CC Score 0-1, day case, LB51B, NHS reference costs 2016/17 (DHSC, 2018).

<b>Input parameter</b>	<b>Deterministic value</b>	<b>Probabilistic distribution</b>	<b>Source of data - comments</b>
Cost of repeat SUI procedure	£4,027	NA (dependant on distribution for colposuspension, bulking agents, and sling)	Colposuspension and sling was assigned the unit cost associated with a complex open, upper or lower genital tract procedures, MA01Z, elective inpatient, NHS reference costs 2016/17. Bulking agents was assigned the unit cost associated with intermediate endoscopic, prostate or bladder neck procedures (male and female), with CC Score 0-1, day case, NHS reference costs 2016/17. The average unit cost of colposuspension, bulking agents, and sling was assigned to the cost of repeat SUI procedure.
Management with the incontinence pads (per annum)	£445	Gamma distribution SE: 20% of mean value (assumption)	The cost of incontinence pads was obtained from the NICE Clinical Guideline (CG171, Urinary Incontinence in women: management, 2013). The reported unit costs were uplifted to 2016/2017 UK pounds using inflation indexes for hospital and community health services (HCHC) (Curtis & Burns, 2017). Also, women on incontinence pads were modelled to have regular six-monthly visits with a specialist nurse (Band 6 Agenda for Change professional) at a unit cost of £44 per hour (Curtis & Burns, 2017). Each consultation was assumed to last half an hour.
Management of complications (per episode) Urge incontinence Infection Pain Mesh extrusion	£401.10 £288.34 £302.64 £1,869.00	Gamma distribution SE: 20% of mean value (assumption)	De novo symptoms of urgency Combination of anticholinergic drugs and bladder training was modelled. An anticholinergic drug such as oxybutynin 5mg 2-3 times per day. The unit cost of oxybutynin 5mg, 56 tbs., was £1.19 (Drug Tariff, 2018). The unit cost for bladder training was obtained from the NICE Clinical Guideline (CG171, Urinary Incontinence in women: management, 2013). The unit cost of £94 included physiotherapy visits and consumables. The reported unit costs were uplifted to 2016/2017 UK pounds using inflation indexes for hospital and community health services (HCHC) (Curtis & Burns, 2017). Infection

Input parameter	Deterministic value	Probabilistic distribution	Source of data - comments
			<p>Co-amoxiclav 250/125mg every 8 hours for approximately 2 weeks (BNF, 2018). The unit cost of co-amoxiclav was £1.67 for 21tbs. (Drug Tariff, 2018).</p> <p>Pain</p> <p>Pharmacological treatment included paracetamol (4g per day), codeine (240mg per day), co-codamol (120/4000mg per day), and pregabalin (150mg per day) (BNF, 2018). The unit cost of paracetamol (500 mg, 32 tbs., £0.31), codeine (60mg, 28 tbs., £1.32), co-codamol (15/500 mg, 100 tbs., £4.93) and pregabalin (150 mg, 56 tbs., £5.88) (Drug Tariff, 2018). The average of all the above pharmacological treatments was used.</p> <p>Mesh extrusion</p> <p>Minor Lower Genital Tract Procedures, elective inpatient, MA22Z, NHS reference costs 2016/17 (DHSC, 2018).</p> <p>All women experiencing complications were modelled to have 2 consultations with urogyynaecologist/gynaecologist. A unit cost of a consultation with urogyynaecologist/gynaecologist was £154 and £130 for initial and follow-up consultation, respectively; NHS reference costs 2016/17 (DHSC, 2018).</p>
Utility weights			
No SUI	0.850		
SUI	0.750	Beta distribution SE: 20% of mean value (assumption)	The utility weights for SUI and no SUI were obtained from Haywood et al., 2008. The utility decrements associated with complications were obtained from Shepherd et al., 2010. The utility decrement was calculated assuming that symptoms of urge incontinence will last for 12 weeks, infection for 2 weeks, pain for 2 weeks, and tape mesh erosion for 24 weeks. So for example, for urge incontinence 0.275 represents the annual utility decrement. To calculate the utility decrement over 12 weeks the annual decrement of 0.275 is multiplied by the weight of 12/52 (that is, utility decrement experienced for 12 weeks out of 52 weeks).
Complications decrement			
Urge incontinence	0.275		
Infection	0.225		
Pain	0.285		
Mesh extrusion	0.290		

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Input parameter	Deterministic value	Probabilistic distribution	Source of data - comments
Discount rate for costs and outcomes	3.5%	NA	NICE (2013)

Abbreviations: AC, Anterior colporrhaphy; CI, Confidence interval; POP, Pelvic organ prolapse; RMUS, Retropubic mid-urethral mesh sling; SD, Standard deviation; SE, Standard error; SUI, Stress urinary incontinence.

## Data analysis and presentation of the results

Two methods were employed to analyse the input parameter data and present the results of the economic analysis.

First, a deterministic analysis was undertaken, where data are analysed as point estimates; results are presented as mean total costs and QALYs associated with each treatment option are assessed. Relative cost effectiveness between alternative treatments was estimated using incremental analysis: all options were ranked from most to least effective. Options that were dominated by absolute dominance (that is, they were less effective and more costly than one or more other options) or by extended dominance (that is, they were less effective and more costly than a linear combination of two alternative options) were excluded from further analysis. Subsequently, incremental cost-effectiveness ratios (ICERs) were calculated for all pairs of consecutive options remaining in the analysis.

ICERs expressed the additional cost per additional unit of benefit associated with one treatment option relative to its comparator. Estimation of such a ratio allowed consideration of whether the additional benefit were worth the additional cost when choosing one treatment option over another.

The treatment option with the highest ICER below the cost-effectiveness threshold was deemed to be the most cost-effective option.

For each treatment option net monetary benefit (NMB) was also estimated which is found by multiplying QALYs for each alternative by the threshold value and subtracting the cost associated with the intervention in question. The higher value of NMB is preferred.

One-way sensitivity analyses explored impact of varying:

- the relative risk of SUI combined repair vs. deferred SUI repair;
- the baseline risk of SUI post AC;
- the probability of opting for SUI repair following an initial procedure;
- the incidence of mesh complications;
- the intervention costs;
- the cost of treatment with incontinence pads;
- the cost of complications;
- the utility values.

In addition to deterministic analysis, a probabilistic analysis was also conducted.

In this case, all model input parameters were assigned probability distributions (rather than being expressed as point estimates), to reflect the uncertainty characterising the available clinical and cost data. Subsequently, 10,000 iterations were performed, each drawing random values out of the distributions fitted onto the model input parameters. This exercise provided more accurate estimates of mean costs and benefits for each intervention assessed (averaging results from the 10,000 iterations), by capturing the non-linearity characterising the economic model structure (Briggs 2006).

The relative risk of SUI post combined AC and RMUS repair (versus AC with a deferred option of RMUS) was assigned a log-normal distribution. The baseline risk of SUI post AC was assigned a beta distribution. The intervention costs for AC, RMUS, and a combination surgery of AC and RMUS were assigned a normal distribution estimate using lower and upper range values and a number of submissions reported alongside NHS reference cost 2016/17 (DHSC, 2018). Beta distributions were also assigned to utility values, using the method of moments.

Results of the probabilistic analysis were presented in the form of cost-effectiveness acceptability curves (CEACs), which demonstrated the probability of each treatment option being the most cost-effective among the strategies assessed at different levels of willingness-to-pay per unit of effectiveness (that is, at different cost-effectiveness thresholds the decision maker may set).

## Economic modelling results

### **Results of the deterministic analysis**

According to deterministic analysis, AC with a deferred option of RMUS was a dominant strategy when compared with AC with a preventative concomitant RMUS procedure. This was mainly because the baseline risk of SUI following anterior repair was low, combined surgery (AC plus RMUS) was associated with higher intervention costs, and also more women were exposed to RMUS-related complications following AC with preventative concomitant RMUS procedure.

Table 84 provides mean costs and QALYs for every strategy assessed in the economic analysis. It also provides NMB, which indicates that anterior repair with the deferred option for RMUS results in the highest NMB at NICE lower cost-effectiveness threshold of £20,000 per QALY.

**Table 84: Mean costs and QALYs for each strategy to prevent postoperative stress urinary incontinence in women undergoing anterior pelvic organ prolapse repair - results per woman.**

Treatment option	Mean total costs	Mean total QALYs	NMB	Cost effectiveness (cost/QALY)
AC with preventative concomitant RMUS	£3,218	1.619	£29,162	Anterior repair with deferred option for RMUS is dominant option
AC with a deferred option for RMUS	£2,447	1.633	£30,213	

Abbreviations: AC, Anterior colporrhaphy; NMB, Net monetary benefit; QALY, Quality adjusted life year; RMUS, Retropubic mid-urethral mesh sling.

There was uncertainty pertaining to the baseline risk of SUI post AC. However, the sensitivity analyses indicated only if the risk of SUI post AC was 0.69 (base-case: 0.07) the ICER of AC with a preventative concomitant RMUS would be just below the lower NICE cost-effectiveness threshold of £20,000 per QALY. There was also uncertainty pertaining to the probability of choosing to undergo further SUI repair following AC with a deferred option for RMUS. In the base case analysis, it was assumed that only 36% of women with SUI following AC will choose to undergo RMUS. However, in the sensitivity analysis where it was assumed that even if all women following AC were to undergo subsequent RMUS, AC with a deferred option of RMUS remained the dominant option.

There was uncertainty as to what the subsequent SUI repair would be following the occurrence of SUI post AC with preventative concomitant RMUS. In the base case analysis, the costs were modelled as the average of colposuspension, bulking agents, or a sling procedure. Moreover, there was a lack of unit cost data for a sling procedure and in consultation with the committee, it was modelled to be the same as for the colposuspension. Nevertheless, the sensitivity analysis where the cost of subsequent SUI procedure was varied did not change the conclusions. This was because only a very few women require further SUI repairs.

Overall, the results were robust to changes in all other model inputs including the risk ratio of SUI associated with AC with the preventative concomitant RMUS (versus AC with a deferred option for RMUS), the risk of RMUS-related complications (including, urge incontinence, mesh extrusion, pain, and infection); intervention costs (including, the cost of AC, combined

AC and RMUS procedure, and RMUS procedure only); the costs associated with managing complications, and utility values.

The deterministic sensitivity analyses are summarised in Table 85.

**Table 85: Summary of the deterministic sensitivity analyses.**

Model input	Base case value and ranges tested	ICER using lower estimate	ICER using upper estimate
SUI post AC	(0.07-0.90)	-£55,254	£12,608
Risk ratio of AC with preventative concomitant RMUS (vs. AC with a deferred option for RMUS)	(0.34-0.77)	-£61,056	-£48,733
Probability of subsequent SUI repair after the failure of the initial procedure	(0.10-0.90)	-£53,145	-£60,039
Cost of AC	(£1,117-£3,351)	-£135,322	£24,777
Cost of AC plus RMUS	(£1,388-£4,164)	£44,199	-£154,743
Cost of RMUS	(£702-£2,106)	-£56,457	-£54,088
Cost of repeat SUI repair	(£2,014-£10,068)	-£53,539	-£64,803
The annual cost of management with the incontinence pads	(£245-£734)	-£56,017	-£54,528
The annual risk of urge incontinence	(0.02-0.05)	-£95,137	-£41,364
The annual risk of infection	(0.04-0.11)	-£57,417	-£53,712
The annual risk of mesh extrusion	(0.001-0.002)	-£57,347	-£53,397
The annual risk of pain	(0.01-0.04)	-£56,615	-£54,114
Cost of managing urinary tract infection	(£144-£433)	-£51,845	-£58,700
Cost of managing pain	(£151-£454)	-£53,956	-£56,588
Cost of managing urge incontinence	(£201-£602)	-£52,252	-£58,293
Cost of managing mesh extrusion	(£935-£2,804)	-£54,603	-£54,938
Utility of SUI	(0.60-0.99)	-£29,373	-£109,184
Utility of no SUI	(0.68-0.99)	-£73,392	-£29,934
Utility decrement for infection	(0.18-0.27)	-£57,644	-£55,731
Utility decrement for pain	(0.23-0.34)	-£56,347	-£55,484
Utility decrement for urge incontinence	(0.22-0.33)	-£68,334	-£57,469
Utility decrement for mesh extrusion	(0.23-0.35)	-£56,353	-£55,485

Abbreviations: AC, Anterior colporrhaphy; ICER, Incremental cost-effectiveness ratio; RMUS, Retropubic mid-urethral mesh sling; SUI, Stress urinary incontinence.

### **Results of the probabilistic analysis**

Conclusions of the probabilistic analysis were very similar to those of the deterministic analysis. The AC with a preventative concomitant RMUS (versus AC with a deferred option for RMUS) remained the dominant option (that is, it resulted in lower costs and higher QALYs) when mean costs and QALYs derived from 10,000 iterations were estimated. Table 86 provides the results of the probabilistic analysis.

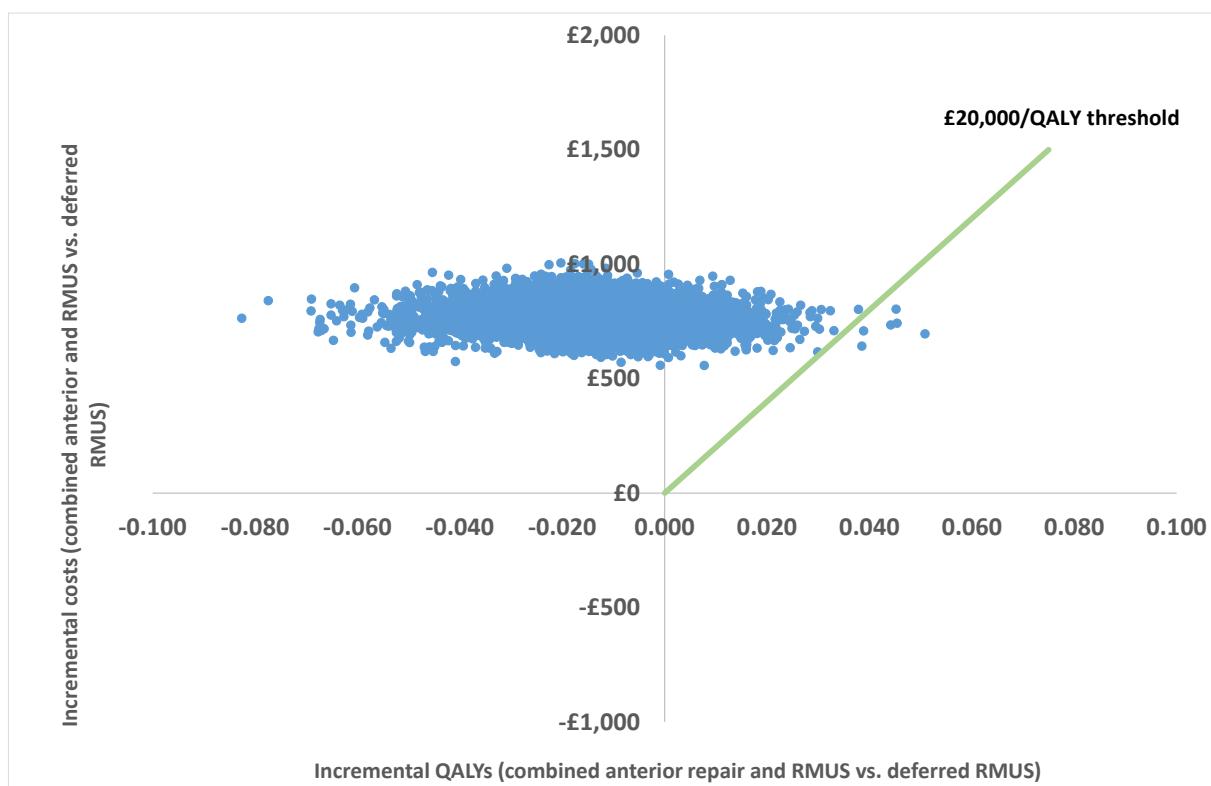
**Table 86: Mean costs and QALYs for each strategy to prevent postoperative stress urinary incontinence in women undergoing anterior pelvic organ prolapse repair – results of the probabilistic analysis per woman.**

Treatment option	Mean total costs	Mean total QALYs	NMB	Cost effectiveness (cost/QALY)
AC with preventative concomitant RMUS	£3,220	1.617	£29,123	AC with a deferred option for RMUS is dominant option
AC with a deferred option for RMUS	£2,446	1.631	£30,179	

Abbreviations: AC, Anterior colporrhaphy; NMB, Net monetary benefit; QALY, Quality adjusted life year; RMUS, Retropubic mid-urethral mesh sling.

Figure 52 provides the cost-effectiveness plane showing the incremental costs and QALYs of AC with preventative concomitant RMUS procedure (versus AC with a deferred option for RMUS procedure). It can be seen that most of the simulated costs and QALYs are distributed across North West and North East quadrants indicating that AC with the preventative concomitant RMUS procedure results in higher costs and lower QALYs (that is, it is dominated) or results in higher costs and higher QALYs.

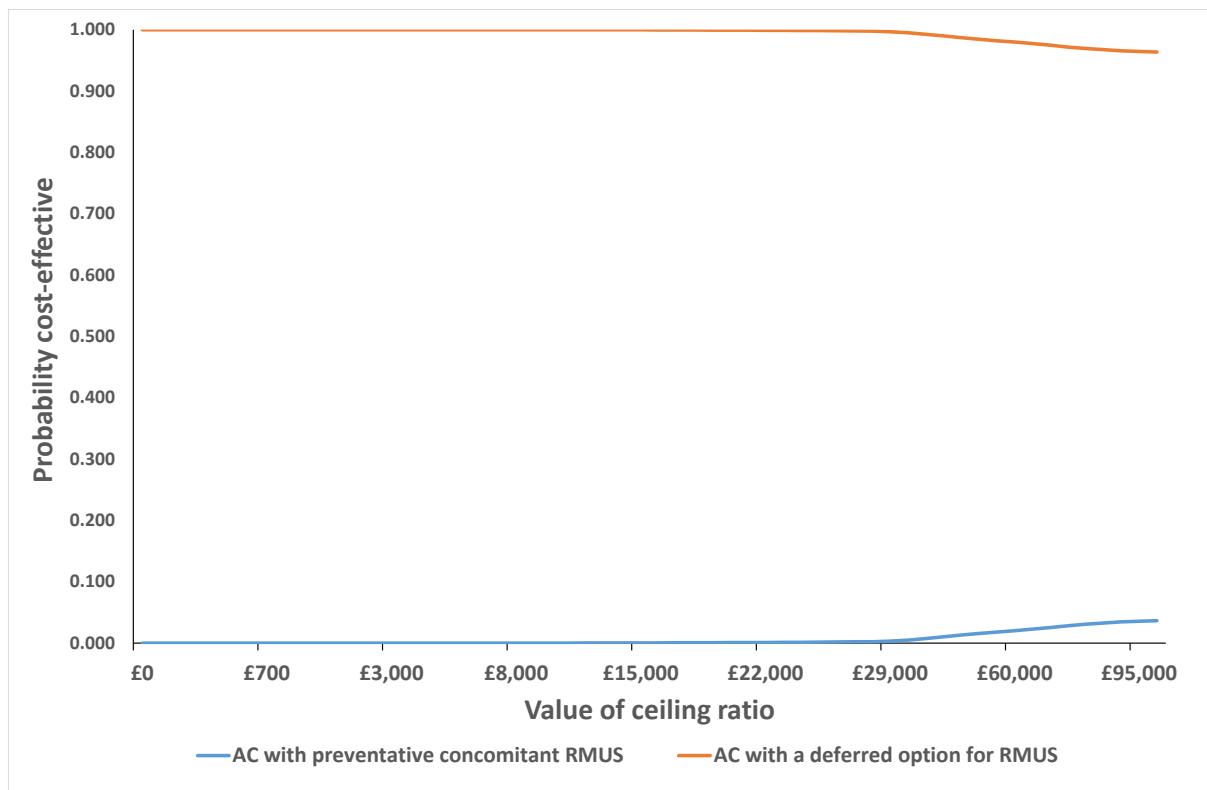
**Figure 52: Cost-effectiveness plane of AC with preventative concomitant RMUS (versus AC with a deferred option for RMUS) – incremental costs and QALYs per woman with anterior pelvic organ prolapse.**



Abbreviations: AC: Anterior colporrhaphy; QALY: Quality adjusted life year; RMUS: Retropubic mid-urethral sling

Figure 53 shows the CEACs generated for each strategy assessed in the economic model. At the lower NICE cost-effectiveness threshold of £20,000 per QALY (NICE, 2008b) the probability of AC with a preventative concomitant RMUS being cost-effective was below 0.01 when taking into account the uncertainty associated with model inputs.

**Figure 53: CEACs of all surgical strategies assessed in the economic analysis.**



Abbreviations: AC, Anterior colporrhaphy; CEAC, Cost-effectiveness acceptability curve; RMUS, Retropubic mid-urethral sling; SUI, Stress urinary incontinence.

### Discussion – limitations of the analysis

The results of the economic analysis suggested that AC with a deferred option for RMUS was likely to be the dominant strategy in women having surgery for anterior pelvic organ prolapse when compared with AC with a preventative concomitant RMUS.

The cost-effectiveness of AC with a deferred option for RMUS was attributed to a number of factors: low baseline risk of SUI post AC, higher intervention cost of a combined procedure, and also more women being exposed to RMUS-related complications including urinary tract infections, de novo urge incontinence symptoms, mesh extrusion, and pain.

The economic analysis considered only data on effectiveness at 1 year which was the longest follow-up identified by the guideline systematic review in this population. However, even using the more optimistic estimate for the effectiveness of AC with a preventative concomitant RMUS when compared with AC with a deferred option for RMUS (which could potentially be expected using the longer term follow-up) the ICER of AC with a preventative concomitant RMUS was still well above the upper NICE cost-effectiveness threshold of £30,000 per QALY.

There was high uncertainty pertaining to the baseline risk of SUI post AC. However, the sensitivity analysis indicated that the baseline risk would need to be approximately 70% (base-case 7%, 10 times higher) for the AC with a preventative concomitant RMUS to be the cost-effective strategy.

The analysis attempted to capture the RMUS-related complications including de novo urge incontinence, urinary tract infection, mesh extrusion, and pain over a long-term follow-up. However, the rates of complications were obtained from relatively small prospective non-UK observational studies. Nevertheless, the sensitivity analyses indicated that the results were robust to changes in the complication incidence rates. Also, the committee advised that the

complication rates used in the analysis are in line with what they would expect the rates to be in the clinical practice in the UK setting.

Overall, the findings were robust to changes in model inputs and seem to support a view that a combined surgical procedure to treat both anterior prolapse and SUI potentially exposes more women to an unnecessary surgery which have important consequences in terms of costs and health-related quality of life. Also, the potential for the cost-effectiveness of AC with preventative concomitant RMUS is reduced since not all women following the occurrence of SUI post AC require (choose to have) further surgery for SUI.

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**NICE 2013**

NICE. Urinary incontinence in women: management. Clinical guideline [CG171], Published date: September 2013

**Reich 2011**

Reich, A., Kohorst, F., Kreienberg, R., Flock, F., Long-term results of the tension-free vaginal tape procedure in an unselected group: a 7-year follow-up study, *Urology*, 78, 774-777, 2011

**Richardson 2013**

Richardson, M.L., Elliott, C. S., Shaw, J. G., Comiter, C. V., Chen, B., Sokol, E. R., To sling or not to sling at time of abdominal sacrocolpopexy: a cost-effectiveness analysis, *The Journal of urology*, 190, 1306-1312, 2013

**Shepherd 2010**

Shepherd, J. P., Lowder, J. L., Jones, K. A., Smith, K. J., Retropubic and transobturator midurethral slings: a decision analysis to compare outcomes including efficacy and complications, *International urogynecology journal*, 21, 787-793, 2010

**Svenningsen 2013**

Svenningsen, R., Staff, A. C., Schiøtz, H. A., Western, K., Kulseng-Hanssen, S., Long-term follow-up of the retropubic tension-free vaginal tape procedure, *International urogynecology journal*, 24, 1271-1278, 2013

**Economic analysis for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

No economic analysis was conducted for this review question.

## Appendix K – Excluded studies

**Excluded studies for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

### Clinical studies

**Table 87: Excluded clinical studies: Effectiveness data**

Study	Reason for Exclusion
Posterior infracoccygeal sacropexy for vaginal vault prolapse (Structured abstract), Health Technology Assessment Database, 2, 2005	Case series: Health Technology Assessment report.
Different operations for patients with third degree uterine prolapse complicated with chronic gastritis: clinical efficacy and impact on abdominal incision, World Chinese journal of digestology, 25, 1663-1666, 2017	Publication not in English
Prolift mesh versus polypropylene mesh in the whole pelvic floor reconstruction, Chinese journal of tissue engineering research, 20, 5122-5128, 2016	Publication not in English
Systematic review of the efficacy and safety of using mesh or grafts in surgery for pelvic organ prolapse (Project record), Health Technology Assessment Database, 2007	Pre-report for NICE IPG
Vault or Uterine prolapse surgery Evaluation two parallel randomised controlled trials of surgical options for upper compartment (uterine or vault) pelvic organ prolapse (VUE) (Project record), Health Technology Assessment Database, 2014	Protocol registration - no outcome data
Mesh sacrocolpopexy for vaginal vault prolapse (Structured abstract), Health Technology Assessment Database, 2, 2007	Health Technology Assessment review
Aarts, Johanna Wm, Nieboer, Theodoor E, Johnson, Neil, Tavender, Emma, Garry, Ray, Mol, Ben Willem J, Kluivers, Kirsten B, Surgical approach to hysterectomy for benign gynaecological disease, Cochrane Database of Systematic Reviews, 2015	Population do not meet criteria - women with any benign pathology, not specifically POP
Abdelmonem, A. M., Vaginal length and incidence of dyspareunia after total abdominal versus vaginal hysterectomy, European Journal of Obstetrics, Gynecology, & Reproductive Biology Eur J Obstet Gynecol Reprod Biol, 151, 190-2, 2010	Prospective cohort study, women did not have POP
Abed, H., Rahn, D. D., Lowenstein, L., Balk, E. M., Clemons, J. L., Rogers, R. G., Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: A systematic review, International Urogynecology Journal, 22, 789-798, 2011	Systematic review - references checked for inclusion
Abrao, M. S., Andres, M. P., Borrelli, G. M., Advances on minimally invasive approach for benign total hysterectomy: A systematic review, F1000Research, 6 (no pagination), 2017	Systematic review - references checked for inclusion

Study	Reason for Exclusion
Aka, N., Kose, G., Gonenc, I., Api, M., Tissue trauma after vaginal hysterectomy and colporrhaphy versus abdominal hysterectomy: A randomised controlled study, Australian and New Zealand Journal of Obstetrics and Gynaecology, 44, 328-331, 2004	Unclear how many women had prolapse. Outcomes not relevant
Ala-Nissila, S., Haarala, M., Jarvenpaa, T., Makinen, J., Long-term follow-up of the outcome of supracervical versus total abdominal hysterectomy, International Urogynecology Journal, 28, 299-306, 2017	Population do not meet inclusion criteria - women did not have prolapse
Ali, S, Han, Hc, Lee, Lc, A prospective randomized trial using Gynemesh PS (trademark) for the repair of anterior vaginal wall prolapse (Abstract number 292), International Urogynecology Journal, 17 Suppl 2, S221, 2006	conference abstract
Allahdin, S., Glazener, C., Bain, C., A randomised controlled trial evaluating the use of polyglactin mesh, polydioxanone and polyglactin sutures for pelvic organ prolapse surgery, Journal of Obstetrics & Gynaecology, 28, 427-31, 2008	No relevant outcome data Intervention not relevant - study compares different sutures not mesh types
Al-Nazer, Ma, Ismail, Wa, Gomaa, Ia, Comparative study between anterior colporraphy versus vaginal wall repair with mesh for management of anterior vaginal wall prolapse (Abstract number 84), International Urogynecology Journal and Pelvic Floor Dysfunction, 18, S49-s50, 2007	Abstract - full report is included (El Nazer 2012)
Altman, D., Elmer, C., Kiilholma, P., Kinne, I., Tegerstedt, G., Falconer, C., Nordic Transvaginal Mesh, Group, Sexual dysfunction after trocar-guided transvaginal mesh repair of pelvic organ prolapse, Obstetrics & GynecologyObstet Gynecol, 113, 127-33, 2009	Non-comparative study prospective study
Altman, D., Mooller Bek, K., Mikkola, T., Gunnarsson, J., Ellstrom Engh, M., Falconer, C., Intra-and perioperative morbidity following pelvic organ prolapse repair using a transvaginal suture capturing mesh device compared to trocar guided transvaginal mesh and traditional colporraphy, Neurourology and Urodynamics, 32 (6), 873-874, 2013	Conference abstract
Amo, E, Burcet, G, Vellve, K, Hernandez, JI, Carreras, R, Quality of life and patients satisfaction after genital prolapse surgery: vaginal hysterectomy versus mesh hysteropexy (Abstract number 189), Proceedings of the 44th Annual Meeting of the International Continence Society (ics), 2014 Oct 20-24, Rio de Janeiro, Brazil, 2014	Conference abstract
Amo, E, Hernandez, JI, Checa, Ma, Banos, N, Gonzalez, M, Basil, C, Surgical treatment of genital prolapsed with tissue fixation system (Abstract number 284), Proceedings of the 42nd annual meeting of the international continence (ics), 2012 oct 15 to 19, beijing, china, 2012	Conference abstract of non-comparative data
Amo, E, Hernandez, JI, Nicolau, P, Miralpeix, E, Carreras, R, Genital prolapse surgical treatment: always hysterectomy? Preliminary results of a trial (Abstract number 658), Proceedings of the 43rd Annual Meeting of the International Continence Society (ics), 2013 Aug 26-30, Barcelona, Spain, 2013	Conference abstract
Anand, M., Weaver, A. L., Fruth, K. M., Borah, B. J., Klingele, C. J., Gebhart, J. B., Perioperative Complications and Cost of Vaginal, Open Abdominal, and Robotic Surgery for Apical Vaginal Vault Prolapse, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 23, 27-35, 2017	Retrospective study

Study	Reason for Exclusion
Anand, M., Weaver, A. L., Fruth, K. M., Gebhart, J. B., Factors Influencing Selection of Vaginal, Open Abdominal, or Robotic Surgery to Treat Apical Vaginal Vault Prolapse, Female pelvic medicine & reconstructive surgery, 22, 236-42, 2016	Retrospective study
Anand, M., Weaver, A. L., Fruth, K. M., Trabuco, E. C., Gebhart, J. B., Symptom Relief and Retreatment After Vaginal, Open, or Robotic Surgery for Apical Vaginal Prolapse, Female pelvic medicine & reconstructive surgery, 24, 24, 2017	Retrospective study
Anand, M., Woelk, J. L., Weaver, A. L., Trabuco, E. C., Klingele, C. J., Gebhart, J. B., Perioperative complications of robotic sacrocolpopexy for post-hysterectomy vaginal vault prolapse, International Urogynecology Journal, 25, 1193-200, 2014	Retrospective study
Andersen, L. L., Ottesen, B., Alling Moller, L. M., Gluud, C., Tabor, A., Zobbe, V., Hoffmann, E., Gimbel, H. M., Subtotal versus total abdominal hysterectomy: Randomized clinical trial with 14-year questionnaire follow-up, American Journal of Obstetrics and Gynecology, 212, 758.e1-758.254, 2015	Population do not meet inclusion criteria - women do not have prolapse
Andersen, L. L., Zobbe, V., Ottesen, B., Gluud, C., Tabor, A., Gimbel, H., Five-year follow up of a randomised controlled trial comparing subtotal with total abdominal hysterectomy, BJOG: An International Journal of Obstetrics and Gynaecology, 122, 851-857, 2015	Population do not meet inclusion criteria - women did not have prolapse
Anger, J. T., Mueller, E. R., Tarnay, C., Smith, B., Stroupe, K., Rosenman, A., Brubaker, L., Bresee, C., Kenton, K., Robotic compared with laparoscopic sacrocolpopexy: A randomized controlled trial, Obstetrics and Gynecology, 123, 5-12, 2014	Intervention not relevant - compared Robotic to laparoscopic sacrocolpopexy
Anger, J.T., Litwin, M.S., Wang, Q., Pashos, C.L., Rodriguez, L.V., The effect of concomitant prolapse repair on sling outcomes, Journal of Urology, 180, 1003-1006, 2008	Retrospective study
Antiphon, P., Elard, S., Benyoussef, A., Fofana, M., Yiou, R., Gettman, M., Hoznek, A., Vordos, D., Chopin, D. K., Abbou, C. C., Laparoscopic promontory sacral colpopexy: is the posterior, recto-vaginal, mesh mandatory?, European urology, 45, 655-61, 2004	Retrospective study
Antosh, D. D., Grotzke, S. A., McDonald, M. A., Shveiky, D., Park, A. J., Gutman, R. E., Sokol, A. I., Short-term outcomes of robotic versus conventional laparoscopic sacral colpopexy, Female pelvic medicine & reconstructive surgery, 18, 158-61, 2012	Retrospective study
Antovska, S. V., Dimitrov, D. G., Vaginosacral colpopexy (VSC)--a new modification of the Mc Call operation using vaginosacral ligaments as autologous sliding grafts in posthysterectomy vault prolapse, Bratislavské Lekarske Listy, 107, 62-72, 2006	Non-comparative cohort study - all participants underwent the same procedure
Baessler, K., Aigmuller, T., Albrich, S., Anthuber, C., Finas, D., Fink, T., Funfgeld, C., Gabriel, B., Henschler, U., Hetzer, F. H., Hubner, M., Junginger, B., Jundt, K., Kropshofer, S., Kuhn, A., Loge, L., Nauman, G., Peschers, U., Pfiffer, T., Schwandner, O., Strauss, A., Tunn, R., Viereck, V., Diagnosis and Therapy of Female Pelvic Organ Prolapse. Guideline of the DGGG, SGGG and OEGGG (S2e-Level, AWMF Registry Number 015/006, April 2016), Geburtshilfe und Frauenheilkunde, 76, 1287-1301, 2016	Clinical guideline - insufficient data to be used

Study	Reason for Exclusion
Bai, S. W., Jung, H. J., Jeon, M. J., Chung, D. J., Kim, S. K., Kim, J. W., Surgical repair of anterior wall vaginal defects, International Journal of Gynaecology & ObstetricsInt J Gynaecol Obstet, 98, 147-50, 2007	Cohort study
Bai, S. W., Kim, E. H., Shin, J. S., Kim, S. K., Park, K. H., Lee, D. H., A comparison of different pelvic reconstruction surgeries using mesh for pelvic organ prolapse patients, Yonsei Medical JournalYonsei Med J, 46, 112-8, 2005	Retrospective study
Baker, R, A randomised controlled trial of trans-anal versus trans-vaginal repair for symptomatic anterior rectocoele (Trials Registry number: ISRCTN58192664), ISRCTN register (available at: <a href="http://www.controlled-trials.com/ISRCTN58192664">http://www.controlled-trials.com/ISRCTN58192664</a> ), 2006	Trial registration - study abandoned due to insufficient funding
Balzarro, M., Rubilotta, E., Porcaro, A. B., Trabacchin, N., Sarti, A., Cerruto, M. A., Siracusano, S., Artibani, W., Long-term follow-up of anterior vaginal repair: A comparison among colporrhaphy, colporrhaphy with reinforcement by xenograft, and mesh, Neurourology & UrodynamicsNeurourol Urodyn, 02, 02, 2017	Retrospective study
Balzarro, M., Rubilotta, E., Porcaro, A. B., Trabacchin, N., Sarti, A., Cerruto, M. A., Siracusano, S., Artibani, W., Long-term follow-up of anterior vaginal repair: A comparison among colporrhaphy, colporrhaphy with reinforcement by xenograft, and mesh, Neurourology and Urodynamics, 37, 278-283, 2018	Retrospective study
Barber, M. D., Amundsen, C. L., Paraiso, M. F., Weidner, A. C., Romero, A., Walters, M. D., Quality of life after surgery for genital prolapse in elderly women: obliterative and reconstructive surgery, International Urogynecology Journal, 18, 799-806, 2007	Non randomised, prospective study
Barber, M. D., Brubaker, L., Burgio, K. L., Richter, H. E., Nygaard, I., Weidner, A. C., Menefee, S. A., Lukacz, E. S., Norton, P., Schaffer, J., Nguyen, J. N., Borello-France, D., Goode, P. S., Jakus-Waldman, S., Spino, C., Warren, L. K., Gantz, M. G., Meikle, S. F., Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: The OPTIMAL randomized trial, JAMA - Journal of the American Medical Association, 311, 1023-1034, 2014	Intervention not relevant: women were randomised to usual care or BPMT (Perioperative behavioural therapy with pelvic floor muscle training)
Barski, D., Otto, T., Gerullis, H., Systematic Review and Classification of Complications after Anterior, Posterior, Apical, and Total Vaginal Mesh Implantation for Prolapse Repair, Surgical Technology International. XXIV, 6, 6, 2014	Unable to obtain full text. Systematic Review
Bastani, P., Shoari, N., Ebrahimi, S. H., Mallah, F., Azadi, A., Comparison of performing and not-performing the prophylactic surgery for urinary incontinence in advanced pelvic organ prolapse, International Journal of Women's Health and Reproduction Sciences, 2, 311-315, 2014	Population do not meet criteria
Bastu, E., Yasa, C., Dural, O., Ozgor, B. Y., Yilmaz, G., Gungor Ugurlucan, F., Buyru, F., Banerjee, S., Comparison of 2 Methods of Vaginal Cuff Closure at Laparoscopic Hysterectomy and Their Effect on Female Sexual Function and Vaginal Length: A Randomized Clinical Study, Journal of minimally invasive gynecology, 23, 986-993, 2016	Unclear how many,(if any) participants had prolapse as presenting symptom

## DRAFT FOR CONSULTATION

Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Benjamin, Feiner, Peter, O'Rourke, Christopher, Maher, A prospective comparison of two commercial mesh kits in the management of anterior vaginal prolapse, International Urogynecology Journal, 23, 279-83, 2012	Non randomised
Benson, J. T., Lucente, V., McClellan, E., Cornella, J., Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: A prospective randomized study with long-term outcome evaluation, American Journal of Obstetrics and Gynecology, 175, 1418-1422, 1996	Outcome data not relevant - unable to determine the results for women who just had apical surgery.
Bergman, I., Soderberg, M. W., Kjaeldgaard, A., Ek, M., Does the choice of suture material matter in anterior and posterior colporrhaphy?, International Urogynecology Journal, 27, 1357-65, 2016	Prospective cohort
Boccasanta, P., Venturi, M., Calabro, G., Trompetto, M., Ganio, E., Tessera, G., Bottini, C., Pulvirenti D'Urso, A., Ayabaca, S., Pescatori, M., Which surgical approach for rectocele? A multicentric report from Italian coloproctologists, Techniques in Coloproctology, 5, 149-56, 2001	Non randomised
Borie, F., Coste, T., Bigourdan, J. M., Guillou, F., Incidence and surgical treatment of synthetic mesh-related infectious complications after laparoscopic ventral rectopexy, Techniques in Coloproctology, 20, 759-765, 2016	Retrospective study
Borstad,E., Abdelnoor,M., Staff,A.C., Kulseng-Hanssen,S., Surgical strategies for women with pelvic organ prolapse and urinary stress incontinence, International Urogynecology Journal, 21, 179-186, 2010	Population do not meet the inclusion criteria - women had SUI surgery
Botros, S. M., Sand, P. K., Beaumont, J. L., Abramov, Y., Miller, J. J., Goldberg, R. P., Arcus-anchored acellular dermal graft compared to anterior colporrhaphy for stage II cystoceles and beyond, International Urogynecology Journal, 20, 1265-71, 2009	Retrospective study
Bradley, C. S., Nygaard, I. E., Brown, M. B., Gutman, R. E., Kenton, K. S., Whitehead, W. E., Goode, P. S., Wren, P. A., Ghetti, C., Weber, A. M., Bowel symptoms in women 1 year after sacrocolpopexy, American Journal of Obstetrics and Gynecology, 197, 642.e1-642.e8, 2007	non-RCT data
Brizzolara, S., Pillai-Allen, A., Risk of mesh erosion with sacral colpopexy and concurrent hysterectomy, Obstetrics & GynecologyObstet Gynecol, 102, 306-10, 2003	Retrospective study
Brubaker,L., Cundiff,G.W., Fine,P., Nygaard,I., Richter,H.E., Visco,A.G., Zyczynski,H., Brown,M.B., Weber,A.M., Abdominal sacrocolpopexy with burch colposuspension to reduce urinary stress incontinence, New England Journal of Medicine, 354, 1557-1566, 2006	Intervention not relevant - stress incontinence surgery
Brubaker,L., Nygaard,I., Richter,H.E., Visco,A., Weber,A.M., Cundiff,G.W., Fine,P., Ghetti,C., Brown,M.B., Two-year outcomes after sacrocolpopexy with and without burch to prevent stress urinary incontinence, Obstetrics and Gynecology, 112, 49-55, 2008	Intervention not relevant - stress urinary incontinence
Bruce, R. G., El-Galley, R. E., Galloway, N. T., Paravaginal defect repair in the treatment of female stress urinary incontinence and cystocele, Urology, 54, 647-51, 1999	Intervention not relevant - stress incontinence surgery

## DRAFT FOR CONSULTATION

Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Bump, R. C., Hurt, W. G., Theofrastous, J. P., Addison, W. A., Fantl, J. A., Wyman, J. F., McClish, D. K., DeLancey, J. O. L., Moffett, A. H., Jr., Washburn, S., Rowland, T. C., Jr., Randomized prospective comparison of needle colposuspension versus endopelvic fascia plication for potential stress incontinence prophylaxis in women undergoing vaginal reconstruction for stage III or IV pelvic organ prolapse, American Journal of Obstetrics and Gynecology, 175, 326-335, 1996	Intervention not relevant - stress incontinence surgery
Burgio,K.L., Nygaard,I.E., Richter,H.E., Brubaker,L., Gutman,R.E., Leng,W., Wei,J., Weber,A.M., Bladder symptoms 1 year after abdominal sacrocolpopexy with and without Burch colposuspension in women without preoperative stress incontinence symptoms, American Journal of Obstetrics and Gynecology, 197, 647-647, 2007	Intervention not relevant - stress incontinence surgery
Callewaert, G., Bosteels, J., Housmans, S., Verguts, J., Van Cleynenbreugel, B., Van der Aa, F., De Ridder, D., Vergote, I., Deprest, J., Laparoscopic versus robotic-assisted sacrocolpopexy for pelvic organ prolapse: a systematic review, Gynecological Surgery, 13, 115-123, 2016	Systematic review of robotic surgery
Campagna, G., Morciano, A., Rossitto, C., Panico, G., Naldini, A., Ercoli, A., Cervigni, M., Scambia, G., A new approach to supracervical hysterectomy during laparoscopic sacral colpopexy for pelvic organ prolapse: A randomized clinical trial, Neurourology and Urodynamics, 36, 798-802, 2017	Intervention not relevant: Compared two methods for cervical incision during laparoscopic sacral colpopexy: monopolar hook and mechanical morcellator versus bipolar laparoscopic loop and bipolar morcellator
Campbell, P., Cloney, L., Jha, S., Abdominal Versus Laparoscopic Sacrocolpopexy: A Systematic Review and Meta-analysis, Obstetrical & Gynecological Survey, 71, 435-42, 2016	Systematic review - references checked for inclusion
Cao, Q., Chen, Y. S., Ding, J. X., Hu, C. D., Feng, W. W., Hu, W. G., Hua, K. Q., Long-term treatment outcomes of transvaginal mesh surgery versus anterior-posterior colporrhaphy for pelvic organ prolapse, Australian & New Zealand journal of obstetrics & gynaecology, 53, 79-85, 2013	Retrospective study
Carey, M., Higgs, P., Goh, J., Lim, J., Leong, A., Krause, H., Cornish, A., Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial, BJOG: An International Journal of Obstetrics & Gynaecology, 116, 1380-6, 2009	Unable to disaggregate outcomes for anterior and posterior surgery
Carramao, S. S., Auge, A. F., Pacetta, A. M., Lemos, N. L., Lopes, E. D., Lunardelli, J. L., Ayoza, P., Aoki, T., The quality of life after the correction of uterine prolapsed using polypropylene mesh type I: Hysterectomy versus hysteropexy, a randomized prospective study, International Urogynecology Journal and Pelvic Floor Dysfunction, 20 (3 SUPPL.), S407-S408, 2009	Conference abstract
Carramao, S. S., Auge, A. F., Pacetta, A. M., Lopes, E. D., Lemos, N. L., Lunardelli, J. L., Ayoza, P., Aoki, T., A randomized comparison of two vaginal procedures for the treatment of uterine prolapse using polypropylene mesh: Hysteropexy versus hysterectomy, International Urogynecology Journal and Pelvic Floor Dysfunction, 20 (3 SUPPL.), S370-S371, 2009	Conference abstract

Study	Reason for Exclusion
Cavkaytar, S., Kokanali, M. K., Topcu, H. O., Aksakal, O. S., Doganay, M., Effects of Horizontal vs Vertical Vaginal Cuff Closure Techniques on Vagina Length After Vaginal Hysterectomy: A Prospective Randomized Study, Journal of Minimally Invasive Gynecology, 21, 884-7, 2014	Intervention not relevant - vertical verses horizontal Vaginal cuff
Cervigni, M, Natale, F, Weir, J, Antomarchi, F, Prospective randomized controlled study of the use of a synthetic mesh (Gynemesh trademark) versus a biological mesh (Pelvicol trademark) in recurrent cystocele (Abstract number 1284), Journal of urology, 177, 423, 2007	Conference abstract with preliminary study data - full report included (Natale 2009)
Chaliha, C., Khalid, U., Campagna, L., Digesu, G. A., Ajay, B., Khullar, V., SIS graft for anterior vaginal wall prolapse--a case-controlled study, International Urogynecology Journal, 17, 492-7, 2006	Case control
Chang, T. C., Hsiao, S. M., Chen, C. H., Wu, W. Y., Lin, H. H., Clinical Outcomes and Urodynamic Effects of Tailored Transvaginal Mesh Surgery for Pelvic Organ Prolapse, BioMed Research International, 2015, 191258, 2015	Non randomised study of stress urinary incontinence and prolapse
Chapple, C. R., Cruz, F., Deffieux, X., Milani, A. L., Arlandis, S., Artibani, W., Bauer, R. M., Burkhard, F., Cardozo, L., Castro-Diaz, D., Cornu, J. N., Deprest, J., Gunnemann, A., Gyhagen, M., Heesakkers, J., Koelbl, H., MacNeil, S., Naumann, G., Roovers, J. W. R., Salvatore, S., Sievert, K. D., Tarcan, T., Van der Aa, F., Montorsi, F., Wirth, M., Abdel-Fattah, M., Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence, European urology, 13, 13, 2017	Consensus statement
Chaturvedi, S, Bansal, R, Ranjan, P, Ansari, Ms, Kapoor, D, Kapoor, R, Trans-vaginal total pelvic floor repair using customized prolene mesh: a safe and cost-effective approach for high-grade pelvic organ prolapse (Provisional abstract), Indian Journal of Urology, 28, 21-27, 2012	Retrospective non-comparative study
Chen, C. H., Wu, W. Y., Sheu, B. C., Chow, S. N., Lin, H. H., Comparison of recurrence rates after anterior colporrhaphy for cystocele using three different surgical techniques, Gynecologic & Obstetric InvestigationGynecol Obstet Invest, 63, 214-21, 2007	Retrospective study
Chen,Y.S., Cao,Q., Ding,J.X., Hu,C.D., Feng,W.W., Hua,K.Q., Midterm prospective comparison of vaginal repair with mesh vs Prolift system devices for prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 164, 221-226, 2012	Cohort study (study included for long term complications)
Chmielewski, L., Walters, M. D., Weber, A. M., Barber, M. D., Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success, American Journal of Obstetrics & Gynecology, 205, 69.e1-8, 2011	Secondary publication from Weber 2001
Cho, M. K., Moon, J. H., Kim, C. H., Non-absorbable and partially-absorbable mesh during pelvic organ prolapse repair: A comparison of clinical outcomes, International Journal Of SurgeryInt J Surg, 55, 5-8, 2018	Retrospective study
Chu, L. C., Chuang, F. C., Kung, F. T., Huang, K. H., Comparison of short-term outcomes following pelvic reconstruction with Perigee and Apogee systems: hysterectomy or not?, International Urogynecology Journal, 23, 79-84, 2012	Retrospective study

Study	Reason for Exclusion
Colombo, M., Vitobello, D., Proietti, F., Milani, R., Randomised comparison of Burch colposuspension versus anterior colporrhaphy in women with stress urinary incontinence and anterior vaginal wall prolapse, BJOG: An International Journal of Obstetrics & Gynaecology, 107, 544-51, 2000	Intervention not relevant - stress incontinence surgery
Colombo, M., Maggioni, A., Zanetta, G., Vignali, M., Milani, R., Prevention of postoperative urinary stress incontinence after surgery for genitourinary prolapse, Obstetrics and Gynecology, 87, 266-271, 1996	Intervention not relevant
Coolen, A. L. W. M., Bui, B. N., Dietz, V., Wang, R., van Montfoort, A. P. A., Mol, B. W. J., Roovers, J. P. W. R., Bongers, M. Y., The treatment of post-hysterectomy vaginal vault prolapse: a systematic review and meta-analysis, International Urogynecology Journal, 28, 1767-1783, 2017	Systematic review - references checked for inclusion
Coolen, A. L. W. M., van IJsselmuiden, M. N., van Oudheusden, A. M. J., Veen, J., van Eijndhoven, H. W. F., Mol, B. W. J., Roovers, J. P., Bongers, M. Y., Laparoscopic sacrocolpopexy versus vaginal sacrospinous fixation for vaginal vault prolapse, a randomized controlled trial: SALTO-2 trial, study protocol, BMC Women's Health, 17 (1) (no pagination), 2017	Protocol paper - full study included (Coolen 2017)
Cornish, A., Carey, M., A comparison of the effectiveness of traditional vaginal colporraphy with colporraphy using mesh augmentation in women with vaginal prolapse as assessed using the pelvic organ prolapse quantification examination, <a href="http://www.anzctr.org.au/ACTRN12605000621617.aspx">Http://www.anzctr.org.au/ACTRN12605000621617.aspx</a> , 2005	Trial registration
Cosma, S., Menato, G., Preti, M., Petruzzelli, P., Tin, M. C., Riboni, F., Benedetto, C., Advanced utero-vaginal prolapse and vaginal vault suspension: synthetic mesh vs native tissue repair, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 289, 1053-60, 2014	Retrospective case control study
Costantini, E., Brubaker, L., Cervigni, M., Matthews, C. A., O'Reilly, B. A., Rizk, D., Giannitsas, K., Maher, C. F., Sacrocolpopexy for pelvic organ prolapse: evidence-based review and recommendations, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 205, 60-5, 2016	Narrative literature review
Costantini, E., Illiano, E., Lazzeri, M., Bini, V., Balsamo, R., Guiggi, P., Carbone, A., Mearini, L., Abdominal vs laparoscopic sacropexy: Subgroup analysis of a prospective randomized trial, Neurourology and Urodynamics, 35, S13-S15, 2016	Conference abstract
Costantini, E., Lazzeri, M., Bini, V., Del Zingaro, M., Frumenzio, E., Porena, M., Pelvic Organ Prolapse Repair with and without Concomitant Burch Colposuspension in Incontinent Women: A Randomised Controlled Trial with at Least 5-Year Followup, Obstetrics & Gynecology International, 2012, 967923, 2012	Intervention not relevant - stress incontinence surgery
Costantini, E., Lazzeri, M., Bini, V., Del Zingaro, M., Zucchi, A., Porena, M., Pelvic organ prolapse repair with and without prophylactic concomitant Burch colposuspension in continent women: a randomized, controlled trial with 8-year followup, Journal of Urology, 185, 2236-40, 2011	Intervention not relevant - stress incontinence surgery
Costantini, E., Lazzeri, M., Bini, V., Del Zingaro, M., Zucchi, A., Porena, M., Burch colposuspension does not provide any additional benefit to pelvic organ prolapse repair in patients with urinary incontinence: a randomized surgical trial, Journal of Urology, 180, 1007-12, 2008	Intervention not relevant - stress incontinence surgery

Study	Reason for Exclusion
Costantini, E., Mearini, L., Bini, V., Zucchi, A., Mearini, E., Porena, M., Uterus preservation in surgical correction of urogenital prolapse, European Urology, 48, 642-9, 2005	Non randomised study
Costantini, E., Porena, M., Lazzeri, M., Mearini, L., Bini, V., Zucchi, A., Changes in female sexual function after pelvic organ prolapse repair: role of hysterectomy, International Urogynecology Journal, 24, 1481-7, 2013	Non randomised study
Costantini, E., Zucchi, A., Giannantoni, A., Mearini, L., Bini, V., Porena, M., Must colposuspension be associated with sacropexy to prevent postoperative urinary incontinence?, European Urology, 51, 788-94, 2007	Intervention not relevant - stress incontinence surgery
Crane, A. K., Geller, E. J., Matthews, C. A., Outlet constipation 1 year after robotic sacrocolpopexy with and without concomitant posterior repair, Southern Medical Journal/South Med J, 106, 409-14, 2013	Retrospective study
Cruikshank, S. H., Kovac, S. R., Randomized comparison of three surgical methods used at the time of vaginal hysterectomy to prevent posterior enterocele, American Journal of Obstetrics and Gynecology, 180, 859-865, 1999	Intervention not relevant - compares three methods for vaginal hysterectomy: Moschcowitz procedure vs. McCall-type culdeplasty vs. Colsure of the cul-de-sac with the peritoneum
Cundiff, G. W., Varner, E., Visco, A. G., Zyczynski, H. M., Nager, C. W., Norton, P. A., Schaffer, J., Brown, M. B., Brubaker, L., Pelvic Floor Disorders Network, Risk factors for mesh/suture erosion following sacral colpopexy, American Journal of Obstetrics & Gynecology, 199, 688.e1-5, 2008	Outcomes not relevant - study examines risk factors for erosion
D. E. Tayrac R, Brouziyne, M., Renaudie, J., 36-Month results on stage 3-4 cystocele repair by the vaginal route using a 4-arm trans-obturator light-weight mesh, Female Pelvic Medicine and Reconstructive Surgery, 20, S249, 2014	Non-comparative cohort study
D'Afiero, A., Tommaselli, G. A., Forleo, F., Affinito, P., Stanco, D., Short-term effects of mesh augmented surgery for pelvic organ prolapse on functional outcomes and QOL: A comparison between trocar guided and single incision devices, International Journal of Gynecology and Obstetrics, 119, S315-S316, 2012	Conference abstract
Dahlgren, E., Kjolhede, P., Long-term outcome of porcine skin graft in surgical treatment of recurrent pelvic organ prolapse. An open randomized controlled multicenter study, Acta obstetricia et gynecologica Scandinavica, 90, 1393-1401, 2011	Unable to disaggregate data for anterior and posterior surgery
Dai, Z, Shu, H, Compare Sacrocolpopexy Versus Laparoscopic Inginal Ligament Hysteropexy for Uterus/Vagianl Vault Prolapse III/IV, <a href="http://www.chictr.org.cn/showproj.aspx?proj=12408">Http://www.chictr.org.cn/showproj.aspx?proj=12408</a> , 2015	Trial registration
Damoiseaux, A., Milani, A. L., Withagen, M. I., Long-term follow-up (7 years) of a randomized controlled trial: Trocar guided mesh compared with conventional vaginal repair in recurrent pelvic organ prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S23-S25, 2015	Conference abstract

Study	Reason for Exclusion
Das, C, Lingam, K, A randomised prospective study comparing intravaginal sling and sacrospinous ligament fixation in the treatment of vault prolapse and enterocele posthysterectomy (Abstract), Proceedings of the International Continence Society United Kingdom 11th Annual Scientific Meeting, Bournemouth, United Kingdom, 18-19 March, 45, 2004	Conference abstract
Davenport, M. T., Sokol, E. R., Comiter, C. V., Elliott, C. S., Does the Degree of Cystocele Predict De Novo Stress Urinary Incontinence After Prolapse Repair? Further Analysis of the Colpopexy and Urinary Reduction Efforts Trial, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 26, 26, 2017	Secondary analysis, outcomes not relevant
Dawood, N. S., Mahmood, R., Haseeb, N., Comparison of vaginal and abdominal hysterectomy: peri-and post-operative outcome, Journal of Ayub Medical College, Abbottabad: JAMC, 21, 116-20, 2009	Population do not meet inclusion criteria - fewer than 30% of participants had prolapse
de Boer, T. A., Gietelink, D. A., Hendriks, J. C., Vierhout, M. E., Factors influencing success of pelvic organ prolapse repair using porcine dermal implant Pelvicol, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 149, 112-6, 2010	Non comparative study
de Castro, E. B., Brito, L. G. O., Giraldo, P. C., Teatin Juliato, C. R., Does the Vaginal Flora Modify When a Synthetic Mesh is Used for Genital Prolapse Repair in Postmenopausal Women? A Pilot, Randomized Controlled Study, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 10, 10, 2018	No relevant outcomes - study measures microflora
De Gouveia De Sa, M., Claydon, L. S., Whitlow, B., Dolcet Artahona, M. A., Laparoscopic versus open sacrocolpopexy for treatment of prolapse of the apical segment of the vagina: a systematic review and meta-analysis, International Urogynecology Journal, 27, 3-17, 2016	Systematic review - references checked for inclusion
De Gouveia De Sa, M., Claydon, L. S., Whitlow, B., Dolcet Artahona, M. A., Robotic versus laparoscopic sacrocolpopexy for treatment of prolapse of the apical segment of the vagina: a systematic review and meta-analysis, International Urogynecology Journal, 27, 355-66, 2016	Systematic review - references checked for inclusion
de Oliveira, S. A., Fonseca, M. C. M., Bortolini, M. A. T., Girao, M. J. B. C., Roque, M. T., Castro, R. A., Hysteropreservation versus hysterectomy in the surgical treatment of uterine prolapse: systematic review and meta-analysis, International Urogynecology Journal, 28, 1617-1630, 2017	Systematic review - references checked for inclusion
De Ridder, D., The Use of Biomaterials in Reconstructive Urology, European Urology, Supplements, 1, 7-11, 2002	Non randomised study
de Tayrac, R., Sentilhes, L., Complications of pelvic organ prolapse surgery and methods of prevention, International Urogynecology Journal, 24, 1859-72, 2013	Systematic review - references checked for inclusion
Deffieux, X., Desseaux, K., de Tayrac, R., Faivre, E., Frydman, R., Fernandez, H., Infracoccygeal sacropexy for uterovaginal prolapse, International Journal of Gynaecology & ObstetricsInt J Gynaecol Obstet, 104, 56-9, 2009	Non comparative retrospective study

Study	Reason for Exclusion
Demirci, F., Birgul, K., Demirci, O., Demirci, E., Akman, Y., Karaalp, E., Dolgun, N., Perioperative complications in vaginal mesh procedures using trocar in pelvic organ prolapse repair, Journal of Obstetrics & Gynaecology of India, 63, 328-31, 2013	Non-comparative retrospective study
Deng, T., Liao, B., Luo, D., Shen, H., Wang, K., Risk factors for mesh erosion after female pelvic floor reconstructive surgery: a systematic review and meta-analysis, BJU International, 117, 323-43, 2016	Systematic review of risk factors for mesh erosion
Deprest, J., De Ridder, D., Roovers, J. P., Werbrouck, E., Coremans, G., Claerhout, F., Medium term outcome of laparoscopic sacrocolpopexy with xenografts compared to synthetic grafts, Journal of Urology, 182, 2362-8, 2009	Non-randomised study
Derpapas, A., Vijaya, G., Digesu, A. G., Fernando, R., Khullar, V., Clinical and ultrasonographic assessment of two different surgical techniques for posterior vaginalwall repair: A randomised control trial, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, S127, 2013	Conference abstract
Descouvieres, C., Rondini, C., Wenzel, C., Morales, A., Alvarez, J., Troncoso, F., Aros, S., Troncoso, C., High uterosacral vault suspension vs. abdominal sacrocolpopexy for enterocele and/or vaginal vault prolapse repair (Abstract number 89), International Urogynecology Journal and Pelvic Floor Dysfunction, 18, S53, 2007	Conference abstract
Detollenaere, R. J., Kreuwel, I. A. M., Dijkstra, J. R., Kluivers, K. B., van Eijndhoven, H. W. F., The Impact of Sacrospinous Hysteropexy and Vaginal Hysterectomy With Suspension of the Uterosacral Ligaments on Sexual Function in Women With Uterine Prolapse: A Secondary Analysis of a Randomized Comparative Study, Journal of sexual medicine, 13, 213-219, 2016	Secondary analysis of included study (Detollenaere 2015)
Devassy, R., Cezar, C., Xie, M., Herrmann, A., Tchartchian, G., De Wilde, R. L., Reconstructive laparoscopic prolapse surgery to avoid mesh erosions, Gms Interdisciplinary Plastic & Reconstructive Surgery Dgpw, 2, Doc11, 2013	Non-randomised study
Dietz, Hp, Reducing the levator hiatus with a puborectalis sling - a multi centre randomised controlled trial for patients undergoing pelvic organ prolapse surgery, ANZCTR (available At: <a href="http://www.anzctr.org.au/ACTRN12612000236897.aspx">Http://www.anzctr.org.au/ACTRN12612000236897.aspx</a> ), 2012	Trial registration
Dietz, V., Maher, C., Pelvic organ prolapse and sexual function, International Urogynecology Journal, 24, 1853-7, 2013	Systematic review - references checked for inclusion
Ding, J., Zhu, L., A prospective randomized study comparing improvement pelvic floor reconstruction and laparoscopic sacral fixation in the treatment of pelvic organ prolapse, <a href="http://www.chictr.org.cn/showproj.aspx?proj=10515">Http://www.chictr.org.cn/showproj.aspx?proj=10515</a> , 2015	Trial registration
Diwadkar, G. B., Barber, M. D., Feiner, B., Maher, C., Jelovsek, J. E., Complication and reoperation rates after apical vaginal prolapse surgical repair: A systematic review [Erratum: Obstetrics and Gynecology 2009; 113(6): 1377], Obstetrics and Gynecology, 113, 367-373, 2009	Systematic review of non-comparative studies
Dogonay, M., Aksakal, O., Minimally invasive sacrospinous ligament suspension: perioperative morbidity and review of the literature, Archives of Gynecology & Obstetrics, 287, 1167-72, 2013	Intervention not relevant - study compares two instruments for carrying out one

Study	Reason for Exclusion
Dong, S., Zhong, Y., Chu, L., Li, H., Tong, X., Wang, J., Age-stratified analysis of long-term outcomes of transvaginal mesh repair for treatment of pelvic organ prolapse, International Journal of Gynaecology & ObstetricsInt J Gynaecol Obstet, 135, 112-6, 2016	procedure; an automatic suturing instrument versus Deschamps suture carrier Non-randomised retrospective study
dos Reis Brandaõ da Silveira, S., Haddad, J. M., de Jarmy-Di Bella, Z. I. K., Nastri, F., Kawabata, M. G. M., da Silva Carramao, S., Rodrigues, C. A., Baracat, E. C., Auge, A. P. F., Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment, International Urogynecology Journal and Pelvic Floor Dysfunction, 26, 335-342, 2014	Outcome data not presented according to prolapse compartment
Duggan, P., Barry, C., Anterior compartment prolapse: Short term results and quality of life in women randomised to mesh or traditional repair, International Urogynecology Journal and Pelvic Floor Dysfunction, 22, S894-S895, 2011	Conference abstract
Dyer, K., Nguyen, J., Simsiman, A., Lukacz, E. S., Luber, K. M., Menefee, S. A., The optimal anterior repair study (OARS): A triple arm randomized double blinded clinical trial of standard colporrhaphy versus paravaginal repair with xenograft or synthetic mesh, Journal of Pelvic Medicine and Surgery, 2), S68-S69, 2010	Conference abstract - full publication included (Menefee 2011)
Ehlert, M. J., Gupta, P., Park, J., Sirls, L. T., Detailed Cost Analysis of Robotic Sacrocolpopexy Compared to Transvaginal Mesh Repair, Urology, 97, 86-91, 2016	Retrospective data of cost analysis
Einarsson, J. I., Cohen, S. L., Gobern, J. M., Sandberg, E. M., Hill-Lydecker, C. I., Wang, K., Brown, D. N., Barbed Versus Standard Suture: A Randomized Trial for Laparoscopic Vaginal Cuff Closure, Journal of Minimally Invasive Gynecology, 20, 492-498, 2013	Population do not meet inclusion criteria - women do not have prolapse
Ek,M., Tegerstedt,G., Falconer,C., Kjaeldgaard,A., Rezapour,M., Rudnicki,M., Altman,D., Urodynamic assessment of anterior vaginal wall surgery: a randomized comparison between colporraphy and transvaginal mesh, Neurourology and Urodynamics, 29, 527-531, 2010	Secondary analysis of included publication (Altman 2011)
El-agwany, A. S., Salem, H. A., Nagaty, A. M., Hanafy, T. M., Comparative study between abdominal versus laparoscopic sacral colpopexy, Progresos de Obstetricia y Ginecologia, 58, 341-349, 2015	Unable to obtain full text
El-Agwany, As, Comparative study of laparoscopic versus abdominal sacral colpopexy in women with Grade III or IV uterovaginal prolapse evaluating operating room time, estimated blood loss , inpatient days, and recurrence, <a href="http://www.anzctr.org.au/ACTRN12615000427572.aspx">Http://www.anzctr.org.au/ACTRN12615000427572.aspx</a> , 2015	Trial registration
Ellis, C. N., Anterior levatorplasty for the treatment of chronic anal fissures in females with a rectocele: A randomised, controlled trial, Diseases of the Colon and Rectum, 47, 1170-1173, 2004	Intervention not relevant - internal sphincterotomy compared to anterior levatorplasty, conducted in a specific subgroup of women with anal fissure in association with rectocele

Study	Reason for Exclusion
Ellis, C. N., Outcomes after the repair of rectoceles with transperineal insertion of a bioprosthetic graft, Diseases of the Colon & Rectum, 53, 213-8, 2010	Retrospective study
Elmer, C, Falconer, C, Hallin, A, Larsson, G, Ek, M, Altman, D, Risk factors for mesh complications after trocar guided transvaginal mesh kit repair of anterior vaginal wall prolapse, Neurourology and Urodynamics, 31, 1165-9, 2012	Secondary analysis of included study (Altman 2011)
Elmer, C., Altman, D., Engh, M. E., Axelsen, S., Vayrynen, T., Falconer, C., Nordic Transvaginal Mesh, Group, Trocar-guided transvaginal mesh repair of pelvic organ prolapse, Obstetrics & GynecologyObstet Gynecol, 113, 117-26, 2009	Non-randomised study
Farid, M., Madbouly, K. M., Hussein, A., Mahdy, T., Moneim, H. A., Omar, W., Randomized controlled trial between perineal and anal repairs of rectocele in obstructed defecation, World Journal of Surgery, 34, 822-9, 2010	No relevant outcome data
Farquhar, Cindy, No implementation without evaluation: the case of mesh in vaginal prolapse surgery, Cochrane Database of Systematic Reviews, 2016	Editorial
Farthmann, J, Prospectively randomised multicenter trial on the influence on mesh exposure rates of partially absorbable transobturatoric mesh after surgery for pelvic organ prolapse in the anterior compartment - PARETO-trial, Http://www.drks.de/DRKS00004566, 2012	Trial registration only
Farthmann, J., Mengel, M., Henne, B., Grebe, M., Watermann, D., Kaufhold, J., Stehle, M., Fuenfgeld, C., Improvement of pelvic floor-related quality of life and sexual function after vaginal mesh implantation for cystocele: primary endpoint of a prospective multicentre trial, Archives of Gynecology & Obstetrics, 294, 115-21, 2016	Non-comparative study
Fauconnier, A, Cosson, M, Debodinance, P, Bader, G, Youssef, Azer Akliadios C, Salet-Lizée, D, Anatomical and functional outcomes of vaginal mesh surgery versus laparoscopic laparoscopic sacrocolpop hysteropexy for cystocele repair: 12-months results of the PROSPERE (PROSthetic PErvic floor REpair) randomized controlled trial (Abstract number 376), Neurourology and Urodynamics, 35, S300-s302, 2017	Conference abstract
Fauconnier, A., Cosson, M., Debodinance, P., Bader, G., Youssef Azer Akliadios, C., Salet-Lizée, D., Campagne-Loiseau, S., Deffieux, X., Ferry, P., De Tayrac, R., Fritel, X., Lucot, J., French multicenter randomized study comparing laparoscopic sacropexy and vaginal mesh surgery in cystocele repair: A preliminary analysis of anatomical and functional outcomes in prospere RCT, Neurourology and Urodynamics, 34, S347-S348, 2015	Conference abstract
Fedorkow, D. M., Kalbfleisch, R. E., Total abdominal hysterectomy at abdominal sacrovaginopexy: a comparative study, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 169, 641-3, 1993	Retrospective cohort study
Feiner, B., Jelovsek, J. E., Maher, C., Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systematic review, BJOG: An International Journal of Obstetrics & Gynaecology, 116, 15-24, 2009	Systematic review - references checked for inclusion

## DRAFT FOR CONSULTATION

Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Feldner Jr, P. C., Delroy, C. A., Martins, S. B., Castro, R. A., Sartori, M. G. F., Girao, M. J. B. C., Sexual function after anterior vaginal wall prolapse surgery, Clinics, 67, 871-875, 2012	Secondary publication from included study (Feldner 2010)
Ferreira, H., Ferreira, C., Nogueira-Silva, C., Tome, A., Guimaraes, S., Correia-Pinto, J., Minilaparoscopic Versus Conventional Laparoscopic Sacrocolpopexy: A Comparative Study, Journal of Laparoendoscopic & Advanced Surgical Techniques. Part AJ Laparoendosc Adv Surg Tech A, 26, 386-92, 2016	Non-randomised study, with only 20 participants
Filimonov, Vb, Vasin, Rv, Vasina, Iv, Kaprin, Ad, Kostin, Aa, Female genital prolapse surgery using ultra lightweight polypropylene mesh, Urologiia (moscow, russia : 1999), 14-23, 2017	Publication not in English language
Foon, R., Tooze-Hobson, P., Latthe, P. M., Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications, International Urogynecology Journal, 19, 1697-706, 2008	Systematic review - references checked for inclusion
Fritel, X., Fauconnier, A., Cosson, M., Debodinance, P., Bader, G., Akladios, C., Salet-Lizee, D. D., Campagne Loiseau, S., Deffieux, X., Ferry, P., Detayrac, R., Lucot, J. P., Randomized controlled trial comparing laparoscopic sacrohysteropexy versus vaginal mesh surgery: Anatomical and functional results at one year. results of the prospere trial, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S19-S20, 2016	Conference abstract
Fuentes, A.E., A prospective randomised controlled trial comparing vaginal prolapse repair with and without tensionfree vaginal tape transobturator tape (TVTO) in women with severe genital prolapse and occult stress incontinence: Long term follow up, International urogynecology journal and pelvic floor dysfunction, 22, S60-S61, 2011	Conference abstract
Gentile, M., De Rosa, M., Carbone, G., Forestieri, P., Combined transvaginal-transanal approach vs. Endorectal proctopexy for rectocele and associated rectal intussusception: A prospective randomized trial, Techniques in Coloproctology, 15 (2), 225, 2011	Population do not meet inclusion criteria - all women had intussusception/ rectal prolapse as well as posterior uterovaginal prolapse. Results are not presented separately for the two procedures.
Geoffrion, R., Hyakutake, M. T., Koenig, N. A., Lee, T., Cundiff, G. W., Bilateral sacrospinous vault fixation with tailored synthetic mesh arms: clinical outcomes at one year, Journal of Obstetrics & Gynaecology Canada: JOGCJ Obstet Gynaecol Can, 37, 129-37, 2015	Prospective cohort study
Gimbel, H., Total or subtotal hysterectomy for benign uterine diseases? A meta-analysis, Acta Obstetricia et Gynecologica Scandinavica, 86, 133-44, 2007	Population do not meet inclusion criteria - unable to identify whether women had had prolapse
Gimbel, H., Zobbe, V., Andersen, B. M., Filtenborg, T., Gluud, C., Tabor, A., Randomised controlled trial of total compared with subtotal hysterectomy with one-year follow up results, BJOG: An International Journal of Obstetrics & Gynaecology, 110, 1088-98, 2003	Population do not meet inclusion criteria - women did not have prolapse

Study	Reason for Exclusion
Gizzo, S., Burul, G., Di Gangi, S., Lamparelli, L., Saccardi, C., Nardelli, G. B., D'Antona, D., LigaSure vessel sealing system in vaginal hysterectomy: safety, efficacy and limitations, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 288, 1067-74, 2013	Prospective cohort study
Goldstein, H. B., Maccarone, J., Naughton, M. J., Aguirre, O. A., Patel, R. C., A multicenter prospective trial evaluating fetal bovine dermal graft (Xenform Matrix) for pelvic reconstructive surgery, BMC Urology, 10, 21, 2010	Non-comparative case series data
Gorlero, F., Lijo, D., Biamonti, M., Lorenzi, P., Pulle, A., Dellacasa, I., Ragni, N., Hysterectomy and women satisfaction: Total versus subtotal technique, Archives of Gynecology and Obstetrics, 278, 405-410, 2008	Population do not meet inclusion criteria - Women do not have prolapse
Gracia, M., Perello, M., Bataller, E., Espuna, M., Parellada, M., Genis, D., Balasch, J., Carmona, F., Comparison between laparoscopic sacral hysteropexy and subtotal hysterectomy plus cervicopexy in pelvic organ prolapse: A pilot study, Neurourology & UrodynamicsNeurourol Urodyn, 34, 654-8, 2015	Non-randomised prospective study
Griffis, K., Evers, M. D., Terry, C. L., Hale, D. S., Mesh erosion and abdominal sacrocolpopexy: A comparison of prior, total, and supracervical hysterectomy, Journal of Pelvic Medicine and Surgery, 12, 25-30, 2006	Non-randomised retrospective study
Grimes, C. L., Lukacz, E. S., Gantz, M. G., Warren, L. K., Brubaker, L., Zyczynski, H. M., Richter, H. E., Jelovsek, J. E., Cundiff, G., Fine, P., Visco, A. G., Zhang, M., Meikle, S., Nichd Pelvic Floor Disorders Network, What happens to the posterior compartment and bowel symptoms after sacrocolpopexy? evaluation of 5-year outcomes from E-CARE, Female pelvic medicine & reconstructive surgery, 20, 261-6, 2014	Non-comparative cohort study
Gupta, P., Payne, J., Killinger, K. A., Ehrlert, M., Bartley, J., Gilleran, J., Boura, J. A., Sirs, L. T., Analysis of changes in sexual function in women undergoing pelvic organ prolapse repair with abdominal or vaginal approaches, International Urogynecology Journal, 27, 1919-1924, 2016	Outcome data not relevant - unable to determine what surgery different women had
Gustilo-Ashby, A. M., Paraiso, M. F. R., Jelovsek, J. E., Walters, M. D., Barber, M. D., Bowel symptoms 1 year after surgery for prolapse: further analysis of a randomized trial of rectocele repair, American Journal of Obstetrics and Gynecology, 197, 76.e1-76.e5, 2007	Conference abstract
Gutman, R. E., Nosti, P. A., Sokol, A. I., Sokol, E. R., Peterson, J. L., Wang, H., Iglesia, C. B., Three-year outcomes of vaginal mesh for prolapse a randomized controlled trial, Obstetrics and Gynecology, 122, 770-777, 2013	Unable to determine compartment surgery was conducted on
Gutman, R. E., Rardin, C. R., Sokol, E. R., Matthews, C., Park, A. J., Iglesia, C. B., Geoffrion, R., Sokol, A. I., Karram, M., Cundiff, G. W., Blomquist, J. L., Barber, M. D., Vaginal and laparoscopic mesh hysteropexy for uterovaginal prolapse: a parallel cohort study, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 216, 38.e1-38.e11, 2017	Non-randomised cohort study
Gutman, R., Maher, C., Uterine-preserving POP surgery, International Urogynecology Journal, 24, 1803-13, 2013	Systematic review - references checked for inclusion

Study	Reason for Exclusion
Hallock, J. L., Fitzgerald, J., Chen, C. C. G., Update on Robotic Versus Laparoscopic Sacrocolpopexy: Outcomes and Costs, Current Obstetrics and Gynecology Reports, 3, 252-264, 2014	Narrative literature review
Halpern-Elenskaia, K., Umek, W., Bodner-Adler, B., Hanzal, E., Anterior colporrhaphy: a standard operation? Systematic review of the technical aspects of a common procedure in randomized controlled trials, International urogynecology journal, 29, 781-788, 2018	Systematic review of surgery techniques
Handel, L. N., Frenkl, T. L., Kim, Y. H., Results of cystocele repair: a comparison of traditional anterior colporrhaphy, polypropylene mesh and porcine dermis, Journal of Urology, 178, 153-6; discussion 156, 2007	Non-randomised retrospective study
Harvie, H. S., Lee, D. D., Andy, U. U., Shea, J. A., Arya, L. A., Validity of utility measures for women with pelvic organ prolapse, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 218, 119.e1-119.e8, 2018	Prospective study to evaluate quality of life assessment tools
Hefni, M, Mesh vs Anterior Repair Surgery for vaginal prolapse, <a href="Http://isrctn.com/ISRCTN69747860">Http://isrctn.com/ISRCTN69747860</a> , 2008	Trial registration
Hefni, M. A., Bhaumik, J., El-Toukhy, T., Kho, P., Wong, I., Abdel-Razik, T., Davies, A. E., Safety and efficacy of using the LigaSure vessel sealing system for securing the pedicles in vaginal hysterectomy: Randomised controlled trial, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 329-333, 2005	Intervention not relevant - study compares methods to secure pedicles in vaginal hysterectomy, (LigaSure versus suture ligation)
Hefni, M., El-Toukhy, T., Bhaumik, J., Katsimannis, E., Sacrospinous cervicocolpopexy with uterine conservation for uterovaginal prolapse in elderly women: an evolving concept, American Journal of Obstetrics & Gynecology, 188, 645-50, 2003	Non-randomised prospective study
Heinonen, P. K., Nieminen, K., Combined anterior vaginal wall mesh with sacrospinous ligament fixation or with posterior intravaginal slingplasty for uterovaginal or vaginal vault prolapse, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 157, 230-3, 2011	fewer than ten participants in the sacrospinous ligament fixation group
Henn, E. W., Nondabula, T., Juul, L., Effect of vaginal infiltration with ornipressin or saline on intraoperative blood loss during vaginal prolapse surgery: a randomised controlled trial, International Urogynecology Journal, 27, 407-12, 2016	Unable to extract data - results pooled for all types of prolapse surgery
Higgs, Pj, Carey, Mp, Goh, Jtw, Krause, Hg, Leong, A, Cornish, A, Randomized controlled trial comparing vaginal prolapse repair with mesh augmentation to traditional vaginal repair: a 6-month follow up (Abstract number 12), International Urogynecology Journal, 17, S64, 2006	Conference abstract
Hill, A. M., Davis, K. M., Clark-Donat, L., Hammons, L. M., Azodi, M., Silasi, D. A., The Effect of Vertical Versus Horizontal Vaginal Cuff Closure on Vaginal Length After Laparoscopic Hysterectomy, Journal of minimally invasive gynecology, 24, 108-113, 2017	Population do not meet inclusion criteria - women do not have prolapse
Hoffman, M. S., Cardosi, R. J., Lockhart, J., Hall, D. C., Murphy, S. J., Vaginectomy with pelvic herniorrhaphy for prolapse, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 189, 364-70; discussion 370-1, 2003	Retrospective study

Study	Reason for Exclusion
Hollander,M.H., Pauwels,E.M.A.M., Buytaert,G.M.J.L., Kinget,K.R.A.A., Anterior and posterior repair with polypropylene mesh (Prolift) for pelvic organ prolapse: Retrospective review of the first 323 patients, Journal of Gynecologic Surgery, 26, 1-5, 2010	Non-randomised retrospective study
Hosni, M. M., El-Feky, A. E., Agur, W. I., Khater, E. M., Evaluation of three different surgical approaches in repairing paravaginal support defects: a comparative trial, Archives of Gynecology & Obstetrics, 288, 1341-8, 2013	Non-randomised study
Hsieh, H. Y., Tsai, C. P., Liu, C. K., Shen, P. S., Hung, Y. C., Hung, M. J., Factors that affect outcomes of prolapse repair using single-incision vaginal mesh procedures, Neurourology and Urodynamics, 37, 298-306, 2018	Non-randomised study
Hsieh, H. Y., Tsai, C. P., Liu, C. K., Shen, P. S., Hung, Y. C., Hung, M. J., Factors that affect outcomes of prolapse repair using single-incision vaginal mesh procedures, Neurourology & UrodynamicsNeurourol Urodyn, 21, 21, 2017	Retrospective study
Huang, L. Y., Chu, L. C., Chiang, H. J., Chuang, F. C., Kung, F. T., Huang, K. H., Medium-term comparison of uterus preservation versus hysterectomy in pelvic organ prolapse treatment with ProliftTM mesh, International Urogynecology Journal and Pelvic Floor Dysfunction, 26, 1013-1020, 2015	Retrospective study
Hudson, C. O., Northington, G. M., Lyles, R. H., Karp, D. R., Outcomes of robotic sacrocolpopexy: a systematic review and meta-analysis, Female Pelvic Medicine & Reconstructive Surgery, 20, 252-60, 2014	Systematic review -references checked for inclusion
Huebner, M., Krzonkalla, M., Tunn, R., Abdominal sacrocolpopexy--standardized surgical technique, perioperative management and outcome in women with posthysterectomy vaginal vault prolapse, Gynakologisch-Geburtshilfliche RundschauGynakol Geburtshilfliche Rundsch, 49, 308-14, 2009	Retrospective series
Hwang, J. H., Lee, J. K., Lee, N. W., Lee, K. W., Vaginal cuff closure: A comparison between the vaginal route and laparoscopic suture in patients undergoing total laparoscopic hysterectomy, Gynecologic and obstetric investigation, 71, 163-169, 2011	Population do not meet inclusion criteria - women do not have prolapse
Ibrahim, A., Eltohamy, O., Ibrahim, M., Ellaithy, M. I., Bahaa, A., Elkady, M., Samaha, I., Sacrospinous colpopexy using Masson luethy needle holder, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 179, 5-10, 2014	Prospective cohort study
Ichikawa, M., Kaseki, H., Akira, S., Laparoscopic versus abdominal sacrocolpopexy for treatment of multi-compartmental pelvic organ prolapse: A systematic review, Asian Journal of Endoscopic SurgeryAsian j, 11, 15-22, 2018	Systematic review - references checked for inclusion
Iglesia, C. B., Sokol, A. I., Sokol, E. R., Kudish, B. I., Gutman, R. E., Peterson, J. L., Shott, S., Vaginal mesh for prolapse: a randomized controlled trial, Obstetrics & Gynecology, 116, 293-303, 2010	Unable to disaggregate outcomes for surgery in each compartment
Ignjatovic,I., Stojkovic,I., Basic,D., Medojevic,N., Potic,M., Optimal primary minimally invasive treatment for patients with stress urinary incontinence and symptomatic pelvic organ prolapse: tension free slings	Intervention not relevant - stress urinary incontinence surgery

Study	Reason for Exclusion
with colporrhaphy, or Prolift with the tension free midurethral sling?, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 150, 97-101, 2010	
Ishchenko, A. I., Aleksandrov, L. S., Ishchenko, A. A., Hudoley, E. P., Method of Surgical Management of Genital Prolapse with Cervical Elongation, Vestnik Rossiiskoi Akademii Meditsinskikh Nauk/Vestn Ross Akad Med Nauk, 71, 413-9, 2016	Publication not in the English language
Ismail, S. I. M. F., Anterior colporrhaphy compared with collagen-coated transvaginal mesh for anterior vaginal wall prolapse: A randomised controlled trial, BJOG: An International Journal of Obstetrics and Gynaecology, 121, 1447-1448, 2014	Letter to the editor
Jacquetin, B., Cosson, M., Debodinance, P., Hinoul, P., Vaginal mesh for prolapse: a randomized controlled trial, Obstetrics & Gynecology, 116, 1457-8; author reply 1458, 2010	Letter to the editor
Jelovsek, J. E., A randomized trial of uterosacral ligament suspension or sacrospinous ligament fixation for apical pelvic organ prolapse: Five-year outcomes, American Journal of Obstetrics and Gynecology, 216 (3 Supplement 1), S566, 2017	Conference abstract
Jelovsek, J. E., Barber, M. D., Norton, P., Brubaker, L., Gantz, M., Richter, H. E., Weidner, A., Menefee, S., Schaffer, J., Pugh, N., Meikle, S., Effect of uterosacral ligament suspension vs sacrospinous ligament fixation with or without perioperative behavioral therapy for pelvic organ vaginal prolapse on surgical outcomes and prolapse symptoms at 5 years in the OPTIMAL randomized clinical trial, JAMA - Journal of the American Medical Association, 319, 1554-1565, 2018	Intervention not relevant - intervention includes behavioural therapy
Jeng, C. J., Yang, Y. C., Tzeng, C. R., Shen, J., Wang, L. R., Sexual functioning after vaginal hysterectomy or transvaginal sacrospinous uterine suspension for uterine prolapse: a comparison, Journal of Reproductive Medicine, 50, 669-74, 2005	Prospective study
Jeon, M. J., Jung, H. J., Choi, H. J., Kim, S. K., Bai, S. W., Is hysterectomy or the use of graft necessary for the reconstructive surgery for uterine prolapse?, International Urogynecology Journal, 19, 351-5, 2008	Retrospective study
Jeon, M. J., Kim, J. Y., Moon, Y. J., Bai, S. W., Yoo, E. H., Two-year urinary outcomes of sacrocolpopexy with or without transobturator tape: results of a prolapse-reduction stress test-based approach, International Urogynecology Journal, 25, 1517-22, 2014	Intervention not relevant - stress urinary incontinence surgery
Jha, S., Gray, T., A systematic review and meta-analysis of the impact of native tissue repair for pelvic organ prolapse on sexual function, International Urogynecology Journal and Pelvic Floor Dysfunction, 26, 321-327, 2014	Systematic review - references checked for inclusion
Jia, X., Glazener, C., Mowatt, G., Jenkinson, D., Fraser, C., Bain, C., Burr, J., Systematic review of the efficacy and safety of using mesh in surgery for uterine or vaginal vault prolapse, International Urogynecology Journal, 21, 1413-31, 2010	Systematic review - references checked for inclusion

Study	Reason for Exclusion
Jia, X., Glazener, C., Mowatt, G., MacLennan, G., Bain, C., Fraser, C., Burr, J., Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis, BJOG: An International Journal of Obstetrics & Gynaecology, 115, 1350-61, 2008	Systematic review - references checked for inclusion
Jirschele, K., Seitz, M., Zhou, Y., Rosenblatt, P., Culligan, P., Sand, P., A multicenter, prospective trial to evaluate mesh-augmented sacrospinous hysteropexy for uterovaginal prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction., 14, 2014	Non-comparative cohort data
Jonsson Funk, M., Visco, A. G., Weidner, A. C., Pate, V., Wu, J. M., Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse, International Urogynecology Journal, 24, 1279-85, 2013	Non-randomised retrospective data
Julian, T. M., The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 175, 1472-5, 1996	Non-randomised study
Juliato, C. R., Santos Junior, L. C., Haddad, J. M., Castro, R. A., Lima, M., Castro, E. B., Mesh Surgery for Anterior Vaginal Wall Prolapse: A Meta-analysis, Revista Brasileira de Ginecologia e Obstetricia, 38, 356-64, 2016	Systematic review - references checked for inclusion
Juliato, Ct, Castro, E, Comparison of two surgical techniques for treatment of uterine prolapse: sacrospinous vault fixation and use anterior mesh with colpopromontofixation, <a href="Http://www.ensaiosclinicos.gov.br/rg/RBR-7t6rg2/">Http://www.ensaiosclinicos.gov.br/rg/RBR-7t6rg2/</a> , 2016	Trial registration
Juneja, M, Munday, D, Kopetz, V, Barry, C, Hysterectomy vs no hysterectomy for uterine prolapse in conjunction with posterior infracoccygeal colpopexy - a randomised pilot study 12 months review (Abstract number 692), Proceedings of the Joint Meeting of the International Continence Society (ICS) and the International Urogynecological Association, 2010 Aug 23-27, Toronto, Canada, 2010	Conference abstract
Kahn, Ma, Kumar, D, Stanton, Sl, Posterior colporrhaphy vs transanal repair of the rectocele: an initial follow up of a prospective randomized controlled trial, British journal of obstetrics and gynaecology, 105 Suppl 17, 57, 1998	Conference abstract
Kannan, K, Rane, A, Anterior Colporrhaphy versus Transobturator mesh repair system for anterior vaginal wall prolapse - A Randomised Controlled Trial - ACT trial, <a href="Http://www.anzctr.org.au/ACTRN12608000378325.aspx">Http://www.anzctr.org.au/ACTRN12608000378325.aspx</a> , 2008	Trial registration
Kapoor, S., Sivanesan, K., Robertson, J. A., Veerasingham, M., Kapoor, V., Sacrospinous hysteropexy: review and meta-analysis of outcomes, International Urogynecology Journal, 1-10, 2017	Narrative literature review
Karagkounis, S., Balaxis, D., Paraschou, G., Taravanis, T., Treating high grade uterine prolapse. Preservation or not of major anatomic structures?, International Urogynecology Journal and Pelvic Floor Dysfunction, 20 (3 SUPPL.), S351, 2009	Conference abstract

Study	Reason for Exclusion
Karateke, A., Verit, F. F., Kahramanoglu, I., Transvaginal use of monofilament polypropylene mesh for anterior and posterior repair: Review of the literature, <i>Turkiye Klinikleri Jinekoloji Obstetrik</i> , 24, 114-119, 2014	Narrative literature review
Karram, M., Maher, C., Surgery for posterior vaginal wall prolapse, <i>International Urogynecology Journal</i> , 24, 1835-41, 2013	Systematic review - references checked for inclusion
Kaufman, Y, Singh, Ss, Alturki, H, Lam, A, Age and sexual activity are risk factors for mesh exposure following transvaginal mesh repair, <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 22, 307-13, 2011	Non-comparative cohort study
Kenton, K., Mueller, E. R., Tarney, C., Bressee, C., Anger, J. T., One-Year Outcomes after Minimally Invasive Sacrocolpopexy, <i>Female Pelvic Medicine and Reconstructive Surgery</i> , 22, 382-384, 2016	Intervention not relevant -study compares robotic surgery to laparoscopic sacrocolpopexy
Khan, A., Alperin, M., Wu, N., Clemens, J. Q., Dubina, E., Pashos, C. L., Anger, J. T., Comparative outcomes of open versus laparoscopic sacrocolpopexy among medicare beneficiaries, <i>International Urogynecology Journal</i> , 24, 1883-1891, 2013	Retrospective analysis using population level data from the Medicare database
Khandwala, S, Jayachandran, C, Transvaginal mesh surgery for pelvic organ prolapse-Prolift+M: A prospective clinical trial, <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 22, 1405-11, 2011	Non-comparative cohort study
Khelaia,V., Anti-incontinence procedures in women with severe urogenital prolapse, <i>European Urology</i> , Supplements, 9, 565-, 2010	Conference abstract
Khullar, V, To assess two methods of surgical repair of posterior vaginal wall prolapse, <a href="http://isrctn.com/ISRCTN57337356">Http://isrctn.com/ISRCTN57337356</a> , 2004	Trial registration
Kinman, C. L., Meriwether, K. V., Powell, C. M., Hobson, D. T. G., Gaskins, J. T., Francis, S. L., Use of an iPadTM application in preoperative counseling for pelvic reconstructive surgery: a randomized trial, <i>International Urogynecology Journal</i> , 1-7, 2017	Intervention not relevant - study compares consent processess
Klauschie, J. L., Suozzi, B. A., O'Brien, M. M., McBride, A. W., A comparison of laparoscopic and abdominal sacral colpopexy: objective outcome and perioperative differences, <i>International Urogynecology Journal</i> , 20, 273-9, 2009	Non-randomised retrospective study
Kocjancic, E, Crivellaro, S, Bernasconi, F, Magatti, F, Frea, B, Meschia, M, Cystocele repair with or without pelvicol implant: a two years follow-up (Abstract number 864), <i>European Urology</i> , Supplements, 6, 238, 2007	Conference abstract
Koduri, S, Lobel, Rw, Winkler, Ha, Tomezsko, J, Culligan, Pjspk, Prospective randomized trial of polyglactin 910 mesh to prevent recurrece of cystoceles and rectoceles, <i>International Urogynecology Journal</i> , 11, S80, 2000	Preliminary report of included study (Sand 2001)

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Study	Reason for Exclusion
Korshunov, My, Sergeeva, Iv, Zhivov, Av, Sazykina, Ei, Plekhanov, Ay, Prospective randomized controlled trial of polypropylene mesh to prevent recurrence of anterior vaginal prolapse (Abstract number, oral poster 40), Journal of Pelvic Medicine & Surgery, 10, S29, 2004	Conference abstract
Kotb, Sz, El-Metwally, M, Shams, N, Khater, A, Laparoscopic-assisted vaginal hysterectomy vs hand-assisted laparoscopic hysterectomy, World journal of laparoscopic surgery, 9, 63-70, 2017	Population do not meet inclusion criteria - women do not have prolapse
Kudish, B. I., Gutman, R. E., Sokol, A. I., Shott, S., Iglesia, C., Impact of vaginal prolapse repair with and without mesh on postoperative vaginal caliber and sexual function, Journal of Pelvic Medicine and Surgery, 2), S127, 2010	Conference abstract
Kwon, C, Goldberg, R, Sanjay, G, Sumana, K, Krotz, S, Sand, P, Protective effect of transvaginal slings on recurrent anterior vaginal wall prolapse after pelvic reconstructive surgery (Abstract number 29), Neurourology and Urodynamics, 21, 321-2, 2002	Conference abstract
Ladanchuk, T, Anterior Pelvic Organ Prolapse Surgery: A randomised controlled trial of Xenform anterior repair versus anterior colporrhaphy evaluating at one-year: recurrence, quality of life and need for re-operation on anterior pelvic organ prolapse, <a href="Http://www.anzctr.org.au/ACTRN12616000159459.aspx">Http://www.anzctr.org.au/ACTRN12616000159459.aspx</a> , 2016	Trial registration
Lamblin, G., Dubernard, G., de Saint Hilaire, P., Jacquot, F., Chabert, P., Chene, G., Golfier, F., Assessment of Synthetic Glue for Mesh Attachment in Laparoscopic Sacrocolpopexy: A Prospective Multicenter Pilot Study, Journal of Minimally Invasive GynecologyJ Minim Invasive Gynecol, 24, 41-47, 2017	Non-comparative study
Lamblin, G., Gouttenoire, C., Panel, L., Moret, S., Chene, G., Courtieu, C., A retrospective comparison of two vaginal mesh kits in the management of anterior and apical vaginal prolapse: long-term results for apical fixation and quality of life, International Urogynecology Journal, 24, 24, 2016	Non randomised retrospective study
Larouche, M., Geoffrion, R., Walter, J. E., No. 351-Transvaginal Mesh Procedures for Pelvic Organ Prolapse, Journal of Obstetrics & Gynaecology Canada: JOGCJ Obstet Gynaecol Can, 39, 1085-1097, 2017	Confernece abstract
Larouche, M., Merovitz, L., Correa, J. A., Walter, J. E., Outcomes of trocar-guided Gynemesh PSTM versus single-incision trocarless PolyformTM transvaginal mesh procedures, International Urogynecology Journal, 26, 71-7, 2015	Non-randomised retrospective study
Leanza, V., Intagliata, E., Leanza, G., Vecchio, R., Pelvic posterior compartment defects: Comparative study of two vaginal surgical procedures, Urogynaecologia, 27, 11-13, 2013	Intervention not relevant -study compares perineal body anchorage of posterior septum, with traditional Denonvilliersâ□™ transversal suture

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Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Lee, J, Leitch, A, Rosamilia, A, In patients with post hysterectomy prolapse, is Anterior Elevate mesh kit as good as or better than Laparoscopic Sacrocolpopexy for prolapse recurrence, <a href="Http://www.anzctr.org.au/ACTRN12611001111965.aspx">Http://www.anzctr.org.au/ACTRN12611001111965.aspx</a> , 2011	Trial registration
Leitch, A, Lee, J, In patients with uterine prolapse, is uterine conservation using Uphold mesh kit as good as or better than vaginal hysterectomy for prolapse recurrence, <a href="Http://www.anzctr.org.au/ACTRN12611000633987.aspx">Http://www.anzctr.org.au/ACTRN12611000633987.aspx</a> , 2011	Trial registration
Lensen, E. J., Withagen, M. I., Kluivers, K. B., Milani, A. L., Vierhout, M. E., Comparison of two trocar-guided trans-vaginal mesh systems for repair of pelvic organ prolapse: a retrospective cohort study, International Urogynecology Journal, 24, 1723-31, 2013	Non-randomised retrospective study
Leone Roberti Maggiore, U., Alessandri, F., Remorgida, V., Venturini, P. L., Ferrero, S., Vaginal sacrospinous colpopexy using the Capio suture-capturing device versus traditional technique: feasibility and outcome, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 287, 267-74, 2013	Non-randomised prospective cohort study
Letouzey, V., Deffieux, X., Gervaise, A., Mercier, G., Fernandez, H., de Tayrac, R., Trans-vaginal cystocele repair using a tension-free polypropylene mesh: more than 5 years of follow-up, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 151, 101-5, 2010	Non-comparative study
Leung, S. W., Chan, C. S., Lo, S. F. L., Pang, C. P., Pun, T. C., Yuen, P. M., Comparison of the different types of "laparoscopic total hysterectomy", Journal of Minimally Invasive Gynecology, 14, 2007	Population do not meet the inclusion criteria - women do not have prolapse
Li, S., Ji, M., Zhao, Z., The effectiveness of two different laparoscopic surgeries for apical support of pelvic organ prolapse, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 188, 74-8, 2015	Intervention not relevant
Liang, S., Zhu, L., Zhang, L., Sun, Z. J., Tao, X., Lang, J. H., Manometric comparison of anorectal function after posterior vaginal compartment repair with and without mesh, Chinese Medical Journal, 128, 438-42, 2015	Non-randomised study
Lim, Y. N., Rosamilia, A., Dwyer, P. L., Alvarez, J., Chao, F., Murray, C., Leitch, A., Schierlitz, L., Desouza, A., Thomas, E., Agnew, G., Lee, J., Randomised controlled trial of posthysterectomy vaginal vault prolapse treatment with extraperitoneal vaginal uterosacral ligament suspension with anterior mesh reinforcement vs sacrocolpopexy (open/laparoscopic), International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S48-S49, 2012	Conference abstract
Lin, X., Du, P., Chen, L., Gan, Y., Zhang, X., A Case of Mesh Erosion to the Sigmoid After Laparoscopic Sacrocolpopexy and a Literature Review of Mesh Related Complications, Female pelvic medicine & reconstructive surgery, 25, 25, 2018	Case study
Liu, C. K., Tsai, C. P., Chou, M. M., Shen, P. S., Chen, G. D., Hung, Y. C., Hung, M. J., A comparative study of laparoscopic sacrocolpopexy and total vaginal mesh procedure using lightweight polypropylene meshes for prolapse repair, Taiwanese journal of obstetrics & gynecology, 53, 552-8, 2014	Non-randomised cohort study

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Study	Reason for Exclusion
Lo, T. S., Bt Karim, N., Cortes, E. F., Wu, P. Y., Lin, Y. H., Tan, Y. L., Comparison between Elevate anterior/apical system and Perigee system in pelvic organ prolapse surgery: clinical and sonographic outcomes, International Urogynecology Journal, 26, 391-400, 2015	Prospective cohort study
Lo, T. S., Cortes, E. F., Wu, P. Y., Tan, Y. L., Al-Kharabsheh, A., Pue, L. B., Assessment of collagen versus non collagen coated anterior vaginal mesh in pelvic reconstructive surgery: prospective study, European Journal of Obstetrics, Gynecology, & Reproductive Biology Eur J Obstet Gynecol Reprod Biol, 198, 138-44, 2016	Prospective cohort study
Lo, T. S., Nawawi, E. A. B., Wu, P. Y., Pue, L. B., Objective and subjective outcome 3 years after synthetic transobturator nonabsorbable anterior mesh use in symptomatic advanced pelvic organ prolapse surgery, Gynecology and Minimally Invasive Therapy, 4, 37-40, 2015	Non-comparative retrospective study
Lo, T. S., Pue, L. B., Hung, T. H., Wu, P. Y., Tan, Y. L., Long-term outcome of native tissue reconstructive vaginal surgery for advanced pelvic organ prolapse at 86 months: Hysterectomy versus hysteropexy, Journal of Obstetrics & Gynaecology Research J Obstet Gynaecol Res, 41, 1099-107, 2015	Retrospective cohort study
Lo, T. S., Uy-Patrimonio, M. C., Hsieh, W. C., Yang, J. C., Huang, S. Y., Chua, S., Sacrospinous ligament fixation for hysteropexy: does concomitant anterior and posterior fixation improve surgical outcome?, International urogynecology journal, 29, 811-819, 2018	Retrospective study
Loffeld, C. J., Thijs, S., Mol, B. W., Bongers, M. Y., Roovers, J. P., Laparoscopic sacrocolpopexy: a comparison of Prolene and Tutoplast mesh, Acta obstetricia et gynecologica Scandinavica, 88, 826-30, 2009	Retrospective study
Long, C. Y., Hsu, C. S., Wu, M. P., Lo, T. S., Liu, C. M., Tsai, E. M., Comparison of the changes in sexual function of premenopausal and postmenopausal women following transvaginal mesh surgery, Journal of sexual medicine, 8, 2009-16, 2011	Outcomes not relevant - study compares outcomes between pre and post menopausal women
Long, C. Y., Lin, K. L., Wang, C. L., A randomised controlled trial of abdominal versus laparoscopic sacrocolpopexy for the treatment of post-hysterectomy vaginal vault prolapse: LAS study. Comment, International Urogynecology Journal, 25, 435, 2014	Letter to the editor
Long, C. Y., Wang, C. L., Tsai, E. M., Re: Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up, American Journal of Obstetrics & Gynecology, 205, e14; author reply e14, 2011	Letter to the editor
Long, C. Y., Wang, C. L., Wu, M. P., Wu, C. H., Lin, K. L., Liu, C. M., Tsai, E. M., Shen, C. J., Comparison of clinical outcomes using "elevate anterior" versus "Perigee" system devices for the treatment of pelvic organ prolapse, BioMed research international, 2015, 479610, 2015	Non-randomised prospective study
Long,C.Y., Hsu,C.S., Jang,M.Y., Liu,C.M., Chiang,P.H., Tsai,E.M., Comparison of clinical outcome and urodynamic findings using "perigee and/or Apogee" versus "prolift anterior and/or posterior" system devices for the treatment of pelvic organ prolapse, International urogynecology journal and pelvic floor dysfunction, 22, 233-239, 2011	Non-randomised prospective study

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Study	Reason for Exclusion
Long,C.Y., Liu,C.M., Wu,T.P., Hsu,S.C., Chang,Y., Tsai,E.M., A randomized comparison of vesicourethral function after laparoscopic hysterectomy with and without vaginal cuff suspension, Journal of Minimally Invasive Gynecology, 12, 137-143, 2005	Population do not meet inclusion criteria - women do not have prolapse
Lopes, Ed, Carramao, Ss, Auge, A, Lemos, N, Lunardelli, J, Aoki, T, A randomized comparison of pre-operative and post-operative quality of life pre-operative and three and six months after reconstructive vaginal surgery for advanced pelvic organ prolapse using polypropylene mesh type I: hysterectomy versus hysteropexy (Abstract number 209), International Urogynecology Journal, 19, S174, 2008	Conference abstract
Lucot, J. P., Cosson, M., Debodinance, P., Bader, G., Youssef Azer Akladios, C., Salet-Lizee, D., Campagne Loiseau, S., Deffieux, X., Ferry, P., De Tayrac, R., Fritel, X., Fauconnier, A., Prospere randomized controlled trial: Laparoscopic sacropexy versus vaginal mesh for cystocele pop repair, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S26-S27, 2015	Conference abstract
Lukacz, E. S., Warren, L. K., Richter, H. E., Brubaker, L., Barber, M. D., Norton, P., Weidner, A. C., Nguyen, J. N., Gantz, M. G., Quality of Life and Sexual Function 2 Years After Vaginal Surgery for Prolapse, Obstetrics & Gynecology, 127, 1071-9, 2016	Secondary analysis
Lukacz, E. S., Warren, L. K., Richter, H. E., Brubaker, L., Barber, M. D., Norton, P., Weidner, A. C., Nguyen, J. N., Gantz, M. G., Meikle, S. F., Long-term quality of life and sexual function after vaginal surgery for apical prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S117-S118, 2015	Conference abstract
Lunardelli, JI, Auge, Af, Lemos, NI, Carramao, Ss, Oliveira, Al, Faria, Aa, Lopes, Ed, Aoki, T, Randomized comparison of polypropylene mesh versus site-specific surgery in the treatment of anterior vaginal prolapse (Abstract number 147), International Urogynecology Journal, 20, S197-s198, 2009	Conference abstract of included study (Lunadelli 2009)
Madbouly, K, Randomized Controlled Trial evaluating the effect of Perineal versus Anal Repairs of Rectocele on functional score, symptom improvement and sexual function in patients with Obstructed Defecation, <a href="http://www.anzctr.org.au/ACTRN12609000802202.aspx">Http://www.anzctr.org.au/ACTRN12609000802202.aspx</a> , 2009	Trial registration
Madhura, P., Agur, W., Roger, K., Mario, H., David, R., Wael, A., Prospective comparative study of vaginal sacrospinous fixation versus laparoscopic sacropexy for women with uterine/vault prolapse, Gynecological surgery, 10, S29, 2013	Conference abstract
Madhuvrata, P., Glazener, C., Boachie, C., Allahdin, S., Bain, C., A randomised controlled trial evaluating the use of polyglactin (Vicryl) mesh, polydioxanone (PDS) or polyglactin (Vicryl) sutures for pelvic organ prolapse surgery: outcomes at 2 years, Journal of Obstetrics & Gynaecology, 31, 429-35, 2011	intervention not relevant - comparison of sutures
Madsen, L. D., Nussler, E., Kesmodel, U. S., Greisen, S., Bek, K. M., Glavind-Kristensen, M., Native-tissue repair of isolated primary rectocele compared with nonabsorbable mesh: patient-reported outcomes, International Urogynecology Journal, 28, 49-57, 2017	Registry data

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Study	Reason for Exclusion
Maguire, T., Mayne, C., Willars, J., Tincello, D., The effect of vaginal closure technique on early post-operative pain following vaginal prolapse surgery: a feasibility pilot study and qualitative assessment, Springerplus, 3, 1, 2014	Outcomes data not relevant. Intervention not relevant - unable to determine specific surgery of women
Maher, C, Laparoscopic sacral colpopexy versus total vaginal mesh in the treatment of vaginal vault prolapse assessing anatomical outcomes, Http://www.anzctr.org.au/ACTRN12609000119291.aspx, 2009	Trial registration
Maher, C. F., Murray, C. J., Carey, M. P., Dwyer, P. L., Ugoni, A. M., Iliococcygeus or sacrospinous fixation for vaginal vault prolapse, <i>Obstetrics &amp; Gynecology</i> , 98, 40-4, 2001	Retrospective study
Maher, C., O'Rourke, P., Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 117, 1435-6; author reply 1436-7, 2011	Letter to the editor
Maher, Cf, Feiner, B, Cuyper, E, Nicholas, C, Hickey, K, Schluter, P, Laparoscopic sacral colpopexy versus total vaginal mesh for the management of vaginal vault prolapse: a randomized controlled trial (Abstract number 089), <i>International Urogynecology Journal</i> , 20, S151-s152, 2009	Conference abstract
Maher, Christopher, Feiner, Benjamin, Baessler, Kaven, Christmann-Schmid, Corina, Haya, Nir, Brown, Julie, Surgery for women with anterior compartment prolapse, Cochrane Database of Systematic Reviews, 2016	Systematic review - references checked for inclusion
Maher, Christopher, Feiner, Benjamin, Baessler, Kaven, Christmann-Schmid, Corina, Haya, Nir, Brown, Julie, Surgery for women with apical vaginal prolapse, Cochrane Database of Systematic Reviews, 2016	Systematic review - references checked for inclusion
Maher, Christopher, Feiner, Benjamin, Baessler, Kaven, Christmann-Schmid, Corina, Haya, Nir, Marjoribanks, Jane, Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse, Cochrane Database of Systematic Reviews, 2016	Systematic review - references checked for inclusion
Mahmood, S., Chowdhury, S. B., Shamim, S., Ara, R., A Comparative Study of Abdominal Hysterectomy versus Vaginal Hysterectomy in Non Descent Cases, <i>Mymensingh Medical Journal: MMJ</i> , 24, 521-7, 2015	Non-randomised study
Mahmoud, S. A., Omar, W., Farid, M., Transanal repair for treatment of rectocele in obstructed defaecation: manual or stapled, <i>Colorectal Disease</i> , 14, 104-10, 2012	Non-randomised study
Malandri, M., Iordanidou, E., Takou, M., Moraitis, B., Balaxis, D., A randomized comparison of two vaginal procedures for the treatment of stage two, or higher uterine prolapse: Hysterectomy with mesh versus only mesh implantation, <i>Neurourology and Urodynamics</i> , 31 (6), 855, 2012	Conference abstract
Mantoo, S., Podevin, J., Regenet, N., Rigaud, J., Lehur, P. A., Meurette, G., Is robotic-assisted ventral mesh rectopexy superior to laparoscopic ventral mesh rectopexy in the management of obstructed defaecation?, <i>Colorectal Disease</i> , 15, e469-75, 2013	Intervention not relevant - robotic surgery

Study	Reason for Exclusion
Margulies, R. U., Rogers, M. A. M., Morgan, D. M., Outcomes of transvaginal uterosacral ligament suspension: systematic review and metaanalysis, American Journal of Obstetrics and Gynecology, 202, 124-134, 2010	Systematic review of non-comparative studies
Markert, S., Niesel, A., Fuenfgeld, C., Kraus, A., Lenz, F., Augenstein, H., Mayser, A., Farthmann, J., Gitsch, G., Watermann, D., Partially absorbable polypropylene meshes for cystocele treatment demonstrate lower extrusion rates than conventional polypropylene meshes, Archives of Gynecology and Obstetrics, 282, S26-S27, 2010	Conference abstract
Marschke, J., Hengst, L., Schwertner-Tiepelmann, N., Beilecke, K., Tunn, R., Transvaginal single-incision mesh reconstruction for recurrent or advanced anterior vaginal wall prolapse, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 291, 1081-7, 2015	Non-randomised retrospective study
Matsuoka, P. K., Pacetta, A. M., Baracat, E. C., Haddad, J. M., Should prophylactic anti-incontinence procedures be performed at the time of prolapse repair? Systematic review, International Urogynecology Journal and Pelvic Floor Dysfunction, 26, 187-193, 2014	Systematic review - references checked for inclusion
Mazloomdoost, D., Pauls, R. N., Hennen, E. N., Yeung, J. Y., Smith, B. C., Kleeman, S. D., Crisp, C. C., Liposomal bupivacaine decreases pain following retropubic sling placement: a randomized placebo-controlled trial, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 08, 08, 2017	Intervention not relevant - assessment of aesthetic techniques
McDermott, C. D., Park, J., Terry, C. L., Woodman, P. J., Hale, D. S., Laparoscopic sacral colpopерineopexy: abdominal versus abdominal-vaginal posterior graft attachment, International Urogynecology Journal, 22, 469-75, 2011	Retrospective study
McDermott, C. D., Park, J., Terry, C. L., Woodman, P. J., Hale, D. S., Sacral colpopexy versus transvaginal mesh colpopexy in obese patients, Journal of Obstetrics & Gynaecology Canada: JOGCJ Obstet Gynaecol Can, 35, 461-7, 2013	Non-randomised retrospective study
McDermott, C. D., Terry, C. L., Woodman, P. J., Hale, D. S., Surgical outcomes following total Prolift: colpopexy versus hysteropexy, Australian & New Zealand journal of obstetrics & gynaecology, 51, 61-6, 2011	Non-randomised retrospective study
Meriwether, K. V., Antosh, D. D., Olivera, C. K., Kim-Fine, S., Balk, E. M., Murphy, M., Grimes, C. L., Sleemi, A., Singh, R., Dieter, A. A., Crisp, C. C., Rahn, D. D., Uterine preservation vs hysterectomy in pelvic organ prolapse surgery: a systematic review with meta-analysis and clinical practice guidelines, American Journal of Obstetrics and Gynecology., 2018	Systematic review - references checked for inclusion
Meschia, M., Baccichet, R., Cervigni, M., Guercio, E., Maglioni, Q., Narducci, P., Perrone, A., Pifarotti, P., Pisapia, Cioffi G., Riva, D., Simonazzi, M., Spreafico, L., A multicenter randomized trial on transvaginal mesh repair of severe genital prolapse with the perigee-apogee system. The Perapo study (Abstract number 16), International Urogynecology Journal and Pelvic Floor Dysfunction, 18 Suppl 1, S10, 2007	Conference abstract

Study	Reason for Exclusion
Meschia, M, Gattei, U, Pifarotti, P, Spennacchio, M, Longatti, D, Barbacini, P, Randomized comparison between infracoccygeal sacropexy (posterior IVS) and sacrospinous fixation in the management of vault prolapse (Abstract), Proceedings of the Joint Meeting of the International Continence Society (ICS) (34th Annual Meeting) and the International UroGynecological Association (IUGA), 2004 Aug 23-27, Paris, France, Abstract number 614, 2004	Conference abstract
Meschia, M, Pifarotti, P, Spennacchio, M, Gattei, U, Buonaguidi, A, Randomized comparison between posterior IVS and sacrospinous fixation in the management of vault prolapse (Abstract), Proceedings of the International Continence Society (ICS), 33rd Annual Meeting, 2003 Oct 5-9, Florence Italy, 182-3, 2003	Conference abstract
Meschia,M., Pifarotti,P., Spennacchio,M., Buonaguidi,A., Gattei,U., Somigliana,E., A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence, American Journal of Obstetrics and Gynecology, 190, 609-613, 2004	Intervention not relevant - stress urinary incontinence surgery
Milani, A. L., Damoiseaux, A., IntHout, J., Kluivers, K. B., Withagen, M. I. J., Long-term outcome of vaginal mesh or native tissue in recurrent prolapse: a randomized controlled trial, International Urogynecology journal, 29, 847-858, 2018	Intervention not relevant - cannot determine which compartment is operated on
Milani, A. L., Damoiseaux, A., IntHout, J., Kluivers, K. B., Withagen, M. I. J., Long-term outcome of vaginal mesh or native tissue in recurrent prolapse: a randomized controlled trial, International Urogynecology Journal, 22, 22, 2017	Intervention not relevant - unclear which compartment surgery is conducted on
Milani, A. L., Withagen, M. I., The, H. S., Nedelcu-van der Wijk, I., Vierhout, M. E., Sexual function following trocar-guided mesh or vaginal native tissue repair in recurrent prolapse: a randomized controlled trial, Journal of Sexual Medicine, 8, 2944-53, 2011	Intervention not relevant - unable to determine which compartment surgery is conducted on
Min, H., Li, H., Bingshu, L., Yanxiang, C., Lu, C., Qing, S., Xuejiao, Z., Wenying, W., Debin, W., Shasha, H., Wenjuan, D., Jie, M., Xiaohong, Z., Wenjun, G., Jianhua, C., Qian, L., Yuling, L., Meta-analysis of the efficacy and safety of the application of adjuvant material in the repair of anterior vaginal wall prolapsed, Archives of Gynecology & Obstetrics, 287, 919-36, 2013	Systematic review - references checked for inclusion
Moore, R. D., Lukban, J. C., Comparison of vaginal mesh extrusion rates between a lightweight type i polypropylene mesh versus heavier mesh in the treatment of pelvic organ prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 23, 1379-1386, 2012	Non-randomised study
Morgan, D. M., Rogers, M. A. M., Huebner, M., Wei, J. T., DeLancey, J. O., Heterogeneity in anatomic outcome of sacrospinous ligament fixation for prolapse: A systematic review, Obstetrics and Gynecology, 109, 1424-1433, 2007	Systematic review - references checked for inclusion

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Mourtialon, P., Letouzey, V., Eglin, G., de Tayrac, R., French Ugytex Study, Group, Cystocele repair by vaginal route: comparison of three different surgical techniques of mesh placement, International Urogynecology Journal, 23, 699-706, 2012	Prospective study comparing mesh placement techniques
Mowat, A., Maher, D., Baessler, K., Christmann-Schmid, C., Haya, N., Maher, C., Surgery for women with posterior compartment prolapse, Cochrane Database of Systematic Reviews, 2018 (3) (no pagination), 2018	Systematic review - references checked for inclusion
Mueller, E. R., Kenton, K., Anger, J. T., Bresee, C., Tarnay, C., Cosmetic Appearance of Port-site Scars 1 Year After Laparoscopic Versus Robotic Sacrocolpopexy: A Supplementary Study of the ACCESS Clinical Trial, Journal of Minimally Invasive Gynecology, 23, 917-21, 2016	Outcomes not relevant - cosmetic appearance of port site
Mueller, E. R., Kenton, K., Tarnay, C., Brubaker, L., Rosenman, A., Smith, B., Stroupe, K., Bresee, C., Pantuck, A., Schulam, P., Anger, J. T., Abdominal Colpopexy: Comparison of Endoscopic Surgical Strategies (ACCESS), Contemporary Clinical Trials, 33, 1011-8, 2012	Protocol - compares robotic and laparoscopic sacrocolpopexy
Nager, C. W., Concomitant anterior repair and subsequent anterior prolapse after vaginal apical surgery, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S77, 2014	Retrospective study
Nager, C. W., Grimes, C. L., Nolen, T. L., Wai, C. Y., Brubaker, L., Jeppson, P. C., Wilson, T. S., Visco, A. G., Barber, M. D., Sutkin, G., Norton, P., Rardin, C. R., Arya, L., Wallace, D., Meikle, S. F., Pelvic Floor Disorders Network, Concomitant Anterior Repair, Preoperative Prolapse Severity, and Anatomic Prolapse Outcomes After Vaginal Apical Procedures, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 11, 11, 2017	Secondary analysis of two studies which did not meet the eligibility criteria of review (OPUS and OPTIMAL study)
Nct,, Laparoscopic Lateral Suspension With Mesh & Sacrocervicopexy for the Treatment of Uterine Prolapse, <a href="https://clinicaltrials.gov/show/nct03421457">Https://clinicaltrials.gov/show/nct03421457</a> , 2018	Case series
Nct,, A Randomised Controlled Trial of Transvaginal Mesh (PROLIFT) Versus Anterior Colporrhaphy in Anterior Vaginal Wall Prolapse, <a href="http://clinicaltrials.gov/show/NCT00566917">Http://clinicaltrials.gov/show/NCT00566917</a> , 2007	Trial registration
Nct,, Alperin, M, Prophylactic Uterosacral Ligament Suspension at the Time of Hysterectomy for Prevention of Vaginal Vault Prolapse (PULS), <a href="http://clinicaltrials.gov/show/NCT01364025">Http://clinicaltrials.gov/show/NCT01364025</a> , 2011	Trial registration only. No publications identified.
Nct,, Bataller, E, Carmona, F, Anatomic and Functional Outcomes of Vaginal Mesh (ELEVATE) Compared With Laparoscopic Sacrocolpopexy for Pelvic Organ Prolapse, <a href="http://clinicaltrials.gov/show/NCT01097200">Http://clinicaltrials.gov/show/NCT01097200</a> , 2010	Trial registration
Nct,, Brandao, S, A National Multicentric Randomised Study of the Correction of Genital Prolapse With Fascial Repair or Mesh (Prolift), <a href="http://clinicaltrials.gov/show/NCT00771225">Http://clinicaltrials.gov/show/NCT00771225</a> , 2008	Trial registration
Nct,, Braun, Nm, Prospective Randomized Study to Compare Anatomical, Functional and Sexual Results of Pelvic Organ Prolapse Repair With One Versus Two Vaginal Meshes While Preserving the Uterus, <a href="https://clinicaltrials.gov/show/NCT02536001">Https://clinicaltrials.gov/show/NCT02536001</a> , 2015	Trial registration

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Nct., Costantini, E, Pelvic Organ Prolapse Repair With or Without Concomitant Burch Colposuspension in Patients With Urinary Incontinence: A Randomised Surgical Trial, <a href="Http://clinicaltrials.gov/show/NCT00576004">Http://clinicaltrials.gov/show/NCT00576004</a> , 2002	Trial registration
Nct., Girao, Mcb, Martins, Sb, Sacrospinous Colpopexy Versus High Uterosacral Colpopexy in the Treatment of Genital Prolapse Grade III/IV in Women With Uterus, <a href="Http://clinicaltrials.gov/show/NCT01347021">Http://clinicaltrials.gov/show/NCT01347021</a> , 2006	Trial registration
Nct., Haddad, Jm, Advanced Genital Prolapse Surgery With and Without Mid Urethral Sling to Prevent Stress Urinary Incontinence. A Multicenter, Randomized, Double-blind, Controlled Study, <a href="Https://clinicaltrials.gov/show/NCT02578056">Https://clinicaltrials.gov/show/NCT02578056</a> , 2014	Trial registration
Nct., Halaska, M, Open, Randomized, Prospective, Comparative, Multicentric to Treat Prolapse of Vaginal Cuff After Hysterectomy With Amreich Procedure or Total Prolift Procedure, <a href="Http://clinicaltrials.gov/show/NCT00572702">Http://clinicaltrials.gov/show/NCT00572702</a> , 2007	Trial registration
Nct., Iglesia, C, A Randomized Clinical Trial of Vaginal Mesh for Prolapse, <a href="Http://clinicaltrials.gov/show/NCT00475540">Http://clinicaltrials.gov/show/NCT00475540</a> , 2007	Trial registration
Nct., Lovatsis, D, Randomized Controlled Trial of Cystocele Plication Risks ("CPR Trial"): A Pilot Study, <a href="Http://clinicaltrials.gov/show/NCT01197248">Http://clinicaltrials.gov/show/NCT01197248</a> , 2009	Trial registration
Nct., Lucot, Jp, Randomized Controlled Trial Comparing Laparoscopic Sacropexy and Vaginal Mesh Surgery for Women Cystocele Repair: Functional and Anatomical Results at Four Years Follow-up, <a href="Http://clinicaltrials.gov/show/NCT02272361">Http://clinicaltrials.gov/show/NCT02272361</a> , 2014	Trial registration
Nct., Lucot, Jp, Randomized Study Comparing Laparoscopic Sacropexy and Vaginal Mesh Surgery in Cystocele Repair, <a href="Http://clinicaltrials.gov/show/NCT01637441">Http://clinicaltrials.gov/show/NCT01637441</a> , 2012	Trial registration
Nct., Minassian, Va, Randomized Trial Comparing Anterior Colporrhaphy to Paravaginal Defect Repair for Anterior Vaginal Wall Prolapse, <a href="Http://clinicaltrials.gov/show/NCT00271102">Http://clinicaltrials.gov/show/NCT00271102</a> , 2005	Trial registration
Nct., Minassian, Va, Randomized Trial Comparing Vaginal Hysterectomy to Laparoscopic Supracervical Hysterectomy With Vault Suspension for Symptomatic Uterine Prolapse, <a href="Http://clinicaltrials.gov/show/NCT01594372">Http://clinicaltrials.gov/show/NCT01594372</a> , 2013	Trial registration
Nct., Nager, Cw, Wallace, D, A Randomized Trial of Vaginal Surgery for Uterovaginal Prolapse: Vaginal Hysterectomy With Native Tissue Vault Suspension vs. Mesh Hysteropexy Suspension, <a href="Http://clinicaltrials.gov/show/NCT01802281">Http://clinicaltrials.gov/show/NCT01802281</a> , 2013	Trial registration
Nct., Nguyen, Jn, Prospective Randomized Trial of Anterior Colporrhaphy Versus Cystocele Repair Using Polypropylene Mesh or Porcine Dermis, <a href="Http://clinicaltrials.gov/show/NCT01393171">Http://clinicaltrials.gov/show/NCT01393171</a> , 2005	Trial registration
Nct., Nguyen, Jn, Outcome After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial, <a href="Http://clinicaltrials.gov/show/NCT00535301">Http://clinicaltrials.gov/show/NCT00535301</a> , 2005	Trial registration
Nct., Nieminen, K, Low-Weight Polypropylene Mesh for Anterior Vaginal Wall Prolapse: A Prospective Randomized Study, <a href="Http://clinicaltrials.gov/show/NCT00420225">Http://clinicaltrials.gov/show/NCT00420225</a> , 2003	Trial registration

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Study	Reason for Exclusion
Nct., Roy, Ca, A Randomized Controlled Trial Study, To Compare Colporrhaphy Versus NAZCA TCT, Macroporous Polypropylene Mesh, In Surgical Treatment To Greater Anterior Vaginal Prolapse, <a href="Http://clinicaltrials.gov/show/NCT00676325">Http://clinicaltrials.gov/show/NCT00676325</a> , 2007	Trial registration
Nct., Sokol, Ai, A Randomized Clinical Trial of Vaginal Mesh for Anterior Prolapse, <a href="Http://clinicaltrials.gov/show/NCT00557882">Http://clinicaltrials.gov/show/NCT00557882</a> , 2007	Trial registration
Nct., Suh, Dh, A Randomized Controlled Study of Laparoscopic/Robotic-assisted Hysteropexy Versus Vaginal Hysterectomy for the Treatment of Uterovaginal Prolapse, <a href="Https://clinicaltrials.gov/show/nct02877407">Https://clinicaltrials.gov/show/nct02877407</a> , 2017	Trial registration
Nct., Sung, Vw, Porcine-Derived Small Intestine Submucosa Graft-Augmented Rectocele Repair-A Randomized Trial, <a href="Http://clinicaltrials.gov/show/NCT00321867">Http://clinicaltrials.gov/show/NCT00321867</a> , 2004	Trial registration
Nct., Tagliaferri, V, Laparoscopic Sacrocolpopexy Versus POPS in the Surgical Management of Pelvic Organ Prolapse: a Prospective Randomized Trial, <a href="Https://clinicaltrials.gov/show/nct02911584">Https://clinicaltrials.gov/show/nct02911584</a> , 2017	Trial registration
Nct., Tayrac, R, Clinical Evaluation of Morbidity and Efficacy of Posterior IVS (Infracoccygeal Sacropexy), in Comparison to the Standard Sacrospinous Suspension in the Surgical Treatment of Vaginal Vault Prolapse by the Vaginal Route, <a href="Http://clinicaltrials.gov/show/NCT00153231">Http://clinicaltrials.gov/show/NCT00153231</a> , 2003	Trial registration
Nct., Tayrac, R, STARR Type Trans-anal Resection Versus Vaginal Rectocele Repair Using a Posterier Elevate Prothesis: a Randomized, Multicentric, Prospective Study on Defecatory Function, <a href="Http://clinicaltrials.gov/show/NCT01257659">Http://clinicaltrials.gov/show/NCT01257659</a> , 2011	Trial registration
Nct., Tayrac, R, Fernandez, H, Comparison of the Prosthesis Ugytex by the Trans-Obturator Approach and Anterior Colporrhaphy for the Surgical Treatment of Anterior Vaginal Wall Prolapse, <a href="Http://clinicaltrials.gov/show/NCT00153257">Http://clinicaltrials.gov/show/NCT00153257</a> , 2005	Trial registration
Nct., Tayrac, R, Suehs, C, Comparison of Long-term Results of UGYTEX® Sub-bladder Mesh Placed Via a Transvaginal Transobturator Approach Versus Subvesical Plication Without Reinforcement in the Surgical Treatment of Bladder Prolapse, <a href="Http://clinicaltrials.gov/show/NCT02255994">Http://clinicaltrials.gov/show/NCT02255994</a> , 2014	Trial registration
Nct., Trabuco, E, Safety and Efficacy of Transvaginal Mesh Colposuspension for Anterior Vaginal Prolapse: the Elevate vs. Anterior Colporrhaphy Trial, <a href="Http://clinicaltrials.gov/show/NCT01497171">Http://clinicaltrials.gov/show/NCT01497171</a> , 2011	Trial registration
Nct., Wei, Jt, Outcomes Following Vaginal Prolapse Repair and Mid Urethral Sling (OPUS) Trial, <a href="Http://clinicaltrials.gov/show/NCT00460434">Http://clinicaltrials.gov/show/NCT00460434</a> , 2007	Trial registration
Nct., Withagen, Mij, Rumpt, L, A Prospective and Comparative Study of the (Cost)Effectiveness Preformance of Tension Free Vaginal Mesh Plus Monocryl (Prolift+M) Versus Conventional Vaginal Prolapse Surgery in Primary Pelvic Organ Prolapse, <a href="Http://clinicaltrials.gov/show/NCT02231099">Http://clinicaltrials.gov/show/NCT02231099</a> , 2011	Trial registration

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Nct., Withagen, Mij, Vierhout, Me, A Prospective and Comparative Study of the Performance of Tension Free Vaginal Mesh (Prolift) Versus Conventional Vaginal Prolapse Surgery in Recurrent Prolapse, <a href="http://clinicaltrials.gov/show/NCT00372190">Http://clinicaltrials.gov/show/NCT00372190</a> , 2006	Trial registration
Nct., Zhu, L, Nationwide Multicenter Randomized Prospective Study to Compare Laparoscopic Sacral Colpopexy and Modified Total Pelvic Floor Reconstructive Surgery With Mesh for Apical Prolapse Stage III-IV, <a href="http://clinicaltrials.gov/show/NCT01762384">Http://clinicaltrials.gov/show/NCT01762384</a> , 2012	Trial registration
Neuman, M., Lavy, Y., Conservation of the prolapsed uterus is a valid option: medium term results of a prospective comparative study with the posterior intravaginal slingplasty operation, International Urogynecology Journal, 18, 889-93, 2007	Non-randomised cohort study
Ng, C. C., Chong, C. Y., The effectiveness of transvaginal anterior colporrhaphy reinforced with polypropylene mesh in the treatment of severe cystoceles, Annals of the Academy of Medicine, SingaporeAnn Acad Med Singapore, 35, 875-81, 2006	Retrospective study
Nieminen, K., Hiltunen, K. M., Laitinen, J., Oksala, J., Heinonen, P. K., Transanal or vaginal approach to rectocele repair: a prospective, randomized pilot study, Diseases of the Colon & Rectum, 47, 1636-42, 2004	No relevant outcomes reported
Nieminen, K., Hiltunen, R., Heiskanen, E., Takala, T., Niemi, K., Merikari, M., Heinonen, P. K., Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh, International Urogynecology Journal, 19, 1611-1616, 2008	Secondary publication from included study (Hiltunen 2007)
Nieminen, K., Hiltunen, R., Takala, T., Heiskanen, E., Merikari, M., Niemi, K., Heinonen, P. K., Outcomes after anterior vaginal wall repair with mesh: A randomized, controlled trial with a 3-year follow-up, Obstetrical and Gynecological Survey, 66, 411-413, 2011	Commentary article
Nieminens,K., Hiltunen,R., Takala,T., Heiskanen,E., Merikari,M., Niemi,K., Heinonen,P.K., Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up, American Journal of Obstetrics and Gynecology, 203, 235-238, 2010	Secondary publication from included study (Hiltunen 2007)
Niu, K., Lu, Y. X., Shen, W. J., Zhang, Y. H., Wang, W. Y., Risk Factors for Mesh Exposure after Transvaginal Mesh Surgery, Chinese medical journal, 129, 1795-9, 2016	Non-randomised retrospective study
Noe, K. G., Schiermeier, S., Alkatout, I., Anapolski, M., Laparoscopic pectopexy: a prospective, randomized, comparative clinical trial of standard laparoscopic sacral colpopervicopexy with the new laparoscopic pectopexy-postoperative results and intermediate-term follow-up in a pilot study, Journal of Endourology, 29, 210-5, 2015	Intervention not included in protocol
Noe, K. G., Spunrup, C., Anapolski, M., Laparoscopic pectopexy: a randomised comparative clinical trial of standard laparoscopic sacral colpo-cervicopexy to the new laparoscopic pectopexy. Short-term postoperative results, Archives of Gynecology & Obstetrics, 287, 275-80, 2013	Intervention not included in protocol

Study	Reason for Exclusion
Nosti, P. A., Carter, C. M., Sokol, A. I., Tefera, E., Iglesia, C. B., Park, A. J., Gutman, R. E., Transvaginal Versus Transabdominal Placement of Synthetic Mesh at Time of Sacrocolpopexy, Female pelvic medicine & reconstructive surgery, 22, 151-5, 2016	Non-randomised retrospective study
Novi, J. M., Bradley, C. S., Mahmoud, N. N., Morgan, M. A., Arya, L. A., Sexual function in women after rectocele repair with acellular porcine dermis graft vs site-specific rectovaginal fascia repair, International Urogynecology Journal, 18, 1163-9, 2007	Non-randomised cohort study
Novi, J. M., Mulvihil, B. H., Arya, L., Vaginal paravaginal repair using porcine or human cadaveric dermal implant: a survival analysis, International SurgeryInt Surg, 94, 88-94, 2009	Non-randomised retrospective study
Nussler, E, Kesmodel, Us, Lofgren, M, Nussler, Ek, Operation for primary cystocele with anterior colporrhaphy or non-absorbable mesh: patient-reported outcomes, International Urogynecology Journal and Pelvic Floor Dysfunction, 26, 359-66, 2014	Non-randomised retrospective study
Nussler, E. K., Greisen, S., Kesmodel, U. S., Lofgren, M., Bek, K. M., Glavind-Kristensen, M., Operation for recurrent cystocele with anterior colporrhaphy or non-absorbable mesh: patient reported outcomes, International Urogynecology Journal, 24, 1925-31, 2013	Non-randomised study -analysis of Swedish registry of surgery
Nygaard, I, Long-term Effectiveness of Abdominal Sacrocolpopexy for the Treatment of Pelvic Organ Prolapse: The Extended Colpopexy and Urinary Reduction Efforts (E-CARE) Study, <a href="http://clinicaltrials.gov/show/NCT00099372">Http://clinicaltrials.gov/show/NCT00099372</a> , 2004	Trial registration
Nygaard, I., A 7-year follow-up study of abdominal sacrocolpopexy with and without burch urethropexy: The ecare (extended colpopexy and urinary reduction efforts) study, Female Pelvic Medicine and Reconstructive Surgery, 2), S56-S57, 2012	Conference abstract
Nygaard, I., Brubaker, L., Zyczynski, H. M., Cundiff, G., Richter, H., Gantz, M., Fine, P., Menefee, S., Ridgeway, B., Visco, A., Warren, L. K., Zhang, M., Meikle, S., Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse, JAMA - Journal of the American Medical Association, 309, 2016-2024, 2013	Intervention not relevant - stress urinary incontinence surgery
Obinata, D., Sugihara, T., Yasunaga, H., Mochida, J., Yamaguchi, K., Murata, Y., Yoshizawa, T., Matsui, T., Matsui, H., Sasabuchi, Y., Fujimura, T., Homma, Y., Takahashi, S., Tension-free vaginal mesh surgery versus laparoscopic sacrocolpopexy for pelvic organ prolapse: Analysis of perioperative outcomes using a Japanese national inpatient database, International Journal of UrologyInt J Urol, 05, 05, 2018	Review of retrospective database
Ow, L. L., Lim, Y. N., Dwyer, P. L., Karmakar, D., Murray, C., Thomas, E., Rosamilia, A., Native tissue repair or transvaginal mesh for recurrent vaginal prolapse: what are the long-term outcomes?, International Urogynecology Journal, 27, 1313-20, 2016	Retrospective study

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Study	Reason for Exclusion
Paek, J., Lee, M., Kim, B. W., Kwon, Y., Robotic or laparoscopic sacrohysteropexy versus open sacrohysteropexy for uterus preservation in pelvic organ prolapse, International Urogynecology Journal, 27, 593-9, 2016	Retrospective study
Paganotto, M. C., Amadori, L., Di Donato, N., Mauloni, M., Busacchi, P., Use of a preventive sling surgery for the simultaneous correction of latent stress urinary incontinence during the cystocele repair: two year follow-up, Minerva Ginecologica, 65, 319-26, 2013	Retrospective study
Pan, K., Cao, L., Ryan, N. A., Wang, Y., Xu, H., Laparoscopic sacral hysteropexy versus laparoscopic sacrocolpopexy with hysterectomy for pelvic organ prolapse, International Urogynecology Journal, 27, 93-101, 2016	Non-randomised retrospective study
Pan, K., Zhang, Y., Wang, Y., Xu, H., A systematic review and meta-analysis of conventional laparoscopic sacrocolpopexy versus robot-assisted laparoscopic sacrocolpopexy, International Journal of Gynecology and Obstetrics, 132, 284-291, 2016	Systematic review - references checked for included studies
Paraiso, M. F. R., Jelovsek, J. E., Frick, A., Chen, C. C. G., Barber, M. D., Laparoscopic compared with robotic sacrocolpopexy for vaginal prolapse: A randomized controlled trial, Obstetrics and Gynecology, 118, 1005-1013, 2011	Intervention not relevant - robotic sacrocolpopexy versus laparoscopic sacrocolpopexy
Park, J., Kassis, N. C., Steele, G. K., Woodman, P. J., Hale, D. S., Biograft addition to posterior synthetic mesh during laparoscopic sacral colpopерineopexy: A randomized controlled clinical trial, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S24-S25, 2014	Conference abstract
Parveen, T., Iqbal, T., Kauser, T., Comparison between conventional abdominal hysterectomy and hysterectomy with autologous rectus sheath sling to prevent vault prolapse, Medical Channel, 20, 70-2, 2014	Population do not meet inclusion criteria - fewer than 30% of participants had prolapse
Parveen, T., Kausar, T., Iqbal, T., Batool, A., Comparison of outcome between vaginal and abdominal hysterectomy, Pakistan Journal of Medical and Health Sciences, 7, 1150-1153, 2013	Population do not meet inclusion criteria - majority of participants had an indication other than prolapse for their surgery
Paz-Valiñas, L., Macía, Cortiñas M., López-García, M., Transvaginal mesh in pelvic organ prolapse repair (Structured abstract), Health Technology Assessment Database, 2014	Publication not in English language
Persson, P., Brynhildsen, J., Kjolhede, P., Pelvic organ prolapse after subtotal and total hysterectomy: A long-term follow-up of an open randomised controlled multicentre study, BJOG: An International Journal of Obstetrics and Gynaecology, 120, 1556-1565, 2013	Population do not meet inclusion criteria - women do not have prolapse symptoms prior to surgery

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Study	Reason for Exclusion
Phillip, H. E., Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 111, 452-3; author reply 453, 2008	Letter to the editor
Pifarotti,P., Spennacchio,M., Gattei,U., Ronchetti,A., Stoppelli,S., Meschia,M., A randomized prospective comparison of TTV and endopelvic fascia plication in the treatment of occult stress urinary incontinence in patients with genital prolapse: Preliminary data, <i>Urogynaecologia International Journal</i> , 15, 55-57, 2001	Intervention not relevant - women have stress urinary incontinence surgery
Porena, M, Nct,, Urinary incontinence and uro-genital prolapse: a randomized trial of pelvic organ prolapse repair plus mini-sling versus pelvic organ prolapse repair alone (Trials Registry number: NCT01384084), ClinicalTrials.gov (available At: <a href="http://clinicaltrials.gov/show/NCT01384084">Http://clinicaltrials.gov/show/NCT01384084</a> ), 2012	Trial registration
Qatawneh, A., Al-Kazaleh, F., Saleh, S., Thekrallah, F., Bata, M., Sumreen, I., Al-Mustafa, M., Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: A prospective randomised study, <i>Gynecological surgery</i> , 10, 79-85, 2013	Outcome data is unclearly reported - all women have sacrospinous colpopexy (for apical prolapse) The outcome is specific to anterior prolapse, yet it is unclear if all women have this procedure
Quiroz, L. H., Gutman, R. E., Shippey, S., Cundiff, G. W., Sanses, T., Blomquist, J. L., Handa, V. L., Abdominal sacrocolpopexy: anatomic outcomes and complications with Pelvicol, autologous and synthetic graft materials, <i>American Journal of Obstetrics &amp; Gynecology Am J Obstet Gynecol</i> , 198, 557.e1-5, 2008	Non-randomised retrospective study
Rahmanou, P., White, B., Price, N., Jackson, S., Laparoscopic hysteropexy: 1- to 4-year follow-up of women postoperatively, <i>International Urogynecology Journal</i> , 25, 131-8, 2014	Non-comparative study
Ramanah, R., Ballester, M., Chereau, E., Rouzier, R., Darai, E., Effects of pelvic organ prolapse repair on urinary symptoms: a comparative study between the laparoscopic and vaginal approach, <i>Neurourology &amp; UrodynamicsNeurourol Urodyn</i> , 31, 126-31, 2012	Non-randomised cohort study
Ramanah,R., Mairot,J., Clement,M.C., Parratte,B., Maillet,R., Riethmuller,D., Evaluating the porcine dermis graft InteXen in three-compartment transvaginal pelvic organ prolapse repair, <i>International urogynecology journal and pelvic floor dysfunction</i> , 21, 1151-1156, 2010	Retrospective study

Study	Reason for Exclusion
Rane, A., Iyer, J., Kannan, K., Corstiaans, A., Prospective study of the PerigeeTM system for treatment of cystocele - our five-year experience, Australian & New Zealand Journal of Obstetrics & Gynaecology, 52, 28-33, 2012	Non-randomised study
Ray, S., Halder, A., Gangopadhyay, M., Halder, S., Pal, P. P., Comparison of two different suture materials for transvaginal sacrospinous fixation of the vault: A prospective randomized trial, Journal of gynecologic surgery, 29, 281-286, 2013	Intervention not relevant - all women underwent transvaginal sacrospinous fixation, comparison of polyglactin with PDS II sutures
Reisenauer, C, Use of absorbable versus non-absorbable sutures for vaginal implant fixation during sacrocolpopexy as part of the surgical treatment of vaginal vault prolapse ICS-POPQ stage II-III, <a href="Http://www.drks.de/DRKS00003263">Http://www.drks.de/DRKS00003263</a> , 2011	Trial registration
Renganathan, A., Cardozo, L., Too early to conclude that infracoccygeal sacropexy is equivalent to sacrospinous suspension, Gynecological surgery, 5, 330-331, 2008	Commentary paper
Richardson, Ml, Elliott, Cs, Shaw, Jg, Comiter, Cv, Chen, B, Sokol, Er, To sling or not to sling at time of abdominal sacrocolpopexy: a cost-effectiveness analysis (Provisional abstract), Journal of urology, 190, 1306-1312, 2013	Outcomes not relevant - only cost effectiveness data
Richter, H. E., Nygaard, I., Burgio, K. L., Handa, V. L., Fitzgerald, M. P., Wren, P., Zyczynski, H., Fine, P., Brown, M. B., Weber, A. M., Pelvic Floor Disorders, Network, Lower urinary tract symptoms, quality of life and pelvic organ prolapse: irritative bladder and obstructive voiding symptoms in women planning to undergo abdominal sacrocolpopexy for advanced pelvic organ prolapse, Journal of urology, 178, 965-9; discussion 969, 2007	Population do not meet inclusion criteria - women have not undergone surgery
Ridder, D, Claerhout, F, Verleyen, P, Boulanger, S, Deprest, J, Porcine dermis xenograft as reinforcement for cystocoele stage III repair: a prospective randomized controlled trial (Abstract), Neurourology and Urodynamics, 23, 435-6, 2004	Conference abstract
Roberts, C. A., Lucente, V. R., Three-year outcomes of vaginal mesh for prolapse: a randomized controlled trial, Obstetrics & Gynecology, 123, 664-5, 2014	Letter to the editor
Rogers, R. G., Nolen, T. L., Weidner, A. C., Richter, H. E., Jelovsek, J. E., Shepherd, J. P., Harvie, H. S., Brubaker, L., Menefee, S. A., Myers, D., Hsu, Y., Schaffer, J. I., Wallace, D., Meikle, S. F., Open sacrocolpopexy and vaginal apical repair: retrospective comparison of success and serious complications, International urogynecology journal, 1-10, 2018	Retrospective study

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Study	Reason for Exclusion
Rogowski, A., Bienkowski, P., Tarwacki, D., Szafarowska, M., Samochowiec, J., Sienkiewicz-Jarosz, H., Jerzak, M., Baranowski, W., Retrospective comparison between the Prolift and Elevate anterior vaginal mesh procedures: 18-month clinical outcome, International Urogynecology Journal, 26, 1815-20, 2015	Non-randomised retrospective study
Roovers, Jpw, Sacrospinous ligament fixation combined with anterior colporrhaphy versus Elevate Anterior procedure in treatment of primary apical and anterior compartment prolapse stage 2 or more: A multi-center randomised controlled trial. - Elevate Anterior Trial, <a href="Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=3074">Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=3074</a> , 2011	Trial registration
Roovers, Jpw, Sacrospinous ligament fixation versus Elevate Posterior procedure in treatment of primary apical prolapse stage 2 or more: A multi-center randomised controlled trial. - Elevate Posterior trial, <a href="Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=3075">Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=3075</a> , 2011	Trial registration
Roovers, Jpw, Vaart, Ch, Abdominal and vaginal prolapse surgical correction of uterine prolapse are equally efficient in correcting co-existing enterocele (Abstract number 320), International Urogynecology Journal, 17, S236-s237, 2006	Conference abstract
Rosen, A., Ron, Y., Condrea, A., Ginat, S., Avni, Y., Shimonov, M., A comparison between stapled transanal rectal resection and posterior colporrhaphy in constipated women with rectocele. A randomized study, Techniques in Coloproctology, 14 (1), 68, 2010	Conference abstract
Rosen, D. M., Shukla, A., Cario, G. M., Carlton, M. A., Chou, D., Is hysterectomy necessary for laparoscopic pelvic floor repair? A prospective study, Journal of minimally invasive gynecology, 15, 729-34, 2008	Non-randomised cohort study
Ross, J. W., Routine Pelvic Support Procedures for Laparoscopic Vaginal Hysterectomies, Journal of the American Association of Gynecologic Laparoscopists, 3, S43, 1996	Non-randomised cohort study
Roy, C, A randomized controlled trial study, to compare colporrhaphy versus NAZCA TC, macroporous polypropylene mesh, in surgical treatment to greater anterior vaginal prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 22, S860, 2011	Preliminary data from an included study (Delroy 2013)

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Study	Reason for Exclusion
Rudnicki, M., Teleman, P., Laurikainen, E., Franklin, J., Pogosean, R., Urnes, A., Kinne, I., Hviid, U., The use of avaulta plus? For anterior repair. A multicenter randomised prospective controlled study, International Urogynecology Journal and Pelvic Floor Dysfunction, 22, S928-S929, 2011	Conference abstract - full publication included (Rudnicki 2016)
Rzepka, J., Brocker, K., Alt, C., Corteville, C., Sohn, C., Lenz, F., Pelvic organ prolapse: does the postoperative course of mesh-repair surgery differ in elderly women when compared with younger patients?, Journal of Obstetrics & GynaecologyJ Obstet Gynaecol, 30, 852-6, 2010	Non-randomised cohort study
Sand, P. K., Koduri, S., Lobel, R. W., Winkler, H. A., Tomezsko, J., Culligan, P. J., Goldberg, R., Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles, American Journal of Obstetrics & Gynecology, 184, 1357-62; discussion 1362-4, 2001	Population did not meet inclusion criteria - women had stress urinary incontinence. Unable to disaggregate data for different compartments.
Sayer, T, Lim, J, Gauld, Jm, Hinoul, P, Jones, P, Franco, N, Drie, D, Slack, M, Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device, International Urogynecology Journal and Pelvic Floor Dysfunction, 23, 487-93, 2012	Non-randomised cohort study
Schierlitz, L., Dwyer, P. L., Rosamilia, A., De Souza, A., Murray, C., Thomas, E., Hiscock, R., Achtari, C., Pelvic organ prolapse surgery with and without tension-free vaginal tape in women with occult or asymptomatic urodynamic stress incontinence: a randomised controlled trial, International Urogynecology Journal, 25, 33-40, 2014	Intervention not relevant - women had surgery for stress urinary incontinence
Schierlitz, L., Dwyer, P., Rosamilia, A., Murray, C., Thomas, E., Fitzgerald, E., Hiscock, R., De Souza, A., A prospective randomised controlled trial comparing vaginal prolapse repair with and without tensionfree vaginal tape (TVT) in women with severe genital prolapse and occult stress incontinence: Long term follow up, International Urogynecology Journal and Pelvic Floor Dysfunction, 21, S2-S3, 2010	Population did not meet inclusion criteria - women had stress urinary incontinence
Schimpf, M. O., Abed, H., Sanses, T., White, A. B., Lowenstein, L., Ward, R. M., Sung, V. W., Balk, E. M., Murphy, M., Society of Gynecologic Surgeons Systematic Review, Group, Graft and Mesh Use in Transvaginal Prolapse Repair: A Systematic Review, Obstetrics & Gynecology, 128, 81-91, 2016	Systematic review - references checked for inclusion

Study	Reason for Exclusion
Schraffordt Koops,S.E., Bisseling,T.M., van Brummen,H.J., Heintz,A.P., Vervest,H.A., Result of the tension-free vaginal tape in patients with concomitant prolapse surgery: a 2-year follow-up study. An analysis from the Netherlands TVT database, International Urogynecology Journal, 18, 437-442, 2007	Outcomes data not reported for different compartments
Seeger, D, Schmidt, A, Schmidt-Petruschkat, S, Kimmig, R, Rectocele repair using biomaterial implants -anatomic outcome associated with improvement of obstructive defecation (Abstract number 596), Proceedings of the International Continence Society (ICS), 35th Annual Meeting, 2005 Aug 28-Sep 2, Montreal, Canada, 2005	Conference abstract
Serati, M., Bogani, G., Sorice, P., Braga, A., Torella, M., Salvatore, S., Uccella, S., Cromi, A., Ghezzi, F., Robot-assisted sacrocolpopexy for pelvic organ prolapse: a systematic review and meta-analysis of comparative studies, European Urology, 66, 303-18, 2014	Systematic review - references checked for inclusion
Shah, H. N., Badlani, G. H., Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review, Indian Journal of Urology, 28, 129-53, 2012	Systematic review - references checked for inclusion
Shveiky, D., Iglesia, C. B., Sokol, A. I., Kudish, B. I., Gutman, R. E., Robotic sacrocolpopexy versus vaginal colpopexy with mesh: choosing the right surgery for anterior and apical prolapse, Female pelvic medicine & reconstructive surgery, 16, 121-7, 2010	Retrospective study
Shveiky, D., Sokol, A. I., Gutman, R. E., Kudish, B. I., Iglesia, C. B., Patient goal attainment in vaginal prolapse repair with and without mesh, International Urogynecology Journal, 23, 1541-6, 2012	Unable to determine which compartment surgery had been conducted on
Siddiqui, N. Y., Fulton, R. G., Kuchibhatla, M., Wu, J. M., Sexual function after vaginal versus nonvaginal prolapse surgery, Female pelvic medicine & reconstructive surgery, 18, 239-42, 2012	Non-randomised cohort study
Siddiqui, N. Y., Geller, E. J., Visco, A. G., Symptomatic and anatomic 1-year outcomes after robotic and abdominal sacrocolpopexy, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 206, 435.e1-5, 2012	Retrospective study

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Study	Reason for Exclusion
Siddiqui, N. Y., Grimes, C. L., Casiano, E. R., Abed, H. T., Jeppson, P. C., Olivera, C. K., Sanses, T. V., Steinberg, A. C., South, M. M., Balk, E. M., Sung, V. W., Mesh sacrocolpopexy compared with native tissue vaginal repair: A systematic review and meta-analysis, <i>Obstetrics and Gynecology</i> , 125, 44-55, 2014	Systematic review - references checked for inclusion
Silva-Filho, A. L., Werneck, R. A., de Magalhaes, R. S., Belo, A. V., Triginelli, S. A., Abdominal vs vaginal hysterectomy: a comparative study of the postoperative quality of life and satisfaction, <i>Archives of Gynecology &amp; Obstetrics</i> , 274, 21-4, 2006	Population do not meet inclusion criteria - study included women with fibroids
Singh, R., Cornish, A., Carey, M. P., Native tissue repair versus mesh for transvaginal prolapse surgery: 5-year follow-up RCT, <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 1), S31-S32, 2014	Conference abstract
Sloth, S. B., Schroll, J. B., Settnes, A., Gimbel, H., Rudnicki, M., Topsoe, M. F., Joergensen, A., Nortvig, H., Moeller, C., Systematic review of the limited evidence for different surgical techniques at benign hysterectomy: A clinical guideline initiated by the Danish Health Authority, <i>European Journal of Obstetrics Gynecology and Reproductive Biology</i> , 216, 169-177, 2017	Systematic review - references checked for inclusion
Sokol,A.I., Iglesia,C.B., Kudish,B.I., Gutman,R.E., Shveiky,D., Bercik,R., Sokol,E.R., One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse, <i>American journal of obstetrics and gynecology</i> , 206, 86-86, 2012	Secondary analysis of excluded study. Excluded as unable to determine which compartment the primary prolapse surgery was conducted on
Song, Y., Wang, X. J., Chen, Y. S., Hua, K. Q., Management of Urinary Incontinence before and after Total Pelvic Reconstruction for Advanced Pelvic Organ Prolapse with and without Incontinence, <i>Chinese Medical Journal Chin Med J</i> , 131, 553-558, 2018	Retrospective study
Stanford, E. J., Moore, R. D., Roovers, J. P., VanDrie, D. M., Giudice, T. P., Lukban, J. C., Bataller, E., Sutherland, S. E., Elevate and Uterine Preservation: Two-Year Results, <i>Female pelvic medicine &amp; reconstructive surgery</i> , 21, 205-10, 2015	Non-randomised cohort
Stepanian, A. A., Miklos, J. R., Moore, R. D., Mattox, T. F., Risk of mesh extrusion and other mesh-related complications after laparoscopic sacral colpopexy with or without concurrent laparoscopic-assisted vaginal hysterectomy: experience of 402 patients, <i>Journal of minimally invasive gynecology</i> , 15, 188-96, 2008	Non-randomised retrospective study

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Study	Reason for Exclusion
Su, T. H., Lau, H. H., Huang, W. C., Hsieh, C. H., Chang, R. C., Su, C. H., Single-incision mesh repair versus traditional native tissue repair for pelvic organ prolapse: results of a cohort study, International Urogynecology Journal, 25, 901-8, 2014	Non-randomised cohort
Sun, Y., Tang, C., Luo, D., Yang, L., Shen, H., The treatment of anterior vaginal wall prolapsed by repair with mesh versus colporrhaphy, International Urology & Nephrology, 48, 155-67, 2016	Systematic review - references checked for inclusion
Sung, V. W., Rardin, C. R., Raker, C. A., LaSala, C. A., Myers, D. L., Changes in bowel symptoms 1 year after rectocele repair, American Journal of Obstetrics & Gynecology, 207, 423.e1-5, 2012	Outcomes not relevant - two groups of participants (with different types of rectocoele repairs) are amalgamated
Sung, V. W., Rogers, R. G., Schaffer, J. I., Balk, E. M., Uhlig, K., Lau, J., Abed, H., Wheeler, T. L., Morrill, M. Y., Clemons, J. L., Rahn, D. D., Lukban, J. C., Lowenstein, L., Kenton, K., Young, S. B., Graft use in transvaginal pelvic organ prolapse repair: A systematic review, Obstetrics and Gynecology, 112, 1131-1142, 2008	Systematic review - references checked for inclusion
Svabik, K., Masata, J., Hubka, P., Martan, A., Randomized trial comparing vaginal mesh repair (prolif total) versus sacrospinous vaginal colpopexy (SSF) in the management of vaginal vault prolapse after hysterectomy for patients with levator ani avulsion injury-6 years-follow-up, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S59-S60, 2016	Conference abstract
Sze, E. H., Miklos, J. R., Partoll, L., Roat, T. W., Karram, M. M., Sacrospinous ligament fixation with transvaginal needle suspension for advanced pelvic organ prolapse and stress incontinence, Obstetrics & GynecologyObstet Gynecol, 89, 94-6, 1997	Population did not meet inclusion criteria - women had stress urinary incontinence
Tamanini, J, Feldner, P, Efficacy And Safety Study With Polipropilene Mesh (Nazca Tc) For The Treatment Of Anterior Vaginal Wall Prolapse, <a href="http://www.ensaiosclinicos.gov.br/rg/RBR-7m2xdy/">Http://www.ensaiosclinicos.gov.br/rg/RBR-7m2xdy/</a> , 2013	Trial registration
Tamanini, J. T. N., De Oliveira Souza Castro, R. C., Tamanini, J. M., Castro, R. A., Sartori, M. G. F., Girao, M. J. B. C., A prospective, randomized, controlled trial of the treatment of anterior vaginal wall prolapse: Medium term followup, Journal of urology, 193, 1298-1304, 2015	Secondary publication from an included study (Tamanini 2013)

Study	Reason for Exclusion
Tan-Kim, J, Menefee, Sa, Luber, Km, Nager, Cw, Lukacz, Es, Robotic-assisted and laparoscopic sacrocolpopexy: comparing operative times, costs and outcomes (Provisional abstract), Female Pelvic Medicine and Reconstructive Surgery, 17, 44-49, 2011	Retrospective cohort study
Tan-Kim, J., Nager, C. W., Grimes, C. L., Luber, K. M., Lukacz, E. S., Brown, H. W., Ferrante, K. L., Dyer, K. Y., Kirby, A. C., Menefee, S. A., A randomized trial of vaginal mesh attachment techniques for minimally invasive sacrocolpopexy, International Urogynecology Journal, 26, 649-56, 2015	Intervention not relevant - Comparison of attachment techniques during sacrocolpopexy, standard non-barbed delayed absorbable sutures versus self-anchoring, barbed delayed absorbable suture
Tantanasis,T., Giannoulis,C., Daniilidis,A., Papathanasiou,K., Loufopoulos,A., Tzafettas,J., Anterior vaginal wall reconstruction: anterior colporrhaphy reinforced with tension free vaginal tape underneath bladder base, Acta Obstetricia et Gynecologica Scandinavica, 87, 464-468, 2008	Non-randomised cohort study
Tayrac, R, Bader, G, Deffieux, X, Fazel, A, Mathe, MI, Fernandez, H, A prospective randomized study comparing posterior IVS and sacrospinous suspension for the surgical treatment of uterine or vaginal vault prolapse (Abstract number 317), International Urogynecology Journal, 17, S234-s235, 2006	Conference abstract - full text article included (de Tayrac 2008)
Thakur, Y, Posterior Intravaginal Slingplasty (Infracoccygeal Sacropexy) with uterine preservation Vs Vaginal Hysterectomy with Posterior Intravaginal Slingplasty in women with at least grade II uterovaginal prolapse, ISRCTN ( <a href="http://isrctn.org/ISRCTN95545591">http://isrctn.org/ISRCTN95545591</a> ), 2005	Trial registration
Theofanides, M. C., Onyeji, I., Matulay, J., Sui, W., James, M., Chung, D. E., Safety of Mesh Use in Vaginal Cystocele Repair: Analysis of National Patient Characteristics and Complications, Journal of urology, 07, 07, 2017	Retrospective review of database of women undergoing cystocele repair
Thijs, S., Deprest, J., De Ridder, D., Claerhout, F., Roovers, J., A randomized controlled trial of anterior colporraphy and PerigeetM as a primary surgical correction of symptomatic cystocele, International Urogynecology Journal and Pelvic Floor Dysfunction, 21, S142-S143, 2010	Conference abstract

Study	Reason for Exclusion
Thomas, E, Lim, Y, Dwyer, P, Randomised Controlled Trial of Post-hysterectomy Vaginal Vault Prolapse Treatment with either Extraperitoneal Uterosacral Ligament Suspension or Sacrocolpopexy (Abdominal and Laparoscopic), <a href="Http://www.anzctr.org.au/ACTRN12608000102370.aspx">Http://www.anzctr.org.au/ACTRN12608000102370.aspx</a> , 2008	Trial registration
Thompson, P. K., McCrery, R. J., Lotze, E. C., Sangi-Haghpeykar, H., Vaginal prolapse surgery: Comparing abdominal sacral colpopexy to uterosacral suspension, <i>Journal of Pelvic Medicine and Surgery</i> , 14, 15-22, 2008	Retrospective case review
Thunedborg, P., Fischer-Rasmussen, W., Bjerregaard Jensen, S., Stress urinary incontinence and posterior bladder suspension defects. Results of vaginal repair versus Burch colposuspension, <i>Acta obstetricia et gynecologica Scandinavica</i> , 69, 55-59, 1990	Population did not meet inclusion criteria - women had stress urinary incontinence. Cohort study
Thys, S. D., Coolen, A., Martens, I. R., Oosterbaan, H. P., Roovers, J., Mol, B., Bongers, M. Y., A comparison of long-term outcome between Manchester Fothergill and vaginal hysterectomy as treatment for uterine descent, <i>International Urogynecology Journal</i> , 22, 1171-8, 2011	Retrospective matched cohort study
Tincello,D.G., Kenyon,S., Slack,M., Toozs-Hobson,P., Mayne,C., Jones,D., Taylor,D., Colposuspension or TTV with anterior repair for urinary incontinence and prolapse: results of and lessons from a pilot randomised patient-preference study (CARPET 1), <i>BJOG: An International Journal of Obstetrics and Gynaecology</i> , 116, 1809-1814, 2009	No outcome data - pilot study of four women
Tolstrup, C. K., Lose, G., Klarskov, N., The Manchester procedure versus vaginal hysterectomy in the treatment of uterine prolapse: a review, <i>International Urogynecology Journal</i> , 28, 33-40, 2017	Systematic review of including non-comparative trials
Tseng, L. H., Chen, I., Chang, S. D., Lee, C. L., Modern role of sacrospinous ligament fixation for pelvic organ prolapse surgery-A systemic review, <i>Taiwanese Journal of Obstetrics and Gynecology</i> , 52, 311-317, 2013	Systematic review - references checked for inclusion
Ucar, M. G., Ilhan, T. T., Sanlikan, F., Celik, C., Sexual functioning before and after vaginal hysterectomy to treat pelvic organ prolapse and the effects of vaginal cuff closure techniques: a prospective randomised study, <i>European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology</i> , 206, 1-5, 2016	Intervention not relevant: All patients had McCall culdeplasty, study compares vertical to horizontal cuff closure

Study	Reason for Exclusion
Urzua, M. J., Rondini, C., Alvarez, J., Kaplan, F., Troncoso, F. R., Permanent versus delayed absorbable suture in uterosacral ligament suspension for the apical compartment: A prospective randomized study with a 24 months mean follow-up, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S20-S21, 2016	Conference abstract
van der Ploeg, J. M., van der Steen, A., Oude Rengerink, K., van der Vaart, C. H., Roovers, J. P., Prolapse surgery with or without stress incontinence surgery for pelvic organ prolapse: a systematic review and meta-analysis of randomised trials, BJOG: An International Journal of Obstetrics & Gynaecology, 121, 537-47, 2014	Systematic review - references checked for inclusion
van der Ploeg, J. M., van der Steen, A., Zwolsman, S., van der Vaart, C. H., Roovers, J. P. W. R., Prolapse surgery with or without incontinence procedure: a systematic review and meta-analysis, BJOG: An International Journal of Obstetrics and Gynaecology, 125, 289-297, 2018	Systematic review - references checked for inclusion
van der Steen, A., van der Ploeg, M., Dijkgraaf, M. G., van der Vaart, H., Roovers, J. P., Protocol for the CUPIDO trials; multicenter randomized controlled trials to assess the value of combining prolapse surgery and incontinence surgery in patients with genital prolapse and evident stress incontinence (CUPIDO I) and in patients with genital prolapse and occult stress incontinence (CUPIDO II), BMC Women's Health, 10, 16, 2010	Trial protocol
Van Rumpt-Van De Geest, D. A., Milani, A. L., Kluivers, K. B., Withagen, M. I., Vaginal repair of primary pelvic organ prolapse; trocar guided partially absorbable mesh or native tissue: A randomized controlled trial, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S29-S30, 2015	Conference abstract
Veit-Rubin, N., Dubuisson, J. B., Gayet-Ageron, A., Lange, S., Eperon, I., Dubuisson, J., Patient satisfaction after laparoscopic lateral suspension with mesh for pelvic organ prolapse: outcome report of a continuous series of 417 patients, International Urogynecology Journal, 1-9, 2017	Retrospective case series
Verleyen, P, Filip, C, Bart, K, Frank, Vda, Jan, D, Dirk, Dr, A prospective randomised trial comparing Pelvicol (trademark) and Vicryl (trademark) for cystocoele repair in the Raz-colposuspension (Abstract), Proceedings of the Joint Meeting of the International Continence Society (ICS) (34th Annual Meeting) and the International UroGynecological Association (IUGA), 2004 Aug 23-27, Paris, France, Abstract number 613, 2004	Conference abstract

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Study	Reason for Exclusion
Vieillefosse, S., Thubert, T., Dache, A., Hermieu, J. F., Deffieux, X., Satisfaction, quality of life and lumbar pain following laparoscopic sacrocolpopexy: suture vs. tackers, European Journal of Obstetrics, Gynecology, & Reproductive Biology Eur J Obstet Gynecol Reprod Biol, 187, 51-6, 2015	Retrospective case control study
Vijaya, G., Dell'Utri, C., Derpapas, A., Digesu, A., Gallo, P., Hendricken, C., Fernando, R., Khullar, V., A prospective randomised trial comparing two surgical techniques for posterior vaginal wall prolapse using subjective and objective measures, Neurourology and Urodynamics, 30 (6), 872-873, 2011	Conference abstract
Visco, A. G., Weidner, A. C., Barber, M. D., Myers, E. R., Cundiff, G. W., Bump, R. C., Addison, W. A., Vaginal mesh erosion after abdominal sacral colpopexy, American Journal of Obstetrics & Gynecology Am J Obstet Gynecol, 184, 297-302, 2001	Retrospective study
Vollebregt, A, A randomised controlled trial comparing the clinical and cost-effectiveness of the Avaulta anterior mesh and the standard anterior colporraphy for the primary surgical treatment of a cystocele stage >= 2 - Avaulta versus anterior colporraphy, <a href="Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1376">Http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1376</a> , 2008	Trial registration
Vollebregt, A., Gietelink, D., Fischer, K., Van Der Vaart, H., One year results of colporraphy anterior versus a trocar guided transobturator synthetic mesh in primary cystocele repair: A randomized controlled trial, International Urogynecology Journal and Pelvic Floor Dysfunction, 21, S76-S78, 2010	Conference abstract - full text article included (Vollebregt 2011)
Vollebregt, A., Van Der Vaart, C. H., Primary surgical repair of anterior vaginal prolapse: A randomised trial comparing anatomical and functional outcome between anterior colporrhaphy and trocar-guided transobturator anterior mesh, BJOG: An International Journal of Obstetrics and Gynaecology, 119, 1151-1152, 2012	Letter to the editor
von Pechmann, W. S., Aungst, M. J., Gruber, D. D., Ghodsi, P. M., Cruess, D. F., Griffis, K. R., A pilot study on vaginally assisted laparoscopic sacrocolpopexy for patients with uterovaginal prolapse, Female pelvic medicine & reconstructive surgery, 17, 115-9, 2011	Retrospective study
Walsh, C. A., Walsh, S. R., Tang, T. Y., Slack, M., Total abdominal hysterectomy versus total laparoscopic hysterectomy for benign disease: a meta-analysis, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 144, 3-7, 2009	Systematic review - References checked for inclusion

## DRAFT FOR CONSULTATION

Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Walter, A. J., Morse, A. N., Hammer, R. A., Hentz, J. G., Magrina, J. F., Cornella, J. L., Magtibay, P. M., Laparoscopic versus open Burch retropubic urethropexy: comparison of morbidity and costs when performed with concurrent vaginal prolapse repairs.[Erratum appears in Am J Obstet Gynecol. 2004 Jan;190(1):274], American Journal of Obstetrics & Gynecology, 186, 723-8, 2002	Retrospective study
Wang, F-M, He, C-N, Song, Y-F, Prospective study of transobturator mesh kit (Prolift) in pelvic reconstructive surgery with vaginal hysterectomy after 3 years' follow-up, Archives of Gynecology and Obstetrics, 288, 355-9, 2013	Non-randomised, non-comparative cohort study
Westermann, L. B., Crisp, C. C., Mazloomdoost, D., Kleeman, S. D., Pauls, R. N., Comparative Perioperative Pain and Recovery in Women Undergoing Vaginal Reconstruction Versus Robotic Sacrocolpopexy, Female pelvic medicine & reconstructive surgery, 23, 95-100, 2017	Non-randomised cohort
Withagen, M. I., Milani, A. L., de Leeuw, J. W., Vierhout, M. E., Development of de novo prolapse in untreated vaginal compartments after prolapse repair with and without mesh: a secondary analysis of a randomised controlled trial, BJOG: An International Journal of Obstetrics & Gynaecology, 119, 354-60, 2012	Outcome data not relevant - unclear which women had Anterior surgery as primary surgery
Withagen, M. I., Milani, A. L., den Boon, J., Vervest, H. A., Vierhout, M. E., Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial, Obstetrics & Gynecology, 117, 242-50, 2011	Unclear the number of participants who had Anterior surgery, cannot determine numbers who had primary surgery of interest.
Withagen, Mi, Milani, Al, Boon, Den J, Vervest, Ha, Vierhout, Me, Tension free vaginal mesh compared to conventional vaginal prolapse surgery in recurrent prolapse; a randomized controlled trial (Abstract number 090), International Urogynecology Journal, 20 Suppl 2, S153-s154, 2009	Conference abstract
Wong, M. T., Abet, E., Rigaud, J., Frampas, E., Lehur, P. A., Meurette, G., Minimally invasive ventral mesh rectopexy for complex rectocele: impact on anorectal and sexual function, Colorectal Disease, 13, e320-6, 2011	Non-randomised prospective cohort
Wong, V., Shek, K. L., Goh, J., Krause, H., Martin, A., Dietz, H. P., Cystocele recurrence after anterior colporrhaphy with and without mesh use, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 172, 131-5, 2014	Non-randomised retrospective cohort

Study	Reason for Exclusion
Wong,M.T., Meurette,G., Rigaud,J., Regenet,N., Lehur,P.A., Robotic versus laparoscopic rectopectomy for complex rectocele: a prospective comparison of short-term outcomes, Diseases of the Colon and Rectum, 54, 342-346, 2011	Non-randomised cohort study
Xiromeritis,P., Marotta,M.L., Royer,N., Kalogiannidis,I., Degeest,P., Devos,F., Outcome of laparoscopic sacrocolpopexy with anterior and posterior mesh, Hippokratia, 13, 101-105, 2009	Non-randomised retrospective cohort
Yang, T. H., Wu, L. Y., Chuang, F. C., Kung, F. T., Huang, K. H., Comparing the midterm outcome of single incision vaginal mesh and transobturator vaginal mesh in treating severe pelvic organ prolapse, Taiwanese journal of obstetrics & gynecology, 56, 81-86, 2017	Non-randomised retrospective cohort
Yang,X., Li,H., A modified anterior compartment reconstruction and Prolift-a for the treatment of anterior pelvic organ prolapse: A non-inferiority study, Archives of Gynecology and Obstetrics, 285, 1593-1597, 2012	Non-randomised cohort
Youssef, M., Emile, S. H., Thabet, W., Elfeki, H. A., Magdy, A., Omar, W., Khafagy, W., Farid, M., Comparative Study Between Trans-perineal Repair With or Without Limited Internal Sphincterotomy in the Treatment of Type I Anterior Rectocele: a Randomized Controlled Trial, Journal of Gastrointestinal SurgeryJ Gastrointest Surg, 21, 380-388, 2017	Intervention not relevant - trans-perineal repair with or without internal sphincterotomy
Yuk,J.S., Jin,C.H., Yi,K.W., Kim,T., Hur,J.Y., Shin,J.H., Anterior Transobturator Polypropylene Mesh in the Correction of Cystocele: 2-Point Method vs 4-Point Method, Journal of Minimally Invasive Gynecology, 19, 737-741, 2012	Intervention not relevant - study compares different methods of fixing mesh
Zhou, Q, Song, Y-F, A Randomized Trial of Pelvic Organ Prolapse Repair Plus TVT-O Versus Pelvic Organ Prolapse Repair Alone, Chinese Trials Registry ( <a href="http://www.chictr.org/en/proj/show.aspx?proj=3975">http://www.chictr.org/en/proj/show.aspx?proj=3975</a> ), 2012	Trial registration
Zhu, L, Sun, Z, Vaginal mesh of two different material used for pelvic floor reconstruction in treatment of severe pelvic organ prolapsed: a prospective randomized controlled trial, <a href="http://www.chictr.org.cn/showproj.aspx?proj=13529">Http://www.chictr.org.cn/showproj.aspx?proj=13529</a> , 2016	Trial registration

Study	Reason for Exclusion
Zhu, L, Sun, Z, Y type mesh of two different material used for laparoscopic sacral colpopexy in treatment of severe pelvic organ prolapsed: a prospective randomized controlled trial, <a href="Http://www.chictr.org.cn/showproj.aspx?proj=13522">Http://www.chictr.org.cn/showproj.aspx?proj=13522</a> , 2016	Trial registration
Zimmermann, E. F., Hayes, R. S., Daniels, I. R., Smart, N. J., Warwick, A. M., Transperineal rectocele repair: a systematic review, ANZ Journal of SurgeryANZ J Surg, 04, 04, 2017	Systematic review - references checked for inclusion
Zucchi, A., Costantini, E., Mearini, L., Fioretti, F., Bini, V., Porena, M., Female sexual dysfunction in urogenital prolapse surgery: colposacropexy vs. hysterocolposacropexy, Journal of sexual medicine, 5, 139-45, 2008	Comparison not relevant - women grouped according to sexual function

**Table 88: Excluded clinical studies: Complications data**

Study	Reason for Exclusion
A. Yakasai I, Bappa, L. A., Paterson, A., Outcome of repeat surgery for genital prolapse using prolift-mesh, Annals of Surgical Innovation & Research [Electronic Resource]Ann Surg Innov Res, 7, 3, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Abbott, P. D., McDonald, T. M., Polyethylene Terephthalate Grafts for Repair of Enterocoeles and Rectoceles, Journal of Pelvic Medicine and Surgery, 10, 27-29, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Abdelwahab, H., Elmissiry, M., Ghoniem, G., Long-term outcomes of rectocele repair with chemically processed (tutoplast) fascia lata: Two and half years follow-up, Journal of Pelvic Medicine and Surgery, 15, 173-177, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Abet, E., Lehur, P. A., Wong, M., Rigaud, J., Darnis, E., Meurette, G., Sexual function and laparoscopic ventral rectopexy for complex rectocoele, Colorectal Disease, 14, e721-6, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Adamakis, I., Katafigiotis, I., Tyritzis, S. I., Mygdalis, V., Sfoungaristos, S., Katafigioti, A., Mitropoulos, D., Constantinides, C. A., Treating anterior vaginal wall prolapse with polypropylene mesh via the transoburator route minimizing the complications with the use of preventing measures. A prospective study with 2-year follow-up, Minerva Ginecologica, 67, 231-8, 2015	Unable to obtain full text article
Adedipe, T. O., Vine, S. J., Immediate and perioperative outcomes of polypropylene mesh in pelvic floor repair in a predominantly obese population, Clinical & Experimental Obstetrics & GynecologyClin Exp Obstet Gynecol, 37, 266-8, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Adekanmi, O. A., Freeman, R. M., Jackson, S. A., Puckett, M., Bombieri, L., Waterfield, M. R., Do the anatomical defects associated with cystocele affect the outcome of the anterior repair? A clinical and radiological study, International Urogynecology Journal, 20, 1369-77, 2009	Study design did not meet the protocol inclusion criteria - followup not long enough
Ahranjani, M., Nora, Ii E., Rezai, P., Bujewski, S., Neugebauer-Le Fort operation for vaginal prolapse: A review of 38 cases, Journal of Reproductive Medicine for the Obstetrician and Gynecologist, 37, 959-964, 1992	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Akladios,C.Y., Dautun,D., Saussine,C., Baldauf,J.J., Mathelin,C., Wattiez,A., Laparoscopic sacrocolpopexy for female genital organ prolapse: establishment of a learning curve, European journal of obstetrics, gynecology, and reproductive biology, 149, 218-221, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Alay, I., Kaya, C., Cengiz, H., The accuracy of comparing laparoscopic hysteropexy versus vaginal hysterectomy for the treatment of uterovaginal prolapse, International Urogynecology Journal, 1, 2018	Letter
Al-Badr, A., Perveen, K., Al-Shaikh, G., Evaluation of Sacrospinous Hysteropexy vs. Uterosacral Suspension for the Treatment of Uterine Prolapse: A Retrospective Assessment, LutsLow Urin Tract Symptoms, 9, 33-37, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

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Study	Reason for Exclusion
Alcalay, M., Cosson, M., Livneh, M., Lucot, J. P., Von Theobald, P., Trocarless system for mesh attachment in pelvic organ prolapse repair--1-year evaluation, International Urogynecology Journal, 22, 551-6, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Aleksic, I., De, E. J. B., Surgical Management of Female Voiding Dysfunction, Surgical Clinics of North America, 96, 469-490, 2016	Narrative literature review
Allahdin, S., Herd, D., Reid, B. A., Twenty-five sacrospinous ligament fixation procedures in a district general hospital: our experience, Journal of obstetrics and gynaecology : the journal of the Institute of Obstetrics and Gynaecology, 25, 361-363, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Alperin, M., Sutkin, G., Ellison, R., Meyn, L., Moalli, P., Zyczynki, H., Perioperative outcomes of the Prolift pelvic floor repair systems following introduction to a urogynecology teaching service, International Urogynecology Journal, 19, 1617-1622, 2008	Study design did not meet the protocol inclusion criteria - followup not long enough
Altman, D., Lopez, A., Gustafsson, C., Falconer, C., Nordenstam, J., Zetterstrom, J., Anatomical outcome and quality of life following posterior vaginal wall prolapse repair using collagen xenograft, International Urogynecology Journal, 16, 298-303, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Altman, D., Mellgren, A., Blomgren, B., Lopez, A., Zetterstrom, J., Nordenstam, J., Falconer, C., Clinical and histological safety assessment of rectocele repair using collagen mesh, Acta Obstetricia et Gynecologica Scandinavica, 83, 995-1000, 2004	Study design did not meet the protocol inclusion criteria - fewer than 7550 cases included
Altman, D., Zetterstrom, J., Lopez, A., Anzen, B., Falconer, C., Hjern, F., Mellgren, A., Functional and anatomic outcome after transvaginal rectocele repair using collagen mesh: A prospective study, Diseases of the Colon and Rectum, 48, 1233-1242, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Altman, D., Zetterstrom, J., Mellgren, A., Gustafsson, C., Anzen, B., Lopez, A., A three-year prospective assessment of rectocele repair using porcine xenograft, Obstetrics and Gynecology, 107, 59-65, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Angulo, A., Kligman, I., Retroperitoneal sacrocolpopexy for correction of prolapse of vaginal vault, Surgery Gynecology and Obstetrics, 169, 319-323, 1989	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ankers, D., Ramage, J., Kozman, E., Hasan, E., Prospective observational study of sacrospinous fixation at a UK district general hospital, BJOG: An International Journal of Obstetrics and Gynaecology, 123, 179, 2016	Poster, not full text
Anonymous,, Pelvic Organ Prolapse, Female Pelvic Medicine and Reconstructive Surgery, 23, 353-364, 2017	Bulliten
Arao,F., Gravante,G., Overton,J., Arao,P., Dati,S., Transvaginal cystocele correction: Midterm results with a transobturator tension-free technique using a combined bovine pericardium/polypropylene mesh, Journal of Obstetrics and Gynaecology Research, 35, 953-960, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Arora, S., Kapoor, R., Yadav, P., Mittal, V., Sureka, S. K., Kapoor, D., Trans-vaginal anterior vaginal wall prolapse repair using a customized tension-free bell-shaped prolene mesh: A single-center experience with long-term functional analysis, Indian Journal of Urology, 31, 339-43, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Arthure, H. G. E., Savage, D., Uterine prolapse and prolapse of the vaginal vault treated by sacral hysteropexy, Journal of obstetrics and gynaecology of the British Empire, 64, 355-360, 1957	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Asoglu, M. R., Selcuk, S., Cam, C., Ayaz, R., Tug, N., Karateke, A., Colpocleisis, patient satisfaction and quality of life, Journal of the Turkish German Gynecology Association, 13, 253-256, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Athanasiou, S., Grigoriadis, T., Chatzipapas, I., Protopapas, A., Antsaklis, A., The vaginally assisted laparoscopic sacrocolpopexy: a pilot study, International Urogynecology Journal, 24, 839-45, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Baessler, K., Schuessler, B., Abdominal sacrocolpopexy and anatomy and function of the posterior compartment, Obstetrics and Gynecology, 97, 678-684, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Baessler,K., Hewson,A.D., Tunn,R., Schuessler,B., Maher,C.F., Severe mesh complications following intravaginal slingplasty, Obstetrics and Gynecology, 106, 713-716, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Baessler,K., Stanton,S.L., Sacrocolpopexy for vault prolapse and rectocele: do concomitant Burch colposuspension and perineal mesh detachment affect the outcome?, American Journal of Obstetrics and Gynecology, 192, 1067-1072, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Bai, S. W., Kim, E. H., Shin, J. S., Kim, S. K., Park, K. H., Lee, D. H., A comparison of different pelvic reconstruction surgeries using mesh for pelvic organ prolapse patients, Yonsei Medical JournalYonsei Med J, 46, 112-8, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Bai, S. W., Kwon, H. S., Chung, D. J., Abdominal high uterosacral colpopexy and abdominal sacral colpopexy with mesh for pelvic organ prolapse, International Journal of Gynaecology & ObstetricsInt J Gynaecol Obstet, 92, 147-8, 2006	Brief communication case series
Balakrishnan, S., Lim, Y. N., Barry, C., Corstians, A., Kannan, K., Rane, A., Prospective evaluation of the safety and efficacy of the ApogeeTM system for treatment of vault prolapse, Journal of Obstetrics and Gynaecology, 28, 618-620, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Balsak, D., Uysal, A., Cavus, Y., Ince, Z., Acar, Z., Gungor, A., Hacivelioglu, S., Treatment of Vaginal Cuff Prolapses with Posterior Intravaginal Sling and Evaluation of Efficiency with International Consultation on Incontinence Questionnaire-Vaginal Symptoms Method in the Long Term: Preliminary Results, LutsLow Urin Tract Symptoms, 5, 140-4, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Banu, L. F., Synthetic sling for genital prolapse in young women, International Journal of Gynecology and Obstetrics, 57, 57-64, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Barber, M. D., Pelvic organ prolapse, BMJ (Online), 354 (no pagination), 2016	Narrative literature review
Barber, M. D., Incontinence: Should mesh be used to correct anterior vaginal prolapse?, Nature Reviews Urology, 8, 476-478, 2011	Commentary paper
Barber, M. D., Visco, A. G., Weidner, A. C., Amundsen, C. L., Bump, R. C., Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse, American Journal of Obstetrics and Gynecology, 183, 1402-1411, 2000	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Barranger, E., Fritel, X., Pigne, A., Abdominal sacrohysteropexy in young women with uterovaginal prolapse: Long-term follow-up, American Journal of Obstetrics and Gynecology, 189, 1245-1250, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Barrington, J. W., Calvert, J. P., Vaginal vault suspension for prolapse after hysterectomy using an autologous fascial sling of rectus sheath, British Journal of Obstetrics and Gynaecology, 105, 83-86, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Barski, D., Arndt, C., Gerullis, H., Yang, J., Boros, M., Otto, T., Kolberg, H. C., Transvaginal PVDF-mesh for cystocele repair: A cohort study, International Journal Of SurgeryInt J Surg, 39, 249-254, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Basu, M., Duckett, J. R. A., Short-term morbidity following vaginal prolapse surgery: What the surgeon does not see, Gynecological Surgery, 7, 343-346, 2010	Study design did not meet the protocol inclusion criteria - followup not long enough
Behnia-Willison, F., Seman, E. I., Cook, J. R., O'Shea, R. T., Keirse, M. J. N. C., Laparoscopic paravaginal repair of anterior compartment prolapse, Journal of Minimally Invasive Gynecology, 14, 475-480, 2007	Unable to obtain full text article
Bhadana, P., Mittal, P., Bachani, S., Tension-free vaginal tape vs tension-free obturator tape for treatment of genuine stress urinary incontinence: a 5-year follow-up, Journal of SAFOG, 9, 95-99, 2017	Population do not meet criteria - not specifically POP
Bhandarkar, D., Laparoscopic rectopexy for complete rectal prolapse: Mesh, no mesh or a ventral mesh?, Journal of Minimal Access Surgery, 10, 1-3, 2014	Narrative literature review
Bickel, D. A., Prolapse of the vagina following abdominal hysterectomy, American Journal of Obstetrics and Gynecology, 56, 152-159, 1948	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Blandon, R. E., Gebhart, J. B., Trabuco, E. C., Klingele, C. J., Complications from vaginally placed mesh in pelvic reconstructive surgery, International Urogynecology Journal, 20, 523-531, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Bonde, L., Puschl, I. C., Moller, L. A., Ottesen, B., Breinegaard, N., Gimbel, H., No evidence of association between native tissue vault suspension and risk of pelvic pain or sexual dysfunction, European Journal of Obstetrics Gynecology and Reproductive Biology, 225, 141-147, 2018	Population do not meet criteria - not specifically POP
Book,N.M., Novi,B., Novi,J.M., Pulvino,J.Q., Postoperative voiding dysfunction following posterior colporrhaphy, Female pelvic medicine & reconstructive surgery, 18, 32-34, 2012	Population fo not meet criteria - not specifically POP
Botros, S. M., Sand, P. K., Beaumont, J. L., Abramov, Y., Miller, J. J., Goldberg, R. P., Arcus-anchored acellular dermal graft compared to anterior colporrhaphy for stage II cystoceles and beyond, International Urogynecology Journal, 20, 1265-71, 2009	Retrospective study design
Bracken, J. N., Tran, D. H., Kuehl, T. J., Larsen, W., Yandell, P. M., Shull, B. L., A novel transvaginal approach to correct recurrent apical prolapse after failed sacral colpopexy: Case series, International Urogynecology Journal and Pelvic Floor Dysfunction, 23, 1429-1433, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Brieger, G. M., Korda, A. R., Houghton, C. R., Abdomino perineal repair of pulsion enterocele, The journal of obstetrics and gynaecology research, 22, 151-156, 1996	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Brizzolara, S., Pillai-Allen, A., Risk of mesh erosion with sacral colpopexy and concurrent hysterectomy, Obstetrics & GynecologyObstet Gynecol, 102, 306-10, 2003	Retrospective study design
Brocker, K. A., Alt, C. D., Corteville, C., Hallscheidt, P., Lenz, F., Sohn, C., Short-range clinical, dynamic magnetic resonance imaging and P-QOL questionnaire results after mesh repair in female pelvic organ prolapse, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 157, 107-12, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Brocker, K. A., Alt, C. D., Rzepka, J., Sohn, C., Hallscheidt, P., One-year dynamic MRI follow-up after vaginal mesh repair: evaluation of clinical, radiological, and quality-of-life results, Acta RadiologicaActa Radiol, 56, 1002-8, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Brown, W. E., Hoffman, M. S., Bouis, P. J., Ingram, J. M., Hopes, S. L., Management of vaginal vault prolapse: retrospective comparison of abdominal versus vaginal approach, Journal of the Florida Medical Association, 76, 249-52, 1989	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Brubaker,L., Sacrocolpopexy and the anterior compartment: Support and function, American Journal of Obstetrics and Gynecology, 173, 1690-1696, 1995	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Bulugma,M., Elmariamy,O., Batur,F., Meghil,S., Zawia,E., Transvaginal mesh repair of the anterior and posterior compartments, Jamahiriya Medical Journal, 9, 118-121, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Cao, T. T., Sun, X. L., Wang, S. Y., Yang, X., Wang, J. L., Porcine Small Intestinal Submucosa Mesh for Treatment of Pelvic Organ Prolapsed.[Erratum appears in Chin Med J (Engl). 2016 5th Dec;129(23):2809; PMID: 27900993], Chinese Medical Journal, 129, 2603-2609, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

## DRAFT FOR CONSULTATION

Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Capobianco, G., Donolo, E., Wenger, J. M., Madonia, M., Cosmi, E., Antimi, L., Dessole, M., Cherchi, P. L., Efficacy and 9 years' follow-up of posterior intravaginal slingplasty for genital prolapse, Journal of Obstetrics & Gynaecology ResearchJ Obstet Gynaecol Res, 40, 219-23, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Capps Jr, W. F., Rectoplasty and perineoplasty for the symptomatic rectocele: a report of fifty cases, Diseases of the Colon and Rectum, 18, 237-244, 1975	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Carey, M. P., Slack, M. C., Transvaginal sacrospinous colpopexy for vault and marked uterovaginal prolapse, British Journal of Obstetrics and Gynaecology, 101, 536-540, 1994	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Caruso,S., Bandiera,S., Cavallaro,A., Cianci,S., Vitale,S.G., Rugolo,S., Quality of life and sexual changes after double transobturator tension-free approach to treat severe cystocele, European Journal of Obstetrics Gynecology and Reproductive Biology, 151, 106-109, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Castellani, D., Galica, V., Saldutto, P., Galatioto, G. P., Vicentini, C., Efficacy and safety of Elevate system on apical and anterior compartment prolapse repair with personal technique modification, International Braz J Urol, 43, 07, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Cespedes, R. D., Winters, J. C., Ferguson, K. H., Colpocleisis for the treatment of vaginal vault prolapse, Techniques in Urology, 7, 152-160, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chakrabarty, A., Ganabathi, K., Alexander, J. S., Hoekstra, P., Martin Jr, J., Zylstra, S., Does pelvic mesh treated with phosphorylcholine improve outcomes? An early experience, European Journal of Obstetrics Gynecology and Reproductive Biology, 167, 230-234, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chaliha, C., Khalid, U., Campagna, L., Digesu, G. A., Ajay, B., Khullar, V., SIS graft for anterior vaginal wall prolapse repair - A case-controlled study, International Urogynecology Journal, 17, 492-497, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chan, C. M., Liang, H. H., Go, W. W., To, W. W., Mok, K. M., Laparoscopic sacrocolpopexy for uterine and post-hysterectomy prolapse: anatomical and functional outcomes, Hong Kong Medical Journal, 17, 301-5, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chan, S. S., Pang, S. M., Cheung, T. H., Cheung, R. Y., Chung, T. K., Laparoscopic sacrocolpopexy for the treatment of vaginal vault prolapse: with or without robotic assistance, Hong Kong Medical Journal, 17, 54-60, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chapin, D. S., Porges, R. F., Teaching sacrospinous colpopexy, American Journal of Obstetrics and Gynecology, 177, 1330-1336, 1997	Study design did not meet the protocol inclusion criteria - review
Chaturvedi,S., Bansal,R., Ranjan,P., Ansari,M.S., Kapoor,D., Kapoor,R., Trans-vaginal total pelvic floor repair using customized prolene mesh: A safe and cost-effective approach for high-grade pelvic organ prolapse, Indian Journal of Urology, 28, 21-27, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Urinary incontinence and pelvic organ prolapse in women: evidence review for surgical management of pelvic organ prolapse DRAFT (October 2018)

Study	Reason for Exclusion
Chaudhary, S. M., Sacrocolpopexy "gold standard" for vault prolapse, Medical Forum Monthly, 18, 24-27, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chen, C. H., Hsiao, S. M., Chang, T. C., Wu, W. Y., Lin, H. H., Transvaginal cystocele repair using pursestring technique reinforced with custom-tailored two-armed mesh, Urology, 78, 1275-80, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chen, G., Wu, D., Zhao, W., Hu, W., Li, J., Ling, B., Modified laparoscopic extraperitoneal uterine suspension to anterior abdominal wall: the easier way to treat uterine prolapse, International Urogynecology Journal, 23, 887-91, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chen,G., Ling,B., Li,J., Xu,P., Hu,W., Zhao,W., Wu,D., Laparoscopic extraperitoneal uterine suspension to anterior abdominal wall bilaterally using synthetic mesh to treat uterovaginal prolapse, Journal of Minimally Invasive Gynecology, 17, 631-636, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chin,H.Y., Chiang,C.H., Lin,K.C., Wang,C.J., Lee,C.L., Soong,Y.K., Prospective assessment of overactive bladder symptoms in women who have undergone transvaginal surgery for advanced vaginal wall prolapse: a preliminary report, Journal of Obstetrics and Gynaecology Research, 35, 732-737, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Cho, M. K., Moon, J. H., Kim, C. H., Non-absorbable and partially-absorbable mesh during pelvic organ prolapse repair: A comparison of clinical outcomes, International Journal Of SurgeryInt J Surg, 55, 5-8, 2018	Retrospective study design
Choi, J. M., Nguyen, V., Khavari, R., Reeves, K., Snyder, M., Fletcher, S. G., Complex rectovaginal fistulas after pelvic organ prolapse repair with synthetic mesh: a multidisciplinary approach to evaluation and management, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 18, 366-71, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Chughtai, B., Barber, M. D., Mao, J., Forde, J. C., Normand, S. L. T., Sedrakyan, A., Association between the amount of vaginal mesh used with mesh erosions and repeated surgery after repairing pelvic organ prolapse and stress urinary incontinence, JAMA Surgery, 152, 257-263, 2017	Study design did not meet the protocol inclusion criteria - followup not long enough
Claerhout, F., De Ridder, D., Van Beckvoort, D., Coremans, G., Veldman, J., Lewi, P., Deprest, J., Sacrocolpopexy using xenogenic acellular collagen in patients at increased risk for graft-related complications, Neurourology & UrodynamicsNeurourol Urodyn, 29, 563-7, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Clemons, J. L., Myers, D. L., Aguilar, V. C., Arya, L. A., Fine, P., Vaginal paravaginal repair with an AlloDerm graft, American Journal of Obstetrics and Gynecology, 189, 1612-1619, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Comiter, C. V., Repair of Enterocèle and Vault Prolapse: Transvaginal Culdosuspension, Techniques in Urology, 7, 146-151, 2001	Unable to obtain full text

Study	Reason for Exclusion
Conde-Agudelo, A., Intrafascial abdominal hysterectomy: Outcomes and complications of 867 operations, International Journal of Gynecology and Obstetrics, 68, 233-239, 2000	Population do not meet criteria - not specifically POP
Cook, J. R., Seman, E. I., O'Shea, R. T., Laparoscopic treatment of enterocele: A 3-year evaluation, Australian and New Zealand Journal of Obstetrics and Gynaecology, 44, 107-110, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Coolen, A. L., van Oudheusden, A. M., van Eijndhoven, H. W., van der Heijden, T. P., Stokmans, R. A., Mol, B. W., Bongers, M. Y., A Comparison of Complications between Open Abdominal Sacrocolpopexy and Laparoscopic Sacrocolpopexy for the Treatment of Vault Prolapse, Obstetrics & Gynecology InternationalObstet Gynecol Int, 2013, 528636, 2013	Study design did not meet the protocol inclusion criteria - followup not long enough
Cooper, J. C., Bondili, A., Deguara, C., Siraj, N., Vaginal repair with polypropylene mesh compared to traditional colporrhaphy for pelvic organ prolapse: Medium-term follow-up, Journal of Gynecologic Surgery, 29, 1-6, 2013	Unable to obtain full text
Cormio, L., Mancini, V., Liuzzi, G., D'Altilia, N., Carrieri, G., Surgical management of female pelvic organ prolapse with and without urinary incontinence, Medicine (United States), 96 (39) (no pagination), 2017	Outcomes not presented at the same timelines for different procedures, data unclear
Cosson, M., Collinet, P., Occelli, B., Narducci, F., Crepin, G., The vaginal patch plastron for vaginal cure of cystocelePreliminary results for 47 patients, European Journal of Obstetrics Gynecology and Reproductive Biology, 95, 73-80, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Costa, J., Towobola, B., McDowell, C., Ashe, R., Recurrent pelvic organ prolapse (POP) following traditional vaginal hysterectomy with or without colporrhaphy in an Irish population, Ulster Medical JournalUlster Med J, 83, 16-21, 2014	Retrospective study design
Costantini, E., Lombi, R., Micheli, C., Parziani, S., Porena, M., Colposacropexy with Gore-tex mesh in marked vaginal and uterovaginal prolapse, European Urology, 34, 111-117, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Costantini, E., Zucchi, A., Lazzeri, M., Del Zingaro, M., Vianello, A., Porena, M., Managing mesh erosion after abdominal pelvic organ prolapse repair: ten years' experience in a single center, Urologia Internationalis, 86, 419-23, 2011	Retrospective study design
Creighton, S. M., Stanton, S. L., The surgical management of vaginal vault prolapse, British Journal of Obstetrics and Gynaecology, 98, 1150-1154, 1991	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Cronje, H. S., Prollius, A., Vaginal anterior colposuspension (VACS) for cystocele, International Journal of Gynecology and Obstetrics, 87, 46-47, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Cronje, H. S., Prollius, A., De Beer, J. A. A., Stage IV cystocele treated by sacrocolpopexy, International Journal of Gynecology and Obstetrics, 92, 153-154, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Cruikshank, S. H., Cox, D. W., Sacrospinous ligament fixation at the time of transvaginal hysterectomy, American Journal of Obstetrics and Gynecology, 162, 1611-1619, 1990	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Cundiff, G. W., Harris, R. L., Coates, K., Low, V. H. S., Bump, R. C., Addison, W. A., Stanhope, R., Abdominal sacral colpopерineopexy: A new approach for correction of posterior compartment defects and perineal descent associated with vaginal vault prolapse, American Journal of Obstetrics and Gynecology, 177, 1345-1355, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Cunjian, Y., Li, L., Xiaowen, W., Shengrong, L., Hao, X., Xiangqiong, L., A retrospective analysis of the effectiveness of a modified abdominal high uterosacral colpopexy in the treatment of uterine prolapse, Cell Biochemistry & BiophysicsCell Biochem Biophys, 64, 95-9, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dal Moro, F., Calpista, A., Mancini, M., 'Cupid and Psyche': a novel technique for robotic hysterosacropexy in the treatment of pelvic organ prolapse, Urologia (Treviso)Urologia, 83, 27-30, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dandolu, V., Akiyama, M., Allenback, G., Pathak, P., Mesh complications and failure rates after transvaginal mesh repair compared with abdominal or laparoscopic sacrocolpopexy and to native tissue repair in treating apical prolapse, International Urogynecology Journal, 28, 215-222, 2017	Retrospective study design
Dandolu, V., Harmanli, O. H., Grotegut, C., Turner, T., Hernandez, E., Grody, M. T., Long-term anatomic and functional outcome following sacrospinous fixation using comprehensive pelvic floor questionnaires, Journal of Pelvic Medicine and Surgery, 13, 177-180, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Daru, P., Magaji, A., Nyango, D., Karshima, J., Pam, I., Shambe, I., Vaginal hysterectomy at jos university teaching hospital, jos, Nigeria, Journal of the West African Colleges of SurgeonsJ, 1, 26-36, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
David-Montefiore, E., Barranger, E., Dubernard, G., Detchev, R., Nizard, V., Darai, E., Treatment of genital prolapse by hammock using porcine skin collagen implant (Pelvicol), Urology, 66, 1314-1318, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
David-Montefiore, E., Barranger, E., Dubernard, G., Nizard, V., Antoine, J. M., Darai, E., Functional results and quality-of-life after bilateral sacrospinous ligament fixation for genital prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 132, 209-213, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
de Castro, E. B., Juliato, C. R., Piedemonte, L. A., dos Santos Junior, L. C., Impact of Sacrospinous Colpopexy Associated with Anterior Colporrhaphy for the Treatment of Dome Prolapse on all Three Vaginal Compartments, Revista Brasileira de Ginecologia e ObstetriciaRev, 38, 77-81, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
de Oliveira, M. S., Cavalcanti Gde, A., da Costa, A. A., Native vaginal tissue repair for genital prolapse surgical treatment: a minimum of 30 months of results, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 201, 75-8, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
de Oliveira, M. S., Cavalcanti Gde, A., da Costa, A. A., Fascial surgical repair for vaginal prolapse: effect on quality of life and related symptoms, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 182, 177-80, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
De Ridder, D., The Use of Biomaterials in Reconstructive Urology, European Urology, Supplements, 1, 7-11, 2002	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
de Tayrac, R., Boileau, L., Fara, J. F., Monneins, F., Raini, C., Costa, P., Bilateral anterior sacrospinous ligament suspension associated with a paravaginal repair with mesh: short-term clinical results of a pilot study, International Urogynecology Journal, 21, 293-8, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
de Tayrac, R., Brouziyne, M., Priou, G., Devoldere, G., Marie, G., Renaudie, J., Transvaginal repair of stage III-IV cystocele using a lightweight mesh: safety and 36-month outcome, International Urogynecology Journal, 26, 1147-54, 2015	Randomised controlled trial - data used in RCT review question
de Tayrac, R., Picone, O., Chauveaud-Lambling, A., Fernandez, H., A 2-year anatomical and functional assessment of transvaginal rectocele repair using a polypropylene mesh, International Urogynecology Journal, 17, 100-105, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Denehy, T. R., Choe, J. Y., Gregori, C. A., Breen, J. L., Elkins, T., Modified Le Fort partial colpocleisis with Kelly urethral plication and posterior colpopерineoplasty in the medically compromised elderly: A comparison with vaginal hysterectomy, anterior colporrhaphy, and posterior colpopерineoplasty, American Journal of Obstetrics and Gynecology, 173, 1697-1702, 1995	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Deng, D. Y., Rutman, M., Rodriguez, L., Raz, S., Correction of cystocele, BJU International, 96, 691-709, 2005	Study design - description of surgery procedure
Diana, M., Schettini, M., Gallucci, M., Treatment of vaginal vault prolapse with abdominal sacral colpopexy using a prolene net, Urogynaecologia International Journal, 13, 25-33, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Diana, M., Zoppe, C., Mastrangeli, B., Treatment of vaginal vault prolapse with abdominal sacral colpopexy using prolene mesh, American Journal of Surgery, 179, 126-128, 2000	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dickins, A., Uterine ligaments and the treatment of prolapse, Journal of the Royal Society of Medicine, 77, 353-356, 1984	Narrative literature review
Dietz, H. P., Chantarasorn, V., Shek, K. L., Levator avulsion is a risk factor for cystocele recurrence.[Erratum appears in Ultrasound Obstet Gynecol. 2011 Apr;37(4):500], Ultrasound in Obstetrics & GynecologyUltrasound Obstet Gynecol, 36, 76-80, 2010	Retrospective study design
Dietz, H. P., Erdmann, M., Shek, K. L., Mesh contraction: myth or reality?, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 204, 173.e1-4, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Dietz, V., Huisman, M., de Jong, J. M., Heintz, P. M., van der Vaart, C. H., Functional outcome after sacrospinous hysteropexy for uterine descensus, International Urogynecology Journal, 19, 747-52, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Diwan, A., Rardin, C. R., Strohsnitter, W. C., Weld, A., Rosenblatt, P., Kohli, N., Laparoscopic uterosacral ligament uterine suspension compared with vaginal hysterectomy with vaginal vault suspension for uterovaginal prolapse, International Urogynecology Journal, 17, 79-83, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Doder, D., Bernardini, L., The Use of Tutomesh for a Tension-Free and Tridimensional Repair of Uterovaginal and Vaginal Vault Prolapse: Preliminary Report, Surgery Research & Practice Printsurg, 2015, 303679, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Doshani, A., Teo, R. E. C., Mayne, C. J., Tincello, D. G., Uterine prolapse, British Medical Journal, 335, 818-823, 2007	Narrative literature review
Doumouchtsis, S. K., Khunda, A., Jeffery, S. T., Franco, A. V. M., Fynes, M. M., Long-term outcomes of modified high uterosacral ligament vault suspension (HUSLS) at vaginal hysterectomy, International Urogynecology Journal, 22, 577-584, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dua, A., Radley, S., Brown, S., Jha, S., Jones, G., The effect of posterior colporrhaphy on anorectal function, International Urogynecology Journal, 23, 749-53, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dubuisson, J. B., Chapron, C., Fauconnier, A., Babaki-Fard, K., Dendrinos, S., Laparoscopic management of genital prolapse: Lateral suspension with two meshes, Gynaecological Endoscopy, 9, 363-368, 2000	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dubuisson, J. B., Yaron, M., Wenger, J. M., Jacob, S., Treatment of Genital Prolapse by Laparoscopic Lateral Suspension Using Mesh: A Series of 73 Patients, Journal of Minimally Invasive Gynecology, 15, 49-55, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dubuisson, J., Eperon, I., Dallenbach, P., Dubuisson, J. B., Laparoscopic repair of vaginal vault prolapse by lateral suspension with mesh, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 287, 307-12, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Dwyer, P.L., Fatton, B., Bilateral extraperitoneal uterosacral suspension: a new approach to correct posthysterectomy vaginal vault prolapse, International Urogynecology Journal, 19, 283-292, 2008	Study design did not meet the protocol inclusion criteria - followup not long enough
Eboue, C., Marcus-Braun, N., von Theobald, P., Cystocele repair by transobturator four arms mesh: monocentric experience of first 123 patients, International Urogynecology Journal, 21, 85-93, 2010	Population do not meet criteria - SUI plus POP, not specifically POP
Eisenberg, V. H., Alcalay, M., Steinberg, M., Weiner, Z., Schiff, E., Itskovitz-Eldor, J., Lowenstein, L., Use of ultrasound in the clinical evaluation of women following colpocleisis, Ultrasound in Obstetrics & GynecologyUltrasound Obstet Gynecol, 41, 447-51, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Eisenberg, V. H., Steinberg, M., Weiner, Z., Schiff, E., Lowenstein, L., Long-term follow-up of sacrocolpopexy mesh implants at two time intervals at least 1 year apart using 4D transperineal ultrasound, Ultrasound in Obstetrics & GynecologyUltrasound Obstet Gynecol, 49, 398-403, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
El Haddad, R., Svabik, K., Masata, J., Koleska, T., Hubka, P., Martan, A., Women's quality of life and sexual function after transvaginal anterior repair with mesh insertion, European Journal of Obstetrics, Gynecology, & Reproductive Biology Eur J Obstet Gynecol Reprod Biol, 167, 110-3, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
El-Azab, A. S., Abd-Elsayed, A. A., Imam, H. M., Patient reported and anatomical outcomes after surgery for pelvic organ prolapse, Neurourology & Urodynamics Neurourol Urodyn, 28, 219-24, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Elizalde Benito, F. X., Elizalde Benito, A. G., Urrea Palos, M., Quintana Martinez, I., Elizalde Amatria, A. G., Results of the treatment of anterior pelvic organ prolapse using the Perigee system, Archivos Espanoles de Urologia Arch Esp Urol, 67, 549-55, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Elliott, D. S., Frank, I., DiMarco, D. S., Chow, G. K., Gynecologic use of robotically assisted laparoscopy: Sacrocolpopexy for the treatment of high-grade vaginal vault prolapse, American Journal of Surgery, 188, 52S-56S, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Elliott, D. S., Krambeck, A. E., Chow, G. K., Long-Term Results of Robotic Assisted Laparoscopic Sacrocolpopexy for the Treatment of High Grade Vaginal Vault Prolapse, Journal of Urology, 176, 655-659, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Elliott, D. S., Siddiqui, S. A., Chow, G. K., Assessment of the durability of robot-assisted laparoscopic sacrocolpopexy for treatment of vaginal vault prolapse, Journal of Robotic Surgery J, 1, 163-8, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Elsaman, A. M., Salem, H. T., Amin, M., Fetih, A. N., Othman, E. E. R., Zahran, K. M., Modified cervicopexy: A novel, less-invasive technique for Stages III and IV uterine prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 183, 159-163, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Epstein, L. B., Graham, C. A., Heit, M. H., Impact of sacral colpopexy on in vivo vaginal biomechanical properties, American Journal of Obstetrics & Gynecology Am J Obstet Gynecol, 199, 664.e1-6, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Falk, H. C., Uterine prolapse and prolapse of the vaginal vault treated by sacropexy, Obstetrics & Gynecology Obstet Gynecol, 18, 113-5, 1961	Narrative literature review
Fan, H. L., Chan, S. S., Cheung, R. Y., Chung, T. K., Tension-free vaginal mesh for the treatment of pelvic organ prolapse in Chinese women, Hong Kong Medical Journal, 19, 511-7, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Fedele, L., Garsia, S., Bianchi, S., Albiero, A., Dorta, M., A new laparoscopic procedure for the correction of vaginal vault prolapse, Journal of Urology, 159, 1179-1182, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Fedorkow, D. M., Kalbfleisch, R. E., Total abdominal hysterectomy at abdominal sacrovaginopexy: a comparative study, American Journal of Obstetrics & Gynecology Am J Obstet Gynecol, 169, 641-3, 1993	Study design did not meet the protocol inclusion criteria - followup not long enough

Study	Reason for Exclusion
Feldman, G. B., Birnbaum, S. J., Sacral colpopexy for vaginal vault prolapse, <i>Obstetrics &amp; Gynecology Obstet Gynecol</i> , 53, 399-401, 1979	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ferreira, H., Ferreira, C., Nogueira-Silva, C., Tome, A., Guimaraes, S., Correia-Pinto, J., Minilaparoscopic Versus Conventional Laparoscopic Sacrocolpopexy: A Comparative Study, <i>Journal of Laparoendoscopic &amp; Advanced Surgical Techniques. Part AJ Laparoendosc Adv Surg Tech A</i> , 26, 386-92, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Fischer, A., Prolapse Surgery Using Biomaterials, <i>European Urology Supplements</i> , 1, 29-32, 2002	Study design did not meet the protocol inclusion criteria - followup not long enough
Fischer, F., Roblick, U., Farke, S., Mirow, L., Bruch, H. P., Transvaginal, transperineal and transrectal approaches for symptomatic rectocele, <i>Coloproctology</i> , 29, 258-264, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Flynn, M. K., Webster, G. D., Amundsen, C. L., Abdominal sacral colpopexy with allograft fascia lata: one-year outcomes, <i>American Journal of Obstetrics and Gynecology</i> , 192, 1496-1500, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Forsgren, C., Zetterstrom, J., Zhang, A., Iliadou, A., Lopez, A., Altman, D., Anal incontinence and bowel dysfunction after sacrocolpopexy for vaginal vault prolapse, <i>International Urogynecology Journal</i> , 21, 1079-84, 2010	Retrospective study design
Gabriel, B., Farthmann, J., Brinstrup, B., Funfgeld, C., Jezek, P., Kraus, A., Lenz, F., Kumbier, E., Niesel, A., Stickeler, E., Watermann, D., Surgical repair of posterior compartment prolapse: Preliminary results of a novel transvaginal procedure using a four-armed polypropylene mesh with infracoccygeal and pararectal suspension, <i>Acta Obstetricia et Gynecologica Scandinavica</i> , 86, 1236-1242, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gabriel, B., Rubod, C., Cordova, L. G., Lucot, J. P., Cosson, M., Prolapse surgery in women of 80 years and older using the ProliftTM technique, <i>International Urogynecology Journal</i> , 21, 1463-70, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gad, N., Duvvuru, A., Burchgart, B., Outcome of Prolift mesh repair in treatment of pelvic organ prolapse and its effect on lower urinary tract symptoms: 5-year retrospective case study, <i>Journal of Obstetrics &amp; Gynaecology Research</i> , 39, 243-9, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gadonneix, P., Ercoli, A., Salet-Lizee, D., Cotelle, O., Bolner, B., Van Den Akker, M., Villet, R., Laparoscopic Sacrocolpopexy with Two Separate Meshes along the Anterior and Posterior Vaginal Walls for Multicompartment Pelvic Organ Prolapse, <i>Journal of the American Association of Gynecologic Laparoscopists</i> , 11, 29-35, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gadonneix, P., Kane, A., Vincens, E., Salet Lizee, D., Villet, R., Laparoscopic promonto-fixation for urogenital prolapsus, <i>Journal of visceral surgery</i> , 152, 45-55, 2015	Narrative literature review

Study	Reason for Exclusion
Gagnon, L. O., Tu, L. M., Mid-term results of pelvic organ prolapse repair using a transvaginal mesh: the experience in Sherbrooke, Quebec, Canadian Urological Association Journal Can Urol Assoc J, 4, 188-91, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gaj, F., Trecca, A., Andreuccetti, J., Crispino, P., Efficacy of two different surgical techniques combined in the treatment of rectocele.[Erratum appears in Updates Surg. 2012 Sep;64(3):245 Note: Andreuccetti, Jacopo [corrected to Andreuccetti, Jacopo]], Updates in Surgery, 64, 107-12, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gaj, F., Trecca, A., Crispino, P., The evolution of transfixated sequential suturing technique (TSST) in the treatment of rectocele: Advantages and efficacy in 10 cases, Minerva Chirurgica, 63, 461-467, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gayen, A., Rymer, M., Pakarian, F., Mastoroudes, H., Abdominal vault suspension with rectus sheath strips: A case series, Journal of Obstetrics and Gynaecology, 28, 787-790, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Geller, E. J., Parnell, B. A., Dunivan, G. C., Pelvic floor function before and after robotic sacrocolpopexy: one-year outcomes, Journal of Minimally Invasive Gynecology, 18, 322-7, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Geller, E. J., Parnell, B. A., Dunivan, G. C., Robotic vs abdominal sacrocolpopexy: 44-month pelvic floor outcomes, Urology, 79, 532-6, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Geoffrion, R., Hyakutake, M. T., Koenig, N. A., Lee, T., Cundiff, G. W., Bilateral sacrospinous vault fixation with tailored synthetic mesh arms: clinical outcomes at one year, Journal of Obstetrics & Gynaecology Canada: JOGCJ Obstet Gynaecol Can, 37, 129-37, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Geomini, P. M. A. J., Brodmann, H. A. M., Van Binsbergen, N. J. M., Mol, B. W., Vaginal vault suspension by abdominal sacral colpopexy for prolapse: A follow up study of 40 patients, European Journal of Obstetrics Gynecology and Reproductive Biology, 94, 234-238, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Germain, A., Thibault, F., Galifet, M., Scherrer, M. L., Ayav, A., Hubert, J., Brunaud, L., Bresler, L., Long-term outcomes after totally robotic sacrocolpopexy for treatment of pelvic organ prolapse, Surgical Endoscopy Surg Endosc, 27, 525-9, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ghanbari, Z., Baratali, B. H., Mireshghi, M. S., Posterior intravaginal slingplasty (infracoccygeal sacropexy) in the treatment of vaginal vault prolapse, International Journal of Gynecology and Obstetrics, 94, 147-148, 2006	Brief communication
Ghosh, D., Wipplinger, P., Byrne, D. L., Can total laparoscopic hysterectomy replace total abdominal hysterectomy? A 5-year prospective cohort study of a single surgeon's experience in an unselected population, Gynecological Surgery, 10, 109-115, 2013	Population do not meet criteria - not specifically POP
Gilligan, J. P., Zimmern, P., Abdominal mesh sacrocolpopexy for recurrent triple-compartment pelvic organ prolapse, BJU International, 103, 1090-4, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Girao, M. J. B. C., Wakavaiaach, V. M. B., Sartori, M. G. F., Baracat, E. C., Rodrigues De Lima, G., Rectus fascia colpopexy in posthysterectomy vaginal prolapse: Analysis of 18 cases, International Urogynecology Journal, 8, 25-29, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Given Jr, F. T., 'Posterior culdeplasty': Revisited, American Journal of Obstetrics and Gynecology, 153, 135-139, 1985	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Glavind, K., Kempf, L., Colpectomy or Le Fort colpocleisis--a good option in selected elderly patients, International Urogynecology Journal, 16, 48-51; discussion 51, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Godin, P. A., Nisolle, M., Smets, M., Squifflet, J., Donnez, J., Combined vaginal and laparoscopic sacrofixation for genital prolapse using a tacking technique: A series of 45 cases, Gynaecological Endoscopy, 8, 277-285, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Goldman, H. B., Fitzgerald, M. P., Transvaginal mesh for cystocele repair, Journal of Urology, 183, 430-2, 2010	Narrative literature review
Goldstein, H. B., Maccarone, J., Naughton, M. J., Aguirre, O. A., Patel, R. C., A multicenter prospective trial evaluating fetal bovine dermal graft (Xenform Matrix) for pelvic reconstructive surgery, BMC Urology, 10, 21, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gosselink, M. J., Van Dam, J. H., Huisman, W. M., Ginai, A. Z., Schouten, W. R., Treatment of enterocoele by obliteration of the pelvic inlet, Diseases of the Colon and Rectum, 42, 940-944, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Govier, F. E., Kobashi, K. C., Kozlowski, P. M., Kuznetsov, D. D., Begley, S. J., McGonigle, K. F., Muntz, H. G., High complication rate identified in sacrocolpopexy patients attributed to silicone mesh, Urology, 65, 1099-1103, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gabriel, B., Farthmann, J., Brintrup, B., Funfgeld, C., Jezek, P., Kraus, A., Lenz, F., Kumbier, E., Niesel, A., Stickeler, E., Watermann, D., Surgical repair of posterior compartment prolapse: preliminary results of a novel transvaginal procedure using a four-armed polypropylene mesh with infracoccygeal and pararectal suspension, Acta Obstetricia et Gynecologica Scandinavica, 86, 1236-42, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gracia, M., Perello, M., Bataller, E., Espuna, M., Parellada, M., Genis, D., Balasch, J., Carmona, F., Comparison between laparoscopic sacral hysteropexy and subtotal hysterectomy plus cervicopexy in pelvic organ prolapse: A pilot study, Neurourology & UrodynamicsNeurourol Urodyn, 34, 654-8, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Granese, R., Adile, B., Tension-free cystocele repair: an analysis after a follow-up of 24 months, Minerva Ginecologica, 59, 369-376, 2007	Unable to obtain full text
Grimes, C. L., Overholser, R. H., Xu, R., Tan-Kim, J., Nager, C. W., Dyer, K. Y., Menefee, S. A., Diwadkar, G. B., Lukacz, E. S., Measuring the impact of a posterior compartment procedure on	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
symptoms of obstructed defecation and posterior vaginal compartment anatomy, International Urogynecology Journal, 27, 1817-1823, 2016	
Groutz, A., Chaikin, D. C., Theusen, E., Blaivas, J. G., Use of cadaveric solvent-dehydrated fascia lata for cystocele repair - Preliminary results, Urology, 58, 179-183, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Grunberger, W., Grunberger, V., Wierrani, F., Pelvic promontory fixation of the vaginal vault in sixty-two patients with prolapse after hysterectomy, Journal of the American College of Surgeons, 178, 69-72, 1994	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gupta, P., Transvaginal Sacrospinous Ligament Fixation for Pelvic Organ Prolapse Stage III and Stage IV Uterovaginal and Vault Prolapse, Iranian Journal of Medical SciencesIran, 40, 58-62, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Gupta, R., Matharu, G., Safety and efficacy of biological mesh repair for pelvic organ prolapse, BJOG: An International Journal of Obstetrics and Gynaecology, 123, 182, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Guyomard, A., Delorme, E., Transvaginal treatment of anterior or central urogenital prolapse using six tension-free straps and light mesh, International Journal of Gynaecology & ObstetricsInt J Gynaecol Obstet, 133, 365-9, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hach, C. E., Krude, J., Reitz, A., Reiter, M., Haferkamp, A., Buse, S., Midterm results of robot-assisted sacrocolpopexy, International Urogynecology Journal, 26, 1321-6, 2015	Retrospective study design
Hafidh, B. A., Chou, Q., Khalil, M. M., Al-Mandeel, H., De novo stress urinary incontinence after vaginal repair for pelvic organ prolapse: One-year follow-up, European Journal of Obstetrics Gynecology and Reproductive Biology, 168, 227-230, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hale, D. S., Rogers Jr, R. M., Abdominal sacrospinous ligament colposuspension, Obstetrics and Gynecology, 94, 1039-1041, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hall, M. E., Oyesanya, T., Cameron, A. P., Results of surgical excision of urethral prolapse in symptomatic patients, Neurourology & UrodynamicsNeurourol Urodyn, 21, 21, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hammett,J., Peters,A., Trowbridge,E., Hullfish,K., Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 465-470, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hammond, K. L., Ellis, C. N., Outcomes after transanal repair of rectoceles, Diseases of the Colon & RectumDis Colon Rectum, 53, 83-7, 2010	Study design did not meet the protocol inclusion criteria - followup not long enough

Study	Reason for Exclusion
Hamuro, A., Tachibana, D., Wang, H., Hayashi, M., Yanai, S., Kurihara, Y., Misugi, T., Katayama, H., Nakano, A., Koyama, M., Combined reconstructive surgery involving uterosacral colpopexy and anterior vaginal mesh implantation for pelvic organ prolapse, <i>Journal of Obstetrics &amp; Gynaecology Research</i> <b>J Obstet Gynaecol Res</b> , 42, 707-15, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hayden, R. C., Levinson, J. M., Total vaginectomy, vaginal hysterectomy, and colpocleisis for advanced procidentia, <i>Obstetrics &amp; Gynecology</i> <b>Obstet Gynecol</b> , 16, 564-6, 1960	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hefni, M. A., El-Toukhy, T. A., Sacrospinous colpopexy at vaginal hysterectomy: Method, results and follow up in 75 patients, <i>Journal of Obstetrics and Gynaecology</i> , 20, 58-62, 2000	Study design did not meet the protocol inclusion criteria - followup not long enough
Heinonen, P. K., Transvaginal sacrospinous colpopexy for vaginal vault and complete genital prolapse in aged women, <i>Acta Obstetricia et Gynecologica Scandinavica</i> , 71, 377-381, 1992	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Heriot, A. G., Skull, A., Kumar, D., Functional and physiological outcome following transanal repair of rectocele, <i>British Journal of Surgery</i> , 91, 1340-1344, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hernandez-Nieto, C. A., Flores-Mendoza, H., Basurto-Diaz, D., Sepulveda-Mendoza, D. L., Garcia-Rodriguez, L. F., Soto-Fuenzalida, G. A., Laparoscopic sacrocolpopexy as pelvic organ prolapse treatment: A case series, <i>Revista Mexicana de Urologia</i> , 76, 218-223, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Higgs, P., Goh, J., Krause, H., Sloane, K., Carey, M., Abdominal sacral colpopexy: an independent prospective long-term follow-up study, <i>Australian and New Zealand Journal of Obstetrics and Gynaecology</i> , 45, 430-434, 2005	Study design did not meet the protocol inclusion criteria - followup not long enough
Hilger, W. S., Poulson, M., Norton, P. A., Weber, A., Long-term results of abdominal sacrocolpopexy, <i>American Journal of Obstetrics and Gynecology</i> , 189, 1606-1611, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hiller, R. I., Repair of enterocele with preservation of the vagina, <i>American Journal of Obstetrics and Gynecology</i> , 64, 409-412, 1952	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hinoul, P., Vanspauwen, R., Smajda, S., Roovers, J. P., The Posterior Intravaginal Slingplasty treatment for apical prolapse: 3 years experience in a single centre setting, <i>Facts Views &amp; Vision in Obgyn</i> <b>Facts views vis</b> , 2, 1-8, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hinoul, P., Ombelet, W.U., Burger, M.P., Roovers, J.P., A prospective study to evaluate the anatomic and functional outcome of a transobturator mesh kit (prolift anterior) for symptomatic cystocele repair, <i>Journal of Minimally Invasive Gynecology</i> , 15, 615-620, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hirata, H., Matsuyama, H., Yamakawa, G. I., Suga, A., Tatsumura, M., Ogata, H., Takemoto, M., Tomimatsu, K., Naito, K., Does Surgical Repair of Pelvic Prolapse Improve Patients' Quality of Life?, <i>European Urology</i> , 45, 213-218, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Hirsch, H. A., Uterosacral ligament suspension of vaginal vault (McCall's culdeplasty), European Journal of Obstetrics, Gynecology, & Reproductive Biology Eur J Obstet Gynecol Reprod Biol, 32, 13, 1989	Outcomes not relevant - no data presented
Hirst, G. R., Hughes, R. J., Morgan, A. R., Carr, N. D., Patel, B., Beynon, J., The role of rectocele repair in targeted patients with obstructed defaecation, Colorectal Disease, 7, 159-163, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hoffman, M. S., Cardosi, R. J., Lockhart, J., Hall, D. C., Murphy, S. J., Vaginectomy with pelvic herniorrhaphy for prolapse, American Journal of Obstetrics & Gynecology Am J Obstet Gynecol, 189, 364-70; discussion 370-1, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hoffman, M. S., Lockhart, J., Garvin, D., Accurate repair of the prolapsed vagina by use of measured lateral flaps, American Journal of Obstetrics and Gynecology, 183, 286-290, 2000	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hoffman, M. S., Lynch, C. M., Nackley, A., Ureteral obstruction from high McCall's culdeplasty, Journal of Gynecologic Surgery, 16, 119-123, 2000	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Holley, R. L., Varner, R. E., Gleason, B. P., Apffel, L. A., Scott, S., Recurrent pelvic support defects after sacrospinous ligament fixation for vaginal vault prolapse, Journal of the American College of Surgeons, 180, 444-448, 1995	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hong, L., Xu, X., Chen, L., Fu, Q., Laparoscopic sacral colpopexy for uterine prolapse with prolene mesh, Clinical & Experimental Obstetrics & Gynecology Clin Exp Obstet Gynecol, 37, 295-8, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hong, M. K., Chu, T. Y., Wei, Y. C., Ding, D. C., High success rate and considerable adverse events of pelvic prolapse surgery with Prolift: a single center experience, Taiwanese Journal of Obstetrics & Gynecology Taiwan, 52, 389-94, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hosni, M. M., El-Feky, A. E. H., Agur, W. I., Khater, E. M., Evaluation of three different surgical approaches in repairing paravaginal support defects: A comparative trial, Archives of Gynecology and Obstetrics, 288, 1341-1348, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hsiao, K. C., Latchamsetty, K., Govier, F. E., Kozlowski, P., Kobashi, K. C., Comparison of laparoscopic and abdominal sacrocolpopexy for the treatment of vaginal vault prolapse, Journal of Endourology, 21, 926-930, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Huang, W. C., Lin, T. Y., Lau, H. H., Chen, S. S., Hsieh, C. H., Su, T. H., Outcome of transvaginal pelvic reconstructive surgery with Prolift after a median of 2 years' follow-up, International Urogynecology Journal, 22, 197-203, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Huang,K.H., Chuang,F.C., Fu,H.C., Kung,F.T., Polypropylene mesh as an alternative option for uterine preservation in pelvic reconstruction in patients with uterine prolapse, Journal of Obstetrics and Gynaecology Research, 38, 97-101, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Huffaker, R. K., Kuehl, T. J., Muir, T. W., Yandell, P. M., Pierce, L. M., Shull, B. L., Transverse cystocele repair with uterine preservation using native tissue, International Urogynecology Journal, 19, 1275-81, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hung, M. J., Liu, F. S., Shen, P. S., Chen, G. D., Lin, L. Y., Ho, E. S., Factors that affect recurrence after anterior colporrhaphy procedure reinforced with four-corner anchored polypropylene mesh, International Urogynecology Journal, 15, 399-406; discussion 406, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Hurd, G. B., Ventral Fixation for Complete Prolapse--a Re-Evaluation, American Journal of Obstetrics & Gynecology Am J Obstet Gynecol, 93, 423-41, 1965	Unable to obtain full text
Ignjatovic, I. M., Potic, M. B., Experimental and clinical use of meshes in urogynecology, Vojnosanitetski Pregled, 71, 673-8, 2014	Narrative literature review
Ignjatovic,I., Stojkovic,I., Stankovic,J., Basic,D., Potic,M., Ignjatovic,B., Simultaneous correction of anterior and apical vaginal prolapse with the modified placement of the transobturator-guided mesh (Anterior ProliftTM) set, Urologia Internationalis, 87, 14-18, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Iliev, V. N., Andonova, I. T., Uterus preserving vaginal surgery versus vaginal hysterectomy for correction of female pelvic organ prolapse, Prilozi Makedonska Akademija Na Naukite I Umetnostite Oddelenie Za Medicinski NaukiPril (Makedon Akad Nauk Umet Odd Med Nauki), 35, 243-7, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Illiano, E., Giannitsas, K., Zucchi, A., Di Biase, M., Del Zingaro, M., Bini, V., Costantini, E., Sacrocolpopexy for posthysterectomy vaginal vault prolapse: long-term follow-up, International Urogynecology Journal, 27, 1563-9, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Illston, J. D., Garris, J. B., Richter, H. E., Wheeler, T. L., Pain Scores and Exposure Rates after Polypropylene Mesh for Pelvic Organ Prolapse, Southern Medical Journal, 108, 715-721, 2015	Retrospective study design
Inoue,H., Sekiguchi,Y., Kohata,Y., Satono,Y., Hishikawa,K., Tominaga,T., Oobayashi,M., Tissue fixation system (TFS) to repair uterovaginal prolapse with uterine preservation: a preliminary report on perioperative complications and safety, Journal of Obstetrics and Gynaecology Research, 35, 346-353, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Iosif, C. S., Abdominal sacral colpopexy with use of synthetic mesh, Acta Obstetricia et Gynecologica Scandinavica, 72, 214-217, 1993	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ismail,S.I.M.F., Recurrent prolapse after sacrocolpopexy for post-hysterectomy vaginal vault prolapse, Journal of Obstetrics and Gynaecology, 27, 292-296, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jambusaria, L. H., Murphy, M., Luente, V. R., One-year functional and anatomic outcomes of robotic sacrocolpopexy versus vaginal extraperitoneal colpopexy with mesh, Female pelvic medicine & reconstructive surgery, 21, 87-92, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Jean, F., Tanneau, Y., Le Blanc-Louvy, I., Leroi, A. M., Denis, P., Michot, F., Treatment of enterocele by abdominal colporectosacropexy - Efficacy on pelvic pressure, Colorectal Disease, 4, 321-325, 2002	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jeffery, S. T., Brouard, K., High risk of complications with a single incision pelvic floor repair kit: results of a retrospective case series, International Urogynecology Journal, 25, 109-16, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jeffery, S. T., Doumouchtsis, S. K., Franco, A. V. M., Fynes, M. M., High uterosacral ligament vault suspension at vaginal hysterectomy: Objective and subjective outcomes of a modified technique, Journal of Obstetrics and Gynaecology Research, 35, 539-544, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jeffery, S. T., Doumouchtsis, S. K., Parappallil, S., Franco, A. V. M., Tosson, F. S., Fynes, M. M., Outcomes, recurrence rates, and postoperative sexual function after secondary vaginal prolapse surgery using the small intestinal submucosa graft, Journal of Pelvic Medicine and Surgery, 15, 151-156, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jeffery, S., Roovers, J. P., Quo vadis, vaginal mesh in pelvic organ prolapse?, International Urogynecology Journal, 1-2, 2018	Study design did not meet the protocol inclusion criteria - commentary paper
Jeffery,S.T., Nieuwoudt,A., Beyond the complications: medium-term anatomical, sexual and functional outcomes following removal of trocar-guided transvaginal mesh. A retrospective cohort study, International Urogynecology Journal, 23, 1391-1396, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jenkins, D. J., McCoubrie, S. J. F., Vault prolapse: A new approach, Australian and New Zealand Journal of Surgery, 62, 805-808, 1992	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jenkins, Ii V. R., Aronson, M. P., Uterosacral ligament fixation for vaginal suspension in uterine and vaginal vault prolapse, American Journal of Obstetrics and Gynecology, 177, 1337-1344, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jeon,M.J., Moon,Y.J., Jung,H.J., Lim,K.J., Yang,H.I., Kim,S.K., Bai,S.W., A long-term treatment outcome of abdominal sacrocolpopexy, Yonsei Medical Journal, 50, 807-813, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jo, H., Kim, J. W., Park, N. H., Kang, S. B., Lee, H. P., Song, Y. S., Efficacy and outcome of anterior vaginal wall repair using polypropylene mesh (Gynemesh), Journal of Obstetrics and Gynaecology Research, 33, 700-704, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Jordaan,D.J., Prollius,A., Cronje,H.S., Nel,M., Posterior intravaginal slingplasty for vaginal prolapse, International urogynecology journal and pelvic floor dysfunction, 17, 326-329, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Joshi, V. M., A new technique of uterine suspension to pectenial ligaments in the management of uterovaginal prolapse, Obstetrics & GynecologyObstet Gynecol, 81, 790-3, 1993	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Joubert, M., Thubert, T., Lefranc, J. P., Vaessen, C., Chartier-Kastler, E., Deffieux, X., Roupert, M., Comparison of functional outcomes with purely laparoscopic sacrocolpopexy and robot-assisted sacrocolpopexy in obese women, Progres en UrologieProg Urol, 24, 1106-13, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Julian, T. M., Grody, T., The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall, American Journal of Obstetrics and Gynecology, 175, 1472-1475, 1996	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kallidonis, P., Al-Aown, A., Vasilas, M., Kyriazis, I., Panagopoulos, V., Fligou, F., Athanasopoulos, A., Fariborz, B., Liatsikos, E., Ozsoy, M., Laparoscopic sacrocolpopexy using barbed sutures for mesh fixation and peritoneal closure: A safe option to reduce operational times, Urology annalsUrol Ann, 9, 159-165, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kapur, K., Dalal, V., Mesh repair of vaginal wall prolapse, Medical Journal Armed Forces IndiaMed, 70, 105-10, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Karacaoglu, M. U., Ozyurek, E. S., Mutlu, S., Odacilar, E., Unilateral sacrospinous ligament fixation (USLF) with a mesh stabilizing anchor set: clinical outcome and impact on quality of life, Clinical & Experimental Obstetrics & GynecologyClin Exp Obstet Gynecol, 43, 216-9, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Karlstrom, U., Graf, W., Nilsson, S., Pahlman, L., Does surgical repair of a rectocele improve rectal emptying?, Diseases of the Colon and Rectum, 39, 1296-1302, 1996	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Karp, D. R., Peterson, T. V., Mahdy, A., Ghoniem, G., Aguilar, V. C., Davila, G. W., Biologic grafts for cystocele repair: does concomitant midline fascial plication improve surgical outcomes?, International Urogynecology Journal, 22, 985-90, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Karpathios, S., Liapis, A., Phylaktou, M., Drakakis, P., Panagopoulos, P., Colpopexy: A modification of Shaw's technique, Journal of Obstetrics and Gynaecology, 18, 365-368, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kashihara, H., Emmanuelli, V., Poncelet, E., Rubod, C., Lucot, J. P., Pouseele, B., Cosson, M., Comparison of dynamic MRI vaginal anatomical changes after vaginal mesh surgery and laparoscopic sacropexy, Gynecological Surgery, 11, 249-256, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Katsara, A., Wight, E., Heinzelmann-Schwarz, V., Kavvadias, T., Long-term quality of life, satisfaction, pelvic floor symptoms and regret after colpocleisis, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 294, 999-1003, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kavallaris, A., Kohler, C., Diebold, H., Vercellino, F., Krause, N., Schneider, A., Repair of prolapse with vaginal sacrocolporectopexy: Technique and results, European Journal of Obstetrics Gynecology and Reproductive Biology, 122, 237-242, 2005	Retrospective study design
Kdous, M., Diari, J., Ferchiou, M., Zhioua, F., Laparoscopic double sacrocolpopexy : a failure for the posterior compartment?, Tunisie MedicaleTunis Med, 94, 128-34, 2016	Publication not in English

Study	Reason for Exclusion
Kenton, K., Mueller, E., Surgical repair of the middle compartment, Clinical Obstetrics and Gynecology, 48, 691-703, 2005	Narrative literature review
Khan, A., Jaleel, R., Nasrullah, F. D., Sacrohysteropexy performed as uterus conserving surgery for pelvic organ prolapse: Review of case files, Pakistan Journal of Medical Sciences, 32, 1174-1178, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Khan, Z. A., Thomas, L., Emery, S. J., Outcomes and complications of trans-vaginal mesh repair using the Prolift™ kit for pelvic organ prolapse at 4 years median follow-up in a tertiary referral centre, Archives of Gynecology and Obstetrics., 01, 2014	Retrospective study design
Khanam, R. A., Rubaiyat, A., Azam, M. S., Sling for correcting uterine prolapse: twelve years experience, Mymensingh Medical Journal: MMJMymensingh Med J, 23, 13-7, 2014	Unable to obtain full text
Khandwala, S., Jayachandran, C., Transvaginal mesh surgery for pelvic organ prolapse-Prolift+M: A prospective clinical trial, International Urogynecology Journal, 22, 1405-1411, 2011	Study design did not meet the protocol inclusion criteria - followup not long enough
Khuchandani, I. T., Sheets, J. A., Stasik, J. J., Hakki, A. R., Endorectal repair of rectocele, Diseases of the Colon and Rectum, 26, 792-796, 1983	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kilic, G., Tunca, J. C., Use of the Labhardt procedure to repair pelvic organ prolapse, Clinical and Experimental Obstetrics and Gynecology, 34, 91-92, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Klapper, A. S., Langer, O., Richter, A., Zakashanskiy, K., Friedman, A. J., Abdominal sacral colpopexy using a porcine dermal graft and bone anchors in the elderly overweight patient, Journal of Pelvic Medicine and Surgery, 10, 231-238, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Klauschie, J. L., Suozzi, B. A., O'Brien, M. M., McBride, A. W., A comparison of laparoscopic and abdominal sacral colpopexy: objective outcome and perioperative differences, International Urogynecology Journal, 20, 273-9, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kobashi, K. C., Mee, S. L., Leach, G. E., A new technique for cystocele repair and transvaginal sling: The cadaveric prolapse repair and sling (CaPS), Urology, 56, 9-14, 2000	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kohli, N., Miklos, J. R., Dermal graft-augmented rectocele repair, International Urogynecology Journal, 14, 146-149, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kohli, N., Walsh, P. M., Roat, T. W., Karram, M. M., Mesh erosion after abdominal sacrocolpopexy, Obstetrics and Gynecology, 92, 999-1004, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Kokanali, M. K., Cavkaytar, S., Aksakal, O., Dotanay, M., McCall Culdoplasty vs. Sacrospinous Ligament Fixation after vaginal hysterectomy: Comparison of postoperative vaginal length and sexual function in postmenopausal women, European Journal of Obstetrics Gynecology and Reproductive Biology, 194, 218-222, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kolusari,A., Yildizhan,R., Adali,E., Kurdoglu,M., Sahin,H.G., Kamaci,M., Sivaslioglu,A., Short-term results of posterior intravaginal slingplasty in grade 4 uterine prolapse, Archives of Gynecology and Obstetrics, 281, 55-58, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kose, O., Saglam, H. S., Kumsar, S., Budak, S., Adsan, O., A novel technique for anterior vaginal wall prolapse repair: anterior vaginal wall darn, ThescientificworldjournalScientificWorldJournal, 2013, 198542, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kose, O., Saglam, H. S., Kumsar, S., Budak, S., Aydemir, H., Adsan, O., Early results of a novel technique for anterior vaginal wall prolapse repair: Anterior vaginal wall darn, BMC Urology, 14 (1) (no pagination), 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Koski,M.E., Chow,D., Bedestani,A., Togami,J.M., Chesson,R.R., Winters,J.C., Colpocleisis for advanced pelvic organ prolapse, Urology, 80, 542-546, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Koyama, M., Yoshida, S., Koyama, S., Ogita, K., Kimura, T., Shimoya, K., Murata, Y., Nagata, I., Surgical reinforcement of support for the vagina in pelvic organ prolapse: Concurrent iliococcygeus fascia colpopexy (Inmon technique), International Urogynecology Journal, 16, 197-202, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kramer, B. A., Whelan, C. M., Powell, T. M., Schwartz, B. F., Robot-assisted laparoscopic sacrocolpopexy as management for pelvic organ prolapse, Journal of Endourology, 23, 655-658, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Krissi, H., Aviram, A., Eitan, R., From, A., Wiznitzer, A., Peled, Y., Risk factors for recurrence after Le Fort colpocleisis for severe pelvic organ prolapse in elderly women, International Journal Of SurgeryInt J Surg, 20, 75-79, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Krissi, H., Aviram, A., Ram, E., Eitan, R., Wiznitzer, A., Peled, Y., Colpocleisis surgery in women over 80 years old with severe triple compartment pelvic organ prolapse, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 195, 206-9, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Krissi, H., Stanton, S. L., Bilateral iliococcygeal fixation for vaginal vault prolapse and enterocele repair using a new suturing device - The digital needle driver, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 1145-1149, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kuah, S. E. S., Lee, K. W., Houghton, C. R. S., Korda, A. R., The management of pulsion enterocoele with the Zacharin abdominoperineal technique (and mesh sacrocolpopexy), Australian and New Zealand Journal of Obstetrics and Gynaecology, 40, 303-307, 2000	Retrospective study design

Study	Reason for Exclusion
Kuhn, A., Brunnmayr, G., Stadlmayr, W., Kuhn, P., Mueller, M. D., Male and female sexual function after surgical repair of female organ prolapse, Journal of Sexual Medicine, 6, 1324-1334, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kuhn, A., Hausermann, A., Brandner, S., Herrmann, G., Schmid, C., Mueller, M. D., Sexual function after sacrocolpopexy, Journal of Sexual Medicine, 7, 4018-4023, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kuhnel, P., Experience with le fort-neugebauer's operation for complete prolapse. report of 58 cases, Acto Obstet, Gynec, Stand. 31, 151-161, 1962	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Kurt, S., Canda, M. T., Tasyurt, A., A new surgical method of suprapubic and extraperitoneal approach with uterine preservation for pelvic organ prolapse: Kurt extraperitoneal ligamentopexy, ISRN Obstetrics and Gynecology, 2013 (no pagination), 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lamah, M., Ho, J., Leicester, R. J., Results of anterior levatorplasty for rectocele, Colorectal Disease, 3, 412-416, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lamblin, G., Meysonnier, C., Moret, S., Nadaud, B., Mellier, G., Chene, G., Opportunistic salpingectomy during vaginal hysterectomy for a benign pathological condition, International Urogynecology Journal, 29, 715-721, 2018	Intervention did not meet the protocol inclusion criteria - intervention not relevant
Lane, F. E., Repair of posthysterectomy vaginal-vault prolapse, Obstetrics & GynecologyObstet Gynecol, 20, 72-7, 1962	Narrative literature review
Langmade, C. F., Cooper Ligament Repair of Vaginal Vault Prolapse, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 92, 601-9, 1965	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Larson, K. A., Smith, T., Berger, M. B., Abernethy, M., Mead, S., Fenner, D. E., DeLancey, J. O. L., Morgan, D. M., Long-term patient satisfaction with michigan four-wall sacrospinous ligament suspension for prolapse, Obstetrics and Gynecology, 122, 967-975, 2013	Retrospective study design
Latini, J. M., Brown, J. A., Kreder, K. J., Abdominal sacral colpopexy using autologous fascia lata, Journal of Urology, 171, 1176-1179, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lavelle, E. S., Giugale, L. E., Winger, D. G., Wang, L., Carter-Brooks, C. M., Shepherd, J. P., Prolapse recurrence following sacrocolpopexy vs uterosacral ligament suspension: a comparison stratified by Pelvic Organ Prolapse Quantification stage, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 218, 116.e1-116.e5, 2018	Study design did not meet the protocol inclusion criteria - followup not long enough
Le Long, E., Rebibo, J. D., Caremel, R., Grise, P., Efficacy of Pelvisoft Biomesh for cystocele repair: assessment of long-term results, International Braz J Urol, 40, 828-34, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Leboeuf, L., Miles, R. A., Kim, S. S., Gousse, A. E., Grade 4 cystocele repair using four-defect repair and porcine xenograft acellular matrix (Pelvicol): Outcome measures using SEAPI, <i>Urology</i> , 64, 282-286, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lee, H. J., Lee, Y. S., Koo, T. B., Cho, Y. L., Park, I. S., Laparoscopic management of uterine prolapse with cystocele and rectocele using "Gynemesh PS", <i>Journal of Laparoendoscopic and Advanced Surgical Techniques</i> , 18, 93-98, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lee, Y. S., Han, D. H., Lee, J. Y., Kim, J. C., Choo, M. S., Lee, K. S., Anatomical and functional outcomes of posterior intravaginal slingplasty for the treatment of vaginal vault or uterine prolapse: A prospective, multicenter study, <i>Korean Journal of Urology</i> , 51, 187-192, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lee, Y. S., Han, D. H., Lim, S. H., Kim, T. H., Choo, M. S., Seo, J. T., Lee, J. Z., Chung, B. S., Lee, J. G., Lee, K. S., Efficacy and Safety of "Tension-free" Placement of Gynemesh PS for the Treatment of Anterior Vaginal Wall Prolapse, <i>International Neurourology Journal</i> , 14, 34-42, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lee,D.S., Park,D.C., Choe,H.S., Choi,J.B., Lee,S.J., Changes in urinary and sexual function 6 months after cystocele repair with a polypropylene mesh, <i>Urologia Internationalis</i> , 88, 415-422, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Leone Roberti Maggiore, U., Ferrero, S., Mancuso, S., Costantini, S., Feasibility and outcome of vaginal paravaginal repair using the Capio suture-capturing device, <i>International Urogynecology Journal</i> , 23, 341-7, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Levy, G., Padoa, A., Fekete, Z., Bartfai, G., Pajor, L., Cervigni, M., Self-retaining support implant: an anchorless system for the treatment of pelvic organ prolapse-2-year follow-up, <i>International Urogynecology Journal</i> , 29, 709-714, 2018	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Li, S., Ji, M., Zhao, Z., The effectiveness of two different laparoscopic surgeries for apical support of pelvic organ prolapse, <i>European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology</i> Eur J Obstet Gynecol Reprod Biol, 188, 74-8, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Liang, C. C., Tseng, L. H., Chang, S. D., Chang, Y. L., Lo, T. S., Resolution of elevated postvoid residual volumes after correction of severe pelvic organ prolapse, <i>International Urogynecology Journal</i> , 19, 1261-1266, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Liang, S., Zhu, L., Song, X., Xu, T., Sun, Z., Lang, J., Long-term outcomes of modified laparoscopic sacrocolpopexy for advanced pelvic organ prolapse: A 3-year prospective study, <i>Menopause</i> , 23, 765-770, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lim, M., Sagar, P. M., Gonsalves, S., Thekkinkattil, D., Landon, C., Surgical management of pelvic organ prolapse in females: Functional outcome of mesh sacrocolpopexy and rectopexy as a combined procedure, <i>Diseases of the Colon and Rectum</i> , 50, 1412-1421, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Limb,J., Wood,K., Weinberger,M., Miyazaki,F., Aboseif,S., Sacral colpopexy using mersilene mesh in the treatment of vaginal vault prolapse, <i>World Journal of Urology</i> , 23, 55-60, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

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Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Lin, T. Y., Su, T. H., Huang, W. C., Polypropylene mesh used for adjuvant reconstructive surgical treatment of advanced pelvic organ prolapse, Journal of Obstetrics and Gynaecology Research, 36, 1059-1063, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lin,L., Wang,P., Wang,Q., Yi,T., Laparoscopic modified sacral hysteropexy: initial experience with an original surgical approach to uterovaginal prolapse, Journal of Minimally Invasive Gynecology, 21, 431-435, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Linder, B. J., El-Nashar, S. A., Mukwege, A. A., Weaver, A. L., McGree, M. E., Rhodes, D. J., Gebhart, J. B., Klingele, C. J., Occhino, J. A., Trabuco, E. C., Long-term outcomes and predictors of failure after surgery for stage IV apical pelvic organ prolapse, International Urogynecology Journal, 1-8, 2017	Retrospective study design
Linder, B. J., El-Nashar, S. A., Mukwege, A. A., Weaver, A. L., McGree, M. E., Rhodes, D. J., Gebhart, J. B., Klingele, C. J., Occhino, J. A., Trabuco, E. C., Long-term outcomes and predictors of failure after surgery for stage IV apical pelvic organ prolapse, International Urogynecology Journal, 29, 803-810, 2018	Retrospective study design
Liu, C. K., Tsai, C. P., Chou, M. M., Shen, P. S., Chen, G. D., Hung, Y. C., Hung, M. J., A comparative study of laparoscopic sacrocolpopexy and total vaginal mesh procedure using lightweight polypropylene meshes for prolapse repair, Taiwanese journal of obstetrics & gynecology, 53, 552-8, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lo, T. S., One-Year Outcome of Concurrent Anterior and Posterior Transvaginal Mesh Surgery for Treatment of Advanced Urogenital Prolapse: Case Series, Journal of Minimally Invasive Gynecology, 17, 473-479, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lo, T. S., Al-Kharabsheh, A. M., Tan, Y. L., Pue, L. B., Hsieh, W. C., Uy-Patrimonio, M. C., Single incision anterior apical mesh and sacrospinous ligament fixation in pelvic prolapse surgery at 36 months follow-up, Taiwanese Journal of Obstetrics and Gynecology, 56, 793-800, 2017	No relevant outcomes data - no complication data at 36 months
Lo, T. S., Tan, Y. L., Cortes, E. F. M., Pue, L. B., Wu, P. Y., Al-Kharabsheh, A., Anterior-apical single-incision mesh surgery (SIMS): Surgical and functional outcomes at 1 year, Journal of Minimally Invasive Gynecology, 22, 50-56, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lo, T. S., Tan, Y. L., Khanuengkitkong, S., Dass, A. K., Surgical outcomes of anterior trans-obturator mesh and vaginal sacrospinous ligament fixation for severe pelvic organ prolapse in overweight and obese Asian women, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, 809-816, 2013	Retrospective study design
Loffeld, C. J. W., Thijs, S., Mol, B. W., Bongers, M. Y., Roovers, J. P. W. R., Laparoscopic sacrocolpopexy: A comparison of Prolene and Tutoplast mesh, Acta Obstetricia et Gynecologica Scandinavica, 88, 826-830, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Long, C. Y., Juan, Y. S., Wu, M. P., Liu, C. M., Chiang, P. H., Tsai, E. M., Changes in female sexual function following anterior with and without posterior vaginal mesh surgery for the treatment of pelvic organ prolapse, Journal of sexual medicine, 9, 2167-74, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

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Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Long, C. Y., Wang, C. L., Ker, C. R., Juan, Y. S., Tsai, E. M., Lin, K. L., Laparoscopic Organopexy with Non-mesh Genital (LONG) Suspension: A Novel Uterine Preservation Procedure for the Treatment of Apical Prolapse, <i>Scientific ReportsSci</i> , 8, 4872, 2018	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lopez, A., Anzen, B., Bremmer, S., Mellgren, A., Nilsson, B. Y., Zetterstrom, J., Holmstrom, B., Durability of success after rectocele repair, <i>International Urogynecology Journal</i> , 12, 97-103, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lovatsis, D., Easton, W., Wilkie, D., No. 248-Guidelines for the Evaluation and Treatment of Recurrent Urinary Incontinence Following Pelvic Floor Surgery, <i>Journal of Obstetrics and Gynaecology Canada</i> , 39, e309-e314, 2017	Study design did not meet the protocol inclusion criteria - Guideline
Lowenstein, E., Moller, L. A., Laigaard, J., Gimbel, H., Reoperation for pelvic organ prolapse: a Danish cohort study with 15-20 years' follow-up, <i>International Urogynecology Journal</i> , 29, 119-124, 2018	Unclear which surgery types were undertaken
Lowman, J. K., Jones, L. A., Woodman, P. J., Hale, D. S., Does the Prolift system cause dyspareunia?, <i>American Journal of Obstetrics &amp; GynecologyAm J Obstet Gynecol</i> , 199, 707.e1-6, 2008	Study design did not meet the protocol inclusion criteria - short followup
Lucioni, A., Rapp, D. E., Gong, E. M., Reynolds, W. S., Fedunok, P. A., Bales, G. T., The surgical technique and early postoperative complications of the Gynecare Prolift pelvic floor repair system, <i>The Canadian journal of urology</i> , 15, 4004-4008, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Lukacz, E. S., Santiago-Lastra, Y., Albo, M. E., Brubaker, L., Urinary incontinence in women a review, <i>JAMA - Journal of the American Medical Association</i> , 318, 1592-1604, 2017	Narrative literature review
Lyons, T. L., Winer, W. K., Laparoscopic rectocele repair using polyglactin mesh, <i>Journal of the American Association of Gynecologic Laparoscopists</i> , 4, 381-384, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Madhu, C., Cooke, J., Harber, P., Holmes, D., Functional outcomes of posterior vaginal wall repair and prespinous colpopexy with biological small intestinal submucosal (SIS) graft, <i>Archives of Gynecology and Obstetrics</i> , 290, 711-716, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Maeda, K., Maruta, M., Hanai, T., Sato, H., Masumori, K., Koide, Y., Matsumoto, M., Ishihara, O., Transvaginal anterior levatorplasty with posterior colporrhaphy for symptomatic rectocele, <i>Techniques in Coloproctology</i> , 7, 181-185, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Maggiore, U. L. R., Alessandri, F., Remorgida, V., Venturini, P. L., Ferrero, S., Vaginal sacrospinous colpopexy using the Capio suture-capturing device versus traditional technique: Feasibility and outcome, <i>Archives of Gynecology and Obstetrics</i> , 287, 267-274, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Maggiore, U. L. R., Ferrero, S., Mancuso, S., Costantini, S., Feasibility and outcome of vaginal paravaginal repair using the Capio suture-capturing device, <i>International Urogynecology Journal</i> , 23, 341-347, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Mahdy, A., Elmissiry, M., Ghoniem, G., The outcome of transobturator cystocele repair using biocompatible porcine dermis graft: Our experience with 32 cases, International Urogynecology Journal, 19, 1647-1652, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mahendran, D., Prashar, S., Smith, A. R. B., Murphy, D., Laparoscopic sacrocolpopexy in the management of vaginal vault prolapse, Gynaecological Endoscopy, 5, 217-222, 1996	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mahendru, R., Rectus fascia colpopexy for post-hysterectomy vault prolapse: a valid option, Journal of the Turkishgerman Gynecological AssociationJ, 11, 69-72, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mahendru, R., An effective and safe innovation for the management of vault prolapse, Annals of Surgical Innovation & Research [Electronic Resource]Ann Surg Innov Res, 4, 6, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Maher, C. F., Carey, M. P., Murray, C. J., Laparoscopic suture hysteropexy for uterine prolapse, Obstetrics and Gynecology, 97, 1010-1014, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Maher, C. F., Cary, M. P., Slack, M. C., Murray, C. J., Milligan, M., Schluter, P., Uterine preservation or hysterectomy at sacrospinous colpopexy for uterovaginal prolapse?, International Urogynecology Journal, 12, 381-385, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Maher, C. F., Qatawneh, A. M., Baessler, K., Schluter, P. J., Midline rectovaginal fascial plication for repair of rectocele and obstructed defecation, Obstetrics and Gynecology, 104, 685-689, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Maher, C. F., Qatawneh, A. M., Dwyer, P. L., Carey, M. P., Cornish, A., Schluter, P. J., Weber, A. M., Insufficient evidence of difference between abdominal and vaginal colpopexy for treatment of vaginal prolapse, Evidence-based Obstetrics and Gynecology, 6, 145-146, 2004	Same study already included in the RCT data. This is a brief report and commentary of the main paper
Mahmoud, S. A., Omar, W., Farid, M., Transanal repair for treatment of rectocele in obstructed defaecation: manual or stapled, Colorectal Disease, 14, 104-10, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Majkusiak, W., Horosz, E., Tomaszik, P., Zwierzchowska, A., Wielgos, M., Barcz, E., Quality of life assessment in women after cervicosacropexy with polypropylene mesh for pelvic organ prolapse: A preliminary study, Przeglad Menopauzalny, 14, 126-129, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mallipeddi, P. K., Steele, A. C., Kohli, N., Karram, M. M., Anatomic and functional outcome of vaginal paravaginal repair in the correction of anterior vaginal wall prolapse, International Urogynecology Journal, 12, 83-88, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mallipeddi, P., Kohli, N., Steele, A. C., Owens, R. G., Karram, M. M., Vaginal paravaginal repair in the surgical treatment of anterior vaginal wall prolapse, Primary Care Update for Ob/GynsPrim, 5, 199-200, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Marana, H. R. C., Andrade, J. M., Fonzar Marana, R. R. N., De Sala, M. M., Philbert, P. M. P., Rodrigues, R., Vaginal hysterectomy for correcting genital prolapse: Long-term evaluation, Journal of Reproductive Medicine for the Obstetrician and Gynecologist, 44, 529-534, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Marcus-Braun, N., von Theobald, P., Cystocele repair with single-incision, trocarless mesh system, International Urogynecology Journal, 25, 285-7, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Marinkovic, S. P., Hughes, S., Xie, D., Gillen, L. M., Marinkovic, C. M., Transvaginal rectocele repair with human dermal allograft interposition and bilateral sacrospinous fixation with a minimum eight-year follow-up, BMC Urology, 16 (1) (no pagination), 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Marschke, J., Hengst, L., Schwertner-Tiepelmann, N., Beilecke, K., Tunn, R., Transvaginal single-incision mesh reconstruction for recurrent or advanced anterior vaginal wall prolapse, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 291, 1081-7, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Marschke, J., Pax, C. M., Beilecke, K., Schwab, F., Tunn, R., Vaginal hysterectomy with apical fixation and anterior vaginal wall repair for prolapse: surgical technique and medium-term results, International Urogynecology Journal, 1-6, 2018	Retrospective study design
Masata, J., Martan, A., Poislova, M., Kobilkova, J., Masatova, D., Jedlickova, A., Svabik, K., Hubka, P., Zvara, K., A comparison of the incidence of early postoperative infections between patients using synthetic mesh and those undergoing traditional pelvic reconstructive surgical procedures, Prague Medical ReportPrague Med Rep, 114, 81-91, 2013	Study design did not meet the protocol inclusion criteria - followup not long enough
Matanes, E., Lauterbach, R., Mustafa-Mikhail, S., Amit, A., Wiener, Z., Lowenstein, L., Single Port Robotic Assisted Sacrocolpopexy: Our Experience With the First 25 Cases, Female Pelvic Medicine & Reconstructive SurgeryFemale pelvic med, 23, e14-e18, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mathlouthi, N., Elloumi, J., Trabelsi, H., Ali, I. B., Dhouib, M., Chaabene, K., Amouri, H., Ayed, B. B., Guermazi, M., Anatomic and functional results after surgical treatment of uro genital prolapse: Prospective study about 93 cases, Tunisie Medicale, 89, 896-901, 2011	Publication not in English
Mattox, T. F., Moore, S., Stanford, E. J., Mills, B. B., Posterior vaginal sling experience in elderly patients yields poor results, American Journal of Obstetrics and Gynecology, 194, 1462-1466, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mattox, T. F., Stanford, E. J., Varner, E., Infected abdominal sacrocolpopexies: Diagnosis and treatment, International Urogynecology Journal, 15, 319-323, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mazer, C., Israel, S. L., The Le Fort colpocleisis. An analysis of 43 operations, American Journal of Obstetrics and Gynecology, 56, 944-949, 1948	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Mc, Call MI, Posterior culdeplasty; surgical correction of enterocele during vaginal hysterectomy; a preliminary report, <i>Obstetrics &amp; Gynecology</i> <i>Obstet Gynecol</i> , 10, 595-602, 1957	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
McAchran, S., Barnes, H., Meller, E., Kieserman-Shmokler, C., Giles, D., Heisler, C., Brown, H., Meshing around: long-term outcomes following vaginal reconstructive surgery with synthetic mesh augmentation, <i>Journal of Urology</i> , 199 (4 Supplement 1), e434-e435, 2018	Retrospective study design
McDermott, C. D., Park, J., Terry, C. L., Woodman, P. J., Hale, D. S., Laparoscopic sacral colpopexy: abdominal versus abdominal-vaginal posterior graft attachment, <i>International Urogynecology Journal</i> , 22, 469-75, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
McDermott, C. D., Park, J., Terry, C. L., Woodman, P. J., Hale, D. S., Surgical Outcomes of Abdominal Versus Laparoscopic Sacral Colpopexy Related to Body Mass Index, <i>Journal of Obstetrics and Gynaecology Canada</i> , 34, 47-56, 2012	No relevant outcome data - outcomes grouped according to BMI
McLean, R., Kipling, M., Musgrave, E., Mercer-Jones, M., Short- and long-term clinical and patient-reported outcomes following laparoscopic ventral mesh rectopexy using biological mesh for pelvic organ prolapse: a prospective cohort study of 224 consecutive patients, <i>Colorectal Disease</i> , 19, 19, 2017	Population do not meet criteria - not specifically POP
McLean, R., Kipling, M., Musgrave, E., Mercer-Jones, M., Short- and long-term clinical and patient-reported outcomes following laparoscopic ventral mesh rectopexy using biological mesh for pelvic organ prolapse: a prospective cohort study of 224 consecutive patients, <i>Colorectal Disease</i> , 20, 424-436, 2018	Population do not meet criteria - not specifically POP
Mearini, L., Nunzi, E., Di Biase, M., Costantini, E., Laparoscopic Management of Vaginal Vault Prolapse Recurring after Pelvic Organ Prolapse Surgery, <i>Urologia Internationalis</i> , 97, 158-164, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Medina, C., Takacs, P., Laparoscopic uterosacral uterine suspension: A minimally invasive technique for treating pelvic organ prolapse, <i>Journal of Minimally Invasive Gynecology</i> , 13, 472-475, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Melich, G., Pai, A., Kwak, M., Bibi, S., Marecik, S., Park, J., Prasad, L. M., Transverse incision transvaginal rectocele repair combined with levatorplasty and biological graft insertion: technical details and case series outcomes, <i>Techniques in Coloproctology</i> , 20, 51-57, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Mellgren, A., Anzen, B., Nilsson, B. Y., Johansson, C., Dolk, A., Gillgren, P., Bremmer, S., Holmstrom, B., Results of rectocele repair: A prospective study, Diseases of the Colon and Rectum, 38, 7-13, 1995	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Menahem, N., Natalia, S., Vladimir, S., Jacob, B., Anterior needle-guided mesh in advanced pelvic organ prolapse: apical fixation on sacrospinous ligaments.[Erratum appears in Eur J Obstet Gynecol Reprod Biol. 2014 Sep;180:210 Note: Meuman, Neuman [corrected to Menahem, Neuman]], European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 172, 120-3, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mercer-Jones, M. A., Sprowson, A., Varma, J. S., Outcome after transperineal mesh repair of rectocele: a case series, Diseases of the Colon & RectumDis Colon Rectum, 47, 864-8, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Meschia, M., Amicarelli, F., Bruschi, F., Curtarelli, M., Ronchetti, A., Savini, P., Pifarotti, P., Sacrospinous fixation for the treatment and prevention of vaginal vault prolapse, Urogynaecologia International Journal, 10, 11-19, 1996	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Meschia, M., Bruschi, F., Amicarelli, F., Pifarotti, P., Marchini, M., Crosignani, P. G., The sacrospinous vaginal vault suspension: Critical analysis of outcomes, International Urogynecology Journal, 10, 155-9, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Meuman, N., Natalia, S., Vladimir, S., Jacob, B., Anterior needle-guided mesh in advanced pelvic organ prolapse: Apical fixation on sacrospinous ligaments, European Journal of Obstetrics Gynecology and Reproductive Biology, 172, 120-123, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Milani, A. L., Heidema, W. M., van der Vloedt, W. S., Kluivers, K. B., Withagen, M. I. J., Vierhout, M. E., Vaginal prolapse repair surgery augmented by ultra lightweight titanium coated polypropylene mesh, European Journal of Obstetrics Gynecology and Reproductive Biology, 138, 232-238, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Milani, A. L., Withagen, M. I. J., Vierhout, M. E., Trocar-guided total tension-free vaginal mesh repair of post-hysterectomy vaginal vault prolapse, International Urogynecology Journal, 20, 1203-1211, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Milani, R., Frigerio, M., Manodoro, S., Cola, A., Spelzini, F., Transvaginal uterosacral ligament hysteropexy: a retrospective feasibility study, International Urogynecology Journal, 28, 73-76, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Milani, R., Frigerio, M., Palmieri, S., Manodoro, S., Transvaginal mesh removal with native-tissue repair for mesh shrinkage and recurrent uterovaginal prolapse following vaginal mesh-augmented surgery, International Journal of Gynecology and Obstetrics, 139, 105-106, 2017	Letter
Ming-Ping, W. U., Laparoscopic modified Halban colpopexy combined with LAVH in treating uterine prolapse, Journal of Gynecologic Surgery, 13, 175-179, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

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Study	Reason for Exclusion
Misrai, V., Roupert, M., Cour, F., Chartier-Kastler, E., Richard, F., De novo urinary stress incontinence after laparoscopic sacral colpopexy, <i>BJU International</i> , 101, 594-597, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mohammed, N., Raschid Hoda, M., Fornara, P., Prolapse surgery in octogenarians: Are we pushing the limits too far?, <i>World Journal of Urology</i> , 31, 623-628, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Moiety, F. M. S., Hegab, H. M., Ghanem, I. A. L., Zedan, W. M., Salem, H. A. F., Abdominal Sacrohysteropexy for uterovaginal prolapse: A prospective study on 33 cases, <i>Archives of Gynecology and Obstetrics</i> , 281, 631-636, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Molsted-Pedersen, L., Rudnicki, M., Lose, G., Transvaginal repair of enterocele and vaginal vault prolapse using autologous fascia lata graft, <i>Acta Obstetricia et Gynecologica Scandinavica</i> , 85, 874-878, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Monk, B. J., Ramp, J. L., Montz, F. J., Lebherz, T. B., Sacrospinous ligament fixation for vaginal vault prolapse: Complications and results, <i>Journal of Gynecologic Surgery</i> , 7, 87-92, 1991	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Montella, J. M., Morrill, M. Y., Effectiveness of the McCall culdeplasty in maintaining support after vaginal hysterectomy, <i>International Urogynecology Journal</i> , 16, 226-229, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Moore, R.D., Mitchell, G.K., Miklos, J.R., Single-incision vaginal approach to treat cystocele and vault prolapse with an anterior wall mesh anchored apically to the sacrospinous ligaments, <i>International Urogynecology Journal</i> , 23, 85-91, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Moreno Sierra, J., Ortiz Oshiro, E., Fernandez Perez, C., Galante Romo, I., Corral Rosillo, J., Prieto Nogal, S., Castillon Vela, I. T., Silmi Moyano, A., Alvarez Fernandez-Represa, J., Long-term outcomes after robotic sacrocolpopexy in pelvic organ prolapse: Prospective analysis, <i>Urologia Internationalis</i> , 86, 414-418, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Moretti, M., Cichero, A., Malcangi, D., Pittaluga, P., Varaldo, M., Tension-free prothetic surgery for stress incontinence and cystocele: Preliminary results, <i>Acta Urologica Italica</i> , 12, 297-300, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Mothes, A. R., Lehmann, T., Kwetkat, A., Radosa, M. P., Runnebaum, I. B., Gynaecological Prolapse Surgery in Very Old Female Patients: A Case-Control Study on Co-Morbidity and Surgical Complications, <i>Geburtshilfe und Frauenheilkunde</i> , 76, 869-874, 2016	Case control study design
Mourik, S. L., Martens, J. E., Aktas, M., Uterine preservation in pelvic organ prolapse using robot assisted laparoscopic sacrohysteropexy: Quality of life and technique, <i>European Journal of Obstetrics Gynecology and Reproductive Biology</i> , 165, 122-127, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Mouritsen, L., Kronschnabl, M., Lose, G., Long-term results of vaginal repairs with and without xenograft reinforcement, International Urogynecology Journal, 21, 467-73, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Muir, T. W., Vaginal surgery for prolapse, Journal of Pelvic Medicine and Surgery, 12, 289-305, 2006	Narrative literature review
Mustafa, S., Amit, A., Filmar, S., Deutsch, M., Netzer, I., Itskovitz-Eldor, J., Lowenstein, L., Implementation of laparoscopic sacrocolpopexy: Establishment of a learning curve and short-term outcomes, Archives of Gynecology and Obstetrics, 286, 983-988, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Nair, R., Nnochiri, A., Barnick, C., Roberts, C., Transvaginal mesh (ProliftTM) repair: 2-year anatomic outcomes, European Journal of Obstetrics Gynecology and Reproductive Biology, 158, 358-360, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Natale, F., Costantini, E., La Penna, C., Illiano, E., Balsamo, R., Carbone, A., Cervigni, M., Trocar-guided trans-vaginal mesh surgery for pelvic organ prolapse: effects on urinary continence and anatomical and functional outcomes. A prospective observational study, European Journal of Obstetrics Gynecology and Reproductive Biology, 210, 29-34, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Neimark, M., Davila, G.W., Kopka, S.L., Le Fort Colpocleisis: A Feasible Treatment Option for Pelvic Organ Prolapse in the Elderly Woman, Journal of Pelvic Medicine and Surgery, 9, 83-89, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ng, C. C. M., Chong, C. Y. L., The effectiveness of transvaginal anterior colporrhaphy reinforced with polypropylene mesh in the treatment of severe cystoceles, Annals of the Academy of Medicine Singapore, 35, 875-881, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ng, S. C., Chen, G. D., Obliterative LeFort colpocleisis for pelvic organ prolapse in elderly women aged 70 years and over, Taiwanese Journal of Obstetrics and Gynecology, 55, 68-71, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Nicita, G., Transvaginal pelvic floor reconstruction with a polypropylene mesh in the treatment of incontinent genito-urinary prolapse, Acta Urologica Italica, 11, 275-279, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Nicita, G., A new operation for genitourinary prolapse, Journal of Urology, 160, 741-745, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Nicita, G., Marzi, V. L., Filocamo, M. T., Dattolo, E., Marzocco, M., Paoletti, M. C., Villari, D., Uterus-sparing vaginal surgery of genitourinary prolapse employing biocompatible material, Urologia Internationalis, 75, 314-318, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Nieminen, K., Heinonen, P. K., Sacrospinous ligament fixation for massive genital prolapse in women aged over 80 years, British Journal of Obstetrics and Gynaecology, 108, 817-821, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Nieminens, K., Huhtala, H., Heinonen, P. K., Anatomic and functional assessment and risk factors of recurrent prolapse after vaginal sacrospinous fixation, <i>Acta Obstetricia et Gynecologica Scandinavica</i> , 82, 471-478, 2003	Retrospective study design
North, C. E., Ali-Ross, N. S., Smith, A. R. B., Reid, F. M., A prospective study of laparoscopic sacrocolpopexy for the management of pelvic organ prolapse, <i>BJOG: An International Journal of Obstetrics and Gynaecology</i> , 116, 1251-1257, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Nurun, N., Kundu, M. R., Akterun, N., Abdominal sacral colpopexy in treatment of vaginal vault prolapse: By less invasive method, <i>Bangladesh Journal of Obstetrics and Gynecology</i> , 25, 3-8, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Nyssonens, V., Talvensaari-Mattila, A., Santala, M., Posterior intravaginal slingplasty versus unilateral sacrospinous ligament fixation in treatment of vaginal vault prolapse, <i>ISRN Obstetrics and Gynecology</i> , 2013 (no pagination), 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Oliver, J. L., Chaudhry, Z. Q., Medendorp, A. R., Wood, L. N., Baxter, Z. C., Kim, J. H., Raz, S., Complete Excision of Sacrocolpopexy Mesh with Autologous Fascia Sacrocolpopexy, <i>Urology</i> , 04, 04, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Oliver, R., Odutola, O., Coker, A., Functional outcomes of posterior intravaginal slingplasty: Report on its impact on urinary, bowel and psychosexual function, <i>Gynecological Surgery</i> , 5, 275-280, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Onol, F. F., Kaya, E., Kose, O., Onol, S. Y., A novel technique for the management of advanced uterine/vault prolapse: Extraperitoneal sacrocolpopexy, <i>International Urogynecology Journal</i> , 22, 855-861, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Oom, D. M. J., Gosselink, M. P., Van Wijk, J. J., Van Dijl, V. R. M., Schouten, W. R., Rectocele repair by anterolateral rectopexy: Long-term functional outcome, <i>Colorectal Disease</i> , 10, 925-930, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Oom, D. M. J., van Dijl, V. R. M., Gosselink, M. P., van Wijk, J. J., Schouten, W. R., Enterocoele repair by abdominal obliteration of the pelvic inlet: Long-term outcome on obstructed defaecation and symptoms of pelvic discomfort, <i>Colorectal Disease</i> , 9, 845-850, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Oreskovic, S., Kalafatic, D., Lovric, H., Zupic, T., Gojetic, A., Banovic, M., Cystocele repair by synthetic mesh secured through the obturator foramen (Perigee System), <i>Gynaecologia et Perinatologia</i> , 17, 29-32, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Oster, S., Astrup, A., A new vaginal operation for recurrent and large rectocele using dermis transplant, <i>Acta Obstetricia et Gynecologica Scandinavica</i> , 60, 493-495, 1981	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Ostrzenski, A., Laparoscopic colposuspension for total vaginal prolapse, International Journal of Gynaecology & ObstetricsInt J Gynaecol Obstet, 55, 147-52, 1996	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Oversand, S. H., Staff, A. C., Sandvik, L., Vollohaug, I., Svenningsen, R., Levator ani defects and the severity of symptoms in women with anterior compartment pelvic organ prolapse, International Urogynecology Journal, 29, 63-69, 2018	Study design did not meet the protocol inclusion criteria - followup not long enough
Ozcan, U., Gungor, T., Ekin, M., Eken, S., Sacrospinous fixation for the prolapsed vaginal vault, Gynecologic and Obstetric Investigation, 47, 65-68, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Pacquee,S., Palit,G., Jacquemyn,Y., Complications and patient satisfaction after transobturator anterior and/or posterior tension-free vaginal polypropylene mesh for pelvic organ prolapse, Acta Obstetricia et Gynecologica Scandinavica, 87, 972-974, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Pan, K., Cao, L., Ryan, N. A., Wang, Y., Xu, H., Laparoscopic sacral hysteropexy versus laparoscopic sacrocolpopexy with hysterectomy for pelvic organ prolapse, International Urogynecology Journal, 27, 93-101, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Pandeva, I., Mistry, M., Fayyad, A., Efficacy and pregnancy outcomes of laparoscopic single sheet mesh sacrohysteropexy, Neurourology and Urodynamics, 36, 787-793, 2017	Retrospective study design
Panel, P., Soffray, F., Roussillon, E., Devins, C., Brouziyne, M., Abramowicz, S., Glue mesh fixation: Feasibility, tolerance and complication assessment. Results 24 months after laparoscopic sacrocolpopexy, Journal of Gynecology Obstetrics and Human Reproduction, 46, 333-338, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Papadopoulos, A. E., Tsalikis, T., Tzeveleakis, F., Grimbizis, G., Papameletiou, V., Tarlatzis, V., Abdominal colposuspension with the use of tension-free tape at the lateral abdominal wall: a novel technique, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 286, 977-81, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Paparella, P., Zullo, M. A., Giorgino, R., Oliva, C., Mancuso, S., Sacral colpopexy: A nine-year experience (1986-1995), Italian Journal of Gynaecology and Obstetrics, 7, 99-104, 1995	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Papcun, P., Krizko, M., Jr., Spodniakova, B., Redecha, M., Gabor, M., Ferianec, V., Holly, I., Long term follow-up of the patients with pelvic organ prolapse after the mesh implantation using strict indication criteria, Bratislavské Lekarske ListyBratisl Lek Listy, 115, 287-91, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Papp, Z., Transabdominal partial vaginal resection and infundibulopelvic colpopexy for posthysterectomy vaginal vault prolapse, Journal of Reproductive Medicine for the Obstetrician and Gynecologist, 52, 1097-1102, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Patel, R. J., Heusinkveld, J. M., Hatch, K. D., A retrospective study on demographic, clinical, and outcome data of women undergoing sacrospinous ligament fixation, Journal of Investigative Medicine, 64 (1), 261-262, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

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Study	Reason for Exclusion
Pauls, R. N., Silva, W. A., Rooney, C. M., Siddighi, S., Kleeman, S. D., Dryfhout, V., Karram, M. M., Sexual function after vaginal surgery for pelvic organ prolapse and urinary incontinence, American Journal of Obstetrics and Gynecology, 197, 622.e1-622.e7, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Pellegrino, A., Damiani, G. R., Villa, M., Sportelli, C., Pezzotta, M. G., Robotic sacrocolpopexy for posthysterectomy vaginal vault prolapse: A case series of 31 patients by a single surgeon with a long term follow-up, Minerva Ginecologica, 69, 13-17, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Peng,P., Zhu,L., Lang,J.H., Wang,W.Y., Shi,H.H., Unilateral sacrospinous ligament fixation for treatment of genital prolapse, Chinese Medical Journal, 123, 1995-1998, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Petros,P.E., Richardson,P.A., The TFS mini-sling for uterine/vault prolapse repair: a three-year follow-up review, Australian and New Zealand Journal of Obstetrics and Gynaecology, 49, 439-440, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Petrizzelli, P., Chiado Fiorio Tin, M., Cosma, S., Parisi, S., Garofalo, A., Todros, T., Combined sacrospinous hysteropexy and cystopexy using a single anterior incision, International Journal of Gynecology and Obstetrics, 135, 101-106, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Pilsgaard, K., Mouritsen, L., Follow-up after repair of vaginal vault prolapse with abdominal colposacropexy, Acta Obstetricia et Gynecologica Scandinavica, 78, 66-70, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Pizarro-Berdichevsky, J., Galleguillos, G., Cuevas, R., Blumel, B., Pattillo, A., Gonzalez, S., Majerson, A., Padilla, O., Cuello, M., Ortiz, J. A., Goldman, H. B., Labhardt's colpopерineocleisis: Subjective results of an alternative treatment for genital prolapse in patients who are not sexually active - 2-year follow-up, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 417-424, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Planells Roig, M., Sanahuja Santafe, A., Garcia Miranda de Larra, J. L., Garcia Espinosa, R., Serralta Serra, A., Prospective analysis of marlex mesh repair for symptomatic rectocele with obstructive defecation, Revista Espanola de Enfermedades Digestivas, 94, 73-77, 2002	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Pohl, J. F., Frattarelli, J. L., Elkins, T. E., Bilateral transvaginal sacrospinous colpopexy: Preliminary experience, American Journal of Obstetrics and Gynecology, 177, 1356-1362, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Popp, L., Augustin, A., Pelvic floor-lifting: an interdisciplinary repair of combined rectal and vaginal prolapse-5 years experience, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 288, 83-90, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Powell, J. L., Joseph, D. B., Abdominal sacral colpopexy for massive genital prolapse, Primary Care Update for Ob/GynsPrim, 5, 201, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

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Study	Reason for Exclusion
Powell, J. L., Joseph, D. B., Abdominal sacral colpopexy for massive genital prolapse and posthysterectomy vaginal vault prolapse, Journal of Gynecologic Techniques, 5, 45-50, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Powers, K., Lazarou, G., Connell, K., Mikhail, M., Paravaginal repairs done by laparoscopy versus laparotomy, Journal of Pelvic Medicine and Surgery, 11, 317-320, 2005	Retrospective study design
Pratt, J. H., Surgical repair of rectocele and perineal lacerations, Clinical Obstetrics and Gynecology, 15, 1160-1172, 1972	Narrative literature review
Prendergast, E., Silver, H., Johnson, L. L., Simon, M., Feinglass, J., Kielb, S., Hairston, J., Lewicky-Gaupp, C., Anatomic outcomes of robotic assisted supracervical hysterectomy and concurrent sacrocolpopexy at a tertiary care institution at initial adaptation of the procedure, Female Pelvic Medicine and Reconstructive Surgery, 22, 29-32, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Price, N., Slack, A., Jackson, S. R., Laparoscopic hysteropexy: The initial results of a uterine suspension procedure for uterovaginal prolapse, BJOG: An International Journal of Obstetrics and Gynaecology, 117, 62-68, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Prodigalidad, L. T., Peled, Y., Stanton, S. L., Krissi, H., Long-term results of prolapse recurrence and functional outcome after vaginal hysterectomy, International Journal of Gynecology and Obstetrics, 120, 57-60, 2013	Population do not meet criteria - not specifically POP
Puigdollers, A., Fernandez-fraga, X., Azpiroz, F., Persistent symptoms of functional outlet obstruction after rectocele repair, Colorectal Disease, 9, 262-265, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Purandare, V. N., Operative treatment of genital prolapse (in young women), J, OBSTET. GYNAEC. India 16, 185-191, 1966	Study design did not meet the protocol inclusion criteria - followup not long enough
Rae, D., Hawthorn, R., Sacrocolpopexy for vaginal vault prolapse: A combined vaginal and laparoscopic approach, Gynaecological Endoscopy, 11, 75-79, 2002	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Rajshekhar, S., Mukhopadhyay, S., Morris, E., Early safety and efficacy outcomes of a novel technique of sacrocolpopexy for the treatment of apical prolapse, International Journal of Gynecology and Obstetrics, 135, 182-186, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Rane, A., Kannan, K., Barry, C., Balakrishnan, S., Lim, Y., Corstiaans, A., Prospective study of the Perigee system for the management of cystoceles - Medium-term follow up, Australian and New Zealand Journal of Obstetrics and Gynaecology, 48, 427-432, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Rapp, D. E., King, A. B., Rowe, B., Wolters, J. P., Comprehensive evaluation of anterior elevate system for the treatment of anterior and apical pelvic floor descent: 2-year followup, Journal of Urology, 191, 389-94, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Raz, S., Little, N. A., Juma, S., Sussman, E. M., Repair of severe anterior vaginal wall prolapse (grade IV cystourethrocele), Obstetrical and Gynecological Survey, 47, 399-400, 1992	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Raz, S., Little, N. A., Juma, S., Sussman, E. M., Repair of severe anterior vaginal wall prolapse (grade IV cystourethrocele), Journal of Urology, 146, 988-992, 1991	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Raz, S., Nitti, V. W., Bregg, K. J., Transvaginal repair of enterocele, Journal of Urology, 149, 724-730, 1993	Unable to obtain full text
Rechberger, T., Futyma, K., Bartuzzi, A., Total Prolift System surgery for treatment posthysterectomy vaginal vault prolapse - Do we treat both anatomy and function?, Ginekologia Polska, 79, 835-839, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Reisenauer, C., Oberlechner, E., Schoenfisch, B., Wallwiener, D., Huebner, M., Modified LeFort colpocleisis: Clinical outcome and patient satisfaction, Archives of Gynecology and Obstetrics, 288, 1349-1353, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Richardson, A. C., Williams, G. A., Treatment of prolapse of the vagina following hysterectomy, American Journal of Obstetrics and Gynecology, 105, 90-93, 1969	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Richter, K., Albrich, W., Long-term results following fixation of the vagina on the sacrospinal ligament by the vaginal route (vaginaefixatio sacrospinalis vaginalis), American Journal of Obstetrics and Gynecology, 141, 811-816, 1981	Intervention not relevant to the protocol - vaginaefixatio sacrospinalis vaginalis
Ridley, J. H., Evaluation of the colpocleisis operation: a report of fifty-eight cases, American Journal of Obstetrics and Gynecology, 113, 1114-1119, 1972	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ridley, J. H., A composite vaginal vault suspension using fascia lata, American Journal of Obstetrics and Gynecology, 126, 590-596, 1976	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Robles, J. E., Rioja, J., Saiz, A., Brugarolas, X., Rosell, D., Zudaire, J. J., Berian, J. M., Anterior compartment prolapse repair with a hybrid biosynthetic mesh implant technique, International Urogynecology Journal, 18, 1191-1196, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Roman, H., Michot, F., Long-term outcomes of transanal rectocele repair, Diseases of the Colon and Rectum, 48, 510-517, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Roovers, J. P. W. R., van der Vaart, C. H., van der Bom, J. G., van Leeuwen, J. H. S., Scholten, P. C., Heintz, A. P. M., Maher, C. F., Vaginal prolapse surgery was less likely than abdominal surgery to result in urinary problems and repeat surgery, Evidence-based Obstetrics and Gynecology, 7, 39-41, 2005	Same study already included in the RCT data. This is a brief report and commentary of the main paper

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Study	Reason for Exclusion
Rosen, D. M. B., Shukla, A., Cario, G. M., Carlton, M. A., Chou, D., Is Hysterectomy Necessary for Laparoscopic Pelvic Floor Repair? A Prospective Study, Journal of Minimally Invasive Gynecology, 15, 729-734, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Rosenblatt, P. L., Apostolis, C. A., Hacker, M. R., DiSciullo, A., Laparoscopic Supracervical Hysterectomy With Transcervical Morcellation and Sacrocervicopexy: Initial Experience With a Novel Surgical Approach to Uterovaginal Prolapse, Journal of Minimally Invasive Gynecology, 19, 749-755, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Rosenblatt, P. L., Chelmow, D., Ferzandi, T. R., Laparoscopic Sacrocervicopexy for the Treatment of Uterine Prolapse: A Retrospective Case Series Report, Journal of Minimally Invasive Gynecology, 15, 268-272, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ross, J. W., The use of a xenogenic barrier to prevent mesh erosion with laparoscopic sacrocolpopexy, Journal of Minimally Invasive Gynecology, 14, 470-474, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Ross, J. W., Preston, M., Laparoscopic sacrocolpopexy for severe vaginal vault prolapse: Five-year outcome, Journal of Minimally Invasive Gynecology, 12, 221-226, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Rozet,F., Mandron,E., Arroyo,C., Andrews,H., Cathelineau,X., Mombet,A., Cathala,N., Vallancien,G., Laparoscopic sacral colpopexy approach for genito-urinary prolapse: experience with 363 cases, European Urology, 47, 230-236, 2005	Population do not meet criteria - not specifically POP
Rutman, M. P., Deng, D. Y., Rodriguez, L. V., Raz, S., Repair of vaginal vault prolapse and pelvic floor relaxation using polypropylene mesh, Neurourology and Urodynamics, 24, 654-658, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Rzepka, J., Brocker, K., Alt, C., Corteville, C., Sohn, C., Lenz, F., Pelvic organ prolapse: Does the postoperative course of mesh-repair surgery differ in elderly women when compared with younger patients, Journal of Obstetrics and Gynaecology, 30, 852-856, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sagar, P. M., Thekkinkattil, D. K., Heath, R. M., Woodfield, J., Gonsalves, S., Landon, C. R., Feasibility and functional outcome of laparoscopic sacrocolporectopexy for combined vaginal and rectal prolapse, Diseases of the Colon and Rectum, 51, 1414-1420, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sah, D. K., Doshi, N. R., Das, C. R., Vaginal hysterectomy for pelvic organ prolapse in Nepal, Kathmandu University Medical Journal, 8, 281-4, 2010	Study design did not meet the protocol inclusion criteria - followup not long enough
Salamon, C. G., Culligan, P. J., Subjective and objective outcomes 1 year after robotic-assisted laparoscopic sacrocolpopexy, Journal of Robotic SurgeryJ, 7, 35-8, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Salem,H.T., Tawfik,R.M., El Saman,A.M., Nasr,A., Anterior abdominal wall cervicopexy for treatment of stage III and stage IV uterine prolapse, International Journal of Gynaecology and Obstetrics, 110, 130-132, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Salomon, L. J., Detchev, R., Barranger, E., Cortez, A., Callard, P., Darai, E., Treatment of Anterior Vaginal Wall Prolapse with Porcine Skin Collagen Implant by the Transobturator Route: Preliminary Results, European Urology, 45, 219-225, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Salvatore, C. A., Treatment of uterine prolapse by vaginal hysterectomy, International Surgery, 52, 395-399, 1969	Unable to obtain full text
Sardeli, C., Axelsen, S. M., Kjaer, D., Bek, K. M., Outcome of site-specific fascia repair for rectocele, Acta Obstetricia et Gynecologica Scandinavica, 86, 973-977, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sauer, H. A., Klutke, C. G., Transvaginal sacrospinous ligament fixation for treatment of vaginal prolapse, Journal of Urology, 154, 1008-1012, 1995	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Saunders, W. G., Kupczak, B., Zimmermann, E. A., Vaginal prolapse: colpopexy by the lateral vaginal approach, Rocky Mountain medical journal, 72, 289-293, 1975	Unable to obtain full text
Scarpero, H. M., Cespedes, R. D., Winters, J. C., Transabdominal approach to repair of vaginal vault prolapse, Techniques in Urology, 7, 139-145, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Schaaf, J. M., Dongol, A., van der Leeuw-Harmsen, L., Follow-up of prolapse surgery in rural Nepal, International Urogynecology Journal, 19, 851-855, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Schauffler, G. C., Significance and management of genital prolapse in the aged, Journal of the American Geriatrics Society, 3, 43-49, 1955	Conference paper
Schettini, M., Fortunato, P., Gallucci, M., Abdominal sacral colpopexy with prolene mesh, International Urogynecology Journal, 10, 295-9, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Schiavi, M. C., D'Oria, O., Faiano, P., Prata, G., Di Pinto, A., Sciuga, V., Colagiovanni, V., Giannini, A., Zullo, M. A., Monti, M., Muzii, L., Benedetti Panici, P., Vaginal Native Tissue Repair for Posterior Compartment Prolapse: Long-Term Analysis of Sexual Function and Quality of Life in 151 Patients, Female pelvic medicine & reconstructive surgery, 04, 04, 2017	Study design did not meet the protocol inclusion criteria - followup not long enough
Schlesinger, R. E., Smith, M. R., Vaginal sacrospinous ligament fixation with the autosuture endostitch device, American Journal of Obstetrics and Gynecology, 176, 1358-1362, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Schmid, C., O'Rourke, P., Maher, C., Laparoscopic sacrocolpopexy for recurrent pelvic organ prolapse after failed transvaginal polypropylene mesh surgery, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, 763-767, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

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Study	Reason for Exclusion
Schmidlin-Enderli, K., Schuessler, B., A new rectovaginal fascial plication technique for treatment of rectocele with obstructed defecation: A proof of concept study, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, 613-619, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Schottini, M., Fortunato, P., Gallucci, M., Abdominal sacral colpopexy with Prolene mesh, International Urogynecology Journal, 10, 295-299, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Schwandner, T., Roblick, M. H., Hecker, A., Brom, A., Kierer, W., Padberg, W., Hirschburger, M., Transvaginal rectal repair: A new treatment option for symptomatic rectocele?, International Journal of Colorectal Disease, 24, 1429-1434, 2009	Study design did not meet the protocol inclusion criteria - retrospective
Schwartz, M., Abbott, K. R., Glazerman, L., Sobolewski, C., Jarnagin, B., Ailawadi, R., Lucente, V., Positive symptom improvement with laparoscopic uterosacral ligament repair for uterine or vaginal vault prolapse: interim results from an active multicenter trial, Journal of Minimally Invasive Gynecology, 14, 570-6, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Segala, C. J., New technique for the repair of vaginal vault prolapse following hysterectomy, International Surgery, 51, 36-47, 1969	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sekiguchi, Y., Kinjo, M., Maeda, Y., Kubota, Y., Reinforcement of suspensory ligaments under local anesthesia cures pelvic organ prolapse: 12-Month results, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 783-789, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sekine, H., Kojima, S. I., Igarashi, K., Toyoshima, T., Hayashi, T., Shimoji, Y., Burch bladder neck suspension for cystocele repair: The necessity of combined vaginal procedures for severe cases, International Journal of Urology, 6, 1-6, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Seman, E. I., Cook, J. R., O'Shea, R. T., Two-year experience with laparoscopic pelvic floor repair, Journal of the American Association of Gynecologic Laparoscopists, 10, 38-45, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sentilhes, L., Sergent, F., Resch, B., Verspyck, E., Descamps, P., Marpeau, L., Midterm Follow-up of High-Grade Genital Prolapse Repair by the Trans-obturator and Infracoccygeal Hammock Procedure after Hysterectomy, European Urology, 51, 1065-1072, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Sentilhes, L., Sergent, F., Resch, B., Verspyck, E., Descamps, P., Marpeau, L., Infracoccygeal sacrocepsy reinforced with posterior mesh interposition for apical and posterior compartment prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 137, 108-113, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Senturk, M. B., Guraslan, H., Cakmak, Y., Ekin, M., Bilateral sacrospinous fixation without hysterectomy: 18-month follow-up, Journal of the Turkish German Gynecology Association, 16, 102-106, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Seracchioli, R., Hourcade, J. A., Vianello, F., Govoni, F., Pollastri, P., Venturoli, S., Laparoscopic treatment of pelvic floor defects in women of reproductive age, Journal of the American Association of Gynecologic Laparoscopists, 11, 332-335, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Serati, M., Braga, A., Bogani, G., Leone Roberti Maggiore, U., Sorice, P., Ghezzi, F., Salvatore, S., Iliococcygeus fixation for the treatment of apical vaginal prolapse: efficacy and safety at 5 years of follow-up, International Urogynecology Journal and Pelvic Floor Dysfunction, 26, 1007-1012, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Serati, M., Braga, A., Cantaluppi, S., Caccia, G., Ghezzi, F., Sorice, P., Vaginal cystocele repair and hysteropexy in women with anterior and central compartment prolapse: efficacy and safety after 30 months of follow-up, International Urogynecology Journal, 29, 831-836, 2018	No relevant outcome data - no outcome data provided
Sergent, F., Zanati, J., Bisson, V., Desilles, N., Resch, B., Marpeau, L., Perioperative course and medium-term outcome of the transobturator and infracoccygeal hammock for posthysterectomy vaginal vault prolapse, International Journal of Gynaecology and Obstetrics, 109, 131-135, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Seror, J., Yates, D. R., Seringe, E., Vaessen, C., Bitker, M. O., Chartier-Kastler, E., Roupert, M., Prospective comparison of short-term functional outcomes obtained after pure laparoscopic and robot-assisted laparoscopic sacrocolpopexy, World Journal of Urology, 30, 393-398, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shah, D. K., Paul, E. M., Rastinehad, A. R., Eisenberg, E. R., Badlani, G. H., Short-term outcome analysis of total pelvic reconstruction with mesh: The vaginal approach, Journal of Urology, 171, 261-263, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shahraki, A. D., Feizi, A., Introducing an easy new surgical method for repairing vaginal vault prolapse, Journal of Research in Medical Sciences, 17, S186-S189, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shaker, D. A., De Boer, F., Performance of the tension free vaginal tape procedure when combined with sacrospinous fixation for apical prolapse, Journal of Obstetrics and Gynaecology, 26, 663-666, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shalev, E., Bustan, M., Peleg, D., Laparoscopic ventrofixation: An alternate treatment approach for uterine prolapse, Journal of Gynecologic Surgery, 12, 105-107, 1996	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shaw, W. F., Final thoughts on the Manchester operation of colporrhaphy for genital prolapse, American Journal of Obstetrics and Gynecology, 68, 450-455, 1954	Narrative literature review

Study	Reason for Exclusion
Sheth, S. S., Vault prolapse repair by suspension to Cooper's ligament, Journal of Obstetrics & GynaecologyJ Obstet Gynaecol, 17, 206-7, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shimko, M. S., Umbreit, E. C., Chow, G. K., Elliott, D. S., Long-term outcomes of robotic-assisted laparoscopic sacrocolpopexy with a minimum of three years follow-up, Journal of Robotic SurgeryJ, 5, 175-80, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shkarupa, D., Kubin, N., Shapovalova, E., Staroseltseva, O., Zaytseva, A., The novel hybrid technique of pelvic organ prolapse treatment based on apical sling: 2 years' follow-up, Journal of Urology, 199 (4 Supplement 1), e1073, 2018	Conference abstract
Shkarupa, D., Kubin, N., Shapovalova, E., Zaytseva, A., Pisarev, A., Staroseltseva, O., The novel technique of post-hysterectomy vaginal vault prolapse repair: Apical sling and "neocervix" formation, European Journal of Obstetrics Gynecology and Reproductive Biology, 214, 11-15, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sho, T., Yoshimura, K., Hachisuga, T., Retrospective study of tension-free vaginal mesh operation outcomes for prognosis improvement, Journal of Obstetrics and Gynaecology Research, 40, 1759-1763, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Shull, B. L., Benn, S. J., Kuehl, T. J., Surgical management of prolapse of the anterior vaginal segment: An analysis of support defects, operative morbidity, and anatomic outcome, American Journal of Obstetrics and Gynecology, 171, 1429-1439, 1994	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Siddiqui, N. Y., Fulton, R. G., Kuchibhatla, M., Wu, J. M., Sexual function after vaginal versus nonvaginal prolapse surgery, Female pelvic medicine & reconstructive surgery, 18, 239-42, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Siegmund, K. C., Reisenauer, C., Speck, S., Barth, S., Kraemer, B., Claussen, C. D., Dynamic magnetic resonance imaging for assessment of minimally invasive pelvic floor reconstruction with polypropylene implant, European Journal of Radiology, 80, 182-187, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Simoncini, T., Russo, E., Mannella, P., Giannini, A., Robotic-assisted apical lateral suspension for advanced pelvic organ prolapse: surgical technique and perioperative outcomes, Surgical Endoscopy and Other Interventional Techniques, 30, 5647-5655, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sivaslioglu, A. A., Gelisen, O., Dolen, I., Dede, H., Dilbaz, S., Haberal, A., Posterior sling (infracoccygeal sacropexy): An alternative procedure for vaginal vault prolapse, Australian and New Zealand Journal of Obstetrics and Gynaecology, 45, 159-160, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Skala,C., Renezeder,K., Albrich,S., Puhl,A., Laterza,R.M., Naumann,G., Koelbl,H., The IUGA/ICS classification of complications of prosthesis and graft insertion: a comparative experience in incontinence and prolapse surgery, International Urogynecology Journal, 22, 1429-1435, 2011	Retrospective study design
Slee, J., Wildschut, H. I. J., Pelvic floor mesh for the transvaginal treatment of a prolapse, Geneesmiddelenbulletin, 51, 2017	Publication not in English

Study	Reason for Exclusion
Sloots, C. E. J., Muelen, A. J., Felt-Bersma, R. J. F., Rectocele repair improves evacuation and prolapse complaints independent of anorectal function and colonic transit time, International Journal of Colorectal Disease, 18, 342-348, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sola,V., Pardo,J., Ricci,P., Guiloff,E., Tension free monofilament macropore polypropylene mesh (Gynemesh PS) in female genital prolapse repair, International Braz J Urol, 32, 410-414, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Song, H. S., Choo, G. Y., Jin, L. H., Yoon, S. M., Lee, T., Transvaginal cystocele repair by purse-string technique reinforced with three simple sutures: Surgical technique and results, International Neurourology Journal, 16, 144-148, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Song, Y., Wang, X. J., Chen, Y. S., Hua, K. Q., Management of Urinary Incontinence before and after Total Pelvic Reconstruction for Advanced Pelvic Organ Prolapse with and without Incontinence, Chinese Medical JournalChin Med J, 131, 553-558, 2018	Retrospective study design
Spennacchio, M., Buonaguidi, A., Bertola, E., Guareschi, B. M., Vignali, M., Abdominal sacral colpopexy for vaginal vault prolapse: A retrospective study, Journal of Gynecologic Surgery, 13, 77-81, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Spennacchio, M., Buonaguidi, A., Bertola, E., Penotti, M., Vignali, M., Vaginal surgery for genital prolapse associated with stress urinary incontinence: A retrospective study, Journal of Gynecologic Surgery, 14, 175-179, 1998	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Stadnik, H., Koscinski, T. M., Prosthetic materials for treating posterior vaginal wall prolapse and rectocele - own experience, Ginekologia Polska, 87, 729-732, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Stanton, S. L., Hilton, P., Norton, C., Cardozo, L., Clinical and urodynamic effects of anterior colporrhaphy and vaginal hysterectomy for prolapse with and without incontinence, British Journal of Obstetrics and Gynaecology, 89, 459-463, 1982	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Stojkovic, S. G., Balfour, L., Burke, D., Finan, P. J., Sagar, P. M., Does the need to self-digitate or the presence of a large or nonemptying rectocoele on proctography influence the outcome of transanal rectocoele repair?, Colorectal Disease, 5, 169-72, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Stoutjesdijk, J. A., Vierhout, M. E., Spruijt, J. W., Massolt, E. T., Does vaginal reconstructive surgery with or without vaginal hysterectomy or trachelectomy improve sexual well being? A prospective follow-up study, International Urogynecology Journal, 17, 131-5, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Stubbs, J. T., 3rd, Short-term results of robotic sacrocolpopexy using the Quill SRS bi-directional polydioxanone (PDO) suture, Journal of Robotic SurgeryJ, 5, 259-65, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Su, K. C. H., Terry, C. L., Hale, D. S., Abdominovaginal sacral colpoperineopexy: A quality of life assessment, Journal of Pelvic Medicine and Surgery, 13, 181-190, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Su,T.H., Lau,H.H., Huang,W.C., Chen,S.S., Lin,T.Y., Hsieh,C.H., Yeh,C.Y., Short term impact on female sexual function of pelvic floor reconstruction with the Prolift procedure, Journal of Sexual Medicine, 6, 3201-3207, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Su,T.H., Liu,P.E., Lau,H.H., Huang,W.C., Lin,T.Y., Hsieh,C.H., Impact of Prolift procedure on bladder function and symptoms in women with pelvic organ prolapse, International Urogynecology Journal, 22, 585-590, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sun, Y., Luo, D., Yang, L., Wei, X., Tang, C., Chen, M., Shen, H., Wei, Q., The Efficiency and Safety of Tension-Free Vaginal Tape (TVT) Abbreviated Procedure Versus TVT Exact in the Normal Weight and Overweight Patients Affected by Stress Urinary Incontinence, Urology., 2017	Population do not meet criteria - not specifically POP
Sun, Z., Zhu, L., Hu, H., Lang, J., Shi, H., Gong, X., Medium-term outcomes after combined trachelectomy and uterosacral ligament suspension among young women with severe uterine prolapse, International Journal of Gynecology and Obstetrics, 132, 224-228, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sundaram, C. P., Venkatesh, R., Landman, J., Klutke, C. G., Laparoscopic sacrocolpopexy for the correction of vaginal vault prolapse, Journal of Endourology, 18, 620-623, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Sung, H. H., Ko, K. J., Suh, Y. S., Ryu, G. H., Lee, K. S., Surgical outcomes and safety of robotic sacrocolpopexy in women with apical pelvic organ prolapse, International Neurourology Journal, 21, 68-74, 2017	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Surico, N., Ruspa, G., Longo, D., Salini, A., Arnulfo, A., Baj, G., Abdominal sacrocolpopexy with collagen biosynthetic mesh: Analysis of 21 cases, Journal of Gynecologic Surgery, 18, 45-48, 2002	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Syan, R., Dallas, K., Sohlberg, E., Elliot, C., Rogo-Gupta, L., Enemchukwu, E., Is prophylactic stress incontinence surgery necessary at the time of pelvic organ prolapse repair?-rates of future surgery in a large population based cohort in California, Journal of Urology, 199 (4 Supplement 1), e149, 2018	Conference abstract
Tanaka, S., Yamamoto, H., Shimano, S., Endoh, T., Hashimoto, M., A vaginal approach to the treatment of genital prolapse, Asia-Oceania journal of obstetrics and gynaecology / AOFOG, 14, 161-165, 1988	Retrospective study design
Tantanasis,T., Giannoulis,C., Daniilidis,A., Papathanasiou,K., Loufopoulos,A., Tzafettas,J., Anterior vaginal wall reconstruction: anterior colporrhaphy reinforced with tension free vaginal tape underneath bladder base, Acta Obstetricia et Gynecologica Scandinavica, 87, 464-468, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Tantanasis,T., Giannoulis,C., Daniilidis,A., Papathanasiou,K., Loufopoulos,A., Tzafettas,J., Tension free vaginal tape underneath bladder base: Does it prevent cystocele recurrence?, Hippokratia, 12, 108-112, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Tawfeek, S., Vermulapalli, R., Afifi, R., Paravaginal repair using White's technique (bilateral incision approach) - Revisited: Objective and subjective assessment, Journal of Pelvic Medicine and Surgery, 11, 307-316, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Thomas, A. Z., Giri, S. K., Cox, A. M., Creagh, T., Long-term quality-of-life outcome after mesh sacrocolpopexy for vaginal vault prolapse, BJU International, 104, 1676-1679, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Thomin, A., Touboul, C., Hequet, D., Zilberman, S., Ballester, M., Darai, E., Genital prolapse repair with Avaulta Plus <sup>®</sup> mesh: Functional results and quality of life, Progres en Urologie, 23, 270-275, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Thornton, M. J., Lam, A., King, D. W., Bowel, bladder and sexual function in women undergoing laparoscopic posterior compartment repair in the presence of apical or anterior compartment dysfunction, Australian & New Zealand Journal of Obstetrics & Gynaecology, 45, 195-200, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Thys, S. D., Coolen, A. L., Martens, I. R., Oosterbaan, H. P., Roovers, J. P. W. R., Mol, B. W., Bongers, M. Y., A comparison of long-term outcome between Manchester Fothergill and vaginal hysterectomy as treatment for uterine descent, International Urogynecology Journal, 22, 1171-1178, 2011	Retrospective study design
Timonen, S., Nuoranne, E., Meyer, B., Operative treatment of genital prolapse, Annales Chirurgiae et Gynaecologiae Fenniae Ann Chir Gynaecol Fenn, 56, 1967	Unable to obtain full text
Tjandra, J. J., Ooi, B. S., Tang, C. L., Dwyer, P., Carey, M., Transanal repair of rectocele corrects obstructed defecation if it is not associated with anismus, Diseases of the Colon and Rectum, 42, 1544-1550, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Toz, E., Ozcan, A., Apaydin, N., Uyar, I., Kocakaya, B., Okay, G., Outcomes of vaginal hysterectomy and constricting colporrhaphy with concurrent levator myorrhaphy and high perineorrhaphy in women older than 75 years of age, Clinical interventions in aging, 10, 1009-1015, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Trochez, R. D., Lane, S., Duckett, J., The use of synthetic mesh for vaginal prolapse in the UK: a review of cases submitted to the British Society of Urogynaecology database, International Urogynecology Journal, 29, 899-904, 2018	Retrospective study design
Tsai, C. P., Hung, M. J., Shen, P. S., Chen, G. D., Su, T. H., Chou, M. M., Factors that affect early recurrence after prolapse repair by a nonanchored vaginal mesh procedure, Taiwanese Journal of Obstetrics & Gynecology, 53, 337-42, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Tulikangas, P. K., Piedmonte, M. R., Weber, A. M., Functional and anatomic follow-up of enterocele repairs, Obstetrics and Gynecology, 98, 265-268, 2001	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Tyagi, V., Perera, M., Guerrero, K., Hagen, S., Pringle, S., Prospective observational study of the impact of vaginal surgery (pelvic organ prolapse with or without urinary incontinence) on female sexual function, International Urogynecology Journal, 29, 837-845, 2018	Outcomes of interest not reported - unclear what type of POP surgery was undertaken
Valaitis, S. R., Stanton, S. L., Sacrocolpopexy: A retrospective study of a clinician's experience, British Journal of Obstetrics and Gynaecology, 101, 518-522, 1994	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Valencic, M., Maricic, A., Oguic, R., Rahelic, D., Sotosek, S., Grskovic, A., Modified extensive anterior vaginal wall repair for cystocele, <i>Collegium Antropologicum</i> , 34 Suppl 2, 191-4, 2010	Retrospective study design
van Brummen, H. J., van de Pol, G., Aalders, C. I., Heintz, A. P., van der Vaart, C. H., Sacrospinous hysteropexy compared to vaginal hysterectomy as primary surgical treatment for a descensus uteri: effects on urinary symptoms, <i>International Urogynecology Journal</i> , 14, 350-5; discussion 355, 2003	Study design did not meet the protocol inclusion criteria followup not long enough
Van Dam, J. H., Ginai, A. Z., Gosselink, M. J., Huisman, W. M., Bonjer, H. J., Hop, W. C. J., Schouten, W. R., Role of defecography in predicting clinical outcome of rectocele repair, <i>Diseases of the Colon and Rectum</i> , 40, 201-207, 1997	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Van der Aa, F., De Ridder, D., Vaginal Pelvic Organ Prolapse Repair Using Mesh: Let's Welcome Science into the Mesh Debate, <i>European Urology</i> , 2018	Editorial report
Van der Hagen, S. J., Van Gemert, W. G., Soeters, P. B., De Wet, H., Baeten, C. G., Transvaginal posterior colporrhaphy combined with laparoscopic ventral mesh rectopexy for isolated Grade III rectocele: A prospective study of 27 patients, <i>Colorectal Disease</i> , 14, 1398-1402, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Van der Weiden, R. M. F., Bergkamp, A. B. M., Colposacropexy with mesh or collagen implant and titanium bone anchors placed in sacral segments 3 and 4, <i>Journal of Pelvic Medicine and Surgery</i> , 9, 9-14, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Van Der Weiden, R. M. F., Bergkamp, A. B. M., Long-term patient satisfaction after sacrocolpopexy with bone anchor fixation, <i>Journal of Pelvic Medicine and Surgery</i> , 14, 357-359, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Van Der Weiden, R. M. F., Rociu, E., Mannaerts, G. H. H., Van Hooff, M. H. A., Vierhout, M. E., Withagen, M. I. J., Dynamic magnetic resonance imaging before and 6 months after laparoscopic sacrocolpopexy, <i>International Urogynecology Journal</i> , 25, 507-515, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
van Huisseling, J. C., A modification of Labhardt's high perineoplasty for treatment of pelvic organ prolapse in the very old, <i>International Urogynecology Journal</i> , 20, 185-91, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Van Iersel, J. J., De Witte, C. J., Verheijen, P. M., Broeders, I. A. M. J., Linters, E., Consten, E. C. J., Schraffordt Koops, S. E., Robot-Assisted Sacrocolporectopexy for Multicompartment Prolapse of the Pelvic Floor: A Prospective Cohort Study Evaluating Functional and Sexual Outcome, <i>Diseases of the Colon and Rectum</i> , 59, 968-974, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Van Laarhoven, C. J. H. M., Kamm, M. A., Bartram, C. I., Halligan, S., Hawley, P. R., Phillips, R. K. S., Relationship between anatomic and symptomatic long-term results after rectocele repair for impaired defecation, <i>Diseases of the Colon and Rectum</i> , 42, 204-211, 1999	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

## DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

Study	Reason for Exclusion
Vancaillie, T. G., MycroMesh is not a suitable soft tissue prosthesis for repair of the defective vaginal wall, Journal of the American Association of Gynecologic Laparoscopists, 10, 424-5, 2003	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Vancaillie, T. G., Butler, D. J., Laparoscopic enterocele repair - Description of a new technique, Gynaecological Endoscopy, 2, 211-216, 1993	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Vashisht, A., Kearney, R., Cutner, A., The new laparoscopic uterine sling suspension procedure: First year follow-up data, Gynecological Surgery, 8, 321-323, 2011	Study design did not meet the protocol inclusion criteria followup not long enough
Vaudano, G., Gatti, M., Correction of vaginal vault prolapse using CapiroTM suture capturing device: our experience, Minerva Ginecologica, 67, 103-111, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Vecchioli-Scaldazza, C., Morosetti, C., Ferrara, V., The degree of satisfaction of women undergoing surgical repair of prolapse, compared with clinical and urodynamic findings, Archivio Italiano di Urologia e Andrologia, 88, 23-27, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Vergeldt, T. F. M., Notten, K. J. B., Kluivers, K. B., Weernhoff, M., Recurrence risk is associated with preoperatively advanced prolapse stage: Is there a difference between women with stage 2 and those with stage 3 or 4 cystocele?, International Urogynecology Journal, 28, 983-987, 2017	Study design did not meet the protocol inclusion criteria followup not long enough
Viana, R., Colaco, J., Vieira, A., Goncalves, V., Retto, H., Cystocele - Vaginal approach to repairing paravaginal fascial defects, International Urogynecology Journal, 17, 621-623, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Vij, M., Bombieri, L., Dua, A., Freeman, R., Long-term follow-up after colpocleisis: Regret, bowel, and bladder function, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 811-815, 2014	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Viljoen, A. C., A uro-gynaecological approach to urinary stress incontinence and vaginal prolapse, South African Journal of Obstetrics and Gynaecology, 7, 4-8, 2001	Unable to obtain full text
Virtanen, H., Hirvonen, T., Makinen, J., Kiilholma, P., Outcome of thirty patients who underwent repair of posthysterectomy prolapse of the vaginal vault with abdominal sacral colpopexy, Journal of the American College of Surgeons, 178, 283-287, 1994	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Vitale, S. G., Caruso, S., Rapisarda, A. M., Valenti, G., Rossetti, D., Cianci, S., Cianci, A., Biocompatible porcine dermis graft to treat severe cystocele: impact on quality of life and sexuality, Archives of Gynecology & ObstetricsArch Gynecol Obstet, 293, 125-31, 2016	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Wang, C. L., Long, C. Y., Juan, Y. S., Liu, C. M., Hsu, C. S., Impact of total vaginal mesh surgery for pelvic organ prolapse on female sexual function, International Journal of Gynecology and Obstetrics, 115, 167-170, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Wang, Y., Wang, D., Li, Y., Liang, Z., Xu, H., Laparoscopic sacrospinous ligament fixation for uterovaginal prolapse: Experience with 93 cases, International Urogynecology Journal, 22, 83-89, 2011	Retrospective study design
Ward, R. M., Sung, V. W., Clemons, J. L., Myers, D. L., Vaginal paravaginal repair with an AlloDerm graft: Long-term outcomes, American Journal of Obstetrics and Gynecology, 197, 670.e1-670.e5, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Weber, A. M., Walters, M. D., Piedmonte, M. R., Ballard, L. A., Hale, D. S., Three surgical techniques for anterior colporrhaphy resulted in similar cure rates of vaginal prolapse, Evidence-based Obstetrics and Gynecology, 4, 146-147, 2002	Same study already included in the RCT data. This is a brief report and commentary of the main paper
Weinberg, M. S., Stone, M. L., ABDOMINAL CYSTOCELE REPAIR. TECHNIC and RESULTS in 96 CASES, Obstet, Gynec. 21, 117-122, 1963	Population do not meet criteria - not specifically POP
Weng, S. S., Liu, C. Y., Laparoscopic pelvic floor repair using polypropylene mesh, Taiwanese Journal of Obstetrics and Gynecology, 47, 312-317, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Wetta, L. A., Gerten, K. A., Wheeler 2nd, T. L., Holley, R. L., Varner, R. E., Richter, H. E., Synthetic graft use in vaginal prolapse surgery: objective and subjective outcomes, International Urogynecology Journal and Pelvic Floor Dysfunction, 20, 1307-1312, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Wheeler, Li T. L., Richter, H. E., Burgio, K. L., Redden, D. T., Chen, C. C. G., Goode, P. S., Varner, R. E., Regret, satisfaction, and symptom improvement: Analysis of the impact of partial colpocleisis for the management of severe pelvic organ prolapse, American Journal of Obstetrics and Gynecology, 193, 2067-2070, 2005	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Wheeler, Li T. L., Richter, H. E., Duke, A. G., Burgio, K. L., Redden, D. T., Varner, R. E., Outcomes with porcine graft placement in the anterior vaginal compartment in patients who undergo high vaginal uterosacral suspension and cystocele repair, American Journal of Obstetrics and Gynecology, 194, 1486-1491, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Wheeler, T. L., 2nd, Gerten, K. A., Richter, H. E., Duke, A. G., Varner, R. E., Outcomes of vaginal vault prolapse repair with a high uterosacral suspension procedure utilizing bilateral single sutures, International Urogynecology Journal, 18, 1207-13, 2007	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
White, W. M., Goel, R. K., Swartz, M. A., Moore, C., Rackley, R. R., Kaouk, J. H., Single-port Laparoscopic Abdominal Sacral Colpopexy: Initial Experience and Comparative Outcomes, Urology, 74, 1008-1012, 2009	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
White, W. M., Pickens, R. B., Elder, R. F., Firooz, F., Robotic-assisted Sacrocolpopexy for Pelvic Organ Prolapse, Urologic Clinics of North America, 41, 549-557, 2014	Narrative literature review
Wille, S., Braun, M., Heidenreich, A., Hofmann, R., Engelmann, U., Sacral colpopexy with concurrent Burch colposuspension in patients with vaginal vault prolapse, Urologia Internationalis, 76, 339-344, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Williams, J. T., Vaginal hysterectomy and colpectomy for prolapse of the uterus and bladder, American Journal of Obstetrics and Gynecology, 59, 365-370, 1950	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Williams, S. B., Orkin, B. A., Holt, B. F., Drenon, E. A., Transanal rectocele repair: Excellent intermediate outcome, Journal of Pelvic Medicine and Surgery, 12, 191-196, 2006	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Winters, J. C., Cespedes, R. D., Vanlangendonck, R., Abdominal sacral colpopexy and abdominal enterocèle repair in the management of vaginal vault prolapse, Urology, 56, 55-63, 2000	Narrative literature review
Winters, J. C., Fitzgerald, M. P., Barber, M. D., The use of synthetic mesh in female pelvic reconstructive surgery, BJU International, 98 Suppl 1, 70-6; discussion 77, 2006	Narrative literature review
Withagen, M. I. J., Vierhout, M. E., Milani, A. L., Mannaerts, G. H. H., Kluivers, K. B., van der Weiden, R. M. F., Laparoscopic sacral colpopexy versus total vaginal mesh for vault prolapse; comparison of cohorts, Gynecological Surgery, 1-8, 2013	Paper considered in Randomised controlled trial review question
Wong, M. T. C., Abet, E., Rigaud, J., Frampas, E., Lehur, P. A., Meurette, G., Minimally invasive ventral mesh rectopexy for complex rectocoele: Impact on anorectal and sexual function, Colorectal Disease, 13, e320-e326, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Wong, V., Shek, K. L., The mesh debate: Transvaginal anterior anchored mesh should not be abandoned, Australian and New Zealand Journal of Obstetrics and Gynaecology, 57, 105-107, 2017	Opinion article
Xiao-chun, L., Lan, Z., Jing-he, L., Hong-hui, S., Xiao-ming, G., Lin, L., Rong, F., Total pelvic floor reconstruction surgery for repair of severe pelvic organ prolapse, Chung-Kuo i Hsueh Ko Hsueh Yuan Hsueh Pao Acta Academiae Medicinae SinicaeChung Kuo I Hsueh Ko Hsueh Yuan Hsueh Pao, 33, 180-4, 2011	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Xylinas, E., Ouzaid, I., Durand, X., Ploussard, G., Salomon, L., Gillion, N., Vordos, D., Hoznek, A., Abbou, C. C., De La Taille, A., Robot-assisted laparoscopic sacral colpopexy: Initial experience in a high-volume laparoscopic reference center, Journal of Endourology, 24, 1985-1989, 2010	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Yan, A., Anne, M., Karine, A., Vanessa, F., Christophe, P., Anne, T., Patrick, M., Cystocele repair by a synthetic vaginal mesh secured anteriorly through the obturator foramen, European Journal of Obstetrics Gynecology and Reproductive Biology, 115, 90-94, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Yeniel, A. O., Ergenoglu, A. M., Askar, N., Itil, I. M., Meseri, R., Quality of life scores improve in women undergoing colpocleisis: A pilot study, European Journal of Obstetrics Gynecology and Reproductive Biology, 163, 230-233, 2012	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Yoon, W. S., Lee, H. N., Lee, Y. S., Jeung, I. C., Park, E. K., Laparoscopic colposuspension to the Cooper's ligament after hysterectomy for uterovaginal prolapse, Journal of Obstetrics & Gynaecology ResearchJ Obstet Gynaecol Res, 39, 714-9, 2013	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

Study	Reason for Exclusion
Youssif, S. N. M., Shahid, J., Sacrospinous colpopexy as prophylactic and therapeutic treatment of vaginal vault prolapse after hysterectomy, Journal of Obstetrics and Gynaecology, 15, 311-315, 1995	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Zargar, M. A., Emami, M., Zargar, K., Jamshidi, M., The results of grade IV cystocele repair using mesh, Urology Journal, 1, 263-7, 2004	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Zhang, L., Zhu, L., Chen, J., Xu, T., Lang, J. H., Tension-free polypropylene mesh-related surgical repair for pelvic organ prolapse has a good anatomic success rate but a high risk of complications, Chinese Medical Journal, 128, 295-300, 2015	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included
Zhu, L., Lang, J. H., Xiao, H., Postoperative evaluation of tension-free vaginal tape procedure in China, International Journal of Gynecology and Obstetrics, 86, 403-404, 2004	Study design did not meet the protocol inclusion criteria followup not long enough
Zucchi, A., Costantini, E., Mearini, L., Fioretti, F., Bini, V., Porena, M., Female sexual dysfunction in urogenital prolapse surgery: colposacropexy vs. hysterocolposacropexy, Journal of sexual medicine, 5, 139-45, 2008	Study design did not meet the protocol inclusion criteria - fewer than 75 cases included

## Economic studies

**Table 89: Excluded economic studies**

Study	Reason for exclusion
Anand, M., Weaver, A.L., Fruth, K.M., Borah, B.J., Klingele, C. J., Gebhart, J. B., Perioperative complications and cost of vaginal, open abdominal, and robotic surgery for apical vaginal vault prolapse, Female pelvic medicine & reconstructive surgery, 23, 27, 2017	Very narrow health care perspective.
Tan-Kim, J., Menefee, S. A., Luber, K. M., Nager, C. W., Lukacz, E. S., Robotic-assisted and laparoscopic sacrocolpopexy: comparing operative times, costs and outcomes, Female pelvic medicine & reconstructive surgery, 17, 44-49, 2011	Costs expressed in cost units.

**Excluded studies for review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Clinical studies**

**Table 90: Excluded clinical studies**

Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?	
Study	Reason for Exclusion
Atiemo,H.O., Should an anti-incontinence procedure be routinely performed at the time of pelvic organ prolapse repair? An evidence-based review, Current Urology Reports, 11, 304-309, 2010	Systematic review – no additional articles identified
Baessler, K., Maher, C., Pelvic organ prolapse surgery and bladder function, International Urogynecology Journal, 24, 1843-52, 2013	Systematic review- no additional articles identified
Bastani, Parvin, Shoari, Neda, Haj Ebrahimi, Sakineh, Mallah, Fatemeh, Azadi, Azadeh, Comparison of Performing and Not-Performing the Prophylactic Surgery for Urinary Incontinence in Advanced Pelvic Organ Prolapse, 2, 311-315, 2014	The authors did not specify the type of procedures that were carried out (both preventative UI and POP repair procedures)
Basu, M., Duckett, J., The association of changes in opening detrusor pressure with the resolution of overactive bladder symptoms after repair of pelvic organ prolapse, Neurourology & UrodynamicsNeurourol Urodyn, 30, 595-8, 2011	Non relevant population - women had detrusor pressure
Bergman, A., Koonings, P. P., Ballard, C. A., Primary stress urinary incontinence and pelvic relaxation: Prospective randomized comparison of three differnt operations, American journal of obstetrics and gynecology, 161, 97-101, 1989	Non relevant population - women had UI prior to surgery
Borstad,E., Abdelnoor,M., Staff,A.C., Kulseng-Hanssen,S., Surgical strategies for women with pelvic organ prolapse and urinary stress incontinence, International Urogynecology Journal, 21, 179-186, 2010	Non relevant population - women had UI prior to surgery
Brubaker, L., Cundiff, G. W., Fine, P., Nygaard, I., Richter, H. E., Visco, A. G., Zyczynski, H., Brown, M. B., Weber, A. M., Pelvic Floor Disorders, Network,	All data reported more recently in Brubaker et al. 2008

<b>Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?</b>	
Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence.[Erratum appears in N Engl J Med. 2016 Jun 9;374(23):2297-8; PMID: 27276579], New England journal of medicine, 354, 1557-66, 2006	
Brubaker, L., Cundiff, G., Fine, P., Nygaard, I., Richter, H., Visco, A., Zyczynski, H., Brown, M. B., Weber, A., A randomized trial of colpopexy and urinary reduction efforts (CARE): Design and methods, Controlled Clinical Trials, 24, 629-642, 2003	Protocol for CARE trial
Buchsbaum, G. M., Lee, T. G., Vaginal Obliterative Procedures for Pelvic Organ Prolapse: A Systematic Review, Obstetrical and Gynecological Survey, 72, 175-183, 2017	Systematic review - included procedures not relevant (obliterative procedures for surgical treatment of POP)
Bump,R.C., Hurt,W.G., Theofrastous,J.P., Addison,W.A., Fantl,J.A., Wyman,J.F., McClish,D.K., Randomized prospective comparison of needle colposuspension versus endopelvic fascia plication for potential stress incontinence prophylaxis in women undergoing vaginal reconstruction for stage III or IV pelvic organ prolapse. The Continence Program for Women Research Group, American Journal of Obstetrics and Gynecology, 175, 326-333, 1996	Intervention did not meet the inclusion criteria -compared two different procedures to prevent SUI
Casiano,E.R., Gebhart,J.B., McGree,M.E., Weaver,A.L., Klingele,C.J., Trabuco,E.C., Does concomitant prolapse repair at the time of midurethral sling affect recurrent rates of incontinence?, International urogynecology journal and pelvic floor dysfunction, 22, 819-825, 2011	Non relevant population - all women had UI
Chai,T.C., Kenton,K., Xu,Y., Sirls,L., Zyczynski,H., Wilson,T.S., Rahn,D.D., Whitcomb,E.L., Hsu,Y., Gormley,E.A., Effects of concomitant surgeries during midurethral slings (mus) on postoperative complications, voiding dysfunction, continence outcomes, and urodynamic variables, Urology, 79, 1256-1261, 2012	Non relevant population - all women had UI
Chang, T. C., Hsiao, S. M., Chen, C. H., Wu, W. Y., Lin, H. H., Clinical Outcomes and Urodynamic Effects of Tailored Transvaginal Mesh Surgery for Pelvic Organ Prolapse, BioMed Research International, 2015, 191258, 2015	Non relevant population
Chermansky,C.J., Krlin,R.M., Winters,J.C., Selective management of the urethra at time of pelvic organ prolapse repair: An assessment of postoperative incontinence and patient satisfaction, Journal of Urology, 187, 2144-2148, 2012	Study design does not meet the inclusion criteria - cohort study

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

Chughtai, B., Barber, M. D., Mao, J., Forde, J. C., Normand, S. T., Sedrakyan, A., Association Between the Amount of Vaginal Mesh Used With Mesh Erosions and Repeated Surgery After Repairing Pelvic Organ Prolapse and Stress Urinary Incontinence, <i>JAMA Surgery</i> <b>JAMA Surg</b> , 152, 257-263, 2017	Non relevant population - some women had UI prior to surgery. Intervention not relevant to the protocol
Clemons,J.L., Aguilar,V.C., Sokol,E.R., Sung,V.W., Myers,D.L., Suburethral sling treatment of occult stress incontinence and intrinsic sphincter deficiency in women with severe vaginal prolapse of the anterior vs posterior/apical compartment, <i>American Journal of Obstetrics and Gynecology</i> , 192, 1566-1572, 2005	Intervention not relevant - the study compared the efficacy of suburethral sling for occult SUI and ISD in women undergoing anterior POP repair, with the efficacy of suburethral sling for occult SUI and ISD in women undergoing posterior/apical POP repair
Colombo, M., Maggioni, A., Scalambrino, S., Vitobello, D., Milani, R., Surgery for genitourinary prolapse and stress incontinence: a randomized trial of posterior pubourethral ligament plication and Pereyra suspension, <i>American Journal of Obstetrics &amp; Gynecology</i> , 176, 337-43, 1997	Non relevant population - all women had POP and UI
Colombo, M., Milani, R., Vitobello, D., Maggioni, A., A randomized comparison of Burch colposuspension and abdominal paravaginal defect repair for female stress urinary incontinence, <i>American Journal of Obstetrics and Gynecology</i> , 175, 78-84, 1996	Non relevant population - all women had UI
Colombo,M., Maggioni,A., Zanetta,G., Vignali,M., Milani,R., Prevention of postoperative urinary stress incontinence after surgery for genitourinary prolapse, <i>Obstetrics and Gynecology</i> , 87, 266-271, 1996	Intervention does not meet the inclusion criteria - the study compared two procedures to prevent SUI in women undergoing POP repair
Costantini, E., Lazzeri, M., Bini, V., Del Zingaro, M., Frumenzio, E., Porena, M., Pelvic Organ Prolapse Repair with and without Concomitant Burch Colposuspension in Incontinent Women: A Randomised Controlled Trial with at Least 5-Year Followup, <i>Obstetrics &amp; Gynecology International</i> , 2012, 967923, 2012	Non relevant population - all women had POP and UI
Costantini, E., Lazzeri, M., Bini, V., Del Zingaro, M., Zucchi, A., Porena, M., Burch colposuspension does not provide any additional benefit to pelvic organ prolapse repair in patients with urinary incontinence: a randomized surgical trial, <i>Journal of Urology</i> , 180, 1007-12, 2008	Non relevant population - all women POP and UI

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

Dati,S., Rombola,P., Cappello,S., Piccione,E., Single-incision minisling (AJUST) vs obturator tensionfree vaginal shortened tape (TVT-ABBREVO) in surgical management of female stress urinary incontinence, International Journal of Gynecology and Obstetrics, 119, S670-, 2012	Conference abstract
Dieter, A. A., Edenfield, A. L., Weidner, A. C., Siddiqui, N. Y., How does site of pelvic organ prolapse repair affect overactive bladder symptoms?, Female pelvic medicine & reconstructive surgery, 20, 203-7, 2014	Non relevant population women had overactive bladder symptoms and POP
Drain, A., Khan, A., Ohmann, E. L., Brucker, B. M., Smilen, S., Rosenblum, N., Nitti, V. W., Use of Concomitant Stress Incontinence Surgery at Time of Pelvic Organ Prolapse Surgery Since Release of the 2011 Notification on Serious Complications Associated with Transvaginal Mesh, Journal of Urology, 197, 1092-1098, 2017	Outcomes not relevant - data on the trends in preoperative UI assessment, concomitant anti-incontinence surgery and postoperative UI treatment
Ek, M., Altman, D., Gunnarsson, J., Falconer, C., Tegerstedt, G., Clinical efficacy of a trocar-guided mesh kit for repairing lateral defects, International Urogynecology Journal, 24, 249-54, 2013	Non relevant population
Ek,M., Tegerstedt,G., Falconer,C., Kjaeldgaard,A., Rezapour,M., Rudnicki,M., Altman,D., Urodynamic assessment of anterior vaginal wall surgery: a randomized comparison between colporraphy and transvaginal mesh, Neurourology and Urodynamics, 29, 527-531, 2010	Intervention does not meet the inclusion criteria - the study used urodynamic testing to assess the difference in de novo incontinence between women undergoing colporraphy and those undergoing transvaginal mesh repair
Elser, D. M., Moen, M. D., Stanford, E. J., Keil, K., Matthews, C. A., Kohli, N., Mattox, F., Tomezsko, J., Urogynecology, Network, Abdominal sacrocolpopexy and urinary incontinence: surgical planning based on urodynamics, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 202, 375.e1-5, 2010	Study design does not meet inclusion criteria - case series
Fatton, B., Is there any evidence to advocate SUI prevention in continent women undergoing prolapse repair? An overview, International Urogynecology Journal, 20, 235-45, 2009	Narrative literature review - on SUI prevention in continent women undergoing prolapse repair
Fuentes, Ae, A prospective randomised controlled trial comparing vaginal prolapse repair with and without tensionfree vaginal tape transobturator tape (TVTO) in women with severe genital prolapse and occult stress incontinence: Long term follow up, International urogynecology journal and pelvic floor dysfunction, 22, S60-s61, 2011	Conference abstract

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

Glazener, C., Cooper, K., Colombo, M., Randomised comparison of Burch colposuspension versus anterior colporrhaphy in women with stress urinary incontinence and anterior vaginal wall prolapse [4] (multiple letters), British journal of obstetrics and gynaecology, 107, 1324-1325, 2000	Letter to the Editor
Huang, W. C., Yang, S. H., Yang, J. M., Tzeng, C. R., Impact of concomitant anterior vaginal reconstructive surgery on transobturator suburethral tape procedures, Ultrasound in Obstetrics & Gynecology, 40, 562-9, 2012	Non relevant population - women had UI
Huang, Wc, Yang, Sh, Yang, Jm, Clinical Importance and Surgical Outcomes of Green Type III Cystocele in Women With Anterior Vaginal Prolapse, Journal of ultrasound in medicine : official journal of the American Institute of Ultrasound in Medicine, 34, 2279-85, 2015	Non relevant population - some women had POP and UI
Ignjatovic,I., Stojkovic,I., Basic,D., Medojevic,N., Potic,M., Optimal primary minimally invasive treatment for patients with stress urinary incontinence and symptomatic pelvic organ prolapse: tension free slings with colporrhaphy, or Prolift with the tension free midurethral sling?, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 150, 97-101, 2010	Non relevant population - women had POP and UI
Jeon, M. J., Kim, J. Y., Moon, Y. J., Bai, S. W., Yoo, E. H., Two-year urinary outcomes of sacrocolpopexy with or without transobturator tape: results of a prolapse-reduction stress test-based approach, International Urogynecology Journal, 25, 1517-22, 2014	Non relevant population - women had POP and UI
Jeong,T.Y., Yang,S.A., Seo,J.T., The effect of posterior colporrhaphy performed concurrently with midurethral sling surgery on the sexual function of women with stress urinary incontinence, International neurourology journal, 14, 177-181, 2010	Non relevant population - women had UI
Jung,H.J., Yim,G.W., Jeon,M.J., Kim,S.K., Bai,S.W., Preoperative maximum urethral closure pressure and valsalva leak point pressure as predictive parameters for midurethral sling, Journal of Reproductive Medicine, 54, 436-440, 2009	Non relevant population - women had UI
Juul, L., Van Rensburg, J. A., Combined stress urinary incontinence surgery at the time of prolapse surgery - Is it justified?, South African journal of obstetrics and gynaecology, 15, 86-88, 2009	Narrative literature review

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

Karateke,A., Tug,N., Cam,C., Selcuk,S., Asoglu,M.R., Concomitant surgical correction of occult stress urinary incontinence by TOT in patients with pelvic organ prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 154, 105-107, 2011	Study design does not meet the inclusion criteria - cohort study
Khullar, V., Anding, R., Robinson, D., Castro-Diaz, D., Dmochowski, R., Cardozo, L., Under what circumstances should stress incontinence surgery be performed at the same time as prolapse surgery? ICI-RS 2015, Neurourology and Urodynamics, 36, 909-914, 2017	Systematic review – no additional articles identified
King, A. B., Goldman, H. B., Stress incontinence surgery at the time of prolapse surgery: mandatory or forbidden?, World Journal of Urology, 33, 1257-62, 2015	Systematic review - no additional articles identified
Kohli, N., Sze, E. H., Roat, T. W., Karram, M. M., Incidence of recurrent cystocele after anterior colporrhaphy with and without concomitant transvaginal needle suspension, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 175, 1476-80; discussion 1480-2, 1996	Non relevant comparison - no preventive UI surgery in women with POP was performed
Lamblin,G., Van-Nieuwenhuyse,A., Chabert,P., Lebail-Carval,K., Moret,S., Mellier,G., A randomized controlled trial comparing anatomical and functional outcome between vaginal colposuspension and transvaginal mesh, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 961-970, 2014	Non relevant population - some women had also UI
Lau,H.Y., Twu,N.F., Chen,Y.J., Horng,H.C., Juang,C.M., Chao,K.C., Comparing effectiveness of combined transobturator tension-free vaginal mesh (Perigee) and transobturator tension-free vaginal tape (TVT-O) versus anterior colporrhaphy and TVT-O for associated cystocele and urodynamic stress incontinence, European Journal of Obstetrics Gynecology and Reproductive Biology, 156, 228-232, 2011	Non relevant population - women all had POP and UI
Liang,C.C., Chang,Y.L., Chang,S.D., Lo,T.S., Soong,Y.K., Pessary test to predict postoperative urinary incontinence in women undergoing hysterectomy for prolapse, Obstetrics and Gynecology, 104, 795-800, 2004	Non relevant population - some women had POP and UI
Lo, T. S., Bt Karim, N., Cortes, E. F., Wu, P. Y., Lin, Y. H., Tan, Y. L., Comparison between Elevate anterior/apical system and Perigee system in pelvic organ prolapse	Intervention does not meet inclusion criteria - the study compared the difference in de novo UI between women undergoing POP repair with single-incision mesh and those

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

surgery: clinical and sonographic outcomes, International Urogynecology Journal, 26, 391-400, 2015	undergoing POP repair with transvaginal mesh with sacrospinous fixation
Lo, T. S., Tan, Y. L., Cortes, E. F., Lin, Y. H., Wu, P. Y., Pue, L. B., Influence of anterior vaginal mesh with concomitant mid-urethral sling surgery on stress urinary incontinence: clinical and sonographic outcome, Australian & New Zealand Journal of Obstetrics & Gynaecology, 55, 593-600, 2015	Non relevant population - all women had POP and UI
Long,C.Y., Hsu,C.S., Jang,M.Y., Liu,C.M., Chiang,P.H., Tsai,E.M., Comparison of clinical outcome and urodynamic findings using "perigee and/or Apogee" versus "prolift anterior and/or posterior" system devices for the treatment of pelvic organ prolapse, International urogynecology journal and pelvic floor dysfunction, 22, 233-239, 2011	Non relevant population - some women had POP and UI
Manodoro, S., Spelzini, F., Frigerio, M., Nicoli, E., Verri, D., Milani, R., Is Occult Stress Urinary Incontinence a Reliable Predictive Marker?, Female Pelvic Medicine and Reconstructive Surgery, 22, 280-282, 2016	Non relevant intervention - no concomitant anti-incontinence procedure was performed
Matsuoka, P. K., Pacetta, A. M., Baracat, E. C., Haddad, J. M., Should prophylactic anti-incontinence procedures be performed at the time of prolapse repair? Systematic review, International Urogynecology Journal, 26, 187-93, 2015	Systematic review - no additional articles identified
Meschia,M., Pifarotti,P., Spennacchio,M., Buonaguidi,A., Gattei,U., Somigliana,E., A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence, American Journal of Obstetrics and Gynecology, 190, 609-613, 2004	Intervention does not meet the inclusion criteria - the study compared two different types of anti-incontinence procedures in women undergoing POP repair
Mohsin Rizvi, R., Akhtar, M., Zuberi, N. F., A Review of Comparison of Complications of Vaginal Hysterectomy with and without Concomitant Surgery for SUI: A 5 Years' Experience at a Tertiary Care Hospital of Pakistan, Obstetrics & Gynecology International, 2013, 540646, 2013	Study design does not meet the inclusion criteria - case series
Naidu, M., Thakar, R., Sultan, A. H., Outcomes of minimally invasive suburethral slings with and without concomitant pelvic organ prolapse surgery, International Journal of Gynaecology & Obstetrics, 127, 69-72, 2014	Non relevant population - all women had UI and POP

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

Nguyen, J. N., Burchette, R. J., Outcome after anterior vaginal prolapse repair: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 111, 891-8, 2008	Non relevant population - women had POP and UI
Nieminen, K., Hiltunen, R., Heiskanen, E., Takala, T., Niemi, K., Merikari, M., Heinonen, P. K., Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh, <i>International Urogynecology Journal</i> , 19, 1611-1616, 2008	Intervention does not meet the inclusion criteria - no preventive UI surgery was performed
Nieminen, K., Hiltunen, R., Takala, T., Heiskanen, E., Merikari, M., Niemi, K., Heinonen, P. K., Outcomes after anterior vaginal wall repair with mesh: A randomized, controlled trial with a 3-year follow-up, <i>Obstetrical and Gynecological Survey</i> , 66, 411-413, 2011	Conference abstract
Nieminen, K., Hiltunen, R., Takala, T., Heiskanen, E., Merikari, M., Niemi, K., Heinonen, P. K., Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up, <i>American Journal of Obstetrics and Gynecology</i> , 203, 235-238, 2010	Non relevant intervention - no preventive UI surgery was performed
Nygaard, I., Brubaker, L., Zyczynski, H. M., Cundiff, G., Richter, H., Gantz, M., Fine, P., Menefee, S., Ridgeway, B., Visco, A., Warren, L. K., Zhang, M., Meikle, S., Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse.[Erratum appears in <i>JAMA</i> . 2013 Sep 11;310(10):1076], <i>JAMA</i> , 309, 2016-24, 2013	Outcome data not presented in a suitable format to be extracted
Onol, F.F., Tosun, F., Guzel, R., Boylu, U., Kucuk, E.V., Gumus, E., Minimum 1.5-year results of "surgeon-tailored" transvaginal mesh repair for female stress urinary incontinence and pelvic organ prolapse, <i>Urology</i> , 80, 273-279, 2012	Non relevant population - all women had POP and UI
Osmundsen, B., Gregory, W. T., Denman, M. A., Adams, K., Edwards, R., Clark, A., Tension-Free Vaginal Tape Failure After Robotic Sacrocolpopexy and Tension-Free Vaginal Tape for Concomitant Prolapse and Stress Incontinence, <i>Female Pelvic Medicine &amp; Reconstructive Surgery</i> , 21, 244-8, 2015	Non relevant population - all women had POP and UI
Paganotto, M. C., Amadori, L., Di Donato, N., Mauloni, M., Busacchi, P., Use of a preventive sling surgery for the simultaneous correction of latent stress urinary	Study design does not meet inclusion criteria - retrospective cohort

<b>Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?</b>	
incontinence during the cystocele repair: two year follow-up, Minerva Ginecologica, 65, 319-26, 2013	
Palva,K., Rinne,K., Aukee,P., Kivela,A., Laurikainen,E., Takala,T., Valpas,A., Nilsson,C.G., A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-Month results, International urogynecology journal and pelvic floor dysfunction, 21, 1049-1055, 2010	Non relevant population - all women had UI
Park, H. K., Paick, S. H., Lho, Y. S., Choo, G. Y., Kim, H. G., Choi, J., Lack of effect of concomitant stage II cystocele repair on lower urinary tract symptoms and surgical outcome after tension-free vaginal tape procedure: randomized controlled trial, International Urogynecology Journal, 24, 1123-6, 2013	Non relevant population - all women had POP and UI
Patel,M., O'Sullivan,D., Tulikangas,P.K., Is Burch or mid-urethral sling better with abdominal sacral colpopexy?, International Urogynecology Journal, 20, 787-790, 2009	Non relevant population - more than half of the population had UI prior to surgery
Pifarotti,P., Spennacchio,M., Gattei,U., Ronchetti,A., Stoppelli,S., Meschia,M., A randomized prospective comparison of TVT and endopelvic fascia plication in the treatment of occult stress urinary incontinence in patients with genital prolapse: Preliminary data, Urogynaecologia International Journal, 15, 55-57, 2001	Intervention does not meet the inclusion criteria - the study compares two anti-incontinence procedures
Richter, H. E., Nygaard, I., Burgio, K. L., Handa, V. L., Fitzgerald, M. P., Wren, P., Zyczynski, H., Fine, P., Brown, M. B., Weber, A. M., Pelvic Floor Disorders, Network, Lower urinary tract symptoms, quality of life and pelvic organ prolapse: irritative bladder and obstructive voiding symptoms in women planning to undergo abdominal sacrocolpopexy for advanced pelvic organ prolapse, Journal of urology, 178, 965-9; discussion 969, 2007	Non relevant comparison - the study compares lower urinary tract and voiding symptoms in stress continent women versus stress incontinent women
Rickey, L., Minor, J., Predictors of improvement in lower urinary tract symptoms after sacrocolpopexy, Journal of urology, 1), e747, 2011	Conference abstract
Roovers,J.P.W.R., Oelke,M., Clinical relevance of urodynamic investigation tests prior to surgical correction of genital prolapse: A literature review, International urogynecology journal and pelvic floor dysfunction, 18, 455-460, 2007	Narrative literature review - of the diagnostic and therapeutic value of urodynamic investigations in women undergoing prolapse surgery

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

Rovner, E. S., Is prophylactic anti-incontinence surgery beneficial at the time of vaginal prolapse repair? Commentary, Current urology reports, 7, 397-398, 2006	Commentary article
Schierlitz, L., Dwyer, P. L., Rosamilia, A., De Souza, A., Murray, C., Thomas, E., Hiscock, R., Achtari, C., Pelvic organ prolapse surgery with and without tension-free vaginal tape in women with occult or asymptomatic urodynamic stress incontinence: a randomised controlled trial, International Urogynecology Journal, 25, 33-40, 2014	Participants all already have occult SUI
Sharifiaghdas, F., Daneshpajoh, A., Mirzaei, M., Simultaneous treatment of anterior vaginal wall prolapse and stress urinary incontinence by using transobturator four arms polypropylene mesh, Korean Journal of Urology, 56, 811-6, 2015	Non relevant population - all women had POP and some also had UI
Stanton, Sl, Chamberlain, Gvp, Holmes, Dm, The control of stress incontinence: comparison of anterior colporrhaphy and colposuspension, Archives of gynecology, 237 Suppl, 401-402, 1985	Conference abstract
Takahashi,S., Obinata,D., Sakuma,T., Matsui,T., Takenobu,Y., Igarashi,T., Yoshizawa,T., Sato,K., Mochida,J., Sugimoto,S., Transvaginal mesh (TVM) reconstruction with TVT/TOT sling for vaginal prolapse concurrent with stress urinary incontinence, Aktuelle Urologie, 41 Suppl 1, S20-S23, 2010	Non relevant population - women had POP and UI
Tincello,D.G., Kenyon,S., Slack,M., Tooze-Hobson,P., Mayne,C., Jones,D., Taylor,D., Colposuspension or TTV with anterior repair for urinary incontinence and prolapse: results of and lessons from a pilot randomised patient-preference study (CARPET 1), BJOG: An International Journal of Obstetrics and Gynaecology, 116, 1809-1814, 2009	Non relevant population - women had POP and UI
Toz, E., Ozcan, A., Apaydin, N., Uyar, I., Kocakaya, B., Okay, G., Outcomes of vaginal hysterectomy and constricting colporrhaphy with concurrent levator myorrhaphy and high perineorrhaphy in women older than 75 years of age, Clinical interventions in aging, 10, 1009-1015, 2015	Study design does not meet inclusion criteria - case series
Tubre, R. W., Padmanabhan, P., Frilot, C. F., 2nd, Porta, W., Gomelsky, A., Outcomes of three sling procedures at the time of abdominal sacral colpopexy, Neurourology & UrodynamicsNeurourol Urodyn, 36, 482-485, 2017	Non relevant population - all women had POP and UI

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

Turgal, M., Sivaslioglu, A., Yildiz, A., Dolen, I., Anatomical and functional assessment of anterior colporrhaphy versus polypropylene mesh surgery in cystocele treatment, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 170, 555-8, 2013	Non relevant intervention - no preventive UI surgery was performed
van der Ploeg, J. M., Oude Rengerink, K., van der Steen, A., van Leeuwen, J. H., Stekelenburg, J., Bongers, M. Y., Weemhoff, M., Mol, B. W., van der Vaart, C. H., Roovers, J. P., Dutch Urogynaecology, Consortium, Transvaginal prolapse repair with or without the addition of a midurethral sling in women with genital prolapse and stress urinary incontinence: a randomised trial, BJOG: An International Journal of Obstetrics & Gynaecology, 122, 1022-30, 2015	Non relevant population - all women had POP and UI
van der Ploeg, J. M., van der Steen, A., Oude Rengerink, K., van der Vaart, C. H., Roovers, J. P., Prolapse surgery with or without stress incontinence surgery for pelvic organ prolapse: a systematic review and meta-analysis of randomised trials, BJOG: An International Journal of Obstetrics & Gynaecology, 121, 537-47, 2014	Systematic review - no additional articles identified
van der Ploeg, J. M., van der Steen, A., Zwolsman, S., van der Vaart, C. H., Roovers, J. W. R., Prolapse surgery with or without incontinence procedure; a systematic review and meta-analysis, 22, 22, 2017	Systematic review - no additional articles identified
van der Steen, A., van der Ploeg, M., Dijkgraaf, M. G. W., van der Vaart, H., Roovers, J. P. W. R., Protocol for the CUPIDO trials; multicenter randomized controlled trials to assess the value of combining prolapse surgery and incontinence surgery in patients with genital prolapse and evident stress incontinence (CUPIDO I) and in patients with genital prolapse and occult stress incontinence (CUPIDO II), BMC Women's Health, 10 (no pagination), 2010	Protocol of CUPIDO-2 study
Visco, A. G., Brubaker, L., Nygaard, I., Richter, H. E., Cundiff, G., Fine, P., Zyczynski, H., Brown, M. B., Weber, A. M., The role of preoperative urodynamic testing in stress-continent women undergoing sacrocolpopexy: The Colpopexy and Urinary Reduction Efforts (CARE) randomized surgical trial, International Urogynecology Journal, 19, 607-614, 2008	Outcome data not relevant - evaluation of the role of urodynamics testing in identifying SUI
Visco, A. G., Brubaker, L., Nygaard, I., Richter, H. E., Cundiff, G., Fine, P., Zyczynski, H., Brown, M. B., Weber, A. M., The role of preoperative urodynamic testing in stress-	Editorial comment

**Excluded studies - 15. RQ8.5 What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

continent women undergoing sacrocolpopexy: The colpopexy and urinary reduction efforts (CARE) randomized surgical trial, Journal of Urology, 184, 1421, 2010	
Weber, A. M., Walters, M. D., Piedmonte, M. R., Ballard, L. A., Anterior colporrhaphy: a randomized trial of three surgical techniques, American Journal of Obstetrics & Gynecology, 185, 1299-304; discussion 1304-6, 2001	Non relevant population - half of the women had UI prior to surgery
Wei, J., Nygaard, I., Richter, H., Brown, M., Barber, M., Xiao, Xu, Kenton, K., Nager, C., Schaffer, J., Visco, A., Weber, A., Pelvic Floor Disorders, Network, Outcomes following vaginal prolapse repair and mid urethral sling (OPUS) trial--design and methods, Clinical Trials, 6, 162-71, 2009	Protocol for OPUS trial
Wein, A. J., Re: Should Prophylactic Anti-Incontinence Procedures be Performed at the Time of Prolapse Repair? Systematic Review, Journal of Urology, 194, 1348-52, 2015	Editorial comment
Yang, T. H., Wu, L. Y., Chuang, F. C., Kung, F. T., Huang, K. H., Comparing the midterm outcome of single incision vaginal mesh and transobturator vaginal mesh in treating severe pelvic organ prolapse, Taiwanese journal of obstetrics & gynecology, 56, 81-86, 2017	Non relevant comparison - no concomitant surgery for UI prevention was performed

### Economic studies

No economic evidence was excluded for this review question. See supplementary material D for further information.

**Excluded clinical and health economic studies for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Clinical studies**

**Table 91: Excluded clinical studies**

Excluded studies - 16. RQ8.6 What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?	
Kinjo, M., Yoshimura, Y., Sekiguchi, Y., Nutahara, K., Comparison of effectiveness between tension-free vaginal mesh surgery and vaginal pessary in patients with symptomatic pelvic organ prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, S126-S127, 2013	Conference abstract
Mamik, M., Komesu, Y. M., Qualls, C., Rogers, R. G., Does goal setting differ between women who choose surgery vs pessary for treatment of symptomatic prolapse?, Female Pelvic Medicine and Reconstructive Surgery, 2), S67, 2012	Conference abstract
Mamik, M., Komesu, Y., Qualls, C., Rogers, R., Goal attainment in patients that choose surgery versus pessary for treatment of symptomatic pelvic organ prolapse, Female Pelvic Medicine and Reconstructive Surgery, 19, S8, 2013	Conference abstract
Wohlrab, K., Raker, C. A., Sung, V., Long-term symptoms, quality of life and goal attainment after surgery versus pessary for pelvic organ prolapse, American Journal of Obstetrics and Gynecology, 1), S468-S469, 2016	Conference abstract
Coolen, A. L., Troost, S., Mol, B. W., Roovers, J. P., Bongers, M. Y., Primary treatment of vaginal prolapse, pessary use versus prolapse surgery, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S61-S62, 2016	Conference abstract, linked to Coolen 2017, no additional data
Lone, F., Thakar, R., Sultan, A., A one year prospective comparison of vaginal pessaries and surgery in the treatment of pelvic organ prolapse using the validated iciq-vs questionnaire, International Urogynecology Journal and Pelvic Floor Dysfunction, 1), S123-S124, 2012	Conference abstract, no new data
Anonymous,, Pelvic organ prolapse, Obstetrics and Gynecology, 110, 717-729, 2007	Bulletin paper
Dancz, C. E., Walker, D., Thomas, D., Hussain, N., Ozell, B., Effect of pessary use on hydronephrosis in women with advanced pelvic organ prolapse: a self-selected interventional trial, International urogynecology journal, 03, 03, 2017	Comparator does not meet inclusion – not pessary

## DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

**Excluded studies - 16. RQ8.6 What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

Mikkelsen, A. L., Felding, C., Clausen, H. V., Clinical effects of preoperative oestradiol treatment before vaginal repair operation - A double-blind, randomized trial, Gynecologic and obstetric investigation, 40, 125-128, 1995	Comparator does not meet inclusion – not pessary
Song, X., Zhu, L., Ding, J., The value of the preoperative 1-h pad test with pessary insertion for predicting the need for a mid-urethral sling following pelvic prolapse surgery: a cohort study, World Journal of Urology, 34, 361-7, 2016	Comparator does not meet inclusion – not pessary
Dandolu, V., Akiyama, M., Allenback, G., Pathak, P., Mesh complications and failure rates after transvaginal mesh repair compared with abdominal or laparoscopic sacrocolpopexy and to native tissue repair in treating apical prolapse, International Urogynecology Journal, 28, 215-222, 2017	Comparator does not meet inclusion – not pessary
Chmielewski, L., Walters, M., Weber, A., Barber, M., Re-analysis of a randomized trial of three methods of anterior colporrhaphy using more clinically relevant definitions of success, International Urogynecology Journal and Pelvic Floor Dysfunction, 21, S144-S145, 2010	Comparator does not meet inclusion – not pessary
Nygaard, I., Brubaker, L., Zyczynski, H. M., Cundiff, G., Richter, H., Gantz, M., Fine, P., Menefee, S., Ridgeway, B., Visco, A., Warren, L. K., Zhang, M., Meikle, S., Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse, JAMA - Journal of the American Medical Association, 309, 2016-2024, 2013	Comparator does not meet inclusion – not pessary
Liapis, A., Bakas, P., Georgantopoulou, C., Creatsas, G., The use of the pessary test in preoperative assessment of women with severe genital prolapse, European Journal of Obstetrics Gynecology and Reproductive Biology, 155, 110-113, 2011	Comparator does not meet inclusion – not pessary
Nemeth, Z., Farkas, N., Farkas, B., Is hysterectomy or prior reconstructive surgery associated with unsuccessful initial trial of pessary fitting in women with symptomatic pelvic organ prolapse?, International Urogynecology Journal, 28, 757-761, 2017	Comparator does not meet inclusion – not pessary
Baessler, K., Aigmuller, T., Albrich, S., Anthuber, C., Finas, D., Fink, T., Funfgeld, C., Gabriel, B., Henscher, U., Hetzer, F. H., Hubner, M., Junginger, B., Jundt, K., Kropshofer, S., Kuhn, A., Loge, L., Nauman, G., Peschers, U., Pfiffer, T., Schwandner, O., Strauss, A., Tunn, R., Viereck, V., Diagnosis and Therapy of Female Pelvic Organ Prolapse. Guideline of the DGGG, SGGG and OEGGG (S2e-Level, AWMF Registry Number 015/006, April 2016), Geburtshilfe und Frauenheilkunde, 76, 1287-1301, 2016	Guideline – references checked for inclusion
de Boer, T. A., Salvatore, S., Cardozo, L., Chapple, C., Kelleher, C., van Kerrebroeck, P., Kirby, M. G., Koelbl, H., Espuna-Pons, M., Milsom, I., Tubaro, A., Wagg, A., Vierhout, M. E., Pelvic organ prolapse and overactive bladder, Neurourology & Urodynamics, 29, 30-9, 2010	Narrative literature review

## DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

**Excluded studies - 16. RQ8.6 What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

Al-Badr, A., Quality of life questionnaires for the assessment of pelvic organ prolapse: Use in clinical practice, LUTS: Lower Urinary Tract Symptoms, 5, 121-128, 2013	Narrative literature review
Anders, K., Devices for continence and prolapse, BJOG: An International Journal of Obstetrics and Gynaecology, 111, 61-66, 2004	Narrative literature review
Jha, S., Sanderson, P., A review of pelvic organ prolapse during pregnancy, Current Women's Health Reviews, 10, 26-32, 2014	Narrative literature review
Khullar, V., Anding, R., Robinson, D., Castro-Diaz, D., Dmochowski, R., Cardozo, L., Under what circumstances should stress incontinence surgery be performed at the same time as prolapse surgery? ICI-RS 2015, Neurourology and Urodynamics, 36, 909-914, 2017	Narrative literature review
Shatkin-Margolis, A., Pauls, R. N., Sexual function after prolapse repair, Current Opinion in Obstetrics and Gynecology, 29, 343-348, 2017	Narrative literature review
Toh, V. V., Bogné, V., Bako, A., Management of recurrent vault prolapse, International Urogynecology Journal, 23, 29-34, 2012	Narrative literature review
van Geelen, J. M., Dwyer, P. L., Where to for pelvic organ prolapse treatment after the FDA pronouncements? A systematic review of the recent literature, International Urogynecology Journal, 24, 707-18, 2013	Narrative literature review
Ross, J. W., Techniques of laparoscopic repair of total vault eversion after hysterectomy, Journal of the American Association of Gynecologic Laparoscopists, 4, 173-183, 1997	Narrative literature review
Chan, S. S., Cheung, R. Y., Yiu, K. W., Lee, L. L., Pang, A. W., Chung, T. K., Symptoms, quality of life, and factors affecting women's treatment decisions regarding pelvic organ prolapse, International Urogynecology Journal, 23, 1027-33, 2012	Outcome – no useable data
Roman, J. D., Subjective outcome of 166 tension-free vaginal tape procedures performed by a single surgeon: the Braemar experience, Australian & New Zealand Journal of Obstetrics & Gynaecology, 56, 503-507, 2016	Population was not Pelvic organ prolapse
Alas, A. N., Anger, J. T., Management of apical pelvic organ prolapse, Current Urology Reports, 16, 33, 2015	Retrospective design

## DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

**Excluded studies - 16. RQ8.6 What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

Alas, A. N., Bresee, C., Eilber, K., Toubi, K., Rashid, R., Roth, C., Shekelle, P., Wenger, N., Anger, J. T., Measuring the quality of care provided to women with pelvic organ prolapse, American Journal of Obstetrics & Gynecology, 212, 471.e1-9, 2015	Retrospective design
Clemons, J. L., Aguilar, V. C., Sokol, E. R., Jackson, N. D., Myers, D. L., Patient characteristics that are associated with continued pessary use versus surgery after 1 year, American Journal of Obstetrics and Gynecology, 191, 159-164, 2004	Study Design – does not report outcomes of interest
Cheon, C., Maher, C., Economics of pelvic organ prolapse surgery, International Urogynecology Journal, 24, 1873-6, 2013	Study Design – economics paper
Doshani, A., Teo, R. E. C., Mayne, C. J., Tincello, D. G., Uterine prolapse, British Medical Journal, 335, 818-823, 2007	Study Design – literature review
Lone, F., Thakar, R., Sultan, A. H., Karamalis, G., A 5-year prospective study of vaginal pessary use for pelvic organ prolapse, International Journal of Gynecology and Obstetrics, 114, 56-59, 2011	Study Design - no surgery arm
Manchana, T., Ring pessary for all pelvic organ prolapse, Archives of Gynecology and Obstetrics, 284, 391-395, 2011	Study Design - no surgery arm
Manchana, T., Bunyavejchevin, S., Impact on quality of life after ring pessary use for pelvic organ prolapse, International Urogynecology Journal, 23, 873-877, 2012	Study Design - no surgery arm
Singh, K., Reid, W. M. N., Non-surgical treatment of uterovaginal prolapse using double vaginal rings, British journal of obstetrics and gynaecology, 108, 112-113, 2001	Study Design - no surgery arm
Brazell, H. D., Patel, M., O'Sullivan, D. M., Mellen, C., LaSala, C. A., The impact of pessary use on bowel symptoms: one-year outcomes, Female pelvic medicine & reconstructive surgery, 20, 95-8, 2014	Study Design – no surgery arm
Annie Hui, S. Y., Symphorosa Chan, S. C., Judy Lam, S. Y., Lau, T. K., Tony Chung, K. H., A prospective study on the prevalence of hydronephrosis in women with pelvic organ prolapse and their outcomes after treatment, International Urogynecology Journal, 22, 1529-1534, 2011	Study Design - not comparative
Sauer, H. A., Klutke, C. G., Transvaginal sacrospinous ligament fixation for treatment of vaginal prolapse, Journal of Urology, 154, 1008-1012, 1995	Study Design - not comparative
Srikrishna, S., Robinson, D., Cardozo, L., Ringing the changes in evaluation of urogenital prolapse.[Erratum appears in Int Urogynecol J Pelvic Floor Dysfunct. 2011 Jul;22(7):901], International Urogynecology Journal, 22, 171-5, 2011	Study Design - not comparative

## DRAFT FOR CONSULTATION

## Surgical management of pelvic organ prolapse

**Excluded studies - 16. RQ8.6 What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

Weil, A., Gianoni, A., Rottenberg, R. D., Krauer, F., The risk of postoperative urinary incontinence after surgical treatment of genital prolapse, International urogynecology journal, 4, 74-79, 1993	Study Design - not comparative
Wu, V., Farrell, S. A., Baskett, T. F., Flowerdew, G., A simplified protocol for pessary management, Obstetrics and Gynecology, 90, 990-994, 1997	Study Design - not comparative
Young, S. B., Simas, T. A. M., McKinnon, M. M., Aronson, M. P., Morse, A. N., Howard, A. E., Extended Colpopерineorrhaphy for Severe Prolapse in Elderly or at Risk Acoital Women, Journal of Pelvic Medicine and Surgery, 10, 9-13, 2004	Study Design - not comparative
Sinha, D., Arunkalaivanan, A. S., Prevalence of occult stress incontinence in continent women with severe genital prolapse, Journal of Obstetrics and Gynaecology, 27, 174-176, 2007	Study Design - not comparative
Ellstrom Engh, A. M., Ekeryd, A., Magnusson, A., Olsson, I., Otterlind, L., Tobiasson, G., Can de novo stress incontinence after anterior wall repair be predicted?, Acta Obstetricia et Gynecologica Scandinavica, 90, 488-93, 2011	Study Design - not comparative
Carey, M., Slack, M., Higgs, P., Wynn-Williams, M., Cornish, A., Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device, BJOG: An International Journal of Obstetrics and Gynaecology, 115, 391-397, 2008	Study Design - not comparative
Chaikin,D.C., Groutz,A., Blaivas,J.G., Predicting the need for anti-incontinence surgery in continent women undergoing repair of severe urogenital prolapse, Journal of Urology, 163, 531-534, 2000	Study Design - not comparative
Komesu, Y. M., Rogers, R. G., Rode, M. A., Craig, E. C., Schrader, R. M., Gallegos, K. A., Villareal, B., Patient-selected goal attainment for pessary wearers: what is the clinical relevance?, American Journal of Obstetrics and Gynecology, 198, 577.e1-577.e5, 2008	Study Design - not comparative
Agarwala,N., Hasiak,N., Shade,M., Graft interposition colpocleisis, perineorrhaphy, and tension-free sling for pelvic organ prolapse and stress urinary incontinence in elderly patients, Journal of Minimally Invasive Gynecology, 14, 740-745, 2007	Study Design - not comparative
Hullfish, K. L., Bovbjerg, V. E., Gurka, M. J., Steers, W. D., Surgical Versus Nonsurgical Treatment of Women With Pelvic Floor Dysfunction: Patient Centered Goals at 1 Year, Journal of Urology, 179, 2280-2285, 2008	Study Design - surgery vs non surgery, no separate details for pessary participants
Lamers, B. H. C., Broekman, B. M. W., Milani, A. L., Pessary treatment for pelvic organ prolapse and health-related quality of life: A review, International Urogynecology Journal, 22, 637-644, 2011	Systematic review - references were checked for inclusion

**Excluded studies - 16. RQ8.6 What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

de Albuquerque Coelho, S. C., de Castro, E. B., Juliato, C. R., Female pelvic organ prolapse using pessaries: systematic review, International Urogynecology Journal, 18, 18, 2016

Systematic review - references were checked for inclusion

**Economic studies**

No economic evidence was excluded for this review question. See supplementary material D for further information.

## Appendix L – Research recommendations

### Research recommendations for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?

1. What is the effectiveness of colpocleisis compared with sacrospinous fixation for pelvic organ prolapse in elderly women?
2. What is the long-term patient satisfaction with pessaries compared with surgery for pelvic organ prolapse in women?
3. What are the long-term risks of mesh surgery compared with non-mesh surgery for pelvic organ prolapse in women?

#### Why this is important?

4. With an ageing population more frail elderly women are presenting with prolapse and for some of these women colpocleisis is a surgical management option. There are no trials comparing colpocleisis to other surgical procedures such as sacrospinous hysteropexy with pelvic floor repair. Data is needed to counsel women on the safety and success rate of colpocleisis compared to other procedures.
5. There are no studies evaluating the long term success rate of pessary use beyond 5 years compared with surgery. Women considering pessary use often ask if it is a successful long term option or is it delaying surgical intervention. The committee felt that long term information was required on the success and complications of pessary use compared with surgical intervention.
6. Mesh can be used in prolapse surgery by both abdominal and vaginal placement but there is no data on the complications associated with mesh use greater than 5 years. The Committee felt it was very important for research to ascertain the success, safety and complications of mesh use over a 5-10 year period.

**Table 92: Research recommendation rationale (question 1)**

Research question	How effective is colpocleisis compared with sacrospinous fixation in elderly women with POP?
Importance to 'patients' or the population	Colpocleisis versus repair and sacrospinous fixation. Colpocleisis is offered to women who don't desire future penetrative vaginal sex as it is considered a lower risk operation than other types of surgery. However there are no RCTs comparing colpocleisis to other prolapse surgery.
Relevance to NICE guidance	There are several surgical options for prolapse surgery with differing benefits and risks. Patient choice is an important factor. Colpocleisis is currently undertaken in the UK but there is no data comparing it to other procedures.
Relevance to the NHS	The care of frail elderly patients with severe prolapse requires significant resources and there is no data regarding surgery outcomes after Colpocleisis.
National priorities	Medium
Current evidence base	There are no RCTs for colpocleisis
Equality	This approach will help ascertain care options in frail elderly women who frequently may not be offered surgical intervention.

**Table 93: Research recommendation modified PICO table (question 1)**

Criterion	Explanation
Population	Older women (over 70) considering surgery for vault or uterine prolapse, not planning future penetrative sex.
Intervention	Colpocleisis

Criterion	Explanation
Comparator	Sacrospinous fixation with or without hysterectomy
Outcome	Quality of life at 1 year; prolapse symptoms; recurrence of prolapse; complications; mortality; renal functions (secondary); surgical complications (secondary).
Study design	RCT
Timeframe	1 year with follow up at 5 years postop
Additional information	None

**Table 94: Research recommendation rationale (question 2)**

Research question	What is the long term satisfaction with pessary use versus surgery in women with POP?
Importance to 'patients' or the population	Surgery versus pessary treatment.
Relevance to NICE guidance	There is very little data comparing surgery to pessary use and this would inform decision making for women and inform future research in this area.
Relevance to the NHS	There is a high rate of recurrence following surgery and no data to compare long term outcome to pessary use.
National priorities	High
Current evidence base	None
Equality	

**Table 95: Research recommendation modified PICO table (question 2)**

Criterion	Explanation
Population	Women considering surgery for prolapse.
Intervention	Any prolapse surgery.
Comparator	Pessary
Outcome	Quality of life; prolapse symptoms; complications.
Study design	Long term prospective cohort following women using pessaries, 2 groups: initially treated with surgery vs initially treated with pessary; stage 2-4 prolapse only? Need to know what the patient journey of prolapse looks like for each woman.
Timeframe	5 years post-op, but 10 year data would be ideal.
Additional information	None

**Table 96: Research recommendation rationale (question 3)**

Research question	What are long term risks of surgery with mesh for pelvic organ prolapse compared with non-mesh surgery?
Importance to 'patients' or the population	Little is known about the long term risks associated with the insertion of mesh for pelvic organ prolapse. And significant public and political concern regarding this.
Relevance to NICE guidance	Mesh surgery has been considered in this guideline and there is a lack of long term data on safety.
Relevance to the NHS	The outcome would affect the types of treatment for prolapse provided by the NHS and may also predict future healthcare needs for women who have had mesh surgery
National priorities	High
Current evidence base	Minimal

Research question	What are long term risks of surgery with mesh for pelvic organ prolapse compared with non-mesh surgery?
Equality	

**Table 97: Research recommendation modified PICO table (question 3)**

Criterion	Explanation
Population	Women who have had surgery for POP (including non-mesh).
Intervention	1. Prolapse surgery with abdominally placed mesh. 2. Prolapse surgery with vaginally placed mesh
Comparator	Prolapse surgery without mesh.
Outcome	Quality of life (e.g. dyspareunia); prolapse symptoms; complications; pain; adverse events; reoperation for mesh exposure; reoperation for prolapse.
Study design	Cross-sectional study (single time point) or prospective (to decide later).
Timeframe	Long term
Additional information	None

**Research recommendations for review question: What is the role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

No research recommendation was made for this review question.

**Research recommendations for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

No research recommendation was made for this review question.

## Appendix M – Economic methodology checklists

**Economic methodology checklists for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

Anterior and/or posterior surgery

**Table 98: Economic methodology checklist for guideline economic analysis**

Study identification		Guideline economic analysis	
Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse		Review question no: 8.4	
Checklist completed by: Eric Slade			
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)		Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?		Yes	<i>Adult women with primary anterior prolapse</i>
1.2 Are the interventions appropriate for the review question?		Yes	<i>Standard repair, synthetic mesh, and biological mesh</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?		Yes	<i>UK study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?		Yes	<i>NHS</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?		Yes	<i>QALYs</i>
1.6 Are all future costs and outcomes discounted appropriately?		Yes	<i>3.5% for costs and outcomes</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).		Yes	<i>QALYs (EQ-5D-3L, UK general population norms)</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?		NA	
1.9 Overall judgement: Directly applicable			
Other comments:			
Section 2: Study limitations (the level of methodological quality)		Yes/partly/no /unclear/NA	Comments
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?		Yes	<i>Markov model with clinical pathways informed by the committee</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?		Yes	<i>Time horizon: 15 years</i>
2.3 Are all important and relevant outcomes included?		Yes	<i>QALYs</i>
2.4 Are the estimates of baseline outcomes from the best available source?		Yes	<i>From naturalistic observational studies</i>
2.5 Are the estimates of relative intervention effects from the best available source?		Yes	<i>From a review of RCTs (NMA)</i>

2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	<i>Committee expert opinion</i>
2.8 Are the unit costs of resources from the best available source?	Yes	<i>National sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Deterministic and probabilistic sensitivity analyses</i>
2.11 Is there any potential conflict of interest?	No	
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Table 99: Economic methodology checklist for Glazener 2016**

<b>Study identification</b>		
Glazener, C., Breeman, S., Elders, A., Hemming, C., Cooper, K., Freeman, R., Smith, A., Hagen, S., Montgomery, I., Kilonzo, M., Boyers, D., Clinical effectiveness and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study-results from the PROSPECT Study, <i>Health technology assessment (Winchester, England)</i> , 20,1, 2016		
Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse		Review question no: 8.4
<b>Checklist completed by: Eric Slade</b>		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with primary anterior and/or posterior vaginal wall prolapse repair (primary or secondary repair)</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Standard repair, synthetic mesh, and biological graft; mesh inlay, mesh kits</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Yes	<i>UK study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>NHS; NHS plus patient and indirect costs</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	<i>QALYs</i>
1.6 Are all future costs and outcomes discounted appropriately?	Yes	<i>3.5% for costs and outcomes</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	<i>QALYs (EQ-5D-3L, UK general population norms)</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	Yes	<i>For participant time, travel and wider economic costs resource use were</i>

		<i>obtained from various published sources and participant questionnaires. Where possible national unit cost estimates were used.</i>
1.9 Overall judgement: Directly applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	<i>Economic analysis alongside RCT plus modelling (Markov model)</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	<i>Primary repair: time horizon was 2 years within RCT and 5 years modelling. Secondary repair time horizon was up to 2 years.</i>
2.3 Are all important and relevant outcomes included?	Yes	QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	<i>From RCT</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	<i>From a single RCT</i>
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	<i>From RCT</i>
2.8 Are the unit costs of resources from the best available source?	Yes	<i>National sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analysis; deterministic and probabilistic sensitivity analyses</i>
2.11 Is there any potential conflict of interest?	No	<i>Conflict of interest none declared. Publicly funded.</i>
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Table 100: Economic methodology checklist for Jacklin 2013**

<b>Study identification</b> <b>Jacklin, P. and Duckett, J., A decision-analytic Markov model to compare the cost–utility of anterior repair augmented with synthetic mesh compared with non-mesh repair in women with surgically treated prolapse, BJOG: An International Journal of Obstetrics &amp; Gynaecology, 120, 217-223, 2013</b>	<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>	<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		

<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with prolapse of the vaginal wall</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Mesh, non-mesh</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Yes	<i>UK study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>NHS</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	<i>QALYs</i>
1.6 Are all future costs and outcomes discounted appropriately?	Yes	<i>3.5% costs and QALYs</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	<i>Utility weights are based on authors' assumptions informed by the published evidence on women with urinary incontinence</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Directly applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	<i>Markov model</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	<i>Time horizon: 5 years; sensitivity analysis 10 years</i>
2.3 Are all important and relevant outcomes included?	Yes	<i>QALYs</i>
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	<i>Published studies supplemented with authors' opinion</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	<i>Published studies supplemented with authors' opinion</i>
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Yes	<i>National published sources (NHS reference costs)</i>
2.8 Are the unit costs of resources from the best available source?	Yes	<i>National sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Sensitivity and scenario analyses</i>
2.11 Is there any potential conflict of interest?	No	<i>None reported. Funding is not reported.</i>

2.12 Overall assessment: Minor limitations

**Other comments:**

**Table 101: Economic methodology checklist for Murray 2011**

<b>Study identification</b>		
<b>Murray, S., Havercorn, R.M., Lotan, Y., Lemack, G. E., Mesh kits for anterior vaginal prolapse are not cost effective, International urogynecology journal, 22, 447-452, 2011</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with anterior vaginal prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Anterior colporrhaphy, hand-cut mesh, and mesh kit</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Cost analysis</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: 2 years</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	<i>Decision tree model</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	<i>Time horizon: 2 years</i>
2.3 Are all important and relevant outcomes included?	NA	<i>Cost analysis</i>
2.4 Are the estimates of baseline outcomes from the best available source?	NA	<i>Cost analysis</i>
2.5 Are the estimates of relative intervention effects from the best available source?	NA	<i>Cost analysis</i>
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if medication, radiology, laboratory costs are included. However, these are likely to account only</i>

		<i>for a small proportion of total costs.</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>From published sources and authors assumptions</i>
2.8 Are the unit costs of resources from the best available source?	Partly	<i>National and local sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	Unclear	<i>None declared. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

## Apical surgery

**Table 102: Economic methodology checklist for Judd 2010**

<b>Study identification</b>		
<b>Judd, J. P., Siddiqui, N. Y., Barnett, J. C., Visco, A. G., Havrilesky, L. J., Wu, J. M., Cost-minimization analysis of robotic-assisted, laparoscopic, and abdominal sacrocolpopexy, Journal of minimally invasive gynecology, 17, 493-499, 2010</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with advanced apical pelvic organ prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Robotic-assisted, laparoscopic, and abdominal sacrocolpopexy</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Cost analysis</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: &lt;1 year</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		

<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	<i>Seems to be immediate post-operative period</i>
2.3 Are all important and relevant outcomes included?	NA	<i>Cost analysis</i>
2.4 Are the estimates of baseline outcomes from the best available source?	NA	<i>Cost analysis</i>
2.5 Are the estimates of relative intervention effects from the best available source?	NA	<i>Cost analysis</i>
2.6 Are all important and relevant costs included?	Yes	<i>However, time horizon wasn't long enough to capture long term follow-up costs.</i>
2.7 Are the estimates of resource use from the best available source?	Yes	<i>Various published studies (including observational studies)</i>
2.8 Are the unit costs of resources from the best available source?	Unclear	<i>Local and national sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	NA	<i>Cost analysis</i>
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	Yes	<i>Conflict of interest: one of the authors has involvement with the manufacturer Funding: not reported</i>
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Table 103: Economic methodology checklist for Anger 2014**

<b>Study identification</b> <b>Anger, J. T., Mueller, E. R., Tarnay, C., Smith, B., Stroupe, K., Rosenman, A., Brubaker, L., Bressee, C., Kenton, K., Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial, Obstetrics and gynecology, 123, 5-12, 2014</b>		
<b>Guidance topic:</b> surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse		<b>Review question no: 8.4</b>
<b>Checklist completed by:</b> Eric Slade		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with symptomatic stage POP II or greater, including significant apical support loss</i>

1.2 Are the interventions appropriate for the review question?	Yes	<i>Laparoscopic and robot-assisted sacrocolpopexy</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	<i>QALYs</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: 6 weeks</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	<i>QALYs (EQ-5D-3L, USA general population norms)</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
Section 2: Study limitations (the level of methodological quality)	Yes/partly/no /unclear/NA	Comments
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	<i>Economic analysis conducted alongside an RCT</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	<i>Time horizon: 6 weeks</i>
2.3 Are all important and relevant outcomes included?	Yes	<i>QALYs</i>
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	<i>From an RCT</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	<i>From a single RCT</i>
2.6 Are all important and relevant costs included?	Partly	<i>Hasn't considered primary care costs However, these are likely to account only for a small proportion of total costs. Time horizon wasn't long enough to capture long term follow-up costs.</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>From an RCT</i>
2.8 Are the unit costs of resources from the best available source?	Partly	<i>Local and national sources (billing information, cost reports, purchase prices of the robots)</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analysis; deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	No	<i>The authors did not report any potential</i>

		<i>conflicts of interest. Funded by the National Institute of Biomedical Imaging and Bioengineering Recovery Act Limited Competition Challenge Grant.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 104: Economic methodology checklist for Paraiso 2011**

<b>Study identification</b>		
<b>Paraiso, M. F., Jelovsek, J. E., Frick, A., Chen, C. C., Barber, M. D., Laparoscopic compared with robotic sacrocolpopexy for vaginal prolapse: a randomized controlled trial, Obstetrics &amp; Gynecology, 118, 1005-1013, 2011</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with stage 2–4 post-hysterectomy vaginal apex prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Laparoscopic and robotic-sacrocolpopexy</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Cost-minimisation analysis</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: 6 weeks</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	<i>Cost-minimisation analysis</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	<i>Economic analysis alongside and RCT (that found no difference in complications, anatomic outcome, QoL)</i>

2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	<i>Time horizon 6 weeks</i>
2.3 Are all important and relevant outcomes included?	NA	
2.4 Are the estimates of baseline outcomes from the best available source?	NA	
2.5 Are the estimates of relative intervention effects from the best available source?	NA	
2.6 Are all important and relevant costs included?	Unclear	<i>Only general cost categories are provided so unclear what these cost categories include.</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>From RCT</i>
2.8 Are the unit costs of resources from the best available source?	Unclear	
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	NA	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analysis</i>
2.11 Is there any potential conflict of interest?	No	<i>Conflict of interest none reported. Funding was not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 105: Economic methodology checklist for Elliot 2012**

Study identification		
Elliott, C. S., Hsieh, M. H., Sokol, E. R., Comiter, C. V., Payne, C. K., Chen, B., Robot-assisted versus open sacrocolpopexy: a cost-minimization analysis, The Journal of urology, 187, 638-643, 2012		
Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse	Review question no: 8.4	
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with symptomatic stage POP II or greater, including significant apical support loss</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Abdominal open, robot-assisted sacrocolpopexy</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Hasn't considered outcomes</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon less than 1 year</i>

1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	<i>Hasn't considered outcomes</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	<i>Time horizon immediate postoperative period: 30 days</i>
2.3 Are all important and relevant outcomes included?	NA	
2.4 Are the estimates of baseline outcomes from the best available source?	NA	
2.5 Are the estimates of relative intervention effects from the best available source?	NA	
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if included laboratory tests pre/post-surgery, pharmacology, radiology costs; and primary care costs. However, these are likely to account only for a small proportion of total costs.</i>
2.7 Are the estimates of resource use from the best available source?	No	<i>From a small retrospective cohort study (N=59 procedures)</i>
2.8 Are the unit costs of resources from the best available source?	Partly	<i>Local and national sources (published data, local county costs, and other local hospital data)</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	NA	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	Unclear	<i>None reported. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 106: Economic methodology checklist for Hoyte 2012**

**Study identification**

**Hoyte, L., Rabbanifard, R., Mezzich, J., Bassaly, R., Downes, K., Cost analysis of open versus robotic-assisted sacrocolpopexy, Female pelvic medicine & reconstructive surgery, 18, 335-339, 2012**

<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>	<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>	
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	
1.1 Is the study population appropriate for the review question?	Yes
1.2 Are the interventions appropriate for the review question?	Yes
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA
1.6 Are all future costs and outcomes discounted appropriately?	NA
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA
1.9 Overall judgement: Partially applicable	
<b>Other comments:</b>	
<b>Section 2: Study limitations (the level of methodological quality)</b>	
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No
2.3 Are all important and relevant outcomes included?	NA
2.4 Are the estimates of baseline outcomes from the best available source?	NA
2.5 Are the estimates of relative intervention effects from the best available source?	NA
2.6 Are all important and relevant costs included?	Yes
2.7 Are the estimates of resource use from the best available source?	Partly

2.8 Are the unit costs of resources from the best available source?	Unclear	<i>Likely local hospital sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	NA	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analyses conducted; deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	Yes	<i>None reported. However, the main author is a paid surgical doctor for a manufacturer of da Vinci Surgical System. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		

**Other comments:**

**Table 107: Economic methodology checklist for Luu 2017**

<b>Study identification</b>		
Luu, L. L., Vicente, E. D., Pathak, P., Lybbert, D., Dandolu, V., Comparative analysis of overall cost and rate of healthcare utilization among apical prolapse procedures, International Urogynecology Journal, 31, 1-8, 2017		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with apical prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Sacrospinous ligament fixation (SSL), abdominal sacrocolpopexy (ASC), laparoscopic sacrocolpopexy (LSC)</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Cost analysis</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: 90 days</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	<i>Cost analysis</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		

<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	<i>Time horizon: 90 days</i>
2.3 Are all important and relevant outcomes included?	NA	<i>Costs analysis</i>
2.4 Are the estimates of baseline outcomes from the best available source?	NA	<i>Cost analysis</i>
2.5 Are the estimates of relative intervention effects from the best available source?	NA	<i>Cost analysis</i>
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if medication, radiology and laboratory tests primary care costs are included. However, these are likely to account only for a small proportion of total costs.</i>
2.7 Are the estimates of resource use from the best available source?	Yes	<i>Large observational cohort study (SSL [n=17,549]; ASC [n= 6,126]; LSC [n = 10,708])</i>
2.8 Are the unit costs of resources from the best available source?	Unclear	<i>Likely from national sources (national claims database)</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	NA	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analysis</i>
2.11 Is there any potential conflict of interest?	Unclear	<i>None declared. Funding is not reported.</i>
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Table 108: Economic methodology checklist for Ohno 2016**

<b>Study identification</b> <b>Ohno, M. S., Richardson, M. L., Sokol, E. R., Abdominal sacral colpopexy versus sacrospinous ligament fixation: a cost-effectiveness analysis, International urogynecology journal, 27, 233-237, 2016</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with apical prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Abdominal sacral colpopexy,</i>

		<i>sacrospinous ligament fixation</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	
1.6 Are all future costs and outcomes discounted appropriately?	No	<i>Outcomes at 3%; costs are not discounted. However, costs were most likely incurred in year 1 only.</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	<i>Outcome measure: QALYs (utility weights generated by focus group)</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	Yes/partly/no /unclear/NA	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	<i>Decision tree model</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	<i>Time horizon: 2 years. However, only immediate postoperative costs were considered.</i>
2.3 Are all important and relevant outcomes included?	Yes	<i>QALYs</i>
2.4 Are the estimates of baseline outcomes from the best available source?	Yes	<i>From SR and other published sources</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Yes	<i>From SR and other published sources</i>
2.6 Are all important and relevant costs included?	Partly	<i>Only included immediate postoperative costs. Hasn't considered primary care and follow up costs.</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>Medicare reimbursement data; published literature</i>
2.8 Are the unit costs of resources from the best available source?	Unclear	<i>National sources (Medicare reimbursement data); unclear for other published cost estimates</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Deterministic sensitivity analysis</i>

2.11 Is there any potential conflict of interest?	Yes	<i>One author received research grants from various manufacturers, he is also a principal investigator with a manufacturer and received consulting fees. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 109: Economic methodology checklist for Carracedo 2017**

Study identification		Review question no: 8.4
<b>Carracedo, D., López-Fando, L., Sánchez, M. D., Jiménez, M. Á., Gómez, J. M., Laso, I., Rodríguez, M.Á., Burgos, F. J., Cost analysis of surgical treatment for pelvic organ prolapse by laparoscopic sacrocolpopexy or transvaginal mesh, Actas Urológicas Españolas (English Edition), 41, 117-122, 2017</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		
Checklist completed by: Eric Slade		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with pelvic organ prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Laparoscopic sacrocolpopexy, vaginal mesh</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>Spanish study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Cost analysis</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon is unclear. However, seems to be immediate postoperative period.</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	<i>Cost analysis</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	Yes/partly/no /unclear/NA	Comments
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	

2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	<i>Time horizon is unclear. However, seems to be immediate postoperative period.</i>
2.3 Are all important and relevant outcomes included?	NA	<i>Cost analysis</i>
2.4 Are the estimates of baseline outcomes from the best available source?	NA	<i>Cost analysis</i>
2.5 Are the estimates of relative intervention effects from the best available source?	NA	<i>Cost analysis</i>
2.6 Are all important and relevant costs included?	Unclear	<i>It is unclear what certain cost categories included (i.e. functioning, intermediate services, structure)</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>From a small observational cohort study (N=138)</i>
2.8 Are the unit costs of resources from the best available source?	Unclear	<i>Seems to be local hospital sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	NA	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analysis</i>
2.11 Is there any potential conflict of interest?	Unclear	<i>None declared. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 110: Economic methodology checklist for Culligan 2013**

Study identification		
Culligan, P. J., Salamon, C., Priestley, J. L., Shariati, A., Porcine dermis compared with polypropylene mesh for laparoscopic sacrocolpopexy: a randomized controlled trial, <i>Obstetrics &amp; Gynecology</i> , 121, 143-51, 2013		
Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse		Review question no: 8.4
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with uterovaginal prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Robotic sacrocolpopexy, vaginal mesh hysteropexy</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>

1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	QALYs
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: 12 months</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	<i>Utility weights derived from a panel of health care providers and lay-women</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
Section 2: Study limitations (the level of methodological quality)	Yes/partly/no /unclear/NA	Comments
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	<i>Decision tree model</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	<i>Time horizon: 12 months</i>
2.3 Are all important and relevant outcomes included?	Yes	QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	<i>Published literature where possible SR; expert opinion</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	<i>Published literature where possible SR; expert opinion</i>
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if included pharmacy, radiology and laboratory tests; and primary care costs. However, these are likely to account for a small proportion of total costs.</i>
2.7 Are the estimates of resource use from the best available source?	Yes	<i>Cohort study and administrative hospital databases</i>
2.8 Are the unit costs of resources from the best available source?	No	<i>Local sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	Yes	<i>Two authors are consultants and instructors for a manufacturer. Funded by unrestricted educational grant from Boston Scientific (manufacturer).</i>
2.12 Overall assessment: Minor limitations		

**Other comments:**

**Table 111: Economic methodology checklist for Ehlert 2016**

<b>Study identification</b>		
<b>Ehlert, M. J., Gupta, P., Park, J., Siris, L. T., Detailed cost analysis of robotic sacrocolpopexy compared to transvaginal mesh repair, Urology, 97, 86-91, 2016</b>		
Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse		Review question no: 8.4
<b>Checklist completed by: Eric Slade</b>		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with apical prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Robotic sacrocolpopexy vs. total transvaginal mesh</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Cost analysis</i>
1.6 Are all future costs and outcomes discounted appropriately?	Partly	<i>Time horizon: not reported but seems to be immediate postoperative</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	<i>Cost analysis</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	<i>Time horizon: not reported but seems to be immediate postoperative</i>
2.3 Are all important and relevant outcomes included?	NA	<i>Cost analysis</i>
2.4 Are the estimates of baseline outcomes from the best available source?	NA	<i>Cost analysis</i>
2.5 Are the estimates of relative intervention effects from the best available source?	NA	<i>Cost analysis</i>
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Yes	<i>Observational cohort study participants (n=226)</i>

2.8 Are the unit costs of resources from the best available source?	Unclear	
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	NA	Cost analysis
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Statistical analysis
2.11 Is there any potential conflict of interest?	Unclear	<i>The authors report no conflicts of interest. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 112: Economic methodology checklist for Maher 2012**

<b>Study identification</b>		
<b>Maher, C. F., Connelly, L. B., Cost minimization analysis of laparoscopic sacral colpopexy and total vaginal mesh, American journal of obstetrics and gynecology, 206, 433-e1, 2012</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with prolapse of the vaginal wall</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Laparoscopic sacral colpopexy, total vaginal mesh</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>Australian study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Partly	<i>Societal</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	<i>Cure and pelvic floor questionnaires that integrated bladder, bowel and sexual function, pelvic organ prolapse, severity, bothersomeness and condition-specific quality of life.</i>
1.6 Are all future costs and outcomes discounted appropriately?	No	<i>Time horizon: 2 years</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	No	<i>Primary measures of outcome: objective success (POP-Q stage 0 or 1 prolapse at all vaginal sites), patient satisfaction on a scale (0-100), APFQ, P-QoL</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		

<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	<i>Economic analysis alongside an RCT</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	<i>Time horizon: 2 years</i>
2.3 Are all important and relevant outcomes included?	Yes	<i>Objective success, patient satisfaction, APFQ, P-QoL</i>
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	<i>From RCT</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	<i>From a single RCT</i>
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if pharmacy, radiology, and primary care costs are included. However, these are likely to account only for a small proportion of total costs.</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>From RCT</i>
2.8 Are the unit costs of resources from the best available source?	No	<i>Local hospital sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analysis, deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	Unclear	<i>The authors report no conflicts of interest. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 113: Economic methodology checklist for Husby 2018**

<b>Study identification</b>		
<b>Husby, K. R., Tolstrup, C. K., Lose, G., Klarskov, N., Manchester–Fothergill procedure versus vaginal hysterectomy with uterosacral ligament suspension: an activity-based costing analysis, International urogynecology journal, 1–1, 2018</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>		<b>Review question no: 8.4</b>
<b>Checklist completed by: Eric Slade</b>		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with apical prolapse</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Manchester–Fothergill procedure vs. uterosacral</i>

		<i>ligament suspension (with vaginal hysterectomy)</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>Danish study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	NA	<i>Cost analysis</i>
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: 20 months</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	NA	<i>Cost analysis</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	NA	
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	<i>Time horizon: 20 months</i>
2.3 Are all important and relevant outcomes included?	NA	<i>Cost analysis</i>
2.4 Are the estimates of baseline outcomes from the best available source?	NA	<i>Cost analysis</i>
2.5 Are the estimates of relative intervention effects from the best available source?	NA	<i>Cost analysis</i>
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Yes	<i>Cohort study (n=590)</i>
2.8 Are the unit costs of resources from the best available source?	Partly	<i>Local hospital sources</i>
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Statistical analysis, deterministic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	Yes	<i>Authors received various fees and travel grants for conference participation, and received consultation and personal fees</i>
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Economic evidence methodology checklists for the review question: What is the role for surgery for preventing postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions?**

**Table 114: Economic methodology checklist for the guideline economic analysis**

Study identification		Review question no: 8.5
Guideline economic analysis		
<b>Guidance topic: The role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions</b>		Review question no: 8.5
<b>Checklist completed by: Eric Slade</b>		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	Adult women with anterior POP
1.2 Are the interventions appropriate for the review question?	Yes	Anterior colporrhaphy with preventative concomitant retropubic mid-urethral sling (RMUS) vs. anterior colporrhaphy with a deferred option of RMUS
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Yes	UK study
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	NHS
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	
1.6 Are all future costs and outcomes discounted appropriately?	Yes	3.5% for costs and outcomes
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	QALYs (EQ-5D-3L and expert opinion)
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Directly applicable		
<b>Other comments:</b>		
Section 2: Study limitations (the level of methodological quality)	Yes/partly/no /unclear/NA	Comments

2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	Decision tree model
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	Time horizon: 2 years with complications captured up to 11 years
2.3 Are all important and relevant outcomes included?	Yes	QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From an observational study conducted in the US
2.5 Are the estimates of relative intervention effects from the best available source?	Yes	From guideline meta-analysis of RCTs
2.6 Are all important and relevant costs included?	Yes	
2.7 Are the estimates of resource use from the best available source?	Partly	Committee expert opinion
2.8 Are the unit costs of resources from the best available source?	Yes	National sources
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Deterministic sensitivity analyses, probabilistic sensitivity analysis
2.11 Is there any potential conflict of interest?	No	
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Table 115: Economic evidence methodology checklist for Richardson 2013**

Study identification		
Richardson, M. L., Elliott, C. S., Shaw, J. G., Comiter, C. V., Chen, B., Sokol, E. R., To sling or not to sling at time of abdominal sacrocolpopexy: a cost-effectiveness analysis, The Journal of urology, 190, 1306-1312, 2013		
Guidance topic: The role of surgery to prevent postoperative urinary incontinence in women having surgery for pelvic organ prolapse, including the sequence of interventions	Review question no: 8.5	
Checklist completed by: Eric Slade		
Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	Adult women with POP

1.2 Are the interventions appropriate for the review question?	Yes	Abdominal sacrocolpopexy (ASC) alone with deferred option for mid urethral sling (MUS), ASC with universal concomitant MUS, preoperative urodynamic study (UDS) for selective MUS
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	US study
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	Health care payer
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	
1.6 Are all future costs and outcomes discounted appropriately?	NA	Time horizon: 1 year
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Partly	QALYs (Health Utilities Index-Mark III [HUI-Mark III], Canadian general population norms; and vignettes)
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		

**Other comments:**

<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	Decision tree model
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	Time horizon: 1 year
2.3 Are all important and relevant outcomes included?	Yes	QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	From a single RCT
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	From RCT
2.6 Are all important and relevant costs included?	Yes	Hasn't considered primary care costs. However, these are likely to account only for a small proportion of total costs.

2.7 Are the estimates of resource use from the best available source?	Partly	Medicare reimbursement data
2.8 Are the unit costs of resources from the best available source?	Yes	National sources
2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	Deterministic sensitivity analyses
2.11 Is there any potential conflict of interest?	Yes	Three authors had financial interest and/or other relationship with the manufacturer.
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Economic evidence methodology checklists for the review question: What is the effectiveness of surgical options for pelvic organ prolapse, compared to pessaries?**

**Table 116: Economic evidence methodology checklist for Hullfish 2011**

Study identification		
<b>Hullfish, K. L., Trowbridge, E. R., Stukenborg, G. J., Treatment strategies for pelvic organ prolapse: a cost-effectiveness analysis. International urogynecology journal, 22, 507-515, 2011</b>		
Guidance topic: surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse	Review question no: 8.4	
Checklist completed by: Eric Slade		
<b>Section 1: Applicability (relevance to specific review questions and the NICE reference case as described in section 7.5)</b>	Yes/partly/no /unclear/NA	Comments
1.1 Is the study population appropriate for the review question?	Yes	<i>Adult women with pelvic organ prolapse (POP) (<math>\geq</math> stage III apical prolapse of the vagina)</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Expectant management; placement of a pessary; surgical management (vaginal reconstructive surgery, traditional/open abdominal sacrocolpopexy, and robotic-assisted</i>

		<i>abdominal sacrocolpopexy.</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>USA study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>Health care payer</i>
1.5 Are all direct effects on individuals included, and are all other effects included where they are material?	Yes	QALYs
1.6 Are all future costs and outcomes discounted appropriately?	NA	<i>Time horizon: 12 months</i>
1.7 Is QALY used as an outcome, and was it derived using NICE's preferred methods? If not, describe rationale and outcomes used in line with analytical perspectives taken (item 1.4 above).	Yes	<i>QALYs (utility weights based on expert opinion)</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	
1.9 Overall judgement: Partially applicable		
<b>Other comments:</b>		
<b>Section 2: Study limitations (the level of methodological quality)</b>	<b>Yes/partly/no /unclear/NA</b>	<b>Comments</b>
2.1 Does the model structure adequately reflect the nature of the topic under evaluation?	Yes	<i>Markov model</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	<i>Time horizon: 12 months</i>
2.3 Are all important and relevant outcomes included?	Yes	QALYs
2.4 Are the estimates of baseline outcomes from the best available source?	Partly	<i>From various published studies</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	<i>From various published studies supplemented with authors' assumptions</i>
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if included pharmacy, radiology and laboratory tests; and primary care costs. However, these are likely to account for a small proportion of total costs.</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>National hospital discharge data, expert opinion</i>
2.8 Are the unit costs of resources from the best available source?	Yes	<i>National sources</i>

2.9 Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Deterministic and probabilistic sensitivity analyses</i>
2.11 Is there any potential conflict of interest?	No	<i>None declared. Funding is not reported.</i>
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

## Appendix N – NMA protocol

**Network meta-analysis protocol for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

**Table 117: NMA protocol**

Item	Details
Review question	<b>What is the comparative effectiveness of surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse</b>
Context	This NMA will aim to identify the most effective surgical treatments (when compared with a standard care treatment, anterior colporrhaphy) for women with pelvic organ prolapse and it will be used to inform the new national clinical guidance 'Urinary incontinence (update) and pelvic organ prolapse in women: management' in England commissioned by the National Institute for Health and Care Excellence.
Searches	<ul style="list-style-type: none"> <li>Sources to be searched will include Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase.</li> <li>All study designs will be included for the purposes of the searches.</li> <li>Standard animal/non-English language filters will be applied.</li> <li>No supplementary search techniques will be used.</li> </ul>
Type of studies to be included	<ul style="list-style-type: none"> <li>Only randomised controlled trials (RCTs) with at least one relevant surgical procedure will be considered for inclusion.</li> <li>We will exclude studies with a duration of less than 1 year of follow-up.</li> <li>We will include double-blind and single-blind RCTs.</li> <li>We will assume that any patient that meets all inclusion criteria is, in principle, equally likely to be randomized to any of the interventions in the synthesis comparator set.</li> </ul>
Condition or domain being studied	This NMA will consider pelvic organ prolapse in adult women. Pelvic organ prolapse is defined as symptomatic descent of one or more of the anterior vaginal wall, the posterior vaginal wall, the cervix or uterus, or the apex of the vagina (vault or cuff). Anterior vaginal wall prolapse, is the most common form of pelvic organ prolapse and the most frequent site of failure. As the result, this analysis will consider only women with anterior vaginal wall prolapse.
Participants/ population	<p>We will include:</p> <ul style="list-style-type: none"> <li>Adult women (<math>\geq 18</math> years).</li> <li>Pelvic organ prolapse of stage <math>\geq 2</math> on POP-Q scale.</li> <li>Women with only <i>anterior</i> compartment prolapse.</li> <li>Women with <i>de novo</i> or <i>recurrent</i> prolapse.</li> </ul> <p>We will exclude:</p> <ul style="list-style-type: none"> <li>Women with other than anterior prolapse (that is, women with posterior, apical, or the combination).</li> <li>Women with co-existing pelvic organ prolapse and urinary incontinence.</li> </ul>
Interventions	<p>Surgical treatments will include:</p> <ol style="list-style-type: none"> <li>Anterior repair (colporrhaphy, cystocele repair, etc.) <ul style="list-style-type: none"> <li>With mesh</li> <li>Without mesh</li> </ul> </li> </ol>

Item	Details
	<ul style="list-style-type: none"> <li>• Biological mesh</li> <li>• Synthetic mesh</li> <li>• Mesh kit</li> <li>• Inlay mesh</li> </ul> <p>2. Paravaginal repair</p> <ul style="list-style-type: none"> <li>• Open or laparoscopic</li> </ul> <p>Data permitting we will attempt to stratify mesh by type (i.e. absorbable, non-absorbable, polypropylene, etc.).</p> <p>We will not consider in the NMA interventions that are not listed above, unless they act as the sole connectors of the interventions of interest (or their combinations) in the network. In this case, interventions not listed above will be included in the NMA but will not form part of the decision problem (decision of interest).</p>
Comparisons	Anterior colporrhaphy is the standard surgical procedure for women with anterior vaginal wall prolapse. All surgical treatments will be compared to anterior colporrhaphy and also to each other.
Outcome(s)	Recurrence of pelvic organ prolapse defined as recurrence at the same site (that is, recurrence of anterior vaginal wall prolapse). Where recurrence is unreported we will use failure data at the same site. Failure and recurrence at the follow up are assumed to mean the same thing.
Risk of bias (quality) assessment	<ul style="list-style-type: none"> <li>• Risk of bias of all included trials will be assessed using Review Manager (RevMan) software.</li> <li>• No other risk of bias analyses is planned.</li> </ul>
Analysis of subgroups or subsets	Where data are available, networks will be examined separately stratified based on the following sub-groups of women with pelvic organ prolapse: <ul style="list-style-type: none"> <li>• De novo and recurrent prolapse.</li> <li>• Older women (<math>\geq 65</math> years).</li> <li>• Women considering future pregnancy.</li> <li>• Grade of prolapse (using POP-Q staging).</li> </ul>
Sifting and data extraction	<ul style="list-style-type: none"> <li>• Dual sifting will be undertaken using STAR software.</li> <li>• Sifting and data extraction will be performed by the systematic reviewer;</li> <li>• Dual weeding will be performed by a second systematic reviewer on 5% or 10% of records (depending on database size), with resolution of discrepancies in discussion with the senior reviewer if necessary.</li> <li>• Excel software will be used for data extraction.</li> <li>• The data extracted will include patients' characteristics including: age at randomisation, de novo or recurrent prolapse, and stage of prolapse (POP-Q staging); intervention details; the total number of women randomised; the number of women having the event of interest; and the number of women at risk at the time of interest. Where possible, the latter two pieces of data will be extracted for multiple time points. In studies where raw data is not reported we will extract summary measures (i.e. HRs), and the associated measures of uncertainty (i.e. 95% CI, SD). The study characteristics will also be extracted including country where the study was conducted, bias characteristics including (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment,</li> </ul>

Item	Details
	<p>incomplete outcome data, selective reporting, and other potential bias).</p> <ul style="list-style-type: none"> <li>• Dual data extraction will not be undertaken. However, a random sample of extracted data will be checked by the second reviewer, with resolution of discrepancies in discussion with the senior reviewer if necessary.</li> </ul>
Strategy for data synthesis	<ul style="list-style-type: none"> <li>• NMA will be conducted using WinBUGS codes (TSU, University of Bristol).</li> <li>• The statistical analysis of recurrence will be based on Binomial likelihoods with cloglog link function. We will include all study durations in one analysis and model the risk of recurrence as an HR assuming the proportional hazards with respect to the follow up time.</li> <li>• Class effect model will be considered to allow borrowing of evidence from other treatments.</li> <li>• The exact model structure will be agreed with a TSU (University of Bristol) following the review of available clinical evidence.</li> <li>• We will use the HRs (95% CrI) for reporting the results of recurrence.</li> <li>• Ranking of treatments will be provided (i.e. ranks, probability being best, and probability of being in the top/bottom three).</li> <li>• Inconsistency will be checked for by comparing the standard network consistency model to an “inconsistency”, or unrelated mean effects model, and node splitting.</li> </ul>
Organisational affiliation of the review	National Guideline Alliance
Review team members and their organisational affiliations	Developer: National Guideline Alliance
Funding sources/sponsors	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Conflict of interest	None
Collaborators	NICE TSU, University of Bristol
Anticipated start and finish dates	08/2017 – 02/2019

## Appendix O - Network meta-analysis methods

### Network meta-analysis methods for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?

The results of conventional pairwise meta-analyses of direct evidence alone do not help to fully inform which surgical procedure is most effective in women requiring surgical management of anterior pelvic organ prolapse.

Each pairwise comparison does not fully inform the choice between the different treatments and having a series of discrete pairwise comparisons can be incoherent and difficult to interpret.

In addition, direct comparisons of treatments of clinical interest are not fully available, for all comparisons.

To overcome these issues, a Bayesian network meta-analysis (NMA) was performed. Advantages of performing this type of analysis are as follows:

- It allows the synthesis of evidence on multiple treatments compared directly and indirectly without breaking randomisation. If treatment A has never been compared to treatment B in a head to head trial, but these two interventions have been compared to a common comparator, then an indirect treatment comparison can be derived using the relative effects of the two treatments versus the common comparator. Indirect estimates can be calculated whenever there is a path linking two treatments through a set of common comparators. All the randomised evidence is considered simultaneously within the same model.
- For every intervention in a connected network, a relative effect estimate (with its 95% credible intervals, CrIs) between any two interventions can be estimated. These estimates provide a useful clinical summary of the results and facilitate the formation of recommendations based on all relevant evidence, whilst appropriately accounting for uncertainty. Ranks of interventions may also be calculated.
- Estimates from the NMA can be used to directly parameterise treatment effectiveness in cost-effectiveness modelling of multiple treatments.

Conventional fixed effect meta-analysis assumes that the relative effect of one treatment compared to another is the same across an entire set of trials. In a random effects model, it is assumed that the relative effects are different in each trial but that they are from a single common distribution and that this distribution is common across all sets of trials.

NMA requires an additional assumption over conventional meta-analysis. The additional assumption is that intervention A has the same effect on people in trials of intervention A compared to intervention B as it does for people in trials of intervention A versus intervention C, and so on. Thus, in an NMA, the assumption is that intervention A has the same effect across trials of A versus B, A versus C and so on.

The terms indirect treatment comparisons, mixed treatment comparisons, and NMA are used interchangeably. We use the term NMA as the network consists of both indirect treatment comparisons (some trials have a common comparator and some do not) and mixed treatment comparisons (with at least one closed loop, combination of direct and indirect evidence).

### Study selection and data collection

For full details see analysis protocol in appendix N.

### Outcome measure

The committee identified recurrence (at the same site) as a critical outcome for assessing the effectiveness of surgical treatments for women with anterior pelvic organ prolapse.

The committee chose recurrence at the same site for the NMA since this was a long term outcome most reflective of treatment success. Data for other outcomes i.e. repeat surgery for recurrence, repeat surgery for postop SUI, etc., and other prolapse types (that is, posterior or apical) was insufficient to inform NMA. We included trials with either anterior prolapse or predominantly anterior prolapse. Trials for primary and secondary anterior repair were included.

Data for recurrence was reported as counts in the RCTs. The rate of recurrence in each arm of a trial was estimated as the number of women in the arm who experienced recurrence, divided by the total number of women in this arm. The definitions of 'recurrence' varied across trials and are summarised in Table 118.

If it was unclear how 'recurrence' was defined, the study was reviewed by the committee sub-group and a decision was made whether to include or exclude the study on an individual basis.

**Table 118: Definitions of recurrence (failure/cure) for women with anterior repair in included studies**

Study	Definition in included studies
Hviid 2010	Recurrence: POP-Q Ba $\geq -1.0$
Meschia 2007	Recurrence: POP-Q Ba $\geq -1.0$
Glazener 2017 (a1)	Recurrence: POP-Q $\geq 2$
Glazener 2017 (b1)	Recurrence: POP-Q $\geq 2$
Gandhi 2005	Recurrence: POP-Q $\geq 2$
Feldner 2010	Recurrence: POP-Q $\geq 2$
Robert 2014	Recurrence: POP-Q $\geq 2$
Gupta 2014	Recurrence: POP-Q $\geq 2$
Hiltunen 2007	Recurrence: POP-Q $\geq 2$
Rudnicki 2014	Recurrence: POP-Q $\geq 2$
Vollebregt 2011	Recurrence: POP-Q $\geq 2$
Natale 2009	Recurrence: POP-Q $\geq 2$
Farthmann 2013	Recurrence: POP-Q $\geq 2$
Guerette 2009	Recurrence: POP-Q (stage unclear)
EI-Nazer 2012	Recurrence: POP-Q (stage unclear)
Sivaslioglu 2008	Failure: POP-Q $\geq 2$
Menefee 2011	Failure: POP-Q $\geq 2$
Minassian 2014	Failure: POP-Q $\geq 2$
Tamanini 2015	Failure: Ba -1
Nguyen 2008	Failure: Aa or Ba $\geq 2$
Lyer 2018	Failure Aa or Ba $\geq -1$
Yuk 2012	1- cure, with cure defined as POP-Q stage $\leq 1$
Turgal 2013	1- cure, with cure defined as cystocele $< 1$ cm
Delroy 2013	1- cure, with cure defined as Ba $< -1$
Dias 2016	1- cure, with cure defined as Ba $< -1$
deTayrac 2013	1- cure, with cure defined as Ba $< -1$

Study	Definition in included studies
Weber 2001	1- cure, with cure defined as satisfactory (stage I) or optimal (stage 0) outcome at points Aa and Ba

Only trials with the follow-up greater than 12 months were considered for inclusion. The longest reported follow-up was taken for each study.

Results for recurrence are presented as posterior median hazard ratios (HRs) and 95% credible intervals (CrIs).

## Intervention groupings

For the purposes of intervention groupings:

- Mesh was classified in each study based on the product name itself and the materials used;
- Facial, bovine and porcine procedures were all combined into 1 category (that is, biological mesh);
- Weber 2001: ultralateral AC was classified as anterior colporrhaphy;
- Sivaslioglu 2008: cystocoele repair, paravaginal defect repair, both with non-absorbable polypropylene mesh low weight light mesh (Sofradim) was classified as AC & synthetic non-absorbable mesh since >90% of women received standard anterior colporrhaphy.

After the discussion with committee it was decided to include withdrawn mesh products (that is, Perigee, Avaulta, etc.), since this information is relevant to the procedures currently available.

## Methodology

### *Model description*

Both fixed and random effects Binomial models with cloglog link were run to synthesise data for recurrence in women undergoing surgical repair for anterior pelvic organ prolapse.

The full description of standard fixed and random effects models using binomial likelihood with cloglog link can be found in NICE DSU Technical Support Document 2 (Dias 2011).

Analysis was undertaken following Bayesian statistics principles and conducted using Markov chain Monte Carlo simulation techniques implemented in WinBUGS 1.4.3. (Lunn 2000; Spiegelhalter 2001).

Each model was run until convergence was satisfactory and then the results were based on a further sample of iterations on three chains.

The posterior mean of the residual deviance, which measures the magnitude of the differences between the observed data and the model predictions of the data, was used to assess and compare the goodness of fit of each model. Smaller values are preferred, and in a well-fitting model the posterior mean residual deviance should be close to the number of data points in the network (each study arm contributes 1 data point) (Spiegelhalter 2002).

In addition to comparing how well the models fit the data using the posterior mean of the residual deviance, models were compared using the deviance information criterion (DIC). This is equal to the sum of the posterior mean of the residual deviance and the effective number of parameters, and thus penalizes model fit with model complexity. Lower values are preferred and typically differences of 3-5 points are considered meaningful (Spiegelhalter 2002).

For each model fixed and random effect models were compared and the best fitting model was chosen based on the criteria described above.

An important assumption made in NMA concerns the consistency, that is, the agreement of the direct and indirect evidence informing the treatment contrasts and there should be no meaningful differences between these two sources of evidence. To determine if there is evidence of inconsistency, the selected consistency model (random effects) was compared to an ‘inconsistency’, or unrelated mean effects, model. The latter is equivalent to having separate, unrelated, meta-analyses for every pairwise contrast, with a common variance parameter assumed in the case of random effects models (Dias 2013; Dias, 2014). Direct estimates of pairwise comparisons produced by the unrelated mean effects model are presented in this guideline. Further checks for evidence of inconsistency were undertaken through node-splitting (Dias 2010; Dias 2011; Dias 2013; van Valkenhoef 2016). Full methods and results of inconsistency checks are summarised in appendix S.

## References

### **Dias 2010**

Dias, S., Welton, N. J., Caldwell, D. M., Ades, A. E., Checking consistency in mixed treatment comparison meta-analysis, Statistics in Medicine, 29, 932-944, 2010

### **Dias 2011**

Dias, S., Welton, N. J., Sutton, A. J., Caldwell, D. M., Lu, G., Ades, A. E., NICE DSU Technical Support Document 4: Inconsistency in networks of evidence based on randomised controlled trials, 2011; last updated April 2014, available from <http://scharr.dept.shef.ac.uk/nicedsu/technical-support-documents/evidence-synthesis-tsd-series/>

### **Dias 2013**

Dias, S., Ades, A., Sutton, A., Welton, N., Evidence Synthesis for Decision Making 2: A Generalized Linear Modeling Framework for Pairwise and Network Meta-analysis of Randomized Controlled Trials, Medical Decision Making, 33, 607-617, 2013

### **Dias 2013**

Dias, S., Welton, N. J., Sutton, A. J., Caldwell, D. M., Lu, G., Ades, A. E., Evidence Synthesis for Decision Making 4: Inconsistency in Networks of Evidence Based on Randomized Controlled Trials, Medical Decision Making, 33, 641-656, 2013

### **Lunn 2000**

Lunn, D. J., Thomas, A., Best, N., Spiegelhalter, D., WinBUGS - a Bayesian modelling framework: concepts, structure, and extensibility, Statistics and Computing, 10, 325-337, 2000

### **Spiegelhalter 2001**

Spiegelhalter, D. J., Thomas, A., Best, N. G., et al. WinBUGS User Manual: Version 1.4. Cambridge: MRC Biostatistics Unit, 2001

### **Spiegelhalter 2002**

Spiegelhalter, D. J., Best, N. G., Carlin, B. P., van der Linde, A., Bayesian measures of model complexity and fit. Journal of the Royal Statistical Society: Series B, 64, 583-616, 2002

### **van Valkenhoef 2016**

van Valkenhoef, G., Dias, S., Ades, A. E., Welton, N.J., Automated generation of node-splitting models for assessment of inconsistency in network meta-analysis, Research Synthesis Methods, 7, 80-93, 2016

## Appendix P – Summary of studies included in the network meta-analysis

**Studies included in the network meta-analysis for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

**Table 119: RCTs reporting data on recurrence for women with anterior prolapse considered in the network meta-analysis**

Study	Follow-up (months)	AC 1	AC & synthetic non-absorbable mesh 2	AC & biological mesh 3	AC & synthetic partially absorbable mesh 4	AC & synthetic absorbable mesh 5	Paravaginal repair & synthetic non-absorbable mesh 6	Paravaginal defect repair (abdominal) 7	Paravaginal repair & biological mesh 8
Glazener 2017 (a1)	12	117/184	114/187						
El Nazer 2012	24	3/23	1/21						
Hiltunen 2007	12	37/97	7/105						
Nguyen 2008	12	17/38	5/38						
Tamanini 2015	24	18/55	10/45						
Turgal 2013	12	5/20	1/20						
Delroy 2013	12	17/39	7/40						
Dias 2016	24	28/45	26/43						
Vollebregt 2011	12	33/64	5/61						
Sivaslioglu 2008	12	12/45	4/45						
Gupta 2014	12	2/55		1/53					
Glazener 2017 (b1)	12	14/21		11/25					
Gandhi 2005	13	23/78		16/76					
Guerette 2009	24	10/47		5/47					
Feldner 2010	12	11/27		4/29					
Hviid 2010	12	4/31		2/30					
Robert 2014	12	27/29		19/28					
Lyer 2018	84	24/70		10/44					
Rudnicki 2014	36	40/82			6/79				
deTayrac 2013	17	39/82			21/80				
Weber 2001	23	47/76				22/38			
Menefee 2011	24	14/32					5/36		12/31
Yuk 2012	12		5/45; 8/42						
Meschia 2007	12		20/106	7/100					
Natale 2009	24		27/96	41/94					

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Study	Follow-up (months)	AC 1	AC & synthetic non-absorbable mesh 2	AC & biological mesh 3	AC & synthetic partially absorbable mesh 4	AC & synthetic absorbable mesh 5	Paravaginal repair & synthetic non-absorbable mesh 6	Paravaginal defect repair (abdominal) 7	Paravaginal repair & biological mesh 8
Farthmann 2013	39		15/102		12/98				
Minassian 2014	24					8/35		10/35	

Note: AC: anterior colporrhaphy

(\*) This RCT is categorised by the GC as comparing the same type of surgical procedure

**Table 120: Included study characteristics**

No.	Study ID	Country	Prolapse	Grade of prolapse (POP-Q staging)	Primary/Secondary repair	Concomitant surgery
1	Glazener 2017 (a1)	UK	Anterior	≥2	Majority primary	As required
2	El Nazer 2012	Egypt	Anterior	≥2	Primary only	No additional
3	Hiltunen 2007	Finland	Anterior	≥2	Majority primary	As required
4	Nguyen 2008	USA	Anterior	≥2	Majority primary	As required
5	Tamanini 2015	Brazil	Anterior	≥2	Unclear	As required
6	Turgal 2013	Turkey	Anterior	≥2	All primary	No additional
7	Delroy 2013	Brazil	Anterior predominant	≥2	Majority primary	As required
8	Dias 2016	Brazil	Anterior predominant	≥2	Majority primary	As required
9	Vollebregt 2011	Netherlands	Anterior predominant	≥2	All primary	As required
10	Sivaslioglu 2008	Turkey	Anterior	Unclear	All primary	Not reported
11	Gupta 2014	India	Anterior	≥2	Majority primary	As required
12	Glazener 2017 (b1)	UK	Anterior	≥2	All primary	As required
13	Gandhi 2005	USA	Anterior	≥2	Unclear	As required
14	Guerette 2009	USA	Anterior	≥2	Majority primary	As required
15	Feldner 2010	Brazil	Anterior	≥2	Majority primary	As required
16	Hviid 2010	Denmark	Anterior	≥2	All primary	No additional
17	Robert 2014	Canada	Anterior	≥2	Majority secondary	As required
18	Lyer 2018	USA	Anterior	≥2	Majority primary	As required
19	Rudnicki 2014	Denmark	Anterior	≥2	All primary	No additional
20	deTayrac 2013	France	Anterior	≥2	Majority primary	As required
21	Weber 2001	USA	Anterior	1 to 4 (majority 2 or more)	Majority primary	As required
22	Menefee 2011	USA	Anterior	≥2	Majority primary	As required
23	Yuk 2012	South Korea	Anterior	≥2	Unclear	As required
24	Meschia 2007	Italy	Anterior	≥2	All primary	As required
25	Natale 2009	Italy	Anterior	≥2	All secondary	As required
26	Farthmann 2013	Germany	Anterior	≥2	Majority primary	As required
27	Minassian 2014	USA	Anterior	≥2	Unclear	As required

## Appendix Q – Studies excluded from the network meta-analysis

**Studies excluded from network meta-analysis for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

Study ID	Reason for exclusion	Reference
Lamblin 2014	Comparing vaginal colposuspension with vaginal colposuspension plus transobturator vaginal mesh (Perigee): treatments were not connected to the rest of the network.	Lamblin, G., Van-Nieuwenhuyse, A., Chabert, P., Lebail-Carval, K., Moret, S., Mellier, G., A randomized controlled trial comparing anatomical and functional outcome between vaginal colposuspension and transvaginal mesh, International urogynecology journal, 25, 961-970, 2014
Altman 2011	Comparing AC with AC and mesh/polypropylene-mesh repair kit (prolift): the definition of recurrence was unclear and following the discussion with the GC it was decided to remove this study from the analysis.	Altman, D., Väyrynen, T., Engh, M.E., Axelsen, S., Falconer, C., Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse, New England Journal of Medicine, 364, 1826-1836, 2011

## Appendix R – Supplementary network meta-analysis results

**Supplementary network meta-analysis results for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?**

### Model fit characteristics

**Table 121: Model fit characteristics for recurrence at the same site (that is, anterior)**

Model	Between-study standard deviation (95% CrI)	Residual deviance <sup>a</sup>	DIC
Fixed effect – consistency model	---	112.5	357.487
Random effects – consistency model	0.63 (0.38, 0.97)	51.91	309.925

Note: CrI: credible interval; DIC: deviance information criterion; N/A: not applicable;

(a) Compare 55 data points

## **Appendix S - NMA inconsistency checks**

# **URINARY INCONTINENCE AND PELVIC ORGAN PROLAPSE: NMA INCONSISTENCY CHECKS**

NICE TSU, University of Bristol

Network meta-analysis inconsistency checks for review question: What are the most effective surgical management options (including mesh and non-mesh procedures) for pelvic organ prolapse?

### **Introduction**

The purpose of this analysis was to assess the consistency assumption in the network meta-analysis (NMA) model used to estimate the comparative effectiveness of interventions for treating women with urinary incontinence and pelvic organ prolapse. Recurrent prolapse was the only outcome included in this analysis.

### **Methods**

#### ***Inconsistency checks***

An important assumption made in NMA concerns the consistency of the direct and indirect evidence informing the treatment contrasts [1,2]. There should be no meaningful differences between these two sources of evidence.

To determine if there is evidence of inconsistency, the selected consistency model (fixed or random effects) was compared to an “inconsistency”, or unrelated mean effects, model [1,2]. The latter is equivalent to having separate, unrelated, meta-analyses for every pairwise contrast, with a common variance parameter assumed in the case of random effects models. Note that the consistency assumption can only be assessed when there are closed loops of direct evidence on 3 treatments that are informed by at least 3 independent sources of evidence [3].

The posterior mean of the residual deviance, which measures the magnitude of the differences between the observed data and the model predictions of the data, was used to assess and compare the goodness of fit of each model [4]. Smaller values are preferred, and in a well-fitting model the posterior mean residual deviance should be close to the number of data points in the network (each study arm contributes 1 data point) [4].

In addition to comparing how well the models fit the data using the posterior mean of the residual deviance, models were compared using the deviance information criterion (DIC). This is equal to the sum of the posterior mean of the residual deviance and the effective number of parameters, and thus penalizes model fit with model complexity [4]. Lower values are preferred and typically differences of 3-5 points are considered meaningful [4].

The posterior mean between-study standard deviation, which measures the heterogeneity of treatment effects estimated by trials within contrasts, was also used to compare models. When comparing consistency and inconsistency models, if the inconsistency model has the smallest heterogeneity, then this indicates potential inconsistency in the data.

We performed further checks for evidence of inconsistency through node-splitting [1-3,5]. This method permits the direct and indirect evidence contributing to an estimate of a relative effect to be split and compared.

## Results

Inconsistency checks were performed using the random effects model, as lower posterior mean residual deviance and DIC models compared to the fixed effect model suggest the random effects model provided a better fit for the data (Table 122).

**Table 122: Model fit statistics**

Model	Between Study Heterogeneity - Standard Deviation (95% CrI) <sup>a</sup>	Residual deviance <sup>b</sup>	DICc <sup>c</sup>
Fixed effect - consistency	---	112.5	357.481
Random effects - consistency	0.61 (0.39, 0.98)	51.88	309.420
Random effects - inconsistency	0.66 (0.42, 1.06)	51.81	310.837

<sup>a</sup> Credible Interval (CrI)

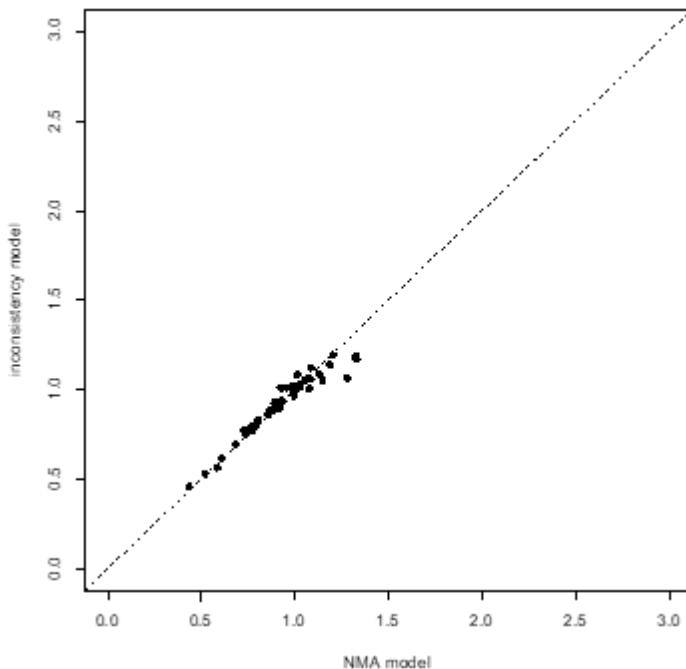
<sup>b</sup> Posterior mean residual deviance compared to 55 total data points

<sup>c</sup> Deviance information criteria (DIC) – lower values preferred

Since there were closed loops of direct evidence within the network that were informed by at least 3 distinct sets of trials, inconsistency checks were possible for this outcome.

Convergence was satisfactory for the random effects model assuming inconsistency after 20,000 iterations, and the consistency and inconsistency models were compared using results based on samples from a further 40,000 iterations on three chains. WinBUGS code for the inconsistency model is provided in appendix 1.

No evidence of inconsistency was found through comparison of the consistency and inconsistency random effects models, as little difference was observed between the fit of the models (Table 122). The area below the line of equality in Figure 54 highlights where the inconsistency model better predicted data points, and the improvements were minimal. The additional parameters in the inconsistency model, which eliminates variation between treatment contrasts, did not result in a decrease in the between-study heterogeneity (Table 122).



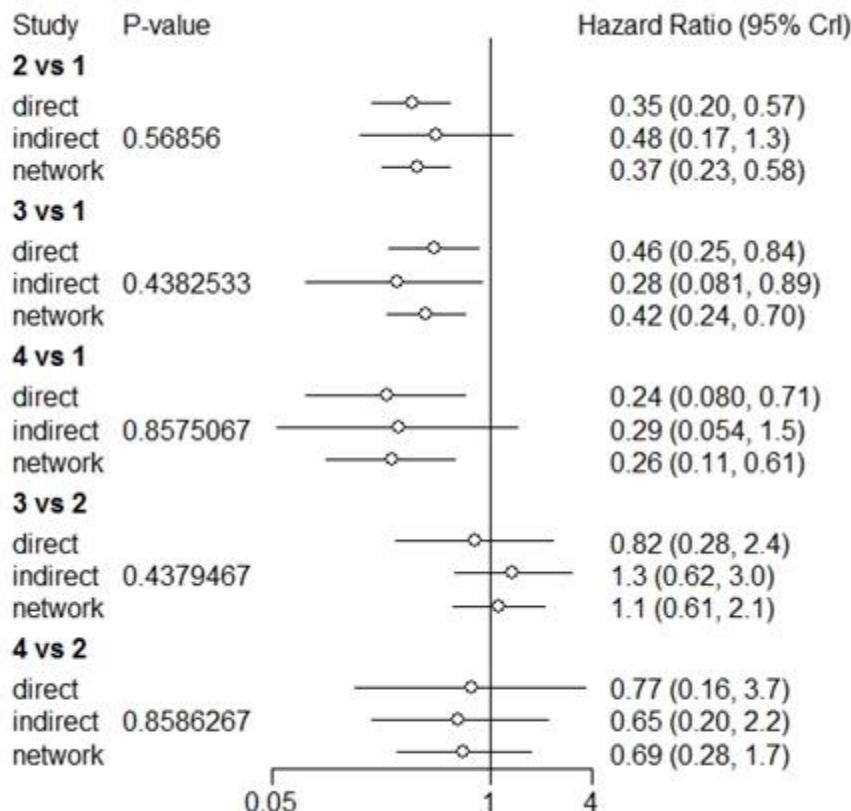
**Figure 54: Deviance contributions for the random effects consistency and inconsistency models.**

Further checks for inconsistency using the node-splitting method (random effects model) did not find any evidence of inconsistency between the direct and indirect estimates (Table 123, Figure 55). In addition to the relative effects estimated through NMA, we present direct (when available) and indirect estimates in Table 124. Where direct evidence is available on treatment comparisons, the direct and indirect estimates are reported based on results given by the node-splitting models. Otherwise, the indirect estimates are taken from the NMA model. All NMA estimates are reported based on the results from the random effects model that assumes consistency [6,7].

**Table 123: Summary of node-splitting results**

Node split model	Heterogeneity (SD)		Residual deviance	DIC	p-value <sup>a</sup>
	median	95% CrI			
AC vs. AC & synthetic non-absorbable mesh	0.65	(0.41, 1.05)	48.89	93.31	0.47
AC vs. AC & biological mesh	0.65	(0.41, 1.04)	48.59	92.85	0.34
AC vs. AC & synthetic partially absorbable mesh	0.65	(0.41, 1.06)	49.03	93.40	0.86
AC & synthetic non-absorbable mesh vs. AC & biological mesh	0.65	(0.41, 1.04)	48.66	92.97	0.34
AC & synthetic non-absorbable mesh vs. AC & synthetic partially absorbable mesh	0.65	(0.41, 1.04)	49.02	93.42	0.87
<b>NMA (no nodes split)</b>	<b>0.63</b>	<b>(0.40, 1.00)</b>	<b>48.89</b>	<b>92.73</b>	---

<sup>a</sup> Posterior mean residual deviance compared to 55 total data points



**Figure 55: Direct, indirect and network estimates of relative treatment effects based on node-splitting results.**

Treatments codes: 1 – AC, 2 – AC & synthetic non-absorbable mesh, 3 – AC & biological mesh, 4 – AC & synthetic partially absorbable mesh.

**Table 124: Direct, indirect and NMA estimates of all relative treatment effects**

Treatment 1	Treatment 2	Direct <sup>a</sup>			Indirect <sup>b</sup>			NMA <sup>c</sup>		
		median log(HR)	2.50%	97.50%	median log(HR)	2.5%	97.5%	median log(HR)	2.5%	97.5%
AC	AC & synthetic non-absorbable mesh	-1.06	-1.63	-0.56	-0.74	-1.78	0.30	-0.96	-1.44	-0.53
AC	AC & biological mesh	-0.77	-1.39	-0.17	-1.27	-2.52	-0.12	-0.82	-1.36	-0.31
AC	AC & synthetic partially absorbable mesh	-1.41	-2.52	-0.34	-1.24	-2.93	0.38	-1.32	-2.20	-0.47
AC	AC & synthetic absorbable mesh				-0.12	-1.52	1.28	-0.12	-1.52	1.28
AC	Paravaginal repair & synthetic non-absorbable mesh				-1.40	-3.12	0.22	-1.40	-3.12	0.22
AC	Paravaginal defect repair (abdominal)				0.16	-1.97	2.29	0.16	-1.97	2.29
AC	Paravaginal repair & biological mesh				-0.17	-1.68	1.34	-0.17	-1.68	1.34
AC & synthetic non-absorbable mesh	AC & biological mesh	-0.20	-1.29	0.86	0.30	-0.48	1.11	0.14	-0.47	0.76
AC & synthetic non-absorbable mesh	AC & synthetic partially absorbable mesh	-0.26	-1.84	1.31	-0.43	-1.61	0.78	-0.36	-1.26	0.55
AC & synthetic non-absorbable mesh	AC & synthetic absorbable mesh				0.85	-0.60	2.34	0.85	-0.60	2.34
AC & synthetic non-absorbable mesh	Paravaginal repair & synthetic non-absorbable mesh				-0.43	-2.20	1.27	-0.43	-2.20	1.27
AC & synthetic non-absorbable mesh	Paravaginal defect repair (abdominal)				1.12	-1.03	3.31	1.12	-1.03	3.31
AC & synthetic non-absorbable mesh	Paravaginal repair & biological mesh				0.80	-0.76	2.39	0.80	-0.76	2.39
AC & biological mesh	AC & synthetic partially absorbable mesh				-0.49	-1.50	0.49	-0.49	-1.50	0.49
AC & biological mesh	AC & synthetic absorbable mesh				0.71	-0.78	2.21	0.71	-0.78	2.21
AC & biological mesh	Paravaginal repair & synthetic non-absorbable mesh				-0.57	-2.36	1.14	-0.57	-2.36	1.14
AC & biological mesh	Paravaginal defect repair (abdominal)				0.98	-1.20	3.19	0.98	-1.20	3.19
AC & biological mesh	Paravaginal repair & biological mesh				0.66	-0.94	2.26	0.66	-0.94	2.26
AC & synthetic partially absorbable mesh	AC & synthetic absorbable mesh				1.20	-0.42	2.86	1.20	-0.42	2.86
AC & synthetic partially absorbable mesh	Paravaginal repair & synthetic non-absorbable mesh				-0.08	-1.98	1.77	-0.08	-1.98	1.77
AC & synthetic partially absorbable mesh	Paravaginal defect repair (abdominal)				1.48	-0.80	3.79	1.48	-0.80	3.79
AC & synthetic partially absorbable mesh	Paravaginal repair & biological mesh				1.15	-0.57	2.91	1.15	-0.57	2.91
AC & synthetic absorbable mesh	Paravaginal repair & synthetic non-absorbable mesh				-1.29	-3.50	0.86	-1.29	-3.50	0.86
AC & synthetic absorbable mesh	Paravaginal defect repair (abdominal)				0.28	-1.33	1.89	0.28	-1.33	1.89
AC & synthetic absorbable mesh	Paravaginal repair & biological mesh				-0.05	-2.12	2.01	-0.05	-2.12	2.01
Paravaginal repair & synthetic non-absorbable mesh	Paravaginal defect repair (abdominal)				1.56	-1.12	4.30	1.56	-1.12	4.30

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Treatment 1	Treatment 2	Direct <sup>a</sup>			Indirect <sup>b</sup>			NMA <sup>c</sup>		
		median log(HR)	2.50%	97.50%	median log(HR)	2.5%	97.5%	median log(HR)	2.5%	97.5%
Paravaginal repair & synthetic non-absorbable mesh	Paravaginal repair & biological mesh				1.23	-0.41	2.96	1.23	-0.41	2.96
Paravaginal defect repair (abdominal)	Paravaginal repair & biological mesh				-0.32	-2.94	2.28	-0.32	-2.94	2.28

<sup>a</sup>Direct estimates presented when available

<sup>b</sup>Indirect estimates obtained from node-splitting models when direct evidence is available, otherwise equal to NMA estimates

<sup>c</sup>Network meta-analysis (NMA) estimates obtained from random effects model, assuming consistency

## Conclusion

The inconsistency checks did not identify any evidence of inconsistency between the direct and indirect evidence included in the network meta-analysis. However, we note the large amount of between-study heterogeneity in the random effects model that assumes consistency; caution should be exercised when interpreting the results.

## Appendix 1. WinBUGS code for inconsistency model used in this report

```
# Binomial likelihood, cloglog link
# Random effects model for multi-arm trials
model{                                # *** PROGRAM STARTS
for(i in 1:ns){                      # LOOP THROUGH STUDIES
    delta[i,1] <- 0                  # treatment effect is zero for control arm
    mu[i] ~ dnorm(0,.0001)           # vague priors for all trial baselines
    for (k in 1:na[i]) {            # LOOP THROUGH ARMS
        r[i,k] ~ dbin(p[i,k],n[i,k]) # Binomial likelihood
    # model for linear predictor
        cloglog(p[i,k]) <- mu[i] + delta[i,k]
        rhat[i,k] <- p[i,k] * n[i,k] # expected value of the numerators
    #Deviance contribution
        dev[i,k] <- 2 * (r[i,k] * (log(r[i,k])-log(rhat[i,k]))
        + (n[i,k]-r[i,k]) * (log(n[i,k]-r[i,k]) - log(n[i,k]-
rhat[i,k])))      }
    # summed residual deviance contribution for this trial
    resdev[i] <- sum(dev[i,1:na[i]])
    for (k in 2:na[i]) {            # LOOP THROUGH ARMS
    # trial-specific LHR distributions
        delta[i,k] ~ dnorm(d[t[i,1],t[i,k]],tau)
    }
}
totresdev <- sum(resdev[])          #Total Residual Deviance

sd ~ dunif(0,5)      # vague prior for between-trial SD
tau <- pow(sd,-2)   # between-trial precision = (1/between-trial
variance)

# pairwise HRs and LHRs for all possible pair-wise comparisons, if
nt>2
for (c in 1:(nt-1)) {
    d[c,c]<-0
    for (k in (c+1):nt) {
        d[c,k] ~ dnorm(0,.0001)
        log(hr[c,k]) <- d[c,k]
    }
}

# *** PROGRAM ENDS *** #
```

## References

1. Dias, S., Welton, N. J., Sutton, A. J., Caldwell, D. M., Lu, G., Ades, A. E., Evidence Synthesis for Decision Making 4: Inconsistency in Networks of Evidence Based on Randomized Controlled Trials, *Medical Decision Making*, 33, 641-656, 2013.
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