

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

**[E] Surgical and physical management of stress urinary incontinence**

*NICE guideline tbc*

*Evidence review*

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# 1 **Surgical and conservative management of stress urinary** 2 **incontinence**

## 3 **Review questions**

4 This evidence report covers a number of review questions within subsections. The following  
5 are the two review questions that are going to be covered in this document:

- 6 • What is the most effective surgical management of stress urinary incontinence, including  
7 mesh and non-mesh procedures?
- 8 • What is the effectiveness of surgical management of stress urinary incontinence (including  
9 mesh and non-mesh procedures) compared to pelvic floor muscle training?

10

# 1 Surgical and conservative management of 2 stress urinary incontinence

## 3 Review question

4 What is the most effective surgical management of stress urinary incontinence, including  
5 mesh and non-mesh procedures?

## 6 Introduction

7 The objective of this review is to identify effective surgical treatment options for stress urinary  
8 incontinence in adult women, updating the review performed and the recommendations  
9 made in the previous guideline. The need to update this question has been highlighted by the  
10 reports of serious adverse events occurring in women who have received mesh or mesh  
11 sling surgery.

## 12 Summary of the protocol

13 For a summary of the Population, Intervention, Comparison and Outcomes (PICO) see Table  
14 1.

### 15 Table 1: Summary of protocol (PICO table)

<b>Population</b>	<p>Women (aged 18 and over) with stress urinary incontinence who have failed conservative treatment or declined conservative treatment; OR, women with mixed UI with confirmed stress predominance who have failed conservative treatment or declined conservative treatment</p> <p>Women who are naïve to treatment or having repeat surgery</p> <p>Women with urodynamic stress incontinence (USI); concurrent intrinsic sphincter deficiency (ISD); concurrent overactive bladder (OAB); or concurrent POP (as indicated by the POP-Q system)</p>
<b>Intervention</b>	<ul style="list-style-type: none"><li>• Suburethral slings (synthetic mesh)<ul style="list-style-type: none"><li>○ Retropubic bottom-up (e.g. TVT, IVS)</li><li>○ Retropubic top-down (e.g. SPARC)</li><li>○ Transobturator inside-out (TVT-O)</li><li>○ Transobturator outside-in (TOT, e.g. MONARC, Obtape)</li><li>○ Single-incision mini-slings (SIMS)<ul style="list-style-type: none"><li>- Non-adjustable (e.g. Contasure Needleless, TVT-Secur, MiniArc, Ophira)</li><li>- Adjustable (retropubic [e.g. Ajust], transobturator [TOA])</li></ul></li></ul></li><li>• Colposuspension (Burch, paravaginal fascial repair)<ul style="list-style-type: none"><li>○ Open abdominal retropubic suspension</li><li>○ Laparoscopic retropubic suspension with sutures</li></ul></li><li>• Biological slings<ul style="list-style-type: none"><li>○ Autologous rectus fascial sling</li><li>○ Non-autologous slings (allografts, xenografts [e.g. porcine])</li></ul></li><li>• Para or transurethral injections (bulking agents)<ul style="list-style-type: none"><li>○ Bulkamid (polyacrylamide hydrogel)</li><li>○ Macroplastique (water soluble gel with silicone elastomer)</li><li>○ Captive</li><li>○ Collagen</li></ul></li></ul>

<b>Comparison</b>	<ul style="list-style-type: none"> <li>• Artificial sphincters</li> <li>• Synthetic sling versus colposuspension</li> <li>• Synthetic sling versus biological sling <ul style="list-style-type: none"> <li>○ Synthetic sling vs autologous sling (e.g. TVT vs rectus fascial sling)</li> <li>○ Synthetic sling vs non-autologous biological sling (e.g. TVT vs porcine dermis sling)</li> </ul> </li> <li>• Retropubic route (e.g. TVT) versus Transobturator route (e.g. TOT)</li> <li>• (Non-adjustable) Single-incision mini-sling versus other synthetic sling (e.g. TVT-Secur vs TOT)</li> <li>• Adjustable sling versus other synthetic sling (e.g. TOA vs TVT)</li> <li>• Laparoscopic colposuspension versus open colposuspension</li> <li>• Colposuspension versus biological sling <ul style="list-style-type: none"> <li>○ Colposuspension vs autologous sling</li> <li>○ Colposuspension vs non-autologous biological sling</li> </ul> </li> <li>• Bulking agent versus other surgical technique</li> <li>• Artificial sphincter versus other surgical technique</li> </ul>
<b>Outcomes</b>	<p><b>Critical</b></p> <ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life <ul style="list-style-type: none"> <li>○ ICIQ</li> <li>○ BFLUTS-SF</li> <li>○ i-QOL</li> <li>○ SUIQQ</li> <li>○ UISS</li> <li>○ SEAPI-QMM</li> <li>○ ISI</li> <li>○ KHQ</li> <li>○ E-PAQ for UI-specific QoL</li> <li>○ PISQ-12 for sexual function</li> </ul> </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>• Complications <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</li> <li>○ De novo overactive bladder symptoms <ul style="list-style-type: none"> <li>- Urge incontinence</li> <li>- Frequency</li> <li>- Urgency</li> <li>- Nocturia</li> </ul> </li> <li>○ Occurrence of POP</li> <li>○ Wound complications</li> </ul> <p>Complications will be stratified by short-term (<math>\leq 1</math> year), medium-term (<math>&gt;1</math> year to <math>\leq 5</math> years), and long-term (<math>&gt;5</math> years)</p> <p><b>Important</b></p> <ul style="list-style-type: none"> <li>• Change in continence status</li> </ul> </li></ul>

- Subjective report
- Objective cure rate
- Negative stress (cough) test
- Number of incontinence episodes per day
- Patient satisfaction/patient-reported improvement
  - Patient global impression of improvement (PGI-I)
- Repeat surgery for UI or POP, or mesh complications

1 *BFLUTS-SF: Bristol Lower Urinary Tract Symptoms Scored Form; EPAQ: Electronic Patient*  
 2 *Assessment Questionnaire-Pelvic Floor; ICIQ: International Consultation on Incontinence Modular*  
 3 *Questionnaire; ISI, Incontinence Severity Index; I-QoL: Urinary Incontinence Quality of Life Scale; IVS:*  
 4 *intravaginal slingplasty; KHQ: King's Health Questionnaire; POP: pelvic organ prolapse; SEAPI-QMM;*  
 5 *Stress, Emptying Ability, Anatomy, Protection, Inhibition of bladder activity-Quality of life, Mobility,*  
 6 *Mental status standardised reporting system; SUIQQ: Stress and Urgency Incontinence and Quality*  
 7 *of Life Questionnaire; TOT: (synthetic) transobturator inside-out mesh sling; UI: urinary incontinence;*  
 8 *UISS: Urinary Incontinence Severity Score.*  
 9 *Brands of mesh sling: AMS MONARC, Bard Ajust; Boston Scientific MiniArc; Contasure-Needleless;*  
 10 *Mentor Obtape, AMS SPARC, Gynecare TVT, Gynecare TVT-O, Gynecare TVT-Secur, Promedon*  
 11 *Ophira.*

12 For details see the review protocol in appendix A.

### 13 **Methods and process**

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

18 For the composite cure outcome and patient satisfaction/patient-reported improvement  
 19 outcome at approximately 1 year after surgery the guideline committee considered the  
 20 published NMA ( ) that examined the effectiveness of surgical  
 21 options for stress urinary incontinence. The version of that was considered  
 22 by the NICE guideline committee was a draft version of the manuscript dated July 2018.  
 23 That version is yet to complete the editorial review process in line with the National Institute  
 24 for Health Research (NIHR) Journals Library policy.

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

### 29 **Clinical evidence**

#### 30 **Included studies**

31 One hundred and forty-one articles reporting 109 RCT were identified as relevant to the  
 32 review on the clinical effectiveness and short- and medium-term complications of surgery for  
 33 stress urinary incontinence (SUI). The majority of studies were two-arm RCT that compared  
 34 either the retropubic and transobturator routes of delivering a synthetic midurethral mesh  
 35 sling (MUS) or a single-incision mini-sling (SIMS) with a more traditional synthetic MUS. No  
 36 relevant RCT that compared an artificial sphincter to an alternative SUI surgical technique  
 37 were identified. The majority of studies included women with some degree of POP although it  
 38 was unclear in the majority of them whether the participants had received concomitant POP  
 39 surgery. The majority of studies also failed to explicitly report whether participants had failed  
 40 or declined conservative treatment such as pelvic floor muscle training.

1 Sixteen articles reporting 12 RCT were identified that compared colposuspension to a  
2 synthetic mesh sling in women with pure SUI, stress-predominant mixed UI, or urodynamic  
3 stress incontinence (Bai 2005; Bandarian 2011; El-Barky 2005; Foote 2006; Liapis 2002;  
4 Paraiso 2004/Jelovsek 2008; Persson 2002; Sivaslioglu 2007; Trabuco 2016, 2018; Ustun  
5 2003; Wang 2003; Ward 2002, 2004, 2008). One RCT was a 3-arm trial that compared TVT,  
6 autologous (rectus) fascial sling, and open colposuspension (Bai 2005). Seven articles  
7 reporting six trials compared open colposuspension with sutures to a retropubic mesh sling  
8 (Bai 2005; El-Barkey 2005; Liapis 2002; Trabuco 2016, 2018; Wang 2003; Ward 2002, 2004,  
9 2008) with all the studies using a bottom-up mesh sling (TVT). Four of the studies compared  
10 laparoscopic colposuspension with sutures to a retropubic mesh sling (Foote 2006; Paraiso  
11 2004/Jelovsek 2008; Persson 2002; Ustun 2003) with one study using a top-down  
12 suprapubic arch sling (SPARC) and three studies using a bottom-up mesh sling (TVT). Two  
13 of the studies compared open colposuspension with sutures to transobturator mesh sling  
14 (Bandarian 2011; Sivaslioglu 2007) both of which used an outside-in mesh sling (TOT). No  
15 studies were identified that compared laparoscopic colposuspension to a transobturator  
16 mesh sling. The majority of studies reported follow up times of 12 and/or 24 months, whilst  
17 the longest follow up time was 65 months. Only four studies reported in 6 articles excluded  
18 participants from having concomitant POP surgery (Bai 2005; Foote 2006; Sivaslioglu 2007;  
19 Ward 2002, 2004, 2008), whilst all the participants in the study by Trabuco 2016 had  
20 concomitant POP surgery.

21 Seventeen articles reporting 14 RCT were identified that compared a biological sling to a  
22 synthetic mesh sling in women with pure SUI, stress-predominant mixed UI, or urodynamic  
23 stress incontinence (Al-Azzawi 2014; Amaro 2009; Arunkalaivanan 2003/Abdel-Fattah 2004;  
24 Bai 2005; Basok 2008; Guerrero 2010/Khan 2015; Sharifiaghdas 2008/Sharifiaghdas 2017;  
25 Sharifiaghdas 2015; Silva-Filho 2006; Tcherniakovsky 2009; Teleb 2011; Ugurlucan 2013a;  
26 Wadie 2005; Wadie 2010). Three of the RCT were 3-arm trials, one of which compared TVT,  
27 an autologous rectus fascial sling and open Burch colposuspension (Bai 2005), one which  
28 compared autologous rectus fascial sling, porcine dermis sling and vaginal wall sling (Teleb  
29 2011) and one which compared TVT, an autologous rectus fascial sling and porcine dermis  
30 sling (Guerrero 2010/Khan 2015). Fourteen articles reporting 11 trials compared an  
31 autologous rectus fascial sling to a synthetic mesh sling (Al-Azzawi 2014; Amaro 2009; Bai  
32 2005; Guerrero 2010/Khan 2015; Sharifiaghdas 2008, 2017; Sharifiaghdas 2015; Silva-Filho  
33 2006; Tcherniakovsky 2009; Teleb 2011; Ugurlucan 2013a; Wadie 2005; Wadie 2010); 2 of  
34 these studies used an adjustable transobturator outside-in mesh sling (TOA; Silva-Filho  
35 2006; Tcherniakovsky 2009), 1 study used a transobturator outside-in mesh sling (TOT; Al-  
36 Azzawi 2014), 1 study used a SIMS (Sharifiaghdas 2015), whilst the remaining 7 studies  
37 used a retropubic bottom-up mesh sling (TVT). Four studies compared a non-autologous  
38 biological (e.g. allograft or xenograft) sling to a synthetic mesh sling: 3 of these compared a  
39 porcine dermis sling to a synthetic mesh sling (Arunkalaivanan 2003/Abdel-Fattah 2004;  
40 Guerrero 2010/Khan 2015; Ugurlucan 2013a) whilst 1 study compared cadaveric fascia lata  
41 to an intravaginal slingplasty (IVS) (Basok 2008). The majority of studies reported follow up  
42 times of at least 12 months, whilst the longest follow up time was a median 126 months. Only  
43 1 study excluded participants from having concomitant POP surgery (Teleb 2011), with the  
44 majority of studies failing to report whether participants had concomitant POP surgery.

45 Fifty-four articles reporting 40 RCT compared a (synthetic) transobturator sling with a  
46 (synthetic) retropubic mesh sling in women with pure SUI, stress-predominant mixed UI, or  
47 urodynamic stress incontinence (Aigmuller 2014/Tammaa 2017; Alkady 2009; Andonian  
48 2007; Aniuliene 2009; Aniuliene 2015; Araco 2008; Barber 2008; Barry 2008; David-  
49 Montefiore 2006/Ballester 2012/Darai 2007; Deffieux 2010; El-Hefnawy 2010; Feng 2018;  
50 Freeman 2011; Jakimuk 2012; Karateke 2009; Krofta 2010; Laurikainen 2007, 2014/Rinne  
51 2008; Liapis 2006; Meschia 2007; Nyyssonen 2014; Palos 2018; Porena 2007/Costantini  
52 2016; Rechberger 2009; Richter 2010/Albo 2012/Brubaker 2011/Kenton 2015/Wai  
53 2013/Zyczynski 2012; Ross 2009, 2016; Scheiner 2012; Schierlitz 2008, 2012; Shirvan 2014;

1 Tanuri 2010; Tarcan 2014; Teo 2011; Ugurlucan 2013b; Wadie 2013; Wang 2006; Wang  
2 2009; Wang 2010; Wang 2011; Zhang 2016; Zhu 2007; Zullo 2007/Angioli 2010). Two  
3 studies were three-arm trials: one compared two types of retropubic mesh sling to a  
4 transobturator mesh sling (Andonian 2007), whilst one compared a retropubic and a  
5 transobturator mesh sling to an SIMS (Wang 2011). The majority of transobturator mesh  
6 slings used were TVT-O and TOT, whilst the majority of retropubic mesh sling used were  
7 TVT with only a handful of studies examining other brands of sling. The majority of studies  
8 reported follow up times of 12 months, whilst the longest follow up time was 100 months.  
9 Only 8 of the 40 trials excluded participants from having concomitant POP surgery (Aigmuller  
10 2014/Tammaa 2017; Deffieux 2010; Feng 2018; Jakimuk 2012; Krofta 2010; Liapis 2006;  
11 Nyssonen 2014; Ross 2009, 2016).

12 Thirty articles reporting 24 RCT were identified that compared a (non-adjustable) single-  
13 incision mini-sling (SIMS) to another type of synthetic mesh sling in women with pure SUI,  
14 stress-predominant mixed UI, or urodynamic stress incontinence (Abdelwahab 2010;  
15 Andrada Hamer 2011/2013; Barber 2012; Basu 2010, 2013; Bianchi-Ferraro 2013, 2014;  
16 Dogan 2018; Fernandez-Gonzalez 2017; Foote 2015; Fu 2017; Gaber 2016; Hinoul 2011;  
17 Hota 2012; Lee 2015; Masata 2012; Maslow 2014; Oliveira 2011; Pastore 2016; Ross 2014;  
18 Schellart 2014, 2016, 2017; Tang 2014; Tieu 2017; Tommaselli 2010; Tommaselli  
19 2013/2015; Wang 2011). Four of the 24 RCT were 3-arm studies, 3 of which compared 2  
20 types of SIMS to another type of synthetic mesh sling (Gaber 2016; Masata 2012; Oliveira  
21 2011) with the remaining study comparing one type of SIMS to 2 other types of synthetic  
22 mesh sling (Wang 2011). The majority of studies compared the TVT-Secur SIMS to a  
23 synthetic mesh sling, with 10 studies (Bianchi-Ferraro 2013, 2014; Hinoul 2011; Hota 2012;  
24 Masata 2012; Maslow 2014; Oliveira 2011; Tang 2014; Tommaselli 2010; Tommaselli  
25 2013/2015; Wang 2011) using a transobturator inside-out mesh sling (TVT-O) and 5 studies  
26 (Abdelwahab 2010; Andrada Hamer 2011/2013; Barber 2012; Ross 2014; Wang 2011) using  
27 a retropubic bottom-up mesh sling (TVT). Six studies (Basu 2010, 2013; Foote 2015; Lee  
28 2015; Oliveira 2011; Schellart 2014, 2016, 2017; Tieu 2017) compared the MiniArc SIMS to  
29 a synthetic mesh sling, four of which used a transobturator outside-in mesh sling (TOT;  
30 Foote 2015; Lee 2015; Schellart 2014, 2016, 2017; Tieu 2017), one which used a retropubic  
31 bottom-up mesh sling (TVT; Basu 2010, 2013) and one which used a transobturator inside-  
32 out mesh sling (TVT-O; Oliveira 2011). Four studies (Dogan 2018; Fernandez-Gonzalez  
33 2017; Fu 2017; Gaber 2016) compared a needleless SIMS to a transobturator outside-in  
34 mesh sling (TOT), whilst 1 study did not specify the type of SIMS used (Pastore 2016). The  
35 majority of studies reported follow up times of 12 months, whilst the longest follow up time  
36 was 60 months. Only 7 studies prevented participants from having concomitant POP surgery  
37 (Andrada Hamer 2011/2013; Dogan 2018; Foote 2015; Hinoul 2011; Masata 2012; Ross  
38 2014; Tang 2014; Wang 2011).

39 Twelve articles reporting 10 RCT were identified that compared an adjustable (synthetic)  
40 mesh sling to another type of synthetic mesh sling in women with pure SUI, stress-  
41 predominant mixed UI, or urodynamic stress incontinence (Djehdian 2014; Elbadry 2015;  
42 Jurakova 2016; Masata 2016; Mostafa 2012, 2013; Rudnicki 2017; Sabadell 2017;  
43 Schweitzer 2015; Sivaslioglu 2010/2012; Xin 2016). Nine of these examined an adjustable  
44 SIMS, whilst one study (Elbadry 2015) examined an adjustable transobturator mesh sling.  
45 Five studies (Jurakova 2016; Masata 2016; Mostafa 2012, 2013; Schweitzer 2015; Xin 2016)  
46 compared an adjustable SIMS to a transobturator inside-out mesh sling (TVT-O); 2 studies  
47 (Djehdian 2014; Sivaslioglu 2010/2012) compared it to a transobturator outside-in mesh sling  
48 (TOT); 1 study (Rudnicki 2017) compared it to a variety of other synthetic midurethral mesh  
49 slings (i.e. TOT, TVT-O or TVT); whilst 1 study (Elbadry 2015) compared an adjustable  
50 transobturator mesh sling to a transobturator outside-in mesh sling. The majority of studies  
51 reported follow up times of 12 months, whilst the longest follow up time was 64 months. Only  
52 2 studies excluded participants from having concomitant POP surgery (Jurakova 2016;  
53 Masata 2016).

1 Seven RCT were identified that compared laparoscopic colposuspension with sutures to  
2 open colposuspension with sutures in women with pure SUI, stress-predominant mixed UI, or  
3 urodynamic stress incontinence (Ankardal 2005; Carey 2006; Cheon 2003; fatty 2001;  
4 Kitchener 2006; Su 1997; Ustun 2005). The majority of studies reported follow up times of 12  
5 months, whilst the longest follow up time was 24 months. Two of the studies excluded  
6 women from having concomitant POP surgery (Ankardal 2005; Kitchener 2006).

7 Seven articles reporting 4 RCT were identified that compared an autologous rectus fascial  
8 sling to colposuspension in women with pure SUI, stress-predominant mixed UI, or  
9 urodynamic stress incontinence (Albo 2007/ Brubaker 2012/Chai 2009; Bai 2005; Demirci  
10 2001; Sand 2000/Culligan 2003). All of the studies compared fascial sling to open Burch  
11 colposuspension with sutures. One RCT (Bai 2005) was a 3-arm study that also compared  
12 TVT to fascial sling and open Burch colposuspension. Three of the studies included at least  
13 some participants who had concomitant POP surgery (Albo 2007/ Brubaker 2012/Chai 2009;  
14 Demirci 2001; Sand 2000/Culligan 2003). Reported followup in the included studies ranged  
15 from 3 months to 72.6 months.

16 One RCT compared macroplastique bulking agent to an autologous rectus fascial sling in  
17 women with SUI and intrinsic sphincter deficiency who had failed conservative treatment  
18 (Maher 2005). This study had a median follow up of 61 months and excluded women with  
19 concomitant POP surgery.

20 Five RCT (Guerrero 2010; Porena 2007; Sharifiaghdas 2008; Sivaslioglu 2010; Zhang 2010)  
21 and 41 observational studies provided data on long-term complications (i.e. greater than 60  
22 months). The observational studies were comprised of 3 prospective cohort studies  
23 (Abougamrah 2015; Ala-Nissila 2010; Antovska 2013), 6 retrospective cohort studies (Al-  
24 Zahrani 2016; Betschart 2011; Chun 2014; Greenwell 2015; Holdo 2017; Tutolo 2017), and  
25 32 case series (Aigmuller 2011; Alcalay 1995; Athanasiou 2014; Braga 2018; Chevrot 2016;  
26 Doo 2006; Errando-Smet 2018; Giberti 2017; Han 2014; Hawkins 2002; Heinonen 2013;  
27 Holmgren 2007; Kjolhede 2005; Kuuva 2006; Ladwig 2004; Lee 2010; Lo 2018; Montera  
28 2018; Nilsson 2004, 2008, 2013; Olsson 2010; Punjani 2017; Reich 2011; Riggs 1986;  
29 Schauer 2017; Serati 2017a; Serati 2017b; Song 2017; Svenningsen 2013; Tsivian 2006;  
30 Ulrich 2016). The majority of long-term complications data were identified for synthetic mesh  
31 slings (including transobturator and retropubic mesh slings, SIMSs and adjustable mesh  
32 slings), with only a handful of studies reporting on long-term complications of  
33 colposuspension and fascial and porcine dermis slings.

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

### 37 **Excluded studies**

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

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40

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

2 A summary of the studies that were included in this review are presented in Table 2, Table 3, Table 4, Table 5, Table 6, Table 7, Table 8, Table 9,  
3 Table 10 and Table 11.

## 4 Colposuspension versus synthetic mesh sling

### 5 Table 2: Summary of included RCT studies for colposuspension versus synthetic mesh sling

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of colposuspension	Type of synthetic mesh sling	Outcomes
Bai 2005 <sup>1</sup> South Korea	64 <sup>2</sup>	Grade 1 or 2 SUI	12	NR	• Open Burch colposuspension	• TVT	• Change in continence status
Bandarian 2011 Iran	62	Continence Incontinence surgery-naïve SUI who failed medical or conservative treatment	Mean 25	NR	• Open Burch colposuspension	• TOT	• Adverse events • Complications • Change in continence status • Improvement in continence status
El-Barky 2005 Egypt	50	USI	3-6	NR	• Open Burch colposuspension	• TVT	• Adverse events
Foote 2006 Australia	97	USI	6, 24	No	• Laparoscopic colposuspension	• SPARC	• Adverse events • Complications • Improvement in continence status
Liapis 2002 Greece	71	Incontinence surgery-naïve genuine SI and ≤stage 1 anterior wall prolapse	24	Y	• Open Burch colposuspension	• TVT	• Adverse events • Complications • Change in continence status

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of colposuspension	Type of synthetic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Improvement in continence status</li> </ul>
Paraiso 2004//Jelovsek 2008 USA	72	Primary USI	Mean 20.6/Median 65	Y	<ul style="list-style-type: none"> <li>• Laparoscopic colposuspension</li> </ul>	<ul style="list-style-type: none"> <li>• TVT</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>
Persson 2002 Sweden	79	USI or stress-predominant MUI	12	No	<ul style="list-style-type: none"> <li>• Laparoscopic colposuspension</li> </ul>	<ul style="list-style-type: none"> <li>• TVT</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Sivaslioglu 2007 Turkey	100	Incontinence surgery-naïve USI	12, 24	NR	<ul style="list-style-type: none"> <li>• Open Burch colposuspension</li> </ul>	<ul style="list-style-type: none"> <li>• TOT</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Trabuco 2016/2018 USA	113	SUI, stress-predominant MUI, or occult SUI and apical or anterior prolapse stage≥2	12/24	100%	<ul style="list-style-type: none"> <li>• Open Burch colposuspension</li> </ul>	<ul style="list-style-type: none"> <li>• TVT</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of colposuspension	Type of synthetic mesh sling	Outcomes
Ustun 2003 Turkey	46	Proven genuine SI	Mean 25	NR	• Laparoscopic colposuspension	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Change in continence status</li> </ul>
Wang 2003 Taiwan	116	USI	Median 22	No	• Open Burch colposuspension	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Ward 2002/2004/2008 UK	344	USI who failed PFMT	6/24/60	No	• Open Burch colposuspension	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>

1 Notes: All colposuspension interventions used sutures. Studies using mesh and staples were not included in this review as their use are not UK standard practice; 1, Bai 2005 was  
2 a 3-arm study that also compared rectus fascial sling (n=28) to TVT and open Burch colposuspension. 2, Sample size is for the TVT and colposuspension arms only.  
3 Abbreviations: HR-QoL: health-related quality of life; MUI: mixed urinary incontinence; NR: not reported; PFMT: pelvic floor muscle training; SI: stress incontinence; SPARC:  
4 retropubic top-down suprapubic arch sling; SUI: stress urinary incontinence; TOT: transobturator outside-in tape; TVT: retropubic bottom-up tension-free vaginal tape; USI:  
5 urodynamic stress incontinence.

6 See appendix D for full evidence tables.

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## 1 Autologous rectus fascial sling versus synthetic mesh sling

2 **Table 3: Summary of included RCT studies for autologous sling versus synthetic mesh sling**

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
Al-Azzawi 2014 Iraq	80	SUI or stress-predominant MUI	12	NR	• Rectus fascial sling	• TOT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Amaro 2009 Brazil	41	SUI and USI	12, Median 44	NR	• Rectus fascial sling	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Bai 2005 <sup>1</sup> South Korea	59 <sup>2</sup>	Grade 1 or 2 SUI	12	NR	• Rectus fascial sling	• TVT	<ul style="list-style-type: none"> <li>• Change in continence status</li> </ul>
Guerrero 2010/Khan 2015 <sup>3</sup> UK	156 <sup>2</sup>	SUI and USI	12/median 120	NR	• Rectus fascial sling	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
Sharifiaghdas 2008/Sharifiaghdas 2017 Iran	100	History of SUI and USI	12, Mean 39/Mean 126	NR	<ul style="list-style-type: none"> <li>Rectus fascial sling</li> </ul>	<ul style="list-style-type: none"> <li>TVT</li> </ul>	<ul style="list-style-type: none"> <li>Adverse events</li> <li>Complications</li> <li>Change in continence status</li> <li>Improvement in continence status</li> <li>Repeat surgery</li> </ul>
Sharifiaghdas 2015 Iran	72	History of SUI and USI who failed conservative treatment	Mean 13.8	NR	<ul style="list-style-type: none"> <li>Rectus fascial sling</li> </ul>	<ul style="list-style-type: none"> <li>SIMS (Ophira)</li> </ul>	<ul style="list-style-type: none"> <li>Adverse events</li> <li>Complications</li> <li>Change in continence status</li> <li>Improvement in continence status</li> <li>Repeat surgery</li> </ul>
Silva-Filho 2006 Brazil	20	USI and no DO	6	NR	<ul style="list-style-type: none"> <li>Rectus fascial sling</li> </ul>	<ul style="list-style-type: none"> <li>TOA (SAFYRE)</li> </ul>	<ul style="list-style-type: none"> <li>Continence-specific health-related quality of life</li> <li>Adverse events</li> <li>Complications</li> <li>Change in continence status</li> </ul>
Tcherniakovsky 2009 Brazil	41	SUI and USI	12	NR	<ul style="list-style-type: none"> <li>Rectus fascial sling</li> </ul>	<ul style="list-style-type: none"> <li>TOA (SAFYRE)</li> </ul>	<ul style="list-style-type: none"> <li>Adverse events</li> <li>Complications</li> <li>Change in continence status</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
Teleb 2011 <sup>4</sup> Egypt	24 <sup>2</sup>	Primary SUI and USI	Mean 18	No	• Rectus fascial sling	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Wadie 2005 Egypt	53	Primary SUI	6	NR	• Rectus fascial sling	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Wadie 2010 Egypt	63	SUI	Median 54	43%	• Rectus fascial sling	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>

1 Notes: <sup>1</sup>, Bai 2005 was a 3-arm study that also compared open Burch colposuspension (n=33) to TVT and rectus fascial sling; <sup>2</sup>, Sample size is for the TVT and fascial sling arms  
2 only; <sup>3</sup>, Guerrero 2010 was a 3-arm study that also compared porcine dermis sling (n=52) to TVT and rectus fascial sling; <sup>4</sup>, Teleb 2011 was a 3-arm study that also compared  
3 vaginal wall sling (n=8) to TVT and rectus fascial sling.  
4 Abbreviations: DO: detrusor overactivity; HR-QoL: health-related quality of life; MUI: mixed urinary incontinence; NR: not reported; SIMS: single-incision mini-sling; SUI: stress  
5 urinary incontinence; TOA: adjustable transobturator outside-in tape; TOT: transobturator outside-in mesh sling; TVT: retropubic bottom-up tension-free vaginal mesh sling; USI:  
6 urodynamic stress incontinence.

7 See appendix D for full evidence tables.

## 1 Non-autologous biological sling versus synthetic mesh sling

2 **Table 4: Summary of included RCT studies for non-autologous biological sling versus synthetic mesh sling**

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
Arunkalaivanan 2003/Abdel-Fattah 2004 UK	142	USI who failed conservative treatment	1.4, 6, 24/36	NR	• Porcine dermis sling	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Basok 2008 Turkey	139	SUI due to urethral hypermobility	12	NR	• Cadaveric fascia lata sling	• Retropubic IVS	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Guerrero 2010/Khan 2015 <sup>1</sup> UK	124 <sup>2</sup>	SUI and USI	12/median 120	NR	• Porcine dermis sling	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>
Ugurlucan 2013a Turkey	100	SUI or USI who failed conservative treatment	12	56%	• Porcine dermis sling	• Align-TO	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>

1 Notes: 1, Guerrero 2010 was a 3-arm study that also compared rectus fascial sling (n=84) with TVT and porcine dermis sling; 2, Sample size is for the TVT and porcine dermis  
2 arms only.  
3 Abbreviations: HR-QoL: health-related quality of life; IVS: retropubic bottom-up intravaginal slingplasty; NR: not reported; SUI: stress urinary incontinence; TO: transobturator mesh  
4 sling; TVT: retropubic bottom-up tension-free tape.

5 See appendix D for full evidence tables.

## 6 Transobturator mesh sling versus retropubic mesh sling

7 **Table 5: Summary of included RCT studies for transobturator mesh sling versus retropubic mesh sling**

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of transobturator mesh sling	Type of retropubic mesh sling	Outcomes
Aigmuller 2014/ Tammaa 2017 Austria	569	Incontinence surgery-naïve USI	3/60	No	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Alkady 2009 Kuwait	30	Pure USI or mixed UI without urodynamically-confirmed contraction	12	Yes if required	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Andonian 2007 Canada	190	SUI or stress-predominant MUI	12	NR	• TOT	• TVT or DUPS	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of transobturator mesh sling	Type of of retropubic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Repeat surgery</li> </ul>
Aniuliene 2009 Lithuania	264	SUI and no OAB	12	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Aniuliene 2015 Lithuania	154	History of SUI, USI and no predominant-OAB	12	NR	• SLING-IUFT	• TVT-EXACT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Araco 2008 Italy	240	Symptomatic Grade 1 or 2 SUI and no OAB	12	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Barber 2008 USA	170	USI and no DO	Mean 18.2	NR	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>
Barry 2008 Australia	187	Symptomatic SUI who failed conservative treatment or surgery for occult SUI during POP repair	3	NR	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
David-Montefiore 2006/Darai 2007/Ballester 2012 France	88	SUI and USI	Mean 10/Mean 52.9	NR	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Deffieux 2010 France	149	USI or MUI, and positive cough stress test	12, 2	No	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of transobturator mesh sling	Type of of retropubic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>
El-Hefnawy 2010 Egypt	40	USI	Mean 19.7	23%	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Feng 2018 China	148	SUI and USI	6, 12, 24	No	• TVT-ABBREVO	• TVT-EXACT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Freeman 2011 UK	192	USI or stress-predominant MUI who failed PFMT	12	NR	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Jakimuk 2012 Poland	35	Incontinence surgery-naïve USI	6	No	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Karateke 2009 Turkey	167	Incontinence surgery-naïve USI and no DO or OAB	12, Mean 14	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Krofta 2010 Czech Republic	300	Incontinence and prolapse surgery-naïve USI who	12	No	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of transobturator mesh sling	Type of of retropubic mesh sling	Outcomes
		failed conservative treatment					<ul style="list-style-type: none"> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Laurikainen 2007/Rinne 2008/Laurikainen 2014 Finland	273	History of SUI, positive cough stress test, detrusor instability score≤7	2/12/60	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Liapis 2006 Greece	91	Incontinence surgery-naïve SUI and no OAB	12	No	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Meschia 2007 Italy	231	Incontinence surgery-naïve SUI, urethral hypermobility and no DO	Median 6	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Nyyssonen 2014 Finland	100	SUI or stress-predominant MUI who failed conservative treatment	Median 14, Median 46	No	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Palos 2018 Brazil	92	Incontinence surgery-naïve USI	12	20%	• TOT	• Unitape VS	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Porena 2007/Costantini 2016 Italy	148	Incontinence surgery-naïve SUI or stress-predominant MUI	Median 35/median 100	NR	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of transobturator mesh sling	Type of of retropubic mesh sling	Outcomes
Rechberger 2009 Poland	537	SUI	18	NR	• IVS-04	• IVS-02	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>
Richter 2010/ Brubaker 2011/Albo 2012/Wai 2013/Kenton 2015 USA/Zyczynski 2012	597	SUI	12/24/60	Yes if required	• TOT or TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Ross 2009/2016 Canada	199	Incontinence surgery-naïve SUI, positive cough stress test and no OAB	12/60	No	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Scheiner 2012 Switzerland	160	Incontinence surgery-naïve USI or stress-predominant MUI	Mean 12.6	8%	• TOT or TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Schierlitz 2008/2012 Australia	164	SUI and ISD who failed conservative treatment	6/36	34%	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Shirvan 2014	100	Stress-predominant UI and positive	12, 18	NR	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of transobturator mesh sling	Type of of retropubic mesh sling	Outcomes
Iran		cough stress test who failed conservative treatment					<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Tanuri 2010 Brazil	30	SUI	12	NR	• TOT	• Retropubic midurethral sling	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Tarcan 2014 Turkey	54	Pure or stress dominant USI	Median 48.5	14.3%	• Obtryx-TO	• Advantage	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> </ul>
Teo 2011 UK	127	Incontinence surgery-naïve USI and no DO	12	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Ugurlucan 2013b Turkey	36	SUI or MUI	Mean 18.4	81%	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Wadie 2013 Egypt	87	Stress-predominant UI and positive stress test	12, 24	NR	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Wang 2006 Taiwan	60	Incontinence surgery-naïve USI	Median 9	NR	• TOT	• SPARC	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> </ul>
Wang 2009 China	315	Mild, moderate or severe SUI who failed conservative treatment	Median 20	>68%	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Wang 2010 China	140	USI	12	37%	• TOT	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of transobturator mesh sling	Type of of retropubic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Change in continence status</li> </ul>
Wang 2011 <sup>1</sup> China	68	Incontinence surgery-naïve stress-predominant MUI	12	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> </ul>
Zhang 2016 China	140	Symptomatic SUI and no ISD	Mean 95	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Zhu 2007 China	56	Mild or moderate SUI who failed conservative treatment	Median 27.6	100%	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Zullo 2007/Angioli 2010 Italy	72	SUI and no OAB, ISD or DO	Median 16/median 60	NR	• TVT-O	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>

- 1 Notes: 1, Wang 2011 was a three-arm trial comparing SIMS (n=34) to TVT and TVT-O. Sample size is for the transobturator and retropubic arms only.
- 2 Abbreviations: DO: detrusor overactivity; DUPS: retropubic distal urethral polypropylene sling; HR-QoL: health-related quality of life; MUI: mixed urinary incontinence; NR: not reported; OAB: overactive bladder; SIMS: single-incision mini-sling; ISD: intrinsic sphincter deficiency; PFMT: pelvic floor muscle training; SUI: stress urinary incontinence; TOT: transobturator outside-in tape; TVT: retropubic bottom-up tension-free tape; TVT-O: transobturator inside-out tape; USI: urodynamic stress incontinence.

5 See appendix D for full evidence tables.

## 6 Single-incision mini-sling versus other synthetic mesh sling

7 **Table 6: Summary of included RCT studies for single-incision mini-sling versus other synthetic mesh sling**

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of single-incision mini-sling	Type of other synthetic mesh sling	Outcomes
Abdelwahab 2010	60	SUI and USI	9	NR	• TVT-S	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of single-incision mini-sling	Type of other synthetic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Andrada Hamer 2011/2013 Sweden	133	History of SUI and USI	12	No	• TVT-S-H	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Barber 2012 USA	263	USI	12	Yes if required	• TVT-S-U	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Basu 2010/2011	71	SUI and USI who failed conservative treatment	6/36	NR	• MiniArc	• TVT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Bianchi-Ferraro 2013/2014 Brazil	122	SUI and USI	12/24	NR	• TVT-S-U	• TVT-O	<ul style="list-style-type: none"> <li>• Continence-specific health-</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of single-incision mini-sling	Type of other synthetic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>related quality of life</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Dogan 2018 Turkey	201	Continence and prolapse surgery-naïve SUI who failed conservative treatment	12, 24	No	• Needleless	• TOT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Fernandez-Gonzalez 2017 Spain	187	Incontinence surgery-naïve SUI	Mean 28.5	Yes if required	• Needleless	• TOT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Foote 2015 Australia	50	USI	6	No	• MiniArc	• TOT	<ul style="list-style-type: none"> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Fu 2017 China	164	Urge incontinence and prolapse surgery-naïve and positive cough stress test	12	NR	• Needleless	• TOT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of single-incision mini-sling	Type of other synthetic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Complications</li> </ul>
Gaber 2016 Egypt	209	SUI and USI	12	Yes if required	<ul style="list-style-type: none"> <li>• Needleless</li> <li>• Endopelvic Free Anchorage</li> </ul>	<ul style="list-style-type: none"> <li>• TOT</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Hinoul 2011 Belgium, Netherlands	194	SUI and/or USI	12	No	<ul style="list-style-type: none"> <li>• TVT-S-H</li> </ul>	<ul style="list-style-type: none"> <li>• TVT-O</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Hota 2012 USA	87	History of SUI, SUI and positive cough stress test	12	49%	<ul style="list-style-type: none"> <li>• TVT-S-H</li> </ul>	<ul style="list-style-type: none"> <li>• TVT-O</li> </ul>	<ul style="list-style-type: none"> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Lee 2015 Australia	225	SUI or USI who failed conservative treatment	12	Y <sup>3</sup>	<ul style="list-style-type: none"> <li>• MiniArc</li> </ul>	<ul style="list-style-type: none"> <li>• TOT</li> </ul>	<ul style="list-style-type: none"> <li>• Change in continence status</li> </ul>
Masata 2012 Czech Republic	197	USI who failed conservative treatment	24	No	<ul style="list-style-type: none"> <li>• TVT-S-H</li> <li>• TVT-S-U</li> </ul>	<ul style="list-style-type: none"> <li>• TVT-O</li> </ul>	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of single-incision mini-sling	Type of other synthetic mesh sling	Outcomes
Maslow 2014 Canada	106	Incontinence surgery-naïve SUI and positive cough stress test	12	NR	• TVT-S-H	• TVT-O	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Oliveira 2011 Portugal	90	Incontinence surgery-naïve SUI and USI	12	NR	<ul style="list-style-type: none"> <li>• TVT-S</li> <li>• MiniArc</li> </ul>	• TVT-O	<ul style="list-style-type: none"> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Pastore 2016 Italy	48	Incontinence surgery-naïve pure SUI	Median 12	NR	• SIMS <sup>1</sup>	• TVT-O	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Ross 2014 Canada	74	Incontinence surgery-naïve SUI	12	No	• TVT-S	• TVT	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Schellart 2014/2016/ 2017 Belgium, France, Netherlands	193	SUI due to urethral hypermobility and/or ISD	12, 24	NR	• MiniArc	• TOT	<ul style="list-style-type: none"> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of single-incision mini-sling	Type of other synthetic mesh sling	Outcomes
Tang 2014 China	94	Pure SUI who failed conservative treatment	12, 24	No	• TVT-S	• TOT	<ul style="list-style-type: none"> <li>• Repeat surgery</li> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> </ul>
Tieu 2017 USA	98	Incontinence surgery-naïve USI	Median 15	Yes if required	• MiniArc	• TOT	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Tommaselli 2010 Italy	84	Incontinence surgery-naïve SUI and USI	12	NR	• TVT-S	• TVT-O	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Tommaselli 2013/2015 Italy	154	SUI and USI who failed PFMT	36/60	NR	• TVT-S-H	• TVT-O	<ul style="list-style-type: none"> <li>• Continence-specific health-</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of single-incision mini-sling	Type of other synthetic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>
Wang 2011 China	108	SUI or Stress-predominant MUI	12	No	• TVT-S (-U or -H) <sup>2</sup>	<ul style="list-style-type: none"> <li>• TVT</li> <li>• TVT-O</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> </ul>

1 Notes: TVT-Secur was manufactured by Gynecare, Ethicon Inc. and has been withdrawn from the UK market. 1, type of sling not reported; 2, hammock position used when  
 2 preoperative abdominal leak point pressure ≥ 60cmH<sub>2</sub>O, and U position used otherwise; 3, reports completer data according to whether participants had concomitant POP surgery  
 3 but numbers unclear.  
 4 Abbreviations: HR-QoL: health-related quality of life; MUI: mixed urinary incontinence; NR: not reported; SIMS: single-incision mini-sling; ISD: intrinsic sphincter deficiency; PFMT:  
 5 pelvic floor muscle training; SUI: stress urinary incontinence; TOT: transobturator outside-in tape; TVT: retropubic bottom-up tension-free vaginal tape; SI: stress incontinence;  
 6 TVT-O: transobturator inside-out tape; TVT-S: TVT-Secur; TVT-S-H: TVT-Secur hammock position; TVT-S-U: TVT-Secur U position; USI: urodynamic stress incontinence.

7 See appendix D for full evidence tables.

## 8 Adjustable mesh sling versus other synthetic mesh sling

9 **Table 7: Summary of included RCT studies for adjustable mesh sling versus other synthetic mesh sling**

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
Djehdian 2014 Brazil	130	USI	12	NR	• Ophira SIMS	• TOT	<ul style="list-style-type: none"> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Elbadry 2015 Egypt	96	Pure SUI	Mean 8.5	NR	• TOA	• TOT	<ul style="list-style-type: none"> <li>• Complications</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
							<ul style="list-style-type: none"> <li>• Change in continence status</li> </ul>
Jurakova 2016 Czech Republic	93	Continence and prolapse-naïve surgery pure USI	Mean 13.0	No	<ul style="list-style-type: none"> <li>• Ophira SIMS</li> </ul>	<ul style="list-style-type: none"> <li>• TVT-O</li> </ul>	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Masata 2016 Czech Republic	100	Pure USI who failed conservative treatment	Mean 14.9	No	<ul style="list-style-type: none"> <li>• Ajust SIMS</li> </ul>	<ul style="list-style-type: none"> <li>• TVT-O</li> </ul>	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Mostafa 2012/2013 UK	137	USI who failed or declined PFMT	4-6/12-18	NR	<ul style="list-style-type: none"> <li>• Ajust SIMS</li> </ul>	<ul style="list-style-type: none"> <li>• TVT-O</li> </ul>	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of adjustable mesh sling	Type of other synthetic mesh sling	Outcomes
Rudnicki 2017 Denmark, Norway & Sweden	307	Incontinence surgery-naïve pure SUI or stress-predominant MUI	12	NR	• Ajust SIMS	• MUS (Various TVT, TVT-O or TOT)	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Sabadell 2017 Spain	58	Eligible for SUI surgery	12	28%	• Ajust SIMS	• Align-TO	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Schweitzer 2015 Netherlands	156	Incontinence surgery-naïve moderate to severe SUI (Sandvik score $\geq$ 3) who failed PFMT	12	NR	• Ajust SIMS	• TVT-O	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>
Sivaslioglu 2010/2012 Turkey	80	Incontinence surgery-naïve pure SUI and VLPP $<$ 60 cm H <sub>2</sub> O who failed conservative treatment	1, Mean 36/Mean 64	NR	• TFS SIMS	• TOT (I-STOP)	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>
Xin 2016 China	368	Incontinence surgery-naïve SUI and USI who failed or declined PFMT	12	NR	• Ajust SIMS	• TVT-O	<ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> </ul>

1 MUI: mixed urinary incontinence; MUS: midurethral mesh sling; NR: not reported; SIMS: single-incision mini-sling; SI: stress incontinence; SUI: stress urinary incontinence; TFS:  
2 Tissue Fixation System; TOA: adjustable transobturator tape; TOT: transobutrator outside-in tape; TVT: retropubic bottom-up tension-free vaginal mesh sling; TVT-O:  
3 transobturator inside-out mesh sling; USI: urodynamic stress incontinence; VLPP: valsalva leak point pressure.

1 See appendix D for full evidence tables.

2 **Laparoscopic colposuspension with sutures versus open colposuspension with sutures**

3 **Table 8: Summary of included RCT studies for laparoscopic colposuspension versus open colposuspension**

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of colposuspension	Type of colposuspension	Outcomes
Ankardal 2005 <sup>1</sup> Sweden	132 <sup>2</sup>	SUI or stress-predominant MUI	12	No	• Laparoscopic colposuspension with sutures	• Open colposuspension with sutures	• Change in continence status
Carey 2006 Australia	200	USI who failed conservative treatment	6, 24	Only simple rectocele repair permitted	• Laparoscopic colposuspension with sutures	• Open colposuspension with sutures	• Adverse events • Complications • Change in continence status
Cheon 2003 Hong Kong, China	90	USI	12	26% hysterectomy	• Laparoscopic colposuspension with sutures	• Open colposuspension with sutures	• Adverse events • Complications • Change in continence status
Fatthy 2001 Egypt	74	USI	18	NR	• Laparoscopic colposuspension with sutures	• Open colposuspension with sutures	• Adverse events • Complications
Kitchener 2006 UK	291	USI	6, 12, 24	No	• Laparoscopic colposuspension with sutures	• Open colposuspension with sutures	• Adverse events • Change in continence status • Improvement in continence status
Su 1997 Taiwan	94	Incontinence surgery-naïve USI	12	30% hysterectomy	• Laparoscopic colposuspension with sutures	• Open colposuspension with sutures	• Complications • Change in continence status

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of colposuspension	Type of colposuspension	Outcomes
Ustun 2005 Turkey	52	History of SUI and USI	Mean 13.6	42%	<ul style="list-style-type: none"> <li>Laparoscopic colposuspension with sutures</li> </ul>	<ul style="list-style-type: none"> <li>Open colposuspension with sutures</li> </ul>	<ul style="list-style-type: none"> <li>Adverse events</li> <li>Complications</li> <li>Change in continence status</li> </ul>

1 Notes: 1, Ankardal 2005 was a three-arm trial that also examined the efficacy of laparoscopic colposuspension with mesh and staples. This arm was not included as the use of  
 2 mesh and staples is not standard UK practice; 2, number randomised does not include participants assigned to laparoscopic colposuspension with mesh and staples arm.  
 3 Abbreviations: HR QoL: health-related quality of life; MUI: mixed urinary incontinence; MUS: midurethral mesh sling; SUI: stress urinary incontinence; TVT: tension-free vaginal  
 4 tape; UK: United Kingdom.

5 See appendix D for full evidence tables.

## 6 Autologous rectus fascial sling versus colposuspension

### 7 Table 9: Summary of included RCT studies for fascial sling versus colposuspension

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of sling	Type of colposuspension	Outcomes
Albo 2007/ Chai 2009/ Brubaker 2012	655	SUI or stress-predominant MUI	24/60	58%	<ul style="list-style-type: none"> <li>Autologous Rectus Fascial Sling</li> </ul>	<ul style="list-style-type: none"> <li>Open Burch colposuspension with sutures</li> </ul>	<ul style="list-style-type: none"> <li>Adverse events</li> <li>Complications</li> <li>Change in continence status</li> <li>Improvement in continence status</li> </ul>
Bai 2005 <sup>1</sup> China	61 <sup>2</sup>	Grade 1 or 2 SUI	12	NR	<ul style="list-style-type: none"> <li>Autologous Rectus Fascial Sling</li> </ul>	<ul style="list-style-type: none"> <li>Open Burch colposuspension with sutures</li> </ul>	<ul style="list-style-type: none"> <li>Change in continence status</li> </ul>
Demirci 2001	46	USI and bladder neck hypermobility	12	37%	<ul style="list-style-type: none"> <li>Autologous Rectus Fascial Sling</li> </ul>	<ul style="list-style-type: none"> <li>Open Burch colposuspension with sutures</li> </ul>	<ul style="list-style-type: none"> <li>Complications</li> <li>Change in continence status</li> </ul>

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of sling	Type of colposuspension	Outcomes
Sand 2000/Culligan 2003	36	Genuine SI with urethral hypermobility	3/Mean 72.6	8.5%	• Autologous Rectus Fascial Sling	• Open Burch colposuspension with sutures	<ul style="list-style-type: none"> <li>• Adverse events</li> <li>• Complications</li> <li>• Change in continence status</li> <li>• Repeat surgery</li> </ul>

1 Notes: 1, Bai 2005 was a 3-arm study that also compared TVT (n=31) with rectus fascial sling and open Burch colposuspension. 2, Sample size is for the fascial sling and  
 2 colposuspension arms only.

3 Abbreviations: HR QoL: health-related quality of life; SUI: stress urinary incontinence.

4 See appendix D for full evidence tables.

## 5 Bulking agent versus other surgical technique

6 **Table 10: Summary of included RCT studies for bulking agent versus other surgical technique**

Study Country	Number randomised	Participants	Follow up (months)	Concomitant POP surgery	Type of bulking agent	Type of sling	Outcomes
Maher 2005 Australia	45	Women with SUI and ISD who failed conservative treatment	Median 61	No	• Macroplastique	• Autologous rectus fascial sling	<ul style="list-style-type: none"> <li>• Complications</li> <li>• Change in continence status</li> <li>• Improvement in continence status</li> <li>• Repeat surgery</li> </ul>

7 ISD: intrinsic sphincter deficiency.

8 See appendix D for full evidence tables.

9

- 1 **Artificial sphincter versus other surgical technique**
- 2 No relevant RCT were identified for this review.

## 1 Long-term complications (>5 years after surgery)

2 The majority of studies that reported long-term complications (greater than 5 years) were  
3 case series reports and therefore did not compare one surgical intervention with another (see  
4 Table 11). Meta-analysis was thus not possible. Instead, the rate of complications was  
5 calculated as weighted averages of the relevant studies including the 5 RCT that reported  
6 long-term complications data (see Table 12 and Table 13).

7 **Table 11: Summary of studies with long-term (>5 years) complication data**

Study Country Sample size Type of study	Intervention	Comparison	Length of followup Outcomes	Study quality <sup>1</sup>	Surgery Classification
Abougamrah 2015 Egypt N=431 Prospective cohort	Generic transobturator tape  With or without abdominal hysterectomy, myomectomy, vaginal hysterectomy (for non- prolapse) or colporrhaphy (for symptomatic stage 1 prolapse)	Monarc TOT Tape  With or without abdominal hysterectomy, myomectomy, vaginal hysterectomy (for non-prolapse) or colporrhaphy (for symptomatic stage 1 prolapse)	<b>79 months (generic) and 87 months (Monarc TOT) data</b> • Pain • Mesh extrusion • De novo urgency	Serious risk of bias	Transobturator synthetic mesh sling
Aigmuller 2011 Austria N=141 Case series	TVT	No comparison	<b>Mean 115.7 months</b> • De novo urgency	Serious risk of bias	Retropubic synthetic mesh sling
Ala-Nissila 2010 Finland N=130 Prospective cohort	TVT (primary UI)  With or without anterior and/or posterior repair, vaginal hysterectomy or sacrospinous fixation for vaginal vault prolapse	TVT (recurrent UI)	<b>Mean 96 months</b> • POP occurrence	Serious risk of bias	Retropubic synthetic mesh sling
Alcalay 1995 UK N=109 Case series	Burch colposuspension  With or without rectocele or enterocele repair	No comparison	<b>Mean 165.6 months data</b> • Infection • De novo urge incontinence • De novo urgency • POP occurrence	Serious risk of bias	Colposuspensio n (method not specified)
Al-Zahrani 2016 Canada N=330 Retrospective cohort	Transobturator synthetic mesh sling	Retropubic synthetic mesh sling	<b>128.4 months data (transobturator) and 153.6 months data (retropubic)</b> • Mesh extrusion • De novo urge incontinence • De novo urgency	Serious risk of bias	Transobturator synthetic mesh sling, retropubic synthetic mesh sling

Study Country Sample size Type of study	Intervention	Comparison	Length of followup Outcomes	Study quality <sup>1</sup>	Surgery Classification
Antovska 2013 Tunisia N=145 Prospective cohort	Modified Burch colposuspension	Burch colposuspension	<b>Mean 103.6 months data</b> • Fistula	Serious risk of bias	Laparoscopic colposuspension
Athanasίου 2014 Greece N=124 Case series	TVT-O  With or without pelvic floor repair, pelvic floor repair plus vaginal hysterectomy or laparoscopic sacrocolpopexy	No comparison	<b>90.3 months data</b> • Mesh extrusion • De novo urge incontinence	Serious risk of bias	Transobturator synthetic mesh sling
Betschart 2011 Switzerland N=422 Retrospective cohort	TVT  With or without concomitant prolapse surgery (hysterectomy, colporrhaphy, sacrospinous ligament fixation, botulinum toxin intravesical)	Monarc TOT  TVT-O  With or without concomitant prolapse surgery (hysterectomy, colporrhaphy, sacrospinous ligament fixation, botulinum toxin intravesical)	<b>Mean 66 months data</b> • Mesh extrusion • Infection	Serious risk of bias	Retropubic synthetic mesh sling
Braga 2018 Italy N=52 Case series	TVT	No comparison	<b>204 months data</b> • Mesh erosion • De novo urge incontinence • POP occurrence	Serious risk of bias	Retropubic synthetic mesh sling
Chevrot 2016 France N=463 Case series	TVT  With or without POP surgery (laparotomy hysterectomy, laparotomy sacrocolpopexy, laparoscopic sacrocolpopexy, vaginal wall repair)	No comparison	<b>Mean 71 months data</b> • Pain • Mesh exposure • Infection • De novo urge incontinence	Serious risk of bias	Retropubic synthetic mesh sling
Chun 2014 Korea N=215 Retrospective cohort	TOT	TVT-O	<b>Median 85.2 months data</b> • Pain • Infection • De novo urge incontinence	Serious risk of bias	Transobturator synthetic mesh sling
Doo 2006 Korea N=134 Case series	TVT	No comparison	<b>Mean 67 months data</b> • Pain • Need for catheterisation • Infection	Serious risk of bias	Retropubic synthetic mesh sling

Study Country Sample size Type of study	Intervention	Comparison	Length of followup Outcomes	Study quality <sup>1</sup>	Surgery Classification
Errando-Smet 2018 Spain N=205 Case series	Remeex readjustable mesh sling	No comparison	<ul style="list-style-type: none"> <li>• De novo urgency</li> </ul> <b>Mean 89 months data</b> <ul style="list-style-type: none"> <li>• Mesh extrusion</li> <li>• Need for catheterisation</li> <li>• Infection</li> <li>• De novo urge incontinence</li> </ul>	Serious risk of bias	Adjustable synthetic mesh sling
Giberti 2017 Italy N=50	Remeex readjustable mesh sling With or without POP surgery	No comparison	<b>Mean 83.8 months data</b> <ul style="list-style-type: none"> <li>• Need for catheterisation</li> <li>• Infection</li> <li>• De novo urgency</li> </ul>	Serious risk of bias	Adjustable synthetic mesh sling
Greenwell 2015 UK N=96 Retrospective cohort	Vaginal Obturator Shelf Urethral Repositioning colposuspension	Burch colposuspension	<b>Median 108.5 months data</b> <ul style="list-style-type: none"> <li>• Need for catheterisation</li> <li>• De novo urge incontinence</li> <li>• POP occurrence</li> </ul>	Serious risk of bias	Open colposuspension
Guerrero 2010 UK N=211 RCT	TVT	Porcine dermis sling Autologous rectus fascial sling	<b>Median 120 months data</b> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Mesh extrusion</li> <li>• Need for catheterisation</li> <li>• De novo urgency</li> </ul>	Low risk of bias	Retropubic synthetic mesh sling, porcine dermis sling, autologous rectus fascial sling
Han 2014 Korea N=88 Case series	TVT	No comparison	<b>144 months data</b> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Need for catheterisation</li> <li>• De novo urge incontinence</li> <li>• De novo urgency</li> </ul>	Serious risk of bias	Retropubic synthetic mesh sling
Hawkins 2002 UK N=132 Case series	Cruciate fascial sling With or without abdominal hysterectomy, vaginal hysterectomy with or without repair, posterior repair or incisional hernia repair	No comparison	<b>Median 72 months data</b> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Need for catheterisation</li> <li>• Infection</li> </ul>	Serious risk of bias	Autologous rectus fascial sling
Heinonen 2013 Finland N=138 Case series	TVT With or without POP surgery or vaginal hysterectomies	No comparison	<b>Mean 126.5 months data</b> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Infection</li> </ul>	Serious risk of bias	Retropubic synthetic mesh sling

Study Country Sample size Type of study	Intervention	Comparison	Length of followup Outcomes	Study quality <sup>1</sup>	Surgery Classification
Holdo 2017 Norway N=614 Retrospective cohort	TVT	Burch colposuspension	≤144 months data • Mesh extrusion • Need for catheterisation	Serious risk of bias	Retropubic synthetic mesh sling, open colposuspension
Holmgreen 2007 Sweden N=463 Case series	TVT	No comparison	Median 62.4 months data • Pain • Infection • De novo urgency	Serious risk of bias	Retropubic synthetic mesh sling
Kjohde 2005 Sweden N=192 Case series	Burch colposuspension	No comparison	Median 168 months data • Infection	Serious risk of bias	Colposuspension (method not specified)
Kuuva 2006 Finland N=129 Case series	TVT	No comparison	Median 72 months data • Mesh extrusion • Infection • De novo urge incontinence	Serious risk of bias	Retropubic synthetic mesh sling
Ladwig 2004 Australia N=374 Case series	Burch colposuspension  With or without hysterectomy	No comparison	Median 110.4 months data • Infection • De novo frequency • De novo urgency • De novo nocturia	Serious risk of bias	Open colposuspension
Lee 2010 Korea N=107 Case series	TVT  With or without hysterectomy	No comparison	72 months data • De novo urge incontinence • De novo urgency	Serious risk of bias	Retropubic synthetic mesh sling
Lo 2018 China N=85 Case series	MiniArc single-incision mini-sling	No comparison	Mean 74.1 months data • Mesh extrusion • De novo urge incontinence	Serious risk of bias	Single-incision mini-sling
Montera 2018 Italy N=50 Case series	TVT-O and anterior colporrhaphy	No comparison	Median 126 months data • Pain • Mesh extrusion	Serious risk of bias	Transobturator synthetic mesh sling
Nilsson 2004, 2008, 2013	TVT	No comparison	Mean 91 months data • Infection	Serious risk of bias	Retropubic synthetic mesh sling

Study Country Sample size Type of study	Intervention	Comparison	Length of followup Outcomes	Study quality <sup>1</sup>	Surgery Classification
Finland, Sweden N=80 Case series			<ul style="list-style-type: none"> <li>• De novo urge incontinence</li> <li>• POP occurrence</li> </ul> <b>Median 141 months data</b> <ul style="list-style-type: none"> <li>• Mesh extrusion</li> <li>• Need for catheterisation</li> </ul> <b>Mean 201 months data</b> <ul style="list-style-type: none"> <li>• Mesh extrusion</li> <li>• POP occurrence</li> </ul>		
Olsson 2010 Sweden N=124 Case series	TVT	No comparison	<b>Median 138 months data</b> <ul style="list-style-type: none"> <li>• De novo urge incontinence</li> <li>• POP occurrence</li> </ul>	Serious risk of bias	Retropubic synthetic mesh sling
Porena 2007 Italy N=148 RCT	TVT	TOT	<b>Median 100 months data</b> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Infection</li> <li>• POP occurrence</li> <li>• Wound complications</li> </ul> POP	High risk of bias	Retropubic synthetic mesh sling, transobturator synthetic mesh sling
Punjani 2017 Canada N=59,556 Case series	Midurethral mesh sling  With or without hysterectomy of POP surgery	No comparison	<b>Median 70.8 months data</b> <ul style="list-style-type: none"> <li>• Infection</li> </ul>	Serious risk of bias	Synthetic mesh sling (type not specified)
Reich 2011 Germany N=108 Case series	TVT  With or without POP surgery (anterior colporrhaphy, posterior colporrhaphy, colpocleisis)	No comparison	<b>Median 102 months data</b> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Mesh extrusion</li> <li>• Infection</li> <li>• De novo urge incontinence</li> <li>• POP occurrence</li> </ul>	Serious risk of bias	Retropubic synthetic mesh sling
Riggs 1986 USA N=719 Case series	Retropubic cystourethropexy  With or without anterior colporrhaphy	No comparison	<b>Mean 192 months data</b> <ul style="list-style-type: none"> <li>• Fistula</li> <li>• Infection</li> <li>• Wound complications</li> </ul>	Serious risk of bias	Open colposuspension
Schauer 2017 Austria N=139 Case series	Retropubic midurethral mesh sling  With or without anterior colporrhaphy, posterior colporrhaphy, meatotomy or other procedure	No comparison	<b>120 months data</b> <ul style="list-style-type: none"> <li>• De novo urgency</li> </ul>	Serious risk of bias	Retropubic synthetic mesh sling

Study Country Sample size Type of study	Intervention	Comparison	Length of followup Outcomes	Study quality <sup>1</sup>	Surgery Classification
Serati 2017a Italy N=160 Case series	TVT-O	No comparison	<b>120 months data</b> • Pain • Mesh extrusion • De novo urge incontinence • POP occurrence	Serious risk of bias	Transobturator synthetic mesh sling
Serati 2017b Italy N=55 Case series	TVT	No comparison	<b>156 months data</b> • Pain • Mesh extrusion • De novo urge incontinence • POP occurrence	Serious risk of bias	Retropubic synthetic mesh sling
Sivaslioglu 2010 Turkey N=80 RCT	Adjustable Tissue Fixation synthetic mesh sling	I-STOP TOT	<b>64 months data</b> • Pain • Mesh extrusion	Unclear risk of bias	Adjustable synthetic mesh sling, transobturator synthetic mesh sling
Sharifiaghdas 2008 Iran N=100 RCT	TVT	Autologous rectus fascial sling	<b>Mean 126 months data</b> • Pain • De novo urgency • De novo urge incontinence • Wound complications	High risk of bias	Retropubic synthetic mesh sling, autologous rectus fascial sling
Song 2017 Korea N=206 Case series	TVT With or without cystocele repair, caruncle excision, posterior colporrhaphy, urethral dilation	No comparison	<b>Mean 162.4 months data</b> • Mesh extrusion • De novo urgency	Serious risk of bias	Retropubic synthetic mesh sling
Svenningsen 2013 Norway N=327 Case series	TVT	No comparison	<b>Median 129 months data</b> • Mesh extrusion • Infection • De novo urge incontinence	Serious risk of bias	Retropubic synthetic mesh sling
Tsivian 2006 Israel N=81 Case series	TVT With or without vaginal hysterectomy, anterior or posterior colporrhaphy, or vaginal vault suspension	No comparison	<b>Median 65 months data</b> • Mesh extrusion • Infection • De novo urgency	Serious risk of bias	Retropubic synthetic mesh sling
Tutolo 2017 Belgium N=381 Retrospective cohort	Monarc TOT	MiniArc single-incision mini-sling	<b>Mean 65 months data</b> • Mesh extrusion • De novo urge incontinence	Serious risk of bias	Transobturator synthetic mesh sling, single-incision mini-sling

Study Country Sample size Type of study	Intervention	Comparison	Length of followup Outcomes	Study quality <sup>1</sup>	Surgery Classification
Ulrich 2016 Austria N=71 Case series	TVT-O  With or without vaginal hysterectomy, vaginal hysterectomy plus colporrhaphy, colporrhaphy only, hysteroscopy, mesh	No comparison	<b>120 months data</b> • Pain • Mesh extrusion • De novo urge incontinence	Serious risk of bias	Transobturator synthetic mesh sling
Zhang 2016 China N=140 RCT	TVT	TVT-O	<b>Mean 95 months data</b> • Pain • Infection	Unclear risk of bias	Retropubic synthetic mesh sling, transobturator synthetic mesh sling

1 Note: 1, Study quality of RCT and non-RCT assessed using the Cochrane RoB tool for randomised controlled  
2 studies and the Cochrane ROBINS-I tool, respectively.  
3 Abbreviations: IVS: intravaginal slingplasty; POP: pelvic organ prolapse; RCT: randomised controlled studies;  
4 TOT: transobturator outside-in tape; TVT: retropubic bottom-up tension-free vaginal tape; TVT-O: transobturator  
5 inside-out tape.

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**Table 12: Long-term complication rates (>5 years) for synthetic mesh slings**

Type of synthetic sling	Synthetic sling [type not specified]			Retropubic synthetic sling			Transobturator synthetic sling			Single-incision mini-sling			Adjustable sling		
	Complication	# of studies	Total # of women	Rate (%)	# of studies	Total # of women	Rate (%)	# of studies	Total # of women	Rate (%)	# of studies	Total # of women	Rate (%)	# of studies	Total # of women
Pain	-	-	-	10	1610	9.0	8	1074	7.1	1	39	0.0	-	-	-
Mesh erosion/exposure	-	-	-	15	2252	1.5	9	1335	2.3	3	169	0.6	1	205	2.0
Fistula	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Need for catheterisation	-	-	-	6	997	2.5	-	-	-	-	-	-	1	205	1.5
Infection	1	59,556	19.7	11	2424	8.4	4	468	3.4	-	-	-	2	255	1.6
De novo urge incontinence	-	-	-	12	1409	14.1	6	851	8.7	1	85	4.7	1	205	23.9
De novo frequency	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
De novo urgency	-	-	-	11	1448	13.7	2	633	4.0	-	-	-	1	50	10.0
De novo nocturia	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
POP occurrence	-	-	-	8	638	4.70	2	200	0.5	-	-	-	-	-	-
Wound complications	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Note: Complication rates calculated as weighted averages.

**Table 13: Long-term complication rates (>5 years) for colposuspension, fascial sling and porcine dermis sling**

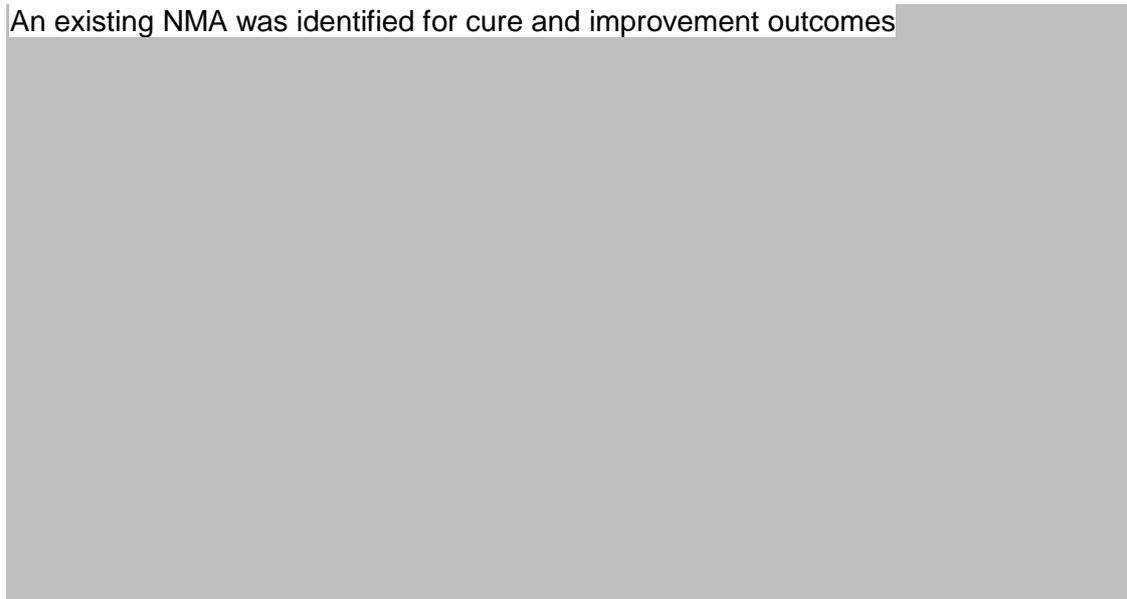
Type of surgery	Colposuspension (Method not specified)			Laparoscopic colposuspension			Open Colposuspension			Fascial sling			Porcine dermis sling		
	# of studies	Total # of women	Rate (%)	# of studies	Total # of women	Rate (%)	# of studies	Total # of women	Rate (%)	# of studies	Total # of women	Rate (%)	# of studies	Total # of women	Rate (%)
Pain	-	-	-	-	-	-	-	-	-	1	132	16.7	1	38	0.0
Mesh erosion/exposure	-	-	-	-	-	-	1	127	0.0	2	93	0	1	38	0.0
Fistula	1	225	0.0	1	145	0.0	-	-	-	-	-	-	-	-	-
Need for catheterisation	-	-	-	-	-	-	2	402	1.1	2	193	3.6	1	38	0.0
Infection	3	526	5.5	-	-	-	1	374	26.2	1	132	6.1	-	-	-
De novo urge incontinence	1	109	7.3	-	-	-	1	50	4.0	1	37	8.1	-	-	-
De novo frequency	-	-	-	-	-	-	1	94	37.2	-	-	-	-	-	-
De novo urgency	1	109	8.3	-	-	-	1	96	10.4	2	93	6.5	1	38	0.0
De novo nocturia	-	-	-	-	-	-	1	170	11.8	-	-	-	-	-	-
POP occurrence	1	109	21.1	-	-	-	1	50	4.0	-	-	-	-	-	-
Wound complications	1	225	0.4	-	-	-	-	-	-	-	-	-	-	-	-

Note: Complication rates calculated as weighted averages.

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

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An existing NMA was identified for cure and improvement outcomes



19 For the completed PRISMA NMA checklist see appendix N.

**20 Composite cure outcome**

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For the composite cure outcome



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**29 Patient satisfaction/patient-reported improvement outcome**

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

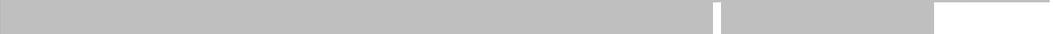
2 The risk of bias of individual studies was assessed using the Cochrane RoB tool, and  
3 the quality of evidence for each outcome, including short- and medium-term  
4 complications, was assessed using GRADE. Details can be found in Appendix F. The  
5 long-term complications data from the included observational studies is not  
6 comparative and GRADE is therefore not appropriate. The risk of bias of the  
7 individual observational studies that contributed long-term complications data was  
8 assessed using the Risk Of Bias In Non-randomised Studies – of Interventions  
9 (ROBINS-I) tool and summary ratings are presented in Table 11. Quality assessment  
10 of studies included in the NMAs ( ) was also conducted by its authors  
11 using GRADE.

12 Data were analysed and/or pooled according to follow up time after surgery following  
13 the time periods specified for complications data in the protocol with ‘short-term’  
14 defined as a follow up of 1 year or less after surgery, ‘medium-term’ as a follow up  
15 after surgery between 1 and 5 years, and ‘long-term’ as a follow up after surgery  
16 greater than 5 years. If data from the same study were reported for multiple  
17 timepoints (e.g. follow up at 2 and 4 years) within the same time period (e.g. between  
18 1 and 5 years), the longest follow up was used.

## 19 Economic evidence

### 20 Included studies

21 The systematic search of the economic literature undertaken for the guideline  
22 identified 7 studies examining the cost-effectiveness or costs of surgical  
23 management options (including mesh and non-mesh procedures) for SUI. Out of  
24 these there was:

- 25 • One UK study 
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- 32 • One USA study on the cost-utility of urethral bulking agents (BA) in the office  
33 setting compared with MUS (transobturator approach or the retropubic approach)  
34 in the operating theatre (Kunkle 2015);
- 35 • One UK study on the cost-effectiveness and cost-utility of a single incision mini  
36 sling (SIMS) compared with a standard midurethral mesh sling (SMUS) in women  
37 with SUI (Boyers 2013);
- 38 • One Canadian study on the cost-utility of a transobturator tape (TOT) compared  
39 with tension-free vaginal tape (TVT) in the surgical treatment of SUI (Lier 2017);
- 40 • One USA study on the cost-utility of retropubic midurethral sling (RMUS)  
41 compared with transobturator midurethral sling (TMUS) in women with pure SUI or  
42 predominantly SUI (Seklehner 2014);
- 43 • One Canadian study that assessed the costs associated with TOT, laparoscopic  
44 Burch colposuspension, and the laparoscopic two team sling procedure in women  
45 with SUI (Lo 2013);
- 46 • One USA study on the cost utility of TVT compared with Burch colposuspension in  
47 women with SUI (Laudano 2013).

**1 Excluded studies**

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

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

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## 19 **Kunkle 2015**

20 Kunkle (2015) evaluated the cost-utility of urethral bulking agents (BA) in the office  
21 setting compared with midurethral slings (MUS; transobturator approach or the  
22 retropubic approach) in the operating theatre in the USA. This was a modelling study  
23 (a decision tree model) with the effectiveness data from published sources (review of  
24 RCTs). The study population comprised of women with SUI without urethral  
25 hypermobility. In the model the treatment outcomes after MUS were either dry (that  
26 is, resolution of symptoms) or wet (that is, no resolution of symptoms). The model  
27 also included complications defined as occurring at the time of the surgery (such as,  
28 hematoma and haemorrhage, bladder injury), short-term complications (such as,  
29 transient urinary retention, thigh or groin pain), and long term complications (such as  
30 persistent urinary retention, de novo urge incontinence, urinary tract infection, mesh  
31 complication, and recurrent stress urinary incontinence). With respect to BA, 3  
32 possible outcomes of BA were modelled: dry (that is, resolution of symptoms), wet  
33 (that is, no resolution of symptoms), or improved (that is, some resolution of  
34 symptoms). Complications from BA were also divided into immediate-term (such as,  
35 pain), short-term (such as, transient urinary retention, dysuria, hematuria, and urinary  
36 tract infection), and long-term (such as, persistent urinary retention, de novo urge  
37 incontinence, need for reinjection, and need for other treatment). The analysis was  
38 conducted from a healthcare payer perspective. The study considered a range of  
39 direct healthcare costs including costs associated with the procedures, management  
40 of complications, and physician visits. The cost estimates were obtained from  
41 national sources (Medicare fee schedule). The measures of outcome for the  
42 economic analysis was QALYs. However, the utility weights were based on expert  
43 opinion. The time horizon of the main analysis was 12 months.

44 MUS when compared with BA resulted in an incremental cost of \$4,365 (in 2013 US  
45 dollars) and a 0.062 QALY gain at 12 months. The ICER of MUS (versus BA) was  
46 \$70,400 per QALY gained. According to the deterministic sensitivity analyses, the  
47 model was most sensitive to the cost of MUS placement, the probability of being dry  
48 at 1 year after MUS, the probability of postoperative urinary retention, and the  
49 probabilities of some long-term complications (such as, SUI, recurrent urinary tract  
50 infection, thigh pain, and need for further treatment including reinjection of BA). When  
51 MUS costs less than \$5,132, it became a cost-effective first-line treatment (base

1 case initial cost of sling was \$6,397), and when it cost less than \$2,035, it became  
2 cost saving. According to the bootstrapping, the probability of BA being cost-effective  
3 was 0.476 and being cost saving was 0.518. The probability of MUS being cost-  
4 effective was less than 0.01.

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

## 7 **Boyers 2013**

8 Boyers (2013) evaluated the cost-utility of a single incision mini sling (SIMS)  
9 compared with a standard midurethral mesh sling (SMUS) in women with SUI  
10 alongside an RCT (Mostafa 2012) (n=137) conducted in the UK. The analysis was  
11 conducted from a healthcare perspective. The study considered a range of direct  
12 healthcare costs including operating time, staff requirements, type of anaesthesia,  
13 consumables, hospital readmission, repeat surgery and outpatient care; GP,  
14 physiotherapist and nurse contact; any further treatment (for example, prescription  
15 medications). The resource use estimates were based on the RCT. The unit costs  
16 were obtained from national sources. The measure of outcome for the economic  
17 analysis was QALYs estimated using a mapping technique. A validated algorithm  
18 was used to map the patients' quality of life data on the King's Health Questionnaire  
19 (KHQ) collected during the RCT, onto the generic preference-based measure EQ-  
20 5D-3L. The time horizon of the analysis was 12 months. Costs were reported using  
21 complete cases analysis and a data set with imputed missing values.

22 Using the base case analysis (complete case analysis) SIMS resulted in fewer  
23 QALYs (-0.003; 95% CI: -0.008 to 0.002) and cost savings of £142.41 (95% CI: -  
24 £316.99 to £32.17) when compared with SMUS; in 2011 prices. The cost savings for  
25 the SIMS were mainly driven by the reduced staff resource required to deliver the  
26 procedure under pure local anaesthesia. The ICER of SIMS (versus SMUS) was  
27 £48,419 per QALY lost (this means that a decision maker would save £48,419 for  
28 every QALY lost). Given that we are willing to pay £20,000 to £30,000 per QALY  
29 gained, we should be willing to accept anything above that for a QALY lost (that is,  
30 the ICER of SIMS compared with SMUS of £48,419 per QALY lost is considered to  
31 be cost-effective). Similarly, when using the dataset with imputed missing values  
32 SIMS resulted in cost savings of £54,732 per QALY lost when compared with SMUS.

33 In the base case analysis it was modelled that SIMS was performed under local  
34 anaesthesia and SMUS under general anaesthesia. Local anaesthesia was the  
35 standard type of anaesthesia in the SIMS group, unless specifically declined by a  
36 participant. A sensitivity analysis was undertaken where it was modelled that all  
37 women in the SIMS group receive local anaesthesia. In this scenario the ICER of  
38 SIMS (versus SMUS) was £76,673 per QALY saved. In another scenario where a  
39 wider perspective on costs was incorporated to include the personal and social costs  
40 SIMS resulted in even greater cost savings when compared with SMUS (the savings  
41 of £476.64, 95% CI: -£823.65; -£129.63). In this scenario the ICER of SIMS (versus  
42 SMUS) was £162,056 per QALY saved.

43 Assuming equivalence in QALY outcomes (that is, the difference in QALYs was not  
44 significant) SIMS was the preferred treatment option when compared with SMUS on  
45 the basis of the cost minimisation.

46 In all scenarios the probability of SIMS being cost-effective ranged from 0.80 to 0.90  
47 at a minimum savings of £20,000 to avoid a QALY loss, 0.69 to 0.99 at a minimum  
48 savings of £30,000 to avoid a QALY loss, and 0.50 to 0.96 at a minimum savings of  
49 £50,000 to avoid a QALY loss.

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

### 3 **Lier 2017**

4 Lier (2017) evaluated the cost-effectiveness and cost-utility of a transobturator tape  
5 (TOT) compared with tension-free vaginal tape (TVT) in the surgical treatment of SUI  
6 in women alongside an RCT (Ross 2016) (n=199) conducted in Canada. The  
7 analysis was conducted from a healthcare payer perspective. The study considered a  
8 range of healthcare costs including TVT and TOT surgical procedures, inpatient and  
9 outpatient care (including A&E visits), clinician visits, prescription medication. The  
10 resource use estimates were based on the RCT (n=195). The unit costs were  
11 obtained from national sources (that is, physician payment records from Alberta). The  
12 measures of outcome for the economic analysis was QALYs calculated using 15D  
13 preference-based measure and the proportion of women without at least one serious  
14 adverse event (SAE) where SAE was defined as the presence of either tape erosion,  
15 urine retention requiring intervention, failure requiring repeat surgery for SUI, or  
16 debilitating pain. The time horizon of the analysis was 5 years. All future costs and  
17 QALYs were discounted by 3% per year. Regression analysis was used to adjust  
18 incremental costs for baseline 15D utility scores and age, whereas the incremental  
19 health effects were adjusted depending on the outcome used, with QALYs adjusted  
20 for 15D baseline utility score and menopause status, and the SAE outcome adjusted  
21 for 15D baseline utility score, age, smoking and menopause status. Bootstrapping  
22 was undertaken to capture uncertainty about estimates of costs and outcomes. In the  
23 primary analysis, missing data were imputed using a multiple imputation procedure.  
24 A secondary analysis was undertaken that reported results based on complete case  
25 analysis (n=104).

26 Using the imputed data set, TOT resulted in greater QALYs compared with TVT (4.31  
27 versus 4.23, respectively; difference 0.04 in favour of TOT, 95% CI: -0.06; 0.13).  
28 Similarly, TOT resulted in a greater proportion of women without SAE (0.79 versus  
29 0.73, respectively; difference 0.03 in favour of TOT, 95% CI: -0.10; 0.16). The mean  
30 total costs per woman were \$13,007 for TOT and \$16,081 for TVT, a difference of  
31 \$2,368 in favour of TOT (95% CI: -\$7,166; \$2,548) in 2011 Canadian dollars.

32 Based on the above costs and outcomes TOT was dominant using both outcome  
33 measures (that is, it resulted in lower costs and also greater QALYs and a greater  
34 proportion of women without SAE). However, none of the differences were  
35 statistically significant. The probability of TOT being cost effective was 79% and  
36 above over the entire range of WTP values per QALY gained and an additional SAE  
37 case averted.

38 Using a complete case analysis, TOT resulted in greater QALYs compared with TVT  
39 (4.37 versus 4.29, respectively; difference 0.04 in favour of TOT, 95% CI: -0.05;  
40 0.12). The mean total costs per woman were \$13,513 for TOT and \$13,436 for TVT,  
41 a difference of \$898 in favour of TVT (95% CI: -\$2,315; \$4,452). Based on the above  
42 costs and QALYs the ICER of TOT (versus TVT) was \$22,450 per QALY gained.

43 Similarly, TOT resulted in a greater proportion of women without SAE (0.80 versus  
44 0.78, respectively; difference 0.02 in favour of TOT, 95% CI: -0.10; 0.16). The mean  
45 total costs per woman were \$14,117 for TOT and \$15,901 for TVT, a difference of  
46 \$1,247 in favour of TOT (95% CI: -\$7,043; \$2,346). Based on the above costs and  
47 outcomes TOT was dominant compared with TVT (that is, it resulted in lower costs  
48 and fewer women reporting SAE).

1 A sensitivity analysis was undertaken on the imputed dataset in which a woman in  
2 the TVT group with the most extreme total costs was removed. In this analysis TVT  
3 resulted in a reduction in the costs (difference \$833, 95% CI: \$4,518; \$2,939) and a  
4 QALY gain (difference 0.02, 95% CI: -0.078; 0.119). Based on the above costs and  
5 outcomes TOT remained dominant when compared with TVT, and its probability of  
6 being cost-effective was approximately 70% across all levels of WTP per QALY  
7 gained. In another sensitivity analysis, where future costs and QALYs were not  
8 discounted, the results remained similar (that is, TOT was dominant when compared  
9 with TVT). Overall the results suggest that TOT (when compared with TVT) is a cost-  
10 effective treatment in women with SUI.

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

### 13 **Seklehner 2014**

14 Seklehner (2014) evaluated the cost-utility of retropubic midurethral sling (RMUS)  
15 compared with transobturator midurethral sling (TMUS) in women with pure SUI or  
16 predominantly SUI in the USA. This was a modelling study (Markov decision model)  
17 with the efficacy data (cure rates) from a review of RCTs. Following the initial  
18 decision to treat with RMUS or TMUS the possible outcomes of surgery were death,  
19 no leakage (dry), or persistent SUI. It was further modelled that people failing initial  
20 treatment would be retreated using RMUS. The possible outcomes following  
21 retreatment were death, dry, or persistent SUI. The analysis was conducted from a  
22 healthcare payer perspective plus out of pocket expenses. The study considered a  
23 range of healthcare costs including devices, anaesthesia, physician fees (sling  
24 placement, cystoscopy), operating room, hospital stay, outpatient visits, treatment of  
25 complications (infection, lower urinary tract symptoms, bladder perforation,  
26 catheterization, drainage of hematoma, treatment of neurological symptoms, sling  
27 excision, and treatment of bleeding). Out of pocket expenses included laundry costs.  
28 The model also included the costs associated with absorbent pads. The cost  
29 estimates were from published national sources (Medicare reimbursement schedule).  
30 The source of unit costs was unclear (most likely national sources). The measure of  
31 outcome for the economic analysis was QALYs. Utility weights were obtained from  
32 published sources and used EQ-5D-3L, the UK population norms. The results were  
33 reported using efficacy expressed in terms of both objective and subjective cure. The  
34 objective cure was assessed using stress test and pad test and the subjective cure  
35 was assessed using patients' perception of clinical improvement, expressed by  
36 validated questionnaires, institutional questionnaires, or open interview. The time  
37 horizon of the analysis was 10 years. Costs and outcomes were discounted at a rate  
38 of 2.26%.

39 Using deterministic results and objective cure, RMUS when compared with TMUS  
40 resulted in a greater number of QALYs at 10 year follow up (6.275 and 6.272 for  
41 RMUS and TMUS, respectively; difference of 0.003). The mean total costs per  
42 woman over 10 years were \$9,579 for RMUS and \$9,017 for TMUS, a difference of  
43 \$561.89 in 2012 USA dollars. The difference in costs was mainly driven by a shorter  
44 operative time and associated hospital costs. Using the above costs and outcomes  
45 the ICER of RMUS (versus TMUS) was \$177,027 per QALY gained. Similarly, when  
46 using subjective cure RMUS when compared with TMUS resulted in a greater  
47 number of QALYs at 10 year follow up (6.264 and 6.261 for RMUS and TMUS,  
48 respectively; difference of 0.003). The mean total costs per woman over 10 years  
49 were \$10,444 for RMUS and \$9,891 for TMUS, a difference of \$552.56. Using the  
50 above costs and outcomes the ICER of RMUS (versus TMUS) was \$163,193 per  
51 QALY gained.

1 According to one-way sensitivity analysis TMUS was more cost-effective than RMUS  
2 as long as the cost of the TMUS device did not exceed \$1,852 (\$1,295 base case).  
3 Conversely, RMUS was only more cost-effective if the cost of the device was less  
4 than \$603 (\$1,170 base case). TMUS was more cost-effective for surgeon fees less  
5 than \$2,800 (\$2,324 base case). TMUS remained more cost-effective than RMUS for  
6 efficacy more than 76.1% (83% and 73% base case objective and subjective cure,  
7 respectively); RMUS would need to demonstrate efficacy of 94% or greater (87% and  
8 76% base case objective and subjective cure, respectively) to become more cost-  
9 effective than TMUS. TMUS surgery could take up to 37.5 min (22.58 min base case)  
10 while remaining more cost-effective than RMUS. In contrast, RMUS surgery would  
11 need to be completed in less than 14 min (29.07 min base case) to become more  
12 cost-effective than TMUS. TMUS was more cost effective if length of hospital stay  
13 was less than 2.7 days (2.18 days base case). In contrast, RMUS was more cost-  
14 effective if length of stay was less than 2.3 days (2.83 days base case). Varying the  
15 retreatment rate and the relative utilities of being incontinent did not alter the results.

16 A two-way sensitivity analysis was also undertaken in which the efficacy of TMUS  
17 and the cost of the TMUS device were simultaneously varied. For example, if the  
18 cost of the TMUS device was \$1,200 (\$1,295 base case), TMUS would be more  
19 cost-effective for TMUS efficacy of more than 69% (0.83 and 0.73 objective and  
20 subjective cure, respectively). An additional, two-way sensitivity analysis was  
21 performed where the probabilities of cure following TMUS and RMUS were varied  
22 simultaneously. For example, if the probability of cure with TMUS and RMUS was 0.8  
23 and 0.6 (0.87 base case in both groups), respectively, then TMUS was more cost-  
24 effective. However, when the cure rates were reversed, RMUS became more cost-  
25 effective.

26 Probabilistic sensitivity analysis indicated that at any WTP value for a QALY the  
27 probability of TMUS being cost-effective was approaching 1.00.

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

### 30 **Lo 2013**

31 Lo (2013) assessed the costs of transobturator tape (TOT), laparoscopic Burch  
32 colposuspension, and the laparoscopic two team sling procedure in women with SUI  
33 in Canada. The analysis was conducted from a healthcare payer perspective. The  
34 study considered a range of direct healthcare costs including equipment costs,  
35 surgeon, surgical assistant, anaesthesiologist, nursing costs, operating and recovery  
36 room costs, and hospital stay. The resource use estimates were based on the  
37 observation cohort study participants (N=18) and associated administrative  
38 databases (that is, patients' medical records). The unit costs were obtained from  
39 local sources (that is, finance department of the hospital and Ontario province  
40 Ministry of Health). The time horizon of the analysis was unclear. However, it seems  
41 to be the immediate postoperative period.

42 The mean total costs per woman were \$2,547 (95% CI: \$2,260 to \$2,833) for TOT  
43 procedure, \$4,354 (95% CI: \$3,465 to \$5,244) for laparoscopic Burch  
44 colposuspension, and \$5,393 (95% CI: \$4,959 to \$5,826) for laparoscopic two-team  
45 sling procedure. The difference between TOT and laparoscopic Burch  
46 colposuspension was \$1,807.88 (in favour of TOT),  $p < 0.001$ ; the difference  
47 between TOT and laparoscopic two team sling procedure was \$2,834.73 (in favour of  
48 TOT procedure),  $p < 0.001$ ; and the difference between laparoscopic Burch  
49 colposuspension and laparoscopic two team sling was \$1,039 (in favour of  
50 laparoscopic Burch colposuspension),  $p < 0.001$ . Based on the above cost estimates

- 1 TOT procedure was the cost saving treatment when compared with laparoscopic  
2 Burch colposuspension and laparoscopic two team sling procedure.
- 3 The analysis was partially applicable to the NICE decision-making context and had  
4 potentially serious methodological limitations.

### 5 **Laudano 2013**

6 Laudano (2013) evaluated the cost-utility of tension free vaginal tape compared with  
7 Burch colposuspension (BC) in women with SUI in the USA. This was a modelling  
8 study (Markov decision model) with the efficacy data (that is, cure rate) from  
9 published sources (review of RCTs). The possible health states after either type of  
10 surgery were death, no leakage (dry), leaking urine (persistent SUI), or a second  
11 surgery which in all cases was assumed to be TVT (that is, primary treatment failure  
12 to TVT or BC was treated with TVT). After this second procedure, the possible  
13 outcomes were death, dry or wet. The analysis was conducted from a healthcare  
14 payer perspective. The study considered a range of direct healthcare costs including  
15 cost of procedures, devices, cystoscopy, operating theatre, hospital stay, physician  
16 visits, treatment of complications, and revision surgery. The complications were  
17 modelled as a weighted average and included haematoma, urinary retention,  
18 detrusor overactivity, UTI, abscess, mesh or suture erosion, recurrent stress  
19 incontinence, pelvic organ prolapse, incisional hernia, bladder perforation, and  
20 revision. The cost data was obtained from national sources (Medicare reimbursement  
21 rates). The source of unit costs was unclear but most likely national sources. The  
22 measure of outcome for the economic analysis was QALYs with utility weights  
23 derived from a UK-based RCT using EQ-5D-3L generic measure with valuations by  
24 the UK general public. The time horizon of the analysis was 10 years. Costs and  
25 outcomes were discounted at a rate of 4.54%.

26 In the base case analysis TVT resulted in a greater QALY gain at 10 years compared  
27 with Burch (5.79 versus 5.78, respectively; difference 0.01). It also resulted in the  
28 cost savings of \$1,894 (\$8,651 and \$10,545 for TVT and burch, respectively); in  
29 likely 2012 USA dollars. Based on the above costs and outcomes TVT was the  
30 dominant treatment (that is, it resulted in better outcomes and lower healthcare  
31 costs). In deterministic sensitivity analyses TVT remained more cost-effective than  
32 BC as long as the costs of the TVT device was <\$3,220 (base case \$1,170). When  
33 the efficacy (cure rate) of TVT was varied, BC became more cost-effective when TVT  
34 efficacy was <42% (base case 77%). Regardless of the utility gain associated with  
35 the cure (dry health state), TVT remained more cost-effective than BC. Two-way  
36 sensitivity analyses were also performed where TVT efficacy and costs were varied.  
37 For example, if the cost of the TVT device was \$2,000 (base case \$1,170), TVT  
38 would be more cost-effective for TVT efficacy >59% (base case 77%). An additional,  
39 two-way sensitivity analysis was performed where probability of cure after TVT  
40 versus probability of cure after BC was varied. For example, if the probability of cure  
41 with BC and TVT were 70% and 40% (base case 68% and 77%), then the BC would  
42 become more cost-effective. However, if the cure rates were reversed, then TVT  
43 becomes more cost-effective. The probabilistic sensitivity analysis indicated that for  
44 any willingness to pay value greater than \$20,000 per QALY the probability of TVT  
45 being cost effective was approximately 0.90 and the probability of Burch being cost-  
46 effective never exceeded 0.10.

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

1 **Economic model**

- 2 This question was not prioritised for economic modelling because the existing  
3 economic evidence on the cost-effectiveness of surgical treatments for women with  
4 SUI was anticipated to be sufficient to inform the committee decision making.  
5

## 1 Clinical evidence statements

### 2 Colposuspension versus synthetic mesh sling

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

- 4 • Very low quality evidence from 1 RCT (n=286) showed no clinically important  
5 difference between colposuspension and synthetic mesh sling on the number of  
6 women with SUI whose urinary symptoms affect their sex life as assessed by the  
7 Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire within 1  
8 year of surgery: RR 0.96 (95% CI 0.65-1.42).
- 9 • Very low quality evidence from 1 RCT (n=177) showed no clinically important  
10 difference between colposuspension and synthetic mesh sling on the number of  
11 women with SUI whose urinary symptoms affect their sex life as assessed by the  
12 Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire between 1  
13 year and 5 years after surgery: RR 0.62 (95% CI 0.26-1.46).

14

#### 15 *Adverse events*

- 16 • Very low quality evidence from 3 RCTs (n=259) showed no clinically important  
17 difference between colposuspension and synthetic mesh sling on the number of  
18 women with SUI who suffered severe bleeding requiring a blood transfusion  
19 during surgery: RR 0.33 (95% CI 0.01-7.92).
- 20 • Low quality evidence from 11 RCTs (n=1086) showed a clinically important  
21 difference favouring colposuspension compared to synthetic mesh sling on the  
22 number of women with SUI who suffer a perioperative bladder injury: RR 0.23  
23 (95% CI 0.1-0.51).
- 24 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
25 difference between colposuspension and synthetic mesh sling on the number of  
26 women with SUI who suffered a perioperative bowel injury: RR 3.0 (95% CI 0.13-  
27 71.28).

28

#### 29 *Complications*

- 30 • Very low quality evidence from 2 RCTs (n=189) showed no clinically important  
31 difference between colposuspension and synthetic mesh sling on the number of  
32 women with SUI who experience pain within 1 year of surgery: RR 0.78 (95% CI  
33 0.05-12.33), random effects analysis.
  - 34 ○ Very low quality evidence from 1 RCT (n=68) showed no clinically important  
35 difference between colposuspension and synthetic mesh sling on the number  
36 of women with SUI who experience pain within 1 year of surgery and who did  
37 not have concomitant POP surgery: RR 0.17 (95% CI 0.001-3.16).
  - 38 ○ Very low quality evidence from 1 RCT (n=121) showed no clinically important  
39 difference between colposuspension and synthetic mesh sling on the number  
40 of women with SUI who experience pain within 1 year of SUI surgery and who  
41 also had concomitant POP surgery: RR 2.75 (95% CI 0.26-29.46).
- 42 • Very low quality evidence from 2 RCTs (n=161) showed no clinically important  
43 difference between colposuspension and synthetic mesh sling on the number of  
44 women with SUI who experience pain between 1 year and 5 years after surgery:  
45 RR 8.76 (95% CI 0.49-156.85).
- 46 • Very low quality evidence from 2 RCTs (n=429) showed no clinically important  
47 difference between colposuspension and synthetic mesh sling on the number of  
48 women with SUI who experience mesh extrusion within 1 year of surgery: RR 0.35  
49 (95% CI 0.06-2.21).

- 1 • Very low quality evidence from 5 RCTs (n=598) showed no clinically important  
2 difference between colposuspension and synthetic mesh sling on the number of  
3 women with SUI who experience mesh extrusion between 1 year and 5 years after  
4 surgery: RR 0.27 (95% CI 0.06-1.27).
- 5 • Low quality evidence from 1 RCT (n=90) showed no women with SUI who  
6 received colposuspension or synthetic mesh sling experienced fistula between 1  
7 year and 5 years after surgery: RR 1.0 (95% CI 0.96-1.04), non-event.
- 8 • Very low quality evidence from 3 RCTs (n=289) showed no clinically important  
9 difference between colposuspension and synthetic mesh sling on the number of  
10 women with SUI who experience need for catheterisation within 1 year of surgery:  
11 RR 1.95 (95% CI 0.46-8.18).
- 12 • Very low quality evidence from 3 RCTs (n=501) showed no clinically important  
13 difference between colposuspension and synthetic mesh sling on the number of  
14 women with SUI who experience need for catheterisation between 1 year and 5  
15 years after surgery: RR 1.97 (95% CI 0.36-10.67).
- 16 • Very low quality evidence from 2 RCTs (n=429) showed no clinically important  
17 difference between colposuspension and synthetic mesh sling on the number of  
18 women with SUI who experience an infection within 1 year of surgery: RR 1.29  
19 (95% CI 0.81-2.04).
- 20 ○ Low quality evidence from 1 RCT (n=316) showed a clinically important  
21 difference favouring synthetic mesh sling over colposuspension on the number  
22 of women with SUI who experience an infection within 1 year of surgery and  
23 who did not have concomitant POP surgery: RR 1.55 (95% CI 1.11-2.17).
- 24 ○ Very low quality evidence from 1 RCT (n=113) showed no clinically important  
25 difference between colposuspension and synthetic mesh sling on the number  
26 of women with SUI who experience an infection within 1 year of surgery and  
27 who also had concomitant POP surgery: RR 0.96 (95% CI 0.55-1.67).
- 28 • Very low quality evidence from 4 RCTs (n=539) showed no clinically important  
29 difference between colposuspension and synthetic mesh sling on the number of  
30 women with SUI who experience an infection between 1 year and 5 years after  
31 surgery: RR 0.59 (95% CI 0.26-1.34).
- 32 • Very low quality evidence from 1 RCT (n=87) showed no clinically important  
33 difference between colposuspension and synthetic mesh sling on the number of  
34 women with SUI who experience de novo urgency within 1 year of surgery: RR  
35 0.44 (95% CI 0.12-1.59).
- 36 • Very low quality evidence from 3 RCTs (n=338) showed no clinically important  
37 difference between colposuspension and synthetic mesh sling on the number of  
38 women with SUI who experience de novo urgency between 1 year and 5 years  
39 after surgery: RR 1.42 (95% CI 0.4-5.04).
- 40 • Very low quality evidence from 2 RCTs (n=155) showed no clinically important  
41 difference between colposuspension and synthetic mesh sling on the number of  
42 women with SUI who experience de novo urge incontinence within 1 year of  
43 surgery: RR 1.25 (95% CI 0.35-4.52).
- 44 • Very low quality evidence from 3 RCTs (n=315) showed no clinically important  
45 difference between colposuspension and synthetic mesh sling on the number of  
46 women with SUI who experience de novo urge incontinence between 1 year and 5  
47 years after surgery: RR 2.61 (95% CI 0.53-12.79).
- 48 • Very low quality evidence from 2 RCTs (n=302) showed a clinically important  
49 difference favouring synthetic mesh sling compared to colposuspension on the  
50 number of women with SUI who have an occurrence of POP between 1 year and  
51 5 years after surgery: RR 1.64 (95% CI 1.10-2.44).

- 1 • Low quality evidence from 1 RCT (n=90) showed no women with SUI who  
2 received colposuspension or synthetic mesh sling experienced wound  
3 complications between 1 year and 5 years after surgery: RR 1.0 (95% CI 0.96-  
4 1.04), non-event.

5

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

7 For composite cure outcome within approximately 1 year of surgery – NMA outcome,  
8 see [clinical evidence profile for NMA outcomes](#).

9

- 10 • Low quality evidence from 4 RCTs (n=625) showed no clinically important  
11 difference between colposuspension and synthetic mesh sling on the number of  
12 women with SUI who are subjectively cured within 1 year or surgery: RR 0.9 (95%  
13 CI 0.8-1.03).
- 14 • Very low quality evidence from 4 RCTs (n=619) showed no clinically important  
15 difference between colposuspension and synthetic mesh sling on the number of  
16 women with SUI who are subjectively cured between 1 year and 5 years after  
17 surgery: RR 0.88 (95% CI 0.74-1.04).
- 18 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
19 difference between colposuspension and synthetic mesh sling on the number of  
20 women with SUI who are subjectively cured more than 5 years after surgery: RR  
21 0.92 (95% CI 0.49-1.74).
- 22 • Very low quality evidence from 5 RCTs (n=689) showed no clinically important  
23 difference between colposuspension and synthetic mesh sling on the number of  
24 women with SUI who are objectively cured within 1 year of surgery: RR 0.88 (95%  
25 CI 0.8-0.96).
- 26 • Low quality evidence from 7 RCTs (n=844) showed no clinically important  
27 difference between colposuspension and synthetic mesh sling on the number of  
28 women with SUI who are objectively cured between 1 year and 5 years after  
29 surgery: RR 0.84 (95% CI 0.74-0.95).
- 30 • Low quality evidence from 1 RCT (n=344) showed no clinically important  
31 difference between colposuspension and synthetic mesh sling on the number of  
32 women with SUI who had a negative cough stress test within 1 year of SUI  
33 surgery only: RR 0.83 (95% CI 0.73-0.94).
- 34 • Low quality evidence from 1 RCT (n=113) showed no clinically important  
35 difference between colposuspension and synthetic mesh sling on the number of  
36 women with SUI who have a negative cough stress test between 1 year and 5  
37 years after SUI surgery and concomitant POP surgery: RR 0.83 (95% CI 0.65-  
38 1.06).

39

### 40 ***Patient satisfaction/patient-reported improvement***

41 For composite outcome of patient satisfaction/patient-reported improvement within  
42 approximately 1 year of surgery – NMA outcome, see [clinical evidence profile for](#)  
43 [NMA outcomes](#).

44

- 45 • Low quality evidence from 5 RCTs (n=441) showed no clinically important  
46 difference between colposuspension and synthetic mesh sling on the number of  
47 women with SUI who experience improvement in continence status between 1  
48 year and 5 years after surgery: RR 0.89 (0.79-0.99).

- 1 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
2 difference between colposuspension and synthetic mesh sling on the number of  
3 women with SUI who experience improvement in continence status more than 5  
4 years after surgery: RR 1.18 (0.75-1.85).

### 6 **Repeat surgery**

- 7 • Very low quality evidence from 2 RCTs (n=168) showed no clinically important  
8 difference between colposuspension and synthetic mesh sling on the number of  
9 women with SUI who have repeat surgery for any reason within 1 year of surgery:  
10 RR 0.86 (95% CI 0.27-2.78).
- 11 • Low quality evidence from 1 RCT (n=316) showed a clinically important difference  
12 favouring synthetic mesh slings compared to colposuspension on the number of  
13 women with SUI who have repeat surgery for any reason between 1 year and 5  
14 years after SUI surgery only: RR 2.66 (95% CI 1.13-6.29).
- 15 • Very low quality evidence from 2 RCTs (n=166) showed no clinically important  
16 difference between colposuspension and synthetic mesh sling on the number of  
17 women with SUI who have repeat surgery for SUI between 1 year and 5 years  
18 after surgery: RR 2.4 (95% CI 0.65-8.95).
- 19 • Very low quality evidence from 1 RCT (n=53) showed no clinically important  
20 difference between colposuspension and synthetic mesh sling on the number of  
21 women with SUI who have repeat surgery for SUI more than 5 years after surgery:  
22 RR 0.89 (95% CI 0.06-13.54).
- 23 • Very low quality evidence from 1 RCT (n=68) showed no clinically important  
24 difference between colposuspension and synthetic mesh sling on the number of  
25 women with SUI who have repeat surgery for mesh complications within 1 year of  
26 surgery: RR 0.4 (95% CI 0.02-9.38).
- 27 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
28 difference between colposuspension and synthetic mesh sling on the number of  
29 women with SUI who have repeat surgery for mesh complications more than 5  
30 years after surgery: RR 0.2 (95% CI 0.01-4.03).

### 31 **Autologous rectus fascial sling versus synthetic mesh sling**

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

- 33 • Very low to low quality evidence from 1 RCT (n=124) showed no clinically  
34 important difference between autologous rectus fascial sling and synthetic mesh  
35 sling in women with SUI on continence-specific health-related quality of life (SMD -  
36 0.15 [95% CI -0.50 to +0.21]) and sexual function (SMD +0.08 [95% CI -0.28 to  
37 +0.43]) as assessed by the Bristol Female Lower Urinary Tract Symptoms  
38 (BFLUTS) questionnaire at a median 10 years after surgery.
- 39 • Very low quality evidence from 1 RCT (n=20) showed a clinically important  
40 difference favouring autologous rectus fascial sling over synthetic mesh sling in  
41 women with SUI on the King's Health Questionnaire subscales of general health  
42 perceptions (SMD -1.04 [95% CI -1.97 to -0.11]), role limitations (SMD -1.39 [95%  
43 CI -2.37 to -0.42]), physical and social limitations (SMD -1.39 [95% CI -2.37 to -  
44 0.42]), emotions (SMD -1.19 [95% CI -2.14 to -0.24]) and severity measures (SMD  
45 -1.47 [95% CI -2.46 to -0.49]) at 6 months after surgery.
- 46 • Very low quality evidence from 1 RCT (n=20) showed no clinically important  
47 difference between autologous rectus fascial sling and synthetic mesh sling in  
48 women with SUI on the King's Health Questionnaire subscales of incontinence  
49 impact (SMD +0.7 [95% CI -1.6 to +0.2]), personal relationships (SMD +0.03 [95%

1 CI -0.85 to +0.91]) and sleep/energy (SMD -0.54 [95% CI -1.43 to +0.36]) at 6  
2 months after surgery.

### 3 4 **Adverse events**

- 5 • Very low quality evidence from 5 RCTs (n=336) showed no clinically important  
6 difference between autologous rectus fascial sling and synthetic mesh sling on the  
7 number of women with SUI who experience severe bleeding requiring a blood  
8 transfusion during surgery: RR 0.4 (95% CI 0.05-2.88).
- 9 • Very low quality evidence from 9 RCTs (n=471) showed a clinically important  
10 difference favouring autologous rectus fascial sling over synthetic mesh sling on  
11 the number of women with SUI who suffer a perioperative bladder injury: RR 0.36  
12 (95% CI 0.16-0.84).

### 13 14 **Complications**

- 15 • Very low quality evidence from 3 RCTs (n=174) showed no clinically important  
16 difference between autologous rectus fascial slings and synthetic mesh slings on  
17 the number of women with SUI who experience pain within 1 year of surgery: RR  
18 0.72 (95% CI 0.02-34.42), random effects analysis.
- 19 ○ Very low quality evidence from 1 RCT (n=53) showed there may be a clinically  
20 important difference favouring retropubic synthetic mesh sling over autologous  
21 rectus fascial sling on the number of women with SUI who experience pain  
22 within 1 year of surgery, although there is some uncertainty: RR 3.92 (95% CI  
23 0.9-17.15).
- 24 ○ Very low quality evidence from 2 RCTs (n=121) showed no clinically important  
25 difference between autologous rectus fascial sling and transobturator synthetic  
26 mesh sling on the number of women with SUI who experience pain within 1  
27 year of surgery: RR 0.09 (95% CI 0.01-1.59).
- 28 • Very low quality evidence from 1 RCT (n=70) showed no clinically important  
29 difference between autologous rectus fascial sling and synthetic mesh sling on the  
30 number of women with SUI who experience pain between 1 year and 5 years after  
31 surgery: RR 0.75 (95% CI 0.18-3.11).
- 32 • Very low quality evidence from 2 RCTs (n=193) showed no clinically important  
33 difference between autologous rectus fascial sling and synthetic mesh sling on the  
34 number of women with SUI who experience pain more than 5 years after surgery:  
35 RR 1.12 (95% CI 0.36-3.52).
- 36 • Very low quality evidence from 3 RCTs (n=174) showed no clinically important  
37 difference between autologous rectus fascial sling and synthetic mesh sling on the  
38 number of women with SUI who experience mesh extrusion within 1 year of  
39 surgery: RR 0.35 (95% CI 0.02-8.1).
- 40 • Very low quality evidence from 2 RCTs (n=133) showed no clinically important  
41 difference between autologous rectus fascial sling and synthetic mesh sling on the  
42 number of women with SUI who experience mesh extrusion between 1 year and 5  
43 years after surgery: RR 0.36 (95% CI 0.06-2.28).
- 44 • Very low quality evidence from 2 RCTs (n=193) showed no clinically important  
45 difference between autologous rectus fascial sling and synthetic mesh sling on the  
46 number of women with SUI who experience mesh extrusion more than 5 years  
47 after surgery: RR 0.22 (95% CI 0.03-1.87).
- 48 • Very low quality evidence from 5 RCTs (n=340) showed no clinically important  
49 difference between autologous rectus fascial sling and synthetic mesh sling on the

- 1 number of women with SUI who experience need for catheterisation within 1 year  
2 of surgery: RR 1.79 (95% CI 0.77-4.17).
- 3 • Very low quality evidence from 1 RCT (n=124) showed no clinically important  
4 difference between autologous rectus fascial sling and synthetic mesh sling on the  
5 number of women with SUI who experience need for catheterisation more than 5  
6 years after surgery: RR 1.38 (95% CI 0.32-5.9).
- 7 • Very low quality evidence from 1 RCT (n=41) showed no clinically important  
8 difference between autologous rectus fascial sling and synthetic mesh sling on the  
9 number of women with SUI who experienced an infection within 1 year of surgery:  
10 RR 7.33 (95% CI 0.4-133.57).
- 11 • Low quality evidence from 1 RCT (n=70) showed no women who received either  
12 autologous rectus fascial sling or synthetic mesh sling experienced an infection  
13 between 1 year and 5 years after surgery: RR 1.0 (95% CI 0.95-1.06), non event.
- 14 • Very low quality evidence from 2 RCTs (n=65) showed no clinically important  
15 difference between autologous rectus fascial sling and synthetic mesh sling on the  
16 number of women with SUI who experience de novo urgency between 1 year and  
17 5 years after surgery: RR 0.96 (95% CI 0.46-2.01).
- 18 • Very low quality evidence from 2 RCTs (n=193) showed no clinically important  
19 difference between autologous rectus fascial sling and synthetic mesh sling on the  
20 number of women with SUI who experience de novo urgency more than 5 years  
21 after surgery: RR 0.77 (95% CI 0.31-1.93).
- 22 • Very low quality evidence from 1 RCT (n=61) showed no clinically important  
23 difference between autologous rectus fascial sling and synthetic mesh sling on the  
24 number of women with SUI who experience de novo urge incontinence between 1  
25 year and 5 years after surgery: RR 5.56 (95% CI 0.74-41.68).
- 26 • Very low quality evidence from 1 RCT (n=69) showed no clinically important  
27 difference between autologous rectus fascial sling and synthetic mesh sling on the  
28 number of women with SUI who experience de novo urge incontinence more than  
29 5 years after surgery: RR 0.77 (95% CI 0.14-4.33).
- 30 • Very low quality evidence from 3 RCTs (n=182) showed a clinically important  
31 difference favouring synthetic mesh sling compared to autologous rectus fascial  
32 sling on the number of women with SUI who experience wound complications  
33 within 1 year of surgery: RR 6.2 (95% CI 1.32-29.06).

34

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

36 For composite cure outcome within approximately 1 year of surgery – NMA outcome,  
37 see [clinical evidence profile for NMA outcomes](#).

38

- 39 • Very low quality evidence from 3 RCTs (n=217) showed no clinically important  
40 difference between autologous rectus fascial sling and synthetic mesh sling on the  
41 number of women with SUI who are subjectively cured within 1 year of surgery:  
42 RR 1.02 (95% CI 0.56-1.86), random effects analysis.
- 43 ○ Very low quality evidence from 2 RCTs (n=197) showed there is a clinically  
44 important difference favouring retropubic synthetic mesh sling over autologous  
45 rectus fascial sling on the number of women with SUI who are subjectively  
46 cured within 1 year of surgery: RR 0.75 (95% CI 0.57-1.0).
- 47 ○ Very low quality evidence from 1 RCT (n=20) showed there is a clinically  
48 important difference favouring autologous rectus fascial sling over  
49 transobturator synthetic mesh sling on the number of women with SUI who are  
50 subjectively cured within 1 year of surgery: RR 3.0 (95% CI 1.14-7.91).

- 1 • Very low quality evidence from 1 RCT (n=41) showed no clinically important  
2 difference between autologous rectus fascial sling and synthetic mesh slings on  
3 the number of women with SUI who are subjectively cured between 1 year and 5  
4 years after surgery: RR 0.88 (95% CI 0.54-1.44).
- 5 • Very low quality evidence from 1 RCT (n=156) showed no clinically important  
6 difference between autologous rectus fascial sling and synthetic mesh sling on the  
7 number of women with SUI who are subjectively cured more than 5 years after  
8 surgery: RR 1.33 (95% CI 0.83-2.12).
- 9 • Low quality evidence from 4 RCTs (n=233) showed no clinically important  
10 difference between autologous rectus fascial sling and synthetic mesh sling on the  
11 number of women with SUI who are objectively cured within 1 year of surgery: RR  
12 1.03 (95% CI 0.96-1.11).
- 13 • Very low quality evidence from 3 RCTs (n=187) showed no clinically important  
14 difference between autologous rectus fascial sling and synthetic mesh sling on the  
15 number of women with SUI who are objectively cured between 1 year and 5 years  
16 after surgery: RR 0.98 (95% CI 0.85-1.13).
- 17 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
18 difference between autologous rectus fascial sling and synthetic mesh slings on  
19 the number of women with SUI who had a negative cough stress test between 1  
20 year and 5 years after surgery: RR 1.01 (95% CI 0.86-1.19).
- 21 • Very low quality evidence from 1 RCT (n=100) showed no clinically important  
22 difference between autologous rectus fascial slings and synthetic mesh slings on  
23 the number of women with SUI who had a negative cough stress test more than 5  
24 years after surgery: RR 1.03 (95% CI 0.91-1.17).

25

### 26 ***Patient satisfaction/patient-reported improvement***

27 For composite outcome of patient satisfaction/patient-reported improvement within  
28 approximately 1 year of surgery – NMA outcome, see [clinical evidence profile for](#)  
29 [NMA outcomes](#).

30

- 31 • Low quality evidence from 3 RCTs (n=137) showed no clinically important  
32 difference between autologous rectus fascial sling and synthetic mesh sling on the  
33 number of women with SUI who experience an improvement in continence status  
34 between 1 year and 5 years after surgery: RR 1.0 (95% CI 0.83-1.2)
- 35 • Very low quality evidence from 2 RCTs (n=256) showed no clinically important  
36 difference between autologous rectus fascial sling and synthetic mesh sling on the  
37 number of women with SUI who experience an improvement in continence status  
38 more than 5 years after surgery: RR 0.85 (95% CI 0.69-1.04)

39

### 40 ***Repeat surgery***

- 41 • Very low quality evidence from 2 RCTs (n=197) showed no clinically important  
42 difference between autologous rectus fascial sling and synthetic mesh sling on the  
43 number of women with SUI who have repeat surgery for any reason within 1 year  
44 of surgery: RR 1.39 (95% CI 0.13-14.50).
- 45 • Very low quality evidence from 1 RCT (n=69) showed no clinically important  
46 difference between autologous rectus fascial sling and synthetic mesh sling on the  
47 number of women with SUI who have repeat surgery for any reason more than 5  
48 years after surgery: RR 1.16 (95% CI 0.08-17.75).

- 1 • Very low quality evidence from 1 RCT (n=124) showed no clinically important  
2 difference between autologous rectus fascial sling and synthetic mesh sling on the  
3 number of women with SUI who have repeat surgery for SUI more than 5 years  
4 after surgery: RR 1.03 (95% CI 0.27-3.95).
- 5 • Very low quality evidence from 1 RCT (n=70) showed no clinically important  
6 difference between autologous rectus fascial sling and synthetic mesh sling on the  
7 number of women with SUI who have repeat surgery for POP or mesh  
8 complications between 1 year and 5 years after surgery: RR 0.2 (95% CI 0.01-  
9 4.02).
- 10 • Very low quality evidence from 1 RCT (n=124) showed no clinically important  
11 difference between autologous rectus fascial sling and synthetic mesh sling on the  
12 number of women with SUI who have repeat surgery for POP or mesh  
13 complications more than 5 years after surgery: RR 2.07 (95% CI 0.39-10.87).

#### 14 **Non-autologous biological sling versus synthetic mesh sling**

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

- 16 • Very low quality evidence from 1 RCT (n=101) showed no clinically important  
17 difference between porcine dermis sling and TVT in women with SUI on  
18 continence-specific health-related quality of life (SMD +0.19 [95% CI -0.21 to  
19 +0.59]) and sexual function (SMD +0.31 [95% CI -0.1 to +0.71]) as assessed by  
20 the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire at a  
21 median 10 years after surgery.
- 22 • Low quality evidence from 1 RCT (n=100) showed no clinically important  
23 difference between porcine dermis sling and Align-TO in women with SUI on  
24 continence-specific health-related quality of life as assessed by the King's Health  
25 Questionnaire total score at 1 year after surgery: MD -53.6 (95% CI -136.34 to  
26 +29.14).

27

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

- 29 • Low quality evidence from 3 RCTs (n=350) showed no women with SUI who  
30 received either a porcine dermis sling or a synthetic mesh sling suffered severe  
31 bleeding during surgery requiring a blood transfusion: RR 1.0 (95% CI 0.98-1.02),  
32 non-event.
- 33 • Very low quality evidence from 1 RCT (n=139) showed no clinically important  
34 difference between cadaveric fascia lata slings and retropubic synthetic mesh  
35 slings on the number of women with SUI who suffer a perioperative bladder injury:  
36 RR 0.4 (95% CI 0.11-1.46).
- 37 • Very low quality evidence from 3 RCTs (n=350) showed no clinically important  
38 difference between porcine dermis slings and synthetic mesh slings on the  
39 number of women with SUI who suffer a perioperative bladder injury: RR 0.36  
40 (95% CI 0.04-3.13).

41

##### 42 ***Complications***

- 43 • Very low quality evidence from 1 RCT (n=100) showed no clinically important  
44 difference between porcine dermis slings and synthetic mesh slings on the  
45 number of women with SUI who experience pain within 1 year of surgery: RR 2.0  
46 (95% CI 0.19-21.36).
- 47 • Very low quality evidence from 1 RCT (n=142) showed no clinically important  
48 difference between porcine dermis sling and TVT on the number of women with

- 1 SUI who experience pain between 1 year and 5 years after surgery: RR 0.61 (95%  
2 CI 0.11-3.56).
- 3 • Very low quality evidence from 1 RCT (n=101) showed no women who received  
4 either porcine dermis sling or TVT experienced pain more than 5 years after  
5 surgery: RR 1.0 (95% CI 0.94-1.04), non-event.
  - 6 • Low quality evidence from 1 RCT (n=139) showed no women who received either  
7 cadaveric fascia lata slings or retropubic IVS experienced mesh extrusion within 1  
8 year of surgery: RR 1.0 (95% CI 0.97-1.03), non-event.
  - 9 • Very low quality evidence from 1 RCT (n=100) showed no clinically important  
10 difference between porcine dermis slings and transobturator synthetic mesh slings  
11 on the number of women with SUI who experience mesh extrusion within 1 year of  
12 surgery: RR 0.33 (95% CI 0.01-7.99).
  - 13 • Very low quality evidence from 1 RCT (n=101) showed no clinically important  
14 difference between porcine dermis slings and TVT on the number of women with  
15 SUI who experience mesh extrusion more than 5 years after surgery: RR 0.55  
16 (95% CI 0.02-13.1).
  - 17 • Very low quality evidence from 1 RCT (n=139) showed no clinically important  
18 difference between cadaveric fascia lata slings and retropubic IVS on the number  
19 of women with SUI who experience a need for catheterisation within 1 year  
20 surgery: RR 1.07 (95% CI 0.43-2.7).
  - 21 • Very low quality evidence from 2 RCTs (n=257) showed no clinically important  
22 difference between porcine dermis slings and synthetic mesh sling on the number  
23 of women with SUI who experience a need for catheterisation within 1 year  
24 surgery: RR 0.61 (95% CI 0.11-3.56).
  - 25 • Very low quality evidence from 1 RCT (n=101) showed no clinically important  
26 difference between porcine dermis slings and TVT on the number of women with  
27 SUI who experienced a need for catheterisation more than 5 years after surgery:  
28 RR 0.23 (95% CI 0.01-4.42).
  - 29 • Low quality evidence from 1 RCT (n=139) showed no women who received either  
30 cadaveric fascia lata sling or retropubic IVS experienced an infection within 1 year  
31 of surgery: RR 1.0 (95% CI 0.97-1.03), non event.
  - 32 • Very low quality evidence from 1 RCT (n=142) showed no clinically important  
33 difference between porcine dermis sling and TVT on the number of women with  
34 SUI who have an infection between 1 year and 5 years after surgery: RR 0.18  
35 (95% CI 0.01-3.77).
  - 36 • Very low quality evidence from 1 RCT (n=128) showed no clinically important  
37 difference between porcine dermis slings and TVT on the number of women with  
38 SUI who experience de novo urgency between 1 year and 5 years after surgery:  
39 RR 1.18 (95% CI 0.53-2.6).
  - 40 • Very low quality evidence from 1 RCT (n=101) showed no clinically important  
41 difference between porcine dermis slings and TVT on the number of women with  
42 SUI who experience de novo urgency more than 5 years after surgery: RR 0.55  
43 (95% CI 0.02-13.1).
  - 44 • Low quality evidence from 1 RCT (n=139) showed a clinically important difference  
45 favouring retropubic IVS over cadaveric fascia lata slings on the number of women  
46 with SUI who experience de novo urge incontinence within 1 year of surgery: RR  
47 2.69 (95% CI 1.74-4.15).
  - 48 • Very low quality evidence from 1 RCT (n=142) showed no clinically important  
49 difference between porcine dermis sling and TVT on the number of women with  
50 SUI who experience de novo urge incontinence within 1 year of surgery: RR 0.61  
51 (95% CI 0.18-2.08).

- 1 • Moderate quality evidence from 1 RCT (n=100) showed no women who received  
2 either porcine dermis sling or Align-TO experienced occurrence of POP within 1  
3 year of surgery: RR 1.0 (95% CI 0.96-1.04), non-event.
- 4 • Very low quality evidence from 1 RCT (n=100) showed no clinically important  
5 difference between porcine dermis slings and synthetic mesh slings on the  
6 number of women with SUI who experience wound complications within 1 year of  
7 surgery: RR 3.0 (95% CI 0.13-71.92).

8

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

10 For composite cure outcome within approximately 1 year of surgery – NMA outcome,  
11 see [clinical evidence profile for NMA outcomes](#).

12

- 13 • Very low quality evidence from 2 RCTs (n=224) showed no clinically important  
14 difference between porcine dermis slings and synthetic mesh slings on the  
15 number of women with SUI who are subjectively cured within 1 year of surgery:  
16 RR 0.61 (95% CI 0.21-1.82), random effects analysis.
- 17 ○ Very low quality evidence from 1 RCT (n=124) showed a clinically important  
18 difference favouring TVT over porcine dermis slings on the number of women  
19 with SUI who are subjectively cured within 1 year of surgery: RR 0.36 (95% CI  
20 0.3-0.66).
- 21 ○ Very low quality evidence from 1 RCT (n=100) showed no clinically important  
22 difference between porcine dermis slings and Align-TO on the number of  
23 women with SUI who are subjectively cured within 1 year of surgery: RR 0.97  
24 (95% CI 0.75-1.26).
- 25 • Very low quality evidence from 1 RCT (n=124) showed a clinically important  
26 difference favouring TVT over porcine dermis sling on the number of women who  
27 are subjectively cured more than 5 years after surgery: RR 0.42 (95% CI 0.18-  
28 0.96).
- 29 • Very low quality evidence from 1 RCT (n=139) showed no clinically important  
30 difference between cadaveric fascia lata slings and retropubic IVS on the number  
31 of women with SUI who are objectively cured within 1 year of surgery: RR 1.11  
32 (95% CI 0.79-1.55).
- 33 • Moderate quality evidence from 1 RCT (n=100) showed no clinically important  
34 difference between porcine dermis sling and Align-TO on the number of women  
35 with SUI who are objectively cured within 1 year of surgery: RR 0.96 (95% CI  
36 0.89-1.04).
- 37 • Low quality evidence from 1 RCT (n=142) showed no clinically important  
38 difference between porcine dermis sling and TVT on the number of women with  
39 SUI who are objectively cured between 1 year and 5 years after surgery: RR 0.97  
40 (95% CI 0.81-1.16).

41

### 42 ***Patient satisfaction/patient-reported improvement***

43 For composite outcome of patient satisfaction/patient-reported improvement within  
44 approximately 1 year of surgery – NMA outcome, see [clinical evidence profile for  
45 NMA outcomes](#).

46

- 47 • Very low quality evidence from 1 RCT (n=124) showed a clinically important  
48 difference favouring TVT compared to porcine dermis slings on the number of

1 women who show an improvement in continence status more than 5 years after  
2 surgery: RR 0.66 (95% CI 0.46-0.95).

3

4 No evidence was identified to inform this outcome for the time period of between 1  
5 and 5 years after surgery.

6

### 7 ***Repeat surgery***

8 • Very low quality evidence from 1 RCT (n=139) showed no clinically important  
9 difference between cadaveric fascia lata slings and retropubic IVS on the number  
10 of women with SUI who have repeat surgery for any reason within 1 year of  
11 surgery: RR 5.37 (95% CI 0.26-109.81).

12 • Very low quality evidence from 1 RCT (n=115) showed a clinically important  
13 difference favouring TVT over porcine dermis slings on the number of women with  
14 SUI who have repeat surgery for any reason within 1 year of surgery: RR 28.3  
15 (95% CI 1.69-474.6).

16 • Very low quality evidence from 1 RCT (n=101) showed that there may be a  
17 clinically important difference favouring TVT over porcine dermis slings on the  
18 number of women with SUI who have repeat surgery for SUI more than 5 years  
19 after surgery, although there is some uncertainty: RR 4.14 (95% CI 0.85-20.32).

20 • Very low quality evidence from 2 RCTs (n=201) showed no clinically important  
21 difference between porcine dermis slings and synthetic mesh slings on the  
22 number of women who have repeat surgery for POP or mesh complications more  
23 than 5 years after surgery: RR 1.41 (95% CI 0.35-5.68).

24

## 25 **Transobturator mesh sling versus retropubic mesh sling**

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

27 • Very low quality evidence from 1 RCT (n=100) showed there may be a clinically  
28 important difference favouring retropubic over transobturator synthetic mesh slings  
29 on the International Consultation on Incontinence Modular Questionnaire-Urinary  
30 Incontinence Quality of Life (ICIQ-UI-QoL) in women with SUI with 1 year of  
31 surgery, although there is some uncertainty: MD -6.37 (95% CI -13.22 to +0.48).

32 • Very low quality evidence from 1 RCT (n=100) showed that there is a clinically  
33 important difference favouring retropubic over transobturator synthetic mesh slings  
34 in women with SUI on the International Consultation on Incontinence Modular  
35 Questionnaire-Urinary Incontinence Quality of Life (ICIQ-UI-QoL) between 1 year  
36 and 5 years after surgery: MD -8.34 (95% CI -14.40 to -2.28).

37 • Low quality evidence from 5 RCTs (n=887) showed no clinically important  
38 difference between transobturator and retropubic synthetic mesh slings on  
39 International Consultation on Incontinence Modular Questionnaire-Urinary  
40 Incontinence Scored Form (ICIQ-UI-SF) in women with SUI within 1 year of  
41 surgery: MD +0.65 (95% CI +0.19 to +1.1).

42 • Low quality evidence from 1 RCT (n=100) showed no clinically important  
43 difference between transobturator and retropubic synthetic slings on the  
44 International Consultation on Incontinence Modular Questionnaire-Urinary  
45 Incontinence Form Scored Form (ICIQ-UI-SF) in women with SUI between 1 year  
46 and 5 years after surgery: MD +0.19 (95% CI -0.49 to +0.87).

47 • Very low quality evidence from 1 RCT (n=125) showed a clinically important  
48 difference favouring TVT-Exact (retropubic) synthetic slings over TVT-Abbrevio  
49 (transobturator) synthetic slings in women with SUI on the Urinary Incontinence

- 1 Quality of Life Scale (I-QoL) within 1 year of surgery: MD -4.54 (95% CI -7.43 to -  
2 1.65).
- 3 • Very low quality evidence from 3 RCTs (n=541) showed no clinically important  
4 difference between transobturator and retropubic synthetic mesh slings in women  
5 with SUI on the following King's Health Questionnaire (KHQ) subscales within 1  
6 year of surgery: General health perceptions (MD -0.7 [95% CI -3.81 to +2.41]),  
7 incontinence impact (MD -4.54 [95% CI -9.82 to +0.74]), role limitations (MD -4.29  
8 [95% CI -8.3 to -0.28]), physical limitations (MD -4.39 [95% CI -8.6 to -0.18]),  
9 social limitations (MD -2.89 [95% CI -5.36 to -0.43]), personal relationships (MD -  
10 3.33 [95% CI -8.48 to +1.82], random effects analysis), emotions (MD -4.66 [95%  
11 CI -8.4 to -0.92]), sleep/energy (MD -0.72 [95% CI -3.52 to -2.09]), and severity  
12 (MD -3.77 [95% CI -8.33 to +0.78]).
  - 13 • Very low quality evidence from 1 RCT (n=480) showed no clinically important  
14 difference between transobturator and retropubic synthetic mesh slings in women  
15 with SUI on the King's Health Questionnaire (KHQ) intercourse subscale within 1  
16 year of surgery: MD -0.66 (95% CI -1.4 to +0.08).
  - 17 • Very low to low quality evidence from 2 RCTs (n=434) showed no clinically  
18 important difference between transobturator and retropubic synthetic mesh slings  
19 in women with SUI on the following King's Health Questionnaire (KHQ) subscales  
20 between 1 year and 5 years after surgery: General health perceptions (MD -0.23  
21 [95% CI -4.29 to +3.82]), incontinence impact (MD +2.26 [95% CI -2.61 to +7.13]),  
22 role limitations (MD +2.55 [95% CI -1.19 to +6.28]), physical limitations (MD +0.17  
23 [95% CI -4.89 to +5.23]), social limitations (MD +1.32 [95% CI -1.42 to +4.05]),  
24 personal relationships (MD -1.69 [95% CI -8.75 to +5.37]), random effects  
25 analysis), emotions (MD +0.57 [95% CI -2.48 to +3.61]), sleep/energy (MD +2.06  
26 [95% CI -1.1 to +5.22]), and severity (MD +2.47 [95% CI -2.23 to +7.17]).
  - 27 • Very low quality evidence from 1 RCT (n=331) showed a clinically important  
28 difference favouring transobturator over retropubic synthetic mesh slings in  
29 women with SUI on the King's Health Questionnaire (KHQ) intercourse subscale  
30 between 1 year and 5 years after surgery: MD -25.6 (95% CI -34.46 to -16.74).
  - 31 • Very low quality evidence from 1 RCT (n=265 to n=263) showed no clinically  
32 important difference between transobturator and retropubic synthetic mesh slings  
33 in women with SUI on the the Urinary Incontinence Severity Score (UISS)  
34 questionnaire within 1 year of surgery (MD -0.3 [95% CI -0.65 to +0.05] and  
35 between 1 year and 5 years after surgery (MD 0.0 [95% CI -0.62 to +0.62]).
  - 36 • Very quality evidence from 2 RCTs (n=722 to n=707) showed no clinically  
37 important difference between transobturator and retropubic synthetic mesh slings  
38 in women with SUI on the overall Pelvic Organ Prolapse/Incontinence Sexual  
39 Questionnaire (PISQ-12) within 1 year of surgery (MD +0.08 [95% CI -0.73 to  
40 +0.89] and between 1 year and 5 years after surgery (MD +0.73 [95% CI -0.21 to  
41 +1.67]).
  - 42 • Low quality evidence from 1 RCT (n=180) showed no clinically important  
43 difference between transobturator and retropubic synthetic mesh slings on the  
44 number of women with SUI who reported that their sexual function was not  
45 affected according to the Bristol Female Lower Urinary Tract Symptoms-Short  
46 Form (BFLUTS-SF) questionnaire within 1 year of surgery: RR 0.94 (95% CI 0.76-  
47 1.17).

#### 48 **Adverse events**

- 49 • Very low quality evidence from 10 RCTs (n=2041) showed no clinically important  
50 difference between transobturator and retropubic synthetic mesh slings in women

- 1 with SUI on the number of women with SUI who experience severe bleeding that  
2 requires a blood transfusion during surgery: RR 0.35 (95% CI 0.06-2.19).
- 3 • Moderate quality evidence from 40 RCTs (n=6654) showed a clinically important  
4 difference favouring transobturator over retropubic synthetic mesh slings on the  
5 number of women with SUI who experience a perioperative bladder injury: RR  
6 0.15 (95% CI 0.1-0.24).
- 7 • Moderate quality evidence from 12 RCTs (n=1455) showed no women with SUI  
8 who received a transobturator synthetic sling or a retropubic sling suffered a  
9 perioperative bowel injury: RR 1.0 (95% CI 0.99-1.01), non-event.

## 10 **Complications**

- 11 • Moderate quality evidence from 19 RCTs (n=3618) showed a clinically important  
12 difference favouring retropubic over transobturator synthetic mesh slings on the  
13 number of women with SUI who experienced pain within 1 year of surgery: RR 2.8  
14 (95% CI 2.04-3.86).
- 15 • Very low quality evidence from 11 RCTs (n=1953) showed no clinically important  
16 difference between transobturator and retropubic synthetic mesh slings on the  
17 number of women with SUI who experienced pain between 1 year and 5 years  
18 after surgery: RR 1.25 (95% CI 0.79-1.97).
- 19 • Very low quality evidence from 2 RCTs (n=207) showed no clinically important  
20 difference between transobturator and retropubic synthetic mesh slings on the  
21 number of women with SUI who experienced pain more than 5 years after  
22 surgery: RR 1.11 (95% CI 0.54-2.27).
- 23 • Low quality evidence from 22 RCTs (n=3829) showed a clinically important  
24 difference favouring retropubic over transobturator synthetic mesh slings on the  
25 number of women with SUI who experienced mesh extrusion within 1 year of  
26 surgery: RR 1.66 (95% CI 1.02-2.71).
- 27 • Very low quality evidence from 12 RCTs (n=2279) showed a clinically important  
28 difference favouring retropubic over transobturator synthetic mesh slings on the  
29 number of women with SUI who experienced mesh extrusion between 1 year and  
30 5 years after surgery: RR 2.17 (95% CI 1.14-4.14).
- 31 • Low quality evidence from 16 RCTs (n=3039) showed a clinically important  
32 difference favouring transobturator over retropubic synthetic mesh slings on the  
33 number of women with SUI who experienced need for catheterisation within 1 year  
34 of surgery: RR 0.61 (95% CI 0.46-0.81).
- 35 • Very low quality evidence from 4 RCTs (n=822) showed no clinically important  
36 difference between transobturator and retropubic synthetic mesh slings on the  
37 number of women with SUI who experienced a need for catheterisation between 1  
38 year and 5 years after surgery: RR 0.67 (95% CI 0.19-2.35).
- 39 • Very low quality evidence from 17 RCTs (n=3245) showed no clinically important  
40 difference between transobturator and retropubic synthetic mesh slings on the  
41 number of women with SUI who experienced an infection within 1 year of surgery:  
42 RR 1.06 (95% CI 0.76-1.48).
- 43 • Very low quality evidence from 7 RCTs (n=1838) showed no clinically important  
44 difference between transobturator and retropubic synthetic mesh slings on the  
45 number of women with SUI who experienced an infection between 1 year and 5  
46 years after surgery: RR 0.76 (95% CI 0.54-1.06).
- 47 • Very low quality evidence from 2 RCTs (n=268) showed no clinically important  
48 difference between transobturator and retropubic synthetic mesh slings on the  
49 number of women with SUI who experienced an infection more than 5 years after  
50 surgery: RR 0.59 (95% CI 0.2-1.76).

- 1 • Very low quality evidence from 8 RCTs (n=1164) showed no clinically important  
2 difference between transobturator and retropubic synthetic mesh slings on the  
3 number of women with SUI who experienced de novo urgency within 1 year of  
4 surgery: RR 0.83 (95% CI 0.53-1.29).
- 5 • Very low quality evidence from 7 RCTs (n=761) showed no clinically important  
6 difference between transobturator and retropubic synthetic mesh slings on the  
7 number of women with SUI who experienced de novo urgency between 1 year  
8 and 5 years after surgery: RR 0.84 (95% CI 0.49-1.46).
- 9 • Very low quality evidence from 5 RCTs (n=1243) showed no clinically important  
10 difference between transobturator and retropubic synthetic mesh slings on the  
11 number of women with SUI who experienced de novo urge incontinence within 1  
12 year of surgery: RR 1.34 (95% CI 0.84-2.13).
- 13 • Very low quality evidence from 4 RCTs (n=987) showed no clinically important  
14 difference between transobturator and retropubic synthetic mesh slings on the  
15 number of women with SUI who experienced de novo urge incontinence between  
16 1 year and 5 years after surgery: RR 1.02 (95% CI 0.38-2.75).
- 17 • Very low quality evidence from 1 RCT (n=88) showed no clinically important  
18 difference between transobturator and retropubic synthetic mesh slings on the  
19 number of women with SUI who experienced de novo nocturia within 1 year of  
20 surgery: RR 0.3 (95% CI 0.03-2.81).
- 21 • Very low quality evidence from 1 RCT (n=71) showed a clinically important  
22 difference favouring retropubic over transobturator synthetic mesh slings on the  
23 number of women with SUI who experienced de novo nocturia between 1 year  
24 and 5 years after surgery: RR 2.6 (95% CI 1.16-5.83).
- 25 • Very low quality evidence from 1 RCT (n=87) showed no clinically important  
26 difference between transobturator and retropubic synthetic mesh slings on the  
27 number of women with SUI who experienced occurrence of POP more than 5  
28 years after surgery: RR 0.28 (95% CI 0.01-6.80).
- 29 • Very low quality evidence from 4 RCTs (n=443) showed no clinically important  
30 difference between transobturator and retropubic synthetic mesh slings on the  
31 number of women with SUI who experienced wound complications within 1 year of  
32 surgery: RR 0.8 (95% CI 0.18-3.56).
- 33 • Very low quality evidence from 2 RCTs (n=248) showed no clinically important  
34 difference between transobturator and retropubic synthetic mesh slings on the  
35 number of women with SUI who experience wound complications between 1 year  
36 and 5 years after surgery: RR 0.32 (95% CI 0.01-7.84).

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

38 For composite cure outcome within approximately 1 year of surgery – NMA outcome,  
39 see [clinical evidence profile for NMA outcomes](#).

- 40
- 41 • Low quality evidence from 15 RCTs (n=2638) showed no clinically important  
42 difference between transobturator and retropubic synthetic mesh slings on the  
43 number of women with SUI who are subjectively cured within 1 year of surgery:  
44 RR 0.96 (95% CI 0.99-1.01), random effects analysis.
- 45 • Low quality evidence from 6 RCTs (n=1340) showed no clinically important  
46 difference between transobturator and retropubic synthetic mesh slings on the  
47 number of women with SUI who are subjectively cured within 1 year of SUI  
48 surgery and who did not have concomitant POP surgery: RR 0.97 (95% CI  
49 0.9-1.05).

- 1 • Low quality evidence from 6 RCTs (n=1227) showed no clinically important  
2 difference between transobturator and retropubic synthetic mesh slings on the  
3 number of women with SUI who are subjectively cured between 1 year and 5  
4 years after surgery: RR 1.05 (95% CI 0.96-1.15).
- 5 • Low quality evidence from 4 RCTs (n=1002) showed no clinically important  
6 difference between transobturator and retropubic synthetic mesh slings on the  
7 number of women with SUI who are subjectively cured between 1 year and 5  
8 years after SUI surgery and who did not have concomitant POP surgery: RR 1.06  
9 (95% CI 0.96-1.18).
- 10 • Very low quality evidence from 2 RCTs (n=288) showed no clinically important  
11 difference between transobturator and retropubic synthetic mesh slings on the  
12 number of women with SUI who are subjectively cured more than 5 years after  
13 surgery: RR 0.92 (95% CI 0.74-1.13).
- 14 • Low quality evidence from 15 RCTs (n=2176) showed no clinically important  
15 difference between transobturator and retropubic synthetic mesh slings on the  
16 number of women with SUI who are objectively cured within 1 year of surgery: RR  
17 0.95 (95% CI 0.91-0.99).
- 18 • Low quality evidence from 3 RCTs (n=323) showed no clinically important  
19 difference between transobturator and retropubic synthetic mesh slings on the  
20 number of women with SUI who are objectively cured within 1 year of SUI surgery  
21 and who did not have concomitant POP surgery: RR 1.07 (95% CI 0.96-1.19).
- 22 • Low quality evidence from 10 RCTs (n=2057) showed no clinically important  
23 difference between transobturator and retropubic synthetic mesh slings on the  
24 number of women with SUI who are objectively cured between 1 year and 5 years  
25 after surgery: RR 1.02 (95% CI 0.97-1.08).
- 26 • Very low quality evidence from 1 RCT (n=199) showed no clinically important  
27 difference between transobturator and retropubic synthetic mesh slings on the  
28 number of women with SUI who are objectively cured between 1 year and 5 years  
29 after SUI surgery and who did not have concomitant POP surgery: RR 1.14 (95%  
30 CI 0.89-1.45).
- 31 • Very low quality evidence from 1 RCT (n=61) showed no clinically important  
32 difference between transobturator and retropubic synthetic mesh slings on the  
33 number of women with pure SUI who are objectively cured between 1 year and 5  
34 years after SUI surgery: RR 1.36 (95% CI 0.89-2.08).
- 35 • Very low quality evidence from 1 RCT (n=84) showed no clinically important  
36 difference between transobturator and retropubic synthetic mesh slings on the  
37 number of women with mixed UI who are objectively cured between 1 year and 5  
38 years after SUI surgery: RR 0.99 (95% CI 0.82-1.2).
- 39 • Very low quality evidence from 2 RCTs (n=288) showed no clinically important  
40 difference between transobturator and retropubic synthetic mesh slings on the  
41 number of women with SUI who are objectively cured more than 5 years after  
42 surgery: RR 0.88 (95% CI 0.74-1.05).
- 43 • Low quality evidence from 9 RCTs (n=2292) showed no clinically important  
44 difference between transobturator and retropubic synthetic mesh slings on the  
45 number of women with SUI who had a negative cough stress test within 1 year of  
46 surgery: RR 0.99 (95% CI 0.95-1.03).
- 47 • Very low quality evidence from 4 RCTs (n=1151) showed no clinically important  
48 difference between transobturator and retropubic synthetic mesh slings on the  
49 number of women with SUI who had a negative cough stress test within 1 year of  
50 SUI surgery and who did not have concomitant POP surgery: RR 0.99 (95% CI  
51 0.93-1.05).

- 1 • Low quality evidence from 5 RCTs (n=1352) showed no clinically important  
2 difference between transobturator and retropubic synthetic mesh slings on the  
3 number of women with SUI who had a negative cough stress test between 1 year  
4 and 5 years after surgery: RR 0.97 (95% CI 0.89-1.06).
- 5 • Very low quality evidence from 2 RCTs (n=703) showed no clinically important  
6 difference between transobturator and retropubic synthetic mesh slings on the  
7 number of women with SUI who had a negative cough stress test between 1 year  
8 and 5 years after surgery and who did not have concomitant POP surgery: RR  
9 1.01 (95% CI 0.88-1.16).
- 10 • Low quality evidence from 1 RCT (n=36) showed no clinically important difference  
11 between transobturator and retropubic synthetic mesh slings in women with SUI  
12 on the number of incontinence episodes experienced per day between 1 year and  
13 5 years after surgery: MD -0.3 (95% CI -1.25 to +0.65).

#### 14 ***Patient satisfaction/patient-reported improvement***

15 For composite outcome of patient satisfaction/patient-reported improvement within  
16 approximately 1 year of surgery – NMA outcome, see [clinical evidence profile for](#)  
17 [NMA outcomes](#).

- 18
- 19 • Low quality evidence from 13 RCTs (n=2771) showed no clinically important  
20 difference between transobturator and retropubic synthetic mesh slings on the  
21 number of women with SUI who show an improvement in continence status  
22 between 1 year and 5 years after surgery: RR 1.03 (95% CI 0.98-1.07).
- 23 • Low quality evidence from 2 RCTs (n=249) showed no clinically important  
24 difference between transobturator and retropubic synthetic mesh slings on the  
25 number of women with SUI who show an improvement in continence status  
26 between 1 year and 5 years after SUI surgery and who did not have concomitant  
27 POP surgery: RR 0.98 (95% CI 0.85-1.13).
- 28 • Very low quality evidence from 1 RCT (n=84) showed no clinically important  
29 difference between transobturator and retropubic synthetic mesh slings on the  
30 number of women with pure SUI who show an improvement in continence status  
31 between 1 year and 5 years after surgery: RR 0.92 (95% CI 0.81-1.05).
- 32 • Very low quality evidence from 1 RCT (n=61) showed no clinically important  
33 difference between transobturator and retropubic synthetic mesh slings on the  
34 number of women with mixed SUI who show an improvement in continence status  
35 between 1 year and 5 years after surgery: RR 1.16 (95% CI 0.95-1.41).
- 36 • Low quality evidence from 1 RCT (n=140) showed no clinically important  
37 difference between transobturator and retropubic synthetic mesh slings on the  
38 number of women with SUI who show an improvement in continence status more  
39 than 5 years after surgery: RR 0.94 (95% CI 0.86-1.03).

#### 40 ***Repeat surgery***

- 41 • Low quality evidence from 5 RCTs (n=1114) showed a clinically important  
42 difference favouring retropubic over transobturator synthetic mesh slings on the  
43 number of women with SUI who have repeat surgery for SUI within 1 year of  
44 surgery: RR 8.98 (95% CI 1.53-52.59).
- 45 • Very low quality evidence from 6 RCTs (n=1022) showed no clinically important  
46 difference between transobturator and retropubic synthetic mesh slings on the  
47 number of women who have repeat surgery for SUI between 1 year and 5 years  
48 after surgery: RR 1.53 (95% CI 0.62-3.75).

- 1 • Very low quality evidence from 1 RCT (n=87) showed no clinically important  
2 difference between transobturator and retropubic synthetic mesh slings on the  
3 number of women who have repeat surgery for SUI more than 5 years after  
4 surgery: RR 7.69 (95% CI 0.43-138.58).
- 5 • Very low quality evidence from 1 RCT (n=554) showed no women with SUI who  
6 received either a transobturator or a retropubic synthetic mesh sling had repeat  
7 surgery for POP within 1 year of surgery: RR 1.0 (95% CI 0.99-1.01), non-event.
- 8 • Very low quality evidence from 1 RCT (n=87) showed no clinically important  
9 difference between transobturator and retropubic synthetic mesh slings on the  
10 number of women who have repeat surgery for POP more than 5 years after  
11 surgery: RR 1.7 (95% CI 0.16-18.08).
- 12 • Very low quality evidence from 13 RCTs (n=2447) showed no clinically important  
13 difference between transobturator and retropubic synthetic mesh slings on the  
14 number of women with SUI who have repeat surgery for mesh complications  
15 within 1 year of surgery: RR 1.11 (95% CI 0.72-1.72).
- 16 • Very low quality evidence from 8 RCTs (n=1688) showed no clinically important  
17 difference between transobturator and retropubic synthetic mesh slings on the  
18 number of women who have repeat surgery for SUI between 1 year and 5 years  
19 after surgery: RR 1.21 (95% CI 0.61-2.38).
- 20 • Very low quality evidence from 1 RCT (n=87) showed no clinically important  
21 difference between transobturator and retropubic synthetic mesh slings on the  
22 number of women who have repeat surgery for SUI more than 5 years after  
23 surgery: RR 2.98 (95% CI 0.66-13.54).

#### 24 **Single-incision mini-sling versus other synthetic mesh sling**

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

- 26 • Low quality evidence from 1 RCT (n=260) showed no clinically important  
27 difference between TVT-Secur single-incision mini-sling and TVT on Incontinence  
28 Severity Index (ISI) total score in women with SUI within 1 year of surgery: MD  
29 +0.7 (+0.14 to +1.26).
- 30 • Low quality evidence from 1 RCT (n=197) showed a clinically important difference  
31 favouring TVT-O compared to TVT-Secur single-incision mini-sling on the Urinary  
32 Incontinence Quality of Life Scale (I-QoL) in women with SUI within 2 years of  
33 surgery: MD -6.24 (-10.93 to -1.55).
- 34 • Low quality evidence from 1 RCT (n=120) showed no clinically important  
35 difference between TVT-Secur single-incision mini-sling and TVT-O on the  
36 number of women with SUI who show an improvement of 20 points or more on the  
37 Urinary Incontinence Quality of Life Scale (I-QoL) within 5 years of surgery: RR  
38 0.86 (0.71-1.05).
- 39 • Very low quality evidence from 2 RCTs (n=206) showed no clinically important  
40 difference between any single-incision mini-sling and any synthetic transoburator  
41 sling on the International Consultation on Incontinence Modular Questionnaire-  
42 Urinary Incontinence Scored Form (ICIQ-UI-SF) in women with SUI within 1 year  
43 of surgery: MD +0.06 (95% CI -0.33 to +0.45).
  - 44 ○ Low quality evidence from 1 RCT (n=164) showed no clinically important  
45 difference between Needleless single-incision mini-sling and TOT on the  
46 International Consultation on Incontinence Modular Questionnaire-Urinary  
47 Incontinence Scored Form (ICIQ-UI-SF) in women with SUI within 1 year of  
48 surgery: MD +0.08 (95% CI -0.32 to +0.48).

- 1       ○ Low quality evidence from 1 RCT (n=42) showed no clinically important  
2       difference between single-incision mini-sling (brand not reported) and TVT-O  
3       on the International Consultation on Incontinence Modular Questionnaire-  
4       Urinary Incontinence Scored Form (ICIQ-UI-SF) in women with SUI within 1  
5       year of surgery: MD -0.3 (95% CI -2.15 to +1.55).
- 6       ● Very low quality evidence from 2 RCTs (n=261) showed no clinically important  
7       difference between any single-incision mini-sling and TOT on the International  
8       Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Scored  
9       Form (ICIQ-UI-SF) in women with SUI between 1 year and 5 years after surgery:  
10      SMD -0.11 (95% CI -0.36 to +0.13).
- 11      ○ Very low quality evidence from 1 RCT (n=83) showed no clinically important  
12      difference between MiniArc single-incision mini-sling and TOT on the  
13      International Consultation on Incontinence Modular Questionnaire-Urinary  
14      Incontinence Scored Form (ICIQ-UI-SF) in women with SUI between 1 year  
15      and 5 years after surgery: SMD +0.2 (95% CI -0.23 to +0.63).
- 16      ○ Moderate quality evidence from 1 RCT (n=178) showed no clinically important  
17      difference between Needleless single-incision mini-sling and TOT on the  
18      International Consultation on Incontinence Modular Questionnaire-Urinary  
19      Incontinence Scored Form (ICIQ-UI-SF) in women with SUI between 1 year  
20      and 5 years after surgery: SMD -0.26 (95% CI -0.55 to +0.04).
- 21      ● Moderate quality evidence from 1 RCT (n=132 to n=133) showed no clinically  
22      important difference between TVT-Secur single-incision mini-sling in either the  
23      H(ammock) position (MD +2.1 [95% CI +0.44 to +3.76]) or the the U position (MD  
24      +1.8 [95% CI +0.33 to +3.27]) and TVT-O on the International Consultation on  
25      Incontinence Modular Questionnaire-Urinary Incontinence Scored Form (ICIQ-UI-  
26      SF) in women with SUI between 1 year and 5 years after surgery.
- 27      ● Low to very low quality evidence from 1 RCT (n=75) showed no clinically  
28      important difference between TVT-Secur single-incision mini-sling and TVT-O in  
29      women with SUI on the King's Health Questionnaire (KHQ) subscales of general  
30      health perceptions (MD -3.9 [95% CI -12.64 to +4.84]), incontinence impact (MD -  
31      2.7 [95% CI -14.11 to +8.71]), role limitations (MD -7.0 [95% CI -20.44 to +6.44]),  
32      physical limitations (MD -8.8 [95% CI -22.28 to +4.68]), social limitations (MD -3.9  
33      [95% CI -13.72 to +5.92]), personal relationships (MD +10.4 [95% CI +1.06 to  
34      +19.74]), emotions (MD +7.1 [95% CI -1.59 to +15.79]), sleep/energy (MD +2.9  
35      [95% CI -6.62 to +12.42]), and severity (MD -7.9 [95% CI -20.08 to +4.28]) at 1  
36      year after surgery.
- 37      ● Low quality evidence from 1 RCT (n=115) showed no clinically important  
38      difference between TVT-Secur single-incision mini-sling and TVT-O in women with  
39      SUI on the King's Health Questionnaire (KHQ) subscales of general health  
40      perceptions (MD -0.59 [95% CI -6.98 to +5.8]), incontinence impact (MD +1.04  
41      [95% CI -5.47 to +7.55]), role limitations (MD +0.15 [95% CI -5.33 to +5.63]),  
42      physical limitations (MD +0.5 [95% CI -3.67 to +4.67]), social limitations (MD -0.39  
43      [95% CI -2.0 to +1.22]), personal relationships (MD +0.42 [95% CI -1.03 to  
44      +0.19]), emotions (MD -0.42 [95% CI -5.99 to +5.15]), sleep/energy (MD -2.78  
45      [95% CI -6.81 to +1.25]), and severity (MD +0.21 [95% CI -5.21 to +5.66]) at 2  
46      years after surgery.
- 47      ● Very low quality evidence from 1 RCT (n=61) showed no clinically important  
48      difference between MiniArc single-incision mini-sling and TVT in women with SUI  
49      on change scores of the King's Health Questionnaire (KHQ) subscales of role  
50      limitations (MD +33.19 [95% CI -96.59 to +162.97]), physical limitations (MD +40.5  
51      [95% CI -21.68 to +102.68]), social limitations (MD +6.8 [95% CI -24.56 to  
52      +38.16]), personal relationships (MD +25.8 [95% CI -28.99 to +80.59]), emotions

- 1 (MD +7.1 [95% CI -9.98 to +24.18]), sleep/energy (MD +3.5 [95% CI -2.17 to  
2 +9.17]), and severity (MD +51 [95% CI 2.89 to +99.11]) at 3 years after surgery.
- 3 • Moderate quality evidence from 1 RCT (n=81) showed no clinically important  
4 difference between TVT-Secur single-incision mini-sling and TVT-O in women with  
5 SUI on sexual function as assessed by the Prolapse/Incontinence Sexual  
6 Questionnaire (PISQ-12) at 1 year (MD 0.0 [95% CI -1.94 to +1.94]) and 2 years  
7 (MD +0.2 [95% CI -1.84 to +2.24]) after surgery.

## 8 **Adverse events**

- 9 • Very low quality evidence from 5 RCTs (n=773) showed no clinically important  
10 difference between any single-incision mini-sling and any other synthetic  
11 transobturator sling on the number of women with SUI who experienced severe  
12 bleeding during surgery that requires a blood transfusion: RR 2.94 (95% CI 0.31-  
13 28.01).
- 14 ○ Low quality evidence from 1 RCT (n=98) showed no women who received  
15 either MiniArc single-incision mini-sling or TOT experienced severe bleeding  
16 during surgery requiring a blood transfusion: RR 1.0 (95% CI 0.96-1.04), non  
17 event.
- 18 ○ Very low quality evidence from 4 RCTs (n=675) showed no clinically important  
19 difference between single-incision mini-sling and any other synthetic  
20 transobturator sling on the number of women with SUI who experienced severe  
21 bleeding during surgery that requires a blood transfusion: RR 2.94 (95% CI  
22 0.31-28.01).
- 23 • Low quality evidence from 13 RCTs (n=1718) showed no clinically important  
24 difference between any single-incision mini-sling and any other synthetic  
25 transobturator sling on the number of women with SUI who suffered a  
26 perioperative bladder injury: RR 0.56 (95% CI 0.27-1.19).
- 27 ○ Very low quality evidence from 2 RCTs (n=169) showed no clinically important  
28 difference between MiniArc single-incision mini-sling and any other synthetic  
29 mesh sling on the number of women with SUI who suffered a perioperative  
30 bladder injury: RR 0.33 (95% CI 0.01-7.99).
- 31 ○ Low quality evidence from 2 RCTs (n=366) showed no clinically important  
32 difference between Needleless single-incision mini-sling and TOT on the  
33 number of women with SUI who suffered a perioperative bladder injury: RR  
34 1.04 (95% CI 0.15-7.15)
- 35 ○ Very low quality evidence from 1 RCT (n=210) showed no clinically important  
36 difference between Needleless or Endopelvic Free Anchorage single-incision  
37 mini-sling and TOT on the number of women with SUI who suffered a  
38 perioperative bladder injury: RR 0.5 (95% CI 0.03-7.88).
- 39 ○ Very low quality evidence from 7 RCTs (n=925) showed no clinically important  
40 difference between TVT-Secur single-incision mini-sling and any other  
41 synthetic mesh sling on the number of women with SUI who suffered a  
42 perioperative bladder injury: RR 0.53 (95% CI 0.21-1.29).
- 43 ○ Low quality evidence from 1 RCT (n=48) showed no women who received  
44 either single-incision mini-sling (brand not reported) or TVT-O suffered a  
45 perioperative bladder injury: RR 1.0 (95% CI 0.92-1.08).
- 46 • Very low quality evidence from 3 RCTs (n=490) showed no clinically important  
47 difference between any single-incision mini-sling and any other synthetic mesh  
48 sling on the number of women with SUI who suffered a perioperative bowel injury:  
49 RR 0.47 (95% CI 0.04-5.09).

- 1      ○ High quality evidence from 1 RCT (n=179) showed no women who received  
2      either Needleless single-incision mini-sling or TOT suffered a perioperative  
3      bowel injury: RR 1.0 (95% CI 0.98-1.02), non-event.
- 4      ○ Very low quality evidence from 1 RCT (n=263) showed no clinically important  
5      difference between single-incision mini-sling and any other synthetic mesh sling  
6      on the number of women with SUI who suffered a perioperative bowel injury:  
7      RR 0.47 (95% CI 0.04-5.09).
- 8      ○ Low quality evidence from 1 RCT (n=48) showed no women who received  
9      either single-incision mini-sling (brand not reported) or TVT-O suffered a  
10     perioperative bowel injury RR 1.0 (95% CI 0.92-1.08), non-event.

### 11 **Complications**

- 12     • Low quality evidence from 12 RCTs (n=1426) showed a clinically important  
13     difference favouring any single-incision mini-sling over any other synthetic mesh  
14     sling on the number of women with SUI who experienced pain within 1 year of  
15     surgery: RR 0.4 (95% CI 0.26-0.62).
- 16     ○ Very low quality evidence from 2 RCTs (n=342) showed no clinically important  
17     difference between Needleless single-incision mini-sling and TOT on the  
18     number of women with SUI who experience pain within 1 year of surgery: RR  
19     0.44 (95% CI 0.02-9.55), random effects analysis.
- 20     ○ Low quality evidence from 9 RCTs (n=994) showed a clinically important  
21     difference favouring TVT-Secur single-incision mini-sling over any other  
22     synthetic mesh sling on the number of women with SUI who experience pain  
23     within 1 year of surgery: RR 0.43 (95% CI 0.27-0.69).
- 24     ○ Very low quality evidence from 1 RCT (n=90) showed no clinically important  
25     difference between MiniArc or TVT-Secur single-incision mini-sling and TOT on  
26     the number of women with SUI who experience pain within 1 year of surgery:  
27     RR 0.25 (95% CI 0.02-2.65).
- 28     • Very low quality evidence from 5 RCTs (n=706) showed a clinically important  
29     difference favouring any single-incision mini-sling compared to any other synthetic  
30     mesh sling on the number of women with SUI who experienced pain between 1  
31     and 5 years after surgery: RR 0.33 (95% CI 0.13-0.84).
- 32     ○ Very low quality evidence from 2 RCTs (n=276) showed no clinically important  
33     difference between MiniArc single-incision mini-sling and TOT on the number of  
34     women with SUI who experienced pain between 1 and 5 years after surgery:  
35     RR 0.56 (95% CI 0.06-5.68), random effects analysis.
- 36     ○ Low quality evidence from 1 RCT (n=178) showed no clinically important  
37     difference between Needleless single-incision mini-sling and TOT on the  
38     number of women with SUI who experienced pain between 1 and 5 years after  
39     surgery: RR 0.2 (95% CI 0.01-4.11).
- 40     ○ Very low quality evidence from 2 RCTs (n=252) showed no clinically important  
41     difference between TVT-Secur single-incision mini-sling and other synthetic  
42     transobturator sling on the number of women with SUI who experienced pain  
43     between 1 and 5 years after surgery: RR 0.28 (95% CI 0.01-6.83).
- 44     • Very low quality evidence from 15 RCTs (n=1890) showed a clinically important  
45     difference favouring any other synthetic mesh sling over any single-incision mini-  
46     sling on the number of women with SUI who experienced mesh extrusion within 1  
47     year of surgery: RR 1.82 (95% CI 1.05-3.13).
- 48     ○ Very low quality evidence from 2 RCTs (n=263) showed no clinically important  
49     difference between MiniArc single-incision mini-sling and TOT on the number of  
50     women with SUI who experienced mesh extrusion within 1 year of surgery: RR  
51     2.19 (95% CI 0.32-14.83).

- 1       ○ Very low quality evidence from 3 RCTs (n=482) showed no clinically important  
2       difference between Needleless single-incision mini-sling and TOT on the  
3       number of women with SUI who experienced mesh extrusion within 1 year of  
4       surgery: RR 1.0 (95% CI 0.3-3.33).
- 5       ○ Low quality evidence from 9 RCTs (n=1097) showed a clinically important  
6       difference favouring other any other synthetic mesh sling over TVT-Secur on  
7       the number of women with SUI who experienced mesh extrusion within 1 year  
8       of surgery: RR 2.54 (95% CI 1.25-5.14).
- 9       ○ Very low quality evidence from 1 RCTs (n=48) showed no clinically important  
10       difference between single-incision mini-sling (brand not reported) and TVT-O  
11       on the number of women with SUI who experienced mesh extrusion within 1  
12       year of surgery: RR 0.2 (95% CI 0.01-3.96).
- 13       ● Very low quality evidence from 5 RCTs (n=725) showed no clinically important  
14       difference between any single-incision mini-sling and any synthetic transobturator  
15       sling on the number of women with SUI who experience mesh extrusion between  
16       1 year and 5 years after surgery: RR 0.98 (95% CI 0.36-2.8), random effects  
17       analysis.
- 18       ○ Very low quality evidence from 2 RCTs (n=276) showed there may be a  
19       clinically important difference favouring MiniArc single-incision mini-sling and  
20       TOT on the number of women with SUI who experience mesh extrusion  
21       between 1 year and 5 years after surgery, although there is some uncertainty:  
22       RR 0.25 (95% CI 0.05-1.16).
- 23       ○ Very low quality evidence from 3 RCTs (n=449) showed no clinically important  
24       difference between TVT-Secur single-incision mini-sling and any other  
25       synthetic transobturator slings on the number of women with SUI who  
26       experienced mesh extrusion between 1 year and 5 years after surgery: RR  
27       2.21 (95% CI 0.78-6.25)
- 28       ● Moderate quality evidence from 1 RCT (n=263) showed no women with SUI who  
29       received either TVT-Secur single-incision mini-sling or TVT experienced fistula  
30       within 1 year of surgery: RR 1.0 (95% CI 0.99-1.01), non-event.
- 31       ● Very low quality evidence from 9 RCTs (n=908) showed no clinically important  
32       difference between any single-incision mini-sling and any other synthetic mesh  
33       sling on the number of women with SUI who experienced a need for  
34       catheterisation within 1 year of surgery: RR 0.91 (95% CI 0.45-1.84).
- 35       ○ Very low quality evidence from 1 RCT (n=70) showed no clinically important  
36       difference between MiniArc single-incision mini-sling and TVT on the number of  
37       women with SUI who experienced a need for catheterisation within 1 year of  
38       surgery: RR 0.89 (95% CI 0.13-5.98).
- 39       ○ Low quality evidence from 1 RCT (n=178) showed no clinically important  
40       difference between Needleless single-incision mini-sling and TVT on the  
41       number of women with SUI who experienced a need for catheterisation within 1  
42       year of surgery: RR 1.0 (95% CI 0.06-15.74).
- 43       ○ Very low quality evidence from 6 RCTs (n=612) showed no clinically important  
44       difference between TVT-Secur single-incision mini-sling and any other  
45       synthetic mesh sling on the number of women with SUI who experienced a  
46       need for catheterisation within 1 year of surgery: RR 0.82 (95% CI 0.36-1.87).
- 47       ○ Very low quality evidence from 1 RCT (n=48) showed no clinically important  
48       difference between single-incision mini-sling (brand not reported) and TVT-O  
49       on the number of women with SUI who experienced a need for catheterisation  
50       within 1 year of surgery: RR 3.0 (95% CI 0.13-70.16).

- 1 • Very low quality evidence from 9 RCTs (n=1197) showed no clinically important  
2 difference between any single-incision mini-sling and any other synthetic mesh  
3 sling on the number of women with SUI who experienced an infection within 1  
4 year of surgery: RR 1.11 (95% CI 0.74-1.67).
- 5 ○ Very low quality evidence from 1 RCT (n=193) showed no clinically important  
6 difference between MiniArc single-incision mini-sling and TOT on the number of  
7 women with SUI who experienced an infection within 1 year of surgery: RR  
8 0.69 (95% CI 0.31-1.53).
- 9 ○ Low quality evidence from 2 RCTs (n=342) showed no women with SUI who  
10 received either Needleless single-incision mini-sling or TOT experienced an  
11 infection within 1 year of surgery: RR 1.0 (95% CI 0.98-1.02), non-event.
- 12 ○ Very low quality evidence from 5 RCTs (n=572) showed no clinically important  
13 difference between TVT-Secur single-incision mini-sling and any other  
14 synthetic mesh sling on the number of women with SUI who experienced an  
15 infection within 1 year of surgery: RR 1.31 (95% CI 0.81-2.12).
- 16 ○ Very low quality evidence from 1 RCT (n=90) showed no clinically important  
17 difference between MiniArc or TVT-Secur single-incision mini-sling and TVT-O  
18 on the number of women with SUI who experienced an infection within 1 year  
19 of surgery: RR 2.54 (95% CI 0.13-51.31).
- 20 • Very low quality evidence from 5 RCTs (n=783) showed no clinically important  
21 difference between any single-incision mini-sling and any other synthetic  
22 transobturator sling on the number of women with SUI who experienced an  
23 infection between 1 year and 5 years after surgery: RR 1.12 (95% CI 0.65-1.91).
- 24 ○ Very low quality evidence from 1 RCT (n=193) showed no clinically important  
25 difference between MiniArc single-incision mini-sling and TOT on the number of  
26 women with SUI who experienced an infection between 1 year and 5 years  
27 after surgery: RR 1.48 (95% CI 0.70-3.14).
- 28 ○ Very low quality evidence from 1 RCT (n=187) showed no clinically important  
29 difference between Needleless single-incision mini-sling and TOT on the  
30 number of women with SUI who experienced an infection between 1 year and 5  
31 years after surgery: RR 2.2 (95% CI 0.20-23.87).
- 32 ○ Very low quality evidence from 3 RCTs (n=403) showed no clinically important  
33 difference between TVT-Secur single-incision mini-sling and any other  
34 synthetic transobturator sling on the number of women with SUI who  
35 experienced an infection between 1 year and 5 years after surgery: RR 0.67  
36 (95% CI 0.29-1.59).
- 37 • Very low quality evidence from 7 RCTs (n=727) showed no clinically important  
38 difference between any single-incision mini-sling and any other synthetic mesh  
39 sling on the number of women with SUI who experienced de novo urgency within  
40 1 year of surgery: RR 0.85 (95% CI 0.49-1.48).
- 41 ○ High quality evidence from 1 RCT (n=178) showed no women who received  
42 either Needleless single-incision mini-sling or TOT experienced de novo  
43 urgency within 1 year of surgery: RR 1.0 (95% CI 0.98-1.02), non-event.
- 44 ○ Very low quality evidence from 5 RCTs (n=459) showed no clinically important  
45 difference between TVT-Secur single-incision mini-sling and any other  
46 synthetic mesh sling on the number of women with SUI who experienced de  
47 novo urgency within 1 year of surgery: RR 0.95 (95% CI 0.5-1.81).
- 48 ○ Very low quality evidence from 1 RCT (n=90) showed no clinically important  
49 difference between MiniArc or TVT-Secur single-incision mini-sling and TVT-O  
50 on the number of women with SUI who experienced de novo urgency within 1  
51 year of surgery: RR 0.6 (95% CI 0.2-1.81).

- 1 • Very low quality evidence from 5 RCTs (n=719) showed no clinically important  
2 difference between any single-incision mini-sling and any other synthetic mesh  
3 sling on the number of women with SUI who experienced de novo urgency  
4 between 1 year and 5 years after surgery: RR 0.73 (95% CI 0.45-1.19).
- 5 ○ Very low quality evidence from 1 RCT (n=83) showed no clinically important  
6 difference between MiniArc single-incision mini-sling and TOT on the number of  
7 women with SUI who experienced de novo urgency between 1 year and 5  
8 years after surgery: RR 0.68 (95% CI 0.12-3.88).
- 9 ○ Very low quality evidence from 1 RCT (n=187) showed no clinically important  
10 difference between Needleless single-incision mini-sling and TOT on the  
11 number of women with SUI who experienced de novo urgency between 1 year  
12 and 5 years after surgery: RR 0.83 (95% CI 0.37-1.87).
- 13 ○ Very low quality evidence from 3 RCTs (n=449) showed no clinically important  
14 difference between TVT-Secur single-incision mini-sling and other synthetic  
15 transobturator sling on the number of women with SUI who experienced de  
16 novo urgency between 1 year and 5 years after surgery: RR 0.84 (95% CI 0.23-  
17 3.02), random effects analysis.
- 18 • Very low quality evidence from 2 RCTs (n=258) showed no clinically important  
19 difference between any single-incision mini-sling and any other synthetic  
20 transobturator sling on the number of women with SUI who experienced de novo  
21 urge incontinence within 1 year of surgery: RR 1.74 (95% CI 0.63-4.83).
- 22 ○ Very low quality evidence from 1 RCT (n=210) showed no clinically important  
23 difference between Needleless or Endopelvic Free Anchorage single-incision  
24 mini-sling and TOT on the number of women with SUI who experienced de  
25 novo urge incontinence within 1 year of surgery: RR 1.63 (95% CI 0.55-4.8).
- 26 ○ Very low quality evidence from 1 RCT (n=48) showed no clinically important  
27 difference between single-incision mini-sling (brand not reported) and TVT-O  
28 on the number of women with SUI who experienced de novo urge incontinence  
29 within 1 year of surgery: RR 3.0 (95% CI 0.13-70.16).
- 30 • Very low quality evidence from 1 RCT (n=197) showed no clinically important  
31 difference between TVT-Secur single-incision mini-slings and other synthetic  
32 transobturator slings on the number of women with SUI who experience de novo  
33 urge incontinence between 1 year and 5 years after surgery: RR 1.02 (95% CI  
34 0.59-1.77).
- 35 • Very low quality evidence from 1 RCT (n=84) showed no clinically important  
36 difference between TVT-Secur single-incision mini-slings and other synthetic  
37 transobturator slings on the number of women with SUI who experience  
38 occurrence of POP between 1 year and 5 years after surgery: RR 0.4 (95% CI  
39 0.02-9.59).

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

41 For composite cure outcome within approximately 1 year of surgery – NMA outcome,  
42 see [clinical evidence profile for NMA outcomes](#).

43

- 44 • Moderate quality evidence from 12 RCTs (n=1679) showed no clinically important  
45 difference between any single-incision mini-sling and any other synthetic mesh  
46 sling on the number of women with SUI who are subjectively cured within 1 year of  
47 surgery: RR 0.9 (95% CI 0.86-0.95).
- 48 ○ Very low quality evidence from 3 RCTs (n=499) showed no clinically important  
49 difference between MiniArc single-incision mini-slings and any other synthetic  
50 mesh sling on the number of women with SUI who are subjectively cured within  
51 1 year of surgery: RR 0.84 (95% CI 0.67-1.07), random effects analysis.

- 1 – Low quality evidence from 1 RCT (n=71) showed a clinically important  
2 difference favouring TVT over MiniArc single-incision mini-sling on the  
3 number of women with SUI who are subjectively cured within 1 year of  
4 surgery: RR 0.6 (95% CI 0.45-0.67).
- 5 – Low quality evidence from 2 RCTs (n=428) showed no clinically important  
6 difference between MiniArc single-incision mini-slings and TOT on the  
7 number of women with SUI who are subjectively cured within 1 year of  
8 surgery: RR 0.96 (95% CI 0.87-1.06).
- 9 ○ High quality evidence from 1 RCT (n=179) showed no clinically important  
10 difference between Needleless single-incision mini-slings and TOT on the  
11 number of women with SUI who are subjectively cured within 1 year of surgery:  
12 RR 1.0 (95% CI 0.91-1.1).
- 13 ○ Very low quality evidence from 7 RCTs (n=953) showed no clinically important  
14 difference between TVT-Secur single-incision mini-slings and any other  
15 synthetic mesh sling on the number of women with SUI who are  
16 subjectively cured within 1 year of surgery: RR 0.9 (95% CI 0.79-1.03), random  
17 effects analysis.
- 18 ○ Very low quality evidence from 1 RCT (n=48) showed no clinically important  
19 difference between single incision mini-sling (brand not reported) and TVT-O  
20 on the number of women with SUI who are subjectively cured within 1 year of  
21 surgery: RR 1.06 (95% CI 0.77-1.44).
- 22 ● Very low quality evidence from 4 RCTs (n=626) showed no clinically important  
23 difference between any single-incision mini-sling and any other synthetic mesh  
24 sling on the number of women with SUI who are subjectively cured within 1 year of  
25 surgery and who did not have concomitant POP surgery: RR 0.87 (95% CI 0.69-  
26 1.09), random effects analysis.
- 27 ○ Moderate quality evidence from 1 RCT (n=119) showed no clinically important  
28 difference between MiniArc single-incision mini-sling and TOT on the number of  
29 women with SUI who are subjectively cured within 1 year of surgery and who  
30 did not have concomitant POP surgery: RR 1.07 (95% CI 0.94-1.22).
- 31 ○ High quality evidence from 1 RCT (n=179) showed no clinically important  
32 difference between Needleless single-incision mini-sling and TOT on the  
33 number of women with SUI who are subjectively cured within 1 year of surgery  
34 and who did not have concomitant POP surgery: RR 1.0 (95% CI 0.91-1.1).
- 35 ○ Low quality evidence from 2 RCTs (n=328) showed a clinically important  
36 difference favouring any other synthetic mesh sling over TVT-Secur single-  
37 incision mini-sling on the number of women with SUI who are subjectively  
38 cured within 1 year of surgery and who did not have concomitant POP surgery:  
39 RR 0.71 (95% CI 0.6-0.84)
- 40 ● Very low quality evidence from 8 RCTs (n=1201) showed no clinically important  
41 difference between any single-incision mini-sling and any other synthetic  
42 transobturator slings on the number of women with SUI who are subjectively cured  
43 between 1 year and 5 years after surgery: RR 0.88 (95% CI 0.79-0.98), random  
44 effects analysis.
- 45 ○ Very low quality evidence from 3 RCTs (n=362) showed there may be a  
46 clinically important difference favouring any other synthetic mesh sling over  
47 MiniArc single-incision mini-slings on the number of women with SUI who are  
48 subjectively cured between 1 year and 5 years after surgery, although there is  
49 some uncertainty: RR 0.76 (95% CI 0.56-1.05), random effects analysis.
- 50 – Low quality evidence from 1 RCT (n=71) showed a clinically important  
51 difference favouring TVT over MiniArc single-incision mini-sling on the

- 1            number of women with SUI who are subjectively cured between 1 year and  
2            5 years after surgery: RR 0.52 (95% CI 0.37-0.74).
- 3            – Very low quality evidence from 2 RCTs (n=291) showed no clinically  
4            important difference between MiniArc single-incision mini-slings and TOT on  
5            the number of women with SUI who are subjectively cured between 1 year  
6            and 5 years after surgery: RR 0.9 (95% CI 0.77-1.07).
- 7            ○ Low quality evidence from 2 RCTs (n=366) showed no clinically important  
8            difference between Needleless single-incision mini-sling and TOT on the  
9            number of women with SUI who are subjectively cured between 1 year and 5  
10           years after surgery: RR 0.97 (95% CI 0.9-1.06).
- 11           ○ Very low quality evidence from 3 RCTs (n=473) showed no clinically important  
12           difference between TVT-Secur single-incision mini-sling and any other  
13           synthetic mesh sling on the number of women with SUI who are subjectively  
14           cured between 1 year and 5 years after surgery: RR 0.86 (95% CI 0.77-0.95).
- 15           ● Moderate quality evidence from 10 RCTs (n=1293) showed no clinically important  
16           difference between any single-incision mini-sling and any other synthetic mesh  
17           sling on the number of women with SUI who are objectively cured within 1 year of  
18           surgery: RR 0.93 (95% CI 0.86-1.01), random effects analysis.
- 19           ○ Low quality evidence from 4 RCTs (n=549) showed no clinically important  
20           difference between MiniArc single-incision mini-sling and any other synthetic  
21           mesh sling on the number of women with SUI who are objectively cured within  
22           1 year of surgery: RR 0.93 (95% CI 0.84-1.03).
- 23           ○ High quality evidence from 1 RCT (n=179) showed no clinically important  
24           difference between Needleless single-incision mini-sling and TOT on the  
25           number of women with SUI who are objectively cured within 1 year of surgery:  
26           RR 1.07 (95% CI 0.96-1.19).
- 27           ○ Very low quality evidence from 4 RCTs (n=475) showed no clinically important  
28           difference between TVT-Secur single-incision mini-sling and any other  
29           synthetic mesh sling on the number of women with SUI who are objectively  
30           cured within 1 year of surgery: RR 0.88 (95% CI 0.79-0.97).
- 31           ○ Very low quality evidence from 1 RCT (n=90) showed no clinically important  
32           difference between MiniArc or TVT-Secur single-incision mini-sling and TVT-O  
33           on the number of women with SUI who are objectively cured within 1 year of  
34           surgery: RR 0.92 (95% CI 0.74-1.14),
- 35           ● Moderate quality evidence from 4 RCTs (n=648) showed no clinically important  
36           difference between any single-incision mini-sling and any other synthetic mesh  
37           sling on the number of women with SUI who are objectively cured between 1 year  
38           and 5 years after surgery: RR 0.95 (95% CI 0.83-1.09), random effects analysis.
- 39           ○ Low quality evidence from 1 RCT (n=193) showed no clinically important  
40           difference between MiniArc single-incision mini-sling and TOT on the number of  
41           women with SUI who are objectively cured between 1 year and 5 years after  
42           surgery: RR 1.0 (95% CI 0.83-1.21).
- 43           ○ High quality evidence from 1 RCT (n=179) showed no clinically important  
44           difference between Needleless single-incision mini-sling and TOT on the  
45           number of women with SUI who are objectively cured between 1 year and 5  
46           years after surgery: RR 1.04 (95% CI 0.93-1.17).
- 47           ○ Very low quality evidence from 2 RCTs (n=276) showed no clinically important  
48           difference between TVT-Secur single-incision mini-sling and TVT-O on the  
49           number of women with SUI who are objectively cured between 1 year and 5  
50           years after surgery: RR 0.82 (95% CI 0.6-1.11), random effects analysis.

- 1 • Very low quality evidence from 7 RCTs (n=1059) showed no clinically important  
2 difference between any single-incision mini-sling and other synthetic mesh sling  
3 on the number of women with SUI who had a negative cough stress test within 1  
4 year of surgery: RR 0.83 (95% CI 0.73-0.95), random effects analysis.
- 5 ○ Low quality evidence from 1 RCT (n=235) showed no clinically important  
6 difference between MiniArc single-incision mini-sling and TOT on the number of  
7 women with SUI who had a negative cough stress test within 1 year of surgery:  
8 RR 0.97 (95% CI 0.83-1.14).
- 9 ○ Low quality evidence from 1 RCT (n=210) showed no clinically important  
10 difference between Needleless or Endopelvic Free Anchorage single-incision  
11 mini-sling and TOT on the number of women with SUI who had a negative  
12 cough stress test within 1 year of surgery: RR 0.95 (95% CI 0.88-1.03).
- 13 ○ Very low quality evidence from 5 RCT (n=614) showed no clinically important  
14 difference between TVT-Secur single-incision mini-sling and any other  
15 synthetic mesh sling on the number of women with SUI who had a negative  
16 cough stress test within 1 year of surgery: RR 0.75 (95% CI 0.68-0.84).
- 17 • Very low quality evidence from 4 RCTs (n=518) showed no clinically important  
18 difference between any single-incision mini-sling and any other synthetic mesh  
19 sling on the number of women with SUI who had a negative cough stress test  
20 within 1 year of surgery and who did not have concomitant POP surgery: RR 0.85  
21 (95% CI 0.72-1.01), random effects analysis.
- 22 ○ Moderate low quality evidence from 1 RCT (n=96) showed no clinically  
23 important difference between MiniArc single-incision mini-slings and TOT sling  
24 on the number of women with SUI who had a negative cough stress test within  
25 1 year of surgery and who did not have concomitant POP surgery: RR 0.99  
26 (95% CI 0.88-1.1).
- 27 ○ Very low low quality evidence from 3 RCTs (n=422) showed no clinically  
28 important difference between TVT-Secur and any other synthetic mesh sling on  
29 the number of women with SUI who had a negative cough stress test within 1  
30 year of surgery and who did not have concomitant POP surgery: RR 0.79 (95%  
31 CI 0.7-0.89).
- 32 • Low quality evidence from 4 RCTs (n=576) showed no clinically important  
33 difference between any single-incision mini-sling and any other synthetic mesh  
34 sling on the number of women with SUI who had a negative cough stress test  
35 between 1 year and 5 years after surgery: RR 0.89 (95% CI 0.81-0.97).
- 36 ○ Very low quality evidence from 1 RCT (n=98) showed no clinically important  
37 difference between MiniArc single-incision mini-sling and TOT on the number of  
38 women with SUI who had a negative cough stress test between 1 year and 5  
39 years after surgery: RR 0.88 (95% CI 0.65-1.19).
- 40 ○ Low quality evidence from 1 RCT (n=187) showed no clinically important  
41 difference between Needleless single-incision mini-sling and TOT on the  
42 number of women with SUI who had a negative cough stress test between 1  
43 year and 5 years after surgery: RR 0.93 (95% CI 0.82-1.06).
- 44 ○ Very low quality evidence from 2 RCTs (n=291) showed no clinically important  
45 difference between TVT-Secur single-incision mini-sling and any other  
46 synthetic transobturator sling on the number of women with SUI who had a  
47 negative cough stress test between 1 year and 5 years after surgery: RR 0.93  
48 (95% CI 0.82-1.56), random effects analysis.
- 49 – Low quality evidence from 1 RCT (n=197) showed a clinically important  
50 difference favouring TVT-O over TVT-Secur single-incision mini-sling on the  
51 number of women with SUI who had a negative cough stress test between 1  
52 year and 5 years after surgery: RR 0.74 (95% CI 0.65-0.85).

- 1           – Low quality evidence from 1 RCT (n=94) showed no clinically important  
2           difference between TVT-Secur single-incision mini-sling and TOT on the  
3           number of women with SUI who had a negative cough stress test between 1  
4           year and 5 years after surgery: RR 1.21 (95% CI 0.85-1.72).
- 5           • Very low quality evidence from 1 RCT (n=98) showed no clinically important  
6           difference between MiniArc single-incision mini-sling and TOT in women with SUI  
7           on the number of incontinence episodes experienced per day between 1 year and  
8           5 years after surgery: MD +0.56 (95% CI +0.01 to +1.11).

9

### 10 ***Patient satisfaction/patient-reported improvement***

11 For composite outcome of patient satisfaction/patient-reported improvement within  
12 approximately 1 year of surgery – NMA outcome, see [clinical evidence profile for](#)  
13 [NMA outcomes](#).

14

- 15           • Moderate quality evidence from 5 RCTs (n=825) showed no clinically important  
16           difference between any single-incision mini-sling and any other synthetic  
17           transobturator sling on the number of women with SUI who show an improvement  
18           in continence status between 1 year and 5 years after surgery: RR 0.87 (95% CI  
19           0.8-0.94).
- 20           ○ Very low quality evidence from 1 RCT (n=193) showed no clinically important  
21           difference between MiniArc single-incision mini-sling and TOT on the number of  
22           women with SUI who show an improvement in continence status between 1  
23           year and 5 years after surgery: RR 0.94 (95% CI 0.77-1.16).
- 24           ○ Low quality evidence from 1 RCT (n=187) showed no clinically important  
25           difference between Needleless single-incision mini-sling and TOT on the  
26           number of women with SUI who show an improvement in continence status  
27           between 1 year and 5 years after surgery: RR 0.85 (95% CI 0.73-0.99).
- 28           ○ Very low quality evidence from 3 RCTs (n=445) showed no clinically important  
29           difference between TVT-Secur single-incision mini-sling and other synthetic  
30           transobturator sling on the number of women with SUI who show an  
31           improvement in continence status between 1 year and 5 years after surgery:  
32           RR 0.85 (95% CI 0.77-0.95).

33 No evidence was identified to inform this outcome for the time period of more than 5  
34 years after surgery.

### 35 ***Repeat surgery***

- 36           • Very low quality evidence from 6 RCTs (n=661) showed there may be a clinically  
37           important difference favouring any other synthetic mesh sling over any single-  
38           incision mini-sling on the number of women with SUI who have repeat surgery for  
39           SUI up to 5 years after initial SUI surgery, although there is some uncertainty: RR  
40           2.64 (95% CI 0.98-7.08), random effects analysis.
- 41           ○ Low quality evidence from 4 RCTs (n=397) showed a clinically important  
42           difference favouring any other synthetic mesh sling over MiniArc single-incision  
43           mini-sling on the number of women with SUI who have repeat surgery for SUI  
44           up to 5 years after initial SUI surgery: RR 3.05 (95% CI 1.43-6.5).
- 45           ○ Low quality evidence from 1 RCT (n=178) showed no clinically important  
46           difference between Needleless single-incision mini-sling and TOT on the  
47           number of women with SUI who have repeat surgery for SUI up to 5 years after  
48           initial SUI surgery: RR 0.67 (95% CI 0.11-3.89).
- 49           ○ Very low quality evidence from 1 RCT (n=86) showed a clinically important  
50           difference favouring TVT-O over TVT-Secur single-incision mini-sling on the

- 1 number of women with SUI who have repeat surgery for SUI up to 5 years after  
2 initial SUI surgery: RR 17.79 (95% CI 1.06-298.88).
- 3 • Very low quality evidence from 1 RCT (n=263) showed no clinically important  
4 difference between TVT-Secur single-incision mini-sling and TVT on the number  
5 of women with SUI who have repeat surgery for POP within 1 year of surgery: RR  
6 0.62 (95% CI 0.11-3.67).
- 7 • Moderate low quality evidence from 6 RCTs (n=940) showed a clinically important  
8 difference favouring any other synthetic mesh sling over TVT-Secur single-incision  
9 mini-sling on the number of women with SUI who have repeat surgery for POP  
10 within 1 year of surgery: RR 2.26 (95% CI 1.36-3.77)
- 11 • Very low quality evidence from 13 RCTs (n=1569) showed no clinically important  
12 difference between any single-incision mini-sling and any other synthetic mesh  
13 sling on the number of women with SUI who have repeat surgery for mesh  
14 complications up to 5 years after initial SUI surgery: RR 1.0 (95% CI 0.54-1.84).
- 15 ○ Very low quality evidence from 4 RCTs (n=397) showed no clinically important  
16 difference between MiniArc single-incision mini-sling and any other synthetic  
17 mesh sling on the number of women with SUI who have repeat surgery for  
18 mesh complications up to 5 years after initial SUI surgery: RR 0.6 (95% CI 0.2-  
19 1.84).
- 20 ○ Low quality evidence from 1 RCT (n=178) showed no clinically important  
21 difference between Needleless single-incision mini-sling and TOT on the  
22 number of women with SUI who have repeat surgery for mesh complications up  
23 to 5 years after initial SUI surgery: RR 1.0 (95% CI 0.06-15.74).
- 24 ○ Very low quality evidence from 7 RCTs (n=904) showed no clinically important  
25 difference between TVT-Secur single-incision mini-slings and other synthetic  
26 transobturator slings on the number of women with SUI who have repeat  
27 surgery for mesh complications up to 5 years after initial SUI surgery: RR 1.83  
28 (95% CI 0.75-4.45).
- 29 ○ Very low quality evidence from 1 RCT (n=90) showed no clinically important  
30 difference between MiniArc or TVT-Secur single-incision mini-sling and TVT-O  
31 on the number of women with SUI who have repeat surgery for mesh  
32 complications up to 5 years after initial SUI surgery: RR 0.1 (95% CI 0.01-2.05).

### 33 **Adjustable mesh sling versus other synthetic mesh sling**

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

- 35 • Low quality evidence from 1 RCT (n=96) showed no clinically important difference  
36 between adjustable sling and other types of synthetic mesh sling in women with  
37 SUI on the Urinary Incontinence Quality of Life Scale (I-QoL) score between 1  
38 year and 5 years after surgery: MD -3 (95% CI -7.81 to +1.81).
- 39 • Very low quality evidence from 2 RCTs (n=505) showed no clinically important  
40 difference between adjustable sling and other types of synthetic mesh sling in  
41 women with SUI on the International Consultation on Incontinence Modular  
42 Questionnaire-Urinary Incontinence Scored Form (ICIQ-UI-SF) change score  
43 within 1 year of surgery: MD +0.02 (95% CI -1.9 to +1.93).
- 44 • Low quality evidence from 2 RCTs (n=186) showed no clinically important  
45 difference between adjustable sling and other types of synthetic mesh sling in  
46 women with SUI on the International Consultation on Incontinence Modular  
47 Questionnaire-Urinary Incontinence Scored Form (ICIQ-UI-SF) total score  
48 between 1 year and 5 years after surgery: MD +0.03 (95% CI -0.69 to +0.74).
- 49 • Low quality evidence from 1 RCTs (n=137) showed no clinically important  
50 difference between adjustable sling and other types of synthetic mesh sling in

- 1 women with SUI on the International Consultation on Incontinence Modular  
2 Questionnaire -Urinary Incontinence Scored Form (ICIQ-UI-SF) change scores  
3 between 1 year and 5 years after surgery: MD +1.22 (95% CI -0.52 to +2.96).
- 4 • Low quality evidence from 1 RCT (n=133) showed no clinically important  
5 difference between adjustable sling and other types of synthetic mesh sling on the  
6 number of women with SUI who improve by 10 or more points on the King's  
7 Health Questionnaire (KHQ) within 1 year of surgery: RR 0.88 (95% CI 0.78-1.0).
  - 8 • Low quality evidence from 1 RCT (n=100) showed no clinically important  
9 difference between adjustable sling and other types of synthetic mesh sling on the  
10 number of women with SUI who improve by 18 or more points on the King's  
11 Health Questionnaire (KHQ) between 1 year and 5 years after surgery: RR 0.88  
12 (95% CI 0.73-1.07).

### 13 **Adverse events**

- 14 • Low quality evidence from 1 RCT (n=58) showed no women with SUI who  
15 received either adjustable sling or another type of synthetic mesh sling  
16 experienced severe bleeding requiring a blood transfusion during surgery: RR 1.0  
17 (95% CI 0.94-1.07), non event.
- 18 • Very low quality evidence from 7 RCTs (n=1192) showed no clinically important  
19 difference between adjustable sling and other types of synthetic mesh sling on the  
20 number of women with SUI who experienced a perioperative bladder injury: RR  
21 0.14 (95% CI 0.01-2.65).
- 22 • Low quality evidence from 3 RCTs (n=563) showed no women with SUI who  
23 received either adjustable sling or another type of synthetic mesh sling  
24 experienced a perioperative bowel injury: RR 1.0 (95% CI 0.99-1.01), non-event.

### 25 **Complications**

- 26 • Very low quality evidence from 4 RCTs (n=519) showed no clinically important  
27 difference between adjustable sling and other types of synthetic mesh sling on the  
28 number of women with SUI who experienced pain within 1 year of surgery: RR  
29 0.56 (95% CI 0.19-1.71), random effects analysis.
  - 30 ○ Very low quality evidence from 2 RCTs (n=322) showed no clinically important  
31 difference between Ajust single-incision mini-sling and other types of synthetic  
32 mesh sling on the number of women with SUI who experienced pain within 1  
33 year of surgery: RR 0.88 (95% CI 0.68-1.15).
  - 34 ○ Low quality evidence from 2 RCTs (n=197) shows there is a clinically important  
35 difference favouring other adjustable slings (Ophira and Tissue Fixation  
36 System) over TOT on the number of women with SUI who experienced pain  
37 within 1 year of surgery: RR 0.06 (95% CI 0.01-0.41).
- 38 • Very low quality evidence from 2 RCTs (n=173) showed no clinically important  
39 difference between adjustable sling and other types of synthetic mesh sling on the  
40 number of women with SUI who experienced pain between 1 year and 5 years  
41 after surgery: RR 1.45 (95% CI 0.24-8.58).
- 42 • Very low quality evidence from 1 RCT (n=77) showed no clinically important  
43 difference between adjustable slings and any other type of synthetic mesh sling on  
44 the number of women with SUI who experienced pain more than 5 years after  
45 surgery: RR 0.32 (95% CI 0.01-7.74).
- 46 • Very low quality evidence from 5 RCTs (n=865) showed no clinically important  
47 difference between adjustable sling and any other type of synthetic mesh sling on  
48 the number of women with SUI who experienced mesh extrusion within 1 year of  
49 surgery: RR 0.9 (95% CI 0.39-2.06).

- 1 • Low quality evidence from 3 RCTs (n=266) showed no women with SUI who  
2 received either adjustable sling or another type of synthetic mesh sling  
3 experienced mesh extrusion between 1 and 5 years after surgery: RR 1.0 (95% CI  
4 0.97-1.03), non-event.
- 5 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
6 difference between adjustable sling and other types of synthetic mesh sling on the  
7 number of women with SUI who experienced mesh extrusion more than 5 years  
8 after surgery: RR 0.33 (95% CI 0.01-7.92).
- 9 • Low quality evidence from 4 RCTs (n=729) showed a clinically important  
10 difference favouring adjustable sling compared to other types of synthetic mesh  
11 sling on the number of women with SUI who experience a need for catheterisation  
12 within 1 year of surgery: RR 0.48 (95% CI 0.25-0.91).
- 13 • Very low quality evidence from 3 RCTs (n=547) showed no clinically important  
14 difference between adjustable sling and other types of synthetic mesh sling on the  
15 number of women with SUI who experienced an infection within 1 year of surgery:  
16 RR 1.23 (95% CI 0.83-1.82).
- 17 • Very low quality evidence from 1 RCT (n=120) showed no clinically important  
18 difference between adjustable sling and other types of synthetic mesh sling on the  
19 number of women with SUI who experienced de novo urgency within 1 year of  
20 surgery: RR 0.88 (95% CI 0.23-3.34).
- 21 • Very low quality evidence from 2 RCTs (n=330) showed no clinically important  
22 difference between adjustable sling and other types of synthetic mesh sling on the  
23 number of women with SUI who experienced de novo urge incontinence within 1  
24 year of surgery: RR 0.85 (95% CI 0.32-2.26).
- 25 • Very low quality evidence from 1 RCTs (n=96) showed no clinically important  
26 difference between adjustable sling and other types of synthetic mesh sling on the  
27 number of women with SUI who experienced de novo urge incontinence between  
28 1 year and 5 years after surgery: RR 1.2 (95% CI 0.34-4.19).

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

- 30 • Low quality evidence from 2 RCTs (n=445) showed no clinically important  
31 difference between adjustable sling and other types of synthetic mesh sling on the  
32 number of women with SUI who are subjectively cured within 1 year of surgery:  
33 RR 0.95 (95% CI 0.81-1.12).
- 34 • Low quality evidence from 2 RCTs (n=173) showed no clinically important  
35 difference between adjustable sling and other types of synthetic mesh sling on the  
36 number of women with SUI who are subjectively cured between 1 year and 5  
37 years after surgery: RR 0.96 (95% CI 0.83-1.11).
- 38 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
39 difference between adjustable sling and other types of synthetic mesh sling on the  
40 number of women with SUI who are subjectively cured more than 5 years after  
41 surgery: RR 0.5 (95% CI 0.05-5.27).
- 42 • Low quality evidence from 3 RCTs (n=284) showed no clinically important  
43 difference between adjustable sling and other types of synthetic mesh sling on the  
44 number of women with SUI who are objectively cured within 1 year of surgery: RR  
45 0.92 (95% CI 0.8-1.05).
- 46 • Very low quality evidence from 1 RCT (n=77) showed no clinically important  
47 difference between adjustable sling and other types of synthetic mesh sling on the  
48 number of women with SUI who are objectively cured between 1 year and 5 years  
49 after surgery: RR 1.07 (95% CI 0.9-1.27).

- 1 • Very low quality evidence from 1 RCT (n=72) showed no clinically important  
2 difference between adjustable sling and other types of synthetic mesh sling on the  
3 number of women with SUI who are objectively cured more than 5 years after  
4 surgery: RR 1.11 (95% CI 0.88-1.41).
- 5 • Low quality evidence from 4 RCTs (n=941) showed no clinically important  
6 difference between adjustable sling and other types of synthetic mesh sling on the  
7 number of women with SUI who had a negative cough stress test within 1 year of  
8 surgery: RR 0.98 (95% CI 0.94-1.02).
- 9 • Low quality evidence from 3 RCTs (n=326) showed no clinically important  
10 difference between adjustable sling and other types of synthetic mesh sling on the  
11 number of women with SUI who had a negative cough stress test between 1 year  
12 and 5 years of surgery: RR 1.06 (95% CI 0.96-1.17).
- 13 • Very low quality evidence from 1 RCT (n=305) showed no clinically important  
14 difference between adjustable slings and other types of synthetic mesh sling on  
15 the number of women with SUI who do not experience any daily incontinence  
16 episodes within 1 year of surgery: RR 1.07 (95% CI 0.84-1.36).

#### 17 ***Patient satisfaction/patient-reported improvement***

- 18 • Low quality evidence from 1 RCT (n=137) showed no clinically important  
19 difference between adjustable sling and other types of synthetic mesh sling on the  
20 number of women who show an improvement in continence status between 1 year  
21 and 5 years after surgery: RR 1.08 (95% CI 0.92-1.27).
- 22 No evidence was identified to inform this outcome for the time period of more than 5  
23 years after surgery.

#### 24 ***Repeat surgery***

- 25 • Very low quality evidence from 1 RCT (n=144) showed no clinically important  
26 difference between adjustable sling and other types of synthetic mesh sling on the  
27 number of women with SUI who have repeat surgery for any reasons within 1 year  
28 of surgery: RR 1.1 (95% CI 0.10-11.8).
- 29 • Very low quality evidence from 2 RCTs (n=233) showed no clinically important  
30 difference between adjustable sling and other types of synthetic mesh sling on the  
31 number of women with SUI who have repeat surgery for any reasons between 1  
32 year and 5 years after surgery: RR 1.2 (95% CI 0.36-4.03).
- 33 • Low quality evidence from 1 RCT (n=58) showed no women who received either  
34 adjustable sling or another type of synthetic mesh sling had repeat surgery for SUI  
35 within 1 year of surgery: RR 1.0 (95% CI 0.94-1.07), non-event.

#### 36 ***Laparoscopic colposuspension with sutures versus open colposuspension with 37 sutures***

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

39 No evidence was identified to inform this outcome.

40

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

- 42 • Very low quality evidence from 1 RCT (n=200) showed no clinically important  
43 difference between laparoscopic colposuspension with sutures and open  
44 colposuspension with sutures on the number of women with SUI who experience  
45 severe bleeding during surgery that requires a blood transfusion: RR 0.36 (95% CI  
46 0.01-8.75).
- 47 • Very low quality evidence from 5 RCTs (n=707) showed a clinically important  
48 difference favouring open colposuspension with sutures compared to laparoscopic

1 colposuspension with sutures on the number of women who suffer a perioperative  
2 bladder injury: RR 3.12 (95% CI 1.08-9.02)

- 3 • Very low quality evidence from 1 RCT (n=291) showed no clinically important  
4 difference between laparoscopic colposuspension with sutures and open  
5 colposuspension with sutures on the number of women with SUI who suffer a  
6 perioperative bowel injury: RR 3.06 (95% CI 0.13-74.55).

7

### 8 **Complications**

- 9 • Very low quality evidence from 1 RCT (n=90) showed no clinically important  
10 difference between laparoscopic colposuspension with sutures and open  
11 colposuspension with sutures on the number of women with SUI who experience  
12 pain (RR 0.69 [95% CI 0.16-2.89]) or occurrence of POP (RR 0.46 [95% CI 0.04-  
13 4.87]) within 1 year of surgery.
- 14 • Very low quality evidence from 1 RCT (n=92) showed no clinically important  
15 difference between laparoscopic colposuspension with sutures and open  
16 colposuspension with sutures on the number of women with SUI who experienced  
17 an infection (RR 1.0 [95% CI 0.06-15.51]), and de novo urgency or de novo urge  
18 incontinence (RR 1.5 [95% CI 0.26-8.56]) within 1 year of surgery.
- 19 • Very low quality evidence from 1 study (n=73) showed no clinically important  
20 difference between laparoscopic colposuspension with sutures and open  
21 colposuspension with sutures on the number of women with SUI who experience  
22 pain between 1 and 5 years after surgery: RR 0.24 (95% CI 0.03-1.97).
- 23 • Very low quality evidence from 1 study (n=74) showed no clinically important  
24 difference between laparoscopic colposuspension with sutures and open  
25 colposuspension with sutures on the number of women with SUI who experience  
26 need for catheterisation (RR 1.18 [95% CI 0.17-7.91] and occurrence of POP (RR  
27 0.88 [95% CI 0.21-3.67]) between 1 and 5 years after surgery.

28

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

30 For composite cure outcome within approximately 1 year of surgery – NMA outcome,  
31 see [clinical evidence profile for NMA outcomes](#).

32

- 33 • Very low quality evidence from 3 RCTs (n=513) showed no clinically important  
34 difference between laparoscopic colposuspension with sutures and open  
35 colposuspension with sutures on the number of women with SUI who are  
36 subjectively cured within 1 year of surgery: RR 1.06 (95% CI 0.90-1.26), random  
37 effects analysis.
- 38 ○ Very low quality evidence from 2 RCTs (n=423) showed no clinically important  
39 difference between laparoscopic colposuspension with sutures and open  
40 colposuspension with sutures on the number of women with SUI who are  
41 subjectively cured within 1 year of surgery and who do not have concomitant  
42 POP surgery: RR 1.14 (95% CI 0.97-1.33).
- 43 ○ Very low quality evidence from 1 RCT (n=90) showed no clinically important  
44 difference between laparoscopic colposuspension with sutures and open  
45 colposuspension with sutures on the number of women with SUI who are  
46 subjectively cured within 1 year of surgery and some of which have  
47 concomitant POP surgery: RR 0.94 (95% CI 0.87-1.13).
- 48 • Very low quality evidence from 2 RCTs (n=491) showed no clinically important  
49 difference between laparoscopic colposuspension with sutures and open  
50 colposuspension with sutures on the number of women with SUI who are

- 1        subjectively cured between 1 year and 5 years after surgery: RR 0.94 (95% CI  
2        0.73-1.21), random effects analysis.
- 3        • Low quality evidence from 4 RCTs (n=715) showed no clinically important  
4        difference between laparoscopic colposuspension with sutures and open  
5        colposuspension with sutures on the number of women with SUI who are  
6        objectively cured within 1 year of surgery: RR 0.95 (95% CI 0.87-1.04).
  - 7        • Very low quality evidence from 2 RCTs (n=343) showed no clinically important  
8        difference between laparoscopic colposuspension with sutures and open  
9        colposuspension with sutures on the number of women with SUI who are  
10       objectively cured between 1 year and 5 years after surgery: RR 1.13 (95% CI  
11       0.93-1.38).
  - 12       • Low quality evidence from 2 RCTs (n=222) showed no clinically important  
13       difference between laparoscopic colposuspension with sutures and open  
14       colposuspension with sutures on the number of women with SUI who had a  
15       negative cough stress test within 1 year of surgery: RR 1.08 (95% CI 0.95-1.24).

16

### 17        ***Patient satisfaction/patient-reported improvement***

18        Patient satisfaction/patient-reported improvement within approximately 1 year of  
19        surgery – NMA outcome, see [clinical evidence profile for NMA outcomes](#).

20

- 21        • Very low quality evidence from 1 RCT (n=291) showed no clinically important  
22        difference between laparoscopic colposuspension with sutures and open  
23        colposuspension with sutures on the number of women with SUI who show an  
24        improvement in continence status between 1 year and 5 years after surgery: RR  
25        1.05 (95% CI 0.83-1.32).

26

27        No evidence was identified to inform this outcome for the time periods of more than 5  
28        years after surgery.

29

### 30        ***Repeat surgery***

31        No evidence was identified to inform this outcome.

32

## 33        **Autologous rectus fascial sling versus colposuspension**

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

35        No evidence was identified to inform this outcome.

36

### 37        ***Adverse events***

- 38        • Very low quality evidence from 1 RCT (n=36) showed no women with SUI who  
39        received either autologous rectus fascial sling or open Burch colposuspension  
40        with sutures experienced severe bleeding requiring a blood transfusion during  
41        surgery: RR 1.0 (95% CI 0.9-1.11), non-event.
- 42        • Very low quality evidence from 2 RCTs (n=688) showed no clinically important  
43        difference between autologous rectus fascial sling and open Burch  
44        colposuspension with sutures on the number of women with SUI who suffered a  
45        perioperative bladder injury: RR 0.26 (95% CI 0.03-2.28).
- 46        • Very low quality evidence from 1 RCTs (n=36) showed no clinically important  
47        difference between autologous rectus fascial sling and open Burch

1 colposuspension with sutures on the number of women with SUI who suffered a  
2 perioperative bowel injury: RR 0.37 (95% CI 0.02-8.53).

### 3 4 **Complications**

- 5 • Very low quality evidence from 1 RCT (n=34) showed no clinically important  
6 difference between autologous rectus fascial sling and open Burch  
7 colposuspension with sutures on the number of women with SUI who experienced  
8 pain within 1 year of surgery: RR 2.0 (95% CI 0.42-9.50).
- 9 • Very low quality evidence from 1 RCT (n=655) showed no clinically important  
10 difference between autologous rectus fascial sling and open Burch  
11 colposuspension with sutures on the number of women with SUI who experience  
12 pain between 1 year and 5 years after surgery: RR 5.05 (95% CI 0.24 to 104.7).
- 13 • Very low quality evidence from 1 RCT (n=36) showed no clinically important  
14 difference between autologous rectus fascial sling and open Burch  
15 colposuspension with sutures on the number of women with SUI who experienced  
16 mesh extrusion within 1 year of surgery: RR 5.56 (95% CI 0.29-108.16).
- 17 • Very low quality evidence from 1 RCT (n=655) showed no clinically important  
18 difference between autologous rectus fascial sling and open Burch  
19 colposuspension with sutures on the number of women with SUI who experience  
20 fistula between 1 year and 5 years after surgery: RR 0.34 (95% CI 0.01-8.23).
- 21 • Very low quality evidence from 1 RCT (n=29) showed no clinically important  
22 difference between autologous rectus fascial sling and open Burch  
23 colposuspension with sutures on the number of women with SUI who experienced  
24 an infection within 1 year of surgery: RR 0.47 (95% CI 0.05-4.6).
- 25 • Very low quality evidence from 1 RCT (n=655) showed no clinically important  
26 difference between autologous rectus fascial sling and open Burch  
27 colposuspension with sutures on the number of women with SUI who experience  
28 de novo urge incontinence between 1 year and 5 years after surgery: RR 1.01  
29 (95% CI 0.44 to 2.3).
- 30 • Very low quality evidence from 1 RCT (n=70) showed no clinically important  
31 difference between autologous rectus fascial sling and open Burch  
32 colposuspension with sutures on the number of women with SUI who experience  
33 occurrence of POP within 1 year of surgery: RR 0.2 (95% CI 0.01-3.88)
- 34 • Low quality evidence from 1 RCT (n=655) showed a clinically important difference  
35 favouring autologous rectus fascial sling over open Burch colposuspension with  
36 sutures on the number of women with SUI who experienced an infection between  
37 1 year and 5 years after surgery: RR 1.49 (95% CI 1.36-1.62).
- 38 • Very low quality evidence from 1 RCT (n=655) showed no clinically important  
39 difference between autologous rectus fascial sling and open Burch  
40 colposuspension with sutures on the number of women with SUI who experience  
41 wound complications between 1 year and 5 years after surgery: RR 1.01 (95% CI  
42 0.77-1.32).

### 43 44 **Change in continence status**

- 45 • Very low quality evidence from 2 RCTs (n=82) showed no clinically important  
46 difference between autologous rectus fascial sling and open Burch  
47 colposuspension with sutures on the number of women with SUI who are  
48 subjectively cured within 1 year of surgery: RR 1.06 (95% CI 0.86-1.3).
- 49 • Very low quality evidence from 1 RCT (n=655) showed a clinically important  
50 difference favouring autologous rectus fascial sling compared to open Burch

1 colposuspension with sutures on the number of women with SUI who are  
2 subjectively cured between 1 year and 5 years after surgery: RR 1.44 (95% CI  
3 1.05-1.97).

- 4 • Very low quality evidence from 1 RCT (n=36) showed no clinically important  
5 difference between autologous rectus fascial sling and open Burch  
6 colposuspension with sutures on the number of women with SUI who are  
7 subjectively cured at more than 5 years after surgery: RR 0.88 (95% CI 0.56-  
8 1.37).
- 9 • Low quality evidence from 2 RCTs (n=97) showed no clinically important  
10 difference between autologous rectus fascial sling and open Burch  
11 colposuspension with sutures on the number of women with SUI who are  
12 objectively cured within 1 year of surgery: RR 1.08 (95% CI 0.95-1.22).
- 13 • Low quality evidence from 1 RCT (n=655) showed no clinically important  
14 difference between autologous rectus fascial sling and open Burch  
15 colposuspension with sutures on the number of women with SUI who are  
16 objectively cured between 1 year and 5 years after surgery: RR 1.06 (95% CI  
17 0.95-1.18).
- 18 • Very low quality evidence from 1 RCT (n=36) showed no clinically important  
19 difference between autologous rectus fascial sling and open Burch  
20 colposuspension with sutures on the number of women with SUI who are  
21 objectively cured at more than 5 years after surgery: RR 1.12 (95% CI 0.75-1.67).
- 22 • Very low quality evidence from 1 RCT (n=655) showed a clinically important  
23 difference favouring autologous rectus fascial sling compared to open Burch  
24 colposuspension with sutures on the number of women with SUI who had a  
25 negative cough stress test between 1 year and 5 years after surgery: RR 1.29  
26 (95% CI 1.14-1.45).
- 27 • Very low quality evidence from 1 RCT (n=28) shows no clinically important  
28 difference between autologous rectus fascial sling compared to open Burch  
29 colposuspension with sutures on the number of daily urge incontinence (MD -0.02  
30 [95% CI -1.97 to +1.93]) or daily stress incontinence (MD +0.15 [95% CI -0.28 to  
31 +0.58]) episodes experienced by women with SUI at more than 5 years surgery.

### 32 ***Patient satisfaction/patient-reported improvement***

- 34 • Very low quality evidence from 1 RCT (n=655) showed no clinically important  
35 difference between autologous rectus fascial sling and open Burch  
36 colposuspension with sutures on the number of women with SUI who experience  
37 improvement in continence status between 1 year and 5 years after surgery: RR  
38 1.19 (95% CI 0.99-1.42).

39  
40 No evidence was identified to inform this outcome for the time period of more than 5  
41 years after surgery.

### 42 ***Repeat surgery***

- 44 • Very low quality evidence from 1 RCT (n=36) showed no clinically important  
45 difference between autologous rectus fascial sling and open Burch  
46 colposuspension with sutures on the number of women with SUI who have repeat  
47 surgery for mesh complications within 1 year of surgery: RR 5.56 (95% CI 0.29-  
48 108.16).

49

**1 Bulking agents versus other surgical technique****2 *Continence-specific health-related quality of life***

3 No evidence was identified to inform this outcome.

4

**5 *Adverse events***

6 No evidence was identified to inform this outcome.

7

**8 *Complications***

- 9 • Very low quality evidence from 1 RCT (n=43) showed no clinically important  
10 difference between Macroplastique bulking agent and any other surgical technique  
11 (autologous rectus fascial sling) on the number of women with SUI and intrinsic  
12 sphincter deficiency who experience need for catheterisation (RR 0.32 [95% CI  
13 0.01-7.42]), infection (RR 0.64 [95% CI 0.12-3.44]) and wound complications (RR  
14 0.32 [95% CI 0.01-7.42]) within 1 year of surgery.

15

**16 *Change in continence status***

- 17 • Very low and low quality evidence from 1 RCT (n=45) showed no clinically  
18 important difference between Macroplastique bulking agent and any other surgical  
19 technique (autologous rectus fascial sling) on the number of women with SUI and  
20 intrinsic sphincter deficiency who are subjectively cured at 1 year (RR 0.86 [95%  
21 CI 0.64-1.15]) and 5 years (RR 8.62 [95% CI 0.49-151.39]) after surgery.
- 22 • Moderate quality evidence from 1 RCT (n=45) showed a clinically important  
23 difference favouring any other surgical technique (autologous rectus fascial sling)  
24 over Macroplastique bulking agent on the number of women with SUI and intrinsic  
25 sphincter deficiency who are objectively cured at 1 year after surgery: RR 0.11  
26 (95% CI 0.03-0.43).

27

**28 *Patient satisfaction/patient-reported improvement***

- 29 • Low quality evidence from 1 RCT (n=45) showed no clinically important difference  
30 between Macroplastique bulking agent and any other surgical technique  
31 (autologous rectus fascial sling) on the number of women with SUI and intrinsic  
32 sphincter deficiency who experience improvement in continence status more than  
33 5 years after surgery: RR 0.43 (95% CI 0.15-1.18).

34

**35 *Repeat surgery***

- 36 • Very low quality evidence from 1 RCT (n=45) showed no clinically important  
37 difference between Macroplastique bulking agent and any other surgical technique  
38 (autologous rectus fascial sling) on the number of women with SUI and intrinsic  
39 sphincter deficiency who have repeat surgery for SUI within 1 year of SUI surgery:  
40 RR 1.91 (95% CI 0.19-19.63).

41

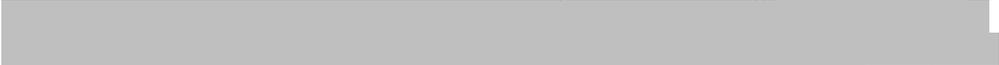
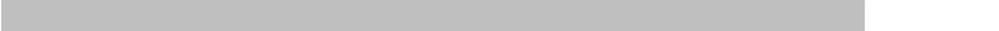
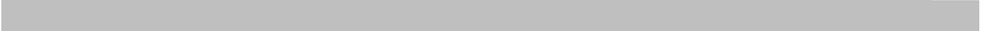
**42 *Long-term complications (>5 years after surgery)***

43 Data from 5 RCT, and 41 observational studies (all of which were at serious risk of  
44 bias), suggests that:

- 45 • the pain rate in women with SUI at more than 5 years after having a fascial sling is  
46 ~16.7%, compared to ~9.0% for retropubic synthetic mesh sling, ~7.1% for  
47 transobturator synthetic mesh sling, and ~0% for single-incision mini-sling and  
48 porcine dermis sling;

- 1 • the mesh erosion/exposure/extrusion rate in women with SUI at more than 5 years  
2 after having a transobturator synthetic mesh sling is ~2.3%, compared to ~2.0%  
3 for an adjustable synthetic mesh sling, ~1.5% for retropubic synthetic mesh sling,  
4 ~0.6% for single-incision mini-sling and 0% for open colposuspension, fascial  
5 sling, and porcine dermis sling;
- 6 • the rate of fistula in women with SUI at more than 5 years after having any  
7 colposuspension and laparoscopic colposuspension is 0%;
- 8 • the need for catheterisation rate in women with SUI at more than 5 years after  
9 having fascial sling is 3.6%, compared to 2.5% for retropubic synthetic mesh sling,  
10 1.5% for adjustable synthetic mesh sling, 1.1% for colposuspension and 0% for  
11 porcine dermis sling;
- 12 • the infection rate in women with SUI at more than 5 years after having any type of  
13 synthetic mesh sling is ~26.2% for open colposuspension, 19.7% for any synthetic  
14 mesh sling, 8.4% for retropubic synthetic mesh sling, 6.1% for fascial sling, 5.5%  
15 for any colposuspension, 3.4% for transobturator synthetic mesh sling, and 1.6%  
16 for adjustable synthetic mesh sling;
- 17 • the de novo urge incontinence rate in women with SUI at more than 5 years after  
18 having an adjustable synthetic mesh sling is ~23.9%, compared to ~14.1% for a  
19 retropubic synthetic mesh sling, ~8.7% for a transobturator synthetic mesh sling,  
20 ~8.1% for fascial sling, ~7.3% for any form of colposuspension, 4.7% for single-  
21 incision mini-sling, and 4% for open colposuspension;
- 22 • the de novo frequency rate in women with SUI at more than 5 years after having  
23 open colposuspension is ~37.2%;
- 24 • the de novo urgency rate in women with SUI at more than 5 years after having  
25 retropubic synthetic mesh sling is ~13.7%, compared to 10.4% for open  
26 colposuspension, ~10% for adjustable synthetic mesh sling, 8.3% for any  
27 colposuspension, 6.5% for fascial sling, ~4% for a transobturator synthetic mesh  
28 sling, and 0% for porcine dermis sling;
- 29 • the de novo nocturia rate in women with SUI at more than 5 years after having  
30 open colposuspension is ~11.8%;
- 31 • the POP occurrence rate in women with SUI at more than 5 years after having any  
32 colposuspension is ~21.1%, compared to ~4.7% for retropubic synthetic mesh  
33 sling, ~4% for open colposuspension, and ~0.5% for transobturator synthetic  
34 mesh sling;
- 35 • the wound complication rate in women with SUI at more than 5 years after having  
36 any colposuspension is ~0.4%.

### 37 **Economic evidence statements**

- 38 • There was evidence from one UK modelling study showing   
39   
40   
41   
42   
43   
44   
45   
46   
47   
48 
- 49 • There was evidence from one USA modelling study showing that midurethral sling  
50 was potentially cost-ineffective when compared with urethral bulking agents in

- 1 women with SUI. This evidence came from a partially applicable study that was  
2 characterised by minor methodological limitations.
- 3 • There was evidence from one UK study based on an RCT (n=137) showing that  
4 single incision mini sling was cost-effective when compared with standard  
5 midurethral mesh sling in women with SUI. This evidence came from a directly  
6 applicable study that was characterised by minor methodological limitations.
  - 7 • There was evidence from one Canadian study based on an RCT (n=199) showing  
8 that transobturator tape was cost-effective when compared with tension-free  
9 vaginal tape in women with SUI. This evidence came from a partially applicable  
10 study that was characterised by minor methodological limitations.
  - 11 • There was evidence from one USA modelling study showing that transobturator  
12 midurethral sling was potentially cost-effective when compared with retropubic  
13 midurethral sling in women with pure SUI or predominantly SUI. This evidence  
14 came from a partially applicable study that was characterised by potentially  
15 serious methodological limitations.
  - 16 • There was evidence from one Canadian study based on a cohort study (n=18)  
17 showing that transobturator tape procedure was cost saving when compared with  
18 laparoscopic Burch colposuspension and laparoscopic two team sling procedure.  
19 This evidence came from a partially applicable study that was characterised by  
20 potentially serious methodological limitations.
  - 21 • There was evidence from one USA modelling study showing that tension-free  
22 vaginal tape was potentially cost-ineffective when compared with Burch  
23 colposuspension in women with SUI. This evidence came from a partially  
24 applicable study that was characterised by minor methodological limitations.

## 25 Recommendations

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E1.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for stress urinary incontinence (UI). Include information about differences in type of anaesthesia, expected length of hospital stay, surgical incisions, and expected recovery period. **[2013, amended 2019]**

33

34

E1.2 If non-surgical management for stress UI has failed, offer the woman a choice of :

35

36

37

38

- colposuspension (open or laparoscopic) **or**
- a retropubic mid-urethral mesh sling **or**
- an autologous rectus fascial sling. **[2019]**

39

40

41

42

E1.3 Advise the woman when offering surgery for stress urinary incontinence that there are long term complications associated with all procedures and uncertainty about the proportion of women affected.

43

44

E1.4 If the woman's chosen procedure is not available from the consulting surgeon, refer her to an alternative surgeon. **[2019]**

45

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

46

1 E1.5 In women having mesh surgery for stress urinary incontinence or  
2 pelvic organ prolapse, or who have mesh-related complications, seek consent  
3 to enter the data listed in recommendation E1.6 in a national registry and give  
4 them a copy of those data.

5 E1.6 Ensure that the following data are collected in a national registry of  
6 surgery involving mesh insertion to treat urinary incontinence (UI) or pelvic  
7 organ prolapse (POP) in women:

8 • all surgical procedures for urinary incontinence or pelvic organ  
9 prolapse that involve the insertion of synthetic polypropylene  
10 mesh, including

11 - date and details of the procedure

12 - mesh material and type of sutures.

13 • the woman's NHS number

14 • hospital and consultant identifiers

15 • follow-up information on key short- and long-term (at least 5  
16 years) outcomes, including:

17 - symptom improvement or deterioration

18 - objective measures of UI or POP

19 - adverse events

20 - suspected and confirmed mesh-related complications

21 • date and details of any investigation for mesh-related  
22 complications

23 • date and details of any surgical or non-surgical intervention for  
24 mesh-related complications. **[2019]**

25 E1.7 The national registry of surgery involving mesh insertion to treat  
26 urinary incontinence or pelvic organ prolapse in women should report  
27 annually and be quality assured. **[2019]**

## 28 **Mid-urethral mesh sling procedures**

29 E1.8 Advise the woman when offering a retropubic mid-urethral mesh sling  
30 that this is a permanent implant and complete removal might not be possible.  
31

32 E1.9 If a retropubic mid-urethral mesh sling is inserted:

33 • give the woman written information on the implant including  
34 name, manufacturer, date of insertion, and implanting surgeon's  
35 name and contact details;





1 effectiveness of surgery. The risk of bias for individual RCT studies was generally  
2 moderate or high due to insufficient information about randomisation method and/or  
3 allocation concealment. The quality of the non-comparative evidence was not  
4 assessed using GRADE. Instead the quality of the individual observational single-  
5 arm studies was assessed using the ROBINS-I tool.

6 The quality of evidence for the 5 comparisons of colposuspension versus synthetic  
7 mesh sling, autologous rectus fascial sling versus synthetic mesh sling, adjustable  
8 synthetic mesh sling versus other synthetic mesh sling, laparoscopic  
9 colposuspension with sutures versus open colposuspension with sutures, and fascial  
10 sling versus colposuspension, ranged from very low to low.

11 The quality of evidence for the 3 comparisons of non-autologous biological sling  
12 versus synthetic mesh sling, transobturator synthetic mesh sling versus retropubic  
13 synthetic mesh sling, and bulking agent versus other surgical technique, ranged from  
14 very low to moderate. The quality of evidence for the comparison of non-adjustable  
15 SIMS versus other synthetic mesh sling ranged from very low to high.

16 Although the outcomes of interest were reported for the majority of the comparisons  
17 in the short and medium term (that is, within 1 year of, and between 1 and 5 years  
18 after, surgery, respectively) only 5 of the identified RCTs reported complication rates  
19 more than 5 years after anti-incontinence surgery. Due to the paucity of long-term  
20 outcomes from the RCTs, evidence from both multi- and single-arm observational  
21 studies that reported complications data on the relevant interventions listed in the  
22 protocol more than 5 years after surgery were considered. All of the observational  
23 studies were assessed as being at serious risk of bias. As such, the specific  
24 complications rates were calculated as weighted averages to take into account the  
25 size of the study. The quality of the observational studies was generally assessed as  
26 being at serious risk of bias due to concerns over confounding, selection of  
27 participants, and measurement of outcomes. The true rates of specific complications  
28 for specific interventions are likely to differ from those estimated above and should  
29 therefore be interpreted with care.

30 The two NMAs ( ), the authors conducted one network for the outcome  
31 'cure' and another network for the outcome 'improvement', did not distinguish  
32 between autologous rectus fascial slings and slings made of other types of biological  
33 material (e.g. porcine dermis) nor between adjustable and non-adjustable single-  
34 incision mini-slings. Therefore the NMAs ( ) do not report 1-year cure  
35 and improvement data for the more specific comparisons involving these  
36 interventions that are considered elsewhere in the clinical review. Consistent with the  
37 quality assessments of the evidence considered in this review, the direct pairwise  
38 meta-analysis of studies included in the NMAs ( ) that report the  
39 outcomes of composite cure and patient satisfaction/patient-reported improvement at  
40 approximately 1 year was also of low quality. There was no inconsistency between  
41 the direct and indirect estimates on the outcome of composite cure, thus there is no  
42 evidence that the underlying assumptions of the NMA do not hold. For the outcome  
43 of patient satisfaction/patient-reported improvement there was some evidence of  
44 inconsistency between the direct and indirect evidence for 3 comparisons: pelvic floor  
45 muscle training (PFMT) versus transobturator synthetic mesh sling; PFMT versus  
46 open colposuspension; and traditional sling versus open colposuspension. Despite  
47 the inconsistency, the comparison involving conservative treatments such as PFMT  
48 did not meet the inclusion criteria for this review. Also, since the evidence did not  
49 allow the committee to distinguish between traditional slings (e.g. porcine dermis)  
50 and open colposuspension, the presence of inconsistency did not influence the  
51 committee's decision making.

## 1 **Benefits and harms**

2 Overall, there are 3 sources of evidence on which the recommendations are based:

- 3 • One overall combined analysis of the relative effectiveness of many surgical  
4 interventions together for treatment of SUI (using the NMAs of 2 outcomes,  
5 [REDACTED]) of composite cure and patient satisfaction/patient-reported  
6 improvement outcomes at approximately 1 year after surgery;
- 7 • Individual meta-analyses of the relative effectiveness and safety of a series of two  
8 surgical interventions compared to each other for the treatment of SUI in the short  
9 ( $\leq 1$  year after surgery), medium (between 1 and 5 years after surgery) and long  
10 term ( $> 5$  years after surgery);
- 11 • Non-comparative data about the rate of long-term complications associated with  
12 synthetic mesh sling, colposuspension and traditional (non-synthetic) slings.

13 The committee noted that there were differences between the findings of the NMAs  
14 and those of the individual comparisons. The NMAs seem to favour synthetic  
15 retropubic midurethral mesh sling, open colposuspension and traditional sling on  
16 composite cure and patient satisfaction/patient-reported improvement at  
17 approximately 1 year after surgery.

18 The individual comparative pairwise evidence generally shows no difference between  
19 anti-incontinence surgical interventions on the majority of reported outcomes. In  
20 particular, although the short- and medium-term complications data show few  
21 differences between interventions, there is a lack of reliable data on the long-term  
22 complications for all comparisons and interventions.

23 In the discussion below, each recommendation is addressed in order, indicating the  
24 benefits and harms associated with the relevant interventions. Due to the multiple  
25 sources of evidence used in this review, a section on long-term complications is  
26 included at the end of the discussion.

### 27 **Surgical procedures for treatment of stress urinary incontinence**

28 The committee agreed, based on the evidence and experience and expertise, that  
29 women need to be fully informed about the all treatment options in order to facilitate  
30 shared decision making (see also the other chapters related to the treatment of  
31 stress urinary incontinence – see chapter J). Such discussions about the risks and  
32 benefits would ensure that treatments can be tailored to the individual woman taking  
33 account of her preferences and individual circumstances. Since all surgical  
34 procedures would be more invasive and would be associated with more  
35 complications than lifestyle or conservative options, these options should be  
36 considered first and surgery offered only if they have all failed.

### 37 **Retropubic mesh sling, colposuspension, and autologous rectus fascial sling**

38 The committee discussed the 2013 recommendation to offer synthetic mesh sling  
39 (referred to as ‘midurethral tape’ in the 2013 guideline), open colposuspension and  
40 autologous rectus fascial sling and agreed that it should be kept with some minor  
41 amendments. In particular, the committee agreed to restrict the offer of synthetic  
42 mesh sling to those that use the retropubic route and to offer laparoscopic, in addition  
43 to open, colposuspension.

44 The pairwise evidence analysed in this review generally suggests that there is no  
45 clinically important difference between retropubic mesh sling, colposuspension, and  
46 autologous rectus fascial sling. [REDACTED]  
47 [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]. Also, retropubic mesh  
4 sling, colposuspension, and autologous rectus fascial sling ranked the highest for  
5 both NMA outcomes. For further details, see [Clinical evidence profile for network](#)  
6 [meta-analysis \(NMA\) outcomes](#).

7 The direct pairwise evidence considered in this review also suggests a similar picture  
8 with no clinically important differences apparent between retropubic mesh sling,  
9 colposuspension and traditional types of sling on the various measures of change in  
10 continence status at longer time frames (i.e. between 1 and 5 years, and greater than  
11 5 years after anti-incontinence surgery), and similarly for the outcome of patient  
12 satisfaction/patient-reported improvement.

13 There were no clinically important differences between colposuspension and  
14 synthetic mesh sling on the majority of outcomes and time periods, although the  
15 former was favoured on several outcomes. Eleven RCTs showed that women who  
16 had mesh sling were much more likely to suffer a bladder injury during surgery  
17 compared to colposuspension. While there was no clinically important difference  
18 between colposuspension and synthetic mesh sling on the number of women who  
19 experienced short-term infection and who had concomitant POP surgery, 1 RCT  
20 showed that women who had colposuspension but no concomitant POP surgery  
21 were over one-and-a-half times as likely to experience short-term infection compared  
22 to those who had synthetic mesh sling POP surgery. Two RCTs showed that  
23 colposuspension had a similar increased risk of medium-term POP occurrence, while  
24 1 RCT showed that women who had colposuspension were more than twice as likely  
25 to have medium-term repeat surgery for any reason, compared to synthetic mesh  
26 sling. The committee agreed, using their knowledge and experience, that the  
27 increased risk of perioperative bladder injury for synthetic mesh sling compared to  
28 colposuspension did not present a substantive reason to prefer the latter as such  
29 injuries are usually straightforward to manage clinically and rarely cause long-term  
30 problems.

31 There were some clinically important differences between autologous rectus fascial  
32 sling and synthetic mesh sling. One small study of 20 women indicated that there  
33 were clinically important differences favouring fascial slings on several subscales of  
34 the King's Health Questionnaire (general health perceptions, role limitations, physical  
35 and social limitations, emotions and severity) at 6-months after surgery, although a  
36 larger study showed no clinically important differences on the BFLUTS-SF  
37 questionnaire at median 10 years post-surgery. Nine RCTs showed that women who  
38 had synthetic mesh sling were at increased risk of suffering a perioperative bladder  
39 injury compared to autologous rectus fascial sling. However, 3 RCTs showed that  
40 they were at lower risk of experiencing short-term wound complications. Data from 3  
41 RCTs showed no difference in the number of women who experience pain  
42 complications with 1 year of surgery, although there was high heterogeneity. A  
43 subgroup analysis showed that although there may be no clinically important  
44 difference between autologous rectus fascial sling and transobturator mesh sling on  
45 short-term pain, there may be an increased risk of short-term pain when compared to  
46 retropubic mesh sling only. Although women who had an autologous rectus fascial  
47 sling were less likely to report short-term subjective cure than those who had a  
48 retropubic mesh sling, they were more likely to report a change of continence status  
49 than women who had a transobturator mesh sling. As explained above for the  
50 comparison of colposuspension to synthetic mesh sling, the committee agreed that  
51 the increased risk of perioperative bladder injury did not provide a substantive reason  
52 to prefer an autologous rectus fascial sling over a synthetic mesh sling as bladder

1 injury is usually straightforward to manage clinically and rarely causes long-term  
2 problems.

3 Although the pairwise evidence comparing colposuspension with autologous rectus  
4 fascial sling and other biological slings generally showed no difference on reported  
5 outcomes, one large RCT showed women who had autologous rectus fascial sling  
6 were more likely in the medium term to be subjectively cured, more likely to have a  
7 negative cough stress test and less likely to experience an infection than women who  
8 had an open Burch colposuspension with sutures. [REDACTED]

9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 was evidence of no difference between laparoscopic and open colposuspension for  
13 [REDACTED]

14 [REDACTED]. The pairwise evidence showed  
15 that there was no clinically important difference between laparoscopic and open  
16 colposuspension with sutures for any outcome at any time period with the exception  
17 of an increased risk of perioperative bladder injury for laparoscopic colposuspension  
18 compared to open colposuspension. However the committee noted that all the  
19 studies were conducted before 2007 and that surgical experience in laparoscopic  
20 colposuspension is likely to have improved since then, leading to fewer bladder  
21 injuries. Furthermore, as mentioned above, the committee agreed, using their  
22 knowledge and experience, that intraoperative bladder injuries are usually  
23 straightforward to manage clinically and rarely cause long-term problems.

24 Although the committee acknowledged that the evidence generally showed no  
25 difference between the three interventions, they recognised that the initial treatment  
26 burden of each intervention varies widely with respect to the type of incision(s)  
27 required, usual length of hospital stay, and typical recovery period and that these  
28 considerations can play a substantive role in a woman's choice of intervention. For  
29 example, a retropubic mesh sling requires two small incisions (1-2 cm) in the lower  
30 abdomen above the pubic bone; an autologous rectus fascial sling requires a larger  
31 abdominal incision and the removal and trimming of muscle lining (i.e. fascia) from  
32 the lower abdomen, which is then passed through an additional small vaginal  
33 incision; an open colposuspension with sutures requires an abdominal incision and  
34 the insertion of sutures on each side of the vagina. The length of hospital stay and  
35 recovery period associated with insertion of a retropubic mesh sling is typically much  
36 shorter than either autologous rectus fascial sling or either form of colposuspension.  
37 For example, women who have a retropubic mesh sling can be treated as day cases  
38 or out patients and normally recover after 2 weeks, while those who have autologous  
39 rectus fascial sling or either form of colposuspension typically will be treated on an  
40 inpatient basis, requiring between 1 and 2 days hospital stay and a recovery period  
41 of approximately 6 weeks. Furthermore, given the uncertainty about the long-term  
42 complications of all the interventions considered in this review (discussed further  
43 below), the committee agreed that none of the three interventions could be  
44 recommended over any other. Thus, given the surgical differences between the three  
45 interventions, the committee agreed that women with SUI should be offered a choice  
46 between them.

47 The committee also discussed the variability of surgical expertise across the UK and  
48 noted that not all consulting surgeons will have enough experience to carry out a  
49 woman's chosen surgical procedure. The committee therefore agreed by consensus  
50 and using their knowledge and expertise, that a referral should be made to an  
51 alternative surgeon who does offer the surgery of choice if this is not available from  
52 the consulting surgeon.

1 The committee discussed the 2013 recommendations on the physical properties of  
2 the synthetic mesh sling that should be used and the advice that women should be  
3 given about the mesh sling procedure itself. They agreed that the recommendations  
4 should be retained with some minor amendments to reflect the updated 2019 scope.  
5 The committee agreed with the 2013 recommendation that only type 1 macroporous  
6 polypropylene (synthetic) mesh should be recommended in case new devices and  
7 materials are developed and introduced without adequate clinically testing. They also  
8 agreed by consensus to retain the recommendation that such type 1 mesh should be  
9 coloured to aid its insertion and removal. Given the dearth of evidence (and  
10 corresponding uncertainty) about the risk of long-term complications following  
11 retropubic mesh sling and the fact that complete removal of such an implant is not  
12 always possible, the committee agreed by consensus, using their knowledge and  
13 experience, that women should be fully informed about this and given a personal  
14 record of the procedure including the name and manufacturer of the implant, the date  
15 of surgery, and the name and contact details of the operating surgeon.

16 The committee agreed that the 2013 recommendation that surgeons should only use  
17 devices they are trained to use should be withdrawn as training issues are outside  
18 the scope of the guideline.

### 19 **Transobturator synthetic mesh sling**

20 The committee, using the evidence and their knowledge and experience, agreed that  
21 transobturator midurethral mesh sling should not be offered except in specific clinical  
22 circumstances. The committee was aware that the transobturator mesh sling  
23 procedure is currently quite widely used in the UK, and so considered this  
24 recommendation very carefully especially as the effectiveness evidence showed few  
25 clinically important differences between it and retropubic synthetic mesh sling.

26 There was evidence from the NMAs (

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34 In the pairwise analysis, one RCT showed a clinically important difference favouring  
35 transobturator over retropubic mesh sling on the intercourse subscale of the King's  
36 Health Questionnaire, while another RCT showed a clinically important difference  
37 favouring the latter over the former on the short- and medium term International  
38 Consultation on Incontinence Questionnaire-Urinary Incontinence Quality of Life  
39 score (ICIQ-UI-QoL). However, there was evidence of no short- and medium-term  
40 difference between the two types of synthetic mesh sling from several other studies  
41 that used other continence-specific health-related quality of life measures (e.g. King's  
42 Health Questionnaire).

43 Transobturator mesh sling also generally had a worse short- and long-term  
44 complications profile than retropubic mesh sling. Although women who had one were  
45 at decreased risk of bladder injury, they were at increased risk of experiencing short-  
46 term pain and mesh extrusion, as well as medium-term de novo nocturia and mesh  
47 extrusion. Five RCTs showed that women who had transoburator mesh sling were at  
48 increased risk of needing repeat surgery for SUI in the short term, although no other  
49 differences on repeat surgery were found at any other time point. However, they  
50 were also less likely to need catheterisation in the short term. The committee noted

1 that the need to insert a catheter may also be due to bladder injury suffered during  
2 insertion of retropubic mesh sling. The committee agreed that the increased risk of  
3 perioperative bladder injury from the use of a retropubic mesh sling, compared to a  
4 transobturator mesh sling, does not provide a substantive reason to prefer the  
5 transobturator route because the injury is usually usually straightforward to manage  
6 clinically and does not cause long-term problems. They also acknowledged that it is  
7 standard practice to perform cystoscopy to look for bladder injury during the insertion  
8 of a retropubic synthetic mesh sling (but not during insertion of transobturator mesh  
9 slings) and that its increased risk may be partly due to detection bias. The committee  
10 also discussed the difficulties in completely removing transobturator mesh sling and  
11 agreed on the basis of their knowledge and experience that it was much harder to  
12 remove than synthetic mesh inserted via the retropubic route (especially if the vaginal  
13 portion of the transobturator mesh sling has been removed).

14 Taking this and the evidence in to account, the committee acknowledged that there  
15 are clinical situations in which surgery via the retropubic space should be avoided  
16 and therefore agreed that provision for this should be made in the recommendations.

### 17 **Top-down retropubic mesh sling and single-incision mini-sling**

18 The majority of studies that examined retropubic mesh sling were on the bottom-up  
19 type of mesh sling such as tension-free vaginal tape (TVT), with only a handful  
20 examining other types of retropubic mesh sling. In lieu of relevant studies on other  
21 types of retropubic mesh sling, the committee agreed to retain the 2013  
22 recommendation to not use retropubic top-down mesh sling (e.g. SPARC) except in a  
23 clinical trial.

24 The committee discussed the evidence on single-incision mini-sling and noted that  
25 their fixation points can vary greatly, which a priori may affect their efficacy and  
26 safety.

27 There was evidence from the NMA (  
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43 Although there were some overall clinically important differences found between  
44 SIMS and other synthetic mesh sling for the risk of experiencing complications,  
45 subgroup analysis of the studies according to type of SIMS showed that the majority  
46 of these differences were powered by the comparison of TVT-Secur to other  
47 synthetic mesh sling with no or little difference between the latter and other types of  
48 SIMS.

1 One RCT showed that there was a clinically important mean difference favouring  
2 TVT-O over TVT-Secur on the Urinary Incontinence Quality of Life Scale (I-QoL)  
3 within 2 years of surgery. However, there were no other reported differences  
4 between SIMS overall (and specific brands) and any other synthetic mesh sling on  
5 any other quality of life measure at any time point.

6 Overall 12 RCTs, 9 of which examined the TVT-Secur brand of SIMS, showed that  
7 women who had a SIMS were less likely to experience short-term pain compared to  
8 other types of synthetic mesh sling. At the medium term, 5 RCTs showed that women  
9 who had any SIMS were less likely to experience pain compared to any other  
10 synthetic mesh sling, but no such difference was apparent for any specific brand of  
11 SIMS. Fifteen RCTs, 9 of which examined TVT-Secur, showed SIMS to have an  
12 increased risk of short-term mesh extrusion compared to any synthetic mesh sling.  
13 However, there was no clinically important difference found between MiniArc and  
14 Needleless brands of SIMS and other synthetic mesh slings. At the medium term,  
15 although 5 RCTs showed no difference between SIMS overall and any other synthetic  
16 mesh sling, 2 of these suggested that there may be a decreased risk of mesh  
17 extrusion for the MiniArc brand of SIMS. There were no other differences in  
18 complications found between SIMS overall (and for particular brands of SIMS) and  
19 any other synthetic mesh sling.

20 Some clinically important differences favouring other synthetic mesh slings over  
21 SIMS were found on change of continence status. One RCT showed that women  
22 who had MiniArc SIMS were less likely to be subjectively cured in the short-term  
23 compared to TVT. Two RCTs in women who had not also had concomitant POP  
24 surgery showed a similar result for TVT-Secur compared to any other synthetic mesh  
25 sling. Eight RCTs showed that women who have any brand of SIMS are no less likely  
26 to be subjectively cured in the medium term compared to synthetic mesh sling,  
27 although there was high heterogeneity. A subgroup analysis showed that women  
28 who had MiniArc SIMS were less likely to have medium-term subjective cure  
29 compared to retropubic bottom-up mesh sling (TVT) but that there was no difference  
30 between them and transobturator inside-out mesh sling (TOT). Two RCTs showed no  
31 difference between TVT-Secur and any other transobturator mesh sling although  
32 there was high heterogeneity. A subgroup analysis showed that women who had  
33 TVT-Secur were less likely to have a negative cough stress test in the medium-term  
34 compared to transobturator inside-out mesh sling (TVT-O), although there was no  
35 difference between TVT-Secur and TOT.

36 There were also some clinically important differences on repeat surgery favouring  
37 other types of synthetic sling. Six RCTs showed that women who had a SIMS may be  
38 over two-and-a-half times as likely to require repeat surgery for any reason, although  
39 there was high heterogeneity in the effect estimate. A subgroup analysis showed  
40 women who had either MiniArc or TVT-Secur were more likely to require repeat  
41 surgery compared to women who had any other synthetic mesh sling. Finally, 6  
42 RCTs showed that women who had TVT-Secur were more likely to require repeat  
43 surgery for POP in the short-term compared to any other synthetic mesh sling.

44 Only 1 type of SIMS (Needleless) is currently available in the UK market. However,  
45 data from 4 RCTs showed no clinically important difference between Needleless  
46 SIMS and any other synthetic mesh sling on any reported outcome.

47 The NMAs ( ) did not have a separate category for adjustable synthetic  
48 mesh sling and included studies on adjustable slings with those on either other  
49 synthetic (transobturator or retropubic) mesh slings or single-incision mini-slings. The  
50 majority of pairwise direct evidence compared the Ajust SIMS to a transobturator  
51 inside-out mesh sling (TVT-O). There was no clinically important difference between

1 adjustable and other types of synthetic mesh sling with the exception of a decreased  
2 risk of a short-term need for catheterisation for adjustable slings compared to other  
3 synthetic mesh slings. The committee agreed that this is expected for adjustable  
4 slings as they are designed precisely to alleviate excessive tension in their fixation  
5 arms, thus obviating the need for catheterisation to enable successful voiding.  
6 Evidence from 4 RCTs showed no clinically important difference between adjustable  
7 and other types of synthetic mesh sling on pain within 1 year, although there was  
8 high heterogeneity. A subgroup analysis of 2 RCTs according to type of adjustable  
9 sling also showed no clinically important difference between the Ajust SIMS and  
10 other types of synthetic mesh sling. However, the Ophira and Tissue Fixation System  
11 SIMS showed a decreased risk of short-term pain compared to transobturator  
12 outside-in mesh sling (TOT).

13 Given the diversity of evidence and the current unavailability of the majority of  
14 various brands of adjustable and non-adjustable single-incision mini-slings, the  
15 committee agreed to amend the 2013 recommendation referring to NICE  
16 interventional procedure guidance IPG262, and to recommend that they not be used  
17 except – as with synthetic retropubic top-down midurethral mesh sling –in clinical  
18 trials. Note that NICE interventional procedure guidance IPG262 has now been  
19 withdrawn and been replaced by [NICE interventional procedure guidance IPG566](#).

#### 20 **Other procedures**

21 This 2019 update did not address the issue of whether anterior colporrhaphy, needle  
22 suspension, paravaginal defect repair and the Marshall-Marchetti-Krantz procedure  
23 are safe and effective as anti-incontinence procedures because these procedures  
24 are no longer standard in UK practice. As such, the committee agreed to retain the  
25 2006 recommendation that these procedures should not be offered as anti-  
26 incontinence surgery. The committee agreed that this 2006 recommendation, which  
27 appeared under the heading 'biological slings', should be retained although observed  
28 that it was incorrectly labelled in the 2013 guideline and should appear under a new  
29 heading titled 'Other procedures'.

#### 30 **Porcine dermis and other traditional slings**

31 The NMAs ( ) classified porcine dermis slings with other 'traditional'  
32 slings made from other biological materials. In the pairwise meta-analysis no  
33 clinically important differences between non-autologous biological sling and synthetic  
34 mesh sling were found on continence-specific health-related quality of life and  
35 adverse events. Data from 2 RCTs showed no clinically important difference between  
36 porcine dermis sling and synthetic mesh sling on short-term subjective cure, although  
37 there was high heterogeneity. A subgroup analysis showed that women who had  
38 porcine dermis sling were less likely to report being subjectively cured when  
39 compared to TVT but that there was no difference when compared to Align-TO. Data  
40 from 1 RCT showed that more than 5 years after SUI surgery, women who had  
41 porcine dermis sling were less likely to report being subjectively cured and  
42 experiencing an improvement in continence status compared to retropubic bottom-up  
43 mesh sling (TVT). There was some evidence to suggest that porcine dermis sling  
44 may be associated with increased risk of short- and long-term repeat surgery  
45 compared to retropubic bottom-up mesh sling (TVT), although there is some  
46 uncertainty. Given the decreased probability of short-term subjective cure, and long-  
47 term subjective cure and improvement in continence status, and possible increased  
48 risk of short- and long-term repeat surgery of porcine dermis sling compared to TVT,  
49 the committee agreed that the former did not present a viable long-term surgical  
50 option to the latter.

1 One RCT that compared cadaveric fascia lata to synthetic mesh sling showed that  
2 women who had the former were more likely to experience de novo urge  
3 incontinence compared to retropubic intravaginal slingplasty. There were no other  
4 clinically important differences apparent between these two interventions. The  
5 committee agreed that the evidence on this intervention, consisting in a single trial on  
6 the 1-year effectiveness and safety of cadaveric fascia lata sling, did not support its  
7 use over retropubic mesh sling.

#### 8 **Bulking agents**

9 There was no clinically important difference on any reported outcome at any time  
10 period in 1 study between Macroplastique bulking agent and autologous rectus  
11 fascial sling with the exception of a difference favouring the latter on objective cure 1  
12 year after surgery. No studies were found for this comparison that reported  
13 continence-specific health-related quality of life and adverse events.

14 The committee recognised that there is a dearth of evidence on the use of bulking  
15 agents in the long term but agreed that, in their experience, some patients (especially  
16 the frail or elderly) find them useful. Furthermore, although there is uncertainty over  
17 the risks, any such risks are less likely to be serious compared to those associated  
18 with synthetic mesh slings. The committee therefore agreed by consensus, using  
19 their knowledge and experience, that bulking agents should not be routinely offered  
20 unless other surgical procedures are not appropriate or not wanted. The committee  
21 further agreed that it should be explained to women considering intramural bulking  
22 agents to treat SUI that repeated injection may be needed to maintain efficacy, that  
23 efficacy diminishes over time, and that retropubic midurethral mesh sling and  
24 autologous rectus fascial sling are more efficacious.

#### 25 **Artificial sphincter**

26 No evidence was identified for this intervention. Despite this, the committee agreed to  
27 retain the 2006 recommendations to consider the use of artificial sphincter only after  
28 the failure of other surgical options and that women who have such a sphincter  
29 should be offered life-long follow up.

#### 30 **Follow up after surgery**

31 The committee discussed the follow up interval for women who have had surgery to  
32 treat SUI and agreed using their knowledge and experience that it should occur  
33 within 6 months of surgery. This would capture whether the procedure has been  
34 effective for the individual woman and provide the opportunity to detect any short-  
35 term complications.

36 The committee discussed the risk of synthetic mesh becoming extruded or exposed  
37 and acknowledged that although the incidence of this is relatively low in the short-  
38 and medium-term, the complications associated with these problems can be  
39 substantial and life changing. They therefore agreed that women who have had a  
40 synthetic retropubic mesh sling should also have a vaginal examination in order to  
41 detect such exposure/extrusion.

42 In addition, the committee agreed by consensus, using their knowledge and  
43 experience, that the principles outlining the 2013 recommendations on what should  
44 happen after unsuccessful SUI surgery or a recurrence of symptoms are still valid but  
45 that they should be updated to reflect the new structure for regional MDTs  
46 recommended elsewhere in this 2019 update – see chapter F. Furthermore they  
47 agreed by consensus that if further treatment is declined, women should be offered

1 advice in line with the recommendation made elsewhere in the guideline regarding  
2 this.

### 3 **Complications**

4 Although there was some evidence from the identified RCTs about the short- and  
5 medium- term complications (i.e. those  $\leq 1$  year, and between 1 and 5 years, after  
6 surgery) associated with each intervention, there is substantial uncertainty about the  
7 long-term complications profile (i.e. those occurring more than 5 years after surgery),  
8 which was derived mainly from publications of case series.

9 The short- and medium-term complications profile suggests that there is little  
10 clinically important difference between any of the interventions. Women who had  
11 colposuspension had an increased medium-term risk of POP, and an increased risk  
12 of short-term infection in those who also did not also have concomitant POP surgery  
13 compared to synthetic mesh sling; autologous rectus fascial sling had an increased  
14 risk of short-term pain compared to retropubic mesh sling and an increased risk of  
15 short-term wound complications compared to any synthetic mesh sling. Cadaveric  
16 fascia lata had an increased risk of short-term de novo urge incontinence compared  
17 to retropubic IVS. Transobturator mesh sling had an increased risk of short-term pain  
18 and mesh extrusion, but a decreased risk of short-term need for catheterisation,  
19 compared to retropubic mesh sling. Single-incision mini-sling had a decreased risk of  
20 short-term and medium-term pain compared to other synthetic mesh sling. Adjustable  
21 mesh sling had a decreased risk of short-term need for catheterisation compared to  
22 other synthetic mesh sling. Finally, 2 RCTs suggested that adjustable synthetic mesh  
23 sling has a decreased risk of short-term pain compared to transobturator outside-in  
24 mesh sling (TOT).

25 There were no other clinically important differences between interventions regarding  
26 the occurrence of short- and medium-term complications.

27 The estimated complication rates at more than 5 years after anti-incontinence  
28 surgery suggest that the most common complications for retropubic synthetic mesh  
29 sling are de novo urge incontinence, de novo urgency and pain (14.1%, 13.7%, and  
30 9% respectively); for transobturator synthetic mesh sling, de novo urge incontinence,  
31 pain and de novo urgency (8.7%, 7.1%, and 4%); for any colposuspension, POP  
32 occurrence, de novo urgency, and de novo urge incontinence (21.1%, 8.3%, and  
33 7.3%); and for open colposuspension, de novo frequency, infection, and de novo  
34 nocturia (37.2%, 26.2%, and 11.8%). The committee expressed the view that the  
35 estimated long-term complication rates were generally consistent with their clinical  
36 experience but were surprised that the estimated long-term pain rate was higher for  
37 retropubic mesh sling and fascial sling rather than transobturator mesh sling (9% and  
38 16.7% vs 7.1%, respectively). However since the majority of data that contributed to  
39 these estimates were from non-comparative case series data, the committee agreed,  
40 generally and in this specific case, that there is substantial uncertainty about the  
41 long-term complications profile of anti-incontinence surgical interventions.

### 42 **Collection of data on mesh surgery and mesh-related complications**

43 The committee was aware of the widespread public concern about the use of  
44 synthetic mesh in the surgical management of women with UI and POP, of the  
45 Independent Medicines and Medical Devices Safety Review, of the final report of  
46 NHS England Mesh Working Group and of the pause on surgical procedures  
47 involving synthetic mesh imposed by NHS England. They were also concerned about  
48 the lack of reliable evidence on the adverse events following surgical interventions for

1 UI and POP, especially those occurring after two years, despite extensive review of  
2 the existing research literature carried out for development of the guideline.

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

11 Due to the limited evidence around the long-term complications of mesh, the  
12 committee made a research recommendation specifically about the long-term risks of  
13 mesh surgery compared with non-mesh surgery for stress urinary incontinence in  
14 women. This is important because although mesh has been used extensively over  
15 the last 20 years, there is little data on the complications of mesh use greater than 5  
16 years. The committee felt it was very important for research to ascertain the success,  
17 safety and complication rates of mesh use of a 5 to 10 year period.

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

19 There was evidence from one-UK based modelling study showing that synthetic  
20 retropubic mesh sling may potentially be cost-effective in women with SUI when  
21 compared with other surgical procedures including traditional sling, transobturator  
22 mesh sling, single incision sling, laparoscopic colposuspension, and open  
23 colposuspension. [REDACTED]

24 [REDACTED]  
25 [REDACTED] Although, the evidence on the complications  
26 suggested that synthetic retropubic mesh sling resulted in higher bladder injury and  
27 short-term need for catheterisation. The committee explained that there is generally  
28 no long-term sequelae to bladder injury and that the associated short-term need to  
29 use a catheter is inexpensive.

30 The committee acknowledged that there is little difference between a traditional sling  
31 and open colposuspension in terms of effectiveness. Even though both interventions  
32 showed some cost-effectiveness, neither was as cost-effective as retropubic mesh  
33 sling. The committee explained that irrespective of the cost-effectiveness, women  
34 may wish not to have mesh procedure and also in some cases it may be  
35 inappropriate to use artificial material and as a result, traditional sling and open  
36 colposuspension should remain available to women with SUI. The committee  
37 explained that both sling and colposuspension are major surgeries and are expected  
38 to have similar intervention costs.

39 The committee noted that there are surgeons in the UK carrying out synthetic  
40 transobturator mesh sling insertion. However, the effectiveness, complication profile,  
41 and the cost-effectiveness all were less favourable for synthetic transobturator mesh  
42 sling when compared with synthetic retropubic mesh sling and open colposuspension  
43 and as a result, there may be cost savings and QALY gains by not undertaking  
44 transobturator MUS. Although, the committee acknowledged that synthetic  
45 transobturator mesh sling could be an option in women where retropubic approach is  
46 not possible on clinical grounds as otherwise nothing could be done for this sub-  
47 group of women.

48 The committee acknowledged the UK-based cost-effectiveness and cost-utility  
49 analysis of a single incision mini sling compared with a standard midurethral mesh

1 sling in women with SUI. However, the analysis compared only a limited number of  
2 available treatment options for women with SUI in the UK. Also, the committee noted  
3 that there may be potential conflict of interest. Due to the above, the committee could  
4 not draw any conclusions from this study.

5 All other existing cost-effectiveness analyses were non-UK based. The studies and  
6 comparisons were too heterogeneous and the committee noted that again most of  
7 the studies were industry-funded which made the findings less reliable and useful for  
8 decision making.

9 Generally, the committee was of a view that recommendations for surgical  
10 procedures in women where conservative management for SUI has failed do not  
11 represent a significant change in the clinical practice and as such are not expected to  
12 result in substantial resource and cost implications to the NHS.

### 13 **Other factors the committee took into account**

14 The committee acknowledged that there was a recent NMA (Song 2018), which  
15 looked at the efficacy (subjective and objective cure rate) and safety (postoperative  
16 complications, bladder perforation, tape erosion, urinary retention, and pain) of  
17 surgical treatments for stress urinary incontinence, and recommended transobturator  
18 outside-in tape procedure (that is, TOT) as the optimal regimen for SUI. The  
19 committee did not consider the 7 NMAs when making recommendations as it was  
20 both less comprehensive and yet broader than that of Brazzelli 2018. For example,  
21 Song 2018 only included data from 45 studies covering just 5 specific brands of  
22 mesh sling (TVT, TOT, TVT-O, and two types of SIMS, TVT-Secur and Ajust SIMS),  
23 whilst Brazzelli 2018 included data from 175 studies covering any type of mesh sling  
24 and other commonly-used SUI surgical procedures for women in the UK. Equally,  
25 Song 2018 conducted NMAs on the overall complication rate and the rate of specific  
26 types of complications, whereas Brazzelli 2018 did not. As with the direct evidence  
27 considered in this review, the indirect evidence considered by Song 2018 failed to  
28 identify substantial significant differences between mesh sling interventions.  
29 Nevertheless, and acknowledging this, Song 2018 recommends TOT on the basis  
30 that the rank plots showed it to have the highest probability of being the most  
31 efficacious type of mesh sling (i.e. on the outcomes of objective cure and subjective  
32 cure) and to have a higher rank than TVT on the outcomes of post-operative  
33 complications, tape erosion, and postoperative pain. By contrast in Brazzelli 2018,  
34 which also examined other more traditional SUI surgical procedures, transobturator  
35 mesh sling (including both inside-out and outside-in varieties) was ranked fourth on  
36 their composite cure outcome, below retropubic mesh sling, traditional sling, and  
37 open colposuspension, and second below retropubic mesh sling on the outcome of  
38 improvement in continence status.

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## 1 Review question

- 2 What is the effectiveness of surgical management of stress urinary incontinence  
3 (including mesh and non-mesh procedures) compared to pelvic floor muscle training?

## 4 Introduction

- 5 Surgical procedures to treat stress urinary incontinence (SUI) have been shown to be  
6 more effective at alleviating symptoms than pelvic floor muscle training (PFMT) but  
7 with higher risks of adverse events. This review aimed to assess if non-invasive  
8 physiotherapy can be a viable first-line treatment as a long-term solution to SUI  
9 before more invasive therapy is considered.

## 10 Summary of the protocol

- 11 Please see Table 14 for a summary of the Population, Intervention, Comparison and  
12 Outcome (PICO) characteristics of this review.

### 13 Table 14: Summary of the protocol (PICO table)

<b>Population</b>	Women (aged 18 and over) with stress urinary incontinence or mixed UI with stress predominance Women who are naïve to treatment or who have undergone treatment repeatedly.
<b>Intervention</b>	<p><b>Surgical treatments</b></p> <ul style="list-style-type: none"> <li>• Suburethral slings (synthetic mesh) <ul style="list-style-type: none"> <li>○ Retropubic bottom-up (e.g. TVT, IVS-02)</li> <li>○ Retropubic top-down (e.g. SPARC)</li> <li>○ Transobturator outside-out (e.g. TVT-O)</li> <li>○ Transobturator outside-in (e.g. TOT)</li> <li>○ Single-incision or mini-sling (e.g. Contasure-Needleless, TVT-Secur, MiniArc, Ophira)</li> <li>○ Adjustable slings (e.g. Ajust) <ul style="list-style-type: none"> <li>- Retropubic</li> <li>- Transobturator (e.g. TOA)</li> </ul> </li> </ul> </li> <li>• Colposuspension <ul style="list-style-type: none"> <li>○ Open abdominal retropubic colposuspension with sutures</li> <li>○ Laparoscopic retropubic colposuspension with sutures</li> </ul> </li> <li>• Biological slings <ul style="list-style-type: none"> <li>○ Autologous rectus fascial slings</li> <li>○ Non-autologous biological slings (allografts, xenografts, e.g. porcine dermis)</li> </ul> </li> <li>• Para or transurethral injections (bulking agents) <ul style="list-style-type: none"> <li>○ Bulkamid (polyacrylamide hydrogel)</li> <li>○ Macroplastique (water soluble gel with silicone elastomer)</li> <li>○ Captive</li> <li>○ Collagen</li> </ul> </li> <li>• Artificial sphincters</li> </ul>
<b>Comparison</b>	Any type of surgery listed above compared to pelvic floor muscle training
<b>Outcomes</b>	<b>Critical</b>

- Continence-specific health-related quality of life
    - ICIQ
    - BFLUTS-SF
    - i-QOL
    - SUIQQ
    - UISS
    - SEAPI-QMM
    - ISI, KHQ
    - E-PAQ
    - Sexual function: PISQ-12
  - Change in continence status
    - Subjective report
    - Objective cure rate
    - Negative stress (cough) test
    - Number of incontinence episodes per day
  - Patient satisfaction, patient reported improvement
    - Patient global impression of improvement (PGII)
    - Number of women who are satisfied
- Important**
- Adverse events (immediate post-op or perioperative)
    - Severe bleeding requiring a blood transfusion
    - Internal organ injury (to bladder or bowel)
  - Complications >1 year
    - Pain
    - Mesh erosion or extrusion (vaginal, bladder, urethra)
    - Fistula
    - Need for catheterisation
    - Infection (recurrent UTI, wound)
    - De novo overactive bladder symptoms
    - Occurrence of POP
    - Wound complications (hernia)
  - Repeat surgery (for UI or POP, or mesh complications)

1 *BFLUTS: Bristol female lower urinary tract symptoms scored form; E-PAQ: electronic personal health*  
 2 *questionnaires; ICIQ: international consultation on incontinence modular questionnaire; I-QOL:*  
 3 *incontinence quality of life; ISI: incontinence severity index; IVS: intravaginal slingplasty; KHQ: King's*  
 4 *health questionnaire; PISQ: pelvic organ prolapse/urinary incontinence sexual questionnaire; POP:*  
 5 *pelvic organ prolapse; SEAPI-QMM: stress-related leak, emptying ability, anatomy, protection inhibition,*  
 6 *quality of life, mobility and mental status incontinence classification system; SPARC: suprapubic arch;*  
 7 *SUIQQ: stress and urgency incontinence and quality of life questionnaire; TOA: transobturator*  
 8 *adjustable; TOT: transobturator tape Sling; TVT: tension-free vaginal tape; TVT-O: tension-free vaginal*  
 9 *tape obturator; UI: urinary incontinence; UISS: urinary incontinence severity score; UTI: urinary tract*  
 10 *infection.*

11 For further details see the review protocol in appendix A.

## 12 Methods and process

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

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

## 6 Clinical evidence

### 7 Included studies

8 Five articles reporting data from four RCT (n=655) were included in the review  
9 (Klarskov 1986 ; Klarskov 1991; Labrie 2013; Tapp 1989; ter Meulen 2009) along  
10 with one prospective observational cohort study (Yalcin 1998)

11 For a summary of included studies see Table 15.

12 All studies (n=655) included only women with stress urinary incontinence (SUI) or  
13 predominately SUI (Labrie 2013). Two studies (n=95) compared PFMT with Burch  
14 colposuspension (Klarskov 1986; Klarskov 1991; Tapp 1989) and another (n=98)  
15 compared PFMT with either Burch or Pereyra surgical treatments (Yalcin 1998). One  
16 study (n=417) compared PFMT with midurethral sling surgery (Labrie 2013), another  
17 (n=45) compared PFMT with the bulking agent Macroplastique® (ter Meulen 2009).

18 One study (n=45) only included women with concomitant pelvic organ prolapse, had  
19 not improved continence status after PFMT and excluded those who had long-term  
20 use of intraurethral continence devices (ter Meulen 2009).

21 See the literature search strategy in appendix B and the study flow chart in appendix  
22 C, clinical evidence tables in appendix D, forest plots in appendix E and GRADE  
23 evidence profiles in appendix F.

### 24 Excluded studies

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

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

28 A summary of the studies that were included in this review are presented in Table 15.

29 **Table 15: Summary of included studies**

Study	Population	Intervention/Comparison	Outcomes
Klarskov 1986/1991  Prospective RCT	Women with genuine SUI who have not received previous surgery or systematic pelvic floor exercises	PFMT + Burch colposuspension and/or vaginal repaira	Change in continence status (subjective cure/number of incontinence episodes every 3 days)
Labrie 2013  Multicentre RCT	Women aged 35-80 who present with objectively-verified moderate to severe predominant SUI at POP-Q>Stage II	PFMT + SUI (midurethral-sling) surgery	Change in continence status (subjective cure/objective cure) Patient satisfaction/patient-reported improvement Complications

Study	Population	Intervention/Comparison	Outcomes
Tapp 1989 Prospective RCT	Women with urodynamically- proven GSI with incontinence.	PFMT + SUI (Burch colposuspension) surgery	Objective cure rate Subjective improvement
ter Meulen 2009 Prospective RCT	Women with urodynamic stress urinary incontinence and urethral hypermobility at POP-Q>Stage II	PFMT + bulking agent (Macroplastique®)	Continence-specific health-related quality of life Subjective report Change in continence status (subjective cure/report)
Yalcin 1998 Prospective cohort	Urinary incontinence with hypermobility of the bladder with minimal urge incontinence	PFMT + SUI (Burch colposuspension) or SUI and vaginal (modified Pereyra) surgery	Subjective report Objective cure rate Long-term complications

1 Notes: <sup>a</sup>, surgical procedures were chosen on the basis of a voiding cystourethrogram; <sup>b</sup>, Objective  
2 confirmation of stress urinary incontinence by either examination, stress-test or urodynamics; <sup>c</sup>,  
3 urodynamic investigations included visual analogue symptom score, perineal pad testing,  
4 videocystourethrography (VCU) and urethral pressure profilometry; <sup>d</sup>, tested with I-QoL questionnaire  
5 including Stamey incontinence rating, frequency-volume chart and 1h pad tests; <sup>e</sup> tested with Q-tip test;  
6 <sup>f</sup>, only complications data was taken from observational studies; <sup>g</sup>, patient questionnaire, 24-hour urinary  
7 diary, physical, genitourinary and urologically oriented neurological examinations, urine culture, one-hour  
8 pad test, stress test, Q-tip test, single channel provocative water column cystometry and perineal  
9 ultrasonography.  
10 Abbreviations: GSI: genuine stress incontinence; PFMT: pelvic floor muscle training; RCT: randomised  
11 controlled trial; POP-Q: pelvic organ prolapse quantification system; SUI: stress urinary incontinence.

12 See also the study evidence tables in appendix D. Meta-analysis was conducted  
13 where appropriate, forest plots can be seen in appendix E.

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

2 GRADE analysis was conducted for critical and important outcomes, the clinical  
3 evidence profiles are presented in appendix F.

## 4 **Economic evidence**

### 5 **Included studies**

6 The systematic search of the economic literature undertaken for the guideline  
7 identified one USA study on the cost-utility of conservative management compared  
8 with surgical management in the treatment of stress urinary incontinence  
9 (Richardson 2014).

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

### 14 **Excluded studies**

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

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

18 Richardson (2014) evaluated the cost-utility of conservative management compared  
19 with surgical management for the initial treatment of SUI in the USA. The study  
20 population comprised of women with uncomplicated de-novo SUI. The conservative  
21 management options included pessary or PFMT and the surgical treatment included  
22 mid-urethral sling (MUS). PFMT consisted of 4 visits every 2 weeks and women were  
23 also given a home programme prescription at the end of 8 weeks to maintain  
24 treatment.

25 This was a modelling study with the effectiveness (that is, subjective cure rates)  
26 derived from RCTs. In the decision tree model following the initial treatment with a  
27 pessary, if a woman experienced persistent SUI a choice of no further treatment,  
28 PFMT or MUS was modelled. After an initial treatment with PFMT if a woman  
29 experienced bothersome SUI symptoms a choice of no further treatment or MUS was  
30 modelled. Following the initial treatment with MUS, a choice of no further treatment or  
31 a repeat MUS was modelled. The analysis also considered the probability of  
32 complications following a surgical procedure including mesh erosion, urinary  
33 retention requiring operative take back, de novo urge incontinence, and recurrent  
34 SUI.

35 The main analysis was conducted from a healthcare perspective. The study  
36 considered intervention costs (pessary, PFMT and MUS) and the management of  
37 complications including sling release, sling removal for mesh exposure, and  
38 anticholinergic medication. The resource use estimates were based on published  
39 sources and authors' assumptions. The unit costs were obtained from national  
40 sources including Medicare reimbursement and physician fee schedules.

41 The measure of outcome for the economic analysis was quality-adjusted life years  
42 (QALYs). The utility weights were obtained from a published study that reported  
43 Health Utilities Index-Mark III (HUI-Mark III) scores for patients with and without

1 chronic conditions including urinary incontinence in Canada. For women treated with  
2 anticholinergic medication, a utility weight was obtained from a study where vignette  
3 technique was used to elicit preferences with valuations obtained using time trade-off  
4 method. The time horizon of the analysis was 1 year. The results below are reported  
5 only for MUS versus PFMT since this was the only comparison of interest that was  
6 identified in the clinical review protocol.

7 The absolute costs and QALYs were not reported. However, the incremental cost-  
8 effectiveness ratio (ICER) of MUS (versus PFMT) was \$32,132 per QALY gained.  
9 The sensitivity analyses indicated that if subjective cure of SUI with PFMT was >44%  
10 (base case: 0.329) then it would be the preferred scenario over MUS. The cost for  
11 initial SUI treatment with MUS would need to be \$5,300 (base case: \$3,938) for the  
12 ICER to be above \$50,000 per QALY gained. Varying the QALYs did not change the  
13 findings. Similarly, the incidence of complications associated with MUS treatment  
14 were varied by 50% and did not impact the conclusions. Based on the above  
15 findings, the authors concluded that surgical treatment was the preferred option for  
16 the initial treatment for women with SUI. However, the ICER of MUS (versus PFMT)  
17 of \$32,132 (£24,000) is above NICE's lower cost-effectiveness threshold of £20,000  
18 per QALY gained.

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

21 Von Bargaen (2015) evaluated the cost-utility of expectant management, PFMT,  
22 PFMT with electrical stimulation, incontinence pessary, and surgical treatment (that  
23 is, mid-urethral sling) in women with SUI in the AUS. However, the absolute costs  
24 and QALYs were not reported, nor has the study reported relevant ICERs. The study  
25 very serious methodological limitations and it was not considered by the committee  
26 when making the recommendations.

## 27 **Clinical evidence statements**

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

- 29 • Low quality evidence from 1 RCT (n= 45) showed a clinically important difference  
30 favouring surgery over PFMT on the number of women who have a better  
31 continence-specific health-related quality of life as assessed by the Urinary  
32 Incontinence Quality of Life scale (I-QoL) within 3 months of-treatment: MD 0.54  
33 (95% CI 0.49 to 0.59).

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

- 36 • Moderate quality evidence from 3 RCTs (n=445) showed a clinically important  
37 difference favouring surgery over PFMT on the number of women who are  
38 subjectively cured within 1 year: RR 1.61 (95% CI 1.39-1.85).
- 39 • Very low quality evidence from 1 RCT (n=30) showed no clinically important  
40 difference between surgery and PFMT on the number of women with SUI who are  
41 subjectively cured more than 5 years since treatment: RR 1.10 (95% CI 0.53-  
42 2.30).
- 43 • Very low quality evidence from 2 RCTs (n=388) showed no clinically important  
44 difference between surgery and PFMT on the number of women with SUI who are  
45 objectively cured within 1 year, although there was very high heterogeneity: RR  
46 2.86 (95% CI 0.44-18.61).

47  
48  
49

**1 Patient satisfaction/patient-reported improvement**

- 2 • High quality evidence from 1 RCTs (n=369) showed a clinically important  
3 difference favouring surgery over PFMT on the number of women with SUI who  
4 experience improvement in continence status within 1 year of treatment: RR 1.41  
5 (95% CI 1.25-1.59).
  - 6 ○ High quality evidence from 1 RCTs (n=395) showed a clinically important  
7 difference favouring surgery over PFMT on the number of women with SUI who  
8 experience improvement in continence status within 2 months of treatment: RR  
9 6.76 (95% CI 4.67-9.78).
  - 10 ○ High quality evidence from 1 RCTs (n=390) showed a clinically important  
11 difference favouring surgery over PFMT on the number of women with SUI who  
12 experience improvement in continence status within a 4 months of treatment:  
13 RR 2.93 (95% CI 2.36-3.64).
  - 14 ○ High quality evidence from 1 RCTs (n=385) showed a clinically important  
15 difference favouring surgery over PFMT on the number of women with SUI who  
16 experience improvement in continence status within 6 months of treatment: RR  
17 1.99 (95% CI 1.68-2.36).
- 18 • Moderate quality evidence from 1 RCTs (n=337) showed a clinically important  
19 difference favouring surgery over PFMT on the number of women with SUI who  
20 experience improvement in continence status between 1 and 5 years after  
21 treatment: RR 1.22 (95% CI 1.11-1.35).
- 22 • Very low quality evidence from 1 RCT (n=30) showed no clinically important  
23 difference between surgery and PFMT on the number of women with SUI who  
24 experience improvement in continence status more than 5 years after treatment:  
25 RR 1.5 (95% CI 0.18 to 12.65).

26

**27 Adverse events**

- 28 • Low quality evidence from 1 RCT (n=417) showed that there may be a clinically  
29 important difference favouring PFMT over surgery on the number of women who  
30 experience bladder perforation during treatment, although there is some  
31 uncertainty: RR 0.08 (95% CI 0.0-1.44).

32

**33 Complications at > 1 year**

- 34 • Very low quality evidence from 1 prospective observational study (n=98) showed  
35 that there may be a clinically important difference favouring PFMT over surgery on  
36 the number of women who experience an infection between 1-and 5 years after  
37 treatment, although there is some uncertainty: RR 0.10 (95% CI 0.0-1.73).
- 38 • Low quality evidence from 1 RCT (n=417) showed that there may be a clinically  
39 important difference favouring PFMT over surgery on the number of women who  
40 de novo urge incontinence during treatment, although there is some uncertainty:  
41 RR 0.41 (95% CI 0.15-1.13).

42

**43 Repeat surgery**

- 44 • Low quality evidence from 1 RCT (n=417) showed no clinically important  
45 difference favouring PFMT over surgery on the number of women who have  
46 repeat surgery between 1-and 5 years after treatment: RR 0.21 (95% CI 0.03-  
47 1.81).

48

## 1 Economic evidence statements

- 2 • There was evidence from one USA modelling study showing that surgical  
3 management was potentially cost-effective when compared with PFMT. However,  
4 the incremental cost-effectiveness ratio expressed in the UK pounds was above  
5 the lower NICE cost-effectiveness threshold of £20,000 per QALY, but below the  
6 upper threshold value of £30,000 per QALY. This evidence came from a partially  
7 applicable study that was characterised by potentially serious methodological  
8 limitations.

## 9 Recommendations

- 10 E2.1 Offer a trial of supervised pelvic floor muscle training of at least 3  
11 months' duration as first-line treatment to women with stress or mixed UI.  
12 **[2006]**  
13
- 14 E2.2 Pelvic floor muscle training programmes should comprise at least 8  
15 contractions performed 3 times per day. **[2006]**  
16
- 17 E2.3 Do not use perineometry or pelvic floor electromyography as  
18 biofeedback as a routine part of pelvic floor muscle training. **[2006]**  
19
- 20 E2.4 Continue an exercise programme if pelvic floor muscle training is  
21 beneficial. **[2006]**

## 22 Rationale and impact

23 To be finalised during consultation

## 24 The committee's discussion of the evidence

### 25 Interpreting the evidence

### 26 *The outcomes that matter most*

27 For this question, the critical outcomes were continence-specific health-related  
28 quality of life, change in continence status, and patient satisfaction and patient  
29 reported improvement. The important outcomes were identified as immediate post-  
30 operative or peri-operative adverse events, long-term complications (>12 months)  
31 and repeat surgery for either persistent urinary incontinence or pelvic organ prolapse,  
32 or mesh complications. In light of the context of the update, patients' quality of life  
33 and personal view of their progress were considered to be the most important  
34 outcomes. All outcomes were informed by RCT except for complications, where data  
35 was taken from a prospective observational study. The outcomes reported in the  
36 included studies covered most of the outcomes in the protocol. The main absence is  
37 medium- and long-term continence-specific health-related quality of life. The only  
38 score that was found for health-related quality of life only had data for up to three  
39 months.

40 Data comparing adverse events and complications for the two interventions were  
41 sparse with only bladder perforation as an adverse event and infection as a  
42 complication reported. The committee noted that risks of different interventions  
43 matter very much to women with UI and that information on this is informative to  
44 women in making decisions.

## 1 **The quality of the evidence**

2 Quality of evidence was assessed using GRADE. For evidence that was downgraded  
3 to low and very low, quality was affected by high risk of bias and high imprecision.  
4 These outcomes were continence-specific health-related quality of life, subjective  
5 and objective measures of change in continence status, patient satisfaction, adverse  
6 events, complications and repeat surgery.

7 In the case of change in continence status low participant numbers contributed to the  
8 imprecision. However, the committee noted that the proportions of women who had a  
9 positive change in continence status after pelvic floor muscle training reflected their  
10 experiences. The low event number contributed to the imprecision for the adverse  
11 events, complications and repeat surgery outcomes. The committee noted the lack of  
12 high-quality longer-term data comparing pelvic floor muscle training to surgery risks.  
13 High risk of bias was down to poor reporting of allocation concealment and blinding in  
14 older studies. The committee is aware of the difficulty in blinding when comparing  
15 surgical and non-surgical interventions. The committee agreed that even though  
16 incomplete blinding was unavoidable, and bias could affect subjective outcomes, this  
17 is comparable to clinical practice and therefore the domain is graded a low risk of  
18 bias.

19 The only outcome that was assessed as having high quality evidence was patient  
20 reported improvement at 2, 4, 6 and 12 months, that was documented in a well-  
21 designed RCT. At 18 months the data was downgraded to a moderate rating due to  
22 imprecision that arose from decreasing effectiveness of surgery in comparison to  
23 pelvic floor muscle training, leading to confidence intervals crossing the clinically  
24 important difference threshold. This informed the committee's decision to keep  
25 recommendations concerning pelvic floor muscle training as currently found in the  
26 guideline.

## 27 **Benefits and harms**

28 The committee agreed that overall the evidence is consistent with their clinical  
29 experience and the previous recommendations reflected this well. The committee  
30 discussed the one recent RCT was identified, which they agreed did produce  
31 moderate to high quality evidence for the first 18 months post-treatment. However,  
32 there was concern over the low subjective cure rate at 12 months in the  
33 physiotherapy only group. This was resolved after assessing that the number of  
34 people who elected to have surgery after pelvic floor muscle training was similar to  
35 the committee's expected subjective cure rate and the objective cure rate was as  
36 expected. This enhanced the committee's confidence in the applicability of the  
37 evidence in this RCT. The subjective and objective cure rates of the 3 other RCTs  
38 were agreed to be reflective of clinical practice but the small cohorts ( $n < 100$ ) limits  
39 the result's reliability.

40 The immediate and short-term effectiveness of surgery is superior to that of  
41 physiotherapy when concerning subjective and objective cure, and therefore fewer  
42 women will be cured initially with physiotherapy. However, the committee agreed that  
43 there are around 50% of women who would be cured by physiotherapy alone, hence  
44 why physiotherapy was agreed to be kept as a low-risk primary option before surgery  
45 is considered. In addition, the effectiveness of surgery in comparison to  
46 physiotherapy decreases in a step-wise manner over time within 18 months from  
47 treatment, based on medium and high quality evidence. By 18 months, the  
48 superiority of surgery is no longer clinically significant. The committee suggested it  
49 may be because women will continue their physiotherapy independently after their  
50 training sessions have finished and over time surgical insertions will begin to fail. This

1 will decrease the number of women who are cured with surgery but the net number  
2 of women cured by physiotherapy will be stable or increase.

3 The committee also discussed that the benefit of any physiotherapy relies on a  
4 minimum time that the exercise is carried out to have an effect. This is to allow  
5 muscles to strengthen over time. The evidence showed that usually the training was  
6 carried out over several months to have an effect and was then continued at home  
7 after the physiotherapy had finished. The committee therefore agreed to retain the  
8 2006 recommendation that pelvic floor muscle training should be trialled for at least 3  
9 months' duration before its effectiveness can be reliably assessed.

10 Higher uptake of physiotherapy as the first course of action will lead to fewer  
11 complications and adverse events, in the short- and medium-term. The committee  
12 agreed this was because physiotherapy-related complications may only include pain  
13 as a condition whereas surgical complications are more complex and have a greater  
14 impact on quality of life. The committee noted that the studies in the review do not  
15 record complications for physiotherapy but agree that some people will experience  
16 complications as a result of the training. These complications will not have the same  
17 severity as surgical complications and adverse events and therefore the possible  
18 physiotherapy complications were deemed preferable when considering the women's  
19 long-term quality of life. As the risks of certain types of surgery to treat incontinence  
20 have become more widely acknowledged and therefore healthcare professionals and  
21 the public may first seek alternative, more conservative therapies before considering  
22 more invasive options.

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

24 The committee acknowledged very limited non-UK economic evidence which showed  
25 that surgery was potentially cost-effective when compared with pelvic floor muscle  
26 training. Although, the incremental cost-effectiveness ratio expressed in UK pounds  
27 was above NICE lower cost-effectiveness threshold but below the upper threshold.  
28 Nevertheless, the committee explained that this study was only partially applicable to  
29 NICE decision making context and was characterised by potentially serious  
30 limitations. The committee discussed the effectiveness estimate associated with  
31 pelvic floor muscle training that was used in this study and noted that it was  
32 substantially lower than expected in the clinical practice in the UK. The committee  
33 also discussed the lack of adverse events with pelvic floor muscle training when  
34 compared with surgery.

35 The committee explained that it is difficult to define a 'standard' or 'typical' pelvic floor  
36 muscle training session and therefore costs will vary according to the actual practices  
37 employed. Nevertheless, generally pelvic floor muscle training will be undertaken by  
38 a physiotherapist in a hospital physiotherapy department. Women would  
39 approximately have six sessions with the physiotherapist. The unit cost of band 7,  
40 physiotherapist is approximately £53 per working hour (Curtis & Burns, 2017). The  
41 committee explained that on average women are expected to have 6 sessions each  
42 lasting approximately 50 minutes. Based on the above the unit cost of pelvic floor  
43 muscle training is expected to be approximately £400. The unit cost of the most  
44 common surgical procedure for SUI is £1,404 (retropubic mid-urethral sling, DHSC  
45 2018), which is substantially more compared with pelvic floor muscle training.

46 Surgical procedures may result in a number of complications including infection, pain,  
47 de novo urge incontinence and mesh erosion. Some of the above complications are  
48 very expensive to manage and may require long-term management. For example,  
49 the unit cost of mesh erosion is £1,548 (Minor Lower Genital Tract Procedures,  
50 DHSC 2018).

1 Overall, the committee were of a view that a stepped approach where pelvic floor  
2 muscle training is offered as initial treatment and surgery only in women where pelvic  
3 floor muscle training is ineffective may potentially result in substantial cost savings to  
4 the NHS given the lower pelvic floor muscle training intervention costs and also the  
5 averted costs associated with managing surgical complications.

## 6 Other considerations

7 The protocol had pre-specified subgroups that the committee agreed could have  
8 provided useful data to inform which treatments are most suitable for these groups.  
9 No separate studies nor separate reporting of outcomes for these different subgroups  
10 were found and therefore subgroup analysis could not be done. The committee  
11 agreed it would have been more informative if data were available to analyse  
12 protocol-specified subgroups separately. The committee believed that there are  
13 groups that will benefit more from one of physiotherapy or surgery than other groups,  
14 for example elderly women or women who have undergone multiple surgeries.  
15 However, there were no reliable data available to aid clinical judgement on the most  
16 appropriate choice of treatment for different subgroups. The committee therefore did  
17 not make specific recommendations for such subgroups of women. The committee  
18 raised that patient choice is an important factor in these subgroups and therefore  
19 data from studies and patient wishes should both be used to come to a decision on  
20 the course of treatment.

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# 1 Appendices

## 2 Appendix A – Review protocols

### 3 Review protocol for review question: What is the most effective surgical management of stress urinary incontinence, 4 including mesh and non-mesh procedures?

#### 5 Table 16: Review protocol for surgical management of women with SUI

Field (based on PRISMA-P)	Content
Review question	What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?
Type of review question	Intervention
Objective of the review	The objective of this review is to identify effective surgical treatment options for stress urinary incontinence in adult women, updating the review performed and the recommendations made in the previous guideline. The need to update this question has been highlighted by the reports of serious adverse events occurring in women who have received mesh surgery. This protocol details the pairwise analysis to be performed.
Eligibility criteria – population/disease/condition/issue/domain	The following participants will be included: Women (aged 18 and over) with stress urinary incontinence who have failed conservative treatment or declined conservative treatment; OR, women with mixed UI with confirmed stress predominance who have failed conservative treatment or declined conservative treatment Women who are naïve to treatment or having repeat surgery. Women with urodynamic stress incontinence (USI); concurrent intrinsic sphincter deficiency (ISD); concurrent overactive bladder (OAB); or concurrent POP (as indicated by the POP-Q system). Women in whom the SUI is caused by a neurological condition will be excluded.
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	<b>Surgical treatments</b> <ul style="list-style-type: none"> <li>• Suburethral slings (synthetic mesh) <ul style="list-style-type: none"> <li>○ Retropubic bottom-up (e.g. TVT, IVS)</li> <li>○ Retropubic top-down (e.g. SPARC)</li> <li>○ Transobturator inside-out (TVT-O)</li> </ul> </li> </ul>

Field (based on <u>PRISMA-P</u> )	Content
	<ul style="list-style-type: none"> <li>○ Transobturator outside-in (TOT)</li> <li>○ Single-incision mini-slings <ul style="list-style-type: none"> <li>- Non-adjustable (e.g. Contasure-Needleless, TVT-Secur, MiniArc, Ophira)</li> <li>- Adjustable (e.g. retropubic [Ajust], transobturator [TOA])</li> </ul> </li> <li>● Colposuspension (Burch, paravaginal fascial repair; MMK no longer relevant to UK practice so this will not be included) <ul style="list-style-type: none"> <li>○ Open abdominal retropubic suspension</li> <li>○ Laparoscopic retropubic suspension with sutures</li> </ul> </li> <li>● Biological slings (autologous [rectus fascia] materials, allografts, xenografts [e.g. porcine])</li> <li>● Para or transurethral injections (bulking agents) <ul style="list-style-type: none"> <li>○ Bulkamid (polyacrylamide hydrogel)</li> <li>○ Macroplastique (water soluble gel with silicone elastomer)</li> <li>○ Captive</li> <li>○ Collagen</li> </ul> </li> <li>● Artificial sphincters</li> </ul> <p>These surgical treatments will complement the following IPGs:</p> <ul style="list-style-type: none"> <li>● IPG138 – Intramural urethral bulking procedures for stress urinary incontinence in women</li> <li>● IPG154 – Insertion of biological slings for stress urinary incontinence in women</li> <li>● IPG566 – Single-incision short sling mesh insertion for stress urinary incontinence in women</li> <li>● IPG576 – Extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women</li> </ul>
Eligibility criteria – comparator(s)/control or reference (gold) standard	<p><b>Specified comparisons</b></p> <ul style="list-style-type: none"> <li>● Synthetic sling (mesh) versus colposuspension</li> <li>● Synthetic sling versus biological sling <ul style="list-style-type: none"> <li>○ Synthetic sling vs autologous rectus fascial sling</li> <li>○ Synthetic sling vs non-autologous biological sling</li> </ul> </li> <li>● Retropubic route (e.g. TVT) versus Transobturator route (e.g. TOT) (within synthetic mesh comparison)</li> </ul>

Field (based on <u>PRISMA-P</u> )	Content
	<ul style="list-style-type: none"> <li>• (Non-adjustable) Single-incision mini-sling versus other synthetic sling (e.g. TVT-Secur vs TOT)</li> <li>• Adjustable sling versus other synthetic sling (e.g. TOA vs TVT)</li> <li>• Laparoscopic versus open colposuspension</li> <li>• Colposuspension versus biological sling                             <ul style="list-style-type: none"> <li>○ Colposuspension vs autologous sling</li> <li>○ Colposuspension vs non-autologous biological sling</li> </ul> </li> <li>• Bulking agent versus other surgical technique</li> <li>• Artificial sphincter versus other surgical technique</li> </ul> <p>NOTE: interventions and implants not approved in the UK, or not used in clinical practice (e.g. MMK, laparoscopic colposuspension with mesh and staples) will not be included in this review. No NMA will be conducted as the NMA conducted by [REDACTED]</p>
Outcomes and prioritisation	<p><b>Critical</b></p> <ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life                             <ul style="list-style-type: none"> <li>○ ICIQ</li> <li>○ BFLUTS-SF</li> <li>○ i-QOL</li> <li>○ SUIQQ</li> <li>○ UISS</li> <li>○ SEAPI-QMM</li> <li>○ ISI</li> <li>○ KHQ</li> <li>○ E-PAQ</li> <li>○ Sexual function: PISQ-12</li> </ul> </li> <li>• Adverse events (immediate post-operative 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>• Complications                             <ul style="list-style-type: none"> <li>○ Pain</li> </ul> </li> </ul>

Field (based on <u>PRISMA-P</u> )	Content
	<ul style="list-style-type: none"> <li>○ Mesh erosion or extrusion (vaginal, bladder, urethra)</li> <li>○ Fistula</li> <li>○ Need for catheterisation (include voiding dysfunction, e.g. retention, slow stream, incomplete emptying)</li> <li>○ Infection (recurrent UTI, wound)</li> <li>○ De novo overactive bladder symptoms (clinically-established but possibly confirmed by urodynamics) <ul style="list-style-type: none"> <li>- Urge incontinence</li> <li>- Frequency</li> <li>- Urgency</li> <li>- Nocturia</li> </ul> </li> <li>○ Occurrence of POP</li> <li>○ Wound complications (hernia)</li> </ul> <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., <math>\leq 1</math> year);</li> <li>● Medium-term: complications occurring after 1 year, and up to 5 years (i.e., <math>&gt;1</math> to <math>\leq 5</math> years); and</li> <li>● Long-term: complications occurring after 5 years (i.e., <math>&gt; 5</math> years)</li> </ul> <p>Important outcomes</p> <ul style="list-style-type: none"> <li>● Change in continence status <ul style="list-style-type: none"> <li>○ Subjective report</li> <li>○ Objective cure rate</li> <li>○ Negative stress (cough) test</li> <li>○ Number of incontinence episodes per day</li> </ul> </li> <li>● Patient satisfaction, patient reported improvement <ul style="list-style-type: none"> <li>○ Patient global impression of improvement (PGII)</li> </ul> </li> <li>● Repeat surgery (for UI or POP, or mesh complications)</li> </ul>
Eligibility criteria – study design	For all outcomes except complications, systematic reviews of RCTs and RCTs will be considered. In the absence of full text published RCTs, conference abstracts will be considered. In the absence of RCTs, prospective and retrospective studies will be considered.

Field (based on PRISMA-P)	Content
	<p>For complications, the following types of study designs will be considered:            RCTs for short- and medium-term complications;            In the absence of RCT data for short- and medium-term complications, or for long-term complications, prospective, retrospective and cross-sectional studies with sample size limit of <math>\geq 50</math> participants will be considered.</p>
Other inclusion exclusion criteria	English language only.
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>• women who have no concurrent POP surgery (regardless of their POP-Q status)</li> <li>• women who have concurrent POP surgery</li> <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> <p>The following subgroup analyses will be considered in the presence of substantial heterogeneity:</p> <p><b>Type of UI</b></p> <ul style="list-style-type: none"> <li>• Pure stress</li> <li>• Mixed UI</li> </ul> <p><b>Surgical status</b></p> <ul style="list-style-type: none"> <li>• Repeat or recurrent surgery</li> <li>• Treatment naïve</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 $\geq 1000$ 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.

Field (based on <u>PRISMA-P</u> )	Content
	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): 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.
Identify if an update	This is an update of an area in the previous guideline CG171 Urinary incontinence <a href="https://www.nice.org.uk/guidance/cg171">https://www.nice.org.uk/guidance/cg171</a> . However, the review question is not identical. Recommendations from the previous guideline that may change on the basis of this review (and corresponding NMA) are: 1.10 Surgical approaches for SUI 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] 1.10.2 If conservative management for SUI has failed, offer: •synthetic mid-urethral tape (see recommendations 1.10.3–8), or •open colposuspension (see also recommendation 1.10.9), or •autologous rectus fascial sling (see also recommendation 1.10.10). [new 2013]  Synthetic tapes 1.10.3 When offering a synthetic mid-urethral tape procedure, surgeons should: •use procedures and devices for which there is current high quality evidence of efficacy and safety[10] •only use a device that they have been trained to use (see recommendations in section 1.11) •use a device manufactured from type 1 macroporous polypropylene tape •consider using a tape coloured for high visibility, for ease of insertion and revision. [new 2013] 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] 1.10.5 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. [new 2013] 1.10.6 Use 'top-down' retropubic tape approach only as part of a clinical trial. [new 2013]

Field (based on <u>PRISMA-P</u> )	Content
	<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>Colposuspension</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>Biological slings</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> <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: The National Guideline Alliance</p> <p><a href="https://www.nice.org.uk/guidance/indevelopment/gid-ng10035">https://www.nice.org.uk/guidance/indevelopment/gid-ng10035</a>.</p>

Field (based on PRISMA-P)	Content
Highlight if amendment to previous protocol	For details please see appendix B of the full guideline.
Search strategy – for one database	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 collection process – forms/duplicate	For details please see evidence tables in 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).
Methods for assessing bias at outcome/study level	<p>Standard study checklists were used to critically appraise individual studies. Appraisal of methodological quality will be conducted using the appropriate tool:</p> <ul style="list-style-type: none"> <li>• ROBIS (systematic reviews and meta-analyses),</li> <li>• Cochrane risk of bias tool (RCTs).</li> <li>• Cochrane ROBINS-I risk of bias tool (Non-randomised studies)</li> </ul> <p>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>. Outcomes will be downgraded if the randomisation and/or concealment methods are unclear or inadequate. Outcomes will also be downgraded if there is considerable missing data (if there is a dropout of more than 20%, or if there is a difference of &gt;20% between groups. Heterogeneity will be assessed using the <math>i^2</math> statistic, outcomes will be downgraded once if <math>i^2 \geq 50\%</math>, twice if <math>i^2 \geq 80\%</math>.</p> <p>GRADE cannot be used for accurate assessment of bias for case series data and will not be used. Determining the quality of case series will include an assessment of bias, consecutive and comparative nature of series.</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. 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

Field (based on PRISMA-P)	Content
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 please see the methods chapter of the full guideline.
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.

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2 **Review protocol for review question: What is the effectiveness of surgical management of stress urinary incontinence**  
3 **(including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

4 **Table 17: Review protocol for surgical management of women with SUI compared to pelvic floor muscle training**

Field (based on PRISMA-P)	Content
Review question	What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures) compared to pelvic floor muscle training?
Type of review question	Intervention
Objective of the review	The objective of this review is to establish the effectiveness of surgical options for the management of stress urinary incontinence, compared to pelvic floor muscle training

Field (based on <b>PRISMA-P</b> )	Content
Eligibility criteria – population/disease/condition/issue/domain	Women (aged 18 and over) with stress urinary incontinence or mixed UI with stress predominance Women who are naïve to treatment or who have undergone treatment repeatedly.
Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	<p><b>Surgical treatments</b></p> <ul style="list-style-type: none"> <li>• Suburethral slings (synthetic mesh) <ul style="list-style-type: none"> <li>○ Retropubic bottom-up (e.g. TVT, IVS-02)</li> <li>○ Retropubic top-down (e.g. SPARC)</li> <li>○ Transobturator outside-out (e.g. TVT-O)</li> <li>○ Transobturator outside-in (e.g. TOT)</li> <li>○ Single-incision or mini-sling (e.g. Contasure-Needleless, TVT-Secur, MiniArc, Ophira)</li> <li>○ Adjustable slings (e.g. Ajust) <ul style="list-style-type: none"> <li>- Retropubic</li> <li>- Transobturator (e.g. TOA)</li> </ul> </li> </ul> </li> <li>• Colposuspension <ul style="list-style-type: none"> <li>○ Open abdominal retropubic colposuspension with sutures</li> <li>○ Laparoscopic retropubic colposuspension with sutures</li> </ul> </li> <li>• Biological slings <ul style="list-style-type: none"> <li>○ Autologous rectus fascial slings</li> <li>○ Non-autologous biological slings (allografts, xenografts, e.g. porcine dermis)</li> </ul> </li> <li>• Para or transurethral injections (bulking agents) <ul style="list-style-type: none"> <li>○ Bulkamid (polyacrylamide hydrogel)</li> <li>○ Macroplastique (water soluble gel with silicone elastomer)</li> <li>○ Captive</li> <li>○ Collagen</li> </ul> </li> <li>• Artificial sphincters</li> </ul>
Eligibility criteria – comparator(s)/control or reference (gold) standard	Any type of surgery listed above compared to pelvic floor muscle training.
Outcomes and prioritisation	<p><b>Critical</b></p> <ul style="list-style-type: none"> <li>• Continence-specific health-related quality of life</li> </ul>

Field (based on <u>PRISMA-P</u> )	Content
	<ul style="list-style-type: none"> <li>○ ICIQ</li> <li>○ BFLUTS-SF</li> <li>○ i-QOL</li> <li>○ SUIQQ</li> <li>○ UISS</li> <li>○ SEAPI-QMM</li> <li>○ ISI, KHQ</li> <li>○ E-PAQ</li> <li>○ Sexual function: PISQ-12</li> <li>● Change in continence status <ul style="list-style-type: none"> <li>○ Subjective report</li> <li>○ Objective cure rate</li> <li>○ Negative stress (cough) test</li> <li>○ Number of incontinence episodes per day</li> </ul> </li> <li>● Patient satisfaction/patient reported improvement <ul style="list-style-type: none"> <li>○ Patient Global Impression of Improvement (PGII)</li> <li>○ Number of women who are satisfied</li> </ul> </li> </ul> <p><b>Important</b></p> <ul style="list-style-type: none"> <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>● 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> </ul> </li> </ul>

Field (based on <u>PRISMA-P</u> )	Content
	<ul style="list-style-type: none"> <li>○ De novo overactive bladder symptoms</li> <li>○ Occurrence of POP</li> <li>○ Wound complications (hernia)</li> <li>● Repeat surgery (for UI or POP, or mesh complications)</li> </ul>
Eligibility criteria – study design	<p>Systematic reviews of RCTs</p> <p>RCTs</p> <p>In absence of full text published RCTs, conference abstracts will be considered.</p> <p>Prospective observational studies for evaluating long-term complications (&gt;12 months).</p>
Other inclusion exclusion criteria	<p>RCTs with &lt;10 participants will not be included.</p> <p>English language only.</p>
Proposed sensitivity/sub-group analysis, or meta-regression	<p>Population Subgroups:</p> <p><b>Type of UI</b></p> <ul style="list-style-type: none"> <li>● Pure stress</li> <li>● Mixed UI</li> </ul> <p><b>Surgical status</b></p> <ul style="list-style-type: none"> <li>● Repeat or recurrent surgery</li> <li>● Treatment naïve</li> <li>● Concomitant POP surgery</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	<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</p>

Field (based on <u>PRISMA-P</u> )	Content
	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 (AMSTAR – 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. For details please see appendix B.
Identify if an update	This is a new review question.
Author contacts	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> .
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	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	For details please see section 6.4 of <a href="#">Developing NICE guidelines: the manual 2014</a> .

Field (based on PRISMA-P)	Content
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	For details please see section 6.2 of <a href="#">Developing NICE guidelines: the manual 2014</a> .
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 ( <a href="https://www.nice.org.uk/guidance/cg171/history">https://www.nice.org.uk/guidance/cg171/history</a> ) developed the evidence review. The committee was convened by the National Guideline Alliance and chaired by 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 evidence review 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 Royal College of Obstetrics and Gynaecology.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by Royal College of Obstetrics and Gynaecology.
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.

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## Appendix B – Literature search strategies

### Literature search strategies for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?

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

Last searched on Embase Classic+Embase 1947 to 2018 June 01, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present.

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

#	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	or/1-6
8	Suburethral Slings/ use ppez
9	Surgical Mesh/ use ppez
10	Urinary Sphincter, Artificial/ use ppez
11	exp suburethral sling/ use emczd
12	exp surgical mesh/ use emczd
13	colposuspension/ use emczd
14	bladder sphincter prosthesis/ use emczd
15	retropubic\$.ti,ab.
16	"bottom up".ti,ab.
17	"top down".ti,ab.
18	(tension\$ adj3 (tape\$ or vagina\$)).ti,ab.
19	TVT\$.ti,ab.
20	((transvagin\$ or trans-vagin\$) adj3 tape\$).ti,ab.
21	(transobturator\$ or trans-obturator\$).ti,ab.
22	"outside in".ti,ab.
23	"inside out".ti,ab.
24	(single adj incision).ti,ab.
25	(minisling\$ or mini-sling\$).ti,ab.
26	((sling\$ or tape\$ or hammock\$) adj3 (procedure\$ or operat\$ or surg\$)).ti,ab.
27	((fascia\$ or subfascia\$ or sub-fascia\$ or autologous\$ or adjust\$) adj3 (sling\$ or tape\$ or hammock\$)).ti,ab.
28	((midurethra\$ or mid-urethra\$ or suburethra\$ or sub-urethra\$ or synthetic\$) adj3 (sling\$ or tape\$ or hammock\$)).ti,ab.
29	MUS.ti,ab.
30	(colposuspen\$ or colpo-suspen\$).ti,ab.
31	((retro-pubi\$ or retropubi\$ or abdomin\$ or open or laparoscopic\$) adj3 suspension\$).ti,ab.
32	(miniarc or monarc or SPARC).ti,ab.
33	((artificial or prosthesis\$) adj3 sphincter\$).ti,ab.
34	((transurethra\$ or trans-urethra\$ or paraurethra\$ or para-urethra\$ or periurethra\$ or peri-urethra\$) adj3 inject\$).ti,ab.
35	(bulk\$ adj3 agent\$).ti,ab.
36	or/8-35
37	7 and 36
38	MMK.ti,ab.
39	(Marshall\$ adj Marchett\$ adj Krantz\$).ti,ab.
40	(anterior adj3 repair).ti,ab.
41	38 or 39 or 40
42	7 and 41
43	37 or 42
44	(controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt. or drug therapy.fs. or (groups or placebo or randomi#ed or randomly or trial).ab.
45	crossover procedure/ or double blind procedure/ or randomized controlled trial/ or single blind procedure/ or (assign* or allocat* or crossover* or cross over* or ((doub* or singl*) adj blind*) or factorial* or placebo* or random* or volunteer*).ti,ab.
46	meta-analysis/
47	meta-analysis as topic/
48	systematic review/

#	Searches
49	meta-analysis/
50	(meta analy* or metanaly* or metaanaly*).ti,ab.
51	((systematic or evidence) adj2 (review* or overview*)).ti,ab.
52	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
53	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
54	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
55	(search* adj4 literature).ab.
56	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
57	cochrane.jw.
58	((pool* or combined) adj2 (data or trials or studies or results)).ab.
59	letter/
60	editorial/
61	news/
62	exp historical article/
63	Anecdotes as Topic/
64	comment/
65	case report/
66	(letter or comment*).ti.
67	59 or 60 or 61 or 62 or 63 or 64 or 65 or 66
68	randomized controlled trial/ or random*.ti,ab.
69	67 not 68
70	animals/ not humans/
71	exp Animals, Laboratory/
72	exp Animal Experimentation/
73	exp Models, Animal/
74	exp Rodentia/
75	(rat or rats or mouse or mice).ti.
76	69 or 70 or 71 or 72 or 73 or 74 or 75
77	letter.pt. or letter/
78	note.pt.
79	editorial.pt.
80	case report/ or case study/
81	(letter or comment*).ti.
82	77 or 78 or 79 or 80 or 81
83	randomized controlled trial/ or random*.ti,ab.
84	82 not 83
85	animal/ not human/
86	nonhuman/
87	exp Animal Experiment/
88	exp Experimental Animal/
89	animal model/
90	exp Rodent/
91	(rat or rats or mouse or mice).ti.
92	84 or 85 or 86 or 87 or 88 or 89 or 90 or 91
93	76 use ppez
94	92 use emczd
95	93 or 94
96	44 use ppez
97	45 use emczd
98	96 or 97
99	or/46-47,50,52-57 use ppez
100	or/48-51,53-58 use emczd
101	99 or 100
102	43 and 95
103	43 not 102
104	98 or 101
105	103 and 104
106	limit 105 to english language
107	remove duplicates from 106 [RCT/SR data]
108	limit 103 to english language
109	remove duplicates from 108 [non-RCT data]

**Database: Cochrane Library via Wiley Online**

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

#	Searches
#1	MeSH descriptor: [Urinary Incontinence, Stress] this term only
#2	(urine near/2 (loss or leak*)):ti,ab,kw (Word variations have been searched)
#3	((stress* or mix* or effort*) near/5 incontinen*):ti,ab,kw (Word variations have been searched)
#4	SUI:ti,ab,kw (Word variations have been searched)
#5	#1 or #2 or #3 or #4
#6	MeSH descriptor: [Suburethral Slings] explode all trees
#7	MeSH descriptor: [Surgical Mesh] this term only
#8	MeSH descriptor: [Urinary Sphincter, Artificial] this term only
#9	retropubic*:ti,ab,kw (Word variations have been searched)
#10	"bottom up":ti,ab,kw (Word variations have been searched)
#11	"top down":ti,ab,kw (Word variations have been searched)
#12	(tension* near/3 (tape* or vagina*)):ti,ab,kw (Word variations have been searched)
#13	TVT*:ti,ab,kw (Word variations have been searched)
#14	((transvagin* or trans-vagin*) near/3 tape*):ti,ab,kw (Word variations have been searched)
#15	(transobturator* or trans-obturator*):ti,ab,kw (Word variations have been searched)
#16	"outside in":ti,ab,kw (Word variations have been searched)
#17	"inside out":ti,ab,kw (Word variations have been searched)
#18	(single next incision):ti,ab,kw (Word variations have been searched)
#19	(minisling* or mini-sling*):ti,ab,kw (Word variations have been searched)
#20	((sling* or tape* or hammock*) near/3 (procedure* or operat* or surg*)):ti,ab,kw (Word variations have been searched)
#21	((fascia\$ or subfascia* or sub-fascia* or autologous* or adjust*) near/3 (sling* or tape* or hammock*)):ti,ab,kw (Word variations have been searched)
#22	((midurethra* or mid-urethra* or suburethra* or sub-urethra* or synthetic*) near/3 (sling* or tape* or hammock*)):ti,ab,kw (Word variations have been searched)
#23	MUS:ti,ab,kw (Word variations have been searched)
#24	(colposuspen* or colpo-suspen*):ti,ab,kw (Word variations have been searched)
#25	((retro-pubi* or retropubi* or abdomin* or open or laparoscopic*) near/3 suspension*):ti,ab,kw (Word variations have been searched)
#26	(miniarc or monarc or SPARC):ti,ab,kw (Word variations have been searched)
#27	((artificial or prosthes*) near/3 sphincter*):ti,ab,kw (Word variations have been searched)
#28	((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)
#29	(bulk* near/3 agent*):ti,ab,kw (Word variations have been searched)
#30	#6 or #7 or #8 or #9 or #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 or #29
#31	#5 and #30
#32	MMK:ti,ab,kw (Word variations have been searched)
#33	(Marshall* next Marchett* next Krantz*):ti,ab,kw (Word variations have been searched)
#34	(anterior near/3 repair):ti,ab,kw (Word variations have been searched)
#35	#32 or #33 or #34
#36	#5 and #35
#37	#31 or #36

## Literature search strategies for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?

### Database: Medline & Embase (Multifile)

Last searched on Embase Classic+Embase 1947 to 2018 January 05, 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: 8<sup>th</sup> January 2018.

#	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	or/1-6
8	Suburethral Slings/ use ppez
9	Surgical Mesh/ use ppez

#	Searches
10	Urinary Sphincter, Artificial/ use ppez
11	exp suburethral sling/ use emczd
12	exp surgical mesh/ use emczd
13	colposuspension/ use emczd
14	bladder sphincter prosthesis/ use emczd
15	retropubic\$.ti,ab.
16	"bottom up".ti,ab.
17	"top down".ti,ab.
18	(tension\$ adj3 (tape\$ or vagina\$)).ti,ab.
19	TVT\$.ti,ab.
20	((transvagin\$ or trans-vagin\$) adj3 tape\$).ti,ab.
21	(transobturator\$ or trans-obturator\$).ti,ab.
22	"outside in".ti,ab.
23	"inside out".ti,ab.
24	(single adj incision).ti,ab.
25	(minisling\$ or mini-sling\$).ti,ab.
26	((sling\$ or tape\$ or hammock\$) adj3 (procedure\$ or operat\$ or surg\$)).ti,ab.
27	((fascia\$ or subfascia\$ or sub-fascia\$ or autologous\$ or adjust\$) adj3 (sling\$ or tape\$ or hammock\$)).ti,ab.
28	((midurethra\$ or mid-urethra\$ or suburethra\$ or sub-urethra\$ or synthetic\$) adj3 (sling\$ or tape\$ or hammock\$)).ti,ab.
29	MUS.ti,ab.
30	(colposuspen\$ or colpo-suspen\$).ti,ab.
31	((retro-pubi\$ or retropubi\$ or abdomin\$ or open or laparoscopic\$) adj3 suspension\$).ti,ab.
32	(miniarc or monarc or SPARC).ti,ab.
33	((artificial or prosthes\$) adj3 sphincter\$).ti,ab.
34	((transurethra\$ or trans-urethra\$ or paraurethra\$ or para-urethra\$ or periurethra\$ or peri-urethra\$) adj3 inject\$).ti,ab.
35	(bulk\$ adj3 agent\$).ti,ab.
36	MMK.ti,ab.
37	(Marshall\$ adj Marchett\$ adj Krantz\$).ti,ab.
38	(anterior adj3 repair).ti,ab.
39	or/8-38
40	7 and 39
41	Urinary Incontinence, Stress/su use ppez
42	Stress Incontinence/su use emczd
43	40 or 41 or 42
44	surg\$.m_titl.
45	7 and 44
46	exp Exercise Therapy/ use ppez
47	exp Physical Therapy Modalities/ use ppez
48	exp exercise/ use emczd
49	pelvic floor muscle training/ use emczd
50	kinesiotherapy/ use emczd
51	muscle training/ use emczd
52	((pelvic floor or PFM) adj5 (training or exercise\$ or physiotherap\$ or physical or therap\$ or rehabilitat\$)).tw.
53	(PFPT or PFME).tw.
54	Resistance Training/ use ppez
55	resistance training/ use emczd
56	physiotherapy/ use emczd
57	physiotherap\$.tw.
58	((strength\$ or resistan\$) adj3 (training or exercise\$ or physiotherap\$)).tw.
59	((pelvic floor or PFM or pelvic muscle\$) adj3 strengthen\$).tw.
60	or/46-59
61	43 and 60
62	45 and 60
63	61 or 62
64	remove duplicates from 63
65	limit 64 to english language
66	letter/
67	editorial/
68	news/
69	exp historical article/
70	Anecdotes as Topic/
71	comment/
72	case report/
73	(letter or comment*).ti.
74	66 or 67 or 68 or 69 or 70 or 71 or 72 or 73
75	randomized controlled trial/ or random*.ti,ab.
76	74 not 75

#	Searches
77	animals/ not humans/
78	exp Animals, Laboratory/
79	exp Animal Experimentation/
80	exp Models, Animal/
81	exp Rodentia/
82	(rat or rats or mouse or mice).ti.
83	76 or 77 or 78 or 79 or 80 or 81 or 82
84	letter.pt. or letter/
85	note.pt.
86	editorial.pt.
87	case report/ or case study/
88	(letter or comment*).ti.
89	84 or 85 or 86 or 87 or 88
90	randomized controlled trial/ or random*.ti,ab.
91	89 not 90
92	animal/ not human/
93	nonhuman/
94	exp Animal Experiment/
95	exp Experimental Animal/
96	animal model/
97	exp Rodent/
98	(rat or rats or mouse or mice).ti.
99	91 or 92 or 93 or 94 or 95 or 96 or 97 or 98
100	83 use ppez
101	99 use emczd
102	100 or 101
103	65 and 102
104	65 not 103

**Database: Cochrane Library via Wiley Online**

Date of last search: 8<sup>th</sup> January 2018.

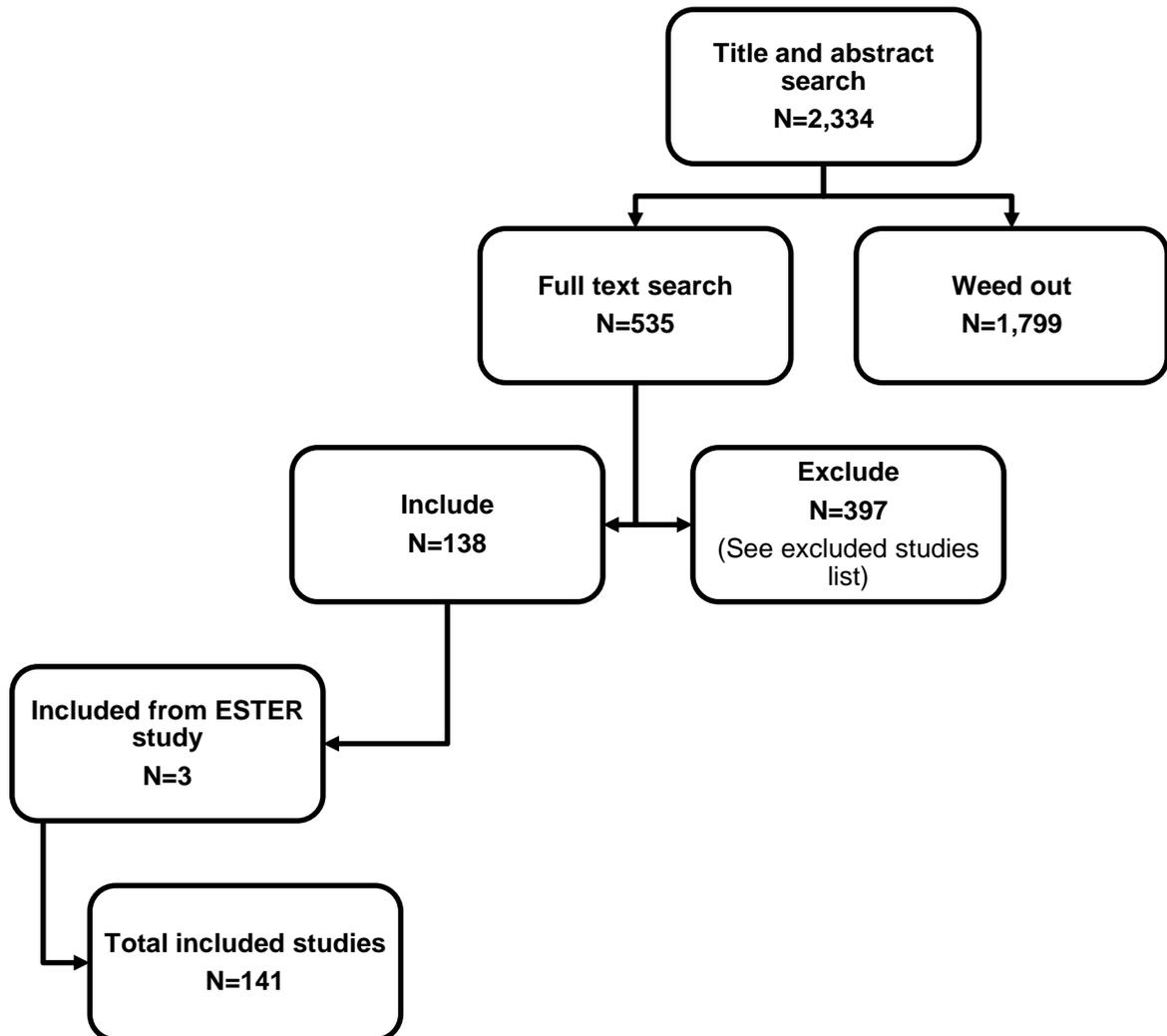
#	Searches
#1	MeSH descriptor: [Urinary Incontinence, Stress] this term only
#2	(urine near/2 (loss or leak*)):ti,ab,kw (Word variations have been searched)
#3	((stress* or mix* or effort*) near/5 incontinen*):ti,ab,kw (Word variations have been searched)
#4	SUI:ti,ab,kw (Word variations have been searched)
#5	#1 or #2 or #3 or #4
#6	MeSH descriptor: [Suburethral Slings] explode all trees
#7	MeSH descriptor: [Surgical Mesh] this term only
#8	MeSH descriptor: [Urinary Sphincter, Artificial] this term only
#9	retropubic*:ti,ab,kw (Word variations have been searched)
#10	"bottom up":ti,ab,kw (Word variations have been searched)
#11	"top down":ti,ab,kw (Word variations have been searched)
#12	(tension* near/3 (tape* or vagina*)):ti,ab,kw (Word variations have been searched)
#13	TVT*:ti,ab,kw (Word variations have been searched)
#14	((transvagin* or trans-vagin*) near/3 tape*):ti,ab,kw (Word variations have been searched)
#15	(transobturator* or trans-obturator*):ti,ab,kw (Word variations have been searched)
#16	"outside in":ti,ab,kw (Word variations have been searched)
#17	"inside out":ti,ab,kw (Word variations have been searched)
#18	(single next incision):ti,ab,kw (Word variations have been searched)
#19	(minisling* or mini-sling*):ti,ab,kw (Word variations have been searched)
#20	((sling* or tape* or hammock*) near/3 (procedure* or operat* or surg*)):ti,ab,kw (Word variations have been searched)
#21	((fascia\$ or subfascia* or sub-fascia* or autologous* or adjust*) near/3 (sling* or tape* or hammock*)):ti,ab,kw (Word variations have been searched)
#22	((midurethra* or mid-urethra* or suburethra* or sub-urethra* or synthetic*) near/3 (sling* or tape* or hammock*)):ti,ab,kw (Word variations have been searched)
#23	MUS:ti,ab,kw (Word variations have been searched)
#24	(colposuspen* or colpo-suspen*):ti,ab,kw (Word variations have been searched)
#25	((retro-pubi* or retropubi* or abdomin* or open or laparoscopic*) near/3 suspension*):ti,ab,kw (Word variations have been searched)
#26	(miniarc or monarc or SPARC):ti,ab,kw (Word variations have been searched)
#27	((artificial or prosthes*) near/3 sphincter*):ti,ab,kw (Word variations have been searched)
#28	((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)
#29	(bulk* near/3 agent*):ti,ab,kw (Word variations have been searched)

#	Searches
#30	MMK:ti,ab,kw (Word variations have been searched)
#31	(Marshall* next Marchett* next Krantz*):ti,ab,kw (Word variations have been searched)
#32	(anterior near/3 repair):ti,ab,kw (Word variations have been searched)
#33	#6 or #7 or #8 or #9 or #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 or #29 or #30 or #31 or #32
#34	MeSH descriptor: [Urinary Incontinence, Stress] this term only and with qualifier(s): [Surgery - SU]
#35	MeSH descriptor: [Exercise Therapy] explode all trees
#36	MeSH descriptor: [Physical Therapy Modalities] explode all trees
#37	((pelvic floor or PFM) near/5 (training or exercise* or physiotherap* or physical or therap* or rehabilitat*)):ti,ab,kw (Word variations have been searched)
#38	(PFPT or PFME):ti,ab,kw (Word variations have been searched)
#39	MeSH descriptor: [Resistance Training] this term only
#40	physiotherap*:ti,ab,kw (Word variations have been searched)
#41	((strength* or resistan*) near/3 (training or exercise* or physiotherap*)):ti,ab,kw (Word variations have been searched)
#42	((pelvic floor or PFM or pelvic muscle*) near/3 strengthen*):ti,ab,kw (Word variations have been searched)
#43	#35 or #36 or #37 or #38 or #39 or #40 or #41 or #42
#44	#5 and #33 and #43
#45	#34 and #43
#46	surg*:ti,ab,kw (Word variations have been searched)
#47	#5 and #46 and #43
#48	#44 or #45 or #47

## Appendix C – Clinical evidence study selection

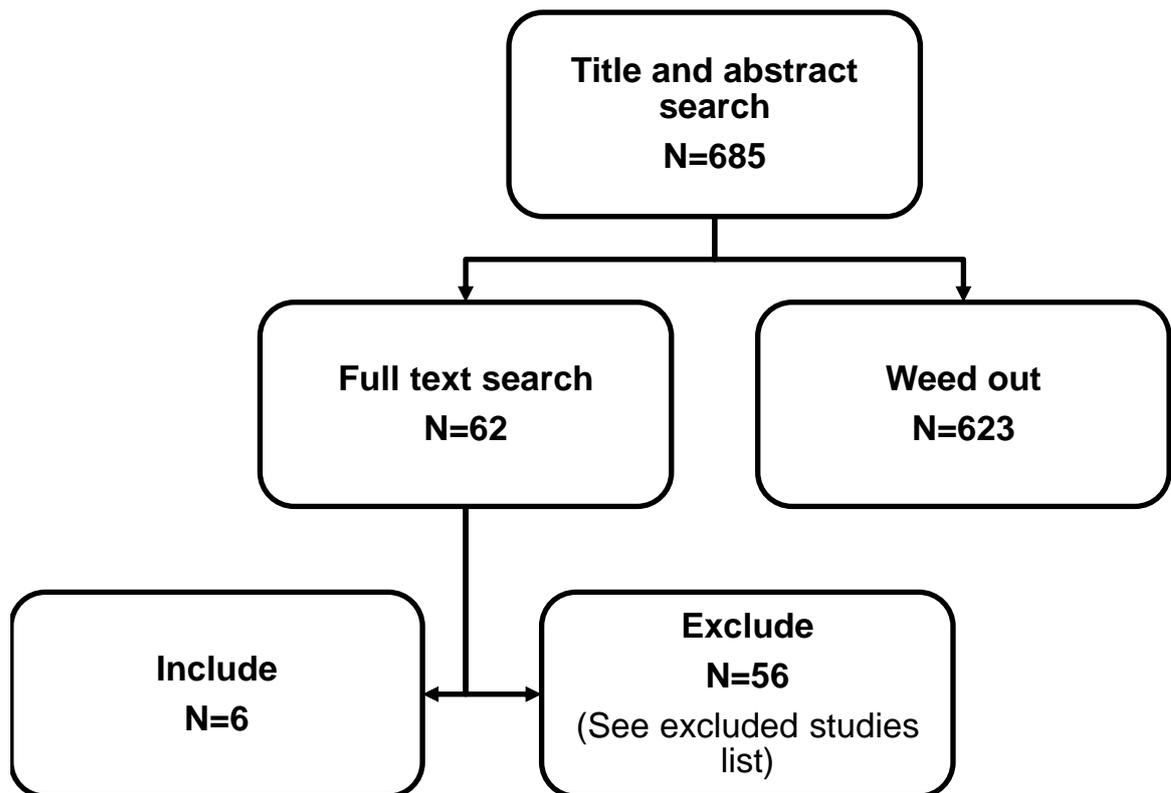
**Clinical evidence study selection for review question: what is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?**

**Figure 1: PRISMA flow chart for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?**



**Clinical evidence study selection for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

**Figure 2: PRISMA flow chart for surgery versus pelvic floor muscle training for stress urinary incontinence**



## Appendix D – Clinical evidence tables

**Evidence tables for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?**

**Table 18: Evidence tables for randomised controlled trials**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Abdel-Fattah,M., Barrington,J.W., Arunkalaivanan, A.S., Pelvicol pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study, European Urology, 46, 629-635, 2004 Ref Id 128378</p>	<p>Sample size N=142 randomised Intervention, n=68 Control, n=74</p> <p>Characteristics See entry for Arunkalaivanan et al. 2003</p> <p>Inclusion criteria See entry for Arunkalaivanan et al. 2003</p> <p>Exclusion criteria See entry for Arunkalaivanan et al. 2003</p>	<p>Interventions Intervention: Synthetic sling Control: Non- autologous biological sling</p>	<p>Details See entry for Arunkalaivanan et al. 2003</p>	<p>Results See entry for Arunkalaivanan et al. 2003</p>	<p>Limitations See entry for Arunkalaivanan et al. 2003</p> <p>Other information Original study reported in Arunkalaivanan et al. 2003</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out UK</p> <p>Study type RCT</p> <p>Aim of the study To present three-year follow up data of TVT compared to Pelvicol sling in women with pure urodynamic stress incontinence</p> <p>Study dates Not reported, 12 month duration</p> <p>Source of funding None reported</p>					
<p>Full citation Abdelwahab,O., Shedid,I., Al-</p>	<p>Sample size N=60 randomised TVT-Secur: n=30</p>	<p>Interventions TVT-Secur TVT</p>	<p>Details Follow up of at least 9 months. TVT-Secur</p>	<p>Results Cure* at 6 months - n (%)</p>	<p>Limitations</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Adl,A.M., Tension-free vaginal tape versus secure tension-free vaginal tape in treatment of female stress urinary incontinence, Current Urology, 4, 93-98, 2010 Ref Id 135793 Country/ies where the study was carried out Egypt Study type RCT Aim of the study To compare outcomes of TVT and TVT-Secur in women with genuine SUI Study dates</p>	<p>TVT: n=30 Characteristics Age (years) - mean <math>\pm</math>SD TVT-Secur: 40.2 (11) TVT: 39.2 (9) BMI - mean <math>\pm</math>SD TVT-Secur: 22.1 (3.3) TVT: 25.6 (2.1) Parity - mean <math>\pm</math>SD TVT-Secur: 2.3 (2.4) TVT: 2.1 (1.2) Postmenopausal - n (%) TVT-Secur: 3 (10) TVT: 2 (7) Inclusion criteria Women with clinically- and urodynamically-proven SUI Exclusion criteria Women with detrusor overactivity; low bladder volume (&lt;200 ml) &gt;grade 2 cystocele;</p>		<p>TVT-Secur procedure using U-shaped technique. TVT Procedure as described by Ulmsten 1995.</p>	<p>TVT-Secur: 28 (93.4) TVT: 26 (90.1) Improvement** at 6 months - n (%) TVT-Secur: 1 (3.3) TVT: 2 (6.6) Success rate (cure + improvement) - n (%) TVT-Secur: 29 (96.7) TVT: 28 (93.3) Adverse events - bladder injury - n (%) TVT-Secur: 0 TVT: 2 (6.7) Complications at 9-months - n (%) Pain (dyspareunia) TVT-Secur: 3 (10) TVT: 1 (3.3) Need for catheterisation TVT-Secur: 3 (10) TVT: 2 (6.7) De novo urgency TVT-Secur: 4 (13.3) TVT: 2 (6.7) Infection TVT-Secur: 8 (26.7) TVT: 6 (20.0)</p>	<p>Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias) Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Unclear, not reported  Source of funding Not reported	Type 0 SUI (Blavias and Olsson classification 1988) recurrent SUI			*defined as self-reported completely dry **defined as wetting but less than before surgery	
Full citation Aigmuller, T., Tammaa, A., Tamussino, K., Hanzal, E., Umek, W., Kolle, D., Kropshofer, S., Bjelic-Radusic, V., Haas, J., Giuliani, A., Lang, P. F. J., Preyer, O., Peschers, U., Jundt, K., Ralph, G., Dungl, A., Riss, P. A., Retropubic vs. transobturator tension-free vaginal tape for female stress urinary incontinence: 3-Month results of	Sample size N=569 randomised Retropubic tension-free vaginal tape (TVT): n=285 treated Transobturator tape (TVT-O): n=269 treated  Characteristics Age (years) - mean ±SD TVT: 59.7 (11.3) TVT-O: 58.6 (10.7) BMI - mean ±SD TVT: 27.7 (5.3) TVT-O: 28.5 (4.9) Parity - mean ±SD TVT: 2.2 (1.2) TVT-O: 2.2 (1.3)  Inclusion criteria	Interventions TVT TVT-O	Details ClinicalTrials.gov, NCT00441454. All participating surgeons experienced with TVT and performed 10 transobturator procedures. Mode of anaesthetic and postoperative analgesia not stipulated. Retropubic sling (TVT) Gynecare TVT used, procedure according to Ulmsten et al. 1996. Cystoscopy performed in all cases. Transobturator sling (TVT-O) Gynecare TVT-O used, procedure according to de Leval et al. 2003	Results Note: 5-year follow up data from Tammaa et al. 2017. Objective cure at 3-month FU (negative cough stress test with stable cystometry to 300 ml) - n (%) TVT: 215 (87.0) TVT-O: 196 (84.1) Objective cure at 5-year FU - n (%) TVT: 115 (83.3) TVT-O: 105 (75.5) Subjective cure at 3-months FU (no self-reported pad use) - n (%) TVT: 157 (64.0) TVT-O: 137 (59.0) Subjective cure at 5-year FU	Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Low risk (central allocation) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: High risk (assessors not blinded to group assignment) Incomplete outcome data: Unclear/High risk (13% dropout in each group at 3-mo follow up for similar reasons; 44% and 37% dropout rate for similar reasons in TVT and TVT-

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>a randomized controlled trial, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 1023-1030, 2014</p> <p>Ref Id 669610</p> <p>Country/ies where the study was carried out Austria</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare objective and subjective outcomes of TVT with TVT-O in women with SUI</p> <p>Study dates 01/2005 to 07/2007</p>	<p>Women with planned primary surgery for urodynamically-proven SUI (positive cough stress test with 300 ml full bladder)</p> <p>no planned concomitant prolapse surgery or hysterectomy</p> <p>willingness to participate in follow up</p> <p>Exclusion criteria Women with detrusor overactivity or a predominant complaint of overactive bladder planned concomitant prolapse or other major surgery previous incontinence surgery other than colporrhaphy residual urine <math>\geq</math>100 ml neurologic disease allergy to local anaesthetic agents</p>			<p>TVT: 81 (59.6)</p> <p>TVT-O: 88 (66.2)</p> <p>Improvement at 3-mo FU (Response of 'very much' or 'much' better on PGI-I) - n (%)</p> <p>TVT: 123 (43.1)</p> <p>TVT-O: 107 (39.8)</p> <p>PGI-S at 3 months - mean <math>\pm</math>SD</p> <p>TVT: 1.48 (0.79)</p> <p>TVT-O: 1.40 (0.76)</p> <p>PGI-S at 5 years - mean <math>\pm</math>SD</p> <p>TVT: 1.5 (0.7)</p> <p>TVT-O: 1.6 (0.8)</p> <p>Adverse events - bladder injury - n (%)</p> <p>TVT: 11 (3.9)</p> <p>TVT-O: 0</p> <p>Adverse events - severe bleeding requiring transfusion - n (%)</p> <p>TVT: 0</p> <p>TVT-O: 0</p> <p>Repeat surgery for SUI at 3-months - n (%)</p> <p>TVT: 0</p> <p>TVT-O: 0</p>	<p>O groups, respectively, at 5-year follow up, sufficient to induce clinically relevant bias in effect estimate)</p> <p>Selective reporting: Low risk (protocol available, all outcomes reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information 5 year follow up data reported in Tammaa et al. 2017.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Funded by Austrian Urogynecology Working Group	coagulation disorders or other contraindications for surgery			<p>Repeat surgery for SUI between 3-mo and 5-years - n (%) TVT: 1 (0.6) TVT-O: 1 (0.6)</p> <p>Repeat surgery for POP at 3-months - n (%) TVT: 0 TVT-O: 0</p> <p>Repeat surgery for mesh complications at 3-months FU - n (%) TVT: 3 (1.0) TVT-O: 1 (0.4)</p> <p>Repeat surgery for mesh complications between 3-mo and 5-year FU - n (%) TVT: 4 (2.5) TVT-O: 3 (1.8)</p> <p>KHQ at 3 months FU (TVT, n=247; TVT-O, n=233) - mean <math>\pm</math>SD General: TVT: 25.93 (18.47); TVT-O: 25.76 (18.37) Incontinence: TVT: 28.70 (36.02); TVT-O: 21.43 (31.84)</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Role limitations: TVT: 18.14 (28.83); TVT-O: 12.28 (21.64) Physical limitations: TVT: 19.00 (29.97); TVT-O: 12.98 (23.72) Social limitations: TVT: 7.86 (18.27); TVT-O: 4.70 (13.85) Personal relationships: TVT: 11.24 (26.90); TVT-O: 5.88 (18.75) Emotions: TVT: 15.63 (25.89); TVT-O: 9.46 (20.81) Sleep/energy: TVT: 12.62 (18.74); TVT-O: 11.41 (15.42) Severity: TVT: 43.88 (29.65); TVT-O: 39.02 (27.35) OAB: TVT: 65.88 (35.03); TVT-O: 70.96 (34.65) SUI: TVT: 87.50 (29.23); TVT-O: 90.13 (24.52) Intercourse: TVT: 100.00 (0.00); TVT-O: 99.34 (5.74)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>KHQ at 5-year FU (TVT, n=161; TVT-O, n=170) - mean <math>\pm</math>SD</p> <p>General: TVT: 31.6 (21.6); TVT-O: 30.7 (23.3)</p> <p>Incontinence: TVT: 23.1 (31.5); TVT-O: 24.8 (32.9)</p> <p>Role limitations: TVT: 12.3 (23.9); TVT-O: 15.7 (26.9)</p> <p>Physical limitations: TVT: 15.1 (26.5); TVT-O: 16.3 (29.4)</p> <p>Social limitations: TVT: 13.7 (18.6); TVT-O: 14.3 (17.7)</p> <p>Personal relationships: TVT: 23.7 (23.0); TVT-O: 18.4 (16.9)</p> <p>Emotions: TVT: 12.6 (27.3); TVT-O: 10.3 (22.5)</p> <p>Sleep/energy: TVT: 14.9 (23.1); TVT-O: 16.6 (23.0)</p> <p>Severity: TVT: 39.6 (27.3); TVT-O: 42.9 (27.3)</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>OAB: TVT: 41.6 (37.6); TVT-O: 31.7 (33.5)</p> <p>SUI: TVT: 38.5 (45.1); TVT-O: 45.5 (46.8)</p> <p>Intercourse: TVT: 43.8 (41.7); TVT-O: 18.2 (40.5)</p> <p>UTI: TVT: 42.9 (45.0); TVT-O: 40.0 (44.7)</p> <p>Bladder pain: TVT: 30.0 (44.7); TVT-O: 8.3 (20.4)</p> <p>Complications - (n; %)</p> <p>Pain at 3-months FU: TVT (10; 4.0); TVT-O (15; 6.4)</p> <p>Pain at 5-year FU: TVT (2; 1.4); TVT-O (4; 2.7)</p> <p>Mesh extrusion at 5- year FU: TVT (4; 3.0); TVT-O (4; 3.0)</p> <p>Infection (wound) at 3- months FU: TVT (1; 0.4); TVT-O (0)</p> <p>Infection (UTI) at 4-5- year FU: TVT (31; 21.2); TVT-O (28; 18.2)</p>	
<p>Full citation Al-Azzawi, I. S., The first Iraqi</p>	<p>Sample size N=80 randomised</p>	<p>Interventions Intervention: Synthetic sling</p>	<p>Details Same surgeon performed both surgeries with patients under</p>	<p>Results Cure* at 1 week - n (%) TOT: 38 (95)</p>	<p>Limitations Random sequence generation: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>experience with the rectus fascia sling and transobturator tape for female stress incontinence: A randomised trial, Arab Journal of Urology Print, 12, 204-8, 2014</p> <p>Ref Id 542569</p> <p>Country/ies where the study was carried out Iraq</p> <p>Study type RCT</p> <p>Aim of the study To describe first Iraqi experience with autologous rectus fascia slings compared to TOT in women with SUI</p> <p>Study dates</p>	<p>Intervention (rectus fascia sling; RFS): n=40</p> <p>Control (transobturator tape; TOT): n=40</p> <p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD TOT: 39.2 (4.7)</p> <p>RFS: 42.8 (6)</p> <p>Parity - mean <math>\pm</math>SD TOT: 4.1 (0.9)</p> <p>RFS: 4.6 (1.1)</p> <p>Previous pelvic/vaginal surgery - n (%) TOT: 22 (55)</p> <p>RFS: 23 (58)</p> <p>Concurrent cystocele - n (%) TOT: 31 (78)</p> <p>RFS: 33 (83)</p> <p>Number of women with pure SUI - n (%) TOT: 29 (73)</p> <p>RFS: 32 (80)</p> <p>Number of women with mixed UI - n (%) TOT: 11 (28)</p>	<p>Control: Autologous fascial sling</p>	<p>general anaesthesia. In both procedures, 18-F Foley catheter urethrally introduced and maintained for 2-4 days.</p> <p>Follow up: mean 1 year FU (range 0.5-4)</p> <p>Synthetic sling (TOT)</p> <p>Technique in line with DeLorme adopted.</p> <p>Autologous rectus fascial sling</p> <p>Autologous recus fascia sling used with surgery performed via combined abdominal-vaginal approach with 12 x 2cm rectus fascia. Two 0-nylon threads sutured at both ends of sling. After positioning for retropubic approach, mid part of sling fixed to perirethral fascia using 4-0 polyglactin sutures.</p>	<p>RFS: 39 (98)</p> <p>Adverse events - bladder injury - n (%) TOT: 0</p> <p>RFS: 0</p> <p>Adverse events - bowel injury - (%) TOT: 0</p> <p>RFS: 0</p> <p>Complications at mean 1 year FU (range 0.5-4)</p> <p>Mesh extrusion: TOT (0); RFS (0)</p> <p>Pain: TOT (5; 13); RFS (0)</p> <p>Wound complications: TOT (0); RFS (8; 20)</p> <p>De novo OAB - detrusor overactivity: TOT (2; 5); RFS (2; 5)</p> <p>*Defined as significant self-reported dryness, no use of pads, negative stress test and acceptable voiding stream [max flow rate <math>\geq</math>15 ml/s]</p>	<p>(random number table used)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (no dropouts reported)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
12/2004 to 07/2012  Source of funding None	RFS: 8 (20)  Inclusion criteria Women with pure SUI or stress-predominant mixed UI BMI<30 kg/m <sup>2</sup>  Exclusion criteria Women with mild degree of UI concomitant cystocele >grade 1 active vaginal infection or urinary tract infection neurogenic voiding dysfunction significant postvoid residual urine volume other bladder or urethral pathologies and fistulae				
Full citation Albo, M. E., Kraus, S. R., Zimmern, P. E., Chai, T. C., Zyczynski, H.,	Sample size N=655 randomised Intervention, n=329 Control, n=326	Interventions Intervention: Colposuspension Control: Fascial sling	Details ClinicalTrials.gov: NCT00064662; SISTER trial (Stress Incontinence Surgical Treatment Efficacy Trial). Both procedures were standardised across participating centres. In both	Results Note: Data for 5-years from Brubaker et al. 2012; complications data from Chai et al. 2009.	Limitations Random sequence generation: Low risk (computer-generated permuted-block)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Diokno, A. C., Lemack, G. E., Mallett, V., Stoddard, A. M., Steers, W., Diokno, A., Khandwala, S., Brubaker, L., Fitzgerald, M., Richter, H. E., Lloyd, L. K., Albo, M., Nager, C., Chai, T., Johnson, H. W., Zyczynski, H. M., Leng, W., Zimmern, P., Lemack, G., Kraus, S., Rozanski, T., Norton, P., Kerr, L., Chang, D., Kusek, J. W., Nyberg, L. M., Weber, A. M., Ashford, R. S., Baker, J., Borello-France, D., Burgio, K. L., Chiang, S., Dabbous, A., Goode, P. S., Hammontree, L.	Characteristics Age (years) - mean ±SD Colposuspension: 52.2 (10.5) Sling: 51.6 (10.1) BMI - mean ±SD Colposuspension: 29.7 (6.1) Sling: 30.3 (6.1) Number of women with vaginal births (0/1-2/≥3) - % Colposuspension: 8/46/46 Sling: 10/39/51 Previous incontinence surgery (%) Colposuspension: 15 Sling: 13 Postmenopausal (%) Colposuspension: 71 Sling: 68 Concomitant surgery (%) No POP surgery: Colposuspension (44); Sling (40) POP surgery with anterior vaginal wall		arms, cystoscopy used to confirm no sutures in bladder and ureteral function and drainage achieved through use of suprapubic or Foley catheter. Follow up: 2 years (Albo et al. 2007), 5 years (Brubaker et al. 2012) Burch colposuspension Modified Burch Tanagho colposuspension conducted. Smallest possible incision made (4– 6 cm unless BMI >30 kg/m <sup>2</sup> ), 2-3 Number≥0 polypropylene sutures used on each side from anterior vagina to ipsilateral Cooper's ligament and one set of sutures at urethrovesical junction. Sutures tied to elevate anterior vagina to minimally retropubic position. Use of laparoscopic procedure, transvaginal Burch and alternative anchoring materials such as absorbable sutures and bone anchors were not permitted. Fascial sling (autologous) Autologous rectus fascia material used of at least 2 × 6 cm. Number≥0 polypropylene suture used with sling placed at proximal half of urethra, bladder neck to mid-urethra. No visible evidence of angulation of the urethra/bladder neck at end of procedure and no tension on the	Cure at 24-months* - n/N Colposuspension: 161/329 Sling: 215/326 *No self-reported symptoms of stress incontinence, negative stress test and no retreatment of stress incontinence Objective cure at 24- months (negative cough stress test) - n/N Colposuspension: 181/329 Sling: 231/326 Objective cure at 24- months (negative pad test) - n/N Colposuspension: 217/329 Sling: 228/326 Subjective cure at 24- months (No self- reported symptoms) - n/N Colposuspension: 125/329 Sling: 164/326	randomisation stratified by clinical site) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (ITT analysis) Selective reporting: Low risk (protocol available, all outcomes reported) Other bias: Low risk (appears free from other sources of bias)  Other information Complications data reported in Chai et al. 2009; 5-year follow up data reported in Brubaker et al. 2012.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
N., Kenton, K., Lesser, D., Luber, K., Lukacz, E., Markland, A., Menefee, S., Moalli, P., Peters, K., Sagan, E., Schaffer, J., Simsiman, A., Sirls, L., Starr, R., Varner, R. E., Bradt, R., Debes, K., Dinh, R., Gruss, J., Hall, L., Howell, A., Jesse, K., Kalinoski, D. L., Koches, K., Leemon, B., Mislavovich, K., O'Meara, S., Parent, J., Pope, N., Prather, C., Rogers, T., Sluder, S., Tulke, M., Dandreo, K. J., Leifer, C. J., McDermott, S., Stoddard, A.,	<p>repair (with or without other repair): Colposuspension (17); Sling (23)</p> <p>POP surgery without anterior vaginal wall repair (including posterior wall and apex): Colposuspension (31); Sling (32)</p> <p>Other non-prolapse surgery: Colposuspension (8); Sling (6)</p> <p>Inclusion criteria Women with self-reported pure SUI or stress-predominant mixed UI for at least 3 months positive standardised urinary stress test eligible for both procedures able to complete 2 year FU mean micturition &lt;12 times per day</p>		<p>sling. Use of laparoscopic procedure, alternative sling materials (e.g. synthetics, dermis, small intestine submucosa, or cadaveric tissue), alternative anchoring materials (e.g. absorbable sutures and bone anchors) not permitted.</p>	<p>Subjective cure at 5-years (No leakage according to response on MESA questionnaire) - n/N</p> <p>Colposuspension: 54/329</p> <p>Sling: 77/326</p> <p>Improvement at 5-years (number satisfied)</p> <p>Colposuspension: 126/329</p> <p>Sling: 148/326</p> <p>Adverse events - bladder injury - n/N</p> <p>Colposuspension: 2/329</p> <p>Sling: 0/326</p> <p>Repeat surgery for SUI at 24-months - n/N</p> <p>Colposuspension: 28/255</p> <p>Sling: 5/265</p> <p>Repeat surgery for SUI at 5 years - n/N</p> <p>Colposuspension: 21/174</p> <p>Sling: 4/183</p> <p>Complications Pelvic pain at 24-months - n/N</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Tennstedt, S., Tinsley, L., Wruck, L., Xu, Y., Gormley, E. A., Abrams, P., Bland, D., Clemens, J. Q., Connett, J., Henderson, W., Fenner, D., Kelsey, S., Myers, D., Mostwin, J., Wadie, B., Burch colposuspensio n versus fascial sling to reduce urinary stress incontinence, New England journal of medicine, 356, 2143-2155, 2007 Ref Id 673659 Country/ies where the study was carried out USA Study type</p>	<p>MESA stress symptom score (percentage of total possible stress score) greater than MESA urge symptom score (percentage of total possible urge score) observation of leakage by provocative stress test at bladder volume ≤300 mL (Valsalva or cough-induced detrusor instability considered mixed UI and therefore allowed) maximal cystometric capacity ≥200 mL PVR ≤150 mL by stress test or UDS with POP Stage I or lower; if POP Stage II- IV, PVR &gt;150 mL is allowed unobstructed voiding (maximal flow rate ≥12 mL/s, PVR ≤150 mL, and detrusor pressure at maximal flow ≤50 cm H<sub>2</sub>O; if POP Stage II–IV, maximal flow rate &lt;12 mL/s, PVR &gt;150 mL, and/or</p>			<p>Colposuspension: 0/329 Sling: 2/326 Fistula at 24-months - n/N Colposuspension: 1/329 Sling: 0/326 Ureteral injury at 24- months - n/N Colposuspension: 2/329 Sling: 0/326 Voiding dysfunction (need for surgical revision to facilitate bladder emptying or use of any type of catheter after 6-wk visit) at 24- months - n/N Colposuspension: 0/329 Sling: 20/326 Need for catheterisation at 24-months - n/N Colposuspension: 22/329 Sling: 54/326 [data from Chai et al. 2009, includes intermittent self-catheterisation and catheter data] De novo OAB - de novo urge incontinence at 24- months - n/N</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Multicentre RCT</p> <p>Aim of the study To compare efficacy and safety of fascial sling and Burch colposuspension 2 years after surgery in women with stress urinary incontinence</p> <p>Study dates 06/2004 to 06/2006</p> <p>Source of funding Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231, U01 DK60379, U01 DK60380, U01 DK60393, U01 DK60395, U01 DK60397,</p>	<p>detrusor pressure at maximal &gt;50 cm H<sub>2</sub>O allowed</p> <p>Exclusion criteria Women &lt;21 years-old nonambulatory (ambulatory with assistive devices allowed) pregnancy by self-report or positive pregnancy test, or self-reported intention to become pregnant in next 24 months current cancer chemotherapy or radiotherapy systemic disease known to affect bladder function (i.e. Parkinson's disease, multiple sclerosis, spina bifida, spinal cord injury or trauma) current or repaired urethral diverticulum</p>			<p>Colposuspension: 11/329 Sling: 11/326 De novo OAB - de novo urge incontinence at 5-years - n/N Colposuspension: 7/174 Sling: 3/183 Infection - serious (recurrent) cystitis at 24-months - n/N Colposuspension: 5/329 Sling: 6/326 Infection - non-serious cystitis at 24-months - n/N Colposuspension: 202/329 Sling: 299/326 Wound complication requiring surgery at 24-months - n/N Colposuspension: 13/329 Sling: 11/326 Wound complication not requiring surgery at 24-months - n/N Colposuspension: 69/329</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
and U01 DK60401) with the National Institute of Diabetes and Digestive and Kidney Diseases and by the National Institute of Child Health and Human Development and Office of Research in Women's Health of the National Institutes of Health. Individual authors also received grants and fees from variety of pharmaceutical and related organisations.	prior augmentation cystoplasty or artificial sphincter <12 mo postpartum (delivery or other termination after 20 weeks) recent pelvic surgery, endoscopic pelvic surgery <6 weeks or open pelvic surgery <6 months participation in another treatment intervention trial that might influence trial results			Sling: 71/326	
Full citation Albo, M. E., Litman, H. J., Richter, H. E.,	Sample size N=597 randomised Intervention, n=298	Interventions Intervention: Retropubic sling Control:	Details See entry for Richter et al. 2010 for more details	Results See entry for Richter et al. 2010 for more details	Limitations See entry for Richter et al. 2010 for more details

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Lemack, G. E., Sirls, L. T., Chai, T. C., Norton, P., Kraus, S. R., Zyczynski, H., Kenton, K., Gormley, E. A., Kusek, J. W.,</p> <p>Treatment success of retropubic and transobturator mid urethral slings at 24 months, Journal of Urology, 188, 2281-2287, 2012</p> <p>Ref Id 673660</p> <p>Country/ies where the study was carried out USA</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To report 2-year outcomes comparing retropubic to</p>	<p>Control, n=299</p> <p>Characteristics See entry for Richter et al. 2010 for more details</p> <p>Inclusion criteria See entry for Richter et al. 2010 for more details</p> <p>Exclusion criteria See entry for Richter et al. 2010 for more details</p>	<p>Transobturator sling</p>			<p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>transobturator slings in women with SUI</p> <p>Study dates 04/2006 to 06/2008</p> <p>Source of funding Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231, U01 DK60379, U01 DK60380, U01 DK60393, U01 DK60395, U01 DK60397, and U01 DK60401) from the National Institute of Diabetes and Digestive and Kidney Diseases and by the National Institute of Child</p>					

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Health and Human Development. Partly funded by NIH grants to 4 authors.					
<p>Full citation Alkady, Hm, Eid, A, Tension-free vaginal tape versus transobturator vaginal tape inside-out for the treatment of female stress urinary incontinence, Medical journal of Cairo University, 77, 317-26, 2009 Ref Id 673662 Country/ies where the study was carried out Kuwait Study type RCT</p>	<p>Sample size N=30 randomised Intervention, n=15 Control, n=15</p> <p>Characteristics Age (years) - mean (range) Retropubic sling: 48 (32-62) Transobturator sling; 50 (30-65) Women with BMI&gt;30 (%) Retropubic sling: 13 Transobuturator sling: 6.7 Parity - mean (range) Retropubic sling: 5 (2-10) Transobturator sling: 6 (1-13) Menopausal (%)</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Gynecare non-absorbable monofilament polypropylene tape used for all slings used in both arms. All patients received iv prophylactic antibiotic at beginning of procedure. Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1999 with exception of use of general or epidural anaesthesia. Cystoscopy performed in all cases. Transobturator sling (TVT-O) Procedure as described by De Leval 2003</p>	<p>Results Objective cure at 12 months (no SUI and negative stress test) - n/N Retropubic sling: 13/15 Transobturator sling: 13/15 Subjective cure at 12 months (no self-reported leakage) - n/N Retropubic sling: 12/15 Transobturator sling: 13/15 Improvement at 1 year (very satisfied or satisfied) - n/N Retropubic sling: : 14/15 Transobturator sling: 15/5 Adverse events - bladder injury - n/N Retropubic sling: 1/15</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Low risk (numbered, opaque, sealed envelopes used) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To compare 12-month outcomes of TVT and TVT-O in treatment of female SUI</p> <p>Study dates 01/2007 to 01/2009</p> <p>Source of funding Not reported</p>	<p>Retropubic sling: 20 Transobturator sling: 26</p> <p>Inclusion criteria Women with visible, genuine and urodynamically-proven SUI or mixed UI without urodynamically-proven contraction. urethral hypermobility on physical examination absence of contractile urinary bladder or obstruction</p> <p>Exclusion criteria Women with acute cystitis urge-predominant incontinence urodynamic detrusor instability Qmax&lt;15ml/s and/or positive residual urine&gt;20% of voided volume</p>			<p>Transobturator sling: 0/15 Repeat surgery for mesh complications - n/N Retropubic sling: 1/15 Transobturator sling: 0/15 Complications at 1 year Mesh extrusion - n/N Retropubic sling: 1/15 Transobturator sling: 0/15 Need for catheterisation - n/N Retropubic sling: 2/15 Transobturator sling: 1/15 Infection - n/N Retropubic sling: 0/15 Transobturator sling: 0/15 Wound complication - n/N Retropubic sling: 0/15 Transobturator sling: 0/15</p>	<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	genital prolapse stage 4 or 5				
<p>Full citation Amaro, J. L., Yamamoto, H., Kawano, P. R., Barros, G., Gameiro, M. O. O., Agostinho, A. D., Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: A prospective randomized trial, International braz j urol, 35, 60-66, 2009 Ref Id 673666 Country/ies where the study was carried out Brazil Study type RCT</p>	<p>Sample size N=41 randomised Intervention, n=20 Control, n=21</p> <p>Characteristics Age (years) - mean (range) Synthetic sling: 52 (26-79) Fascial sling: 49 (26-69) BMI - mean (range) Synthetic sling: 28.2 (24-42) Fascial sling: 30.2 (22-34) Parity - mean (range) Synthetic sling: 4 (1-12) Fascial sling: 4 (1-9)</p> <p>Inclusion criteria Women with primary complaint of SUI</p>	<p>Interventions Intervention: Synthetic sling Control: Autologous fascial sling</p>	<p>Details Cystoscopy performed in all patients. Median FU=44 months (range 36-54) Synthetic sling (TVT) Performed as described by Ulmsten et al. 1999 except spinal anaesthesia used. Autologous rectus fascial sling Procedure conducted as described in Blaivas &amp; Jacobs 1991 with modifications.</p>	<p>Results Subjective cure at 12 months (self-reported complete dryness with no pad usage) - n/N Synthetic sling: 14/20 Fascial sling: 12/21 Subjective cure at 36 months - n/N Synthetic sling: 13/20 Fascial sling: 12/21 Improvement at 36 months (number of women satisfied) - n/N Synthetic sling: : 12/20 Fascial sling: 17/21 Adverse events - bladder injury - n/N Synthetic sling: 2/20 Fascial sling: 1/21 Complications De novo urgency at 36 months - n/N Synthetic sling: 8/20 Fascial sling: 8/21</p>	<p>Limitations Random sequence generation: Unclear risk (raffle procedure used with folded pieces of paper) Allocation concealment: Low risk (allocation determined just before surgery) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To evaluate efficacy and quality of life of autologous fascial sling compared to TVT in women with SUI</p> <p>Study dates 01/2001 to 03/2002</p> <p>Source of funding Not reported</p>	<p>urodynamically-confirmed SUI</p> <p>Exclusion criteria Women with involuntary detrusor contraction pre-existing bladder outlet obstruction</p>				
<p>Full citation Andonian,S., St-Denis,B., Lemieux,M.C., Corcos,J., Prospective clinical trial comparing Obtape and DUPS to TVT: one-year safety and efficacy results,</p>	<p>Sample size N=190 randomised Intervention (TVT or DUPS), n=112 (includes 32 participants randomised to discontinued DUPS arm) Control (TOT), n=78</p> <p>Characteristics</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Originally 3-arm trial but Distal Urethral Polypropylene Sling (DUPS) arm discontinued after 32 patients recruited in each arm due to high postoperative retention and some complaints of suprapubic abdominal discomfort on straining. Participants therein randomised to TVT and Obtape groups after this. Most patients had spinal anaesthesia. Ethicon polypropylene mesh used.</p>	<p>Results Objective cure at 1 year (1-hr pad test ≤2g) - n/N TVT: 99/112 Obtape: 64/78 Continence-specific HR-QoL - ICIQ-UI-SF at 1 year - mean (95% CI) TVT: 3.7 (95% CI 2.7-4.7), n=80 Obtape: 5.2 (95% CI 3.3-7.1), n=77</p>	<p>Limitations Random sequence generation: Low risk (envelope method used) Allocation concealment: Low risk (randomisation occurred immediately before surgery) Blinding of participants/personnel: Low risk (participants blinded to group assignment)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>European Urology, 52, 245-251, 2007 Ref Id 100533 Country/ies where the study was carried out Canada Study type RCT Aim of the study To compare outcomes of TOT, Distal Urethral Polypropylene Sling, and TVT in women with SUI Study dates 02/2003 to 05/2005 Source of funding Not reported</p>	<p>Age (years) - mean (range) TVT: 61.1 (35.4-94.6) DUPS: 56.6 (34.6-83.7) Obtape: 56.2 (21.7-85.7) Grade 1 SUI (%) TVT: 16 DUPS: 18 Obtape: 4 Grade 2 SUI (%) TVT: 62 DUPS: 50 Obtape: 74 Grade 3 SUI (%) TVT: 22 DUPS: 32 Obtape: 22 Inclusion criteria Women SUI with or without POP Exclusion criteria Women with</p>		<p>Retropubic sling (TVT or DUPS) TVT (Gynecare) procedure as described by Ulmsten et al. 1996; DUPS procedure as described by Rodriguez and Raz 2001 (with exception that suprapubic tube not inserted) and after surgeons were trained by Dr Raz. Transobturator sling (TOT) Obtape TOT (Mentor) used, procedure as described by Delorme et al. 2001.</p>	<p>Adverse events - bladder injury - n/N TVT: 11/112 Obtape: 0/78 Repeat surgery for SUI at 1 year - n/N TVT: 1/112 Obtape: 2/78 Repeat surgery for mesh complications at 1 year - n/N TVT: 1/112 Obtape: 3/78 Complications at 1 year Mesh extrusion - n/N TVT: 0/112 Obtape: 2/78 Infection (UTI) - n/N TVT: 2/112 Obtape: 1/78 Wound infection- n/N TVT: 1/112 Obtape: 0/78 Need for catheterisation - n/N TVT: 12/112 Obtape: 6/78 De novo OAB - urge - n/N</p>	<p>Blinding of outcome assessment: Low risk (assessor blinded to group assignment) Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant bias in effect estimates) Selective reporting: Unclear risk (insufficient information) Other bias: High risk (At baseline, participants in TVT group were significantly older than those in Obtape group) Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>mixed UI and cystometrogram showing non-normal capacity, non-compliance, or uninhibited contractions</p> <p>obstruction, unstable bladder function, or neurogenic bladder</p> <p>current urinary tract infection</p>			<p>TVT: 5/112</p> <p>Obtape: 6/78</p>	
<p>Full citation</p> <p>Andrada Hamer, M., Larsson, P. G., Teleman, P., Bergqvist, C. E., Persson, J.,</p> <p>One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur,</p> <p>International Urogynecology Journal, 24, 223-9, 2013</p> <p>Ref Id</p>	<p>Sample size</p> <p>N=133 randomised</p> <p>Intervention, n=64</p> <p>Control, n=69</p> <p>Characteristics</p> <p>See entry for Andrada-Hamer et al. 2011 for more details</p> <p>Inclusion criteria</p> <p>See entry for Andrada-Hamer et al. 2011 for more details</p> <p>Exclusion criteria</p>	<p>Interventions</p> <p>Intervention: Single-incision mini-sling</p> <p>Control: Other Synthetic sling</p>	<p>Details</p> <p>See entry for Andrada-Hamer et al. 2011 for more details</p>	<p>Results</p> <p>See entry for Andrada-Hamer et al. 2011 for more details</p>	<p>Limitations</p> <p>See entry for Andrada-Hamer et al. 2011 for more details</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
542577 Country/ies where the study was carried out Sweden Study type Multicentre RCT  Aim of the study To compare one-year FU results of TVT-Secur-H and TVT in women with predominant stress urinary incontinence  Study dates 2007-2009  Source of funding Funded by Gynecare Scandinavia	See entry for Andrada-Hamer et al. 2011 for more details				
Full citation	Sample size N=133 randomised	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Andrada Hamer, M., Larsson, P. G., Teleman, P., Eten-Bergqvist, C., Persson, J., Short-term results of a prospective randomized evaluator blinded multicenter study comparing TVT and TVT-Secur, International Urogynecology Journal, 22, 781-7, 2011</p> <p>Ref Id 673674</p> <p>Country/ies where the study was carried out Sweden</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare efficacy and safety of TVT-</p>	<p>Intervention, n=64 Control, n=69</p> <p>Characteristics</p> <p>Age (years) - median (range) TVT-Secur: 47 (33-84) TVT: 48 (33-78)</p> <p>BMI - median (range) TVT-Secur: 25.4 (20.3-42.1) TVT: 24.6 (18.8–36)</p> <p>Parity - median (range) TVT-Secur: 2 (0–8) TVT: 2 (2–5)</p> <p>Postmenopausal (%) TVT-Secur: 31 TVT: 36</p> <p>Inclusion criteria Women with age≥18 years-old history of SUI wish for surgical treatment no wish for future pregnancy</p>	<p>Intervention: Single-incision min-isliling</p> <p>Control: Other Synthetic sling</p>	<p>Six surgeons all with experience of ≥100 sling operations performed all procedures and trained before study in TVT-Secur technique.</p> <p>Single-incision mini-sling (TVT-Secur-H)</p> <p>Gynecare TVT-Secur used, procedure as described by manufacturer.</p> <p>Other Synthetic sling (TVT)</p> <p>Gynecare TVT used, procedure as described by manufacturer.</p>	<p>Note: 1-year data from Andrada Hamer et al. 2013</p> <p>Objective cure at 1 year (negative cough stress test) - n/N TVT-Secur: 40/64 TVT: 56/69</p> <p>Subjective cure at 2 months (self-reported no SUI symptoms) - n/N TVT-Secur: 24/64 TVT: 40/69</p> <p>Subjective cure at 1 year - n/N TVT-Secur: 28/64 TVT: 47/69</p> <p>Improvement at 2 months (number subjectively cured + number self-reportedly improved) - n/N TVT-Secur: 44/64 TVT: 57/69</p> <p>Improvement at 1 year - n/N TVT-Secur: 48/64 TVT: 60/69</p> <p>Adverse events - bladder injury - n/N</p>	<p>Random sequence generation: Low risk (shuffling of envelopes used)</p> <p>Allocation concealment: Low risk (sequentially numbered, sealed, opaque envelopes used; central allocation)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Low risk (assessor blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to make clinically relevant impact on effect estimates)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Secur-H and TVT in women with predominant stress urinary incontinence</p> <p>Study dates 2007-2009</p> <p>Source of funding Funded by Gynecare Scandinavia</p>	<p>≥3 mL leakage at a standardized pad test with 300 ml bladder volume</p> <p>cough-synchronous leakage at stress test (up to ten coughs in standing position) with 300ml bladder volume</p> <p>Exclusion criteria Women with need for concomitant surgery for genital POP undergoing regular pelvic floor training in past 3 months with planned or current pregnancy who had previous UI surgery with bladder capacity &lt;300 ml with residual urinary volume &gt;100 ml with known detrusor instability had &gt;4 occurrences of cystitis in past 12 months</p>			<p>TVT-Secur: 0/61 TVT: 2/62 Repeat surgery for SUI at ≤1 year - n/N TVT-Secur: 1/64 TVT: 0/69 Repeat surgery for mesh complications at ≤1 year - n/N TVT-Secur: 2/61 TVT: 0/62 Complications Pain (including dyspareunia) at 1 year - n/N TVT-Secur: 5/55 TVT: 5/60 Mesh extrusion at 3 months - n/N TVT-Secur: 1/61 TVT: 0/62 Mesh extrusion at 1 year - n/N TVT-Secur: 3/55 TVT: 2/60 Need for catheterisation at 2 months - n/N TVT-Secur: 2/61 TVT: 0/62</p>	<p>1-year follow up data reported in Andrada Hamer et al., 2013.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>had &gt;1 occurrence pyelonephritis in past 5 years</p> <p>with known or suspected neurological conditions</p> <p>having current anticoagulation therapy that could not be interrupted in time prior to surgery</p> <p>with known abnormal coagulation</p> <p>with allergy to local anesthetics and/or metronidazol</p> <p>with cognitive or language problems precluding comprehension of written study information or questionnaires</p>			<p>Infection (UTI) at 2 months - n/N TVT-Secur: 9/61 TVT: 6/62</p> <p>Infection (UTI) at 1 year - n/N TVT-Secur: 14/60 TVT: 12/61</p> <p>De novo OAB - de novo urge at 2 months - n/N TVT-Secur: 11/61 TVT: 4/62</p> <p>De novo OAB - de novo urge at 1 year - n/N TVT-Secur: 7/60 TVT: 10/61</p>	
<p>Full citation Angioli,R., Plotti,F., Muzii,L., Montera,R., Panici,P.B., Zullo,M.A.,</p>	<p>Sample size N=72 randomised Intervention, n=35 Control, n=37</p> <p>Characteristics</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details See entry for Zullo et al. 2007 for further details</p>	<p>Results See entry for Zullo et al. 2007 for further details</p>	<p>Limitations See entry for Zullo et al. 2007 for further details</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Tension-free vaginal tape versus transobturator suburethral tape: Five-year follow-up results of a prospective, randomised trial, European Urology, 58, 671-677, 2010</p> <p>Ref Id 135795</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type RCT</p> <p>Aim of the study To report 5-year outcomes of TVT and TVT-O in women with SUI</p> <p>Study dates 07/2005 to 05/2005</p>	<p>See entry for Zullo et al. 2007 for further details</p> <p>Inclusion criteria See entry for Zullo et al. 2007 for further details</p> <p>Exclusion criteria See entry for Zullo et al. 2007 for further details</p>				Original study reported in Zullo et al. 2007.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported					
<p>Full citation Aniuliene,R., Tension-free vaginal tape versus tension- free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence, Medicina (Kaunas, Lithuania), 45, 639-643, 2009 Ref Id 100543 Country/ies where the study was carried out Lithuania Study type RCT</p>	<p>Sample size N=264 randomised Intervention, n=114 Control, n=150</p> <p>Characteristics Age (years) - mean ±SD Retropubic sling: 51 (10.1) Transobturator sling: 49 (9.5) BMI - mean ±SD Retropubic sling: 27.9 (4) Transobturator sling: 28.2 (3.8) Parity - mean ±SD Retropubic sling: 2.6 (1.1) Transobturator sling: 2.5 (1.2)</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Surgical procedures all performed by same surgeon. Retropubic sling (TVT) Gynecare TVT used, procedure according to manufacturer's description. Cystoscopy performed in all cases. Transobturator sling (TVT-O) Gynecare TVT-O used, procedure according to manufacturer's description.</p>	<p>Results Objective cure at 1 year (Number of women that showed (a) No SUI symptoms, no urge to urinate, no dysuria, and no use of inlay, + (b) No SUI symptoms, very mild urge to urinate, no dysuria, + (c) No SUI, need to urinate with minimal leakage, very mild dysuria) - n/N Retropubic sling: : 111/114 Transobturator sling: 147/150 Adverse events - bladder injury - n/N Retropubic sling: 1/114 Transobturator sling:0/150 Complications at 1 year Infection (UTI) - n/N Retropubic sling: 5/114</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Un clear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To compare effectiveness and safety outcomes of TVT to TVT-O in women with SUI</p> <p>Study dates Not reported</p> <p>Source of funding Not reported</p>	<p>Inclusion criteria Women with stress urinary incontinence agreement to buy a TVT or TVT-O set</p> <p>Exclusion criteria Women with urogenital prolapse&gt;stage 2 urinary retention overactive bladder mental disorder</p>			<p>Transobturator sling: 1/150 Need for catheterisation - n/N Retropubic sling: 18/114 Transobturator sling: 5/150 Wound complication - n/N Retropubic sling: 2/114 Transobturator sling: 3/150</p>	
<p>Full citation Aniuliene, R., Aniulis, P., Skaudickas, D., TVT-Exact and midurethral sling (SLING-IUFT) operative procedures: a randomized study, Open Medicine, 10, 311-317, 2015 Ref Id 618353</p>	<p>Sample size N=154 randomised Intervention, n=78 Control, n=76</p> <p>Characteristics Age (years) - mean ±SD Retropubic sling: 50 (8.9) Transobturator sling: 67 (9.5) BMI - mean ±SD</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details All procedures performed by same surgeon. Antibiotic prophylaxis provided in all cases. Retropubic sling (TVT-Exact) Standardised procedure followed. Cystoscopy performed in all cases. Transobturator sling (SLING-IUFT) Standardised procedure followed.</p>	<p>Results Objective cure at 1 year (Number of women that showed (a) No SUI symptoms, no urge to urinate, no dysuria, and no use of inlay, + (b) No SUI symptoms, very mild urge to urinate, no dysuria, + (c) No SUI, need to urinate with minimal leakage, very mild dysuria) - n/N Retropubic sling: : 72/76</p>	<p>Limitations Random sequence generation: Low risk (envelope technique used) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Lithuania Study type RCT  Aim of the study To compare effectiveness and safety outcomes of TVT-Exact to SLING-IUFT in women with SUI  Study dates 04/2009 to 04/2011  Source of funding Not reported	Retropubic sling: 28.5 (3.5) Transobturator sling: 28.2 (3.8) Parity - mean $\pm$ SD Retropubic sling: 2.1 (1.1) Transobturator sling: 2.5 (1.2) Menopause (1-30 years) - n/N Retropubic sling: 38/76 Transobturator sling: 55/78 POP-Q 1, 2 - n Retropubic sling: 41, 35 Transobturator sling: 21, 57  Inclusion criteria Women with history of SUI with a demonstrable impact of SUI upon coughing and Valsalva tests during urodynamic (cystometry and uroflowmetry) testing			Transobturator sling: 47/78 Adverse events - bladder injury - n/N Retropubic sling: 1/76 Transobturator sling: 0/78 Complications at 1 year Pain: 1/76; 5/78 Mesh extrusion - n/N Retropubic sling: 0/76 Transobturator sling: 1/78 Need for catheterisation - n/N Retropubic sling: 12/76 Transobturator sling: 1/78	Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: High risk (At baseline, TVT-Exact group were significantly younger and less menopausal than SLING-IUFT group)  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>Exclusion criteria Women with previous suburethral sling predominant overactive bladder symptoms POP stage 2 or more elevated postvoid residual &gt;100 mL urinary retention progressive neurological disease psychiatric disease evidence of systematic infection.</p>				
<p>Full citation Ankardal, M., Milsom, I., Stjerdahl, J.H., Engh, M.E., A three-armed randomized trial comparing open Burch colposuspension using sutures with laparoscopic</p>	<p>Sample size N= 211 randomised Intervention 1, n=53 Intervention 2, n=79 Control, n=79</p> <p>Characteristics Age (years) - mean ±SD Intervention 1: 35.5 (41.8)</p>	<p>Interventions Intervention 1: Laparoscopic colposuspension with sutures Intervention 2: Laparoscopic colposuspension with mesh and staples Control: Open colposuspension</p>	<p>Details All procedures performed by experienced senior surgeons. All women in laparoscopic surgery groups received antibiotic prophylaxis (preoperative: cefuroxime, metronidazole; postoperative: cefadroxil). Follow up: 1 year postop Laparoscopic colposuspension with sutures</p>	<p>Results Objective cure at 1-yr FU (leakage &lt;8g/24 hours at 48-h pad test) - n/N Intervention 1: 39/53 Intervention 2: 51/79 Intervention 3: 56/79 Objective cure at 1-yr FU (leakage &lt;5g at stress test) - n/N Intervention 1: 43/53</p>	<p>Limitations Random sequence generation: Unclear risk (at beginning of study, randomised ratio 2:1:2 to, respectively, laparoscopic mesh group, laparoscopic suture group, and open group; changed to 1:2:1 after 1/3 sample recruited to ensure sufficient numbers in laparoscopic suture group. However,</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>colposuspension using sutures and laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence, Acta Obstetrica et Gynecologica Scandinavica, 84, 773-779, 2005</p> <p>Ref Id 100544</p> <p>Country/ies where the study was carried out Sweden</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare open Burch colposuspension using sutures with laparoscopic colposuspension</p>	<p>Intervention 2: 37.9 (36.9)</p> <p>Intervention 3: 38.8 (37.8)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>Intervention 1: 25.6 (3.0)</p> <p>Intervention 2: 24.8 (3.2)</p> <p>Intervention 3: 25.5 (3.9)</p> <p>Parity - mean <math>\pm</math>SD</p> <p>Intervention 1: 2.4 (1.1)</p> <p>Intervention 2: 2.2 (1.2)</p> <p>Intervention 3: 2.3 (1.1)</p> <p>Postmenopausal (%)</p> <p>Intervention 1: 33</p> <p>Intervention 2: 47</p> <p>Intervention 3: 46</p> <p>POP status: not reported, women scheduled for POP surgery excluded</p> <p>Inclusion criteria Women with</p>		<p>Number 0 non-resorbable polybutylated-coated polyester suture (Surgidac) used. Catheter used during surgery left in situ until day after surgery.</p> <p>Laparoscopic colposuspension with mesh and staples</p> <p>Polypropylene mesh (Prolene) and staples used. Urine volume checked by ultrasound until &lt;150 mL.</p> <p>Open colposuspension</p> <p>Number 0 non-resorbable polybutylated-coated polyester suture (Surgidac) used. Suprapubic catheter introduced for post-op drainage, removed post-op when residual volume &lt;150 mL.</p>	<p>Intervention 2: 44/79</p> <p>Intervention 3: 55/79</p> <p>Subjective cure at 1-yr FU (self-report) - n/N</p> <p>Intervention 1: 42/53</p> <p>Intervention 2: 45/79</p> <p>Intervention 3: 58/79</p> <p>Improvement in continence status at 1-yr FUleakage/no bother + # improvement in VAS score) - n/N</p> <p>Intervention 1: 45/53</p> <p>Intervention 2: 59/79</p> <p>Intervention 3: 57/79</p> <p>Adverse events - bladder perforation - n/N</p> <p>Intervention 1: 4/75</p> <p>Intervention 2: 1/63</p> <p>Intervention 3: 3/49</p>	<p>no further details provided)</p> <p>Allocation concealment: Unclear risk (opaque, sealed enveloped used but no further details provided)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: High risk (missing data in open group ~20% sufficient to have clinically relevant impact on effect size)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information Data from laparoscopic colposuspension with mesh and staples arm is</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>n using either sutures or mesh and staples in women with pure SUI or stress-predominant mixed UI</p> <p>Study dates 1996 to 2000</p> <p>Source of funding Supported by grants from the Swedish Medical Research Council (B95-17X-11237-01 A), the Goteborg Medical Society Fund</p>	<p>SUI or stress-predominant mixed UI</p> <p>Exclusion criteria Women with recurrent incontinence detrusor instability diagnosed during filling cystometry.</p>				<p>not included as this technique is not standard practice in the UK.</p>
<p>Full citation Araco, F., Gravante, G., Sorge, R., Overton, J., De Vita, D., Sesti, F., Piccione, E.,</p>	<p>Sample size N=240 randomised Intervention, n=120 Control, n=120</p> <p>Characteristics</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Two surgeons, both with &gt;40 TVT/TVT-O procedure experience, performed all procedures in inpatient setting. Oral anticoagulants discontinued 7 days before surgery if appropriate. NICE guidelines for</p>	<p>Results Note: Data for each group combines figures for SUI grade 1 and SUI grade 2 subgroups.</p>	<p>Limitations Random sequence generation: High risk (participant chose 1 of 2 identical closed envelopes containing presented to</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>TVT-O vs TVT: A randomized trial in patients with different degrees of urinary stress incontinence, International Urogynecology Journal, 19, 917-926, 2008</p> <p>Ref Id 631186</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type RCT</p> <p>Aim of the study To compare effectiveness and safety of TVT to TVT-O in women with grade 1 and grade 2 SUI</p> <p>Study dates</p>	<p>Note: Data for whole sample</p> <p>Age (years) - mean <math>\pm</math>SD 54 (5.7)</p> <p>BMI - median (range) 28 (21.8-38.5)</p> <p>Vaginal deliveries - mean <math>\pm</math>SD 1.8 (0.7)</p> <p>Inclusion criteria Women with symptomatic grade 1 and 2 SUI</p> <p>Exclusion criteria Women with SUI grade 3 overactive bladder associated prolapses neurovegetative disorders recurrent SUI receiving rehabilitative or medical therapies for SUI (i.e. pelvic floor muscle training or duloxetine)</p>		<p>preop testing followed. Spinal anaesthesia used in all cases.</p> <p>Retropubic sling (TVT) Gynecare TVT and regional anaesthetic used.</p> <p>Transobturator sling (TVT-O) Gynecare TVT-O used. Cystoscopy performed in all cases.</p>	<p>Cure at 1 year (No SUI symptoms on ambulatory urodynamic tests) - n/N</p> <p>Retropubic sling: 108/108</p> <p>Transobturator sling: 83/100</p> <p>I-QoL at 1 year - mean <math>\pm</math>SD</p> <p>Retropubic sling: 104 (5.8)</p> <p>Transobturator sling: 73 (31)</p> <p>Adverse events - bladder injury - n/N</p> <p>Retropubic sling: 3/108</p> <p>Transobturator sling: 0/100</p> <p>Repeat surgery for mesh complications - n/N</p> <p>Retropubic sling: 19/108</p> <p>Transobturator sling: 17/100</p> <p>Complications at 1 year</p> <p>Mesh extrusion - n/N</p> <p>Retropubic sling: 1/108</p> <p>Transobturator sling: 3/100</p>	<p>them to determine group assignment)</p> <p>Allocation concealment: Unclear risk (reports sealed envelopes but no further information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data similar across groups for similar reasons)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
01/2004 to 03/2006  Source of funding Not reported				Need for catheterisation - n/N Retropubic sling: 15/108 Transobturator sling: 17/100	
Full citation Arunkalaivanan, A.S., Barrington, J.W., Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: A questionnaire-based study, International urogynecology journal and pelvic floor dysfunction, 14, 17-23, 2003 Ref Id	Sample size N=142 randomised Intervention, n=68 Control, n=74  Characteristics TVT (n=68); Fascial sling (n=74) Age (years) - median (range) TVT: 54 (32-91) Fascial sling: 53 (34-79) Parity - median (range) TVT: 2 (0-6) Fascial sling: 2 (0-4) Previous incontinence surgery (%) TVT: 12 Fascial sling: 14 Hysterectomy (%)	Interventions Intervention: Synthetic sling Control: Non-autologous biological sling	Details Patients discharged postoperatively if residual urine volume <100 ml and/or voided volume is twice that of residual volume. Follow up: 24 months (Arunkalaivanan 2003), 36 months (Abdel-Fattah 2004) Synthetic (TVT) Performed as described by Ulmsten et al. 1996 with operation carried out under general or regional anaesthesia. Biological sling (Porcine dermis) Pelvicol used, performed as described by Barrington.	Results Note: data for 36 months from Abdel-Fattah et al. 2004 Objective cure at 24 months (no leakage on cough stress test, QoL improvement ≥90%, and patient reporting continent status as dry) - n/N TVT: 50/68 Fascial sling: 56/74 Objective cure at 36 months - n/N TVT: 53/68 Fascial sling: 56/74 Improvement at 24 months (≥75% and <90% QoL improvement and/or patient reporting continent status as significantly improved;	Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (sealed, opaque envelopes used but no further information provided) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk for 24 month data (no dropouts at 24 months; missing data at 36 months not sufficient to have clinically relevant impact on effect estimate)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>144057</p> <p>Country/ies where the study was carried out UK</p> <p>Study type RCT</p> <p>Aim of the study To compare Pelvicol sling with TVT on subjective outcomes and complications in women with urodynamically-proven stress incontinence</p> <p>Study dates Not reported, 24 month trial duration</p> <p>Source of funding None reported</p>	<p>TVT: 37</p> <p>Fascial sling: 26</p> <p>Inclusion criteria Women with urodynamically-proven stress incontinence who have had unsuccessful conservative treatment</p> <p>Exclusion criteria Women in whom bladder surgery is contraindicated (detrusor instability) unhappy with being randomised</p>			<p>QoL scale used not stated) - n/N</p> <p>TVT: 7/68</p> <p>Fascial sling: 10/74</p> <p>Improvement at 36 months - n/N</p> <p>TVT: 3/60</p> <p>Fascial sling: 7/68</p> <p>Adverse events - severe bleeding requiring blood transfusion - n/N</p> <p>TVT: 0/60</p> <p>Fascial sling: 0/68</p> <p>Adverse events - urethral injury - n/N</p> <p>TVT: 0/60</p> <p>Fascial sling: 0/68</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 0/60</p> <p>Fascial sling: 0/68</p> <p>Complications</p> <p>Pain (including dyspareunia) at 24 months - n/N</p> <p>TVT: 0/68</p> <p>Fascial sling: 1/74</p> <p>Pain (including dyspareunia) at 36 months - n/N</p>	<p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information Three-year follow-up data reported in Abdel-Fattah et al. 2004</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TVT: 3/60 Fascial sling: 1/68 Infection at 24 months - n/N TVT: 1/68 Fascial sling: 0/74 Infection at 36 months- n/N TVT: 1/68 Fascial sling: 0/74 Need for catheterisation within 6 weeks postop - n/N TVT: 3/68 Fascial sling: 2/74 Need for catheterisation at 24 months - n/N TVT: 3/68 Fascial sling: 1/74 De novo OAB - de novo urgency at 36 months - n/N TVT: 9/60 Fascial sling: 12/68 De novo OAB - de novo urge incontinence at 6 months - n/N TVT: 6/68 Fascial sling: 4/74	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Bai,S.W., Sohn,W.H., Chung,D.J., Park,J.H., Kim,S.K., Comparison of the efficacy of Burch colposuspensio n, pubovaginal sling, and tension-free vaginal tape for stress urinary incontinence, International Journal of Gynaecology and Obstetrics, 91, 246-251, 2005 Ref Id 100553 Country/ies where the study was carried out South Korea Study type RCT</p>	<p>Sample size N=92 randomised Intervention 1 (TVT), n=31 Intervention 2 (fascial sling), n=28 Control (colposuspension), n=33  Characteristics Age (years) - mean ±SD Synthetic sling: 58.2 (3.3) Fascial sling: 56.3 (2.9) Colposuspension: 56.5 (3.1) BMI - mean ±SD Synthetic sling: 29.3 (3.3) Fascial sling: 28.5 (6.1) Colposuspension: 28.1 (4.7) Parity - mean ±SD Synthetic sling: 2.9 (1.8) Fascial sling: 3.1 (1.3)</p>	<p>Interventions Intervention 1: Synthetic sling Intervention 2: Autologous fascial sling Control: Colposuspension</p>	<p>Details All procedures performed by same surgeon. Follow up: 1 year Synthetic sling (TVT) Procedure conducted as described by Ulmsten et al. 1996. Fascial sling (autologous rectus fascia) Fascial sling procedure conducted as described by Ulmsten et al. 1996. Colposuspension Open Burch procedure conducted as described by Ulmsten et al. 1996.</p>	<p>Results Cure at 6-mo FU (self- reported absence of leakage, and no leakage on stress test with bladder full 300 ml followed by stimulation) - n/N Synthetic sling: 29/31 Fascial sling: 26/28 Colposuspension: 30/33 Cure at 1-year FU - n/N Synthetic sling: 27/31 Fascial sling: 26/28 Colposuspension: 29/33 No relevant complications reported.</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Un clear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no dropouts in either arm) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To compare cure rate and confirm clinical efficacy of Burch colposuspension, autologous rectus pubovaginal fascial sling, and TVT in women with SUI</p> <p>Study dates 01/2001 to 05/2003</p> <p>Source of funding Not reported</p>	<p>Colposuspension: 27 (1.2) Menopause (%) Synthetic sling: 23 Fascial sling: 29 Colposuspension: 21</p> <p>Inclusion criteria Women Grade 1 or 2 SUI</p> <p>Exclusion criteria Women with detrusor overactivity urinary tract infections intrinsic sphincter deficiency POP stage&gt;2</p>				
<p>Full citation Ballester, M., Bui, C., Frobert, J. L., Grisard-Anaf, M., Lienhart, J., Fernandez, H., David-Montefiore, E., Rouzier, R.,</p>	<p>Sample size N=88 randomised Intervention, n=42 Control, n=46</p> <p>Characteristics See entry for David-Montefiore et al. 2006 for further details</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details See entry for David-Montefiore et al. 2006 for further details</p>	<p>Results See entry for David-Montefiore et al. 2006 for further details</p>	<p>Limitations See entry for David-Montefiore et al. 2006 for further details</p> <p>Other information Original study reported in David-Montefiore et al. 2006; Functional outcomes and quality of</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Darai, E., Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicentre study comparing the retropubic and transobturator routes, World Journal of Urology, 30, 117-22, 2012</p> <p>Ref Id 542592</p> <p>Country/ies where the study was carried out France</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To report 4-year long-term outcomes of</p>	<p>Inclusion criteria See entry for David-Montefiore et al. 2006 for further details</p> <p>Exclusion criteria See entry for David-Montefiore et al. 2006 for further details</p>				<p>life outcomes at 10 months reported in Darai et al. 2007.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
retropubic and transobturator slings in women with SUI  Study dates 03/2004 to 05/2005  Source of funding Not reported					
Full citation Bandarian,M., Ghanbari,Z., Asgari,A., Comparison of transobturator tape (TOT) vs Burch method in treatment of stress urinary incontinence, Journal of Obstetrics and Gynaecology, 31, 518-520, 2011 Ref Id 135083	Sample size N=62 randomised Intervention, n=31 Control, n=31  Characteristics Age (years) - mean ±SD Synthetic sling: 49.39 (12.59) Colposuspension: 46.94 (8.98) Parity - mean ±SD Synthetic sling: 5.9 (3.09) Colposuspension: 5.35 (2.44)	Interventions Intervention: Synthetic sling Control: Colposuspension	Details All procedures performed by one surgeon. patients discharged when post-voiding residue <100ml. Synthetic sling (TOT) Procedure performed as described by Delorme 2001. Mean FU: 22 months (range 8-26) Colposuspension Burch colposuspension performed as described by Ulmsten & Petros 1995. Mean FU: 28 months (range 12-38)	Results Subjective cure(no self- reported urinary incontinence) - n/N Synthetic sling: 28/31 Colposuspension: 23/31 Improvement (number cured + number with urinary incontinence <1 every 2 weeks) - n/N Synthetic sling: 31/31 Colposuspension: 29/31 Adverse events - bladder injury - n/N Synthetic sling: 0/31 Colposuspension: 0/31	Limitations Random sequence generation: Unclear risk (states simple randomisation but no further details) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Un clear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out Iran</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy of TOT to Burch colposuspension in treatment of women with SUI</p> <p>Study dates 2002 to 2006</p> <p>Source of funding Not reported</p>	<p>Postmenopausal (%) Synthetic sling: 36 Colposuspension: 16</p> <p>Inclusion criteria Women with proven SUI had no previous SUI surgery who did not respond to medical or conservative treatment</p> <p>Exclusion criteria Women with chronic disease (e.g. collagen vascular disease) with neuropathy, coagulopathy or history of urogenital cancer who were pregnant with history of pelvic radiation with urge incontinence urodynamic detrusor overactivity POP-Q stage <math>\geq 2</math> genital prolapse</p>			<p>Complications at &gt;1 year to <math>\leq 5</math> year FU Mesh extrusion - n/N Synthetic sling: 1/31 Colposuspension: 0/31 Infection (urinary tract/wound): Synthetic sling: 0/31 Colposuspension: 3/31</p>	<p>Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Barber,M.D., Kleeman,S., Karram,M.M., Paraiso,M.F.R., Walters,M.D., Vasavada,S., Ellerkmann,M., Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: A randomized controlled trial, Obstetrics and Gynecology, 111, 611-621, 2008</p> <p>Ref Id 135923</p> <p>Country/ies where the study was carried out USA</p> <p>Study type Multicentre RCT</p>	<p>Sample size N=170 randomised Intervention, n=88 Control, n=82</p> <p>Characteristics Age (years) - mean ±SD Retropubic sling: 52 (11) Transobturator sling: 53 (12) BMI - mean ±SD Retropubic sling: 30 (7) Transobturator sling: 29 (6) Parity - median (range) Retropubic sling: 2 (0–6) Transobturator sling: 2 (0–8) Concomitant urge symptoms (%) Retropubic sling: 76 Transobturator sling: 66</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details ClinicalTrials.gov, NCT00475839. All surgeons had performed at least 10 TVT operations, anaesthetic method at their discretion. Intraoperative cystoscopy performed in all cases with concomitant surgery performed at discretion of surgeon (but declared before randomisation). Mean FU=18.2 (6) months. Retropubic sling (TVT) Gynecare TVT, procedure as described by manufacturer. Transobturator sling (TOT) Monarc (AMS) TOT used, procedure as described by manufacturer.</p>	<p>Results Objective cure at 2 years (negative cough stress test) - n/N Retropubic sling: 73/88 Transobturator sling: 62/82 Subjective cure at 2 years (ISI score=0) - n/N Retropubic sling: 50/88 Transobturator sling: 48/82 Improvement at 2 years (response of 'very much' or 'much' better on PGIII) - n/N Retropubic sling: 63/88 Transobturator sling: 61/82 Adverse events - bladder injury - n/N Retropubic sling: 7/88 Transobturator sling: 0/82 Adverse events - bowel injury Retropubic sling: 0/88 Transobturator sling: 0/82</p>	<p>Limitations Random sequence generation: Low risk (computer-generated random block randomisation) Allocation concealment: Low risk (sequentially numbered, opaque, sealed envelopes used) Blinding of participants/personnel: Un clear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (missing data similar across groups, not sufficient to induce clinically relevant impact on effect size) Selective reporting: Low risk (protocol available, all relevant outcomes reported)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To evaluate whether TOT is not inferior to TVT in treatment of SUI in women with or without co-occurrent POP</p> <p>Study dates 11/2004 to 01/2006</p> <p>Source of funding Partly funded by research grant from American Medical Systems, Minnetonka, MN, USA</p>	<p>Inclusion criteria Women with urodynamic stress urinary incontinence on multi-channel urodynamic testing ≥21 years-old desired surgical correction of their incontinence</p> <p>Exclusion criteria Women with detrusor overactivity on urodynamic testing who had a postvoid residual volume &gt;100 ml who had previous sling procedure desire to childbear with history of hidradenitis suppurativa, inguinal lymphadenopathy, or an inguinal or vulvar mass with history of bleeding diathesis or currently</p>			<p>Adverse events - severe bleeding requiring blood transfusion - n/N</p> <p>Retropubic sling: 1/88 Transobturator sling: 0/82</p> <p>Repeat surgery for SUI at 2 years Retropubic sling: 1/85 Transobturator sling: 0/77</p> <p>Complications at 2 years Pain at 2 years - n/N Retropubic sling: 2/85 Transobturator sling: 3/77</p> <p>Mesh extrusion at 2 years - n/N Retropubic sling: 5/85 Transobturator sling: 1/77</p> <p>Infection (UTI) at 1 year (within 6-wks postop) - n/N Retropubic sling: 12/88 Transobturator sling: 11/82</p>	<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	on anticoagulation therapy who had a current genitourinary fistula or urethral diverticulum contraindication for surgery			Need for catheterisation at 2 years - n/N Retropubic sling: 4/85 Transobturator sling: 2/77	
Full citation Barber,M.D., Weidner,A.C., Sokol,A.I., Amundsen,C.L., Jelovsek,J.E., Karram,M.M., Ellerkmann,M., Rardin,C.R., Iglesia,C.B., Toglia,M., Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: A randomized controlled trial, Obstetrics and gynecology,	Sample size N=263 randomised Intervention, n=136 Control, n=127  Characteristics Age (years) - mean $\pm$ SD TVT-Secur: 54.6 (10.5) TVT: 54.6 (11.3) BMI - mean $\pm$ SD TVT-Secur: 29.6 (6.4) TVT: 30 (5.7) Parity - median (range) TVT-Secur: 2 (0-6) TVT: 2 (0-6)  Inclusion criteria Women	Interventions Intervention: Single-incision mini-sling Control: Other Synthetic sling	Details All surgeons who performed procedures had performed at least 5 minisling operations before study. Anaesthetic methods left to surgeon discretion. Cystoscopy performed in all cases at end of procedure with concomitant surgery at discretion of operating surgeon (but declared before randomisation). Single-incision mini-sling (TVT-Secur-U) Gynecare TVT-Secur used, procedure according to manufacturer's instructions. Other Synthetic sling (TVT) Gynecare TVT used, procedure according to manufacturer's instructions.	Results Subjective cure at 1-year FU (Incontinence severity index score=0 and no retreatment for SUI) - n/N TVT-Secur: 77/136 TVT: 77/127 Incontinence episodes per day - n (range) TVT-Secur: 0 (0-1.8) TVT: 0 (0-1) Improvement at 1 year FU (Response of 'very much better' or 'much better' on PGII) - n/N TVT-Secur: 87/136 TVT: 91/127 Adverse events - bladder injury - n/N TVT-Secur: 1/136 TVT: 6/127	Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Low risk (consecutively numbered, sealed, opaque envelopes used) Blinding of participants/personnel: Low risk (participants masked to group assignment through use of 'sham' incisions) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (ITT analysis for main outcomes; missing data not likely to have

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>119, 328-337, 2012 Ref Id 188330 Country/ies where the study was carried out USA Study type Multicentre RCT  Aim of the study To compare efficacy of TVT-Secur-U with TVT in women with SUI and with or without concurrent POP  Study dates 08/2007 to 03/2010  Source of funding Funded by grant from Foundation for Female Health Awareness</p>	<p>≥21 years-old with urodynamically-proven SUI on multichannel urodynamic testing desired SUI surgery  Exclusion criteria Women with detrusor overactivity on urodynamic testing with postvoid residual volume &gt; 100 mL history of previous synthetic, biologic, or fascial suburethral sling surgery who desire childbearing currently using anticoagulation therapy or had a known bleeding diathesis who had current urethral diverticulum or fistula of the lower urinary tract</p>			<p>Adverse events - bowel injury - n/N TVT-Secur: 1/136 TVT: 2//127 Adverse events - severe bleeding requiring blood transfusion - n/N TVT-Secur: 1/136 TVT: 0/127 Repeat surgery for UI - n/N TVT-Secur: 2/136 TVT: 4/127 Repeat surgery for POP - n/N TVT-Secur: 2/136 TVT: 3/127 Repeat surgery for mesh complications - n/N TVT-Secur: 0/136 TVT: 1/127 Continence-specific health-related QoL - Mean ISI score at 1 year ±SD TVT-Secur: 2.2 (2.7), n=134 TVT: 1.5 (1.9), n=126</p>	<p>relevant impact on effect estimate) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	contraindication for surgery			Complications>6 weeks to 1-year FU - n/N Pain: 1/136; 0/127 Mesh extrusion TVT-Secur: 0/136 TVT: 1/127 Fistula TVT-Secur: 0/136 TVT: 0/127	
Full citation Barry,C., Lim,Y.N., Muller,R., Hitchins,S., Corstiaans,A., Foote,A., Greenland,H., Frazer,M., Rane,A., A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling	Sample size N=187 randomised Intervention, n=107 Control, n=80  Characteristics Age (years) - mean ±SD TVT: 53.6 (12.1) TOT: 54.2 (11.4) BMI - mean ±SD TVT: 28.4 (5.4) TOT: 28.5 (5.8) Parity - mean ±SD TVT: 2.7 (1.4) TOT: 2.9 (1.1) Postmenopausal (%) TVT: 44	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details Experienced surgeons (>20 procedures in each technique). Catheter not routinely placed unless bladder injury occurred. Retropubic sling (TVT) Gynecare TVT used, conducted as described by Ulmsten et al. 1996 except type of anaesthesia determined by surgeon. Transobturator sling (TOT) Monarc (AMS) sling used. Sling tension standardised using either cough test or Crede manoeuvre with 300ml full bladder.	Results Objective cure at 3-mo (negative cough stress test in supine or standing position with 300 ml full bladder) - n/N TVT: 64/107 TOT: 48/80 Improvement at 3-mo (Satisfied according to BFLUTS) - n/N TVT: 70/107 TOT: 48/80 BFLUTS QoL: difference between groups, p=0.4, TVT, n=82, TOT, n=58 Repeat surgery for mesh complications - n/N TVT: 0/82	Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Low risk (participants blinded to group assignment) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data similar in both groups and for similar reasons)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>treatment of urodynamic stress incontinence: the TORP study, International Urogynecology Journal, 19, 171-178, 2008</p> <p>Ref Id 100557</p> <p>Country/ies where the study was carried out Australia</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare safety and efficacy of TOT to TVT in women with urodynamic stress incontinence</p> <p>Study dates 07/2004 to 10/2005</p>	<p>TOT: 31</p> <p>Inclusion criteria Women who failed conservative management for symptomatic stress incontinence or required prophylactic incontinence surgery during prolapse repair for occult stress incontinence</p> <p>Exclusion criteria Women with significant voiding dysfunction (maximum urine flow rate &lt;10th percentile according to Liverpool nomogram and post-void residual volume &gt;50 ml) with known allergy to polypropylene receiving immunosuppressant therapy with past history of neurological disease, urogenital</p>			<p>TOT: 1/58</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 7/82</p> <p>TOT: 0/58</p> <p>Adverse events - bowel injury - n/N</p> <p>TVT: 0/82</p> <p>TOT: 0/58</p> <p>Complications at 3-mo FU - n/N</p> <p>Mesh extrusion</p> <p>TVT: 1/82</p> <p>TOT: 3/58</p> <p>Infection (UTI)</p> <p>TVT: 11/82</p> <p>TOT: 9/58</p> <p>De novo OAB</p> <p>TVT: 1/82</p> <p>TOT: 0/58</p>	<p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported	malignancy, fistula or pelvic radiotherapy				
Full citation Basok,E.K., Yildirim,A., Atsu,N., Basaran,A., Tokuc,R., Cadaveric fascia lata versus intravaginal slingplasty for the pubovaginal sling: surgical outcome, overall success and patient satisfaction rates, Urologia Internationalis, 80, 46-51, 2008 Ref Id 100559 Country/ies where the study was carried out Turkey Study type	Sample size N=139 randomised Intervention, n=72 Control, n=67  Characteristics Age (years) - mean $\pm$ SD Synthetic sling: 50.3 (9) Biological sling: 47.4 (10.4) BMI - mean $\pm$ SD Synthetic sling: 29.2 (3.5) Biological sling: 28.3 (2.6) Mixed UI (%) Synthetic sling: 61 Biological sling: 73  Inclusion criteria Women	Interventions Intervention: Synthetic sling Control: Non-autologous biological sling	Details All procedures conducted under general or regional anaesthetic. Follow up: 12 months Synthetic sling/mesh (retropubic intravaginal slingplasty) 8mm non-absorbable multifilament polypropylene IVS mesh (IVS Tunneller, Tyco) used. Biological sling (cadaveric fascia lata) 2 x 20 cm solvent-dehydrated cadaveric fascia lata (Tutogen Medical GmbH) sling used with 2 polypropylene sutures tied above rectus fascia.	Results Objective cure at 12-mo FU (Totally dry patient on pad test) - n/N Synthetic sling: 34/72 Biological sling: 35/67 Improvement at 12-mo FU (Number cured + number who use of 1 pad/day on pad test) - n/N Synthetic sling: 51/72 Biological sling: 53/67 Satisfaction - n/N Synthetic sling: 63/72 Biological sling: 55/67 Adverse events - bladder injury - n/N Synthetic sling: 8/72 Biological sling: 3/67 Repeat surgery - n/N Synthetic sling: 0/72 Biological sling: 2/67	Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no dropouts in either group) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>RCT</p> <p>Aim of the study To evaluate effectiveness of cadaveric fascia lata pubvaginal sling compared to (retropubic) intravaginal slingplasty in women with SUI</p> <p>Study dates Not reported</p> <p>Source of funding Not reported</p>	<p>with SUI due to urethral hypermobility</p> <p>Exclusion criteria Women with intrinsic sphincter deficiency uterine prolapse rectocele enterocele grade III or IV cystocele</p>			<p>Complications at 12 months FU - n/N</p> <p>Mesh extrusion Synthetic sling: 0/72 Biological sling: 0/67</p> <p>Need for catheterisation Synthetic sling: 8/72 Biological sling: 8/67</p> <p>Infection Synthetic sling: 0/72 Biological sling: 0/67</p> <p>De novo OAB - urge urinary incontinence Synthetic sling: 18/72 Biological sling: 45/67</p> <p>De novo - OAB - de novo detrusor overactivity Synthetic sling: 5/72 Biological sling: 15/67</p> <p>Wound complication Synthetic sling: 0/72 Biological sling: 0/67</p>	
<p>Full citation Basu,M., Duckett,J., A randomised trial of a retropubic</p>	<p>Sample size N=71 randomised Intervention, n=38 Control, n=33</p>	<p>Interventions Intervention: Single-incision mini-sling</p>	<p>Details Procedures conducted under general or regional anaesthesia depending on patient choice with majority having former. Cystoscopy</p>	<p>Results Note: data for 3-year outcomes from Basu et al. 2013.</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block randomisation)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>tension-free vaginal tape versus a mini-sling for stress incontinence, BJOG: An International Journal of Obstetrics and Gynaecology, 117, 730-735, 2010</p> <p>Ref Id 100560</p> <p>Country/ies where the study was carried out UK</p> <p>Study type RCT</p> <p>Aim of the study To compare mini-sling to TVT in treatment of SUI and urodynamic SI in women</p> <p>Study dates</p>	<p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>MiniArc: 49.7 (10.7)</p> <p>TVT: 48.2 (9.4)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>MiniArc: 30.1 (7.6)</p> <p>TVT: 28.2 (5.6)</p> <p>Parity - median</p> <p>MiniArc: 2</p> <p>TVT: 2</p> <p>Postmenopausal (%)</p> <p>MiniArc: 32</p> <p>TVT: 27</p> <p>Inclusion criteria</p> <p>Women with SUI symptoms and objective evidence of urodynamic SI who failed conservative treatment deemed suitable for a continence procedure</p> <p>Exclusion criteria</p> <p>Women</p>	<p>Control: Other synthetic sling</p>	<p>performed in all cases. Patients discharged if post-void residual &lt;100ml. Follow up at 6 months and 3 years.</p> <p>Single-incision mini-sling (MiniArc)</p> <p>MiniArc (AMS) used, 8 cm macroporous polypropylene tape passed into obturator via 1cm incision below external urethral meatus and anchored via self-fixating tips at both ends.</p> <p>Other synthetic sling (TVT)</p> <p>Advantage TVT (Boston Scientific) used and procedure conducted as described by Ulmsten &amp; Petros 1995.</p>	<p>Objective cure at 6 months (no USI on urodynamic testing) - n/N</p> <p>MiniArc: 24/38</p> <p>TVT: 29/33</p> <p>Subjective cure at 6 months (No SUI according to KHQ and self-report) - n/N</p> <p>MiniArc: 22/38</p> <p>TVT: 32/33</p> <p>Subjective cure at 3 years - n/N</p> <p>MiniArc: 18/38</p> <p>TVT: 30/33</p> <p>Adverse events - bladder injury - n/N</p> <p>MiniArc: 0/38</p> <p>TVT: 0/33</p> <p>Repeat surgery for mesh complications at 6-months - n/N</p> <p>MiniArc: 2/38</p> <p>TVT: 0/33</p> <p>Repeat surgery for SUI at 6-months - n/N</p> <p>MiniArc: 9/38</p> <p>TVT: 0/33</p>	<p>Allocation concealment: Unclear risk (opaque envelopes used but no further information)</p> <p>Blinding of participants/personnel: Low risk (participants blinded to group assignment)</p> <p>Blinding of outcome assessment: Unclear risk for 6-mo outcomes (insufficient information); Low risk for 3-year outcomes (self-reported outcomes only)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient of have clinically-relevant impact on effect estimates)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p> <p>Three-year follow-up data reported in Basu et al. 2013.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
01/2008 to 02/2009  Source of funding Funded by grant from American Medical Systems.	with history of previous continence surgery  evidence of voiding dysfunction known bladder pathology, prolapse of POP-Q $\geq$ 2 recurrent urinary tract infections planning to conceive			Repeat surgery for SUI at 3-years - n/N MiniArc: 9/38 TVT: 0/33 King's Health Questionnaire at 3 years (MiniArc, n=35; TVT, n=26) - mean differences $\pm$ SD Note:MD and SDs below calculated from reported pre- and post- scores and within-group p-values as SDs for these values not reported Role limitations: MiniArc -46.7 (378.13); TVT -79.89 (88.19) Physical limitations: MiniArc -41.7 (115.52); TVT -82.2 (127.51) Social limitations: MiniArc -27.8 (67.37); TVT -34.6 (57.31) Personal relationships: MiniArc -27.8 (77.01); TVT -53.6 (126.15) Emotions: MiniArc -8.8 (27.83); TVT -15.9 (37.42)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Sleep/energy: MiniArc +0.7 (7.61); TVT -2.8 (13.21)</p> <p>Severity: MinArc -18.6 (56.56); TVT -69.6 (115.29)</p> <p>Complications - n/N</p> <p>Mesh extrusion at 6-months</p> <p>MiniArc: 2/37</p> <p>TVT: 0/33</p> <p>Need for catheterisation at 6-months</p> <p>MiniArc: 2/37</p> <p>TVT: 2/33</p> <p>De novo detrusor overactivity at 6-mo</p> <p>MiniArc: 2; 37</p> <p>TVT: 2/33</p>	
<p>Full citation</p> <p>Basu, M., Duckett, J., Three-year results from a randomised trial of a retropubic mid-urethral sling versus the Miniarc single incision mini-</p>	<p>Sample size</p> <p>N=71 randomised</p> <p>Intervention, n=38</p> <p>Control, n=33</p> <p>Characteristics</p> <p>See entry for Basu et al. 2010 for further details.</p>	<p>Interventions</p> <p>Intervention: Single-incision mini-sling</p> <p>Control: Other synthetic sling</p>	<p>Details</p> <p>See entry for Basu et al. 2010 for further details.</p>	<p>Results</p> <p>See entry for Basu et al. 2010 for further details.</p>	<p>Limitations</p> <p>See entry for Basu et al. 2010 for further details.</p> <p>Other information</p> <p>3-year follow up study to Basu et al. 2010.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>slings for stress urinary incontinence, International Urogynecology Journal, 24, 2059-64, 2013</p> <p>Ref Id 542601</p> <p>Country/ies where the study was carried out Uk</p> <p>Study type RCT</p> <p>Aim of the study To report 3-year outcomes of MiniArc single-incision sling compared to TVT in women with SUI and USI</p> <p>Study dates 01/2008 to 02/2009</p>	<p>Inclusion criteria See entry for Basu et al. 2010 for further details.</p> <p>Exclusion criteria See entry for Basu et al. 2010 for further details.</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Funded by grant from American Medical Systems.					
Full citation Bianchi-Ferraro, A. M., Jarmy-DiBella, Z. I., de Aquino Castro, R., Bortolini, M. A., Sartori, M. G., Girao, M. J., Randomized controlled trial comparing TVT-O and TVT-S for the treatment of stress urinary incontinence: 2-year results, International Urogynecology Journal, 25, 1343-8, 2014 Ref Id 541277 Country/ies where the study was carried out	Sample size N=122 randomised Intervention, n=66 Control, n=56  Characteristics See entry for Biancho-Ferraro et al. 2013 for more details.  Inclusion criteria See entry for Biancho-Ferraro et al. 2013 for more details.  Exclusion criteria See entry for Biancho-Ferraro et al. 2013 for more details.	Interventions Intervention: Single-incision mini-sling Control: Other Synthetic sling	Details See entry for Biancho-Ferraro et al. 2013 for more details.	Results See entry for Biancho-Ferraro et al. 2013 for more details.	Limitations See entry for Biancho-Ferraro et al. 2013 for more details.  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Brazil</p> <p>Study type RCT</p> <p>Aim of the study To compare 2-year FU cure rates of TVT-Secur-U with TVT-O in women with SUI</p> <p>Study dates Start date of 02/2009; unknown whether trial has been completed</p> <p>Source of funding Funded by Federal University of Sao Paulo</p>					
<p>Full citation Bianchi-Ferraro, A. M. H. M., Bella, Z. I. K. J. D., De, A.</p>	<p>Sample size N=122 randomised Intervention, n=66 Control, n=56</p>	<p>Interventions Intervention: Single-incision mini-sling</p>	<p>Details Clinicaltrials.gov, NCT 01095159. Procedures performed by 5 surgeons, all of which were experienced in TVT-O and also had</p>	<p>Results Note: 2-year FU data from Bianchi-Ferraro et al. 2014.</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Castro R., Bortolini, M. A. T., Sartori, M. G. F., Girao, M. J. B. C., Single-incision sling compared with transobturator sling for treating stress urinary incontinence: A randomized controlled trial, International Urogynecology Journal, 24, 1459-1465, 2013</p> <p>Ref Id 631258</p> <p>Country/ies where the study was carried out Brazil</p> <p>Study type RCT</p> <p>Aim of the study To compare cure rates of TVT-Secur-U</p>	<p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>TVT-Secur: 54.05 (11.37)</p> <p>TVT-O: 52.13 (8.79)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>TVT-Secur: 29.84 (5.35)</p> <p>TVT-O: 30.02 (4.69)</p> <p>Parity - n (range)</p> <p>TVT-Secur: 4 (0-13)</p> <p>TVT-O: 3 (0-15)</p> <p>Inclusion criteria</p> <p>Women with clinically and urodynamically-confirmed stress urinary incontinence</p> <p>Exclusion criteria</p> <p>Women with Detrusor overactivity (urodynamic study)</p> <p>Urodynamic changes suggesting reduced vesical capacity</p>	<p>Control: Other Synthetic sling</p>	<p>performed at least 5 TVT-S procedures before study. Cystoscopy performed only if suspicion of bladder injury at time of operation or during FU if postop irritative urinary symptoms/recurrent UTI. All participants received prophylactic antibiotics cefazolin and metronidazole 1 hour before surgery.</p> <p>Single-incision mini-sling (TVT-Secur-U)</p> <p>Gynecare TVT-Secur used under local anaesthetic and iv sedation, or under spinal anaesthesia.</p> <p>Other Synthetic sling (TVT-O)</p> <p>Gynecare TVT-O used</p>	<p>Objective cure at 1 year (negative stress test, negative pad test, and no leakage on urodynamic assessment) - n/N</p> <p>TVT-Secur: 53/66</p> <p>TVT-O: 47/56</p> <p>Objective cure at 2 years - n/N</p> <p>TVT-Secur: 51/66</p> <p>TVT-O: 48/56</p> <p>Subjective cure at 1 year (no leakage as assessed by KHQ score=0) - n/N</p> <p>TVT-Secur: 58/66</p> <p>TVT-O: 49/56</p> <p>Subjective cure at 2 years - n/N</p> <p>TVT-Secur: 50/66</p> <p>TVT-O: 45/56</p> <p>Repeat surgery at 2 years for SUI - n/N</p> <p>TVT-Secur: 1/66</p> <p>TVT-O: 1/56</p> <p>Repeat surgery for mesh complications at <math>\leq</math>1 year - n/N</p> <p>TVT-Secur: 2/66</p>	<p>Allocation concealment: Low risk (investigator enrolling participants had no contact with patients and no information about their status)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to make clinically relevant impact on effect estimates)</p> <p>Selective reporting: Unclear risk (protocol available but insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p> <p>2-year follow up data reported in Bianchi-Ferraro et al. 2014.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>with TVT-O in women with SU1</p> <p>Study dates Start date of 02/2009; unknown whether trial has been completed</p> <p>Source of funding Funded by Federal University of Sao Paulo</p>	<p>Associated neurological diseases</p> <p>Coagulopathies</p> <p>Pregnancy</p> <p>Foreign matter sensitiveness history</p> <p>Acute urinary tract infection</p> <p>Sequel from high ionizing radiation exposure</p> <p>Use of drugs that may result in high surgical risk and/or significant postoperative complication</p> <p>Anesthetic procedure contraindication</p> <p>Vulvovaginitis: presence of vaginal secretion with infection clinically or lab supported</p>			<p>TVT-O: 1/56</p> <p>Repeat surgery for mesh complications at &gt;1 year to ≤2 years - n/N</p> <p>TVT-Secur: 3/66</p> <p>TVT-O: 2/56</p> <p>KHQ scores at 2 years (TVT-S-U, n=61; TVT-O, n=54) - mean ±SD</p> <p>General health perception:</p> <p>TVT-Secur: 22.1 (14.65)</p> <p>TVT-O: 22.69 (19.59)</p> <p>Incontinence impact:</p> <p>TVT-Secur: 5.48 (18.44)</p> <p>TVT-O: 4.44 (17.19)</p> <p>Role limitation:</p> <p>TVT-Secur: 3.55 (13.30)</p> <p>TVT-O: 3.40 (16.31)</p> <p>Physical limitation:</p> <p>TVT-Secur: 3.28 (11.71)</p> <p>TVT-O: 2.78 (11.10)</p> <p>Social limitation:</p> <p>TVT-Secur: 0.64 (2.89)</p> <p>TVT-O: 1.03 (5.40)</p> <p>Personal relationships:</p> <p>TVT-Secur: 0.00 (0.00)</p> <p>TVT-O: 0.42 (2.27)</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Emotions: TVT-Secur: 3.28(13.66) TVT-O: 3.70 (16.44) Sleep/energy: TVT-Secur: 0.00 (0.00) TVT-O: 2.78 (15.10) Severity measures: TVT-Secur: 5.46 (14.42) TVT-O: 5.25 (15.30) Complications - n/N Pain at ≤6 months TVT-Secur: 1/66 TVT-O: 15/56 Pain at >1 year to ≤2 years TVT-Secur: 0/66; 1/56 Mesh extrusion at ≤1 year TVT-Secur: 2/66 TVT-O: 1/56 Mesh extrusion at >1 year to ≤2 years TVT-Secur: 3/66 TVT-O: 2/56 Need for catheterisation at ≤6 months TVT-Secur: 2/66 TVT-O: 2/56	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Infection (UTI) at $\leq 1$ year TVT-Secur: 3/66 TVT-O: 4/56 Infection (UTI) at $>1$ year to $\leq 2$ years TVT-Secur: 0/66 TVT-O: 0/56 De novo OAB - de novo urge at $\leq 1$ year TVT-Secur: 1/66 TVT-O: 2/56 De novo OAB - de novo urge at $>1$ year to $\leq 2$ years TVT-Secur: 0/66 TVT-O: 0/56	
Full citation Brubaker, L., Norton, P. A., Albo, M. E., Chai, T. C., Dandreo, K. J., Lloyd, K. L., Lowder, J. L., Sirls, L. T., Lemack, G. E., Arisco, A. M., Xu, Y., Kusek, J. W., Urinary	Sample size N=597 randomised Intervention, n=298 Control, n=299  Characteristics See entry for Richter et al. 2010 for more details  Inclusion criteria	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details See entry for Richter et al. 2010 for more details	Results See entry for Richter et al. 2010 for more details	Limitations See entry for Richter et al. 2010 for more details  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Incontinence Treatment, Network, Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study, American Journal of Obstetrics &amp; GynecologyAm J Obstet Gynecol, 205, 498.e1-6, 2011</p> <p>Ref Id 673728</p> <p>Country/ies where the study was carried out USA</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To report &gt;2-year complications of</p>	<p>See entry for Richter et al. 2010 for more details</p> <p>Exclusion criteria See entry for Richter et al. 2010 for more details</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>retropubic compared to transobturator slings in women with SUI</p> <p>Study dates 04/2006 to 06/2008</p> <p>Source of funding Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231, U01 DK60379, U01 DK60380, U01 DK60393, U01 DK60395, U01 DK60397, and U01 DK60401) from the National Institute of Diabetes and Digestive and Kidney Diseases and by</p>					

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
the National Institute of Child Health and Human Development. Partly funded by NIH grants to 4 authors.					
Full citation Brubaker, L., Richter, H. E., Norton, P. A., Albo, M., Zyczynski, H. M., Chai, T. C., Zimmern, P., Kraus, S., Sirls, L., Kusek, J. W., Stoddard, A., Tennstedt, S., Gormley, E. A., 5-year continence rates, satisfaction and adverse events of burch urethropexy and fascial sling surgery for urinary incontinence,	Sample size  Characteristics  Inclusion criteria  Exclusion criteria	Interventions	Details	Results	Limitations  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Journal of Urology, 187, 1324-1330, 2012 Ref Id 673729 Country/ies where the study was carried out Study type  Aim of the study  Study dates  Source of funding</p>					
<p>Full citation Carey, M. P., Goh, J. T., Rosamilia, A., Cornish, A., Gordon, I., Hawthorne, G., Maher, C. F., Dwyer, P. L., Moran, P., Gilmour, D. T., Laparoscopic versus open</p>	<p>Sample size N=200 randomised Intervention, n=96 Control, n=104  Characteristics Age (years) - mean <math>\pm</math>SD Laparoscopic: 51.0 (9.9), n=96 Open: 52.3 (10.6), n=104</p>	<p>Interventions Intervention: Laparoscopic colposuspension with sutures Control: Open colposuspension with sutures</p>	<p>Details Transurethral Foley catheter removed ~18 hrs after surgery but reinserted if unable to void and/or had residual of more than 150 ml. Standardised anaesthesia protocol and postoperative pain relief protocol with iv patient-controlled analgesia and nonsteroidal anti-inflammatory suppositories used. Seven surgeons performed all procedures with Number 0 braided polyester suture on a CT-2 needle</p>	<p>Results Objective cure at 6 months (# absence of urodynamic stress incontinence) - n/N Laparoscopic: 60/96 Open: 72/104 Subjective cure at 24 months (# not reporting stress incontinence) - n/N Laparoscopic: 48/96</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block randomisation lists, stratified by centre and by women undergoing concomitant rectocele repair) Allocation concealment: Low risk (independent investigator, surgeons/staff informed of</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Burch colposuspension: A randomised controlled trial, BJOG: An International Journal of Obstetrics and Gynaecology, 113, 999-1006, 2006</p> <p>Ref Id 673751</p> <p>Country/ies where the study was carried out Australia</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare laparoscopic with open Burch colposuspension on perioperative characteristics, short- and long-term outcomes in women with urodynamics</p>	<p>BMI - mean <math>\pm</math>SD</p> <p>Laparoscopic: 29.0 (5.7), n=76</p> <p>Open: 28.0 (4.8), n=80</p> <p>Parity - mean <math>\pm</math>SD</p> <p>Laparoscopic: 2.8 (1.3), n=94</p> <p>Open: 2.6 (1.3), n=100</p> <p>POP status: not reported, major degrees of POP excluded</p> <p>Preoperative urge incontinence (n=200, whole sample): 67%</p> <p>Detrusor overactivity at urodynamic testing (n=200, whole sample): 11%</p> <p>Inclusion criteria Women with urodynamic stress incontinence failed conservative therapy</p> <p>Exclusion criteria Women with</p>		<p>(Ethibond) used in both interventions. Follow up: 6 months, 24 months</p> <p>Laparoscopic colposuspension with suture</p> <p>Transperitoneal approach with 2 or 3 sutures used.</p> <p>Open colposuspension</p> <p>2 or 3 sutures used with urethral catheter inserted at end of surgery.</p>	<p>Open: 63/104</p> <p>Adverse events - severe bleeding requiring blood transfusion - n/N</p> <p>Laparoscopic: 0/96</p> <p>Open: 1/104</p> <p>Adverse events - bladder injury - n/N</p> <p>Laparoscopic: 5/96</p> <p>Open: 1/104</p>	<p>group assignment immediately before surgery)</p> <p>Blinding of participants/personnel: Low risk (patients blinded by using one type of dressing and iodine for all operations)</p> <p>Blinding of outcome assessment: Low risk (attempt to blind postop nursing staff by using one type of dressing and iodine for all operations)</p> <p>Incomplete outcome data: Unclear risk (insufficient information)</p> <p>Selective reporting: Low risk (missing data similar across groups for similar reasons)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
stress incontinence  Study dates 01/1997 to 12/1998  Source of funding Supported by research grant from The Royal Women's Hospital, Foundation, Melbourne, Australia	previous retropubic continence surgery maximum urethral closure pressure of 20 cm H <sub>2</sub> O or less medically unsuitable for laparoscopic or open surgery major degrees of coexisting pelvic organ prolapse, requiring surgery other than a simple rectocele repair				
Full citation Chai, T. C., Albo, M. E., Richter, H. E., Norton, P. A., Dandreo, K. J., Kenton, K., Lowder, J. L., Stoddard, A. M., Complications in Women Undergoing Burch Colposuspensio	Sample size  Characteristics  Inclusion criteria  Exclusion criteria	Interventions	Details	Results	Limitations  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>n Versus Autologous Rectus Fascial Sling for Stress Urinary Incontinence, Journal of Urology, 181, 2192-2197, 2009 Ref Id 673761 Country/ies where the study was carried out Study type  Aim of the study  Study dates  Source of funding</p>					
<p>Full citation Cheon, W. C., Mak, J. H. L., Liu, J. Y. S., Prospective randomised controlled trial</p>	<p>Sample size N=90 randomised Intervention, n=47 Control, n=43  Characteristics</p>	<p>Interventions Intervention: Laparoscopic colposuspension with sutures</p>	<p>Details 2 x 1-0 unabsorbable polybutylate- coated polyester sutures (Ethibond) used in both procedures. Antibiotic prophylaxis given to both groups (metronidazole, cefuroxime). Follow up: 1 year</p>	<p>Results Objective cure at 1 year (# dry during cough test) - n/N Laparoscopic: 40/47 Open: 37/43</p>	<p>Limitations Random sequence generation: Low risk (computer-generated random number table) Allocation concealment: Low risk (sealed,</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>comparing laparoscopic and open colposuspension, Hong Kong Medical Journal, 9, 10-14, 2003 Ref Id 609479 Country/ies where the study was carried out Hong Kong, China Study type RCT</p> <p>Aim of the study To compare efficacy, safety, complications and short-term outcomes of laparoscopic vs open colposuspension in women with pure stress incontinence</p> <p>Study dates</p>	<p>Age (years) - mean <math>\pm</math>SD Laparoscopic: 51.1 (9.2) Open: 50.4 (9.2) Parity - mean <math>\pm</math>SD Laparoscopic: 2.7 (1.2) Open: 2.9 (1.2) Concomitant hysterectomy - n/N Laparoscopic: 7/47 Open: 16/43 POP status: not reported</p> <p>Inclusion criteria Women with urodynamically-proven pure stress incontinence</p> <p>Exclusion criteria Women with pathological condition that might limit flexibility of vaginal wall (e.g. reduced</p>	<p>Control: Open colposuspension with sutures</p>	<p>Laparoscopic colposuspension with sutures Both transperitoneal and extraperitoneal approach used. Indwelling catheter inserted and bladder emptied, removed only if satisfactory voiding. All women stayed in hospital until catheters removed. Open colposuspension with sutures Bladder draining using Bornarno suprapubic catheter</p>	<p>Subjective cure at 1 year (# self-reported absence of SUI) - n/N Laparoscopic: 38/47 Open: 37/43 Adverse events - bladder injury - n/N Laparoscopic: 2/47 Open: 0/43 Complications at 6-12 months - n/N Number with de novo detrusor instability Laparoscopic: 12/47 Open: 5/43 Number with dyspareunia - n/N Laparoscopic: 3/47 Open: 4/43 Number with enterocoele - n/N Laparoscopic: 1/47 Open: 2/43 Patient satisfaction (# very satisfied/satisfied/not satisfied) - n Laparoscopic: 14/32/1 Open: 13/28/2</p>	<p>sequentially numbered, opaque envelopes used) Blinding of participants/personnel: Unclear risk (Blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (No missing outcome data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
07/1999 to 08/2001  Source of funding None reported	vaginal capacity or fibrosis) previous anti-continenence surgery or intrinsic sphincter deficiency (resting maximum urethral closure pressure <20 cm H2O or Valsalva leak point pressure <60 cm H2O)				
Full citation Costantini, E., Kocjancic, E., Lazzeri, M., Giannantoni, A., Zucchi, A., Carbone, A., Bini, V., Palleschi, G., Pastore, A. L., Porena, M., Long-term efficacy of the trans-obturator and retropubic mid-urethral slings for stress urinary incontinence:	Sample size N=148 randomised Intervention, n=73 Control, n=75  Characteristics See entry for Porena et al. 2007 for further details.  Inclusion criteria See entry for Porena et al. 2007 for further details.  Exclusion criteria	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details See entry for Porena et al. 2007 for further details.	Results See entry for Porena et al. 2007 for further details.	Limitations See entry for Porena et al. 2007 for further details.  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>update from a randomized clinical trial, World Journal of Urology, 34, 585-93, 2016</p> <p>Ref Id 541328</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type RCT</p> <p>Aim of the study To report 5-year complications, functional outcomes and success rates of TVT and TOT in women with SUI</p> <p>Study dates 05/2003 to 11/2005</p> <p>Source of funding Not reported</p>	<p>See entry for Porena et al. 2007 for further details.</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Culligan, P. J., Goldberg, R. P., Sand, P. K., A randomized controlled trial comparing a modified Burch procedure and a suburethral sling: long-term follow-up, International Urogynecology Journal, 14, 229-33; discussion 233, 2003 Ref Id 541337 Country/ies where the study was carried out Study type  Aim of the study  Study dates	Sample size  Characteristics  Inclusion criteria  Exclusion criteria	Interventions	Details	Results	Limitations  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding					
<p>Full citation</p> <p>Darai, E., Frobert, J. L., Grisard-Anaf, M., Lienhart, J., Fernandez, H., Dubernard, G., David-Montefiore, E., Functional Results After the Suburethral Sling Procedure for Urinary Stress Incontinence: A Prospective Randomized Multicentre Study Comparing the Retropubic and Transobturator Routes, European Urology, 51, 795-802, 2007</p> <p>Ref Id 618505</p>	<p>Sample size</p> <p>N=88 randomised Intervention, n=42 Control, n=46</p> <p>Characteristics</p> <p>See entry for David-Montefiore et al. 2006 for further details</p> <p>Inclusion criteria</p> <p>See entry for David-Montefiore et al. 2006 for further details</p> <p>Exclusion criteria</p> <p>See entry for David-Montefiore et al. 2006 for further details</p>	<p>Interventions</p> <p>Intervention: Retropubic sling</p> <p>Control: Transobturator sling</p>	<p>Details</p> <p>See entry for David-Montefiore et al. 2006 for further details</p>	<p>Results</p> <p>See entry for David-Montefiore et al. 2006 for further details</p>	<p>Limitations</p> <p>See entry for David-Montefiore et al. 2006 for further details</p> <p>Other information</p> <p>Original study reported in David-Montefiore et al. 2006; Four-year follow up results reported in Ballester et al. 2012</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out France</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To report functional outcomes, urodynamic parameters and quality of life of retropubic and tranobturator slings in women with SUI</p> <p>Study dates 03/2004 to 05/2005</p> <p>Source of funding Not reported</p>					
<p>Full citation David-Montefiore, E.,</p>	<p>Sample size N=88 randomised Intervention, n=42</p>	<p>Interventions Intervention: Retropubic sling</p>	<p>Details All surgeons had substantial experience with retropubic sling</p>	<p>Results Note: ~10-mo data from Darai et al. 2007; 4-year</p>	<p>Limitations Random sequence generation: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Frobert,J.L., Grisard-Anaf,M., Lienhart,J., Bonnet,K., Poncelet,C., Darai,E., Peri- operative complications and pain after the suburethral sling procedure for urinary stress incontinence: a French prospective randomised multicentre study comparing the retropubic and transobturator routes, European Urology, , 133- 138, 2006 Ref Id 100780 Country/ies where the study was carried out France</p>	<p>Control, n=46</p> <p>Characteristics Age (years) - mean ±SD TVT: 56.8 (12) TOT: 53.4 (10.5) BMI - mean ±SD TVT: 25 (4) TOT: 26 (4) Nulliparous (%) TVT: 2.4 TOT: 6.5 Postmenopausal (%) TVT: 67 TOT: 59</p> <p>Inclusion criteria Women &gt;18 years-old urodynamically- and clinically-proven SUI</p> <p>Exclusion criteria Women with previous history of radiotherapy or chemotherapy, or anticoagulant or</p>	<p>Control: Transobturator sling</p>	<p>procedures and had performed ≥30 transobturator sling procedures. I-STOP® device used for both procedures, macroporous non- elastic monofilament polypropylene mesh tape. All procedures performed in modified dorsal- lithotomy position. Choice of general or regional anaesthetic made in each centre. Cystoscopy performed in all cases. Discharged when residual urine volume &lt;150ml. Mean short-term FU=~10 mo Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1996. long-term FU=52.7 months (range 48-61). Transobturator sling (TOT) Procedure as described by Delorme 2001. Mean long-term FU=53.1 (range 48-63).</p>	<p>data from Ballester et al. 2012. Adverse events - bladder injury - n/N TVT: 4/42 TOT: 0/46 Objective Cure at ~10- mo (no stress incontinence on clinical and urodynamic examination) - n/N TVT: 37/42 TOT: 40/46 Objective cure at 4 years (no stress incontinence on clinical and urodynamic examination, negative cough stress test, and no urinary retention on spontaneous voiding &lt;150ml) - n/N TVT: 27/42 TOT: 32/ 46 Complications - n/N Need for catheterisation in ≤6 weeks TVT: 0/42 TOT: 0/46 Mesh extrusion at ~10 months</p>	<p>(computer-generated randomisation code) Allocation concealment: Low risk (central allocation revealed just before procedure) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data similar between groups and for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: High risk (participants in retropubic group had significantly lower urethral closure pressure at baseline than those in transobturator group) Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study type Multicentre RCT</p> <p>Aim of the study To compare perioperative complications, pain and functional results of TVT procedure using same polypropylene tape in retropubic and transobturator positions</p> <p>Study dates 03/2004 to 05/2005</p> <p>Source of funding Not reported</p>	<p>antipsychotic treatment who are pregnant</p>			<p>TVT: 0/42 TOT: 0/46 De novo urgency at ~10-months TVT: 2/42 TOT: 4/46 De novo urgency at 4 years TVT: 7/34 TOT: 10/37 De novo nocturia at ~10-months TVT: 3/42 TOT: 1/46 De novo nocturia at 4 years TVT: 9/34 TOT: 18/37 Infection at ~10 months TVT: 0/42 TOT: 0/46</p>	<p>Functional outcomes and quality of life outcomes at 10 months reported in Darai et al. 2007; Four-year follow up results reported in Ballester et al. 2012</p>
<p>Full citation Deffieux,X., Daher,N., Mansoor,A., Debodinance,P.,</p>	<p>Sample size N=149 randomised Intervention, n=75 Control, n=74</p>	<p>Interventions Intervention: Retropubic sling</p>	<p>Details ClinicalTrials.gov, NCT00135616. All surgeons substantial experience with TVT and TVT-O procedures before study enrolment. Cystoscopy</p>	<p>Results Cure at 6 months (no leakage and negative cough stress test) - n/N TVT: 63/75</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block randomisation)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Muhlstein,J., Fernandez,H., Transobturator TVT-O versus retropubic TVT: results of a multicenter randomized controlled trial at 24 months follow-up, International Urogynecology Journal, 21, 1337-1345, 2010 Ref Id 124241 Country/ies where the study was carried out France Study type Multicentre RCT  Aim of the study To compare TVT and TVT-O in in women with SUI</p>	<p>Characteristics Age (years) - mean ±SD TVT: 54.6 (10.9) TVT-O: 54.6 (10.9) BMI - mean ±SD TVT: 26.3 (4.5) TVT-O: 26.3 (5.7) Parity - mean ±SD TVT: 2.4 (1.2) TVT-O: 2.4 (1.3) Postmenopausal (%) TVT: 57 TVT-O: 54 Cystocele Stage 1 (%) TVT: 32 TVT-O: 32  Inclusion criteria Women with ≥18 years-old isolated or mixed USI (ICS classification) surgery for USI indicated positive cough stress test during cystometry</p>	<p>Control: Transobturator sling</p>	<p>performed in all cases. Vaginal incision same in both groups. Retropubic sling (TVT) Gynecare TVT, procedure according to Ulmsten et al. 1996. Transobturator sling (TVT-O) Gynecare TVT-O used, procedure according to De Leval 2003.</p>	<p>TVT-O: 65/74 Cure at 12 months - n/N TVT: 62/75 TVT-O: 61/74 Cure at 2 years - n/N TVT: 54/75 TVT-O: 56/74 Objective cure at 6 months (negative cough stress test) - n/N TVT: 69/75 TVT-O: 68/74 Objective cure at 12 months - n/N TVT: 65/75 TVT-O: 67/74 Objective cure at 2 years -n/N TVT: 61/75 TVT-O: 65/74 Subjective cure at 6 months (no self-reported leakage and no use of pads) - n/N TVT: 63/75 TVT-O: 66/74 Subjective cure at 12 months - n/N TVT: 63/75</p>	<p>Allocation concealment: Unclear risk (sealed, opaque envelopes but no further details) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data similar across groups at each time point and for similar reasons) Selective reporting: Low risk (protocol available, all primary and secondary outcome reported) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates 01/2005 to 12/2007</p> <p>Source of funding Not reported</p>	<p>in sitting position (full bladder 200-300 ml)</p> <p>Exclusion criteria Women with planned concomitant pelvic organ prolapse surgery concomitant hysterectomy previous incontinence surgery with pregnancy receiving anticoagulant therapy, POP-Q&gt;1 unable to understand the purpose of trial</p>			<p>TVT-O: 61/74 Subjective cure at 2 years - n/N TVT: 55/75 TVT-O: 56/74 Adverse events - bladder injury - n/N TVT: 4/75 TVT-O: 2/74 Adverse events - bowel injury - n/N TVT: 0/75 TVT-O: 0/74 Adverse events - severe bleeding requiring transfusion - n/N TVT: 0/75 TVT-O: 0/74 Repeat surgery for mesh complications at 2 years - n/N TVT: 2/75 TVT-O: 1/74 Complications - n/N Mesh extrusion at 2 months TVT: 0/75 TVT-O: 1/74 Need for catheterisation at 2 months</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TVT: 6/75 TVT-O 2/74	
<p>Full citation Demirci,F., Yucel,O., Comparison of pubovaginal sling and burch colposuspensio n procedures in type I/II genuine stress incontinence, Archives of Gynecology and Obstetrics, 265, 190-194, 2001 Ref Id 128412 Country/ies where the study was carried out Turkey Study type RCT Aim of the study To compare Burch colposuspensio</p>	<p>Sample size N=46 randomised Intervention, n=23 Control, n=23  Characteristics Age (years) - mean ±SD Colposuspension: 48. 13 (6.73) Fascial sling; 48.86 (6.31) BMI - mean ±SD Colposuspension: 28. 05 (4.74) Fascial sling: 28.64 (3.64) Parity - mean ±SD Colposuspension: 4.4 3 (2.53) Fascial sling: 4.13 (1.63) Posmenopausal (%) Colposuspension: 35 Fascial sling: 26</p>	<p>Interventions Intervention: Colposuspension Control: Fascial sling</p>	<p>Details All surgical procedures performed by same experienced surgeon. All patients received suprapubic catheter, clamped on 3rd postoperative day. Colposuspension with sutures Burch colposuspension performed as described by Tanagho et al. 1976, using 2 sutures. Fascial sling Autologous rectus fascial sling performed as described by McGuire &amp; Wan 1992</p>	<p>Results Subjective cure at 1 year (symptom free/completely dry) - n/N Colposuspension: 15/23 Fascial sling: 16/23 Complications at 1 year - n/N Pain Colposuspension: 2/17 Fascial sling: 4/17 Infection Colposuspension: 2/14 Fascial sling: 1/15 De novo detrusor instability Colposuspension: 1/17 Fascial sling: 1/17 POP occurrence Colposuspension: 2/17 Fascial sling: 0/17</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Un clear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data balanced across groups for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>n to autologous rectus fascial sling in women with type I or II stress incontinence</p> <p>Study dates Unclear, not reported</p> <p>Source of funding None reported</p>	<p>Concomitant POP surgery (%) Colposuspension: 39 Fascial sling: 35</p> <p>Inclusion criteria Women with genuine urinary stress incontinence according to urodynamic studies bladder neck hypermobility according to perineal ultrasonography</p> <p>Exclusion criteria Women with Valsalva leak point pressure (VLPP) &lt;90 cm H<sub>2</sub>O water previous anti incontinence surgery detrusor instability severe genital prolapsus (cystocele, rectocele, enterocele)</p>				
Full citation	Sample size N=130 randomised	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Djehdian, L. M., Araujo, M. P., Takano, C. C., Del-Roy, C. A., Sartori, M. G. F., Girao, M. J. B. C., Castro, R. A., Transobturator sling compared with single-incision mini-sling for the treatment of stress urinary incontinence: A randomized controlled trial, Obstetrics and Gynecology, 123, 553-561, 2014 Ref Id 673816 Country/ies where the study was carried out Brazil Study type RCT Aim of the study</p>	<p>Intervention, n=69 Control, n=61</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD Adjustable sling: 54.2 (9.6) TOT: 51.9 (10) BMI - mean <math>\pm</math>SD Adjustable sling: 27.2 (4.7) TOT: 28.5 (4.7) Parity - mean <math>\pm</math>SD Adjustable sling: 3.4 (2) TOT: 3.4 (1.7) Postmenopausal (%) Adjustable sling: 73 TOT: 57</p> <p>Inclusion criteria Women &gt;18 years-old with SUI (confirmed by a positive cough stress test, &gt;2g on standardised pas test with 250ml bladder</p>	<p>Intervention: Adjustable sling Control: Other Synthetic sling</p>	<p>ClinicalTrials.gov, NCT01094353. All procedures performed according to 5 surgeons, all of whom had extensive experience in transobturator surgery and had performed at least 5 mini-sling procedures. Adjustable sling (Ophira) Single-incision Ophira (Promedon) mini-sling used, procedure performed under local anaesthetic, according to technique described by Palma et al. 2008. Cystoscopy not routinely performed. Other synthetic sling (TOT) Promedon TOT used, procedure according to Delorme 2001. Cystoscopy performed only if suspected tissue injury.</p>	<p>Objective cure at 1-year FU (negative result in both cough stress test and 20-min pad test [<math>\leq</math>2g]) - n/N Adjustable sling: 47/69 TOT: 50/61 Improvement at 1-year FU (self-reported satisfaction with treatment) - n/N Adjustable sling: 56/69 TOT: 54/61 Continence-specific health-related QoL - I-QoL Avoidance + limiting behaviour at 1 year - mean <math>\pm</math>SD Adjustable sling: 86.8 (18.1), n=64 TOT: 92.7 (11.5), n=56 Continence-specific health-related QoL - I-QoL Psychosocial affect at 1 year - mean <math>\pm</math>SD Adjustable sling: 93.4 (15.2), n=64 TOT: 98 (7.5), n=56 Continence-specific health-related QoL - I-QoL Social</p>	<p>Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Low risk (consecutively numbered, sealed, opaque envelopes used) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (8% dropout rate, balanced across groups for similar reasons) Selective reporting: Unclear risk (protocol registered but does not provide sufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>To compare efficacy and quality of life outcomes of Ophira minisling and TOT in women with SUJ</p> <p>Study dates 08/2008 to 12/2011</p> <p>Source of funding Funding provided by Federal University of Sao Paulo.</p>	<p>volume, urodynamic tests)</p> <p>Exclusion criteria Women with concomitant POP stage &gt; 1 detrusor overactivity postvoid residual volume &gt;100 ml coagulation disorders current urinary tract infection sequela of previous pelvic radiation therapy anticoagulant therapy acute vulvovaginitis anaesthesia contraindications</p>			<p>embarrassment at 1 year - mean <math>\pm</math>SD Adjustable sling: 82.2 (25.2), n=64 TOT: 91.3 (17.2), n=56 Complications at 1-year FU - n/N Pain Adjustable sling: 0/64 TOT: 4/56 Mesh extrusion Adjustable sling: 6/64 TOT: 5/56 Infection Adjustable sling: 18/64 TOT: 12/56 De novo OAB - de novo urge Adjustable sling: 4/64 TOT: 4/56</p>	
<p>Full citation Dogan, O., Kaya, A. E., Pulatoglu, C., Basbug, A., Yassa, M., A randomized comparison of a single-incision</p>	<p>Sample size N=179 randomised Intervention, n=90 Control, n=89</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD</p>	<p>Interventions Intervention: Single-incision mini-sling (SIMS) Control: Other synthetic sling</p>	<p>Details All procedures performed by same surgeon with ~100 anti-incontinence procedures caseload per year, with experience of <math>\geq</math>50 cases of each procedure. Patients blinded using sham bilateral incisions in groin. All patients received spinal anaesthesia and perioperative antibiotic</p>	<p>Results Subjective cure at 1 year (Response of 'never/urine does not leak' to Q6 of ICIQ-SF) - n/N SIMS: 81/90 Other synthetic sling: 80/89</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Unclear risk (reports sealed opaque envelopes but no further details)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>needleless (Contasure-needleless) mini-sling versus an inside-out transobturator (Contasure-KIM) mid-urethral sling in women with stress urinary incontinence: 24-month follow-up results, International urogynecology journal, 1-9, 2018</p> <p>Ref Id 865003</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type RCT</p> <p>Aim of the study To compare effectiveness of Contasure-</p>	<p>SIMS: 49.03 (9.18)</p> <p>Other synthetic sling: 51.92 (6.98)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>SIMS: 27.94 (5.03)</p> <p>Other synthetic sling: 26.61 (3.87)</p> <p>Parity - median</p> <p>SIMS: 3 (range 0-9)</p> <p>Other synthetic sling: 3 (range 1-6)</p> <p>Menopausal (%)</p> <p>SIMS: 42</p> <p>Other synthetic sling: 47</p> <p>Inclusion criteria</p> <p>Women</p> <p><math>\geq</math>18 years-old</p> <p>with clinically-proven SUI</p> <p>who failed conservative treatment</p> <p>Exclusion criteria</p> <p>Women</p> <p>with mixed or urge-predominant urinary incontinence and overactive bladder</p>		<p>prophylaxis cefazoline. No planned concomitant surgery nor cystoscopy performed.</p> <p>Single-incision mini-sling (Contasure-Needleless)</p> <p>Needleless sling inserted using Hammock position with procedure according to manufacturer, as described in Fernandez-Gonzalez et al. 2017.</p> <p>Other synthetic sling (Contasure KIM TOT)</p> <p>Procedure as described in Franco &amp; Tardiu 2015.</p>	<p>Subjective cure at 2 years - n/N</p> <p>SIMS: 80/90</p> <p>Other synthetic sling: 78/89</p> <p>Objective cure at 1 year (Absence of SUI and negative cough stress test) - n/N</p> <p>SIMS: 82/90</p> <p>Other synthetic sling: 76/89</p> <p>Objective cure at 2 years - n/N</p> <p>SIMS: 80/90</p> <p>Other synthetic sling: 76/89</p> <p>Adverse events - bladder injury - n/N</p> <p>SIMS: 0/90</p> <p>Other synthetic sling: 1/89</p> <p>Adverse events - bowel injury - n/N</p> <p>SIMS: 0/90</p> <p>Other synthetic sling: 0/89</p> <p>ICIQ-SF at 2 years - median</p> <p>SIMS: 1 (range 0-20)</p>	<p>Blinding of participants/personnel: Low risk (participants blinded to group assignment)</p> <p>Blinding of outcome assessment: Low risk (assessors blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Needleless single-incision sling to TOT in treatment of female SUI</p> <p>Study dates 05/2014 to 05/2016</p> <p>Source of funding Not reported</p>	<p>symptoms (based on initial clinical assessment and anamnesis) who had previous POP and UI surgery with concomitant POP≥ stage 2 with history of surgery for POP and urinary incontinence who have post-void residual volume &gt;100 ml and bladder capacity &lt; 300 ml (assessed by bladder Foley catheter) with known malignancy with recurrent urinary tract infection with chronic pelvic pain known neurologic or psychiatric disorder preventing assessment</p>			<p>Other synthetic sling: 3 (0-20), p=0.089 (favouring SIMS group)</p> <p>Repeat surgery for SUI at 2 years - n/N SIMS: 2/89</p> <p>Other synthetic sling: 3/89</p> <p>Repeat surgery for mesh complications at 2 years - n/N SIMS: 1/89</p> <p>Other synthetic sling: 1/89</p> <p>Complications - n/N</p> <p>Pain at ≤1 year SIMS: 1/89</p> <p>Other synthetic sling: 10/89</p> <p>Pain at &gt;1 year to ≤5 years\ SIMS: 0/89</p> <p>Other synthetic sling: 2/89</p> <p>Mesh extrusion at ≤1 year SIMS: 5/89</p> <p>Other synthetic sling: 5/89</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Need for catheterisation at $\leq 1$ year SIMS: 1/89 Other synthetic sling: 1/89 De novo urgency at $\leq 1$ year SIMS: 0/89 Other synthetic sling: 0/89 Infection at 1 year SIMS: 0/89 Other synthetic sling: 0/89	
Full citation Elbadry, M. S., Gabr, A. H., Shabaan, A. M., Hammady, A. R., Fathelbab, T. K., Abdelhamid, A. M., Eldin, W. G., Eldahshoury, M. Z., Elhefnawy, A. S., Adjustable vs. ordinary transobturator tape for female stress	Sample size N=96 randomised Intervention, n=48 Control, n=48  Characteristics Women <50 years-old - n TOA: 34 TOT: 38 Women >50 years old - n TOA: 14 TOT: 10	Interventions Intervention: Adjustable sling Control: Other Synthetic sling	Details All women operated under spinal anaesthesia and placed in exaggerated lithotomy position, 1 g of third-generation cephalosporin at time of anaesthesia. 18-F Foley catheter inserted in bladder and urine evacuated. Outside-in technique applied in both groups, incision closed using 3-0 polyglactin sutures. Catheter removed 12-hr after surgery in all patients. Adjustable sling (adjustable transobturator tape [TOA]) If patient well enough, standing stress test one day after surgery;	Results Objective cure at 6-12 months (loss of <200 mL of urine or the use of one pad per day and negative stress test; mean follow up was 8 (sd 6) months for adjustable group and 9 (sd 5) months for TOT group) - n/N TOA: 40/48 TOT: 38/48 Complications - n/N Mesh extrusion	Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
incontinence. Is there a difference?, Arab Journal of Urology Print, 13, 134-8, 2015 Ref Id 542690 Country/ies where the study was carried out Egypt Study type RCT Aim of the study To assess effectiveness and complication rate of adjustable transobturator tape and normal transobturator tape in women with SUI Study dates 02/2012 to 02/2013	Parity - mean $\pm$ SD TOA: 4(1) TOT: 4(2) Postmenopausal women (%) TOA: 32 TOT: 23 Previous surgery (%) TOA: 44 TOT: 23 Women with Stamey SUI degree Grade I/II/III - n TOA: 22/23/3 TOT: 24/19/5 POP stage 0 (%) TOA: 76 TOT: 43 Pop stage 1 (%) TOA: 24 TOT: 57 Inclusion criteria Women with pure stress incontinence Exclusion criteria Women with		tape tightened by traction ~0.5 cm if urine leakage at bladder volume of 250 ml, repeated until no leakage. If postvoid residual urine volume >100 ml or Qmax<10 ml/s, tape loosened by traction by 0.5 cm. Mean FU= 8 (6) months. Other synthetic sling (TOT) Obtyrx tape used. Mean FU=9 (5) months	TOA: 0/48 TOT: 0/48	Incomplete outcome data: Unclear risk (insufficient information) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias) Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding None	<p>urge or mixed UI</p> <p>any abnormality in the contractility of the bladder</p> <p>small bladder capacity (&lt;300 mL) or low bladder compliance</p> <p>any neurological pathology affecting the bladder</p> <p>history of radio- or chemotherapy, antipsychotic treatment, urogenital prolapse of &gt;grade I (according to the Baden and Walker classification)</p> <p>any serious medical condition that might affect postoperative course (bronchial asthma, diabetes mellitus, etc.)</p> <p>anticoagulation therapy</p> <p>active perineal or urethral lesions</p>				
Full citation	Sample size N=50 randomised	Interventions	Details Synthetic sling (TVT)	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>El-Barky,E., El-Shazly,A., El-Wahab,O.A., Kehinde,E.O., Al-Hunayan,A., Al-Awadi,K.A., Tension free vaginal tape versus Burch colposuspension for treatment of female stress urinary incontinence, International Urology and Nephrology, 37, 277-281, 2005</p> <p>Ref Id 100602</p> <p>Country/ies where the study was carried out Egypt</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy and safety of TVT to Burch</p>	<p>Intervention, n=25 Control, n=25</p> <p>Characteristics Age (years) - mean ±SD TVT: 50 (14) Open colposuspension: 50 (12) Parity (range) TVT: 2-5 Open colposuspension: 3-4</p> <p>Inclusion criteria Women with urodynamically-confirmed SUI</p> <p>Exclusion criteria Women with uninhibited detrusor contraction during bladder filling&gt;15 cm H2O incompetent internal urethral sphincter &gt;grade I cystocele</p>	<p>Intervention: Synthetic sling Control: Colposuspension</p>	<p>Performed following standard procedure with patient in lithotomy position. Cystoscopy performed in all patients.</p> <p>Open colposuspension with sutures Standard procedure followed.</p>	<p>Cure at 3-6 months year (no self-reported SUI 3-6 months after surgery) - n/N TVT: 18/25 Open colposuspension: 18/25</p> <p>Improvement at 3-6 months (number cured + number occasional SUI but reduction in severity of SUI symptoms) - n/N TVT: 23/25 Open colposuspension: 22/25</p> <p>Adverse events - bladder injury - n/N TVT: 2/25 Open colposuspension: 0/25</p> <p>Postoperative complications from 3-mo to at least 2 years - n/N De novo urgency TVT: 2/25 Open colposuspension: 3/25</p> <p>Need for catheterisation TVT: 5/25 Open colposuspension: 3/25</p>	<p>Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>colposuspension in women with urodynamically-proven SUI</p> <p>Study dates Unclear, not reported</p> <p>Source of funding Not reported</p>	<p>previous failed surgical SUI repair</p>			<p>Infection (wound/UTI) TVT: 5/25 Open colposuspension: 5/25</p>	
<p>Full citation El-Hefnawy, A. S., Wadie, B. S., El Mekresh, M., Nabeeh, A., Bazeed, M. A., TOT for treatment of stress urinary incontinence: How should we assess its equivalence with TVT?, International urogynecology journal, 21, 947-953, 2010</p>	<p>Sample size N=40 randomised Intervention, n=19 Control, n=21</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD TVT: 47 (5) TOT: 45 (7) BMI - mean <math>\pm</math>SD TVT: 33.6 (5) TOT: 32.2 (5) Parity - mean <math>\pm</math>SD TVT: 4.2 (2) TOT: 3.6 (1)</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details All procedures conducted using spinal anesthesia. UI. Mean FU=19.7 (7) months Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1996. Cystoscopy performed only in patients with mixed UI. Mean FU=20.8 (7) months. Transobturator sling (TOT) Procedure as described by Delorme 2001. Mean FU=18.8 (7) months.</p>	<p>Results Objective cure (no self-reported incontinence, negative stress test, and negative 1hr pad test [<math>\leq</math>2g]) - n/N TVT: 18/19 TOT: 14/21 Adverse events - bladder injury - n/N TVT: 0/19 TOT: 1/21 Repeat surgery for SUI at &gt;1 year to <math>\leq</math>5 years - n/N TVT: 0/19 TOT: 2/21</p>	<p>Limitations Random sequence generation: Unclear risk (states closed envelopes used but no further details) Allocation concealment: Unclear risk (states closed envelopes but no further details) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Ref Id 668984</p> <p>Country/ies where the study was carried out Egypt</p> <p>Study type RCT</p> <p>Aim of the study To compare short-term outcomes of TVT and TOT in women with SUI</p> <p>Study dates 01/2006 to 09/2008</p> <p>Source of funding Not reported</p>	<p>Concomitant POP surgery in whole sample (%): 23</p> <p>Inclusion criteria Women with urodynamically-proven SUI</p> <p>Exclusion criteria Women who underwent pelvic or vaginal surgery in past 6 months with associated urethral and/or bladder pathology with active urinary tract infection on urine culture test with urge-predominant incontinence</p>			<p>Complications &gt;1 year to ≤5 years - n/N</p> <p>Pain TVT: 1/19 TOT: 3/21</p> <p>Mesh extrusion TVT: 0/19 TOT: 1/21</p> <p>Infection (recurrent UTI) - n/N TVT: 1/19 TOT: 1/21</p>	<p>Incomplete outcome data: Low risk (no missing data)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>
<p>Full citation Fatthy, H., El Hao, M., Samaha, I., Abdallah, K., Modified Burch</p>	<p>Sample size N=74 randomised Intervention, n=34 Control, n=40</p>	<p>Interventions Intervention: Laparoscopic colposuspension Control: Open colposuspension</p>	<p>Details Follow up=18 months Modified Laparoscopic Burch colposuspension with sutures Standard procedure followed with addition of modification to distention</p>	<p>Results Subjective cure at 18 months (completely continent or only rarely requiring pad when</p>	<p>Limitations Random sequence generation: Low risk (random number table with blinding and disguised block length)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>colposuspension: Laparoscopy versus laparotomy, Journal of the American Association of Gynecologic Laparoscopists, 8, 99-106, 2001 Ref Id 673849</p> <p>Country/ies where the study was carried out Egypt</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy and complications of laparoscopic colposuspension to open modified Burch colposuspension in women with genuine stress incontinence</p>	<p>Characteristics</p> <p>Age (years) - median (range) Laparoscopic: 40.29 (30-55) Open: 42.9 (30-65)</p> <p>Weight (kg) - median (range) Laparoscopic: 71.18 (60-80) Open: 74.55 (65-90)</p> <p>Parity - median (range) Laparoscopic: 4.03 (1-11) Open: 5.05 (1-10)</p> <p>Menopausal (%) Laparoscopic: 77 Open: 73</p> <p>Inclusion criteria Women with urodynamic genuine stress incontinence</p> <p>Exclusion criteria Women with detrusor instability underactive detrusor</p>		<p>balloon system (Origin Medsystems) to allow repeated use (by replacing balloon with middle finger of size 8 glove tightened and knotted with . Flexible cystoscopy performed in all patients. Foley catheter removed after 24 hours if postvoid volume &lt;100ml.</p> <p>Open Burch colposuspension with sutures</p> <p>Standard procedure used.</p>	<p>stressed and completely satisfied) - n/N Laparoscopic: 29/34 Open: 34/40</p> <p>Negative cough stress test at 18 months - n/N Laparoscopic: 28/34 Open: 31/40</p> <p>Adverse events - bladder injury - n/N Laparoscopic: 1/34 Open: 1/40</p> <p>Complications - n/N Pain at 18 months Laparoscopic: 1/33 Open: 5/40</p> <p>De novo detrusor instability Laparoscopic: 2/33 Open: 3/40</p> <p>Need for catheterisation at ≤8 weeks Laparoscopic: 2/34 Open: 2/40</p> <p>POP occurrence at 18 months Laparoscopic: 3/34 Open: 4/40</p>	<p>Allocation concealment: Low risk (independent statistician with surgeons/patients blinded until just before surgery)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates Unclear, not reported</p> <p>Source of funding Not reported</p>	<p>intrinsic sphincter deficiency (Valsalva leak point pressure &lt;90 cm H<sub>2</sub>O)</p> <p>limited vaginal mobility</p> <p>contraindication to laparoscopy and surgery in general</p>				
<p>Full citation Feng, S., Luo, D., Liu, Q., Yang, T., Du, C., Li, H., Wang, K., Shen, H., Three- and twelve-month follow-up outcomes of TVT-EXACT and TVT-ABBREVO for treatment of female stress urinary incontinence: a randomized clinical trial, World Journal of UrologyWorld J</p>	<p>Sample size N=148 randomised Intervention, n=74 Control, n=74</p> <p>Characteristics Data for TVT-Exact, n=63; TVT-ABBREVO, n=62 Age (years) - mean ±SD TVT-EXACT: 52.24 (7.54) TVT-ABBREVO: 53.26 (6.33) BMI - mean ±SD TVT-EXACT: 25.19 (2.57) TVT-ABBREVO; 24.51 (2.2)</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Chinese Clinical Trail Registry, ChiCTR-IOR-17011788. All procedures performed by one surgeon using Gynecare products. Retropubic sling (TVT-EXACT) Procedure in accordance with manufacturer instructions and as described by Ulmsten et al. 1996. Transobturator sling (TVT-ABBREVO) Procedure as described by de Leval et al. 2011</p>	<p>Results Negative cough stress test at 1 year - n/N TVT-EXACT: 53/74 TVT-ABBREVO: 50/74 Subjective cure at 1 year (PGII score=1) TVT-EXACT: 40/74 TVT-ABBREVO: 43/74 Improvement at 1 year (number PGII score=1-3) - n/N TVT-EXACT: 57/74 TVT-ABBREVO: 56/74 ICIQ-SF at 1 year - mean ±SD TVT-EXACT: 2.02 (2.15) TVT-ABBREVO: 3.9 (3.62)</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: High risk (23% dropout rate at 12 months)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Urol, 36, 459-465, 2018</p> <p>Ref Id 864999</p> <p>Country/ies where the study was carried out China</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy and safety of TVT-ABBREVO and TVT-EXACT in treatment of female SUI</p> <p>Study dates 04/2015 to 04/2016</p> <p>Source of funding Reports trial supported by 1.3.5 Porject for Disciplines of Excellence,</p>	<p>Parity - mean <math>\pm</math>SD TVT-EXACT: 1.78 (0.89) TVT-ABBREVO: 1.61 (0.8)</p> <p>Inclusion criteria Women with aged 40-75 years-old clinically- and urodynamically-proven stress urinary incontinence</p> <p>Exclusion criteria Women with mixed urinary incontinence with history of sling or other genitourinary tract surgery with recent genitourinary tract infection requiring concomitant hysterectomy or prolapse surgery unfit for surgery</p>			<p>PISQ-12 at 1 year - mean <math>\pm</math>SD TVT-EXACT: 21.97 (3.52) TVT-ABBREVO: 21.47 (3.95)</p> <p>i-Qol at 1 year - mean <math>\pm</math>SD TVT-EXACT: 103.54 (6.46) TVT-ABBREVO: 99 (9.7)</p> <p>Adverse events - Bladder injury - n/N TVT-EXACT: 2/63 TVT-ABBREVO: 0/62</p> <p>Adverse events - Severe bleeding requiring blood transfusion - n/N TVT-EXACT: 0/63 TVT-ABBREVO: 0/62</p> <p>Repeat surgery for SUI at <math>\leq</math>1 year - n/N TVT-EXACT: 0/63 TVT-ABBREVO: 0/62</p> <p>Complications at <math>\leq</math>1 year - n/N Pain TVT-EXACT: 11/63 TVT-ABBREVO: 8/62</p>	<p>Selective reporting: Unclear risk (appears all outcomes reported but protocol retrospectively registered)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
West China Hospital, Sichuan University.				Infection (UTI) TVT-EXACT: 1/63 TVT-ABBREVO: 0/62 De novo urgency TVT-EXACT: 4/63 TVT-ABBREVO: 5/62	
Full citation Fernandez-Gonzalez, S., Martinez Franco, E., Lin Miao, X., Amat Tardiu, L., Contasure-needleless compared with Monarc for the treatment of stress urinary incontinence, International Urogynecology Journal, 28, 1077-1084, 2017 Ref Id 673853 Country/ies where the study was carried out	Sample size N=187 randomised Intervention, n=89 Control, n=98  Characteristics Age (years) - mean $\pm$ SD SIMS: 57.6 (11.03) TOT: 57.8 (57.83) BMI - mean $\pm$ SD SIMS: 28.7 (4.97) TOT: 28.1 (4.44) Parity - median (range) SIMS: 2 (0-6) TOT: 2 (0-8) Menopausal (%) SIMS: 70 TOT: 61 Previous conservative treatment (%)	Interventions Intervention: Single-incision mini-sling (SIMS) Control: Other Synthetic sling	Details Both procedures performed by urogynaecology surgeon or supervised trainee. Local and spinal anaesthetic used with prophylactic cefazolin administered before procedure. Each participants also received individualised POP surgery as appropriate; POP stage 2 or more treated with anterior/posterior repair/hysterectomy as appropriate. Single-incision mini-sling (Contasure-Needleless) Contasure-Needlesless mini-sling composed of 114 x 12 mm polypropylene monofilament mesh. Procedure conducted with participant in lithotomy position. Mean FU=30 months (12.14) Other synthetic sling (TOT) Monarc (AMS) TOT used, procedure as described by Delorme 2001. Mean FU=27 months (12.68).	Results Objective cure at 2-3 years FU (negative cough stress test with full bladder in lithotomy position) - n/N SIMS: 72/89 TOT: 85/98 Subjective cure at 2-3 years FU (SSI score=0) - n/N SIMS: 47/89 TOT: 61/98 Improvement at 2-3 years FU: 64/89; 83/98 (SSI SCORE=0 or lower SSI score at FU than at baseline) Satisfaction at 2-3 years FU: 22+51/87; 51+37/96 ('very satisfied' + 'satisfied')	Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Low risk (computer-generated allocation) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: High risk (assessors not blinded to group assignment, potential detection bias) Incomplete outcome data: Low risk (missing data not sufficient to have clinically relevant impact on effect estimate)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Spain Study type RCT  Aim of the study To establish whether Contasure-Needleless single-incision mini-sling  Study dates 05/2010 to 06/2014  Source of funding Not reported	SIMS: 50 TOT: 54  Inclusion criteria Women with clinically-verified SUI candidate for both Needleless and TOT procedures  Exclusion criteria Women with previous SUI surgical treatment intrinsic sphincter deficiency (Valsalva leak point pressure < 60 cmH <sub>2</sub> O and absence of urethral hypermobility) who would be candidates for pelvic floor physiotherapy rehabilitation urodynamically-proven urge-predominant mixed incontinence			Continence-specific health-related QoL - ICIQ-SF Q5 at 2-3 years FUmuch does leaking urine interfere with everyday life?) - mean $\pm$ SD SIMS: 2.04 (3.05) TOT: 0.91 (2.16) Adverse events - bladder injury - n/N SIMS: 1/89 TOT: 0/98 Complications at 2-3 year FU - n/N Mesh extrusion SIMS: 4/89 TOT: 7/98 Infection (UTI) SIMS: 2/89 TOT: 1/98 De novo OAB - de novo urgency SIMS: 9/89 TOT: 12/98	Selective reporting: Unclear risk (insufficient information) Other bias: Unclear risk (At baseline, significantly higher percentage of smokers in Needleless group compared to TOT group)  Other information
Full citation	Sample size N=50 randomised	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Foote, A., Randomized prospective study comparing Monarc and Miniarc suburethral slings, Journal of Obstetrics &amp; Gynaecology Research, 41, 127-31, 2015</p> <p>Ref Id 542706</p> <p>Country/ies where the study was carried out Australia</p> <p>Study type RCT</p> <p>Aim of the study To evaluate postoperative recovery, effectiveness and complications of MiniArc mini-sling and Monarc TOT in women with SUI</p>	<p>Intervention, n=25 Control, n=25</p> <p>Characteristics</p> <p>Age (years) - mean ±SD MiniArc: 49.6 (11.8) TOT: 46.2 (11.3)</p> <p>Weight (kg) - mean ±SD MiniArc: 70.8 (16.4) TOT: 70.8 (14.6)</p> <p>Parity - mean ±SD MiniArc: 2.1 (1.3) TOT: 2.3 (1.4)</p> <p>Inclusion criteria Women with urodynamically-proven genuine stress incontinence no previous retropubic incontinence surgery no allergy to polypropylene no significant voiding difficulty fit for surgery</p>	<p>Intervention: Single-incision mini-sling</p> <p>Control: Other synthetic sling</p>	<p>Registered on Australian New Zealand Clinical Trials Registry, ACTRN 1261 2000 3148 20. All surgeries performed by author or directly supervised by him with patients under general anaesthesia. Tension of slings in both groups corrected until no leakage with suprapubic pressure at 300ml full bladder. All patients had cystoscopy and discharged postvoid volume &lt;100ml and VAS pain score&lt;5.</p> <p>Single-incision mini-sling (MiniArc)</p> <p>No details provided, presumably standard procedure</p> <p>Other synthetic sling (TOT Monarc)</p> <p>Standard procedure</p>	<p>Objective cure at 6 months (1h pad test ≤1g) - n/N</p> <p>MiniArc: 21/25 TOT: 23/25</p> <p>Repeat surgery for SUI at 6 months - n/N</p> <p>MiniArc: 3/25 TOT: 1/25</p> <p>Repeat surgery for mesh complications at 6 months - n/N</p> <p>MiniArc: 0/25 TOT: 3/25</p>	<p>Random sequence generation: Unclear risk (insufficient information)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: High risk (performing surgeon conducted follow up assessments, potential detection bias)</p> <p>Incomplete outcome data: Low risk (no missing data)</p> <p>Selective reporting: Unclear risk (protocol retrospectively registered)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Unclear, not reported	No other concurrent vaginal surgery Able to complete study questionnaire				
Source of funding Not reported	Exclusion criteria				
Full citation Foote,A.J., Maughan,V., Carne,C., Laparoscopic colposuspension versus vaginal suburethral slingplasty: a randomised prospective trial, Australian and New Zealand Journal of Obstetrics and Gynaecology, 46, 517-520, 2006 Ref Id 100612	Sample size N=97 randomised Intervention, n=49 Control, n=48  Characteristics Age (years) - mean ±SD SPARC: 52.4 (10.9) Colposuspension: 51.2 (8.5) Weight (kg) - mean ±SD SPARC: 73.1 (9.2) Colposuspension: 70 (9) Parity - mean ±SD SPARC: 2.5 (1) Colposuspension: 2.6 (1)	Interventions Intervention: Synthetic sling Control: Colposuspension	Details All surgeries performed by same surgeon with experience of over 50 of each procedure. Follow up: 6 months FU Synthetic sling (SPARC) Retropubic bottom-up vaginal suburethral polypropylene sling inserted tension free using 1cm anterior vaginal incision with mesh via 2 suprapubic 2mm incisions. Colposuspension Laparoscopic colposuspension with sutures performed using 3 ports (1 umbilical 10 mm, 2 lateral 5 mm).	Results Improvement at 6-mo FU (number cured + number with >50% improvement in leaks per week and VAS score from baseline) - n/N SPARC: 36/49 Colposuspension: 38/48 Improvement at 2-year FU - n/N SPARC: 24/49 Colposuspension: 22/48 Adverse events - bladder injury - n/N SPARC: 5/49 Colposuspension: 1/48 Adverse events - severe bleeding requiring transfusion - n/N	Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Unclear risk (40% dropout rate, reasons not provided)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out Australia Study type RCT</p> <p>Aim of the study To determine effectiveness of laparoscopic colposuspension and vaginal suburethral slingplasty (SPARC) in women with urodynamically-proven stress urinary incontinence</p> <p>Study dates 01/2002 to 03/2004</p> <p>Source of funding None reported</p>	<p>Previous hysterectomy (%) SPARC: 39 Colposuspension: 27</p> <p>Inclusion criteria Women with urodynamic stress incontinence</p> <p>Exclusion criteria Women with other bladder diagnoses (e.g. detrusor instability or voiding difficulty) had previous incontinence surgery weight of more than 100 kg who have significant prolapse who require other gynaecological surgery who are unsuitable for laparoscopic surgery</p>			<p>SPARC: 0/49 Colposuspension: 0/48 Complications - n/N Mesh extrusion at 2-year FU SPARC: 1/31 Colposuspension: 0/27 De novo OAB - urgency at 6-mo FU SPARC: 7/44 Colposuspension: 3/43</p>	<p>Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Freeman,R., Holmes,D., Hillard,T., Smith,P., James,M., Sultan,A., Morley,R., Yang,Q., Abrams,P., What patients think: Patient-reported outcomes of retropubic versus trans-obturator mid-urethral slings for urodynamic stress incontinence-a multi-centre randomised controlled trial, International urogynecology journal and pelvic floor dysfunction, 22, 279-286, 2011 Ref Id 136054</p>	<p>N=193 randomised Intervention, n=93 Control, n=100</p> <p>Characteristics Age (years) - median (IQR) TVT: 50 (44-60) TOT: 54 (45-59) BMI - median (IQR) TVT: 27 (24-31) TOT: 29 (25-32)</p> <p>Inclusion criteria Women &gt;21 years-old with Urodynamic SI or stress-predominant mixed UI who failed pelvic floor muscle training willing and able to complete a 4-day urinary diary</p> <p>Exclusion criteria Women with neurological disease</p>	<p>Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Anaesthetic used (local, regional, or general) chosen by patient. Prophylactic antibiotics and venous thromboembolism provided in all cases. Retropubic sling (TVT) Gynecare TVT used, procedure according to standard technique. Transobturator sling (TOT) Monarc (AMS) TOT used, procedure according to standard technique.</p>	<p>Cure at 1 year (Response of 'no' to 'Does urine leak when you are physically active, exert yourself, cough or sneeze?' of ICIQ-FLUTS) - n/N TVT: 55/93 TOT: 59/100 Improvement at 1 year (Response of 'very much' or 'much' better on PGII) - n/N TVT: 71/93 TOT: 76/100 QoL - ICIQ-FLUTS sexual function at 1 year (response of 'not at all' to 'does your urinary problem affect your sex life?' of ICIQ-FLUTS) - n/N TVT: 57/85 TOT: 60/95 Adverse events - bladder injury - n/N TVT: 2/93 TOT: 0/100 Repeat surgery for mesh complications at 1 year - n/N</p>	<p>Random sequence generation: Low risk (block randomisation list used) Allocation concealment: Low risk (sequentially numbered, opaque, sealed envelopes used) Blinding of participants/personnel: Low risk (participants and surgical staff blinded to group assignment through use of dressings) Blinding of outcome assessment: Low risk (outcomes used self-report questionnaires) Incomplete outcome data: Low risk (missing data similar across groups for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To assess whether TOT is equivalent but not inferior to TVT in women with urodynamic stress incontinence</p> <p>Study dates Not reported</p> <p>Source of funding Commissioned by NIHR.</p>	<p>previous urodynamic USI</p> <p>urodynamic detrusor overactivity or low compliance</p> <p>post-void residual of &gt;100 ml on two occasions</p> <p>pregnant within the last 3 months or planning pregnancy during the study period</p> <p>inguinal or vulval mass lymphadenopathy or abscess or history of hidradenitis suppurativa</p> <p>bleeding diathesis</p> <p>current anticoagulation therapy</p> <p>POP extending beyond the hymen</p>			<p>TVT: 0/93 TOT: 2/100</p> <p>Complications at 1 year - n/N</p> <p>Pain TVT: 1/85 TOT: 8/95</p> <p>Mesh extrusion TVT: 2/85 TOT: 3/95</p> <p>Need for catheterisation TVT: 9/85 TOT: 11/95</p> <p>Infection (wound) TVT: 0/85 TOT: 2/95</p> <p>De novo OAB TVT: 4/85 TOT: 4/95</p>	
<p>Full citation Fu, Q., Lv, J., Fang, W., Jiang, C., Gu, Y., Leng, J., Xue,</p>	<p>Sample size N=164 randomised</p> <p>Intervention, n=78 Control, n=86</p>	<p>Interventions Intervention: Single-incision mini-sling (SIMS)</p>	<p>Details All patients received general anaesthesia or continuous spinal anaesthetic.</p>	<p>Results Improvement at 6-mo FU (PGII score 1-3) - n/N SIMS: 78/78</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>W., The clinical efficacy of needleless sling technique and tot in the treatment of female stress urinary incontinence: A prospective randomized controlled trial, International journal of clinical and experimental medicine, 10, 7084-7090, 2017 Ref Id 673873 Country/ies where the study was carried out China Study type RCT Aim of the study To evaluate efficacy and safety of single-</p>	<p>Characteristics Age (years) - mean <math>\pm</math>SD SIMS: 52.35 (10.02) TOT: 52.43 (10.86) BMI - mean <math>\pm</math>SD SIMS: 26.04 (3.46) TOT: 25.85 (3.71) Parity - mean <math>\pm</math>SD SIMS: 1.64 (0.64) TOT: 1.64 (0.72)  Inclusion criteria Women 35-70 years-old Positive cough stress test in lithotomy position (full bladder 250 ml)  Exclusion criteria Women with abdominal pressure &lt;60 cmH2O leak point pressure &lt;60 cmH2O</p>	<p>Control: Other Synthetic sling</p>	<p>Single-incision mini-sling (Needleless) Brand of needleless sling not reported. Sling penetrated through incision in anterior vaginal wall, T sling expanded and fixed after breaking through obturator membrane. Other synthetic sling (TOT) Brand of TOT sling not reported. Sling penetrated through incision in anterior vaginal wall, traversed obturator membrane and out both sides of incision in root of thigh.</p>	<p>TOT: 86/86 Improvement at 12-mo FU (PGII score 1-3) - n/N SIMS: 78/78 TOT: 86/86 Continence-specific health-related QoL - ICIQ-SF at 6-mo FU - mean <math>\pm</math>SD SIMS: 1.37 (1.5) TOT: 1.48 (1.61) Continence-specific health-related QoL - ICIQ-SF at 12-mo FU - mean <math>\pm</math>SD SIMS: 1.32 (1.43) TOT: 1.24 (1.15) Complications - n/N Pain at 1-year FU SIMS: 2/78 TOT: 1/86 Mesh extrusion at 6-mo FU SIMS: 0/78 TOT: 0/86 Mesh extrusion at 1-year FU SIMS: 0/78 TOT: 0/86</p>	<p>Allocation concealment: High risk (assignment envelopes used without appropriate safeguards) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no dropouts in either group) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>incision needleless mini-sling technique in treatment of women with SUI</p> <p>Study dates 09/2014 to 09/2015</p> <p>Source of funding Supported by grant # SHDC12015911</p>	<p>urge urinary incontinence urethral sphincter injury (maximal urethral closure pressure &lt;20 cmH2O) pelvic organ prolapse history of urge urinary incontinence or pelvic organ prolapse operation pelvic organ disease (e.g. terine fibromyomata)</p>			<p>Infection at 6-mo FU SIM: 0/78 TOT: 0/86 Infection at 1-year FU SIMS: 0/78 TOT: 0/86</p>	
<p>Full citation Gaber, M. E., Borg, T., Samour, H., Nawara, M., Reda, A., Two new mini-slings compared with transobturator tension-free vaginal tape for treatment of stress urinary incontinence: A 1-year follow-up</p>	<p>Sample size N=210 randomised Intervention 1 (Contasure-Needleless), n=70 Intervention 2 (Endopelvic Free Anchorage), n=70 Control (TOT), n=70</p> <p>Characteristics Age (years) - mean ±SD</p>	<p>Interventions Intervention 1: Single-incision mini-sling 1 Intervention 2: Single-incision mini-sling 2 Control: Other Synthetic sling</p>	<p>Details All surgeons attended formal training for all 3 procedures and had performed at least 10 of each procedure. General or spinal anaesthesia according to participant's medical condition and preference after consultation. Reconstructive POP surgery conducted if participant had co-occurrent POP. Single-incision mini-sling 1 (Contasure-Needleless)</p>	<p>Results Objective cure at 12-mo FU (negative cough stress test whilst standing with full bladder) - n/N Intervention 1: 64/70 Intervention 2: 62/70 Control: 66/70 Patient satisfaction at 12-mo (reduction ≥8 points on ICIQ-UI-SF) - n/N Intervention 1: 60/70</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (reports concealed allocation but no further details provided) Blinding of participants/personnel: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>randomized controlled trial, Journal of obstetrics and gynaecology research, 42, 1773-1781, 2016</p> <p>Ref Id 673875</p> <p>Country/ies where the study was carried out Egypt</p> <p>Study type RCT</p> <p>Aim of the study To compare outcomes of 2 single-incision minislings (Contasure-Needleless, Endopelvic Free Anchorage) and TOT in women with SUI</p> <p>Study dates</p>	<p>Intervention 1: 44.1 (7)</p> <p>Intervention 2: 42.7 (5.4)</p> <p>Control: 44.3 (8.5)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>Intervention 1: 26.5 (2.5)</p> <p>Intervention 2: 28.4 (2.7)</p> <p>Contrl: 25.7 (2.4)</p> <p>Parity - median (range)</p> <p>Intervention 1: 3 (3-4)</p> <p>Intervention 2: 4 (3-4)</p> <p>Control: 3 (3-4).</p> <p>Postmenopausal (%)</p> <p>Intervention 1: 33</p> <p>Intervention 2: 52</p> <p>Control: 33</p> <p>Concurrent Prolapse (%)</p> <p>Intervention 1: 86</p> <p>Intervention 2: 84</p> <p>Control: 84</p> <p>Inclusion criteria Women</p> <p>with clinically-proven SUI (involuntary</p>		<p>Procedure as described by Navazo et al. 2009. Tape manually prepared using polypropylene Promesh T (Surgical IOC)</p> <p>Single-incision mini-sling 2 (Endopelvic Free Anchorage)</p> <p>Procedure as described by Ricapa et al. 2010. Tape manually prepared using polypropylene Promesh T (Surgical IOC)</p> <p>Other synthetic sling (TOT)</p> <p>Monarc (AMS) TOT used, procedure as described by Delorme 2001.</p>	<p>Intervention 2: 54/70</p> <p>Control: 62/70</p> <p>Improvement at 12-mo (PGII response of 'very much improved' or 'much improved') - n/N</p> <p>Intervention 1: 64/70</p> <p>Intervention 2: 61/70</p> <p>Control: 66/70</p> <p>Adverse events - Bladder injury - n/N</p> <p>Intervention 1: 0/70</p> <p>Intervention 2: 1/70</p> <p>Control: 1/70</p> <p>Complications - n/N</p> <p>Mesh extrusion at &lt;6 months FU</p> <p>Intervention 1: 0/70</p> <p>Intervention 2: 0/70</p> <p>Control: 0/70</p> <p>De novo OAB - de novo urge incontinence at 1-mo FU</p> <p>Intervention 1: 5/70</p> <p>Intervention 2: 8/70</p> <p>Control: 4/70</p>	<p>(participants blinded to treatment)</p> <p>Blinding of outcome assessment: Low risk (assessors blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (1 dropout before surgery in EFA group, not sufficient to affect effect estimate)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: High risk (women in EFA group had significantly higher parity and BMI than TVT-O group, and significantly higher BMI than Needleless group)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
08/2014 to 07/2015  Source of funding Not reported	leakage of urine on effort, sneezing, or coughing to a degree affecting social life), or urodynamically-proven SUI  Exclusion criteria Women with previous failed anti-incontinence procedure evident neurological disease evidence of detrusor contraction				
Full citation Guerrero,K.L., Emery,S.J., Wareham,K., Ismail,S., Watkins,A., Lucas,M.G., A randomised controlled trial comparing TVT, Pelvicol and autologous fascial slings for the treatment of	Sample size N=211 randomised Intervention 1 (TVT), n=72 Intervention 2 (Porcine dermis sling), n=52 Control (Autologous fascial sling), n=84  Characteristics Age (years) - mean (range)	Interventions Intervention 1: Synthetic sling (TVT) Intervention 2: Non-autologous biological sling (porcine dermis) Control: Fascial sling (autologous biological sling)	Details Clinicaltrials.gov NCT01057550. All surgeons experienced in all 3 procedures, with technique standardised across participating centres. Anaesthesia method determined by operating team at each centre. Concurrent POP surgery permitted and documented. Cystoscopy performed in all cases. Follow up: 12 months (Guerrero et al. 2010); median 10 years (range 6.6-12.6; Khan et al. 2015) Synthetic sling (TVT)	Results Note: Data at median 10 year long-term follow up from Khan et al. 2015 Subjective cure at 6 months (Self-reported completely dry since operation) - n/N ITT analysis Intervention 1: 36/72 Intervention 2: 20/52 Control: 35/84 PPA	Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Low risk (central allocation) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>stress urinary incontinence in women, BJOG: An International Journal of Obstetrics and Gynaecology, 117, 1493-1502, 2010</p> <p>Ref Id 100631</p> <p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare effectiveness of autologous fascial sling, porcine dermis and TVT in women requiring primary surgery for SUI</p> <p>Study dates</p>	<p>Intervention 1: 54.3 (34–80)</p> <p>Intervention 2: 52.4 (31–78)</p> <p>Control: 52.1 (33–72)</p> <p>BMI - mean (range)</p> <p>Intervention 1: 28.7 (20.2–41.0)</p> <p>Intervention 2: 28.8 (19.6–40.0)</p> <p>Control: 28.7 (20.3–43.4)</p> <p>Inclusion criteria</p> <p>Women</p> <p>&gt;18 years-old clinically- and urodynamically-proven SUI</p> <p>Exclusion criteria</p> <p>Women</p> <p>had previous SUI surgery</p> <p>had demonstrated evidence of neurological disease with POP stage&gt;2 with detrusor overactivity on</p>		<p>Gynecare TVT used, procedure as described by Ulmsten et al. 1996.</p> <p>Non-autologous biological sling (porcine dermis)</p> <p>12 x 2 cm Pelvicol graft used, with lateral dissection to puncture endopelvia fascia. Graft mounted on 1.0 nylon threads and passed retropubically (bottom-up); threads secured to rectus sheath in same manner as TVT.</p> <p>Fascial sling (autologous rectus)</p> <p>Sling-on-a-string technique used. 8010 cm x 1.5 cm graft harvested, mounted on 1.0 nylon thread at each end, and passed retropubically in same manner as Pelvicol group.</p>	<p>Intervention 1: 36/71</p> <p>Intervention 2: 20/45</p> <p>Control: 35/73</p> <p>Subjective cure at 1 year - n/N</p> <p>ITT analysis</p> <p>Intervention 1: 38/72</p> <p>Intervention 2: 10/52</p> <p>Control: 32/84</p> <p>PPA</p> <p>Intervention 1: 38/69</p> <p>Intervention 2: 10/46</p> <p>Control: 32/67</p> <p>Subjective cure at 10 years - n/N</p> <p>ITT analysis</p> <p>Intervention 1: 20/72</p> <p>Intervention 2: 6/52</p> <p>Control: 31/84</p> <p>Improvement at 6 months (Self-reported improvement since operation) - n/N</p> <p>ITT analysis</p> <p>Intervention 1: 65/72</p> <p>Intervention 2: 33/52</p> <p>Control: 69/84</p> <p>PPA</p> <p>Intervention 1: 65/71</p>	<p>Blinding of outcome assessment: Low risk (outcome assessors blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to have clinically relevant impact)</p> <p>Selective reporting: High risk (only reports data for quality of life where improvement of symptoms for TVT and autologous fascial slings was significantly better than porcine dermis)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p> <p>Ten-year long-term follow up reported in Khan et al. 2015.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Unclear, 6-year recruitment period.</p> <p>Source of funding Funded by trial unit (funds from pharmaceutical companies and peer-funding); several of authors received fees and payments from variety of medical technology companies.</p>	<p>urodynamic assessment with bladder hypocompliance (assessed urodynamically as a pressure rise of +20 cm H<sub>2</sub>O at capacity or 500 ml, filled at 50 ml/minute)</p>			<p>Intervention 2: 33/45 Control: 69/73 Improvement at 1 year - n/N ITT analysis Intervention 1: 64/72 Intervention 2: 28/52 Control: 60/84 PPA Intervention 1: 64/69 Intervention 2: 28/46 Control: 60/67 Improvement at 10 years - n/N Intervention 1: 46/72 Intervention 2: 22/52 Control: 46/84 Continence-specific health-related QoL at 1 year - BFLUTS daytime frequency &gt;7 (women who report symptom and described it as bit of problem, quite a problem or serious problem) - n/N Intervention 1: 14/69 Intervention 2: 25/46 Control: 23/67</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Continence-specific health-related QoL at 1 year - BFLUTS urge incontinence (women who report symptom and described it as bit of problem, quite a problem or serious problem) - n/N</p> <p>Intervention 1: 28/69 Intervention 2: 34/46 Control: 29/67</p> <p>Continence-specific health-related QoL at 1 year - BFLUTS incontinence frequency (women who report symptom and described it as bit of problem, quite a problem or serious problem) - n/N</p> <p>Intervention 1: 26/69 Intervention 2: 30/46 Control: 27/67</p> <p>Continence-specific health-related QoL at 1 year - BFLUTS stress incontinence (women who report symptom and described it as bit of problem, quite</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>a problem or serious problem) - n/N            Intervention 1: 14/69            Intervention 2: 27/46            Control: 15/67            Continence-specific health-related QoL at 1 year - BFLUTS unexplained incontinence (women who report symptom and described it as bit of problem, quite a problem or serious problem) - n/N            Intervention 1: 16/69            Intervention 2: 23/46            Control: 13/67            Continence-specific health-related QoL at 1 year - BFLUTS quantity of urine loss (women who report symptom and described it as bit of problem, quite a problem or serious problem) - n/N            Intervention 1: 0/69            Intervention 2: 0/46            Control: 0/67</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Continence-specific health-related QoL at 10 years - BFLUTS filling score: TVT (n=63) vs autologous fascial sling (n=61), p=0.88; TVT (n=63) vs Porcine dermis sling (n=38), p=0.07</p> <p>Continence-specific health-related QoL at 10 years - BFLUTS UI score: TVT (n=63) vs autologous fascial sling (n=61), p=0.033 ; TVT (n=63) vs Porcine dermis sling (n=38), p=0.22</p> <p>Continence-specific health-related QoL at 10 years - BFLUTS voiding score: TVT (n=63) vs autologous fascial sling (n=61), p=0.53 ; TVT (n=63) vs Porcine dermis sling (n=38), p=0.24</p> <p>Continence-specific health-related QoL at 10 years - BFLUTS sexual function: TVT (n=63) vs autologous fascial sling</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>(n=61), p=0.67 ; TVT (n=63) vs Porcine dermis sling (n=38), p=0.14</p> <p>Continence-specific health-related QoL at 10 years - BFLUTS</p> <p>HRQoL: TVT (n=63) vs autologous fascial sling (n=61), p=0.42 ; TVT (n=63) vs Porcine dermis sling (n=38), p=0.36</p> <p>Adverse events - bladder injury - n/N</p> <p>Intervention 1: 4/72</p> <p>Intervention 2: 1/50</p> <p>Control: 2/79</p> <p>Adverse events - severe bleeding requiring blood transfusion - n/N</p> <p>Intervention 1: 0/72</p> <p>Intervention 2: 0/50</p> <p>Control: 0/79</p> <p>Repeat surgery at 1 year- n/N</p> <p>Intervention 1: 0/69</p> <p>Intervention 2: 9/46</p> <p>Control: 0/67</p> <p>Repeat surgery for SUI at 10 years - n/N</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Intervention 1: 2/63 Intervention 2: 5/38 Control: 0/61 Repeat surgery for POP or mesh complication at 10 years - n/N Intervention 1: 2/63 Intervention 2: 3/38 Control: 4/61 Complications - n/N Pain at 10 years Intervention 1: 0/63 Intervention 2: 0/38 Control: 2/61 Mesh extrusion at 10 years Intervention 1: 1/63 Intervention 2: 0/38 Control: 0/61 Need for catheterisation at 6 months Intervention 1: 0/71 Intervention 2: 0/45 Control: 1/73 Need for catheterisation at 1 year Intervention 1: 0/69 Intervention 2: 0/46 Control: 0/67	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>Need for catheterisation at 10 years</p> <p>Intervention 1: 3/63</p> <p>Intervention 2: 0/38</p> <p>Control: 4/61</p> <p>De novo OAB - de novo urgency at 10 years</p> <p>Intervention 1: 1/63</p> <p>Intervention 2: 0/38</p> <p>Control: 0/61</p>	
<p>Full citation</p> <p>Hinoult, P., Vervest, H. A. M., Den Boon, J., Venema, P. L., Lakeman, M. M., Milani, A. L., Roovers, J. P. W. R., A randomized, controlled trial comparing an innovative single incision mini-sling with an established transobturator sling to treat female stress urinary</p>	<p>Sample size</p> <p>N=195 randomised</p> <p>Intervention, n=97</p> <p>Control, n=98</p> <p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>TVT-Secur-H: 52.3 (11)</p> <p>TVT-O: 53.2 (12)</p> <p>Parity - median (range)</p> <p>TVT-Secur-H: 2 (0-5)</p> <p>TVT-O: 2 (0-7)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>TVT-Secur-H: 25.9 (3.7)</p>	<p>Interventions</p> <p>Intervention: Single-incision minisling</p> <p>Control: Other Synthetic sling</p>	<p>Details</p> <p>All surgeons had extensive experience with SUI treatment, all with experience of 5-10 TVT-Secur operations.</p> <p>Single-incision mini-sling (TVT-Secur-H)</p> <p>Gynecare TVT-Secur used, hammock procedure as described by manufacturer.</p> <p>Other Synthetic sling (TVT-O)</p> <p>Gynecare TVT-O used, procedure as described by manufacturer.</p>	<p>Results</p> <p>Objective cure at 6-mo FU (negative cough stress test with 300 ml full bladder or &gt;70% maximal bladder capacity as determined by participant's voiding diary) - n/N</p> <p>TVT-Secur-H: 65/97</p> <p>TVT-O: 87/98</p> <p>Objective cure at 12-mo FU - n/N</p> <p>TVT-Secur-H: 63/97</p> <p>TVT-O: 83/98</p> <p>Subjective cure at 6-mo FU (No reported SUI episodes in last month) - n/N</p>	<p>Limitations</p> <p>Random sequence generation: Low risk (computer-generated block randomisation at each centre)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Low risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>incontinence, Journal of Urology, 185, 1356-1362, 2011 Ref Id 673921 Country/ies where the study was carried out Belgium, Netherlands Study type Multicentre RCT  Aim of the study To compare efficacy and morbidity of TVT-Secur with TVT-O in women with SUI  Study dates 04/2007 to 01/2009  Source of funding</p>	<p>TVT-O: 28.1 (5.8)  Inclusion criteria Women with clinically- and/or urodynamically-proven SUI  Exclusion criteria Women with recurrent SUI any concomitant surgery genital prolapse stage 2 or more</p>			<p>TVT-Secur-H: 59/97 TVT-O: 83/98 Subjective cure at 12- mo FU - n/N TVT-Secur-H: 57/97 TVT-O: 78/98 Adverse events - severe bleeding requiring transfusion - n/N TVT-Secur-H: 0/96 TVT-O: 0/92 Repeat surgery: OR 2.3 (95% CI 1.9-2.7) [reports 14 cases of repeat surgery for SUI in TVT-Secur-H group but unclear how many in TVT-O group] Complications - n/N Mesh extrusion at 1-yr FU TVT-Secur-H: 7/96 TVT-O: 1/92 Infection (UTI) TVT-Secur-H: 6/96 TVT-O: 2/92 Infection (wound) TVT-Secur-H: 1/96 TVT-O: 0/92</p>	<p>similar across groups and for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Supported by grant from Ethicon					
<p>Full citation Hota,L.S., Hanaway,K., Hacker,M.R., Disciullo,A., Elkadry,E., Dramitinos,P., Shapiro,A., Ferzandi,T., Rosenblatt,P.L., TVT-Secur (Hammock) versus TVT-Obturator: a randomized trial of suburethral sling operative procedures, Female pelvic medicine &amp; reconstructive surgery, 18, 41-45, 2012 Ref Id 188440 Country/ies where the study was carried out</p>	<p>Sample size N=87 randomised Intervention, n=43 Control, n=44</p> <p>Characteristics Median Age (years) TVT-Secur: 52 (IQR 45-62) TVT-O: 50.5 (IQR 45.5-60) Median BMI TVT-Secur: 29.7 (IQR 25.2-32.4) TVT-O: 29.3 (IQR 24.9-33.7) Parity 0/1/≥2 (%) TVT-Secur:11.9/23.8/64.3 TVT-O: 4.6/13.6/81.8 Postmenopausal (%) TVT-Secur: 48 TVT-O: 36 Concomitant POP surgery (%)</p>	<p>Interventions Intervention: Single-incision mini-sling Control: Other synthetic sling</p>	<p>Details One patient excluded from TVT-S group before surgery due to not meeting inclusion criteria. Single-incision mini-sling (TVT-Secur) TVT-S (Ethicon) hammock method used. Other synthetic sling (TVT-O) Ethicon TVT-O used.</p>	<p>Results Negative cough stress test at 1 year - n/N TVT-Secur: 11/42 TVT-O: 20/44 Repeat surgery for SUI at 1 year - n/N TVT-Secur: 8/42 TVT-O: 0/44 Repeat surgery for mesh complications at 1 year - n/N TVT-Secur: 1/42 TVT-O: 0/44 Complications - n/N Mesh extrusion at 1 year TVT-Secur: 8/42 TVT-O: 0/44</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Low risk (sequentially numbered, opaque, sealed enveloped opened on day of surgery) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates) Selective reporting: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>USA</p> <p>Study type RCT</p> <p>Aim of the study To compare TVT-Secur and TVT-O slings in treatment of SUI in women</p> <p>Study dates Unclear, not reported</p> <p>Source of funding Funded by Ethicon Women's Health &amp; Urology (division of Ethicon, Inc, Johnson &amp; Johnson)</p>	<p>TVT-Secur: 47.6 TVT-O: 50</p> <p>Inclusion criteria Women with history of SUI demonstrable impact of SUI as assessed by quality-of-life questionnaires positive cough stress test during urodynamics</p> <p>Exclusion criteria Women with with intrinsic sphincter deficiency (MUCP&lt;20 cm H2O) with previous suburethral sling surgery with predominant overactive bladder symptoms intending pregnancy with elevated postvoid residual&gt;100 ml</p>				<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	with bleeding condition or undergoing anticoagulant therapy with immunosuppression, progressive neurological disease, or evidence of systemic infection				
<p>Full citation Jakimiuk, Aj, Issat, T, Fritz-Rdzanek, A, Maciejewski, T, Rogowski, A, Baranowski, W, Is there any difference? A prospective, multicenter, randomized, single blinded clinical trial, comparing TVT with TVT-O (POLTOS study) in management of stress urinary incontinence. Short-term outcomes,</p>	<p>Sample size N=35 randomised Intervention, n=19 Control, n=16</p> <p>Characteristics Reports no significant difference on age and BMI but no further details provided.</p> <p>Inclusion criteria Women naive to surgery aged 40-80 years-old SUI confirmed by 1=hour pad test and positive urodynamic tests with 300 ml full bladder</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details POLTOS study. Gynecare products (needles and tapes) used in both arms with spinal anaesthesia used in all patients. Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1996. Transobturator sling (TVT-O) Procedure as described by de Leval &amp; Waltrgny 2005.</p>	<p>Results Objective cure at 6 months (Negative pad test at 6 months) - n/N TVT: 14/19 TVT-O: 14/16 Improvement at 6 months (self-reported 'significant' or 'insignificant' improvement in condition) - n/N TVT: 14/19 TVT-O: 14/16 Adverse events - bladder injury - n/N TVT: 3/19 TVT-O: 0/16 Adverse events - bowel injury - n/N TVT: 0/19</p>	<p>Limitations Random sequence generation: Low risk (web-based randomisation) Allocation concealment: Low risk (web-based central allocation) Blinding of participants/personnel: Low risk (participants blinded to group assignment) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Pelviperineology , 31, 5-9, 2012 Ref Id 673942 Country/ies where the study was carried out Poland Study type Multicentre RCT  Aim of the study To compare effectiveness and safety of TVT and TVT-O in women with SUI  Study dates 10/2006 to 10/2009  Source of funding Supported by grant #N40301331/04 69, Ministry of Science and Higher	Exclusion criteria Women with BMI>33 kg/m2 urinary tract infection with pathology in reproductive organ or in lower pelvis which should be qualified for surgical treatment with bladder pathology with past hysterectomy with or without salpingectomy with neurological urinary incontinence with overactive bladder with hypotony of detrusor muscle or any form of mixed incontinence who are pregnant who had past pelvic radiotherapy with hypersensitivity to anaesthetic drugs with post voiding volume >150ml with pelvic organ prolapse			TVT-O: 0/16 King's Health Questionnaire at 6 months (TVT, n=15; TVT-O, n=16) - mean $\pm$ SD General health perception TVT: 13.9 (15.4) TVT-O: 20 (16.9) Incontinence impact TVT: 18.5 (30.7) TVT-O: 17.8 (30.5) Role limitations TVT: 10.2 (19.1) TVT-O: 13.3 (23.7) Physical limitations TVT: 24.1 (18.3) TVT-O: 28.9 (25.6) Social limitations TVT: 0 (0) TVT-O: 4.8 (12) Personal relationships TVT: 1.2 (4.5) TVT-O: 11.1 (24.1) Emotions TVT: 6.8 (17.1) TVT-O: 12.6 (22.6) Sleep/energy	Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Education, Poland	who had myocardial infarction or hemorrhagic or ischemic stroke within past 6 months prior to randomisation with history or family history of auto immunologic disorders or cancer			TVT: 9.3 (14.3) TVT-O: 10.7 (14) Severity measures TVT: 25.6 (25.3) TVT-O: 27.4 (31.3) Complications at 6-months - n/N Pain TVT: 2/15 TVT-O: 1/16 Mesh extrusion TVT: 0/15 TVT-O: 0/16 Infection TVT: 0/15 TVT-O: 1/16	
Full citation Jelovsek, J.E., Barber, M.D., Karram, M.M., Walters, M.D., Paraiso, M.F.R., Randomised trial of laparoscopic Burch colposuspension versus tension-free	Sample size  Characteristics  Inclusion criteria  Exclusion criteria	Interventions	Details	Results	Limitations  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
vaginal tape: Long-term follow up, BJOG: An International Journal of Obstetrics and Gynaecology, 115, 219-225, 2008 Ref Id 135590 Country/ies where the study was carried out Study type  Aim of the study  Study dates  Source of funding					
Full citation Jurakova, M., Huser, M., Belkov, I., Janku, P., Hudecek, R., Stourac, P., Jarkovsky, J.,	Sample size N=93 randomised Intervention, n=45 Control, n=48  Characteristics	Interventions Intervention: Adjustable sling Control: Other synthetic sling	Details ClinicalTrials.gov, NCT02506309. All procedures in both arms conducted by same experienced surgeon (>100 previous sling surgeries, including >29 single-incision surgeries) according to standard techniques recommended by	Results Negative cough stress test at 1 year - n/N Adjustable sling:40/45 Other synthetic sling: 40/48	Limitations Random sequence generation: Unclear risk (randomised using sealed envelopes at time of surgery but no further details)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Ventruba, P., Prospective randomized comparison of the transobturator mid-urethral sling with the single-incision sling among women with stress urinary incontinence: 1- year follow-up study, International Urogynecology Journal, 27, 791-6, 2016 Ref Id 542797 Country/ies where the study was carried out Czech Republic Study type RCT  Aim of the study To compare efficacy and safety of Ophira</p>	<p>Age (years) - mean ±SD Adjustable sling: 62.3 (10.3) Other synthetic sling: 64.3 (10.6) BMI - mean ±SD Adjustable sling: 28.5 (6.5) Other synthetic sling: 29.4 (6.2) Parity - mean ±SD Adjustable sling: 2.3 (1.4) Other synthetic sling: 2.4 (1.1)  Inclusion criteria Women with pure urodynamic SUI (confirmed during cystometry by positive cough stress test with 250ml bladder in lithotomy position)  Exclusion criteria Women with</p>		<p>manufacturers with patients under general anaesthesia. No other concomitant surgeries were performed. Adjustable (single-incision) sling (Ophira) Ophira (Promedon) adjustable SIMS used, polypropylene macroporous monofilament Type I mesh. Mean FU: 12.9 months (0.8) Other synthetic sling TVT-O (Gynecare, Ethicon) used. Mean FU: 13.1 months (1.0)</p>	<p>Improvement at 1 year (Response of 'vey much', 'much' and 'a little' better on PGII) - n/N Adjustable sling: 41/45 Other synthetic sling: 42/48 PGII score at 1 year - mean ±SD Adjustable sling: 1.3 (0.8), n=44 Other synthetic sling: 1.4 (0.9), n=46 ICIQ-SF at 1 year - mean ±SD Adjustable sling: 3.3 (2), n=44 Other synthetic sling: 3.2 (2), n=46 Complications - n/N Mesh extrusion at 1 year Adjustable sling: 0/45 Other synthetic sling: 0/48 No severe intraoperative or major postoperative complications in either group</p>	<p>Allocation concealment: Unclear risk (randomised using sealed envelopes at time of surgery but no further details) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (independent assessor but no further details) Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates) Selective reporting: Low risk (protocol available, all outcomes reported) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>single-incision mini-sling to TVT-O in women with SUI</p> <p>Study dates 01/2012 to 12/2013</p> <p>Source of funding Supported by Czech Republic Ministry of Health projects FNBr 65269705 and IGA NT11124</p>	<p>urge incontinence or urge-predominant mixed UI urgency</p> <p>intrinsic sphincter deficiency (MUCP&lt;20 cm H2O)</p> <p>POP-Q&gt;2</p> <p>previous SUI or POP surgery</p> <p>presence of other pelvic pathological conditions</p>				
<p>Full citation Karateke,A., Haliloglu,B., Cam,C., Sakalli,M., Comparison of TVT and TVT-O in patients with stress urinary incontinence: short-term cure rates and factors</p>	<p>Sample size N=164 randomised Intervention, n=81 Control, n=83</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD TVT: 49.31 (5.00) TVT-O: 49.08 (4.93) BMI - mean <math>\pm</math>SD</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Use of spinal and general anaesthesia determined by patient and anaesthesiologist preference. Mean FU=14 months Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1996 except for midurethral transverse incision used. Cystoscopy performed in all cases. Transobturator sling (TVT-O)</p>	<p>Results Objective cure at 3 months (negative cough stress test) - n/N TVT: 74/81 TVT-O: 74/83 Objective cure at 14-mo FU - n/N TVT: 72/81 TVT-O: 72/83</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>influencing the outcome. A prospective randomised study, Australian and New Zealand Journal of Obstetrics and Gynaecology, 49, 99-105, 2009</p> <p>Ref Id 100648</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type RCT</p> <p>Aim of the study To examine cure and complication rates of TVT compared to TVT-O in women with SUI</p> <p>Study dates</p>	<p>TVT: 25.99 (1.27) TVT-O: 26.18 (1.88)</p> <p>Parity - mean <math>\pm</math>SD TVT: 2.53 (1.08) TVT-O: 2.58 (1.07)</p> <p>Menopause (%) TVT: 20 TVT-O: 17</p> <p>Inclusion criteria Women with urodynamically-proven SUI</p> <p>Exclusion criteria Women with urogenital prolapse &gt;stage 1 detrusor overactivity overactive bladder symptoms urinary retention (peak flow rate &lt; 15 mL/s) previous anti-incontinence surgery including anterior colporrhaphy neurological bladder</p>		<p>Procedure as described by De Leval 2003 except for midurethral transverse incision used.</p>	<p>Improvement at 14-mo FU year (very satisfied or satisfied) - n/N TVT: 76/81 TVT-O: 76/83</p> <p>Adverse events - bladder injury - n/N TVT: 3/81 TVT-O: 0/83</p> <p>Complications - n/N Mesh extrusion at 12 months TVT: 4/81 TVT-O: 2/83</p> <p>Need for catheterisation at 6 weeks TVT: 8/81 TVT-O: 6/83</p> <p>De novo OAB - de novo urge incontinence at 12 months TVT: 6/81 TVT-O: 5/83</p>	<p>participants not attempted)</p> <p>Blinding of outcome assessment: Low risk (assessors blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (no missing data)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
12/2004 to 03/2006  Source of funding Not reported					
Full citation Kenton, K., Stoddard, A. M., Zyczynski, H., Albo, M., Rickey, L., Norton, P., Wai, C., Kraus, S. R., Sirls, L. T., Kusek, J. W., Litman, H. J., Chang, R. P., Richter, H. E., 5-year longitudinal followup after retropubic and transobturator mid urethral slings, Journal of Urology, 193, 203-10, 2015 Ref Id 542809	Sample size N=597 randomised Intervention, n=298 Control, n=299  Characteristics See entry for Richter et al. 2010 for more details  Inclusion criteria See entry for Richter et al. 2010 for more details  Exclusion criteria See entry for Richter et al. 2010 for more details	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details See entry for Richter et al. 2010 for more details	Results See entry for Richter et al. 2010 for more details	Limitations See entry for Richter et al. 2010 for more details  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out USA Study type Multicentre RCT  Aim of the study To report 5-year outcomes comparing retropubic to transobturator slings in women with SUI  Study dates 04/2006 to 06/2008  Source of funding Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231, U01 DK60379, U01 DK60380,					

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
U01 DK60393, U01 DK60395, U01 DK60397, and U01 DK60401) from the National Institute of Diabetes and Digestive and Kidney Diseases and by the National Institute of Child Health and Human Development. Partly funded by NIH grants to 4 authors.					
Full citation Khan, Z. A., Nambiar, A., Morley, R., Chapple, C. R., Emery, S. J., Lucas, M. G., Long-term follow-up of a multicentre randomised controlled trial comparing	Sample size N=211 randomised Intervention 1, n=72 Intervention 2, n=52 Control, n=84  Characteristics Clinicaltrials.gov NCT01057550. See entry for Guerrero et al. 2010 for details.	Interventions Intervention 1: Synthetic sling Intervention 2: Non-autologous biological (Porcine dermis) sling Control: Autologous fascial sling	Details See entry for Guerrero et al. 2010 for details.	Results See entry for Guerrero et al. 2010 for details.	Limitations See entry for Guerrero et al. 2010 for details.  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence in women, BJU International, 115, 968-77, 2015</p> <p>Ref Id 542810</p> <p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To evaluate effectiveness of TVT, porcine dermis and autologous fascial slings at long-term follow up in women with SUI</p>	<p>Inclusion criteria See entry for Guerrero et al. 2010 for details.</p> <p>Exclusion criteria See entry for Guerrero et al. 2010 for details.</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates 2001 to 2006</p> <p>Source of funding See entry for Guerrero et al. 2010 for details.</p>					
<p>Full citation Kitchener,H.C., Dunn,G., Lawton,V., Reid,F., Nelson,L., Smith,A.R.B., Laparoscopic versus open colposuspensio n - Results of a prospective randomised controlled trial, BJOG: An International Journal of Obstetrics and Gynaecology, 113, 1007-1013, 2006</p>	<p>Sample size N=291 randomised Intervention, n=144 Control, n=147</p> <p>Characteristics Median age (years) Laparoscopic: 50.5 Open: 50 Number of women &gt;50 years-old Laparoscopic: 72 Open: 67 Parity=0 - n Laparoscopic: 2 Open: 3 Parity=1 - n Laparoscopic: 11 Open: 13</p>	<p>Interventions Intervention: Laparoscopic colposuspension with sutures Control: Open colposuspension with sutures</p>	<p>Details COLPO trial (COLposuspension; is Lapraoscopic Preferable to Open?). Women recruited from 6 UK gynaecology units with all surgery performed by surgeons with established experience with both forms of colposuspension. Standard operative procedure included antibiotic prophylaxis, skin preparation, suprapubic catheterisation and post-operative patient-controlled analgesic. Two sutures (Ethibond) used in both procedures, with no other concomitant procedures performed. Negative pad test defined as <math>\leq 1</math> g/hr. Urodynamic assessment at 6 months and subsequently only if positive pad test. Follow up: 6 months, 12 months, 24 months</p>	<p>Results Objective cure at 6 months (&lt;1g negative 1-hr pad test) - n/N Laparoscopic: 105/144 Open: 109/147 Objective cure at 12 months - n/N Laparoscopic: 90/144 Open: 90/147 Objective cure at 24 months - n/N Laparoscopic: 98/144 Open: 82/147 Subjective cure at 6 months (Patient never leaks or leaks less than once a month) - n/N Laparoscopic: 71 (56+15)/144</p>	<p>Limitations Random sequence generation: Low risk (random block 2-4 randomisation stratified by centre, age&gt;50 years and previous bladder neck surgery) Allocation concealment: Low risk (central allocation) Blinding of participants/personnel: Unclear risk (Blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Ref Id 135340</p> <p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare effectiveness and cost- effectiveness of open and laparoscopic colposuspensio n in women with stress urinary incontinence</p> <p>Study dates 03/1999 to 02/2002</p> <p>Source of funding Funded by the Medical Research Council</p>	<p>Parity 2-4 - n Laparoscopic: 82 Open: 89</p> <p>Parity≥5 Laparoscopic: 10 Open: 7</p> <p>Previous bladder neck surgery Laparoscopic: 10 Open: 10</p> <p>POP status: not reported</p> <p>Inclusion criteria Women with urodynamic stress incontinence where colposuspension chosen to treat incontinence</p> <p>Exclusion criteria Women with detrusor overactivity previous retropubic surgery who were grossly obese and considered</p>			<p>Open: 58 (52+6)/147 Subjective cure at 12 months - n/N Laparoscopic: 71 (52+19)/144 Open: 78 (53+25)/147 Subjective cure at 24 months - n/N Laparoscopic: 71 (39+32)/144 Open: 68 (48+20)/147 Improvement at 6 months (Response of 'perfectly happy' or 'pleased' to item 33 of Bristol Female Lower Urinary Tract Symptom questionnaire) - n/N Laparoscopic: 83 (62+21)/144 Open: 77 (57+20)/147 Improvement at 12 months - n/N Laparoscopic: 86 (69+17)/144 Open: 76 (56+20)/147 Improvement at 24 months - n/N Laparoscopic: 73 (60+13)/144 Open: 71 (48+23)/147</p>	<p>similar across groups for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	unsuitable for any surgery unfit for general anaesthetic			Adverse events - bladder injury - n/N Laparoscopic: 4/144 Open: 1/147 Adverse events - bowel injury - n/N Laparoscopic: 1/144 Open: 0/147	
Full citation Krofta,L., Feyereisl,J., Otcenasek,M., Velebil,P., Kasikova,E., Krcmar,M., TVT and TVT-O for surgical treatment of primary stress urinary incontinence: prospective randomized trial, International Urogynecology Journal, 21, 141-148, 2010 Ref Id 100662	Sample size N=300 randomised Intervention, n=149 Control, n=151  Characteristics Age (years) - mean ±SD TVT: 57.19 (10.65) TVT-O: 57.82 (10.35) BMI - mean ±SD TVT: 27.82 (3.2) TVT-O: 28.21 (5.7) Parity 0 (%) TVT: 8 TVT-O: 6 Parity 1 (%) TVT: 19 TVT-O: 17 Parity 2 (%)	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details Three surgeons conducted all operations and were experienced in both types of procedure. All participants received iv prophylactic cefazoline at beginning of surgery. Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1996, under local anaesthesia and iv analgosedation. Cystoscopy/cough test conducted in all cases. Transobturator sling (TVT-O) Procedure as described by DeLeval 2003, under spinal or local anaesthesia and iv analgosedation. Hydrodissection in case of latter anaesthesia. Gynecare Winged Guide used in all cases.	Results Objective cure at 1 year (negative cough stress test at 300 ml full bladder and 1-hr pad test>1g) - n/N TVT: 127/149 TVT-O: 130/151 Subjective cure at 1 year (Response of 'never' to ICIQ-UI-SF frequency question) - n/N TVT: 111/149 TVT-O: 112/151 Improvement at 1 year (number of women subjectively cured + number of women whose leakage frequency is less than at	Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant impact on effect estimate)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out Czech Republic</p> <p>Study type RCT</p> <p>Aim of the study To assess effectiveness and safety of TVT and TVT-O procedures in women with SUI</p> <p>Study dates 01/2005 to 12/2006</p> <p>Source of funding Supported by grant # NR-9309 from Internal Grant Agency, Ministry of Health of the Czech Republic</p>	<p>TVT: 60 TVT-O: 54 Parity 3 (%) TVT: 10 TVT-O: 18 Parity ≥4 (%) TVT: 3 TVT-O: 5</p> <p>Inclusion criteria Women with urodynamically-proven SUI (inc. positive stress test) failed conservative therapy</p> <p>Exclusion criteria Women with predominant urge incontinence urodynamic detrusor instability preoperative use of anticholinergic medication previously failed antiincontinence surgery</p>			<p>baseline on ICIQ-UI-SF) - n/N TVT: 138/149 TVT-O: 143/151 ICIQ-UI-SF total - mean ±SD TVT: 3 (4.92), n=141 TVT-O: 3.5 (3.47), n=147</p> <p>Adverse events - bladder injury - n/N TVT: 1/149 TVT-O: 0/151</p> <p>Adverse events - bowel injury - n/N TVT: 0/149 TVT-O: 0/151</p> <p>Repeat surgery for mesh complications - n/N TVT: 1/149 TVT-O: 1/151</p> <p>Complications at 1 year - n/N Pain TVT: 6/149 TVT-O: 8/151 Mesh extrusion TVT: 2/141 TVT-O: 2/147</p>	<p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>previous prolapse or radical pelvic surgery or radiotherapy</p> <p>postvoid residual volume (PVR) &gt;100 mL</p> <p>stage II, III, or IV POP (ICS system)</p> <p>concomitant operations</p>			<p>Need for catheterisation at 2 weeks</p> <p>TVT: 4/149</p> <p>TVT-O: 10/151</p> <p>Infection (UTI)</p> <p>TVT: 5/149</p> <p>TVT-O: 8/151</p> <p>Infection (wound)</p> <p>TVT: 0/141</p> <p>TVT-O: 0/147</p> <p>De novo OAB - de novo urge incontinence</p> <p>TVT: 9/141</p> <p>TVT-O: 20/147</p>	
<p>Full citation</p> <p>Laurikainen, E., Valpas, A., Aukee, P., Kivela, A., Rinne, K., Takala, T., Nilsson, C. G., Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence,</p>	<p>Sample size</p> <p>N=273 randomised</p> <p>Intervention, n=136 received TVT</p> <p>Control, n=132 received TVT-O</p> <p>Characteristics</p> <p>See entry for Laurikainen et al. 2007 for more details.</p> <p>Inclusion criteria</p>	<p>Interventions</p> <p>Intervention: Retropubic sling</p> <p>Control: Transobturator sling</p>	<p>Details</p> <p>See entry for Laurikainen et al. 2007 for more details.</p>	<p>Results</p> <p>See entry for Laurikainen et al. 2007 for more details.</p>	<p>Limitations</p> <p>See entry for Laurikainen et al. 2007 for more details.</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>European Urology, 65, 1109-14, 2014</p> <p>Ref Id 542851</p> <p>Country/ies where the study was carried out Finland</p> <p>Study type Mutlicentre RCT</p> <p>Aim of the study To compare 5-year outcomes of TVT to TVT-O in women with SUI</p> <p>Study dates 03/2004 to 11/2005</p> <p>Source of funding Finnish government research funding</p>	<p>See entry for Laurikainen et al. 2007 for more details.</p> <p>Exclusion criteria See entry for Laurikainen et al. 2007 for more details.</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Laurikainen,E., Valpas,A., Kivela,A., Kalliola,T., Rinne,K., Takala,T., Nilsson,C.G., Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial, Obstetrics and Gynecology, 109, 4-11, 2007 Ref Id 100672 Country/ies where the study was carried out Finland Study type Multicentre RCT Aim of the study</p>	<p>Sample size N=273 randomised Intervention, n=136 received TVT Control, n=132 received TVT-O</p> <p>Characteristics Age (years) - mean ±SD TVT: 53 (10) TVT-O: 54 (10) BMI - mean ±SD TVT: 26 (3) TVT-O: 26 (4) Median parity TVT: 2 (range 0-8) TVT-O: 2 (range 0-7) Postmenopausal (%) TVT: 52 TVT-O: 60</p> <p>Inclusion criteria Women with History of stress urinary incontinence indication for SUI surgery</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details clinicaltrials.gov, NCT00379314. Local anaesthetic and light iv sedation used; iv prophylactic cefuroxime or metronidazole administered. Retropubic sling (TVT) Gynecare TVT used, procedure as described by Ulmsten et al. 1996. Cystoscopy conducted twice during procedure after each needle pass. Transobturator sling (TVT-O) Gynecare TVT-O used, procedure as described by deLeval 2003. Cystoscopy conducted once during procedure.</p>	<p>Results Note: 1-year follow up data from Rinne et al. 2008; 5-year follow up data from Laurikainen et al. 2014 Objective cure at 2 months (negative cough stress test) - n/N TVT: 134/136 TVT-O: 125/132 Objective cure at 1 year - n/N TVT: 128/136 TVT-O: 122/132 Objective cure at 5 years (negative cough stress test, negative pad test, and no retreatment for SUI) - n/N TVT: 111/136 TVT-O: 106/132 Improvement at 1 year (satisfied with operation) - n/N TVT: 121/134 TVT-O: 122/131 Improvement at 5 years (treatment completely or partly satisfying expectations) - n/N</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Low risk (central allocation) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: High risk (some assessments conducted by operating surgeon or study nurses, potential detection bias) Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant impact on effect estimates) Selective reporting: Low risk (all primary and secondary outcomes reported at 1- and 5 years) Other bias: Low risk (appears free from other sources of bias)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>To compare intraoperative and early post-operative outcomes of TVT to TVT-O in women with SUI</p> <p>Study dates 03/2004 to 11/2005</p> <p>Source of funding Finnish government research funding</p>	<p>Positive cough stress test</p> <p>Detrusor Instability Score<math>\leq</math>7</p> <p>Exclusion criteria Women with Previous incontinence surgery Postvoid residual urine volume more than 100ml Lower urinary tract anomaly Current urinary tract infection (UTI) or more than three UTI episodes within the past year POP&gt;2nd degree (Baden-Walker) BMI&gt;35 kg/m<sup>2</sup> Previous radiation therapy of pelvis Active malignancy Anticoagulant therapy Haemophilia Neurogenic disease associated with bladder disorders</p>			<p>TVT: 128/136 TVT-O: 121/132 QoL - UISS at 2 months - mean <math>\pm</math>SD TVT: 0.7 (1.6) TVT-O: 0.1 (1) QoL - UISS at 1 year - mean <math>\pm</math>SD TVT: 0.7 (1.8), n=134 TVT-O: 0.4 (1), n=131 QoL - UISS at 5 years - mean <math>\pm</math>SD TVT: 1 (3), n=131 TVT-O: 1 (2), n=132 Adverse events - bladder injury - n/N TVT: 1/136 TVT-O: 0/131 Adverse events - severe bleeding requiring blood transfusion - n/N TVT: 1/136 TVT-O: 0/131 Repeat surgery for mesh complications at 5 years - n/N TVT: 1/131 TVT-O: 1/123 Complications - n/N</p>	<p>Other information 1 year follow up data reported in Rinne et al. 2008; 5-year results reported in Laurikainen et al. 2014.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Anticholinergic or duloxetine medication who is immobile			Pain at 2-mo TVT: 2/136 TVT-O: 21/131 Pain at 1 year TVT: 0/131 TVT-O: 1/131 Mesh extrusion at 1 year TVT: 0/134 TVT-O: 1/131 Mesh extrusion at 5 years TVT: 0/131 TVT-O: 0/123 Infection (UTI) at 2-mo TVT: 11/136 TVT-O: 17/131 Infection (UTI) at 1 year TVT: 2/134 TVT-O: 3/131 Infection (Wound) at 2-mo TVT: 1/136 TVT-O: 0/131 Need for catheterisation at 2-mo TVT: 1/136 TVT-O: 2/131 De novo OAB - de novo urge at 2-mo	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TVT: 3/136 TVT-O: 3/131 De novo OAB - de novo urge at 1 year TVT: 2/134 TVT-O: 3/131 De novo OAB - de novo urge incontinence at 5 years TVT: 4/131 TVT-O: 3/123	
<p>Full citation Lee, J. K. S., Rosamilia, A., Dwyer, P. L., Lim, Y. N., Muller, R., Randomized trial of a single incision versus an outside-in transobturator midurethral sling in women with stress urinary incontinence: 12 month results, American Journal of Obstetrics and</p>	<p>Sample size N=235 randomised Intervention, n=117 Control, n=118</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD MiniArc: 52.2 (10.0) TOT: 51.0 (9.4) BMI - mean <math>\pm</math>SD MiniArc: 27.4 (5.8) TOT: 27.6 (5.5) Median Parity MiniArc: 2 (IQR 2-3) TOT: 2 (IQR 2-3) Menopause (%)</p>	<p>Interventions Intervention: Single-incision mini-sling Control: Other Synthetic sling</p>	<p>Details Registered on <a href="http://www.anzctr.org.au">www.anzctr.org.au</a>, ACTRN12608000624381. All procedures conducted by surgeons proficient with TOT and at least 10 MiniArc operations. All participants had general anaesthetic and cystoscopy was conducted in all cases.</p> <p>Single-incision mini-sling (MiniArc) MiniArc (AMS) mini-sling used, procedure according to manufacturer's instructions.</p> <p>Other synthetic sling (TOT) Monarc (AMS) TOT used, procedure according to manufacturer's instructions.</p>	<p>Results Objective cure at 6-mo FU (negative urodynamic stress or cough test) - n/N MiniArc: 77/117 TOT: 82/118 Objective cure at 12-mo FU (Negative cough stress test in supine position) - n/N MiniArc: 84/117 TOT: 87/118 Objective cure at 6-mo FU (no prolapse surgery only) - n/N MiniArc: 47/58 TOT: 43/51</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (reports concealed allocation but no further details provided) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Gynecology, 213, 35.e1-35.e9, 2015</p> <p>Ref Id 669602</p> <p>Country/ies where the study was carried out Australia</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To examine 6-month and 1-year cure rates and safety of MiniArc and Monarc slings in women with SUI</p> <p>Study dates 05/2009 to 12/2014</p> <p>Source of funding Supported by external research grant from American</p>	<p>MiniArc: 45 TOT: 43</p> <p>Inclusion criteria Women with SUI or urodynamically-proven stress incontinence who failed conservative treatment who requested SUI surgery</p> <p>Exclusion criteria Women with intrinsic sphincter deficiency previous MUS operation untreated detrusor overactivity significant voiding dysfunction (maximum flow rate &lt;15 mL/s or &lt;10%) Liverpool nomogram and/or postvoid residual &gt;100 ml)</p>			<p>Objective cure at 12-mo FU (no prolapse surgery only) - n/N MiniArc: 47/51 TOT: 42/45</p> <p>Subjective cure at 6-mo FU (Absence of leakage with coughing and exercise according to Q3 and Q5 of ICIQ-UI-SF) - n/N MiniArc: 105/117 TOT: 99/118</p> <p>Subjective cure at 12-mo FU - n/N MiniArc: 95/117 TOT: 97/118</p> <p>Subjective cure at 6-mo FU (no prolapse surgery only) MiniArc: 63/66 TOT: 52/56</p> <p>Subjective cure at 12-mo FU (no prolapse surgery only) MiniArc: 57/62 TOT: 49/57</p> <p>Continence-specific health-related QoL - ICIQ-UI-SF at 6-mo FU - median</p>	<p>Incomplete outcome data: Low risk (missing data similar across groups and for similar reasons)</p> <p>Selective reporting: Low risk (protocol available, all outcomes reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Medical Systems, Minnetonka, MN, USA.				MiniArc: 4 (IQR 0-7), n=103 TOT: 3 (IQR 0-6), n=103 Continence-specific health-related QoL - ICIQ-UI-SF at 12-mo FU - median MiniArc: 4 (IQR 0-6), n=98 TOT: 3 (IQR 0-6), n=95 Continence-specific health-related QoL - ICIQ-OAB at 6-mo FU - median MiniArc: 3 (IQR 2-5), n=104 TOT: 3 (IQR 2-5), n=102 Continence-specific health-related QoL - ICIQ-OAB at 12-mo FU - median MiniArc: 3 (IQR 1-4), n=102 TOT: 3 (IQR 2-5), n=96 Continence-specific health-related QoL (sexual function) - PISQ-12 at 6-mo FU - median MiniArc: 36 (IQR 33-40), n=78	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>TOT: 39 (IQR 33-41), n=74                      Continence-specific health-related QoL (sexual function) - PISQ-12 at 12-mo FU - median                      MiniArc: 37 (IQR 34-41), n=69                      TOT: 38 (IQR 33-41), n=73                      Patient improvement - PGII at 6-mo FU - median                      MiniArc: 1 (IQR 1-2)                      TOT: 1 (IQR 1-2)                      Patient improvement - PGII at 12-mo FU - median                      MiniArc: 1 (IQR 1-2)                      TOT: 1 (IQR 1-2)</p>	
<p>Full citation                      Liapis,A.,                      Bakas,P.,                      Creatsas,G.,                      Burch                      colposuspension and tension-free vaginal tape in the</p>	<p>Sample size                      N=71 women underwent surgery                      Intervention, n=36                      Control, n=35                        Characteristics                      Mean age (years)</p>	<p>Interventions                      Intervention:                      Synthetic sling                      Control:                      Colposuspension</p>	<p>Details                      Two surgeons performed all procedures. Follow up=24 months                      Synthetic sling (TVT)                      Procedure performed in lithotomy position as described by Ulmsten &amp; Petros 1995 except for use of number 16 Foley catheter. All patients had cystoscopy.</p>	<p>Results                      Objective cure at 2 years (1-hr pad weight difference &lt;1g) - n/N                      TVT: 30/35                      Open colposuspension: 30/36</p>	<p>Limitations                      Random sequence generation: High risk (type of surgery alternated relative to order on waiting list)                      Allocation concealment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>management of stress urinary incontinence in women, European Urology, 41, 469-473, 2002</p> <p>Ref Id 128482</p> <p>Country/ies where the study was carried out Greece</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy and complications of TVT to Burch colposuspension in treatment of female genuine stress incontinence</p> <p>Study dates Unclear, not reported</p>	<p>TVT: 46.5 (range? 32-62)</p> <p>Open colposuspension: 48.4 (range? 35-64)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>TVT: 27.2 (2.2)</p> <p>Open colposuspension: 26.6 (2.1)</p> <p>Parity - mean <math>\pm</math>SD</p> <p>TVT: 2.1 (1.1)</p> <p>Open colposuspension: 1.9 (0.8)</p> <p>Inclusion criteria Women with genuine stress urinary incontinence <math>\leq</math>Stage 1 anterior wall prolapse (ICS classification)</p> <p>No previous SUI surgery</p> <p>No urge incontinence</p> <p>Competent intrinsic urethral sphincter</p>		<p>Open colposuspension with sutures</p> <p>Standard procedure used.</p>	<p>Improvement at 2 years (number cured + number reduction in urine leakage to 50% preop) - n/N</p> <p>TVT: 32/35</p> <p>Open colposuspension: 33/36</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 4/35</p> <p>Open colposuspension: 0/36</p> <p>Complications at 2 years - n/N</p> <p>Pain</p> <p>TVT: 0/35</p> <p>Open colposuspension: 4/36</p> <p>Need for catheterisation</p> <p>TVT: 0/35</p> <p>Open colposuspension: 3/36</p> <p>De novo detrusor instability</p> <p>TVT: 6/35</p> <p>Open colposuspension: 5/36</p> <p>De novo urgency</p> <p>TVT: 2/35</p>	<p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (no missing data)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported	Exclusion criteria			Open colposuspension: 1/36 Infection (UTI) TVT: 5/35 Open colposuspension: 2/36	
Full citation Liapis,A., Bakas,P., Giner,M., Creatsas,G., Tension-free vaginal tape versus tension- free vaginal tape obturator in women with stress urinary incontinence, Gynecologic and Obstetric Investigation, 62, 160-164, 2006 Ref Id 100677 Country/ies where the study was carried out	Sample size N=91 randomised Intervention, n=46 completers Control, n=43 completers  Characteristics Age (years) - mean ±SD TVT: 53 (9.1) TVT-O: 52 (10.2) BMI - mean ±SD TVT: 26.5 (3.8) TVT-O: 27.2 (4.1) Parity - median (range) TVT: 2.1 (1) TVT-O: 2.4 (1.1) Menopausal (%) TVT: 48	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details All procedures conducted by same surgeon. Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1996 Transobturator sling (TVT-O) Patient placed in gynaecological position with thighs in hyperflexion. Gynecare TVT Winged guide used. Standard procedure followed.	Results Objective cure at 1 year (Negative cough stress test and 1-hour pad test<1g) - n/N TVT: 41/46 TVT-O: 39/43 Subjective cure at 1 year (self-reported no SUI) - n/N TVT: 34/46 TVT-O: 33/43 Improvement at 1 year (number cured + number self-reported improved) - n/N TVT: 44/46 TVT-O: 40/43 Adverse events - bladder injury - n/N TVT: 3/46 TVT-O: 0/43	Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimate) Selective reporting: Unclear risk (insufficient information)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Greece</p> <p>Study type RCT</p> <p>Aim of the study To compare effectiveness and safety of TVT and TVT-O in treatment of female SUI</p> <p>Study dates 11/2003 to 10/2004</p> <p>Source of funding Not reported</p>	<p>TVT-O: 60</p> <p>Inclusion criteria Women with evidence of SUI without bladder overactivity</p> <p>Exclusion criteria Women with detrusor instability with gynaecological disease requiring hysterectomy or other gynaecological operation who previously failed SUI surgery</p>			<p>Repeat surgery for mesh complications - n/N</p> <p>TVT: 1/46 TVT-O: 0/43</p> <p>Complications at ≤1 year - n/N</p> <p>Mesh extrusion TVT: 1/46 TVT-O: 0/43</p> <p>Need for catheterisation - n/N</p> <p>TVT: 4/46 TVT-O: 0/43</p> <p>Infection (UTI) TVT: 3/46 TVT-O: 1/43</p> <p>De novo detrusor instability TVT: 4/46 TVT-O: 0/43</p> <p>De novo urgency TVT: 5/46 TVT-O: 0/43</p> <p>Wound complications TVT: 0/46 TVT-O: 0/43</p>	<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Maheer,C.F., O'Reilly,B.A., Dwyer,P.L., Carey,M.P., Cornish,A., Schluter,P., Pubovaginal sling versus transurethral Macroplastique for stress urinary incontinence and intrinsic sphincter deficiency: a prospective randomised controlled trial, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 797-801, 2005</p> <p>Ref Id 100691</p> <p>Country/ies where the study was carried out Australia</p>	<p>N=45 randomised Intervention, n=23 Control, n=22</p> <p>Characteristics Median age (years) Bulking agent: 65 (range 34-84) Other surgery; 63 (range 43-81) Median BMI Bulking agent: 30 (range 21-37) Other surgery: 29 (range 21-47) Median Parity Bulking agent: 3 (range 0-4) Other surgery: 3 (range 0-6) Menopausal (%) Bulking agent: 52 Other surgery: 46</p> <p>Inclusion criteria Women with SUI and intrinsic sphincter deficiency (MUCP≤20 cm H2O)</p>	<p>Intervention: Bulking Agent (Macroplastique) Control: Other surgery</p>	<p>All procedures performed under supervision of 1 of 2 consultant urogynaecologists and all surgeons had prior experience with transurethral injectables and slings. Women with recurrent SUI offered top-up injections. Median long-term FU=61 months (range 43-71).</p> <p>Bulking agent Macroplastique (Uroplasty, MN, USA) - vulcanised silicone microimplant suspended in povidine gel - used with injections (volume 5-7.5 ml) performed under general anaesthesia. Catheters removed on day one and patient discharged if residual &lt;100ml on bladder scanning. Median short-term FU: 12 months</p> <p>Other surgery Pubovaginal (autologous rectus fascial) sling used, procedure as described by McGuire et al. 1987. Combined abdominal-vaginal approach using 11-12 cm harvested sling. Catheter clamped on day 3 with spontaneous voiding allowed, and discharged when ready. Median short-term FU: 15 months.</p>	<p>Objective cure at 6-mo (no urinary leakage due to SUI on repeat urodynamic testing) - n/N Bulking agent: 2/23 Other surgery: 17/22 Subjective cure at 6-mo (&lt;1 stress incontinence episode per week) - n/N Bulking agent: 17/23 Other surgery: 19/22 Subjective cure at &gt;5 years - n/N Bulking agent: 4/23 Other surgery: 0/22 Improvement at 6-mo (number of women satisfied with procedure) - n/N Bulking agent: 13/23 Other surgery: 7/22 Improvement at &gt;5 years - n/N Bulking agent: 4/23 Other surgery: 9/22 Repeat surgery for SUI at ≤1 year - n/N Bulking agent: 2/23 Other surgery: 1/22</p>	<p>Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Low risk (blinding not possible for participants and surgical staff) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data balanced in numbers across groups) Selective reporting: Unclear risk (insufficient information) Other bias: High risk (50% of women in sling group had preoperative detrusor instability compared to only 11% of bulking agent group).</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study type RCT</p> <p>Aim of the study To compare pubovaginal sling and transurethral Macroplastique in women with SUI and intrinsic sphincter deficiency</p> <p>Study dates 08/1997 to 12/2000</p> <p>Source of funding None reported</p>	<p>who failed to respond to conservative treatment</p> <p>Exclusion criteria Women who required prolapse surgery had a sling procedure unsuitable for general anaesthesia</p>			<p>Complications - n/N Need for catheterisation at 12-mo Bulking agent: 0/22 Other surgery: 1/21 De novo OAB - detrusor overactivity at 12-mo Bulking agent: 0/22 Other surgery: 1/21 Reports no new OAB symptoms at 5 year FU. Infection (UTI)at 12-mo Bulking agent: 2/22 Other surgery: 3/21 Wound complicationsat 12-mo Bulking agent: 0/22 Other surgery: 1/21</p>	
<p>Full citation Masata, J., Svabik, K., Zvara, K., Drahoradova, P., El Haddad, R., Hubka, P., Martan, A., Randomized</p>	<p>Sample size N=197 randomised Intervention 1 (TVT-Secur-H), n=64 Intervention 2 (TVT-Secur-U), n=65 Control (TVT-O), n=68</p>	<p>Interventions Intervention 1: Single-incision mini-sling 1 Intervention 2: Single-incision mini-sling 2</p>	<p>Details All procedures performed under general anaesthesia with participant in lithotomy position. All participants received preoperative prophylactic ampicillin + iv sulbactam or clindamycin. Single-incision mini-sling 1 (TVT-Secur-H)</p>	<p>Results Objective cure at 2-year FU (Negative cough stress test at 300 ml full bladder in supine and standing positions) - n/N Intervention 1: 44/64 Intervention 2: 45/65</p>	<p>Limitations Random sequence generation: Low risk (states envelope technique used) Allocation concealment: Unclear risk (reports sequentially opened sealed envelopes but no</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women-2-year follow-up, International Urogynecology Journal and Pelvic Floor Dysfunction, 23, 1403-1412, 2012</p> <p>Ref Id 669601</p> <p>Country/ies where the study was carried out Czech Republic</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy of TVT-</p>	<p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>Intervention 1: 55.2 (10.2)</p> <p>Intervention 2: 57.7 (10.1)</p> <p>Control: 56.6 (9.7)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>Intervention 1: 26.2 (4.2)</p> <p>Intervention 2: 27.6 (4.8)</p> <p>Control: 27.0 (4.5)</p> <p>Parity - mean <math>\pm</math>SD</p> <p>Intervention 1: 2.1 (0.9)</p> <p>Intervention 2: 2.0 (0.7)</p> <p>Control: 1.8 (0.9)</p> <p>Mixed UI (%)</p> <p>Intervention 1: 42</p> <p>Intervention 2: 39</p> <p>Control: 43</p> <p>Inclusion criteria</p> <p>Women</p> <p><math>\geq</math>18 years-old</p>	<p>Control: Other Synthetic sling</p>	<p>Procedure according to manufacturer's instructions.</p> <p>Single-incision mini-sling (TVT-Secur-U)</p> <p>Procedure according to manufacturer's instructions.</p> <p>Cystoscopy performed in all cases after second inserter.</p> <p>Other synthetic sling (TVT-O)</p> <p>Gynecare TVT-O used, procedure as described by deLeval 2003.</p> <p>Cystoscopy not routinely performed.</p>	<p>Control: 63/68</p> <p>Subjective cure at 2-year FU (Response of 'never - urine does not leak' to Q6 of ICIQ-UISF) - n/N</p> <p>Intervention 1: 44/64</p> <p>Intervention 2: 40/65</p> <p>Control: 58/68</p> <p>Improvement at 2-year FU (Likert scale 1-5 assessing satisfaction, Response of 5 ('cured/very satisfied') or 4 ('improved/satisfied')) - n/N</p> <p>Intervention 1: 52/64</p> <p>Intervention 2: 58/65</p> <p>Control: 66/68</p> <p>Adverse events - bladder injury - n/N</p> <p>Intervention 1: 1/64</p> <p>Intervention 2: 0/65</p> <p>Control: 0/68</p> <p>Repeat surgery for SUI at 2 years - n/N</p> <p>Intervention 1: 8/64</p> <p>Intervention 2: 7/65</p> <p>Control: 0/68</p>	<p>further information provided)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (Missing data imputed using appropriate [LOCF and LFCF] methods)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>O with TVT-Secur (U or H positions) in women with SUI</p> <p>Study dates 01/2007 to 11/2009</p> <p>Source of funding Supported by grant NS 10586-3/2009 from the Grant Agency of the Ministry of Health of the Czech Republic</p>	<p>with urodynamically-proven SUI who failed conservative therapy agreed to postoperative FU</p> <p>Exclusion criteria Women with predominant urge incontinence urodynamic detrusor instability immobile urethra previously failed anti-incontinence surgery previous radiotherapy postvoid residual volume &gt;100 ml bladder capacity &lt;300 ml POP-Q stage ≥2 II or greater planned concomitant surgery</p>			<p>Continence-specific health-related QoL - ICIQ-UI-SF Total at 2 year FU - mean ±SD Intervention 1: 4.9 (5.8) Intervention 2: 4.6 (4.9) Control: 2.8 (3.6)</p> <p>Continence-specific health-related QoL - I-QoL at 2 year FU - mean ±SD Intervention 1: 91.1 (22.4) Intervention 2: 94.6 (18.3) [combined means/SDs: 92.86 [20.33], n=129] Control: 99.1 (13.1)</p> <p>Complications at 2 years FU - n/N Mesh extrusion Intervention 1: 5/64 Intervention 2: 4/65 Control: 1/68 Infection (UTI) Intervention 1: 0/64 Intervention 2: 1/65 Control: 2/68 De novo OAB - de novo urgency</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Intervention 1: 8/64 Intervention 2: 5/65 Control: 13/68 De novo OAB - de novo urge incontinence Intervention 1: 14/64 Intervention 2: 15/65 Control: 15/68	
<p>Full citation Masata, J., Svabik, K., Zvara, K., Hubka, P., Toman, A., Martan, A., Comparison of the efficacy of tension-free vaginal tape obturator (TVT-O) and single-incision tension-free vaginal tape (AjustTM) in the treatment of female stress urinary incontinence: a 1-year follow-up randomized trial,</p>	<p>Sample size N=100 randomised Intervention, n=50 Control, n=50</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD Adjustable sling: 55.8 (10.2) TVT-O: 58.9 (12.4) BMI (kg/m<sup>2</sup>) - mean <math>\pm</math>SD Adjustable sling: 27.3 (4.8) TVT-O: 27.9 (4.4) Parity - mean <math>\pm</math>SD Adjustable sling: 2.0 (0.9)</p>	<p>Interventions Intervention: Adjustable sling Control: Tension-free vaginal tape obturator (TVT-O)</p>	<p>Details All women admitted to hospital 1 day before surgery with all surgical procedures performed by 2 senior experienced surgeons (both certified urogynaecologists with &gt;19 Ajust procedures conducted). Surgery performed with patient under general anaesthesia, urethral catheter inserted, and placed in lithotomy position. Incision started after articaine + epinephrine infiltration. 16F Foley catheter kept in place for 24 hrs and vaginal packing for 6-12 hr. All patients received preoperative iv antibiotic prophylaxis (ampicillin+sulbactam; or clindamycin for women allergic to penicillin). Mean FU: 452 (128) days; 445 (158) days Adjustable sling (Ajust)</p>	<p>Results Objective cure at 1 year (negative cough stress test with bladder filled to 300 ml, supine and standing positions) - n/N Adjustable sling: 44/49 TVT-O: 41/47 Subjective cure at 1 year (no stress leakage of urine after surgery based on response to Q6 of ICIQ-UI SF) - n/N Adjustable sling: 44/49 TVT-O: 43/47 Continence-related quality of life - ICIQ-UI SF - mean <math>\pm</math>SD Adjustable sling: 2.2 (3.6), n=49 TVT-O: 2.4 (3.6), n=47</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information about generation method) Allocation concealment: Low risk (opaque, sequentially-numbered, sealed enveloped used) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (reasons for missing data unlikely related to true outcome)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>International Urogynecology Journal, 27, 1497-505, 2016 Ref Id 542906 Country/ies where the study was carried out Czech Republic Study type RCT</p> <p>Aim of the study To compare efficacy of Ajust adjustable single-incision sling and tension-free vaginal tape obturator in women with SUI</p> <p>Study dates 05/2010 to 05/2012</p> <p>Source of funding</p>	<p>TVT-O: 2 (0.6) Number of sexually active women Adjustable sling: 34 TVT-O: 28 Number of women with mixed UI Adjustable sling: 22 TVT-O: 23 POP status: not reported but 6 women in Ajust group and 9 women in TVT-O group had previous vaginal wall repair.</p> <p>Inclusion criteria Women 18 years or older provision of signed informed consent with the presence of urodynamic SUI Failed conservative therapy</p> <p>Exclusion criteria Women aged &lt;18 years-old, or Women with</p>		<p>Ajust single-incision sling used with procedure performed according to technique recommended by manufacturer. Other synthetic sling (TVT-O) TVT-O (Ethicon) tape used with procedure performed according to technique originally described by de Leval 2003.</p>	<p>Continence-related quality of life - i-QoL - mean <math>\pm</math>SD Adjustable sling: 88.5 (12.8), n=49 TVT-O: 91.5 (11.2), n=47 Adverse events - bladder injury - n/N Adjustable sling: 0/50 TVT-O: 0/50 Adverse events - urethral injury Adjustable sling: 0/50 TVT-O: 0/50 Adverse events - vaginal wall perforation - n/N Adjustable sling: 0/50 TVT-O: 0/50 Repeat surgery for SUI - n/N Adjustable sling: 0/49 TVT-O: 1/47 Short-term complications at 1 year - n/N De novo urgency Adjustable sling: 5/49 TVT-O: 4/47 De novo dyspareunia</p>	<p>Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Supported by grant NT 14162-3/2013 from the Grant Agency of the Ministry of Health of the Czech Republic	<p>predominant urge incontinence</p> <p>urodynamic detrusor instability</p> <p>previous failed anti-incontinence surgery</p> <p>previous radiotherapy</p> <p>postvoid residual volume (PVR) greater than 100 ml</p> <p>bladder capacity less than 300 ml</p> <p>POP-Q Stage 3 or greater</p> <p>planned concomitant surgery</p>			<p>Adjustable sling: 2/49</p> <p>TVT-O: 0/47</p> <p>Tape erosion</p> <p>Adjustable sling: 0/49</p> <p>TVT-O: 0/47</p>	
<p>Full citation</p> <p>Maslow, K., Gupta, C., Klippenstein, P., Girouard, L., Randomized clinical trial comparing TVT Secur system and trans vaginal obturator tape for the surgical management of</p>	<p>Sample size</p> <p>N=106 randomised</p> <p>Intervention, n=56</p> <p>Control, n=50</p> <p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>TVT-Secur-H: 48.75 (9.3)</p> <p>TVT-O: 48.7 (8.3)</p> <p>BMI - mean <math>\pm</math>SD</p>	<p>Interventions</p> <p>Intervention: Single-incision mini-sling</p> <p>Control: Other Synthetic sling</p>	<p>Details</p> <p>ClinicalTrials.gov NCT00527696. All participants received local anaesthesia with sedation.</p> <p>Single-incision mini-sling (TVT-Secur-H)</p> <p>Gynecare TVT-S used, hammock position as described by manufacturer.</p> <p>Other Synthetic sling (TVT-O)</p> <p>Procedure as described by Delorme 20101.</p>	<p>Results</p> <p>Objective cure at 1-year FU (negative cough stress test) - n/N</p> <p>TVT-Secur-H: 33/56</p> <p>TVT-O: 43/50</p> <p>Subjective cure at 1-year FU - n/N</p> <p>TVT-Secur-H: 42/56</p> <p>TVT-O: 44/50</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT-Secur-H: 1/56</p>	<p>Limitations</p> <p>Random sequence generation: Low risk (computer-generated block randomisation list)</p> <p>Allocation concealment: Low risk (sequentially numbered, opaque, sealed envelopes used)</p> <p>Blinding of participants/personnel: Low risk (participants blinded to group assignment)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>stress urinary incontinence, International Urogynecology Journal, 25, 909-14, 2014</p> <p>Ref Id 542907</p> <p>Country/ies where the study was carried out Canada</p> <p>Study type RCT</p> <p>Aim of the study To compare safety and efficacy of TVT-Secur-H with TVT-O in women with SUI</p> <p>Study dates 05/2008 to 10/2011</p> <p>Source of funding Funded by Department</p>	<p>TVT-Secur-H: 29.3 (4.9)</p> <p>TVT-O: 27.6 (4.2)</p> <p>Parity - mean <math>\pm</math>SD</p> <p>TVT-Secur-H: 2.4 (1.08)</p> <p>TVT-O: 2.3 (1.15)</p> <p>Postmenopausal (%): 38; 33</p> <p>Inclusion criteria Women with SUI symptoms with positive cough test who required surgical management</p> <p>Exclusion criteria Women with withurge-predominant symptoms POP-Q Stage &gt;1 or POP requiring surgery Detrusor overactivity on cystometrogram at urodynamic testing Previous incontinence surgery</p>			<p>TVT-O: 0/50</p> <p>Repeat surgery for mesh complications - n/N</p> <p>TVT-Secur-H: 1/56</p> <p>TVT-O: 0/50</p> <p>Complications at 1 year FU - n/N</p> <p>Pain (vaginal or groin) TVT-Secur-H: 1/52</p> <p>TVT-O: 3/50</p> <p>Dyspareunia TVT-Secur-H: 3/50</p> <p>TOT-O: 6/42</p> <p>Mesh extrusion TVT-Secur-H: 1/44</p> <p>TVT-O: 0/49</p>	<p>Blinding of outcome assessment: Low risk (assessors blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to have clinically relevant impact on effect estimates)</p> <p>Selective reporting: Low risk (protocol available, all primary and secondary outcomes reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
of Obstetrics and Gynecology at the University of Manitoba.	Intrinsic sphincter deficiency (MUCP<20 cm H2O or Q-tip <30°) Voiding dysfunction with post-void residual >100 ml				
<p>Full citation Meschia,M., Bertozzi,R., Pifarotti,P., Baccichet,R., Bernasconi,F., Guercio,E., Magatti,F., Minini,G., Peri-operative morbidity and early results of a randomised trial comparing TVT and TVT-O, International Urogynecology Journal, , 1257-1261, 2007 Ref Id 100695 Country/ies where the study was carried out Italy</p>	<p>Sample size N=231 randomised Intervention, n=114 Control, n=117</p> <p>Characteristics Age (years) - mean ±SD TVT: 56 (9) TVT-O: 58 (10) Median parity TVT: 2 (range 0-6) TVT-O: 2 (range 0-5) BMI - mean ±SD TVT: 25.6 (3) TVT-O: 26.1 (3) Previous hysterectomy (%) TVT: 12 TVT-O: 8 Women with OAB symptoms (%)</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Retropubic sling (TVT) No details of manufacturer nor procedure reported. Transobturator sling (TVT-O) No details of manufacturer nor procedure reported.</p>	<p>Results Objective cure at median 6-mo (negative cough stress test in sitting and standing positions with 300 ml full bladder) - n/N TVT: 99/114 TVT-O: 98/117 Subjective cure/Improvement at median 6-mo (no urine loss during stress) - n/N TVT: 99/114 TVT-O: 96/117 ICIQ-UI-SF at median 6-mo - mean ±SD TVT: 2.5 (4.3), n=108 TVT-O: 2.8 (4.8), n=110 PGII at median 6-mo - mean ±SD TVT: 1.6 (3.4), n=108 TVT-O: 1.3 (2.9), n=110</p>	<p>Limitations Random sequence generation: Low risk (Centralised computer-generated random list) Allocation concealment: Low risk (Central telephone system used) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant impact on effect estimates) Selective reporting: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study type Multicentre RCT</p> <p>Aim of the study To compare morbidity and short-term efficacy of TVT and TVT-O in women with primary SUI.</p> <p>Study dates 12/2004 to 09/2005</p> <p>Source of funding Not reported</p>	<p>TVT: 37 TVT-O: 39</p> <p>Inclusion criteria Women with Stress urinary incontinence urethral hypermobility</p> <p>Exclusion criteria Women with previous anti-incontinence surgery vaginal prolapse requiring treatment co-existing pelvic pathology known bleeding diathesis or current anti-coagulant therapy detrusor over-activity and urethral hypo-mobility (<math>\Delta</math> Q-tip <math>&lt;20^\circ</math> from the horizontal with straining)</p>			<p>Repeat surgery for mesh complications at median 6-mo - n/N TVT: 2/114 TVT-O: 0/117</p> <p>Adverse events - bladder injury - nN TVT: 5/114 TVT-O: 0/117</p> <p>Complications - n/N Pain at median 6-mo TVT: 0/114 TVT-O: 6/117</p>	<p>Other bias: High risk (ICIQ-UI-SF score in TVT group at baseline significantly lower than TVT-O group)</p> <p>Other information</p>
<p>Full citation Mostafa, A., Agur, W., Abdel-All, M.,</p>	<p>Sample size N=137 randomised Intervention, n=69 Control, n=68</p>	<p>Interventions Intervention: Adjustable sling</p>	<p>Details Conducted in 6 urogynaecology units. All surgeons each performed &gt;100 TVT-O procedures; all</p>	<p>Results Note: outcomes for 12-18 months from Mostafa et al. 2013.</p>	<p>Limitations Random sequence generation: Low risk (computer-generated</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Guerrero, K., Lim, C., Allam, M., Yousef, M., N'Dow, J., Abdel-Fattah, M., A multicentre prospective randomised study of single-incision mini-sling Ajust versus tension-free vaginal tape-obturator (TVT-OTM) in the management of female stress urinary incontinence: Pain profile and short-term outcomes, European Journal of Obstetrics Gynecology and Reproductive Biology, 165, 115-121, 2012 Ref Id 674124</p>	<p>Characteristics Age (years) - mean <math>\pm</math>SD Adjustable sling: 52.6 (11.2) TVT-O: 49.4 (8.8) Median BMI Adjustable sling: 27 (IQR 24-30.3) TVT-O: 28 (IQR 25.25-30) Parity - mean <math>\pm</math>SD Adjustable sling: 2.14 (1.0) TVT-O: 2.25 (1.19) Number of women with SUI Adjustable sling: 63 TVT-O: 56 Number of women with mixed UI Adjustable sling: 6 TVT-O: 12  Inclusion criteria Women with urodynamic SI</p>	<p>Control: Other synthetic sling</p>	<p>attended formal training session for Ajust procedure and conducted 12-20 procedures (at least 6 of these under local anaesthetic) prior to trial participation. General anaesthetic protocol in both arms varied according to each centre. Postop analgesia standardised protocol used in both arms (paracetamol; second line: diclofenac sodium or ibuprofen; third line: tramadol). Follow up: 4-6 months post-op (Mostafa et al. 2012); 1 year (range 12-18 months) post-op (Mostafa et al. 2013) Adjustable sling (Ajust) Ajust (Bard Inc) used, procedure as originally described by Abdel-Fattah. Other synthetic sling (TVT-O) Manufacturer not reported, procedure as originally described by de Leval.</p>	<p>Objective cure at 4-6 months (negative standing cough stress test with comfortably full bladder) - n/N Adjustable sling: 62/69 TVT-O: 66/68 Objective cure at 12-18 months - n/N Adjustable sling: 56/69 TVT-O: 51/68 Subjective cure at 4-6 months ('very much improved' or 'much improved' response on PGI-I) - n/N Adjustable sling: 59/69 TVT-O: 62/68 Subjective cure at 12-18 months- n/N Adjustable sling: 58/69 TVT-O: 53/68 Continence-specific health-related quality of life - Mean change (SD) in ICIQ-Short form (pre-post) at 4-6 months Adjustable sling: -11.2 (5.59) TVT-O: -12.32 (4.5)</p>	<p>randomisation, stratified by centre) Allocation concealment: Low risk (central telephone allocation) Blinding of participants/personnel: Un clear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (follow up assessor blinded to group assignment) Incomplete outcome data: Low risk (ITT analysis, only 6 dropouts in TVT-O group at 12-18 mo follow up) Selective reporting: Unclear risk (insufficient information, states registered on clinicaltrials.gov but unable to locate record) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare postoperative pain profile, perioperative details, and short-term patient-reported and objective success rates of adjustable single-incision slings versus standard midurethral slings</p> <p>Study dates 10/2009 to 10/2010</p> <p>Source of funding</p>	<p>failed or declined pelvic floor muscle training</p> <p>Exclusion criteria Women with POP-Q<math>\geq</math>2 previous continence surgery concomitant surgery previous pelvic irradiation neurological condition (e.g. multiple sclerosis)</p>			<p>Continence-specific health-related quality of life - Mean change (SD) in ICIQ-Short form (pre-post) at 12-18 months Adjustable sling: -10.43 (5.95) TVT-O: -11.65 (4.33)</p> <p>Continence-specific health-related quality of life - Number of women with <math>\geq</math>10 point improvement in total KHQ score at 4-6 months - n/N Adjustable sling: 57/69 TVT-O: 60/64</p> <p>Continence-specific health-related quality of life - Number of women with <math>\geq</math>18 point improvement in total KHQ score at 12-18 months - n/N Adjustable sling: 38/50 TVT-O: 43/50</p> <p>Adverse events - Bladder injury - n/N Adjustable sling: 0/69 TVT-O: 0/68</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Funded by Henry Smith Charity.				Adverse events - Urethral injury - n/N Adjustable sling: 0/69 TVT-O: 0/68 Repeat surgery at 12-18 months - n/N Adjustable sling: 5/69 TVT-O: 3/68 Short-term complications at 4-6 months - n/N Mesh extrusion Adjustable sling: 1/69 TVT-O: 2/68 Need for catheterisation due to voiding dysfunction Adjustable sling: 3/69 TVT-O:8/68	
Full citation Mostafa, A., Agur, W., Abdel-All, M., Guerrero, K., Lim, C., Allam, M., Yousef, M., N'Dow, J., Abdel-Fattah, M., Multicenter	Sample size N=137 randomised Intervention, n=69 Control, n=68  Characteristics See Mostafa et al. 2012 for details	Interventions Intervention: Adjustable single-incision sling Control: Transobturator inside-out tape (TVT-O)	Details See entry for Mostafa et al. 2012 for further details	Results See Mostafa et al. 2012 for 12-18 month FU outcomes	Limitations See Mostafa et al. 2012 for risk of bias assessment  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>prospective randomized study of single-incision mini-sling vs tension-free vaginal tape-obturator in management of female stress urinary incontinence: a minimum of 1-year follow-up, Urology, 82, 552-9, 2013</p> <p>Ref Id 542930</p> <p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare postoperative pain profile, perioperative details, and short-term patient-reported</p>	<p>Inclusion criteria See entry for Mostafa et al. 2012 for further details</p> <p>Exclusion criteria See entry for Mostafa et al. 2012 for further details</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>and objective success rates of adjustable single-incision slings versus standard midurethral slings</p> <p>Study dates 10/2009 to 10/2010</p> <p>Source of funding Funded by Henry Smith Charity.</p>					
<p>Full citation Nyyssonen, V., Talvensaari-Mattila, A., Santala, M., A prospective randomized trial comparing tension-free vaginal tape versus transobturator tape in patients</p>	<p>Sample size N=100 randomised Intervention, n=50 Control, n=50</p> <p>Characteristics Age (years) - median TVT: 51 (range 33-70) TOT: 54 (range 36-74) BMI - median TVT: 25 (range 20-38)</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details One surgeon conducted all procedures. Prophylactic cefuroxime given to all participants. Median FU: 3, 14, 36 months Retropubic sling (TVT) Gynecare TVT used, procedure as described in Ulmsten et al. 1996 under local anaesthesia with iv sedation. Cystoscopy conducted twice in all cases during operation. Transobturator sling (TOT)</p>	<p>Results Subjective cure at 14 months (UISS score &lt;8) - n/N TVT: 40/50 TOT: 36/50 Subjective cure at 46 months - n/N TVT: 38/50 TOT: 37/50</p>	<p>Limitations Random sequence generation: Unclear risk (envelopes used but no further details provided) Allocation concealment: Unclear risk (sealed and numbered envelopes used but no further details provided) Blinding of participants/personnel:</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>with stress or mixed urinary incontinence: subjective cure rate and satisfaction in median follow-up of 46 months, Scandinavian Journal of Urology, 48, 309-15, 2014 Ref Id 542955 Country/ies where the study was carried out Finland Study type RCT</p> <p>Aim of the study To assess subjective cure rate and patient satisfaction of TVT and TOT in women with pure SUI or stress-</p>	<p>TOT: 28 (range 21-35) Parity - median TVT: 2 (range 0-11) TOT: 3 (range 0-16)</p> <p>Inclusion criteria Women with SUI or stress-predominant mixed UI (as diagnosed by positive cough stress test or through use of specific questionnaires) failed conservative treatment (i.e. pelvic floor muscle training) willingness to participate in the study.</p> <p>Exclusion criteria Women with urge incontinence previous minimally-invasive operation for SUI need for another concomitant surgical procedure</p>		<p>Monarc (AMS) TOT used, procedure as described by Delorme 2001 under general anaesthesia.</p>	<p>Adverse events - bladder injury - n/N TVT: 0/50 TOT: 0/50 Adverse events - bowel injury - n/N TVT: 0/50 TOT: 0/50 Complications at 46 months - n/N Pain TVT: 1/47 TOT: 0/46 Mesh extrusion TVT: 0/47 TOT: 2/46 De novo OAB - de novo urge TVT: 8/47 TOT: 3/46</p>	<p>Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (self-report questionnaires used) Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant bias on effect estimate) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>predominant mixed UI</p> <p>Study dates 01/2004 to 11/2006</p> <p>Source of funding None</p>					
<p>Full citation Oliveira,R., Botelho,F., Silva,P., Resende,A., Silva,C., Dinis,P., Cruz,F., Exploratory study assessing efficacy and complications of TVT-O, TVT-Secur, and Mini-Arc: results at 12-month follow-up, European Urology, 59, 940-944, 2011 Ref Id</p>	<p>Sample size N=90 randomised Intervention 1 (TVT-Secur), n=30 Intervention 2 (MiniArc), n=30 Control, n=30</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD Intervention 1: 52.7 (10.9) Intervention 2: 52.6 (11.8) Control: 52 (11.7) BMI - mean <math>\pm</math>SD Intervention 1: 26.3 (6.6)</p>	<p>Interventions Intervention 1: Single-incision mini-sling (TVT-Secur) Intervention 2: Single-incision mini-sling (MiniArc) Control: Other synthetic sling (TVT-O)</p>	<p>Details All procedures conducted by authors of study with patient in lithotomy position. All surgeons had experience of at least 30 cases of each procedure. Iv ceftriaxon prophylactic antibiotic used. Single-incision mini-sling 1 (TVT-Secur) TVT-Secur positioned in hammock position as described in Oliveira et al. 2009 and Neuman 2007. Single-incision mini-sling 2 (MiniArc) Procedure as originally described by Moore et al. 2009 and Kennelly et al. 2010. Other synthetic sling (TVT-O) Procedure as described by De Leval 2003.</p>	<p>Results Objective cure at 1 year (no leakage episodes, no use of pads, and negative cough stress test) - n/N Intervention 1: 20/30 Intervention 2: 26/30 Control: 25/30 Improvement at 1 year (number objectively cured + maintenance of SUI or positive cough stress test, but reduction of &gt;50% incontinence protection and satisfied with surgery) - n/N Intervention 1: 24/30 Intervention 2: 28/30</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>135218</p> <p>Country/ies where the study was carried out Portugal</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy, complications and effect on quality of life of TVT-Secur, MiniArc, and TVT-O</p> <p>Study dates 01/2008 to 09/2008</p> <p>Source of funding Reported no funding received</p>	<p>Intervention 2: 29.8 (5.4)</p> <p>Control: 27.2 (5.3)</p> <p>Parity - mean <math>\pm</math>SD</p> <p>Intervention 1: 1.8 (2)</p> <p>Intervention 2: 2.1 (2.2)</p> <p>Control: 1.5 (1.1)</p> <p>Inclusion criteria Women with clinically- and urodynamically-proven SUI</p> <p>Exclusion criteria Women with previous SUI surgeries for SUI POP-Q<math>\geq</math>2 urgency, frequency or nocturia complaints detrusor overactivity</p>			<p>Control: 28/30</p> <p>Repeat surgery for mesh complications - n/N</p> <p>Intervention 1: 0/30</p> <p>Intervention 2: 0/30</p> <p>Control: 2/30</p> <p>Complications at 1 year - n/N</p> <p>Pain</p> <p>Intervention 1: 0/30</p> <p>Intervention 2: 1/30</p> <p>Control: 2/30</p> <p>Infection (UTI)</p> <p>Intervention 1: 1/30</p> <p>Intervention 2: 1/30</p> <p>Control: 0/30</p> <p>De novo urgency</p> <p>Intervention 1: 3/30</p> <p>Intervention 2: 3/30</p> <p>Control: 5/30</p>	<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>
<p>Full citation Palos, C. C., Maturana, A. P.,</p>	<p>Sample size N=92 randomised Intervention, n=45</p>	<p>Interventions Intervention: Retropubic sling</p>	<p>Details Clinicaltrials.gov, NCT02540564. Procedures conducted by 4</p>	<p>Results</p>	<p>Limitations Random sequence generation: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Ghersel, F. R., Fernandes, C. E., Oliveira, E., Prospective and randomized clinical trial comparing transobturator versus retropubic sling in terms of efficacy and safety, International urogynecology journal, 29, 29-35, 2018</p> <p>Ref Id 864980</p> <p>Country/ies where the study was carried out Brazil</p> <p>Study type RCT</p> <p>Aim of the study To evaluate efficacy of retropubic and transobturator slings in</p>	<p>Control, n=47</p> <p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>Retropubic: 54.24 (1.63)</p> <p>Transobturator: 55.72 (1.82)</p> <p>% of women BMI&lt;30</p> <p>Retropubic: 77.8</p> <p>Transobturator: 63.8</p> <p>% of women BMI<math>\geq</math>30</p> <p>Retropubic: 22.2</p> <p>Transobturator: 36.2</p> <p>Parity - mean <math>\pm</math>SD</p> <p>Retropubic: 4.88 (0.39)</p> <p>Transobturator: 4.63 (0.41)</p> <p>Menopausal (%)</p> <p>Retropubic: 56</p> <p>Transobturator: 68</p> <p>Concomitant POP surgery (%)</p> <p>Retropubic: 18</p> <p>Transobturator: 21</p> <p>Inclusion criteria</p>	<p>Control: Transobturator sling</p>	<p>surgeons all with <math>\geq</math>5 years experience with all patients receiving spinal anaesthesia and urethroscopy.</p> <p>Retropubic sling (Unitape VS)</p> <p>Unitape VS (Promedon) used.</p> <p>Transobturator sling (TOT)</p> <p>Unitape T Plus (Promedon) TOT used.</p>	<p>Objective cure at 1 year (Negative pad test [<math>&lt;</math>2g]) - n/N</p> <p>Retropubic: 40/45</p> <p>Transobturator: 38/47</p> <p>Subjective cure at 1 year (No self-reported SUI complaints and satisfied with surgery) - n/N</p> <p>Retropubic: 37/45</p> <p>Transobturator: 37/47</p> <p>Adverse events - bladder injury - n/N</p> <p>Retropubic: 1/45</p> <p>Transobturator: 1/47</p> <p>Repeat surgery for SUI at <math>\leq</math>1 year - n/N</p> <p>Retropubic: 0/40</p> <p>Transobturator: 0/41</p> <p>Complications at <math>\leq</math>1 year - n/N</p> <p>Pain</p> <p>Retropubic: 1/40</p> <p>Transobturator: 0/41</p> <p>Mesh extrusion</p> <p>Retropubic: 0/40</p> <p>Transobturator: 1/41</p> <p>Infection</p> <p>Retropubic: 12/40</p>	<p>(computer-generated randomisation)</p> <p>Allocation concealment: Low risk (sequentially numbered, opaque and sealed envelopes used)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data similar across groups for similar reasons)</p> <p>Selective reporting: Unclear risk (reports registered on clinicaltrials.gov but no record of trial found)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>treatment of female SUI</p> <p>Study dates 2013 to 2015</p> <p>Source of funding Reports not sponsored by industry nor Promedon</p>	<p>Women with urodynamically-proven stress incontinence</p> <p>Exclusion criteria Women with mixed urinary incontinence who had previous anti-incontinence surgery who had voiding dysfunction on urodynamic testing with urinary tract infection (UTI) who have contraindication for surgery or anaesthesia</p>			<p>Transobturator: 12/41 De novo urgency Retropubic: 0/40 Transobturator: 1/41</p>	
<p>Full citation Paraiso, M. F. R., Walters, M. D., Karram, M. M., Barber, M. D., Laparoscopic Burch colposuspension versus tension-free</p>	<p>Sample size N=72 randomised Intervention, n=36 Control, n=36</p> <p>Characteristics Age (years) - mean ±SD TVT: 53.3 (9.5) Burch: 54.8 (9.3)</p>	<p>Interventions Intervention: Synthetic sling Control: Colposuspension</p>	<p>Details Prophylactic antibiotics administered 1-hr before surgery. Mean short term FU=20.6 months (sd=8); median long-term FU=65 months (range 12-88) Synthetic sling (TVT) Gynecare TVT used with procedure as described in Ulmsten et al. 1996 and performed under local</p>	<p>Results Note: data for long-term (4-8 years) follow up from Jelovsek et al. 2008. Objective cure at short-term FU: 30/36; 26/36 (no leakage on urodynamic studies) - n/N TVT: 30/36</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation schedule) Allocation concealment: Unclear risk (sealed opaque envelope but no further details) Blinding of participants/personnel:</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>vaginal tape: A randomized trial, Obstetrics and Gynecology, 104, 1249-1258, 2004</p> <p>Ref Id 618968</p> <p>Country/ies where the study was carried out USA</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare efficacy of laparoscopic Burch colposuspension to TVT in women with SUI</p> <p>Study dates 08/1999 to 08/2002</p> <p>Source of funding</p>	<p>BMI - mean <math>\pm</math>SD TVT: 30.1 (6.2) Burch: 28.5 (6.1) Median Parity TVT: 2 (range 0-7) Burch: 2 (range 0-5) Postmenopausal (%) TVT: 64 Burch: 56 Concomitant POP surgery (%) TVT: 50 Burch: 40</p> <p>Inclusion criteria Women who were candidates for surgical correction of primary urodynamic stress incontinence with abdominal leak pressure <math>\geq</math>60cm H<sub>2</sub>O (or positive cough stress test if no leakage with catheter in place) urethral hypermobility (maximal straining cotton-tipped swab angle <math>\geq</math>30°)</p>		<p>anaesthesia with iv sedation or under general/regional anaesthesia.</p> <p>Laparoscopic Burch colposuspension with sutures</p> <p>Procedure as described by Tanagho 1976 with cystoscopy performed; All patients received general anaesthesia.</p>	<p>Burch: 26/36 Subjective cure (of any urinary incontinence) at 4-8 years (Response of 'never' to ISI question 'How often do you experience urine leakage?') - n/N TVT: 13/36 Burch: 12/36 Improvement at 4-8 years (response of 'very much' or 'much' better on PGII) - n/N TVT: 17/36 Burch: 20/36 Adverse events - severe bleeding requiring transfusion - n/N TVT: 1/36 Burch: 0/36 Adverse events - bladder injury - n/N TVT: 2/36 Burch: 0/36 Adverse events - bowel injury - n/N TVT: 0/36 Burch: 1/36</p>	<p>Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (assessors of urodynamics blinded to preoperative results but unclear whether blinded to group assignment; unclear whether nurse assessors blinded to group assignment) Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates for both follow-up periods) Selective reporting: Unclear risk (insufficient information) Other bias: Unclear risk (women in colposuspension group had significantly more concomitant lysis of adhesions compared to sling group)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Supported by grant from Minimally Invasive Surgery Center, The Cleveland Clinic Foundation, Cleveland, OH, USA.	able to tolerate general anaesthesia and laparoscopy no previous anti-incontinence surgery no detrusor overactivity on urodynamic study no anterior vaginal wall prolapse to or beyond hymen willing to participant in follow up  Exclusion criteria			Repeat surgery for mesh complications at $\leq 2$ years - n/N TVT: 2/36 Burch: 0/36 Repeat surgery for SUI at $\leq 2$ years - n/N TVT: 1/36 Burch: 2/36 Repeat surgery for SUI at 4-8 years - n/N TVT: 1/25 Burch: 1/28 Complications - n/N Mesh extrusion at $\leq 2$ years TVT: 1/36 Burch: 0/36 POP occurrence at $\leq 2$ years TVT: 0/36 Burch: 0/36	Follow-up data for 64.8 months reported in Jelovsek et al. 2008
Full citation Pastore, A. L., Palleschi, G., Al Salhi, Y., Riganelli, L., Fuschi, A., Autieri, D.,	Sample size N=48 randomised Intervention, n=24 Control, n=24  Characteristics	Interventions Intervention: Single-incision mini-sling (SIMS) Control: Other synthetic sling	Details One surgeon performed all procedures with patient under epidural anaesthesia. Single-incision mini-sling Brand of SIMS not specified.	Results Subjective cure at 1 year (self-reported cure) - n/N SIMS: 19/24 TVT-O: 18/24	Limitations Random sequence generation: Unclear risk (computer-generated random number table)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Petrozza, V., Carbone, A., Evaluation of Sexual Function and Quality of Life in Women Treated for Stress Urinary Incontinence: Tension-Free Transobturator Suburethral Tape Versus Single-Incision Sling, Journal of Women's Health, 25, 355-9, 2016</p> <p>Ref Id 542981</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type RCT</p> <p>Aim of the study To assess effect of TVT-O compared to transobturator</p>	<p>Mean Age (years) SIMS: 50.2 (range 31-68) TVT-O: 49.8 (range 33-67) BMI - mean <math>\pm</math>SD SIMS: 28.2 (3.05) TVT-O: 29.8 (2.3) Mean parity SIMS: 2 (range 0-4) TVT-O: 2 (range 1-4) Menopausal (%) SIMS: 52 TVT-O: 57</p> <p>Inclusion criteria Women with pure SUI with maximum urethral closure pressure at rest &gt;20cm H2O with negative urine culture with absence of postvoiding residue and upper urinary tract dilation on ultrasonography who are sexually active (<math>\geq</math>1 sexual</p>		<p>Other Synthetic sling (TVT-O) Brand of TVT-O not specified.</p>	<p>Improvement at 1 year (number cured + number reporting improvement) - n/N SIMS: 21/24 TVT-O: 19/24 FSFI Total score at 1 year - mean <math>\pm</math>SD SIMS: 27.42 (3.42) TVT-O: 28.09 (3.84) ICIQ-SF at 1 year - mean <math>\pm</math>SD SIMS: 2.4 (2.8), n=21 TVT-O: 2.7 (3.3), n=21 Adverse events - bladder injury - n/N SIMS: 0/24 TVT-O: 0/24 Adverse events - bowel injury - n/N SIMS: 0/24 TVT-O: 0/24 Complications - n/N Mesh extrusion at 1 year SIMS: 0/24 TVT-O: 2/24 Need for catheterisation at 1 year SIMS: 1/24</p>	<p>Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimate) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>single-incision mini-sling on sexual function and quality of life in women with SUI</p> <p>Study dates 12/2013 to 01/2015</p> <p>Source of funding Not reported</p>	<p>activity in past 3 months)</p> <p>Exclusion criteria Women with urge incontinence neurogenic bladder previous incontinence surgery severe mental or neurological disorder refusal to consent</p>			<p>TVT-O: 0/24 De novo urge incontinence at 1 year SIMS: 1/24 TVT-O: 0/24</p>	
<p>Full citation Persson, J., Teلمان, P., Eten-Bergquist, C., Wolner-Hanssen, P., Cost-analyzes based on a prospective, randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure, Acta obstetrica ET</p>	<p>Sample size N=79 randomised Intervention, n=38 received surgery Control, n=33 received surgery</p> <p>Characteristics Median age (years) TVT: 48 (range 28–68) Colposuspension: 51 (range 30–68) Median BMI TVT: 25.8 (range 20.5–35.6)</p>	<p>Interventions Intervention: Synthetic sling Control: Colposuspension</p>	<p>Details Procedures typically performed by 1 surgeon and 1 nurse. All patients had cystoscopy and discharged when residual urine &lt;100ml on one measurement or &lt;150 ml on 2 repeated measurements. Synthetic sling (TVT) Gynecare TVT used following procedure as described by Ulmsten et al. 1996 and under local anaesthesia. Laparoscopic colposuspension with sutures Performed under general anaesthesia using 2 single-bite</p>	<p>Results Subjective cure at 1 year (self-reported) - n/N TVT: 21/37 Colposuspension: 16/31 Objective cure at 1 year (negative pad test [no leakage]) - n/N TVT: 33/37 Colposuspension: 27/31 Improvement (Number of women 'Much improved' or 'Little improved') - n/N TVT: 13/37</p>	<p>Limitations Random sequence generation: Low risk (envelope method) Allocation concealment: Low risk (sealed, opaque, numbered envelopes used) Blinding of participants/personnel: Un clear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>gynecologica scandinavica, 81, 1066-1073, 2002</p> <p>Ref Id 674192</p> <p>Country/ies where the study was carried out Sweden</p> <p>Study type RCT</p> <p>Aim of the study To compare TVT to laparoscopic colposuspension in women with significant SUI symptoms</p> <p>Study dates 12/1998 to 09/2000</p> <p>Source of funding Not reported</p>	<p>Colposuspension: 23.8 (range 20.1–32.4)</p> <p>Median parity</p> <p>TVT: 2 (range 1–5)</p> <p>Colposuspension: 2 (range 2–4)</p> <p>Postmenopausal without HRT (%)</p> <p>TVT: 15</p> <p>Colposuspension: 3</p> <p>Inclusion criteria Women with urethral closing pressure <math>\geq 20</math>cm H<sub>2</sub>O urethral functional length <math>\geq 25</math>mm bladder neck hypermobility (<math>\geq 45^\circ</math> down rotation at valsalva manoeuvre) <math>\geq 5</math> ml pad test leakage</p> <p>Exclusion criteria Women who have urge-predominant incontinence</p>		<p>polytetrafluoroethylene (Goretex) sutures</p>	<p>Colposuspension: 15/31</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 1/37</p> <p>Colposuspension: 0/31</p> <p>Repeat surgery for SUI at <math>\leq 1</math> year - n/N</p> <p>TVT: 3/37</p> <p>Colposuspension: 1/31</p> <p>Repeat surgery for mesh complications at <math>\leq 1</math> year - n/N</p> <p>TVT: 1/37</p> <p>Colposuspension: 0/31</p> <p>Complications at <math>\leq 1</math> year - n/N</p> <p>Pain</p> <p>TVT: 3/37</p> <p>Colposuspension: 0/31</p> <p>Need for catheterisation</p> <p>TVT: 1/37</p> <p>Colposuspension: 0/31</p>	<p>(assessor blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to induce clinically-relevant impact)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>who had previous SUI surgery</p> <p>who are incontinent after previous vaginal repair</p> <p>with <math>\geq</math>Grade 2 uterovaginal prolapse</p> <p>who are pregnant</p> <p>who need additional gynecologic surgery</p> <p>with contraindication to incontinence surgery</p> <p>at increased risk of complications during general anaesthesia or laparoscopic surgery (e.g. cardiovascular disease, abdominal obesity)</p>				
<p>Full citation</p> <p>Porena,M., Costantini,E., Frea,B., Giannantoni,A., Ranzoni,S., Mearini,L.,</p>	<p>Sample size</p> <p>N=148 randomised</p> <p>Intervention, n=73</p> <p>Control, n=75</p> <p>Characteristics</p>	<p>Interventions</p> <p>Intervention: Retropubic sling</p> <p>Control: Transobturator sling</p>	<p>Details</p> <p>Median FU: 35 months, 100 months (range 75-131). All procedures performed under general or spinal anaesthetic according to centre preference.</p> <p>Retropubic sling (TVT)</p>	<p>Results</p> <p>Note: 6-year follow up data from Costantini et al. 2016.</p> <p>Cure at 3 years (no leakage during clinical and/or stress tests)</p>	<p>Limitations</p> <p>Random sequence generation: Low risk (computer-generated randomisation)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Bini, V., Kocjancic, E., Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial, European Urology, 52, 1481-1490, 2007</p> <p>Ref Id 100727</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare complications, functional outcomes and success rates of</p>	<p>Age (years) - mean <math>\pm</math>SD</p> <p>TVT: 61.8 (10.7)</p> <p>TOT: 60.6 (10)</p> <p>Median parity</p> <p>TVT: 2 (range 0-5)</p> <p>TOT: 2 (range 0-4)</p> <p>Median BMI</p> <p>TVT: 26.9 (range 21.4–39.0)</p> <p>TOT: 26.7 (range 19.5–38.0)</p> <p>Pure SUI - n/N</p> <p>TVT: 42/73</p> <p>TOT: 41/75</p> <p>Mixed UI</p> <p>TVT: 32/73</p> <p>TOT: 34/75</p> <p>Previous hysterectomy - n/N</p> <p>TVT: 30/73</p> <p>TOT: 34/75</p> <p>Inclusion criteria</p> <p>Women with stress or stress-predominant mixed urinary incontinence (ICS definition)</p>		<p>Gynecare TVT used, procedure as described by Ulmsten et al. 1996.</p> <p>Transobturator sling (TOT)</p> <p>Obtape TOT (Mentor-Porges) used, procedure as described by Delorme 2001</p>	<p>and/or no self-reported leakage) - n/N</p> <p>TVT: 50/73</p> <p>TOT: 68/75</p> <p>Cure at 3 years for pure SUI participants - n/N</p> <p>TVT: 36/43</p> <p>TOT: 34/41</p> <p>Cure at 3 years for mixed UI participants - n/N</p> <p>TVT: 14/27</p> <p>TOT: 24/34</p> <p>Objective cure at 3 years (negative cough stress test, negative 1-hr pad test and no retreatment for UI) - n/N</p> <p>TVT: 63/73</p> <p>TOT: 67/75</p> <p>Objective cure at 6 years - n/N</p> <p>TVT: 35/73</p> <p>TOT: 33/75</p> <p>Subjective cure at 6 years (no leakage according to 3-day voiding diary) - n/N</p> <p>TVT: 28/73</p> <p>TOT: 30/75</p>	<p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Low risk (assessors blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant bias in effect estimates at either 3 or 6 year follow up)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: High risk (Significantly higher number of participants in TOT group at baseline compared to those in TVT group experienced detrusor overactivity)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>TVT and TOT in women with SUI</p> <p>Study dates 05/2003 to 11/2005</p> <p>Source of funding Not reported</p>	<p>Exclusion criteria Women with previous anti-incontinence surgery &gt;POP stage 1 (Half-Way system and POP-Q classification) in any vaginal compartment</p>			<p>Improvement at 3 years (number cured and self-reportedly improved [wet but improved symptoms]) - n/N TVT: 63/73 TOT: 68/75</p> <p>Improvement at 3 years for pure SUI participants - n/N TVT: 41/43 TOT: 36/41</p> <p>Improvement at 3 years for mixed UI participants - n/N TVT: 22/27 TOT; 32/34</p> <p>Repeat surgery for SUI at 6 years - n/N TVT: 0/40 TOT: 4/47</p> <p>Repeat surgery for POP at 6 years - n/N TVT: 1/40 TOT: 2/47</p> <p>Repeat surgery for mesh complications at 1 year - n/N TVT: 0/73 TOT: 2/75</p>	<p>6 year follow up data reported in Costantini et al. 2016</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Repeat surgery for mesh complications at 3 years - n/N TVT: 1/73 TOT: 3/75 Repeat surgery for mesh complications at 6 years - n/N TVT: 2/40 TOT: 7/47 Adverse events - bladder injury - n/N TVT: 2/73 TOT: 1/75 Complications - n/N Pain at 3 years TVT: 0/73 TVT-O: 0/75 (data from Costantini et al. 2016) Pain at 6 years TVT: 0/40 TVT-O; 0/47 Mesh extrusion at 3 years TVT: 0/73 TVT-O: 7/75 (data from Costantini et al. 2016) Infection (UTI) at 6 years TVT: 8/40	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TOT: 8/47 Infection (recurrent UTI) at 6 years - n/N TVT: 3/73 TOT: 2/75 De novo OAB - de novo voiding symptoms at 3 years TVT: 5/56 TOT: 4/59 De novo OAB - de novo voiding symptoms at 6 years TVT: 5/40 TOT: 7/47 De novo OAB - de novo storage symptoms at 3 years TVT: 5/35 TOT: 4/36 De novo OAB - de novo storage symptoms at 6 years TVT: 2/40 TOT: 7/47 POP occurrence at 6 years TVT: 1/40 TOT: 0/47	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Wound complications (hernia) at 3 years TVT: 1/73 TOT: 0/75	
<p>Full citation Rechberger,T., Futyma,K., Jankiewicz,K., Adamiak,A., Skorupski,P., The clinical effectiveness of retropubic (IVS-02) and transobturator (IVS-04) midurethral slings: randomized trial, European Urology, 56, 24-30, 2009 Ref Id 100729 Country/ies where the study was carried out Poland Study type RCT</p>	<p>Sample size N=537 randomised Intervention, n=269 Control, n=268</p> <p>Characteristics Age (years) - mean ±SD IVS-02: 55.56 (10.19) IVS-04: 55.75 (11.29) Parity - mean ±SD IVS-02: 2.63 (1.19) IVS-04; 2.62 (1.11) Number of women with BMI kg/m2 18.5-24.9 IVS-02: 41 IVS-04: 43 Number of women with BMI kg/m2 25-29.9 IVS-02: 80 IVS-04: 81</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Surgery carried out according to standard protocol using midline incision at midurethra. Retropubic sling (Intravaginal slingplasty [IVS]-02) Bottom-up technique; Blue needles (IVS-02) and multifilament tape (type 3) used. All patients checked for bladder injury using cystoscopy with 70° lens. Transobturator sling (Intravaginal slingplasty [IVS]-04) Outside-in technique; green needles (IVS-04) and multifilament tape (type 3) used. First 150 patients checked for bladder injury using cystoscopy with 70° lens but discontinued due to no reported cases.</p>	<p>Results Cure at 18-mo FU (no SUI symptoms, negative cough stress test in supine and standing position, self-report of pad usage as not necessary) - n/N IVS-02: 136/269 IVS-04: 146/268 Improvement at 18-mo FU (number cured + number with negative cough stress test, self-reported still some leakage but less than at preop and some pad use) - n/N IVS-02: 167/269 IVS-04: 174/268 Adverse events - bladder injury - n/N IVS-02: 13/269 IVS-04: 0/268</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation in 1:1 ratio) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (missing data similar across groups and for similar reasons) Selective reporting: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To examine clinical outcomes of retropubic slings (IVS-02) compared to transobturator slings (IVS-04) in women with SUI</p> <p>Study dates 01/2003 to 12/2005</p> <p>Source of funding Supported by grant no. N407 309433, Komitet Badan Naukowych.</p>	<p>Number of women with BMI kg/m<sup>2</sup> ≥30: 80; 73</p> <p>Number of premenopausal women IVS-02: 82 IVS-04: 72</p> <p>Number postmenopausal women IVS-02: 119 IVS-04: 125</p> <p>Inclusion criteria Women with clinically-diagnosed SUI (including complete history, standard urodynamic evaluation, urinalysis, urine culture, complete gynecologic examination, and cough provocation test in supine and standing positions with a comfortably full bladder)</p> <p>Exclusion criteria</p>			<p>Repeat surgery for mesh complications - n/N</p> <p>IVS-02: 4/201 IVS-04: 5/197</p> <p>Complications at 18-mo FU - n/N</p> <p>Mesh extrusion IVS-02: 4/201 IVS-04: 5/197</p> <p>De novo OAB symptoms IVS-02: 17/201 IVS-04: 10/197</p> <p>Infection (UTI) IVS-02: 15/201 IVS-04: 11/197</p>	<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Women with gynaecologic diseases (e.g. uterine myoma, ovarian cyst, or uterine or vaginal prolapse POP-Q Stage>1)				
<p>Full citation Richter,H.E., Albo,M.E., Zyczynski,H.M., Kenton,K., Norton,P.A., Sirls,L.T., Kraus,S.R., Chai,T.C., Lemack,G.E., Dandreo,K.J., Varner,R.E., Menefee,S., Ghetti,C., Brubaker,L., Nygaard,I., Khandwala,S., Rozanski,T.A., Johnson,H., Schaffer,J., Stoddard,A.M., Holley,R.L., Nager,C.W., Moalli,P.,</p>	<p>Sample size N=597 randomised Intervention, n=298 Control, n=299</p> <p>Characteristics Age (years) - mean ±SD TVT: 52.7 (10.5) TOT or TVT-O: 53.1 (11.5) BMI - mean ±SD TVT: 30.6 (7) TOT or TVT-O: 30 (6.5) Vaginal deliveries=0 (%) TVT: 12 TOT or TVT-O: 12 Vaginal deliveries 1-2 (%) TVT: 49</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details www.clinicaltrials.gov, NCT00325039; TOMUS study. Urodynamic testing in all participants and reporting of adverse events standardised across centres. Retropubic sling (TVT) Gynecare TVT used. Transobturator sling (TOT or TVT-O) Gynecare inside-out TVT-O and Monarc outside-in TOT used. Choice of transobturator sling at surgeons discretion.</p>	<p>Results Note: Data for 12-mo from Richter et al. 2010 unless otherwise stated; data for 2-years from Albo et al. 2012 (cure outcomes, complications), Brubaker et al. 2011 (adverse events), Wai et al. 2013 (patient improvement), Data for 12-mo and 2-year PISQ- 12 score from Zyczynski et al. 2012; 5-year cure data from Kenton et al. 2015. Objective cure at 12-mo (negative stress test, negative 24-hr pad test, and no SUI retreatment) - n/N TVT: 235/298 TOT or TVT-O: 227/299</p>	<p>Limitations Random sequence generation: Low risk (stratified permuted block randomisation schedule) Allocation concealment: Low risk (randomisation occurred after administration of anaesthesia) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant bias in effect estimates)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Mueller,E., Arisco,A.M., Corton,M., Tennstedt,S., Chang,T.D., Gormley,E.A., Litman,H.J., Retropubic versus Transobturator Midurethral Slings for Stress Incontinence, New England Journal of Medicine, 362, 2066-2076, 2010 Ref Id 135626 Country/ies where the study was carried out USA Study type Multicentre RCT  Aim of the study To assess efficacy and safety of retropubic</p>	<p>TOT or TVT-O: 49 Vaginal deliveries ≥3 TVT: 39 TOT or TVT-O: 40 Menopausal (%) TVT: 70 TOT or TVT-O: 69 POP-Q 0-1 (%) TVT: 44 TOT or TVT-O: 46 POP-Q 2 (%) TVT: 48 TOT or TVT-O: 46 POP-Q 3+4 (%) TVT: 8 TOT or TVT-O: 8 Concomitant surgery (%) TVT: 25 TOT or TVT-O: 26  Inclusion criteria Women ≥21-years old diagnosis of SUI (≥3- mo history of stress- predominant UI symptoms, and/or positive stress test</p>			<p>Objective cure at 2- years - n/N TVT: 196/298 TOT or TVT-O: 190/299 Subjective cure at 12- mo (no self-reported SUI symptoms on MESA questionnaire, no leakage on 3-day voiding diary, and no SUI retreatment) - n/N TVT: 181/298 TOT or TVT-O: 163/299 Subjective cure at 2- years - n/N TVT: 141/298 TOT or TVT-O: 127/299 Subjective cure at 5- years (no self-reported SUI symptoms on MESA questionnaire and no SUI retreatment) - n/N TVT: 149/298 TOT or TVT-O: 127/299 Improvement at 12-mo (ISSQ number satisfied) [data from Wai et al. 2013] - n/N TVT: 255/298 TOT or TVT-O: 259/299</p>	<p>Selective reporting: Unclear risk (Kenton et al. 2015 changes definition of subjective cure used in previous studies; PISQ-12 data not reported in appropriate manner) Other bias: High risk (Participants in retropubic group had significantly lower valsalva leak-point pressure at baseline compared to transobturator group)  Other information 12-month improvement data reported in Wai et al. 2013; 2-year follow-up data published in Albo et al. 2012 (cure outcomes), Brubaker et al. 2011 (adverse events), and Zyczynski et al. 2012 (PISQ-12); 5-year cure data reported in Kenton et al. 2015.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>compared to transobturator slings in women with SUI</p> <p>Study dates 04/2006 to 06/2008</p> <p>Source of funding Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231, U01 DK60379, U01 DK60380, U01 DK60393, U01 DK60395, U01 DK60397, and U01 DK60401) from the National Institute of Diabetes and Digestive and Kidney Diseases and by</p>	<p>≤300 ml bladder volume and/or MESA stress symptom score greater than MESA urge symptom score and/or bladder capacity ≥200ml by stress test)</p> <p>post-void residual volume ≤100 ml with POP stage ≤1, or ≤500ml if POP stage &gt;1</p> <p>planning to undergo SUI surgery</p> <p>No medical contraindications</p> <p>American Society of Anesthesiologists class 1-3</p> <p>No current intermittent catheterisation</p> <p>Available for 24-months FU and able to complete assessment</p> <p>Exclusion criteria Women who are non-ambulatory</p>			<p>Improvement at 2-years (Response of 'very much' or 'much' better on PGII) - n/N</p> <p>TVT: 218/298</p> <p>TOT or TVT-O: 233/299</p> <p>PISQ-12 scores at 12-mo (mean [SD])</p> <p>TVT: 36.45 (6.42), n=298</p> <p>TOT or TVT-O: 36.88 (6.36), n=299 [means of data reported for 'success' and 'failure' in each group combined and SDs calculated from reported SEs]</p> <p>PISQ-12 scores at 2-years (mean [SD])</p> <p>TVT: 36.35 (6.41), n=298</p> <p>TOT or TVT-O: 37.11 (6.5), n=299 [means of data reported for 'success' and 'failure' in each group combined and SDs calculated from reported SEs]</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 15/298</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
the National Institute of Child Health and Human Development. Partly funded by NIH grants to 4 authors.	<p>are pregnant or planning pregnancy</p> <p>are currently receiving chemotherapy or radiotherapy, or history of pelvic radiotherapy</p> <p>have systemic disease known to affect bladder function (e.g. Parkinson's Disease)</p> <p>have current or previous rethral diverticulum</p> <p>have had prior augmentation cystoplasty or artificial sphincter</p> <p>have had nerve stimulators implanted for urinary symptoms with history of synthetic sling for stress urinary incontinence</p> <p>are &lt;12 months post-partum</p> <p>had laparoscopic or open pelvic surgery &lt;3 months ago</p> <p>had current evaluation or treatment for</p>			<p>TOT or TVT-O: 0/299</p> <p>Complications - n/N</p> <p>Pain at 12-mo</p> <p>TVT: 7/298</p> <p>TOT or TVT-O: 6/299</p> <p>Pain at 13-24 mo</p> <p>TVT: 0/298</p> <p>TOT or TVT-O: 0/299</p> <p>Mesh extrusion at 12-mo</p> <p>TVT: 1/298</p> <p>TOT or TVT-O: 1/299</p> <p>Mesh extrusion at 13-24-mo</p> <p>TVT: 0/298</p> <p>TOT or TVT-O: 0/299</p> <p>Need for catheterisation at 12 mo</p> <p>TVT: 6/298</p> <p>TOT or TVT-O: 2/299 [data from Albo et al. 2012]</p> <p>Need for catheterisation at 13-24 mo</p> <p>TVT: 0/298</p> <p>TOT or TVT-O: 2/299</p> <p>De novo OAB - de novo urge incontinence at 12-mo</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>chronic pelvic pain (painful bladder syndrome)</p> <p>are participating in another treatment intervention trial that might influence the results of this trial</p> <p>need for concomitant surgery requiring an abdominal incision, use of graft material in the anterior compartment, or any use of synthetic graft material</p> <p>are enrolled in other urinary incontinence trials including SISTEr/E-SISTEr or BE-DRI/E-BE-DRI</p>			<p>TVT: 0/298</p> <p>TOT or TVT-O: 1/299</p> <p>De novo OAB - de novo urge incontinence at 24-mo</p> <p>TVT: 0/298</p> <p>TOT or TVT-O: 0/298</p> <p>Infection (recurrent UTI) at 12-mo</p> <p>TVT: 1/298</p> <p>TOT or TVT-O: 0/299</p> <p>Infection (recurrent UTI) at 13-24-mo</p> <p>TVT: 18/299</p> <p>TOT or TVT-O: 10/298</p> <p>Infection (wound) at 12-mo</p> <p>TVT: 2/298</p> <p>TOT or TVT-O: 4/299</p> <p>Infection (wound) at 13-24 mo</p> <p>TVT: 0/298</p> <p>TOT or TVT-O: 1/299</p>	
<p>Full citation</p> <p>Rinne,K., Laurikainen,E., Kivela,A., Aukee,P., Takala,T.,</p>	<p>Sample size</p> <p>N=273 randomised</p> <p>Intervention, n=136 received TVT</p>	<p>Interventions</p> <p>Intervention: Retropubic sling</p>	<p>Details</p> <p>See entry for Laurikainen et al. 2007 for further details</p>	<p>Results</p> <p>See entry for Laurikainen et al. 2007 for further details</p>	<p>Limitations</p> <p>See entry for Laurikainen et al. 2007 for further details</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Valpas,A., Nilsson,C.G., A randomized trial comparing TVT with TVT-O: 12-month results, International Urogynecology Journal, 19, 1049-1054, 2008</p> <p>Ref Id 100734</p> <p>Country/ies where the study was carried out Finland</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To report 1-year results of TVT compared to TVT-O in women with SUI</p> <p>Study dates 03/2004 to 11/2005</p>	<p>Control, n=132 received TVT-O</p> <p>Characteristics See entry for Laurikainen et al. 2007 for further details</p> <p>Inclusion criteria See entry for Laurikainen et al. 2007 for further details</p> <p>Exclusion criteria See entry for Laurikainen et al. 2007 for further details</p>	<p>Control: Transobturator sling</p>			<p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Finnish government research funding					
Full citation Ross,S., Robert,M., Swaby,C., Dederer,L., Lier,D., Tang,S., Brasher,P., Birch,C., Cenaiko,D., Mainprize,T., Murphy,M., Carlson,K., Baverstock,R., Jacobs,P., Williamson,T., Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial, Obstetrics and Gynecology,	Sample size N=199 randomised Intervention, n=105 Control, n=94  Characteristics Age (years) - mean $\pm$ SD TVT: 51.8 (10.4) TOT: 50.1 (8.3) BMI - mean $\pm$ SD TVT: 28.1 (5.4), n=103 TOT: 27.8 (5.7), n=93 Nulliparous (%) TVT: 5.7 TOT: 2.1 Postmenopausal (%) TVT: 44 TOT: 39  Inclusion criteria Women who	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details ClinicalTrials.gov, NCT00234754. All procedures conducted according to practice of participating surgeons, consistent with Boston Scientific recommendations. Anaesthesia local or general depending on patient choice/clinical state and anaesthesiologist. Cystoscopy performed for all cases. Retropubic sling (TVT) Advantage TVT (Boston Scientific) used. Transobturator sling (TOT) Obtryx Halo outside-in TOT (Boston Scientific) used.	Results Note: 5-year FU data from Ross et al. 2016. Objective cure at 12-mo (pad test <1g) - n/N TVT: 67/105 TOT: 68/94 Objective cure at 5-years - n/N TVT: 56/105 TOT: 57/94 Subjective cure at 12-mo: (reports no urine leakage when stressed or no problem/small problem of urine leakage in past 7 days) - n/N TVT: 88/105 TOT: 85/94 Subjective cure at 5 years (no problem/small problem of urine	Limitations Random sequence generation: Low risk (computer-generated permuted block randomisation list stratified by surgeon) Allocation concealment: Unclear risk (reports surgical staff and patient did not know next allocation but no details provided as to how this ensured) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (reports independent nurse was assessor but no further details provided;

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>114, 1287-1294, 2009</p> <p>Ref Id 100738</p> <p>Country/ies where the study was carried out Canada</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To assess effectiveness of TVT compared to TOT in women with SUI</p> <p>Study dates 10/2005 to 06/2007</p> <p>Source of funding Peer-reviewed funding from Alberta Heritage Fund for Medical Research. Grant-in-aid industry funding</p>	<p>elected to have SUI surgery</p> <p>were visualized leaking urine from the urethra with cough</p> <p>were suitable for either TVT or TOT procedure</p> <p>Exclusion criteria Women who had previous incontinence surgery required any concurrent surgery had an overactive bladder (urinary frequency and urgency with or without urge incontinence) had &gt;100 mL postvoid residual planned to have more children had Alzheimer's or Parkinson's disease or progressive neurological disease were immunocompromised</p>			<p>leakage in past 7 days) - n/N</p> <p>TVT: 82/105</p> <p>TOT: 79/94</p> <p>Improvement at 12-mo (surgery satisfied expectations) - n/N</p> <p>TVT: 80/105</p> <p>TOT: 78/94</p> <p>PISQ-12 - mean <math>\pm</math>SD</p> <p>TVT: 35.3 (6.5), n=52</p> <p>TOT: 35.9 (5.4), n=58</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 3/105</p> <p>TOT: 0/93</p> <p>Repeat surgery for mesh complications at 12-mo - n/N</p> <p>TVY: 2/90</p> <p>TOT: 4/85</p> <p>Repeat surgery for mesh complications at 5-years - n/N</p> <p>TVT: 2/93</p> <p>TOT: 3/83</p> <p>Repeat surgery for SUI at 5-years - n/N</p> <p>TVT: 3/87</p> <p>TOT: 1/78</p>	<p>urogynaecological examinations performed by clinicians blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data similar across groups and for similar reasons)</p> <p>Selective reporting: Low risk (protocol available, all relevant outcomes reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information 5-year follow up data reported in Ross et al. 2016.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
from Boston Scientific (Natick, MA)	were unable to understand English would be unavailable for follow-up.			Complications - n/N Pain at 12-mo TVT: 5/90 TOT: 13/85 Pain at 5-years TVT: 21/87 TOT: 10/78 Mesh extrusion at 12-mo TVT: 0/90 TOT: 5/85	
Full citation Ross, S., Tang, S., Eliasziw, M., Lier, D., Girard, I., Brennand, E., Dederer, L., Jacobs, P., Robert, M., Transobturator tape versus retropubic tension-free vaginal tape for stress urinary incontinence: 5-year safety and effectiveness outcomes following a	Sample size N=199 randomised Intervention, n=105 Control, n=94  Characteristics See entry for Ross et al. 2009 for further details  Inclusion criteria See entry for Ross et al. 2009 for further details  Exclusion criteria	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details See entry for Ross et al. 2009 for further details	Results See entry for Ross et al. 2009 for further details	Limitations See entry for Ross et al. 2009 for further details  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>randomised trial, International Urogynecology Journal, 27, 879-86, 2016</p> <p>Ref Id 543018</p> <p>Country/ies where the study was carried out Canada</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To assess long-term 5-year effectiveness of TVT compared to TOT in women with SUI</p> <p>Study dates 10/2005 to 06/2007</p> <p>Source of funding Original peer-reviewed funding from</p>	<p>See entry for Ross et al. 2009 for further details</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Alberta Heritage Fund for Medical Research. Grant-in-aid industry funding from Boston Scientific (Natick, MA). Peer-review funding for 5-year follow-up was provided by the Canadian Institutes of Health Research (CIHRMOP 106692).					
Full citation Ross, S., Tang, S., Schulz, J., Murphy, M., Goncalves, J., Kaye, S., Dederer, L., Robert, M., Single incision device (TVT Secur) versus retropubic tension-free vaginal tape	Sample size N=40 randomised Intervention, n=40 Control, n=34  Characteristics Age (years) - mean $\pm$ SD TVT-Secur: 52.4 (12.3) TVT: 47.2 (10.8) Median BMI	Interventions Intervention: Single-incision mini-sling Control: Other synthetic sling	Details ClinicalTrials.gov, NCT00685217. Five surgeons, all with $\geq$ 8 years incontinence surgery experience with TVT, at 5 centres performed surgeries. All surgeons performed at least 5 TVT-Secur operations. Type of anaesthesia (local, general, spinal with or without local) determined by surgeon, anaesthesiologist and patient. Single-incision mini-sling (TVT-Secur)	Results Objective cure at 1 year (Pad test <1g with 300 ml full bladder) - n/N TVT-Secur: 27/40 TVT: 25/34 Subjective cure at 1 year (Self-reported no loss or leakage under stress, or self-reported urine loss 'small' or 'no' problem in past 7 days) - n/N	Limitations Random sequence generation: Low risk (computer-generated variable block randomisation stratified by surgeon) Allocation concealment: Low risk (central allocation by email) Blinding of participants/personnel: Low risk (participants)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>device (TVT) for the management of stress urinary incontinence in women: a randomized clinical trial, BMC Research Notes, 7, 941, 2014</p> <p>Ref Id 543019</p> <p>Country/ies where the study was carried out Canada</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare effectiveness, complications and effects on quality of life of TVT-Secur and TVT in women with SUI</p> <p>Study dates</p>	<p>TVT-Secur: 27.2 (IQR 7.1), n=40 TVT: 27.8 (IQR 7.8), n=33</p> <p>Nulliparous (%) TVT-Secur: 5 TVT: 6</p> <p>Postmenopausal (%) TVT-Secur: 45 TVT: 32</p> <p>Inclusion criteria Women electing surgical management for SUI leaked urine with increased abdominal pressure suitable for both types of surgery</p> <p>Exclusion criteria Women who had previous incontinence surgery required concomitant POP surgery who had primary complaint of overactive bladder or</p>		<p>Ethicon Gynecare slings used with procedure conducted according to surgeon's usual practice</p> <p>Other synthetic sling (TVT) Ethicon Gynecare slings used with procedure conducted according to surgeon's usual practice</p>	<p>TVT-Secur: 35/40 TVT: 29/34</p> <p>Improvement at 1 year (number women surgery met expectations) - n/N TVT-Secur: 26/40 TVT: 28/34</p> <p>Adverse events - bladder injury - n/N TVT-Secur: 1/40 TVT: 0/34</p> <p>Repeat surgery for mesh complications at 1 year - n/N TVT-Secur: 1/40 TVT: 0/34</p> <p>Complications at 1 year - n/N Pain TVT-Secur: 1/40 TVT: 0/34</p> <p>Mesh extrusion TVT-Secur: 1/40 TVT: 0/34</p>	<p>blinded to group assignment)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates)</p> <p>Selective reporting: Low risk (protocol available, all relevant outcomes reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
02/2009 to 03/2011  Source of funding Grant-in-aid funding and training for TVT-Secur provided by Johnson & Johnson. Alberta Health Services provided financial support for research nurses.	incontinence caused by bladder overflow intended to have children with Alzheimer's or Parkinson's Disease, or other progressive neurological disease unable to understand English unavailable for follow up				
Full citation Rudnicki, M., von Bothmer-Ostling, K., Holstad, A., Magnusson, C., Majida, M., Merkel, C., Prien, J., Jakobsson, U., Teleman, P., Adjustable mini-sling compared to conventional	Sample size N=307 randomised Intervention, n=155 Control, n=150  Characteristics Age (years) - mean ±SD Adjustable sling: 44.9 (6.9) Other synthetic sling: 46.1 (7.2)	Interventions Intervention: Adjustable sling Control: Other synthetic sling (TVT, TVT-O, TOT)	Details Clinicaltrials.gov NCT01754558. All surgeons urogynaecological specialists who had each performed >100 MUS procedures and minimum of 2 Adjust procedures supervised by main investigators of trial. Type of midurethral sling (MUS) and anaesthesia used determined by preference of one of 8 local centres in the relevant countries. All women prescribed paracetamol and ibuprofen as needed postoperatively, with diclofenac	Results Objective cure at 12 months (negative stress test) - n/N Adjustable sling: 134/155 Other synthetic sling: 137/150 Subjective cure at 12 months (Response of 'never' to Q3 of ICIQ-UI SF) - n/N Adjustable sling: 69/155	Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Low risk (sealed, opaque envelopes used, independent allocation) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>mid-urethral slings in women with urinary incontinence. A randomized controlled trial, Acta obstetrica ET gynecologica scandinavica, 16, 16, 2017</p> <p>Ref Id 674241</p> <p>Country/ies where the study was carried out Denmark, Norway, Sweden</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare objective/subjective outcomes and short-term complications of adjustable single-incision sling and midurethral slings</p>	<p>BMI (kg/m<sup>2</sup>) - mean <math>\pm</math>SD</p> <p>Adjustable sling: 26.1 (4.6)</p> <p>Other synthetic sling: 26.6 (4.6)</p> <p>Median Parity</p> <p>Adjustable sling: 2.0 (IQR 3)</p> <p>Other synthetic sling: 2.0 (IQR 2)</p> <p>Number of women with pure SUI</p> <p>Adjustable sling: 118/155</p> <p>Other synthetic sling: 118/150</p> <p>Number of women with mixed UI</p> <p>Adjustable sling: 37/155</p> <p>Other synthetic sling: 32/150</p> <p>Inclusion criteria Women with medical history of stress UI, or stress-predominant mixed urinary</p>		<p>sodium prescribed as needed. All women asked to fill bladder diary for 2 consecutive days at trial inclusion and follow ups. Follow up: 1 year</p> <p>Adjustable sling (Ajust)</p> <p>Ajust SIMS used in procedure and anchored in obturator membrane on both sides, then adjusted in similar manner to MUS. Local anesthesia + iv analgesic (alfentanil bolus injection) or general anaesthesia used according to centre preference.</p> <p>Other synthetic sling (Various) TVT (Ethicon), TVT-O (Ethicon) or TOT (Monarc) MUS used in procedures.</p>	<p>Other synthetic sling: 75/150</p> <p>Number of incontinence episodes per day 0/1/2/3/4/&gt;4 episodes (from bladder diary) - n</p> <p>Adjustable sling: 74/6/3/3/0/0</p> <p>Other synthetic sling: 67/7/2/1/0/1</p> <p>Continence-specific health-related QoL at 12 months - ICIQ sum Q3-5 - mean <math>\pm</math>SD</p> <p>Adjustable sling: 3.1 (3.9)</p> <p>Other synthetic sling: 2.5 (3.7)</p> <p>Adverse events - bladder perforation - n/N</p> <p>Adjustable sling: 0/155</p> <p>Other synthetic sling: 3/150</p> <p>Patient-reported improvement at 3-mo FU - n</p> <p>PGI-S Normal/Minor/Moderate/Severe</p> <p>Adjustable sling: 98/24/6/0</p>	<p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data imputed using appropriate methods, ITT analysis)</p> <p>Selective reporting: Low risk (protocol available, all primary/secondary outcomes reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates 05/2012 to 04/2014</p> <p>Source of funding Funded by Grant No. NF12013 from Nordic Federation of Obstetrics and Gynecology Research Fund</p>	<p>incontinence (involuntary leakage complaint associated with urgency and stress incontinence with more stress episodes)</p> <p>Stress UI confirmed by positive standardised cough test including 300 cm<sup>3</sup> in bladder and failed or declined pelvic floor muscle training.</p> <p>Exclusion criteria Women aged 60 years or more predominant urge incontinence POP-Q Stage 2 or more previous incontinence or pelvic organ prolapse surgery planned or present pregnancy residual urine volume &gt; 100 ml previous pelvic irradiation</p>			<p>Other synthetic sling: 98/23/9/3 PGI-I Significantly improved/much improved/some improvement/Unchange d/Slightly worse/Worse/Much worse</p> <p>Adjustable sling: 90/30/9/0/1/0/0</p> <p>Other synthetic sling: 96/22/7/3/3/0/1</p> <p>Patient-reported improvement at 12-mo FU - n PGI-S Normal/Minor/Moderate/ Severe</p> <p>Adjustable sling: 96/30/9/0</p> <p>Other synthetic sling: 98/29/1/1</p> <p>PGI-I Significantly improved/much improved/some improvement/Unchange d/Slightly worse/Worse/Much worse</p> <p>Adjustable sling: 96/26/7/3/0/0/0</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>repeated urinary tract infections (four or more during the past year)</p> <p>neurological conditions such as multiple sclerosis</p> <p>current treatment with corticoids</p> <p>inability to understand the protocol</p> <p>history of genital or abdominal cancer or a pelvic mass</p>			<p>Other synthetic sling: 106/13/6/1/0/1/1</p> <p>Short-term complications at 3-mo FU (Ajust, n=141; MUS, n=142) - n</p> <p>Pain (groin or abdominal pain only)</p> <p>Adjustable sling: 0</p> <p>Other synthetic sling: 1</p> <p>Infection - Urinary tract</p> <p>Adjustable sling: 12</p> <p>Other synthetic sling: 7</p> <p>Infection - Wound</p> <p>Adjustable sling: 0</p> <p>Other synthetic sling: 1</p> <p>De novo OAB - urge incontinence</p> <p>Adjustable sling: 0</p> <p>Other synthetic sling: 2</p> <p>Short-term complications at 12-mo FU (Ajust, n=141; MUS, n=139) - n</p> <p>Infection - Urinary tract</p> <p>Adjustable sling: 24</p> <p>Other synthetic sling: 22</p> <p>Pain - De novo dyspareunia (PISQ-12) (number of women</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				with some form of de novo dyspareunia) Adjustable sling: 54 Other synthetic sling: 64	
<p>Full citation Sabadell, J., Palau-Gene, M., Huguet, E., Montero-Armengol, A., Salicru, S., Poza, J. L., Multicentre randomized trial of the Ajust™ single-incision sling compared to the Align™ transobturator tape sling, International Urogynecology Journal, 28, 1041-1047, 2017 Ref Id 674246 Country/ies where the study was carried out</p>	<p>Sample size N=58 randomised Intervention, n=30 Control, n=28</p> <p>Characteristics Median age (years) Adjustable sling: 60.8 (range 43.2-73.7) Adjustable TOT: 59.1 (range 45.7-78.9) Median BMI Adjustable sling: 29.1 (range 22.6–44.0) Adjustable TOT: 29.6 (range 18.9–40.9) Median vaginal deliveries Adjustable sling: 2 (range 1–6) Adjustable TOT: 2 (range 1–4) Menopause (%) Adjustable sling: 83</p>	<p>Interventions Intervention: Adjustable sling Control: Other synthetic sling</p>	<p>Details ClinicalTrials.gov NCT01699425. All procedures performed by experienced surgeons (all &gt;10 procedures with Ajust SIMS). POP surgery performed if necessary. Adjustable sling Ajust (Bard) single-incision mini-sling used. Other synthetic sling (Adjustable TOT) Align-TO (Bard) outside-in transobturator sling used</p>	<p>Results Subjective cure at 1 year (No self-reported SUI according to Sandvik classification) - n/N Adjustable sling: 16/30 Adjustable TOT: 15/28 Objective cure at 1 year (negative cough stress test and fully satisfied with operation as assessed by ICIQ-SF) - n/N Adjustable sling: 19/30 Adjustable TOT: 20/28 Improvement at 1 year (number cured + number with negative cough stress test and moderately satisfied with surgery due to urinary frequency and/or sporadic urgency episodes) - n/N</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block randomisation) Allocation concealment: Low risk (consecutively numbered, opaque, sealed envelopes used, envelopes opened just before surgery) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no dropouts) Selective reporting: Low risk (protocol available, all outcomes reported)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Spain Study type Multicentre RCT  Aim of the study To compare effectiveness and complications of Adjust single-incision mini-sling to transobturator Align sling in women with SUI  Study dates 03/2013 to 03/2015  Source of funding Supported by grant from Palex Medical to cover cost of civil liability insurance.	Adjustable TOT: 71 Concomitant POP surgery (%) Adjustable sling: 27 Adjustable TOT: 29  Inclusion criteria Women with planned surgery for SUI  Exclusion criteria Women aged <18 years-old had previous continence surgery with urge-predominant mixed UI with detrusor overactivity with intrinsic sphincter deficiency (MUCP ≤20cm H2O or less) with presence of a low mobile urethra (Q-tip test angle of <30°) with neurogenic bladder			Adjustable sling: 28/30 Adjustable TOT: 27/28 Repeat surgery for SUI at ≤1 year - n/N Adjustable sling: 0/30 Adjustable TOT: 0/28 Adverse events -Severe bleeding requiring blood transfusion - n/N Adjustable sling: 0/30 Adjustable TOT: 0/28 Adverse events - Bladder injury - n/N Adjustable sling: 0/30 Adjustable TOT: 0/28 Adverse events - Bowel injury - n/N Adjustable sling: 0/30 Adjustable TOT: 0/28 Complications - n/N Pain Adjustable sling: 6/30 Adjustable TOT: 0/28 Mesh extrusion Adjustable sling: 0/30 Adjustable TOT: 0/28 Need for catheterisation Adjustable sling: 1/30 Adjustable TOT: 0/28	Other bias: Low risk (appears free from other sources of bias)  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Infection (recurrent cystitis) Adjustable sling: 0/30 Adjustable TOT: 2/28 De novo urgency Adjustable sling: 3/30 Adjustable TOT: 1/28	
Full citation Sand, P. K., Winkler, H., Blackhurst, D. W., Culligan, P. J., A prospective randomized study comparing modified Burch retro pubic urethropexy and suburethral sling for treatment of genuine stress incontinence with low-pressure urethra, American journal of obstetrics and gynecology, 182, 30-34, 2000	Sample size N=37 randomised Intervention, n=19 received colposuspension Control, n=17 received sling  Characteristics Age (years) - mean $\pm$ SD Colposuspension: 61.3 (10.3) Fascial sling: 60.4 (8.5) BMI - mean $\pm$ SD Colposuspension: 21.8 (3.7) Fascial sling: 23.7 (5.6) Parity - mean $\pm$ SD	Interventions Intervention: Colposuspension with sutures Control: Fascial sling	Details All procedures conducted under supervision of senior author of study. Subprapubic catheter placed in all patients with voiding trials on day 1; catheters removed when postvoid residual volume <100 ml and did not exceed 1/3 of spontaneously voided volume in 24 hrs. Long-term mean FU: 72.6 months (range 33-116) Open Burch colposuspension with sutures Four 2-0 polytetrafluoroethylene (Goretex) sutures used, colposuspension conducted according to Tanagho modification with exception of tension placed on periurethral sutures. Fascial sling (autologous rectus) Sling procedure conducted according to Horbach et al. 1988 with sling tension determined by	Results Note: data for >5 year FU from Culligan et al. 2003. Objective cure at 3 months (no urine leakage at maximum cystometric capacity while coughing or performing Valsalva manoeuvres in sitting or standing position during urodynamic studies) - n/N Colposuspension: 17/19 Fascial sling: 17/17 Objective cure at >5 years FU (no urine leakage on stress test with bladder volume of 250 ml and a negative pad test) - n/N Colposuspension: 13/19	Limitations Random sequence generation: Low risk (random number table used) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Low risk (participants blinded to group assignment) Blinding of outcome assessment: High risk (assessors not blinded to group assignment) Incomplete outcome data: Low risk (Missing data not likely to have clinically-relevant impact on effect estimates)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Ref Id 674253</p> <p>Country/ies where the study was carried out USA</p> <p>Study type RCT</p> <p>Aim of the study To compare modified Burch colposuspension to suburethral sling in women with pure urinary stress incontinence with low-pressure urethra</p> <p>Study dates 04/0990 to 11/1996</p> <p>Source of funding None reported</p>	<p>Colposuspension: 2.8 (1.8)</p> <p>Fascial sling: 3.2 (1.1)</p> <p>Concurrent POP surgery (%)</p> <p>Colposuspension: 5</p> <p>Fascial sling: 12</p> <p>Inclusion criteria Women with genuine stress incontinence with urethral hypermobility (maximum straining angle <math>\geq 30^\circ</math> during cotton swab testing) MUCP <math>\leq 20</math>cm H<sub>2</sub>O in sitting position No significant anterior pelvic support defects</p> <p>Exclusion criteria Women with anterior vaginal wall prolapse below midvaginal plane</p>		<p>cotton swab testing and under minimal tension (resting urethra angle of 0-10°).</p>	<p>Fascial sling: 13/17 Subjective cure at 3 months (no self-reported leakage during any activity that increases intra-abdominal pressure) - n/N Colposuspension: 18/19 Fascial sling: 17/17 Subjective cure at &gt;5 year FU (no incontinence episodes on 1 week voiding diary) - n/N Colposuspension: 14/19 Fascial sling: 11/17 Mean (SD) urge incontinence episodes per day Colposuspension: 0.33 (2.63), n=15 Fascial sling: 0.31 (2.63), n=13 (SD calculated from reported between-group 95% CIs) Mean (SD) stress incontinence episodes per day Colposuspension: 0 (0.58), n=15</p>	<p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: High risk (At baseline, significantly more patients in colposuspension group had detrusor instability and higher average postvoid residual volume compared to those in sling group)</p> <p>Other information Long-term follow-up data reported in Culligan et al. 2003.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Fascial sling: 0.15 (0.58), n=13 (SD calculated from reported between-group 95% CIs) Adverse events - bladder injury - n/N Colposuspension: 1/19 Fascial sling: 0/17 Reports no other adverse events. Repeat surgery for mesh complications - n/N Colposuspension: 0/19 Fascial sling: 2/17 Complications - n/N Mesh extrusion at 3-mo Colposuspension: 0/19 Fascial sling: 0/17 Mesh extrusion at 3-12 months Colposuspension: 0/19 Fascial sling: 2/17 De novo OAB - detrusor instability at 3-mo Colposuspension: 1/19 Fascial sling: 4/17 POP occurrence at 3-mo	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Colposuspension: 0/19 Fascial sling: 0/17	
<p>Full citation Scheiner,D.A., Betschart,C., Wiederkehr,S., Seifert,B., Fink,D., Perucchini,D., Twelve months effect on voiding function of retropubic compared with outside-in and inside-out transobturator midurethral slings, International urogynecology journal and pelvic floor dysfunction, 23, 197-206, 2012 Ref Id 188443 Country/ies where the study was carried out</p>	<p>Sample size N=160 randomised Intervention 1 (TVT), n=80 Intervention 2 (TOT), n=40 Intervention 3 (TVT- O), n=40</p> <p>Characteristics Age (years) - mean ±SD TVT: 57.8 (13.0) TOT: 56.6 (10.3) TVT-O: 59.3 (12.1) BMI - mean ±SD TVT: 26.4 (3.7) TOT: 27.8 (4.6) TVT-O: 27.6 (4.8) Parity - mean ±SD TVT: 2 (1) TOT: 2.6 (1.5) TVT-O: 2.3 (1.1) Concomitant POP surgery (%)</p>	<p>Interventions Intervention 1: Retropubic sling Intervention 2: Transobturator sling 1 Intervention 3: Transobturator sling 2</p>	<p>Details Clinicaltrials.gov, NCT00642109. Women with POP-Q stage≥2 was corrected before SUI surgery and experienced surgeons performed all procedures usually under analgesia and sedation. Prophylactic single- shot cefazolin (or clindamycin if allergic to penicillin) administered. Cystocopy performed in all cases. Trial stopped early due to high occurrence of de novo sexual dysfunction in TOT group. Retropubic sling (TVT) Gynecare TVT used. Mean FU: 12.4 (0.8) months. Transobturator (outside-in) sling (TOT) Monarc (AMS) TOT used. Mean FU: 12.8 (1.6) months. Transobturator (inside-out) sling (TVT-O) Gynecare TVT-O used. Mean FU: 12.5 (1.3)</p>	<p>Results Objective cure at 12-mo (negative cough stress test in supine position and negative short-pad test [<math>&lt;3g</math>], both with 300ml full bladder) - n/N TVT: 58/80 TOT: 31/40 TVT-O: 33/40 Subjective cure at 12- mo (patient global impression, 'cured') - n/N TVT: 57/80 TOT: 28/40 TVT-O: 29/40 Improvement at 12-mo (patient global impression, number 'cured' + number improved) - n/N TVT: 63/80 TOT: 34/40 TVT-O: 37/40</p>	<p>Limitations Random sequence generation: Low risk (computer-generated block size 8 randomisation in ratio of 2:1:1) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: High risk (assessors not blinded to group assignment, potential detection bias) Incomplete outcome data: Low risk (missing data not sufficient to induce clinically relevant impact on effect sizes) Selective reporting: Unclear risk (protocol</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Switzerland Study type Mutlicentre RCT	TVT: 8 TOT: 0 TVT-O: 8			Adverse events - bladder injury - n/N TVT: 3/80 TOT: 0/40 TVT-O: 0/40	available but insufficient information provided) Other bias: Low risk (appears free from other sources of bias)
Aim of the study To compare TVT, TVT-O and TOT in women with SUI	Inclusion criteria Women with urodynamically- confirmed SUI or stress-predominant mixed UI			Repeat surgery for mesh complications at 12-mo - n/N TVT: 2/80 TOT: 0/40 TVT-O: 1/40	Other information
Study dates 01/2006 to 10/2009	Exclusion criteria Women with missing urodynamic assessment who had previous sling procedure with predominant overactive bladder syndrome with a post-void residual urine volume>100 ml who are pregnant or considering further pregnancy with known or suspected coagulopathy			Repeat surgery for SUI - n/N TVT: 1/80 TOT: 1/40 TVT-O:/40	
Source of funding None				Continence-specific HR- QoL - KHQ at 12-mo (TVT, n=47; TOT, n=28; TVT-O, n=28) - mean $\pm$ SD General health perception TVT: 22.3 (18.4) TOT: 22.3 (19.6) TVT-O: 25.0 (20.8) Incontinence impact TVT: 8.5 (14.7) TOT: 11.9 (22.6) TVT-O: 10.7 (18.6)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	with known allergy to local anaesthetics unable to understand German unavailable or unwilling to attend follow-up			Role limitations TVT: 4.6 (11.4) TOT: 6.8 (17.5) TVT-O: 6.0 (12.6) Physical limitations TVT: 5.3 (12.1) TOT: 6.0 (20.9) TVT-O: 4.9 (7.7) Social limitations TVT: 1.7 (6.6) TOT: 6.0 (20.4) TVT-O: 1.4 (5.0) Personal relationships TVT: 3.2 (8.0) TOT: 7.1 (18.7) TVT-O: 3.1 (9.1) Emotional problems TVT: 2.4 (7.3) TOT: 2.8 (7.8) TVT-O: 5.8 (15.4) Sleep/energy TVT: 4.3 (8.1) TOT: 6.5 (13.1) TVT-O: 6.7 (12.7) Severity measures TVT: 16.4 (20.3) TOT: 17.5 (22.1) TVT-O: 7.3 (17.8)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Overactive bladder TVT: 3.9 (13.0) TOT: 5.2 (19.3) TVT-O: 4.9 (14.5) Complications - n/N Pain at 12-mo TVT: 1/80 TOT: 3/40 TVT-O: 1/40 Mesh extrusion at 6-mo TVT: 1/80 TOT: 0/40 TVT-O: 0/40 Mesh extrusion at 12-mo TVT: 1/80 TOT: 4/40 TVT-O: 0/40 De novo OAB - de novo urgency TVT: 1/80 TOT: 0/40 TVT-O: 0/40	
Full citation Schellart, R. P., Oude Rengerink, K., Van Der Aa, F.,	Sample size N=193 randomised Intervention, n=97 Control, n=96	Interventions Intervention: Singl e-incision mini- sling	Details <a href="http://www.trialregister.nl/trialreg/index.aspx">www.trialregister.nl/trialreg/index.aspx</a> , NTR3783. Surgical procedures standardised across participating centres, with all surgeons having	Results Note: 2-year follow up data from Schellart et al. 2016; 3-year follow-up	Limitations Random sequence generation: Low risk (computer-generated)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Lucot, J. P., Kimpe, B., De Ridder, D. J. M. K., Dijkgraaf, M. G. W., Roovers, J. P. W. R., A randomized comparison of a single-incision midurethral sling and a transobturator midurethral sling in women with stress urinary incontinence: Results of 12-mo follow-up, European urology, 66, 1179-1185, 2014</p> <p>Ref Id 669303</p> <p>Country/ies where the study was carried out Belgium, France and Netherlands</p> <p>Study type Multicentre RCT</p>	<p><b>Characteristics</b></p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>MiniArc: 53 (11)</p> <p>TOT: 53 (11)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>MiniArc: 26.0 (4.3)</p> <p>TOT: 25.7 (3.7)</p> <p>Median parity</p> <p>MiniArc: 2 (IQR 2)</p> <p>TOT: 2 (IQR 2–3)</p> <p>Postmenopausal (%)</p> <p>MiniArc: 47</p> <p>TOT: 36</p> <p><b>Inclusion criteria</b></p> <p>Women with symptomatic stress urinary incontinence due to urethral hypermobility and/or intrinsic sphincter deficiency</p> <p><b>Exclusion criteria</b></p> <p>Women</p>	<p>Control: Other Synthetic sling</p>	<p>extensive experience with SUI surgery. All participants received single dose antibiotics before surgery.</p> <p>Single-incision mini-sling (MiniArc)</p> <p>MiniArc (AMS) mini-sling used. Introduced through single 1.5 cm incision at midurethra level after bilateral periurethral dissection to posterior portion of ischiopubic ramus. Needle tracked until midline mark on mesh under urethra. Fixation of tip into obturator internus fascia an needle removed. Same procedure on contralateral side.</p> <p>Other synthetic sling (TOT)</p> <p>Monarc (AMS) TOT used, with same incision and dissection as for MiniArc performed.</p>	<p>data from Schellart et al. 2017.</p> <p>Objective cure at 1 year (negative cough stress test in supine position with <math>\geq</math>250ml full bladder or <math>&gt;</math>70% maximum bladder capacity according to voiding diary) - n/N</p> <p>MiniArc: 74/97</p> <p>TOT: 73/96</p> <p>Objective cure at 2 years - n/N</p> <p>MiniArc: 64/97</p> <p>TOT: 65/96</p> <p>Objective cure at 3 years - n/N</p> <p>MiniArc: 67/97</p> <p>TOT: 66/96</p> <p>Subjective cure at 1 year (Response of 'very much' or 'much' improved on PGII) - n/N</p> <p>MiniArc: 71/97</p> <p>TOT: 76/96</p> <p>Subjective cure at 2 years - n/N</p> <p>MiniArc: 61/97</p> <p>TOT: 64/96</p>	<p>variable block randomisation)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (assessors of adverse events not blinded to group assignment; insufficient information regarding assessment of follow up data)</p> <p>Incomplete outcome data: Low risk (missing data similar at 1-, 2- and 3-year follow up, for similar reasons)</p> <p>Selective reporting: Low risk (protocol available, all outcomes of concern reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To report 1-year follow up results of single incision mini-sling compared to TOT in women with SUI</p> <p>Study dates 12/2009 to 12/2011</p> <p>Source of funding Supported by unrestricted research grant of American Medical Systems, Minneapolis, M N, USA.</p>	<p>with ICS Stage 2 genital prolapse who are due to have surgery for recurrent SUI</p> <p>who are due to have concomitant surgery who are pregnant or want to become pregnant</p> <p>not capable of giving informed consent.</p>			<p>Subjective cure at 3 years - n/N MiniArc: 61/97 TOT: 64/96</p> <p>Repeat surgery for SUI at <math>\leq 1</math> year MiniArc: 1/97 TOT: 2/96</p> <p>Repeat surgery for SUI at <math>&gt;1</math> year to <math>\leq 2</math> years MiniArc: 2/97 TOT: 0/96</p> <p>Repeat surgery for SUI at <math>&gt;2</math> years to <math>\leq 3</math> years - n/N MiniArc: 5/97 TOT: 0/96</p> <p>Repeat surgery for mesh complications <math>\leq 1</math> year MiniArc: 1/97 TOT: 1/96</p> <p>Repeat surgery for mesh complications at <math>&gt;1</math> year to <math>\geq 2</math> years - n/N MiniArc: 0/97 TOT: 2/96</p> <p>Repeat surgery for mesh complications at</p>	<p>2-year follow up data reported in Schellart et al. 2016; 3-year follow-up data reported in Schellart et al. 2017</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				>2 years to ≤3 years - n/N MiniArc: 1/97 TOT: 3/96 Complications - n/N Pain >1 year to ≤2 years MiniArc: 2/97 TOT: 12/96 Pain >2 years to ≤3 years (dyspareunia) MiniArc: 1/97 TOT: 0/96 Mesh extrusion ≤1 year MiniArc: 1/97 TOT: 1/96 Mesh extrusion >1 year to ≤2 years MiniArc: 0/97 TOT: 2/96 Mesh extrusion >2 years to ≤3 years MiniArc: 1/97 TOT: 3/96 Infection (UTI) ≤1 year MiniArc: 9/97 TOT: 13/96 Infection (UTI) >1 year to ≤2 years MiniArc: 15/97	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TOT: 10/96	
<p>Full citation Schellart, R. P., Rengerink, K. O., Van der Aa, F., Lucot, J. P., Kimpe, B., Dijkgraaf, M. G. W., Roovers, J. P. W. R., A randomised comparison of single-incision versus traditional transobturator midurethral sling in women with stress urinary incontinence: results of a 24-month follow-up, International Urogynecology Journal and Pelvic Floor Dysfunction, 27, 871-877, 2016 Ref Id 674259</p>	<p>Sample size N=193 randomised Intervention, n=97 Control, n=96</p> <p>Characteristics</p> <p>Inclusion criteria See entry for Schellart et al., 2014 for more details.</p> <p>Exclusion criteria See entry for Schellart et al., 2014 for more details.</p>	<p>Interventions Intervention: Mini-sling Control: Other Synthetic sling</p>	<p>Details See entry for Schellart et al., 2014 for more details.</p>	<p>Results See entry for Schellart et al., 2014 for more details.</p>	<p>Limitations See entry for Schellart et al., 2014 for more details.</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out Belgium, France and Netherlands</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To report 2-year follow up results comparing single-incision mini-sling and TOT in women with SUI</p> <p>Study dates 12/2009 to 12/2011</p> <p>Source of funding Supported by unrestricted research grant of American Medical Systems, Minneapolis, MN, USA.</p>					

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Schellart, R. P., Zwolsman, S. E., Lucot, J. P., de Ridder, D. J. M. K., Dijkgraaf, M. G. W., Roovers, J. P. W. R., A randomized, nonblinded extension study of single-incision versus transobturator midurethral sling in women with stress urinary incontinence, International Urogynecology Journal, 1-8, 2017</p> <p>Ref Id 674260</p> <p>Country/ies where the study was carried out Belgium, France and Netherlands</p> <p>Study type</p>	<p>Sample size N=193 randomised Intervention, n=97 Control, n=96</p> <p>Characteristics See entry for Schellart et al., 2014 for more details.</p> <p>Inclusion criteria See entry for Schellart et al., 2014 for more details.</p> <p>Exclusion criteria See entry for Schellart et al., 2014 for more details.</p>	<p>Interventions Intervention: Mini-sling Control: Other Synthetic sling</p>	<p>Details See entry for Schellart et al., 2014 for more details.</p>	<p>Results See entry for Schellart et al., 2014 for more details.</p>	<p>Limitations See entry for Schellart et al., 2014 for more details.</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Multicentre RCT</p> <p>Aim of the study To report 3-year follow up results comparing single-incision mini-sling and TOT in women with SUI</p> <p>Study dates 12/2009 to 12/2011</p> <p>Source of funding Supported by unrestricted research grant of American Medical Systems, Minneapolis, MN, USA.</p>					
<p>Full citation Schierlitz, L., Dwyer, P. L., Rosamilia, A., Murray, C.,</p>	<p>Sample size N=164 randomised Intervention, n=82 Control, n=82</p>	<p>Interventions Intervention: Retropubic sling</p>	<p>Details See entry for Schierlitz et al. 2008 for further details.</p>	<p>Results See entry for Schierlitz et al. 2008 for further details.</p>	<p>Limitations See entry for Schierlitz et al. 2008 for further details.</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Thomas, E., De Souza, A., Hiscock, R., Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency, <i>Obstetrics &amp; Gynecology</i>, 119, 321-7, 2012</p> <p>Ref Id 541672</p> <p>Country/ies where the study was carried out Australia</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare 3-year efficacy of</p>	<p>Characteristics See entry for Schierlitz et al. 2008 for further details.</p> <p>Inclusion criteria See entry for Schierlitz et al. 2008 for further details.</p> <p>Exclusion criteria See entry for Schierlitz et al. 2008 for further details.</p>	<p>Control: Transobturator sling</p>			

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>TVT to TOT in treatment of women with SUI and intrinsic sphincter deficiency</p> <p>Study dates Unclear, not reported</p> <p>Source of funding None</p>					
<p>Full citation Schierlitz, L., Dwyer, P. L., Rosamilia, A., Murray, C., Thomas, E., De Souza, A., Lim, Y. N., Hiscock, R., Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary</p>	<p>Sample size N=164 randomised Intervention, n=82 Control, n=82</p> <p>Characteristics Age (years) - mean ±SD TVT: 60 (11.5) TOT: 60 (10.9) Median BMI TVT: 26 (IQR 23-30) TOT: 28 (IQR 24-31) Median Parity</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details www.anzctr.org.au, ACTRN 12608000093381. Surgeons experienced in both procedures. All participants received prophylactic antibiotics at start of surgery; anaesthesia was either local + sedation, spinal or general, depending on patient choice and surgeon preference. Cystoscopy performed in all cases. Retropubic sling (TVT) Gynecare TVT with procedure performed according to Ulmsten et al. 1996. Transobturator sling (TOT)</p>	<p>Results Note: 3-year follow up data from Schierlitz et al. 2012. Objective cure at 6-mo (no urodynamically-proven stress incontinence) - n/N TVT: 53/82 TOT: 39/82 Subjective cure at 6-mo (number reporting no leakage [includes 10 in TVT and 7 in TOT groups that declined subsequent urodynamic</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>incontinence and intrinsic sphincter deficiency: a randomized controlled trial, Obstetrics &amp; Gynecology, 112, 1253-61, 2008</p> <p>Ref Id 541673</p> <p>Country/ies where the study was carried out Australia</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare efficacy of TVT to TOT in treatment of women with SUI and intrinsic sphincter deficiency</p> <p>Study dates</p>	<p>TVT: 3 (IQR 2-4) TOT: 3 (IQR 2-4) Postmenopausal (%) TVT: 80 TOT: 83 Concomitant POP surgery (%) TVT: 35 TOT: 32</p> <p>Inclusion criteria Women diagnosis of SUI diagnosis of intrinsic sphincter deficiency on urodynamic assessment (maximum urethral closure pressure of <math>\leq 20</math> cm H<sub>2</sub>O and/or pressure rise from baseline required to cause incontinence <math>\leq 60</math> cm H<sub>2</sub>O) failed conservative therapy</p> <p>Exclusion criteria</p>		<p>Monarc (AMS) TOT with procedure performed according to manufacturer's instructions.</p>	<p>assessment on basis that they were 'cured') - n/N TVT: 69/82 TOT: 63/82 Improvement at 6-months subjectively cured + number reporting some leakage but not bothersome) - n/N TVT: 70/82 TOT: 67/82 Adverse events - bladder injury - n/N TVT: 6/82 TOT: 0/82 Adverse events - bowel injury - n/N TVT: 0/82 TOT: 0/82 Adverse events - severe bleeding requiring transfusion TVT: 0/82 TOT: 0/82 Repeat surgery for mesh complications at 6-mo - n/N TVT: 3/82 TOT: 2/82</p>	<p>Incomplete outcome data: Low risk (missing data similar across groups and for similar reasons) Selective reporting: Unclear risk (protocol retrospectively registered, primary outcome at 3-years not reported appropriately) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information Three-year follow up data reported in Schierlitz et al. 2012.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Unclear, not reported  Source of funding None	Women with presence of pelvic infection  a persistent postvoid residual volume >100 mL  malignancy, fistula, congenital or neurogenic bladder disorder  inability to give informed consent			Repeat surgery for SUI at 6-mo - n/N TVT: 0/82 TOT: 9/82 (data from Schierlitz et al. 2012) Repeat surgery for SUI at >6-mo to 3-years - n/N TVT: 1/82 TOT: 6/82 Complications - n/N Pain at 6 months TVT: 1/82 TOT: 4/82 Need for catheterisation at 6-mo TVT: 9/82 TOT: 4/82 De novo OAB - de novo urgency TVT: 17/82 TOT: 8/82 De novo OAB - de novo urge incontinence TVT: 11/82 TOT: 11/82	
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Schweitzer, K. J., Milani, A. L., Van Eijndhoven, H. W. F., Gietelink, D. A., Hallensleben, E., Cromheecke, G. J., Van Der Vaart, C. H., Postoperative pain after adjustable single-incision or transobturator sling for incontinence: A randomized controlled trial, Obstetrics and gynecology, 125, 27-34, 2015 Ref Id 669310 Country/ies where the study was carried out Netherlands Study type RCT</p>	<p>N=156 randomised Intervention, n=100 Control, n=56</p> <p>Characteristics Age (years) - mean ±SD Adjustable sling: 50.8 (9.6) TVT-O: 48.3 (10.2) History of gynaecological surgery (%) Adjustable sling: 17 TVT-O: 18</p> <p>Inclusion criteria Women aged between 35 and 80 years with moderate to severe SUI (Sandvik score≥3) who failed pelvic floor muscle training with good knowledge of Dutch language.</p> <p>Exclusion criteria Women with</p>	<p>Intervention: Adjustable sling Control: Other synthetic sling</p>	<p><a href="http://www.trialregister.nl">www.trialregister.nl</a> NTR2558. Women recruited at outpatient clinic of university clinic and 4 large teaching hospitals. Surgeons all conducted at least 10 procedures with adjustable slings and procedures in both groups performed according to manufacturers instructions.. All women received perioperative antibiotic prophylaxis and mode of anaesthesia (general or locoregional spinal analgesia) as per patient request. Immediate postop, all women received acetaminophen with subsequent pain medication determined by use of VAS scale according to strict pain protocol. Follow up: 12 months post-op Adjustable sling Ajust (Bard Urological) SIMS used. TVT-O Manufacturer of tape not reported.</p>	<p>Objective cure at 12 months (negative stress cough test, bladder volume ≥300 ml) - n/N Adjustable sling: 79/87 TVT-O: 39/44 Subjective cure at 12 months (negative response to Q4 of UDI) - n/N Adjustable sling: 71/92 TVT-O: 35/48 Patient satisfaction/patient-reported improvement at 12 months (response of 'very much' or 'much better' to PGI-I) - n/N Adjustable sling: 81/90 TVT-O: 40/44 Adverse events (perioperative) - Vaginal perforation - n/N Adjustable sling: 1/96 TVT-O: 0/56 Adverse events (postoperative) - Bladder injury - n/N Adjustable sling: 0/96 TVT-O: 0/51</p>	<p>Random sequence generation: Unclear risk (2:1 ratio but no further information about randomisation method) Allocation concealment: Low risk (sequentially numbered, opaque, sealed envelopes, central telephone allocation) Blinding of participants/personnel: Low risk (Participants blinded using 2 sham incisions and not told of group assignment until 6 weeks postop) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (ITT analysis used) Selective reporting: Low risk (protocol available, all primary/secondary outcomes reported) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To compare adjustable single-incision sling to inside-out transobturator tension-free tape on surgery-related pain outcomes</p> <p>Study dates 09/2010 to 08/2011</p> <p>Source of funding Supported by grant from CR Bard inc.</p>	<p>a history of anti incontinence surgery postvoiding residual volume &gt;100 mL POP-Q score <math>\geq 2</math> desire for future pregnancy Co-morbidity (ASA 3 or 4) History of recurrent cystitis Psychiatric illness Poor cognitive function Chronic or current neurologic illness.</p>			<p>Repeat surgery for SUI - n/N Adjustable sling: 2/93 TVT-O: 1/51 Short-term complications at 12 months - n/N Pain - De novo dyspareunia (Positive response to Q3 of UDI) Adjustable sling: 10/26 TVT-O: 4/16 Mesh extrusion Adjustable sling: 4/93 TVT-O: 0/51 Need for catheterisation Adjustable sling: 8/96 TVT-O: 5/51 Infection - Urinary tract Adjustable sling: 8/96 TVT-O: 2/51 De novo urge OAB - Urge urinary incontinence Adjustable sling: 7/28 TVT-O: 4/19</p>	
Full citation	Sample size N=100 randomised	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Sharifiaghdas, F., Mirzaei, M., Daneshpajoo, A., Narouie, B., Long-term results of tension-free vaginal tape and pubovaginal sling in the treatment of stress urinary incontinence in female patients, Clinical and Experimental Obstetrics and Gynecology, 44, 44-47, 2017</p> <p>Ref Id 669312</p> <p>Country/ies where the study was carried out Iran</p> <p>Study type RCT</p> <p>Aim of the study To report long-term follow up for TVT</p>	<p>Intervention, n=48 Control, n=52</p> <p>Characteristics See Sharifiaghdas &amp; Mortyazavi 2008 for details.</p> <p>Inclusion criteria See Sharifiaghdas &amp; Mortyazavi 2008 for details.</p> <p>Exclusion criteria See Sharifiaghdas &amp; Mortyazavi 2008 for details.</p>	<p>Intervention: Synthetic sling</p> <p>Control: Autologous fascial sling</p>	<p>See Sharifiaghdas &amp; Mortyazavi 2008 for details.</p>	<p>See Sharifiaghdas &amp; Mortyazavi 2008 for details.</p>	<p>See Sharifiaghdas &amp; Mortyazavi 2008 for details.</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>compared to autologous rectus fascia pubovaginal sling in women with SUI</p> <p>Study dates 2000 to 2004</p> <p>Source of funding Reports no industry funding nor involvement</p>					
<p>Full citation Sharifiaghdas,F. , Mortazavi,N., Tension-free vaginal tape and autologous rectus fascia pubovaginal sling for the treatment of urinary stress incontinence: a medium-term follow-up, Medical Principles and</p>	<p>Sample size N=100 randomised Intervention, n=48 Control, n=52</p> <p>Characteristics Mean age (years) TVT: 49.1 (range 32–68) Fascial sling: 55 (range 34–70) Mean parity TVT: 3 (range 2-8)</p>	<p>Interventions Intervention: Synthetic sling Control: Autologous fascial sling</p>	<p>Details All procedures performed by one surgeon experienced in both techniques (&gt;15 operations in each) in inpatient setting. All participants received spinal anaesthesia and were secured in lithotomy position. Mean short-term mean FU=39 months; Mean long-term FU=10.5 years Synthetic sling (TVT) TVT procedure as described by Ulmsten et al. 1996. Fascial sling</p>	<p>Results Note: data for 10-year FU from Sharifiaghdas et al. 2017 Objective cure at mean 39 months FU (Negative cough stress test with full bladder [<math>\geq 250</math> ml] in the lithotomy and standing position, and 1 hour pad test<math>\leq 2</math>g) - n/N TVT: 36/48 Fascial sling: 37/52</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (sealed, opaque envelopes used but no further details) Blinding of participants/personnel: Low risk (participants blinded to group assignment)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Practice, 17, 209-214, 2008 Ref Id 100749 Country/ies where the study was carried out Iran Study type RCT</p> <p>Aim of the study To compare TVT and autologous rectus fascial sling at medium-term follow up in women with SUI</p> <p>Study dates 2000 to 2004</p> <p>Source of funding No industry sponsorship nor involvement</p>	<p>Fascial sling: 3 (range 2-8)</p> <p>Inclusion criteria Women with history of USI positive 1-hour pad (&gt;2g leak) objective positive cough (effort or exertion)-induced stress test normal cystourethroscopy and multichannel urodynamic confirmation of type II USI (abdominal leak point pressure of 60–90 cm H<sub>2</sub>O) urethral hypermobility competent bladder neck</p> <p>Exclusion criteria Women with history&gt;3 UTI episodes over past 2 years other gynecological problems that might</p>		<p>1-1.5 cm x 6 cm anterior rectus fascia pubovaginal sling used.</p>	<p>Objective cure at mean 10.5 year FU (negative cough stress test) - n/N TVT: 43/48 Fascial sling: 48/52 Subjective cure at mean 39 months (mean IIQ score) TVT: 44.3 (range 35.2-61.5) Fascial sling: 48.5 (range 38.5-69.7) Subjective cure at mean 10.5 year FU (No self-reported urine leakage in any circumstances) - n/N TVT: 26/48 Fascial sling: 23/52 Improvement at mean 10.5 year FU (subjective cure + Self-reported improvement without cure) - n/N TVT: 30/48 Fascial sling: 27/52 Adverse events - bladder injury - n/N TVT: 6/25 Fascial sling: 2/36</p>	<p>Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: High risk (39% dropout rate before 1-year FU, group assignment not specified; 31% dropout rate at 10 year follow up, similar proportion for each group) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>affect the result of surgery or need simultaneous repairs (e.g. high grade POP)</p> <p>abnormal filling phase of urodynamic study (evidence of uninhibited bladder contraction, low capacity or low compliance)</p> <p>flow rate &lt; 15 ml/s</p> <p>&gt; 100ml residual urine</p> <p>trabeculated bladder mucosa on cystourethroscopy</p> <p>history of major pelvic trauma and fractures that might negatively affect urethral function.</p>			<p>Adverse events - severe bleeding requiring blood transfusion - n/N</p> <p>TVT: 1/25</p> <p>Fascial sling: 1/36</p> <p>Repeat surgery 6-12 mo FU - n/N</p> <p>TVT: 1/25</p> <p>Fascial sling: 2/36</p> <p>Repeat surgery at 10.5 year FU - n/N</p> <p>TVT: 1/37</p> <p>Fascial sling: 1/32</p> <p>Complications - n/N</p> <p>Pain (including dyspareunia) at mean 10.5 years FU</p> <p>TVT: 5/37</p> <p>Fascial sling: 3/32</p> <p>Need for catheterisation at 4 weeks after surgery: p=0.4</p> <p>De novo OAB - de novo urgency at mean 10.5 years FU</p> <p>TVT: 6/37</p> <p>Fascial sling: 6/32</p> <p>De novo OAB - de novo urge incontinence at mean 39 months FU</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TVT: 1/25 Fascial sling: 8/36 De novo OAB - de novo urge incontinence at mean 10.5 years FU TVT: 3/37 Fascial sling: 2/32 Wound complications (hernia) at 1 year FU TVT: 1/25 Fascial sling: 1/36	
Full citation Sharifiaghdas, F., Nasiri, M., Mirzaei, M., Narouie, B., Mini Sling (Ophira) versus Pubovaginal Sling for Treatment of Stress Urinary Incontinence: A Medium-term Follow-up, Prague Medical Report, 116, 210-8, 2015 Ref Id 543054	Sample size N=72 randomised Intervention, n=35 Control, n=37  Characteristics Age (years) - mean $\pm$ SD SIMS: 55.6 (9.8) Fascial sling: 52.2 (9.3) Weight (kg) - mean $\pm$ SD SIMS: 71.7 (11.4) Fascial sling: 72.4 (9.8)	Interventions Intervention: Synthetic sling (SIMS) Control: Fascial sling	Details All surgery conducted with patient in lithotomy position using spinal anaesthesia with same surgeon conducting all procedures. All patients had cystourethroscopy. Mean FU=13.8 months (4.4) Synthetic sling (Single-incision mini-sling) Ophira (Promedon) SIMS used with standard procedure. Autologous rectus fascial sling 6-8 c, x 1-1.5 cm anterior rectus fascia sheet harvested and sutured by vicryl at both ends. Foley catheter fixed and removed 1-3 days postop. Patient discharged postvoid <100ml.	Results Negative cough stress test at FU - n/N SIMS: 31/35 Fascial sling: 33/37 Improvement at FU (number of women satisfied with operation) - n/N SIMS: 28/35 Fascial sling: 25/37 Adverse events - bladder injury - n/N SIMS: 0/35 Fascial sling: 1/35 Repeat surgery for mesh complications - n/N	Limitations Random sequence generation: Unclear risk (states sealed envelopes but no further details) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data not sufficient to have)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out Iran</p> <p>Study type RCT</p> <p>Aim of the study To compare safety and efficacy of Ophira mini-sling to autologous rectus fascial in women with SUI</p> <p>Study dates 01/2009 to 12/2011</p> <p>Source of funding Not reported</p>	<p>Inclusion criteria Women with history of SUI failed conservative managements urethral hypermobility positive cough stress test at <math>\geq 300</math> ml full bladder</p> <p>Exclusion criteria Women with persistent or active UTI evidences of urogynecological malignancies <math>\geq</math>grade 3 cystocele history of neurogenic bladder, abnormal filling or voiding phase on urodynamics abnormal cystourethroscopy findings</p>			<p>SIMS: 2/35 Fascial sling: 0/35 Complications at FU - n/N Pain SIMS: 4/35 Fascial sling: 3/35 Mesh extrusion SIMS: 2/35 Fascial sling: 1/35 Infection SIMS: 0/35 Fascial sling: 0/35</p>	<p>clinically-relevant impact on effect estimates) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>
<p>Full citation Shirvan, M. K., Rahimi, H. R.,</p>	<p>Sample size N=100 randomised Intervention, n=50</p>	<p>Interventions Intervention: Retropubic sling</p>	<p>Details</p>	<p>Results Cure at 12-months (completely objectively)</p>	<p>Limitations Random sequence generation: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Darabi Mahboub, M. R., Sheikhi, Z., Tension-free vaginal tape versus transobturator tape for treatment of stress urinary incontinence: A comparative randomized clinical trial study, Urological Science, 25, 54- 57, 2014 Ref Id 669316 Country/ies where the study was carried out Iran Study type RCT  Aim of the study To evaluate short- and medium-term outcomes of</p>	<p>Control, n=50  Characteristics Age (years) - mean ±SD TVT: 52.02 (37.7) TOT: 52.27 (34.7) BMI - mean ±SD TVT: 32.57 (74.4) TOT: 33.63 (88.7)  Inclusion criteria Women with predominant clinical diagnosis of SUI having urinary leakage synchronous with increased intra- abdominal pressure due to stress positive cough test who failed after 3-mo of conservative treatment for 3 months, normal values of uroflowmetry, cystometry (normal intravesical pressure</p>	<p>Control: Transobturator sling</p>	<p>All procedures performed by same surgeon, with patients under general or spinal anaesthesia. Retropubic sling (TVT) Performed as described in Ulmsten 1996. Cystoscopy performed in all patients. Transobturator sling (TOT) Performed as described in Delorme 2004.</p>	<p>[cough test, 1-hr pad test, urodynamics] and subjectively dry during increase in intra- abdominal pressure) - n/N TVT: 47/50 TOT: 48/50 Cure at 18 months - n/N TVT: 47/50 TOT: 48/50 ICIQ-UI-SF at 12-mo FU - mean ±SD TVT: 0.65 (1.38) TOT: 0.83 (2.15) ICIQ-UI-SF at 18-mo FU - mean ±SD TVT: 0.63 (1.25) TOT: 0.82 (2.12) ICIQ-QoL at 12-mo FU - mean [Not clear whether SD or SE reported, assumed to be SE as reports no significant difference between groups] TVT: 105.09 (2.38) TOT: 98.72 (2.56) ICIQ-QoL at 18-mo FU - mean ±SD</p>	<p>(computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>TVT and TOT in women with SUI</p> <p>Study dates 03/2008 to 10/2010</p> <p>Source of funding None</p>	<p>&lt; than 5-20 cmH2O) during filling and normal capacity (300-500 ml) without any uninhibited contracture, and electromyography (bladder and striated sphincter coordination) on urodynamic study</p> <p>Exclusion criteria Women POP-Q Stage&gt;2 or other significant pelvic floor abnormalities with high-pressure instability with neuromuscular disorders with known vesicoureteral reflux with uncontrolled diabetes pregnant, lactating or planning to become pregnant during study who are morbidly obesity (&gt;45.4 kg over ideal body weight) who have BMI≥40 and who are not expected</p>			<p>TVT: 106.87 (2.25) TOT: 98.53 (2.12) Adverse events - severe bleeding requiring transfusion - n/N TVT: 0/50 TOT: 0/50 Adverse events - bladder injury - n/N TVT: 0/50 TOT: 0/50 Adverse events - bowel injury - n/N TVT: 0/50 TOT: 0/50 Complications at 18-mo FU - n/N Mesh extrusion TVT: 0/50 TOT: 0/50 De novo OAB - de novo urge incontinence TVT: 3/50 TOT: 3/50 Infection TVT: 0/50 TOT: 0/50 Reports no other complications</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>to benefit from treatment</p> <p>with any current or acute conditions involving cystitis or urethritis</p> <p>who have history of urogenital cancer</p> <p>who plan to receive radiotherapy to urethra or adjacent structures, or history of such therapy</p> <p>currently using medication for UI treatment</p> <p>with uncared for physical or mental disability</p> <p>with urinary retention</p>				
<p>Full citation</p> <p>Silva-Filho,A.L., Candido,E.B., Noronha,A., Triginelli,S.A., Comparative study of autologous pubovaginal sling and synthetic</p>	<p>Sample size</p> <p>N=20 randomised</p> <p>Intervention, n=10</p> <p>Control, n=10</p> <p>Characteristics</p> <p>Age (years) - mean</p> <p>TOT: 55.2 (SEM 13.4)</p>	<p>Interventions</p> <p>Intervention:</p> <p>Synthetic sling</p> <p>Control:</p> <p>Autologous fascial sling</p>	<p>Details</p> <p>Synthetic sling (Adjustable TOT)</p> <p>SAFYRE (Promedon) adjustable transobturator outside-in sling used, procedure in line with Delorme 2001 with spinal anaesthesia. No cystoscopy required.</p> <p>Autologous rectus fascial sling</p>	<p>Results</p> <p>No adverse events reported.</p> <p>Subjective cure at 6-mo - n/N</p> <p>TOT: 3/10</p> <p>Fascial sling: 9/10</p> <p>Need for catheterisation - n/N</p> <p>TOT: 1/10</p>	<p>Limitations</p> <p>Random sequence generation: Unclear risk (insufficient information)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>transobturator (TOT) SAFYRE sling in the treatment of stress urinary incontinence, Archives of Gynecology and Obstetrics, 273, 288-292, 2006 Ref Id 100752 Country/ies where the study was carried out Brazil Study type RCT Aim of the study To compare short-term results of autologous rectus fascial sling and TOT in women with SUI Study dates 07/2003 to 01/2004</p>	<p>Fascial sling: 49.8 (SEM 9.1) BMI - mean TOT: 25.1 (SEM 3.3) Fascial sling: 27.1 (SEM 2.5) Parity - mean TOT: 3.2 (SEM 1.6) Fascial sling: 4 (SEM 1.1) Postmenopausal (%) TOT: 70 Fascial sling: 60 Inclusion criteria Women receiving primary treatment for SUI urodynamically-confirmed SUI without detrusor overactivity Exclusion criteria</p>		<p>Standard procedure used with peridural anaesthesia. Cystoscopy performed in all patients.</p>	<p>Fascial sling: 0/10 King's Health Questionnaire at 6-mo (Note: data is mean and standard errors) General health perception TOT: 37.5 (17.7) Fascial sling: 17.5 (20.6), p=0.032 Incontinence impact TOT: 73.3 (37.8) Fascial sling: 43.3 (47.3), p=0.136 Role limitations TOT: 60 (41.7) Fascial sling: 13.3 (23.3); p=0.006 Physical and social limitations TOT: 73.3 (38.6) Fascial sling: 21.7 (36), p=0.006 Personal relationships TOT: 35.6 (32.5) Fascial sling: 36.7 (42.1), p=0.950 Emotions TOT: 57.8 (46.5)</p>	<p>participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias) Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported				Fascial sling: 12.2 (23.1), p=0.016 Sleep/energy TOT: 54.2 (35.8) Fascial sling: 33.3 (41.6), p=0.246 Severity TOT: 61.3 (34.7) Fascial sling: 18.2 (20.9), p=0.004	
Full citation Sivaslioglu, Aa, Unlubilgin, E, Aydogmus, S, Celen, E, Dolen, I, A prospective randomized comparison of transobturator tape and tissue fixation system minisling in 80 patient with stress urinary incontinence - 3 year results, Pelviperineology , 29, 56-9, 2010 Ref Id 674293	Sample size N=80 randomised Intervention, n=40 Control, n=40  Characteristics Age (years) - mean ±SD Adjustable sling: 54 (13.6) TOT: 51.5 (12.5) BMI - mean ±SD Adjustable sling: 28.7 (3.1) TOT: 29.6 (2.7) Parity - mean ±SD Adjustable sling: 2.7 (1.3)	Interventions Intervention: Adjustable sling Control: Other synthetic sling	Details All procedures performed in lithotomy position and all patients received 1g iv cephazolin. Follow up: 3 years post-op (36 months±1 month; Sivaslioglu et al. 2010) and 5 years post-op (64 months, range 58-70 months; Sivaslioglu et al. 2012) Adjustable sling TFS (TFS Surgical Adelaide) - tissue fixation system - SIMS used. Small channel made between vagina and urethra in same manner as first part of TVT. Anchers inserted into inferior surface of pubovaginalis muscles, immediately behind urogenital diaphragm. Tape tightened over 18 gauge rigid Foley catheter until they touch but not indenting urethra. Other synthetic sling (TOT)	Results Note: data at 5 years from Sivaslioglu et al. 2012. Objective cure at 3 years (<1 g urine loss supine cough stress pad test and patient-reported urinary continence) - n/N Adjustable sling: 35/39 TOT: 32/38 Objective cure at 5 years - n/N Adjustable sling: 30/36 TOT: 27/36 Subjective cure at 3 years (restoration of urinary continence but	Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Low risk (participants blinded to group assignment) Blinding of outcome assessment: Unclear risk (assessor not involved in operations but no further details) Incomplete outcome data: Low risk (missing data not

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out Turkey Study type RCT</p> <p>Aim of the study To compare efficacy of adjustable minisling and transobturator outside-in tape (TOT) in women with urodynamically-proven SUI</p> <p>Study dates 09/2005 to 09/2006</p> <p>Source of funding None reported</p>	<p>TOT: 2.5 (1.7) Postmenopausal (%) Adjustable sling: 74 TOT: 71</p> <p>Inclusion criteria Women with genuine stress incontinence (GSI) with a Valsalva leak point pressure &lt; 60 cm H<sub>2</sub>O surgery naive for SUI who failed to respond to conservative management (e.g. physiotherapy, drugs)</p> <p>Exclusion criteria Women with overflow incontinence, pure urge incontinence or mixed incontinence neurological lesions overactive bladder transient causes of urinary incontinence such as urinary tract infection</p>		<p>Standard outside-in method used with tape inserted at clitoral level, non-stretch 10mm wide monofilament tape (I-STOP, CL Medical).</p>	<p>positive supine cough stress test) - n/N Adjustable sling: 1/39 TOT: 2/38 Subjective cure at 5 years - n/N Adjustable sling: 1/36 TOT: 2/36 Adverse events - Bladder injury - n/N Adjustable sling: 0/39 TOT: 0/38 Complications - n/N Complications - need for catheterisation due to urinary retention at &lt; 6 months Adjustable sling: 0/39 TOT: 2/38 Complications - post-op groin pain at 3 years Adjustable sling: 0/39 TOT: 12/38 Complications - post-op groin pain at 5 years Adjustable sling: 0/39 TOT: 12/38 Complications - mesh extrusion at 3 years Adjustable sling: 0/39</p>	<p>sufficient to have impact on effect sizes) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information Five-year follow-up data reported in Sivaslioglu et al. 2010.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	previous surgery for the correction of urinary incontinence			TOT: 0/38 Complications - mesh extrusion at 5 years Adjustable sling: 0/36 TOT: 1/36	
Full citation Sivaslioglu,A.A., Caliskan,E., Dolen,I., Haberal,A., A randomized comparison of transobturator tape and Burch colposuspension in the treatment of female stress urinary incontinence, International Urogynecology Journal, 18, 1015-1019, 2007 Ref Id 100756 Country/ies where the study was carried out	Sample size N=100 randomised Intervention, n=49 Control, n=51  Characteristics Age (years) - mean $\pm$ SD TOT: 45.4 (6.8) Colposuspension: 46.1 (7.9 0.6) BMI - mean $\pm$ SD TOT: 29.8 (5.3) Colposuspension: 29.3 (7.2 0.6) Parity - mean $\pm$ SD TOT: 2.6 (1.1) Colposuspension: 2.4 (1.5) Postmenopausal (%) TOT: 29 Colposuspension: 29	Interventions Intervention: Synthetic sling/mesh Control: Colposuspension	Details All procedures conducted by one surgeon with cystoscopy performed in all cases. Follow up: 1 year Synthetic sling/mesh (TOT) SafyreTM (Promedon) used under spinal anaesthesia. Colposuspension Open Burch colposuspension conducted as described by Walters et al. 1993.	Results Objective cure rate at 1 year FU (Negative supine cough stress test and self-reportedly continent) - n/N TOT: 42/49 Colposuspension: 41/51 Objective cure rate at 2 year FU - n/N TOT: 28/49 Colposuspension: 26/51 Subjective cure rate at 1 year FU (Self-reportedly continent regardless of cough stress test result) - n/N TOT: 42/49 Colposuspension: 43/51 Subjective cure rate at 2 year FU - n/N TOT: 28/49 Colposuspension: 27/51	Limitations Random sequence generation: Low risk (Computer-generated block randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (assessors not involved in operations but no further information) Incomplete outcome data: Low risk (no dropouts at 1 year FU) Selective reporting: Unclear risk (insufficient information)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Turkey</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy of TOT and Burch colposuspension in women with SUI</p> <p>Study dates 11/2003 to 11/2005</p> <p>Source of funding Not reported</p>	<p>Inclusion criteria Women with urodynamically-proven SUI</p> <p>Exclusion criteria Women who had previous incontinence surgery with urge incontinence with urodynamic detrusor overactivity genital prolapse ≥POP-Q stage 2</p>			<p>Adverse events - bladder injury - n/N TOT: 0/49 Colposuspension: 0/51</p> <p>Repeat surgery for SUI at 12-mo - n/N TOT: 3/49 Colposuspension: 4/51</p> <p>Complications - n/N Need for catheterisation at ≤6 months FU TOT: 0/49 Colposuspension: 2/51</p> <p>De novo OAB - urge incontinence at 1 year FU TOT: 1/49 Colposuspension: 3/51</p>	<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>
<p>Full citation Sivaslioglu,A.A., Unlubilgin,E., Aydogmus,S., Keskin,L., Dolen,I., A prospective randomized controlled trial of the transobturator</p>	<p>Sample size N=80 randomised Intervention, n=40 Control, n=40</p> <p>Characteristics See entry for Sivaslioglu et al. 2010 for further details.</p>	<p>Interventions Intervention: Adjustable single-incision sling Control: Transobturator outside-in tape (TOT)</p>	<p>Details See entry for Sivaslioglu et al. 2010 for further details.</p>	<p>Results See entry for Sivaslioglu et al. 2010 for details.</p>	<p>Limitations See entry for Sivaslioglu et al. 2010 for details.</p> <p>Other information 5-year FU to Sivaslioglu et al. 2010</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>tape and tissue fixation minisling in patients with stress urinary incontinence: 5-year results, Journal of Urology, 188, 194-199, 2012</p> <p>Ref Id 188046</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy of adjustable minisling and transobturator outside-in tape (TOT) in women with urodynamically-proven SUI</p>	<p>Inclusion criteria See entry for Sivaslioglu et al. 2010 for further details.</p> <p>Exclusion criteria See entry for Sivaslioglu et al. 2010 for further details.</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates 09/2005 to 09/2006</p> <p>Source of funding None reported</p>					
<p>Full citation Su, T. H., Wang, K. G., Hsu, C. Y., Wei, H. J., Hong, B. K., Prospective comparison of laparoscopic and traditional colposuspensio ns in the treatment of genuine stress incontinence, Acta Obstetrica et Gynecologica Scandinavica, 76, 576-82, 1997 Ref Id 619127</p>	<p>Sample size N=94 randomised Intervention, n=46 Control, n=46</p> <p>Characteristics Age (years) - mean ±SD Laparoscopic: 42.4 (6.6) Open: 44.3 (7.9) Parity - mean ±SD Laparoscopic: 2.5 (0.9) Open: 2.9 (1.3) Number of women who underwent laparotomic hysterectomy immediately after procedures Laparoscopic: 14/46</p>	<p>Interventions Intervention: Laparoscopic colposuspension with sutures Control: Open colposuspension with sutures</p>	<p>Details All operations conducted by senior gynaecologists. Follow up: 3 months postop and every 6 months thereafter Laparoscopic colposuspension One or two Number 1 unabsorbable polybutylate-coated polyester sutures (Ethibond) used. Open colposuspension 2 to 3 Ethibond sutures used.</p>	<p>Results Objective cure at minimum of 1 year (# dry on cough test and bouncing on urodynamic testing) - n/N Laparoscopic: 37/46 Open: 44/46 Short-term complications - n/N Infection (urinary tract) Laparoscopic: 1/46 Open: 1/46 De novo detrusor instability Laparoscopic: 2/46 Open: 3/46</p>	<p>Limitations Random sequence generation: Low risk (computer-generated random number table) Allocation concealment: Low risk (sealed, opaque, sequentially-numbered envelopes used) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no randomised patient dropped out) Selective reporting: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Taiwan Study type RCT Aim of the study To prospectively compare laparoscopic and open coloposuspension in women with pure stress incontinence Study dates 01/1993 to 06/1994 Source of funding None reported	Open: 14/46 POP status: all women had less than first-degree cystocele Inclusion criteria Women with urodynamic stress incontinence Exclusion criteria Women with detrusor instability, underactive detrusor or outflow obstruction previous anti-incontinence surgery previous hysterectomy				Other bias: Low risk (appears free from other sources of bias) Other information
Full citation Tammaa, A., Aigmuller, T., Hanzal, E., Umek, W.,	Sample size N=569 randomised Intervention, n=285 Control, n=269	Interventions Intervention: Retropubic sling	Details See entry for Aigmuller et a. 2014 for more details.	Results See entry for Aigmuller et a. 2014 for more details.	Limitations See entry for Aigmuller et a. 2014 for more details. Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Kropshofer, S., Lang, P. F. J., Ralph, G., Riss, P., Koelle, D., Jundt, K., Tamussino, K., Bjelic-Radicic, V., Austrian Urogynecology Working, Group, Retropubic versus transobturator tension-free vaginal tape (TVT vs TVT-O): Five-year results of the Austrian randomized trial, Neurourology &amp; UrodynamicsNe urourol Urodyn, 02, 02, 2017 Ref Id 674333 Country/ies where the study was carried out Austria Study type Multicentre RCT</p>	<p>Characteristics See entry for Aigmuller et a. 2014 for more details.</p> <p>Inclusion criteria See entry for Aigmuller et a. 2014 for more details.</p> <p>Exclusion criteria See entry for Aigmuller et a. 2014 for more details.</p>	<p>Control: Transobturator slin g</p>			

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To report 5-year subjective and objective outcomes of TVT compared to TVT-O in women with SUI</p> <p>Study dates 01/2005 to 07/2007</p> <p>Source of funding Funded by Austrian Urogynecology Working Group</p>					
<p>Full citation Tang, X., Zhu, L., Liang, S., Lang, J., Outcome and sexual function after transobturator tape procedure versus tension-free vaginal tape</p>	<p>Sample size N=94 randomised Intervention, n=46 Control, n=48</p> <p>Characteristics Note: TVT-Secur, n=39; TVT-O, n=42 Age - mean <math>\pm</math>SD</p>	<p>Interventions Intervention: Single-incision mini-sling Control: Other synthetic sling</p>	<p>Details Same surgeon conducted all procedures. All patients received prophylactic antibiotic of iv levofloxacin. Patients discharged when post-void volume &lt;50ml. Single-incision mini-sling (TVT-Secur) Gynecare (Ethicon) sling used with procedure conducted according to manufacturer's instructions</p>	<p>Results Negative cough stress test at 1 year - n/N TVT-Secur: 31/46 TVT-O; 37/48 Negative cough stress test at 2 years - n/N TVT-Secur: 29/46 TVT-O: 25/48</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>SECUR: a randomized controlled trial, Menopause, 21, 641-5, 2014 Ref Id 541717 Country/ies where the study was carried out China Study type RCT</p> <p>Aim of the study To compare efficacy, safety and sexual function of TVT-O to TVT-Secur in women with SUI</p> <p>Study dates 08/2008 to 08/2010</p> <p>Source of funding Not reported</p>	<p>TVT-Secur: 48.8 (10.1) TVT-O: 51.3 (7.5) BMI - mean <math>\pm</math>SD TVT-Secur: 25.2 (3.0) TVT-O: 24.7 (3.3) Parity - mean <math>\pm</math>SD TVT-Secur: 1.4 (0.8) TVT-O: 1.2 (0.5) Postmenopausal (%) TVT-Secur: 33 TVT-O: 48</p> <p>Inclusion criteria Women demonstrable SUI (involuntary leakage without detrusor contraction with 300 ml full bladder on cough) failed conservative treatment</p> <p>Exclusion criteria Women with pregnancy urinary tract infection</p>		<p>Other synthetic sling (TVT-O) Gynecare (Ethicon) sling used with procedure conducted according to manufacturer's instructions</p>	<p>Improvement at 1 year (number with negative cough stress test + number with &gt;50% reduction in both urine leakage and weight on 1-hr pad test) - n/N TVT-Secur: 35/46 TVT-O: 40/48 Improvement at 2 years - n/N TVT-Secur: 33/46 TVT-O: 37/48 Adverse events - severe bleeding requiring transfusion - n/N TVT-Secur: 0/46 TVT-O: 0/48 PISQ-12 at 1 year - mean <math>\pm</math>SD TVT-Secur: 33.9 (4.5), n=39 TVT-O: 33.9 (4.4), n=42 PISQ-12 at 2 years - mean <math>\pm</math>SD TVT-Secur: 33.7 (5.1), n=39 TVT-O: 33.5 (4.2), n=42 Complications - n/N Pain at 1 year</p>	<p>participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data similar between groups and for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>urge or mixed incontinence</p> <p>postvoid residual volume &gt; 100 mL, POP requiring extensive surgical treatment</p> <p>intrinsic sphincter deficiency</p> <p>history of neurological disease</p> <p>urogenital malignancy, fistula, or pelvic radiotherapy</p>			<p>TVT-Secur: 2/39</p> <p>TVT-O: 11/42</p> <p>Mesh extrusion at 1 year</p> <p>TVT-Secur: 1/39</p> <p>TVT-O: 3/42</p> <p>De novo urgency</p> <p>TVT-Secur: 2/39</p> <p>TVT-O: 2/42</p> <p>Infection: 0/39; 0/42</p>	
<p>Full citation</p> <p>Tanuri, A. L., Feldner, P. C., Jr., Bella, Z. I., Castro, R. A., Sartori, M. G., Girao, M. J., [Retropubic and transobturator sling in treatment of stress urinary incontinence], Revista Da Associacao Medica</p>	<p>Sample size</p> <p>N=30 randomised</p> <p>Intervention, n=10</p> <p>Control, n=20</p> <p>Characteristics</p> <p>Reports participants similar in terms of age, parity, mode of child delivery, repeat surgery status, hysterectomy status, and intrinsic sphincter deficiency status. No details reported.</p>	<p>Interventions</p> <p>Intervention: Retropubic sling</p> <p>Control: Transobturator sling</p>	<p>Details</p> <p>All patients received intradural block anaesthesia. All patients who were not cured underwent sling revision.</p> <p>Retropubic sling (Safyre adjustable sling)</p> <p>Safyre retropubic (suprapubic) procedure used.</p> <p>Transobturator sling (Safyre adjustable sling)</p> <p>Safyre TOT (transvaginal) procedure followed.</p>	<p>Results</p> <p>Subjective cure at 1 year (unclear how defined) - n/N</p> <p>Retropubic: 9/10</p> <p>Transobturator: 18/20</p> <p>Objective cure at 1 year (Stress/pad test) - n/N</p> <p>Retropubic: 8/10</p> <p>Transobturator: 16/20</p> <p>Adverse events - bladder injury - n/N</p> <p>Retropubic: 0/10</p> <p>Transobturator: 0/20</p>	<p>Limitations</p> <p>Random sequence generation: Unclear risk (insufficient information)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Brasileira, 56, 348-54, 2010</p> <p>Ref Id 619140</p> <p>Country/ies where the study was carried out Brazil</p> <p>Study type RCT</p> <p>Aim of the study To compare outcomes and complications of retropubic sling and Safyre TOT slings in women with SUI</p> <p>Study dates Unclear, not reported</p> <p>Source of funding Not reported</p>	<p>Inclusion criteria Women with diagnosis of SUI sufficiently fit for surgery</p> <p>Exclusion criteria Women taking adrenergic, anticholinergic or serotonergic drugs</p> <p>who received hormone therapy in last 6 months</p> <p>who had prior pelvic radiotherapy or having current chemotherapy or hormone therapy with uterine prolapse anterior or posterior vaginal prolapse&gt;stage II with mixed urinary incontinence</p>			<p>Adverse events - bowel injury - n/N</p> <p>Retropubic: 0/10</p> <p>Transobturator: 0/20</p> <p>Complications at 1 year - n/N</p> <p>Pain</p> <p>Retropubic: 0/10</p> <p>Transobturator: 1/20</p> <p>Mesh extrusion</p> <p>Retropubic: 0/10</p> <p>Transobturator: 0/20</p> <p>Infection</p> <p>Retropubic: 0/10</p> <p>Transobturator: 0/20</p> <p>De novo urge incontinence</p> <p>Retropubic: 1/10</p> <p>Transobturator: 1/20</p> <p>King's health Questionnaire at 1 year - mean <math>\pm</math>SD</p> <p>General health perception</p> <p>Retropubic: 30 (19.7)</p> <p>Transobturator: 27.5 (24.2)</p> <p>Incontinence impact</p> <p>Retropubic: 3.3 (10.5)</p>	<p>Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Transobturator: 8.3 (23.9) Role limitations Retropubic: 1.7 (5.3) Transobturator: 5 (22.4) Physical limitations Retropubic: 1.7 (5.3) Transobturator: 5 (22.4) Social limitations Retropubic: 1.1 (3.5) Transobturator: 3.7 (17.4) (groups significantly different at baseline) Personal relationships Retropubic: 0 (0) Transobturator: 0 (0) Emotions Retropubic: 0 (0) Transobturator: 5 (23.4) Sleep/energy Retropubic: 0 (0) Transobturator: 5 (22.4) Severity measures Retropubic: 5 (13.1) Transobturator: 6.3 (19.3)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Tarcan, T., Mangir, N., Sahan, A., Tanidir, Y., Sulukaya, M., Ilker, Y., Safety and efficacy of retropubic or transobturator midurethral slings in a randomized cohort of Turkish women, Urologia Internationalis, 93, 449-53, 2014 Ref Id 543088 Country/ies where the study was carried out Turkey Study type RCT Aim of the study To evaluate safety and</p>	<p>Sample size N=54 randomised Intervention, n=27 Control, n=27  Characteristics Reports no significant difference on age, BMI and parity. No details reported. Concomitant POP surgery for whole sample (%): 14.3  Inclusion criteria Women with urodynamically-proven SUI (pure or stress-predominant)  Exclusion criteria Women with neurogenic bladder previous anti-incontinence surgery presence of urogenital prolapse≥3</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Median FU=48.5 months (21.8). Retropubic sling (Advantage) Advantage (Boston Scientific) retropubic system with procedure as described by Ulmsten et al. 1996. Urethrocystoscopy performed in all cases. Transobturator sling (Obtryx) Obtryx (Boston Scientific) transobturator system with procedure as described by Delorme 2001.</p>	<p>Results Adverse events - bladder injury - n/N Retropubic: 0/27 Transobturator: 0/27 Complications at ~4 years - n/N De novo urgency Retropubic: 2/27 Transobturator: 1/27 Need for catheterisation Retropubic: 2/27 Transobturator: 0/27</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: High risk (reports majority of outcomes for overall sample rather than by group) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>efficacy of retropubic and transobturator slings in treatment of female SUI</p> <p>Study dates 08/2006 to 02/2013</p> <p>Source of funding Not reported</p>					
<p>Full citation Tcherniakovsky, M., Fernandes,C.E., Bezerra,C.A., Del Roy,C.A., Wroclawski,E.R. , Comparative results of two techniques to treat stress urinary incontinence: synthetic transobturator and aponeurotic slings,</p>	<p>Sample size N=41 randomised Intervention, n=21 Control, n=20</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD TOT: 46.5 (10.9) Fascial sling: 52.1 (10.5) BMI - mean <math>\pm</math>SD TOT: 27.2 (4) Fascial sling: 26.6 (3.9)</p>	<p>Interventions Intervention: Synthetic sling Control: Autologous fascial sling</p>	<p>Details Patients discharged when residual urine &lt;100ml or &gt;20% maximum cystometric capacity. Synthetic sling (Adjustable TOT) SAFYRE (Promedon) adjustable TOT sling used. Long-term bladder catheter removed on postop day 1. Autologous rectus fascial sling Sling placed retropubically with long-term bladder catheter removed on postop day 2.</p>	<p>Results Objective cure at 12 months (self-reported absence of SUI and no leakage on stress tests) - n/N TOT: 19/21 Fascial sling: 19/20 Improvement at 12 months - n/N TOT: 19/21 Fascial sling: 19/20 Adverse events - bladder injury - n/N TOT: 1/21</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>International Urogynecology Journal, 20, 961-966, 2009 Ref Id 100767 Country/ies where the study was carried out Brazil Study type RCT</p> <p>Aim of the study To compare efficacy and complications of adjustable TOT to autologous rectus fascia sling</p> <p>Study dates 04/2004 to 10/2005</p> <p>Source of funding Not reported</p>	<p>Parity - mean <math>\pm</math>SD TOT: 3.8 (2.3) Fascial sling: 3.4 (2.2) Postmenopausal (%) TOT: 33 Fascial sling: 40</p> <p>Inclusion criteria Women with clinically- and urodynamically-confirmed SUI</p> <p>Exclusion criteria</p>			<p>Fascial sling: 0/20 Reports no other adverse events. Complications at 12 months - n/N Pain TOT: 0/21 Fascial sling: 0/20 Mesh extrusion TOT: 1/21 Fascial sling: 0/20 Infection TOT: 0/21 Fascial sling: 3/20 Wound complication TOT: 0/21 Fascial sling: 1/20</p>	<p>Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Teleb, M., Salem, E. A., Naguib, M., Kamel, M., Hasan, U., Elfayoumi, A. R., Kamel, H. M., El Adl, M., Evaluation of transvaginal slings using different materials in the management of female stress urinary incontinence, Arab Journal of Urology, 9, 283-287, 2011 Ref Id 669491 Country/ies where the study was carried out Egypt Study type RCT Aim of the study</p>	<p>Sample size N=32 randomised Intervention 1 (Synthetic sling), n=12 Control 1 (Autologous rectus fascial sling), n=12 Control 2 (Autologous vaginal wall sling), n=8  Characteristics Age (years) - mean <math>\pm</math>SD Intervention 1: 41.8 (8.2) Intervention 2: 41.4 (7.8) Control: 44.4 (9.4) BMI - mean <math>\pm</math>SD Intervention 1: 30.2 (3.5) Intervention 2: 29.5 (3.4) Control: 30.7 (3.1) Menopause (%) Intervention 1: 50 Intervention 2: 88 Control: 50</p>	<p>Interventions Intervention 1: Synthetic sling Control 1: Autologous fascial sling Control 2: Autologous vaginal wall sling</p>	<p>Details All procedures performed by same surgery team using transvaginal tension-free retropubic slings under mid-urethra in lithotomy position. All patients received spinal anaesthesia and 3rd-gen iv cephalosporin before surgery. Mean FU=18 (range 12-36) months.  Synthetic sling (TVT) Tailored 7 x 1.5 cm Ethicon prolene sling with number 0 prolene suture at each end with procedure otherwise in line with Ulmsten &amp; Petros 1995. Cystourethroscopy used after each TVT needle advance. Mean FU: 18.5 months Autologous rectus fascial sling 5 x 1.5 cm sling harvested from patient in supine position with number 0 prolene sutures at each end with procedure in line with Blaivas &amp; Jacobs 1989. Mean FU: 18 months Vaginal wall sling Rectangular anterior sling ~5 x 1.5 cm harvested from patient with number 0 prolene sutures at each end with procedure in line with Raz 1989 except using TVT semicircular needle rather than Stamey. Mean FU: 18 months</p>	<p>Results Objective cure at 12-36 months (no self-reported leakage and negative stress test) - n/N Intervention 1: 9/12 Intervention 2: 8/12 Control: 6/8 Improvement at 12-36 months (number cured + number with leakage only with severe exertion) - n/N Intervention 1: 11/12 Intervention 2: 11/12 Control: 7/8 Adverse events - bladder injury - n/N Intervention 1: 1/12 Intervention 2: 0/12 Control: 1/8 Complications - n/N Need for catheterisation at <math>\leq</math>1 month Intervention 1: 1/12 Intervention 2: 0/12 Control: 1/8 De novo urgency at 12-36 months Intervention 1: 1/12</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: High risk (~66% dropout rate) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>To compare TVT, autologous rectus fascial sling and vaginal wall sling to treat female SUI</p> <p>Study dates 05/2008 to 05/2010</p> <p>Source of funding Not reported</p>	<p>Inclusion criteria Women with primary complaint of SUI confirmed by history, SEAPI questionnaire, voiding diary, stress and Q-top tests, and urodynamic evaluation</p> <p>Exclusion criteria Women with neurological disease overactive bladder other causes and types of incontinence (overflow or pure urge) recurrent SUI (after anti-incontinence procedure) any form of prolapse requiring surgery</p>			<p>Intervention 2: 1/12 Control: 1/8</p>	
<p>Full citation Teo,R., Moran,P., Mayne,C., Tincello,D., Randomized trial of tension-</p>	<p>Sample size N=127 randomised Intervention, n=66 Control, n=61</p> <p>Characteristics</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details All procedures conducted using local anaesthetic and iv sedation and intraoperative cystoscopy with 70° cystoscope (twice after each trocar pass for TVT; once at end of TVT-O procedure), as well as same</p>	<p>Results Objective cure at 1-year FU (24-hr pad test &lt;5g) - n/N TVT: 33/66 TVT-O: 25/61</p>	<p>Limitations Random sequence generation: Low risk (computer-generated variable block randomisation)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>free vaginal tape and tension-free vaginal tape-obturator for urodynamic stress incontinence in women, Journal of Urology, 185, 1350-1355, 2011</p> <p>Ref Id 135601</p> <p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare efficacy of TVT and TVT-O in women with pure urodynamic SUI</p> <p>Study dates 03/2005 to 03/2007</p>	<p>Age (years) - mean <math>\pm</math>SD</p> <p>TVT: 52.4 (11.8)</p> <p>TVT-O: 50.9 (11.4)</p> <p>Median BMI</p> <p>TVT: 27 (range 21-37)</p> <p>TVT-O: 29 (range 21-50)</p> <p>Median parity</p> <p>TVT: 2 (range 0-8)</p> <p>TVT-O: 2 (range 0-8)</p> <p>Postmenopausal (%)</p> <p>TVT: 24/66</p> <p>TVT-O: 19/61</p> <p>Previous hysterectomy (%)</p> <p>TVT: 26</p> <p>TVT-O: 28</p> <p>Inclusion criteria</p> <p>Women with urodynamically-proven SUI</p> <p>no previous continence surgery</p> <p>Exclusion criteria</p> <p>Women with detrusor overactivity</p>		<p>macroporous monofilament polypropylene mesh. Intraoperative 120 mg iv gentamicin, plus 100 mg diclofenac rectally at end of procedure.</p> <p>Retropubic sling (TVT)</p> <p>Performed as described in Ulmsten 1999.</p> <p>Transobturator sling (TVT-O)</p> <p>Performed as described in de Leval 2005 except for use of local anaesthesia and sedation rather than general anaesthesia.</p>	<p>Improvement at 1-year FU (response of 'very much' better on PGII) - n/N</p> <p>TVT: 35/66</p> <p>TVT-O: 26/61</p> <p>ICIQ-UI-SF No leakage at 1-year FU - n/N</p> <p>TVT: 13/37</p> <p>TVT-O: 15/27</p> <p>Adverse events - severe bleeding requiring transfusion - n/N</p> <p>TVT: 0/66</p> <p>TVT-O: 0/61</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 0/66</p> <p>TVT-O: 0/61</p> <p>Repeat surgery for mesh complications - n/N</p> <p>TVT: 3/57</p> <p>TVT-O: 1/50</p> <p>Complications at 12-mo FU - n/N</p> <p>Pain</p> <p>TVT: 1/59</p> <p>TVT-O: 14/53</p> <p>Mesh extrusion</p>	<p>Allocation concealment: Unclear risk (reports numbered, opaque envelopes used but no further details provided)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: High risk (assessors not blinded to group assignment, potential detection bias)</p> <p>Incomplete outcome data: Low risk (missing data similar across groups and for similar reasons)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Two authors declared financial interest and/or other relationship with variety of medical technology companies (e.g. Astellas, Gynecare, AMS, Bard, Boston Scientific) and one author with BJOG.	POP-Q stage>1 voiding dysfunction (maximum flow rate<15ml or post-void residual urine volume≥100 ml)			TVT: 3/57 TVT-O: 1/50 Need for catheterisation TVT: 3/66 TVT-O: 1/61	
Full citation Tieu, A. L., Hegde, A., Castillo, P. A., Davila, G. W., Aguilar, V. C., Transobturator versus single incision slings: 1-year results of a randomized controlled trial, International	Sample size N=98 randomised Intervention, n=49 Control, n=49  Characteristics Age (years) - mean ±SD MiniArc: 52.9 (11.2) TOT Monarc: 48.9 (9.4) BMI - mean ±SD	Interventions Intervention: Single-incision mini-sling Control: Other synthetic sling	Details Two surgeons with experience of over 10 SIMS procedures, directed procedures performed by urogynaecological fellows. Standard methods used by 2 surgeons with exception of difference between tensioning technique (one did not use a spacer, one used pair of Metzenbaum scissors as spacer for sling placement). Majority of patients received general anaesthesia with concomitant POP repair conducted if	Results Negative cough stress test at >1 year (after catheterisation at 250ml full bladder in standing/supine positions) - n/N MiniArc: 29/49 TOT Monarc: 33/49 Subjective cure at >1 year (self-reported cured) - n/N	Limitations Random sequence generation: Low risk (computer-generated block randomisation of varying sizes) Allocation concealment: Unclear risk (sequentially-placed sealed envelopes used, but no further details) Blinding of participants/personnel:

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Urogynecology Journal, 28, 461-467, 2017</p> <p>Ref Id 619153</p> <p>Country/ies where the study was carried out USA</p> <p>Study type RCT</p> <p>Aim of the study To compare 1 year surgical outcomes of MiniArc single-incision mini-sling to Monarc TOT in women with SUI</p> <p>Study dates 2008 to 2011</p> <p>Source of funding Not reported</p>	<p>MiniArc: 28.4 (5.9) TOT Monarc: 26.3 (4.7)</p> <p>Median Parity MiniArc: 2 (range 0-4) TOT Monarc: 2 (range 0-4)</p> <p>Postmenopausal (%) MiniArc: 53 TOT Monarc: 37</p> <p>Concomitant POP surgery (%) MiniArc: 59 TOT Monarc: 69</p> <p>Inclusion criteria Women with urodynamically-proven SUI</p> <p>Exclusion criteria Women with history of incontinence surgery intrinsic sphincter deficiency or low pressure urethra made by urodynamic testing (Valsalva leak point pressure &lt;60 cmH2O)</p>		<p>required. Cystoscopy performed in all patients.</p> <p>Single-incision mini-sling (MiniArc) Standard methods used. Median FU: 61 weeks (range 52-99)</p> <p>Other synthetic sling (TOT Monarc) Standard methods used. Median FU: 66.5 weeks (range 51-105)</p>	<p>MiniArc: 31/49 TOT Monarc: 37/49</p> <p>Incontinence episodes per day - mean <math>\pm</math>SD MiniArc: 0.96 (1.7) TOT Monarc: 0.4 (1.0)</p> <p>Improvement at &gt;1 year (number not significantly bothered by SUI) - n/N MiniArc: 35/49 TOT Monarc: 37/49</p> <p>Adverse events - bladder injury - n/N MiniArc: 0/49 TOT Monarc: 1/49</p> <p>Adverse events - severe bleeding requiring transfusion - n/N MiniArc: 0/49 TOT Monarc: 0/49</p> <p>Repeat surgery for SUI at &gt;1 year - n/N MiniArc: 6/41 TOT Monarc: 5/42</p> <p>Repeat surgery for mesh complications at &gt;1 year - n/N MiniArc: 1/41 TOT Monarc: 1/42</p>	<p>Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (missing data similar across groups for similar reasons)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	and/or maximal urethral closure pressure <40 cm H <sub>2</sub> O) mixed incontinence with detrusor overactivity predominance			ICIQ-SF at >1 year - mean ±SD MiniArc: 3.9 (4.3), n=41 TOT Monarc: 3.1 (3.8), n=42 Complications at >1 year - n/N Pain MiniArc: 1/41 TOT Monarc: 0/42 De novo urgency MiniArc: 2/41 TOT Monarc: 3/42 Mesh extrusion MiniArc: 1/41 TOT Monarc: 3/42	
Full citation Tommaselli, G. A., D'Afiero, A., Di Carlo, C., Formisano, C., Fabozzi, A., Nappi, C., Tension-free vaginal tape-O and -Secur for the treatment of stress urinary incontinence: a	Sample size N=154 randomised Intervention, n=77 Control, n=77  Characteristics Age (years) - mean ±SD TVT-Secur-H: 56.4 (8.5) TVT-O: 60.5 (9.1) BMI - mean ±SD	Interventions Intervention: Singl e-incision mini-sling Control: Other Synthetic sling	Details All procedures performed by one surgeon at each site with all participants receiving iv prophylactic cefazolin and spinal anaesthesia. Cystoscopy and cough test not performed during operations. Single-incision mini-sling (TVT-Secur-H) Gynecare TVT-Secur used, hammock procedure as described by Neuman 2008. Other Synthetic sling (TVT-O)	Results Note: 5-year data from Tommaselli et al. 2015, unless otherwise stated. Objective cure at 3-year FU (No leakage on challenge stress test) - n/N TVT-Secur-H: 50/77 TVT-O: 57/77 Objective cure at 5-year FU (No leakage on	Limitations Random sequence generation: Low risk (computer-generated block randomisation list) Allocation concealment: Low risk (sequentially numbered, opaque and sealed envelopes used) Blinding of participants/personnel: Low risk (participants

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>thirty-six-month follow-up single-blind, double-arm, randomized study, Journal of Minimally Invasive Gynecology, 20, 198-204, 2013</p> <p>Ref Id 543098</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare efficacy of TVT-O and TVT-Secur-H at 3-year FU in women with SUI</p> <p>Study dates 04/2008 to 04/2009</p>	<p>TVT-Secur-H: 26.6 (3.5) TVT-O: 29.3 (6.3)</p> <p>Median parity TVT-Secur-H: 2 (range 0-3) TVT-O: 2 (range 0-4)</p> <p>Menopausal (%) TVT-Secur-H: 88 TVT-O: 86</p> <p>Inclusion criteria Women ≥30 years-old with clinically- and urodynamically-proven SUI who had previously failed pelvic floor muscle training</p> <p>Exclusion criteria Women who had previous SUI surgery with isolated overactive bladder symptoms ≥POP-Q stage 2</p>		<p>Procedure as described by de Leval 2003.</p>	<p>challenge stress test) - n/N TVT-Secur-H: 26/77 TVT-O: 38/77</p> <p>Subjective cure at 3-year FU (Self-reported absence of leakage) - n/N TVT-Secur-H: 50/77 TVT-O: 55/77</p> <p>Improvement at 3-year FU (number subjectively cured + number reporting &gt;50% reduction of urine loss) - n/N TVT-Secur-H: 56/77 TVT-O: 59/77</p> <p>Improvement at 5-year FU (response of 'very much' or 'much' improved on PGII) - n/N TVT-Secur-H: 37/77 TVT-O: 49/77</p> <p>Reports no significant difference between groups on I-QoL, PGIS, PGII and PISQ-12 at 3-year FU. Continence-specific health-related QoL - ≥20</p>	<p>blinded regarding group assignment) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (missing data similar across groups for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information 5-year follow up data reported in Tommaselli et al. 2015.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Study self-funded but two authors had travel expenses paid for by Ethicon Gynecare	with neurologic disease with serious contraindications to surgical procedures			point increase in I-QoL score at 5-year FU - n/N TVT-Secur-H: 42/58 TVT-O: 52/62 Adverse events - severe bleeding requiring transfusion - n/N TVT-Secur-H: 1/64 TVT-O: 0/66 Repeat surgery for mesh complications - n/N TVT-Secur-H: 1/64 TVT-O: 0/66 Repeat surgery for SUI at $\leq 3$ -year FU - n/N TVT-Secur-H: 6/77 TVT-O: 4/77 (data from Tommaselli et al. 2015) Repeat surgery for SUI $>3$ years to $\leq 5$ -year FU - n/N TVT-Secur-H: 15/77 TVT-O: 9/77 Complications - n/N Need for catheterisation $<1$ month FU TVT-Secur-H: 1/64 TVT-O: 2/66 Pain at 3-year FU	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TVT-Secur-H: 0/64 TVT-O: 3/66 Pain at 5-year FU TVT-Secur-H: 0/64 TVT-O: 0/66 Mesh extrusion at 3-year FU TVT-Secur-H: 3/64 TVT-O: 2/66 Mesh extrusion at 5-year FU TVT-Secur-H: 0/64 TVT-O: 0/66 Infection (UTI) at 5-year FU TVT-Secur-H: 6/38 TVT-O: 9/46 De novo OAB - de novo urgency at 3-year FU TVT-Secur-H: 4/64 TVT-O: 2/66 POP occurrence at 5-year FU TVT-Secur-H: 0/38 TVT-O: 1/46	
Full citation	Sample size N=154 randomised	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Tommaselli, G. A., D'Afiero, A., Di Carlo, C., Formisano, C., Fabozzi, A., Nappi, C., Tension-free vaginal tape-obturator and tension-free vaginal tape-Secur for the treatment of stress urinary incontinence: a 5-year follow-up randomized study, European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology, 185, 151-5, 2015</p> <p>Ref Id 543099</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type Multicentre RCT</p>	<p>Intervention, n=77 Control, n=77</p> <p>Characteristics See entry for Tommaselli et al. 2013 for more details.</p> <p>Inclusion criteria See entry for Tommaselli et al. 2013 for more details.</p> <p>Exclusion criteria See entry for Tommaselli et al. 2013 for more details.</p>	<p>Intervention: Mini-sling Control: Other Synthetic sling</p>	<p>See entry for Tommaselli et al. 2013 for more details.</p>	<p>See entry for Tommaselli et al. 2013 for more details.</p>	<p>See entry for Tommaselli et al. 2013 for more details.</p> <p>Other information Five-year follow up to Tommaselli et al. 2013</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To compare efficacy of TVT-O and TVT-Secur-H at 5-year FU in women with SUI</p> <p>Study dates 04/2008 to 04/2009</p> <p>Source of funding Study self-funded but two authors had travel expenses paid for by Ethicon Gynecare</p>					
<p>Full citation Tommaselli, G. A., Di Carlo, C., Gargano, V., Formisano, C., Scala, M., Nappi, C., Efficacy and</p>	<p>Sample size N=84 randomised Intervention, n=42 Control, n=42</p> <p>Characteristics</p>	<p>Interventions Intervention: Single-incision mini-sling Control: Other synthetic sling</p>	<p>Details Patients in both arms received spinal anaesthesia and iv antibiotic prophylaxis cefazolin. Single-incision mini-sling (TVT-Secur) Procedure as described by Neuman 2008.</p>	<p>Results Objective cure at 1 year (negative cough stress test and no leakage on exertion during urodynamic testing) - n/N TVT-Secur: 31/42</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation list) Allocation concealment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-Year follow-up, International urogynecology journal, 21, 1211-1217, 2010</p> <p>Ref Id 669373</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type RCT</p> <p>Aim of the study To compare efficacy and safety of TVT-Secur and TVT-O in women with SUI</p> <p>Study dates</p>	<p>Age (years) - mean <math>\pm</math>SD TVT-Secur: 57.8 (9.1) TVT-O: 58.2 (9.1)</p> <p>BMI - mean <math>\pm</math>SD TVT-Secur: 28.7 (4.3) TVT-O: 26.3 (5.3)</p> <p>Menopausal (%) TVT-Secur: 84 TVT-O: 76</p> <p>Inclusion criteria Women with clinically- and urodynamically-proven SUI duration of SUI <math>\geq</math>2 years <math>\geq</math>40 years-old</p> <p>Exclusion criteria Women with who had previous surgical and/or pharmacological treatment of SUI predominant or isolated urge incontinence POP-Q<math>\geq</math>2</p>		<p>Other synthetic sling (TVT-O) Procedure as described by de Leval 2003.</p>	<p>TVT-O: 31/42 Improvement at 1 year (number cured + number with occasional leakage on exertion during urodynamic testing) - n/N TVT-Secur: 35/42 TVT-O: 36/42 King's Health Questionnaire at 1 year - mean <math>\pm</math>SD General health perceptions TVT-Secur: 36.2 (19.8) TVT-O: 40.1 (18.8) Incontinence impact TVT-Secur: 28.0 (24.8) TVT-O: 30.7 (25.6) Role limitations TVT-Secur: 24.1 (28.9) TVT-O: 31.1 (30.5) Physical limitations TVT-Secur: 18.9 (26.4) TVT-O: 27.7 (32.9) Social limitations TVT-Secur: 34.8 (22.6) TVT-O: 38.7 (20.7) Personal relationships</p>	<p>Blinding of participants/personnel: Unclear risk (participants blinding until end of surgical procedure) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (Missing data similar across groups and for similar reasons) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
03/2007 to 03/2008  Source of funding Not reported	serious contraindications to surgery			TVT-Secur: 28.1 (17.8) TVT-O: 17.7 (23.2) Emotions TVT-Secur: 22.7 (16.4) TOT-O: 15.6 (21.7) Sleep/energy TVT-Secur: 27.6 (23.9) TOT-O: 24.7 (17.6) Severity measures TVT-Secur: 46.9 (26.3) TVT-O: 54.8 (27.5) Complications at 1 year - n/N Pain TVT-Secur: 0/37 TVT-O: 3/38 Mesh extrusion TVT-Secur: 1/37 TVT-O: 0/38 Need for catheterisation TVT-Secur: 0/37 TVT-O: 2/38 De novo urgency TVT-Secur: 2/37 TVT-O: 1/38	
Full citation Trabuco, E. C., Klinge, C. J.,	Sample size N=113 randomised	Interventions	Details Clinicaltrials.gov NCT00934999. All surgeons experienced in performing	Results	Limitations Random sequence generation: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Blandon, R. E., Occhino, J. A., Weaver, A. L., McGree, M. E., Lemens, M. A., Gebhart, J. B., Burch</p> <p>Retropubic Urethropexy Compared With Midurethral Sling With Concurrent Sacropopexy: A Randomized Controlled Trial, Obstetrics &amp; Gynecology, 128, 828-35, 2016</p> <p>Ref Id 543111</p> <p>Country/ies where the study was carried out USA</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To determine whether Burch</p>	<p>Intervention, n=57 Control, n=56</p> <p>Characteristics Age (years) - mean ±SD TVT: 56 (11) Colposuspension: 56 (10) BMI - mean ±SD TVT: 28.1 (5.3) Colposuspension: 28.3 (4.8) Parity 0 (%) TVT: 2 Colposuspension: 0 Parity 1 (%) TVT: 4 Colposuspension: 7 Parity 2 (%) TVT: 30 Colposuspension: 39 Parity ≥3 (%) TVT: 65 Colposuspension: 54 Menopausal (%) TVT: 60 Colposuspension: 66</p>	<p>Intervention: Synthetic sling Control: Colposuspension</p>	<p>both techniques (&gt;20 procedures each). All women had concomitant abdominal sacropopexy as described by Maher et al. 2004. Concomitant posterior repair conducted at surgeon discretion. Synthetic sling (TVT) Bard TVT used, procedure as described by Ulmsten et al. 1996. Colposuspension Open Burch (Tanagho) procedure with sutures used as described by Brubaker et al. 2006.</p>	<p>Note: Data for 1 - and 2-year followup from Trabuco et al. 2018.</p> <p>Subjective cure at 6-mo FU (ICIQ score=0) - n/N TVT: 31/57 Colposuspension: 24/56</p> <p>Subjective cure at 2 years - n/N TVT: 27/57 Colposuspension: 21/56</p> <p>Objective cure at 1 year (Response of 'never' or 'rarely' to 6 questions from stress-specific subdomain of MESAA questionnaire, negative cough stress test and no reoperation for SUI) - n/N TVT: 40/57 Colposuspension: 26/56</p> <p>Objective cure at 2 years - n/N TVT: 27/57 Colposuspension: 18/56</p> <p>Negative cough stress test at 2 years - n/N TVT: 44/57 Colposuspension: 36/56</p>	<p>(web-based randomisation) Allocation concealment: Low risk (central allocation with sealed, opaque envelopes) Blinding of participants/personnel: Low risk (participants masked to group assignment) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (missing data not sufficient to have clinically relevant impact on effect estimates) Selective reporting: Low risk (protocol available, all outcomes reported) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information One and two-year follow-up results reported in Trabuco et al. 2018.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>colposuspension or TVT should be conducted concomitantly with abdominal sacrocolpopexy</p> <p>Study dates 06/2009 to 08/2013</p> <p>Source of funding Funded by Mayo Clinic Center for Clinical and Translational Science, grant number UL1 TR000135 from the National Center for Advancing Translational Sciences, NIH.</p>	<p><b>Inclusion criteria</b> Women ≥21 years-old with apical or anterior vaginal wall prolapse stage 2 or more who opted for abdominal prolapse repair who are symptomatic SUI, stress-predominant mixed UI, or occult SUI with cystometric capacity ≥200 ml given written consent who are willing to complete FU</p> <p><b>Exclusion criteria</b> Women with known or suspected disease that affects bladder function (eg, multiple sclerosis) who are pregnant or desired fertility urethral diverticulum</p>			<p>Improvement at 6-mo FU (VAS score of 10 indicating participant perceives success of surgery as 'very successful') - n/N TVT: 35/57</p> <p>Colposuspension: 26/56 Improvement at 2 years - n/N TVT: 33/56</p> <p>Colposuspension: 25/57 Adverse events - bladder injury (from online supplementary material) - n/N TVT: 0/57</p> <p>Colposuspension: 0/56 Adverse events - urethral injury<sup>6</sup> (from online supplementary material) - n/N TVT: 0/57</p> <p>Colposuspension: 0/5 Repeat surgery for SUI at 2 years - n/N TVT: 2/48</p> <p>Colposuspension: 5/46 Complications at 6 months FU - n/N</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	with history of radical pelvic surgery or pelvic radiation therapy receiving current chemotherapy or radiation therapy for malignancy			Mesh extrusion at 6 months (from online supplementary material) TVT: 3/57 Colposuspension: 1/56 Infection at 6 months (from online supplementary material) TVT: 18/57 Colposuspension: 17/56 De novo urge incontinence at 6 months TVT: 3/28 Colposuspension: 2/27 De novo urge incontinence at 2 years TVT: 1/22 Colposuspension: 2/26	
Full citation Trabuco, E. C., Linder, B. J., Klingele, C. J., Blandon, R. E., Occhino, J. A., Weaver, A. L., McGree, M. E., Gebhart, J. B., Two-Year Results of Burch	Sample size N=113 randomised Intervention, n=57 Control, n=56  Characteristics See entry for Trabuco et al. 2016 for more details	Interventions Intervention: Synthetic sling Control: Colposuspension	Details See entry for Trabuco et al. 2016 for more details	Results See entry for Trabuco et al. 2016 for more details	Limitations See entry for Trabuco et al. 2016 for more details  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Compared With Midurethral Sling With Sacrocolpopexy: A Randomized Controlled Trial, Obstetrics and gynecology, 131, 31-38, 2018</p> <p>Ref Id 864973</p> <p>Country/ies where the study was carried out USA</p> <p>Study type Mutlicentre RCT</p> <p>Aim of the study To assess 2 year outcomes of Burch colposuspension or TVT with abdominal sacrocolpopexy in women with both SUI and POP</p>	<p>Inclusion criteria See entry for Trabuco et al. 2016 for more details</p> <p>Exclusion criteria See entry for Trabuco et al. 2016 for more details</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates 06/2009 to 08/2013</p> <p>Source of funding Funded by Mayo Clinic Center for Clinical and Translational Science, grant number UL1 TR000135 from the National Center for Advancing Translational Sciences, NIH.</p>					
<p>Full citation Ugurlucan, F. G., Erkan, H. A., Onal, M., Yalcin, O., Randomized trial of graft materials in transobturator tape operation: biological versus synthetic, International</p>	<p>Sample size N=100 randomised Intervention, n=50 Control, n=50</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD Adjustable TOT: 52.9 (10.6)</p>	<p>Interventions Intervention: Synthetic sling Control: Non-autologous biological sling</p>	<p>Details One surgeon performed all operations with 1g cephazolin antibiotic prophylaxis administered 30min before surgery and local/general anaesthesia as preferred by patient. Postmenopausal women received local oestrogen for 1-mo before and after surgery. Both procedures conducted as described by Delorme</p>	<p>Results Objective cure at 1 year (negative pad test) - n/N Adjustable TOT: 49/50 Porcine dermis sling: 47/50 Subjective cure at 1 year (self-reported dry) - n/N Adjustable TOT: 35/50</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (states allocation prepared by investigator with no clinical involvement but no further details)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Urogynecology Journal, 24, 1315-23, 2013 Ref Id 543119 Country/ies where the study was carried out Turkey Study type RCT  Aim of the study To compare outcomes of outside-in biological and synthetic TOT in women with SUI  Study dates 06/2008 to 06/2010  Source of funding Supported by Scientific Research Projects Coordination	Porcine dermis sling: 55 (12.3) BMI - mean $\pm$ SD Adjustable TOT: 31.3 (4.8) Porcine dermis sling: 31.8 (6.6) Parity -mean $\pm$ SD Adjustable TOT: 3.3 (2.2) Porcine dermis sling: 2.9 (1.3) Postmenopausal (%) Adjustable TOT: 59 Porcine dermis sling: 57 Concomitant POP surgery (%) Adjustable TOT: 56 Porcine dermis sling: 56 Type of incontinence (%) Stress UI Adjustable TOT: 14 Porcine dermis sling: 18 Urge UI Adjustable TOT: 2 Porcine dermis sling: 4		et al. 2004. Cystoscopy performed only in suspected cases of injury. Synthetic sling (Adjustable TOT) Align-TO adjustable urethral support system (Bard) used, type 1 monofilament polypropylene mesh. Non-autologous biological sling (porcine dermis sling) Pelvilace-TO system (Bard) used, self-anchoring 1.5 cm x 40 cm, natural tissue (porcine dermis) suburethral sling.	Porcine dermis sling: 34/50 Improvement at 1 year (number subjective cure + number reporting improvement) - n/N Adjustable TOT: 48/50 Porcine dermis sling: 46/50 Repeat surgery for mesh complications at $\leq$ 1 year - n/N Adjustable TOT: 1/50 Porcine dermis sling: 0/50 Reports no adverse events King's Health Questionnaire at 1 year - mean $\pm$ SD General Health perception Adjustable TOT: 33.9 (22.7) Porcine dermis sling: 30.6 (21.6) Incontinence impact Adjustable TOT: 33.3 (35.3) Porcine dermis sling: 25 (36.8)	Blinding of participants/personnel: Low risk (participants blinded to type of sling material used) Blinding of outcome assessment: Low risk (assessor blinded to group assignment) Incomplete outcome data: Low risk (no missing data for relevant outcomes) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Unit, Istanbul University	<p>Mixed UI Adjustable TOT: 78 Porcine dermis sling: 76</p> <p>Occult UI Adjustable TOT: 6 Porcine dermis sling: 2</p> <p>Inclusion criteria Women with clinically- or urodynamically-proven SUI who failed conservative treatment</p> <p>Exclusion criteria Women with intrinsic sphincter deficiency</p>			<p>Role limitations Adjustable TOT: 24.2 (30.6) Porcine dermis sling: 17.6 (28.7)</p> <p>Physical limitations Adjustable TOT: 22.6 (32.9) Porcine dermis sling: 15.8 (31.3)</p> <p>Social limitations Adjustable TOT: 12.8 (24.2) Porcine dermis sling: 12.7 (25.3)</p> <p>Personal relationships Adjustable TOT: 10.9 (25.9) Porcine dermis sling: 8.4 (24.7)</p> <p>Emotions Adjustable TOT: 22.5 (28.9) Porcine dermis sling: 15.5 (30.9)</p> <p>Sleep/energy Adjustable TOT: 21.4 (28.3) Porcine dermis sling: 14.4 (27.3)</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Severity Adjustable TOT: 39.4 (30.6) Porcine dermis sling: 29.1 (33.2) Total Adjustable TOT: 220.9 (199.1) Porcine dermis sling: 167.3 (222.4) Complications at 1 year - n/N Pain Adjustable TOT: 1/50 Porcine dermis sling: 2/50 Mesh extrusion Adjustable TOT: 1/50 Porcine dermis sling: 0/50 POP occurrence Adjustable TOT: 0/50 Porcine dermis sling: 0/50 Wound complications Adjustable TOT: 0/50 Porcine dermis sling: 1/50	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Ugurlucan, F. G., Erkan, H. A., Yasa, C., Yalcin, O., Does tension-free vaginal tape and tension-free vaginal tape-obturator affect urodynamics? Comparison of the two techniques, Clinical &amp; Experimental Obstetrics &amp; Gynecology, 40, 536-41, 2013 Ref Id 543120 Country/ies where the study was carried out Turkey Study type RCT Aim of the study To evaluate effects of TVT</p>	<p>Sample size N=36 randomised Intervention, n=17 Control, n=19</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD TVT: 50.6 (8) TVT-O: 51.1 (9.3) BMI - mean <math>\pm</math>SD TVT: 30.4 (4.3) TVT-O: 30.9 (4.9) Parity - mean <math>\pm</math>SD TVT: 3.06 (1.3) TVT-O: 3.58 (1.54) Menopausal (%) TVT: 52 TVT-O: 47 Pure SUI (%) TVT: 24 TVT-O: 26 Mixed UI (%) TVT: 76 TVT-O: 74 Concomitant POP surgery (%) TVT: 82 TVT-O: 79</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details Same surgeon performed all procedures using either spinal or general anaesthesia according to patient preference. Gynecare products used in both arms. Patients discharged when postvoid volume &lt;100ml. Mean FU=18.4 (6.8) months. Retropubic sling (TVT) Procedure as described by Ulmsten. Cystoscopy performed in all cases. Transobturator sling (TVT-O) Procedure as described by de Leval. Cystoscopy performed in cases of suspected cases.</p>	<p>Results Mean number of incontinence episodes per day <math>\pm</math>SD TVT: 0.8 (1.8) TVT-O: 0.5 (0.9) Improvement at ~18 months - n/N TVT: 17/17 TVT-O: 19/19 Adverse events - bladder injury - n/N TVT: 2/17 TVT-O: 0/19 Complications at &gt;1 year to &lt;5 years - n/N Pain TVT: 0/17 TVT-O: 1/19 De novo urge incontinence TVT: 0/17 TVT-O: 1/19</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>and TVT-O on urodynamics, and subjective and objective outcomes in women with stress or mixed UI</p> <p>Study dates Unclear, not reported</p> <p>Source of funding Not reported</p>	<p>Inclusion criteria Women with SUI or mixed UI</p> <p>Exclusion criteria</p>				
<p>Full citation Ustun, Y., Engin-Ustun, Y., Gungor, M., Tezcan, S., Tension-free vaginal tape compared with laparoscopic Burch urethropexy, Journal of the American Association of Gynecologic</p>	<p>Sample size N=46 randomised Intervention, n=23 Control, n=23</p> <p>Characteristics Age (years) - mean ±SD TVT: 45.57 (10.04) Colposuspension: 45.78 (11.44) Median parity TVT: 3 (range 1-7)</p>	<p>Interventions Intervention: Synthetic sling Control: Colposuspension</p>	<p>Details Synthetic sling (TVT) Standard procedure in line with Ulmsten et al. 1998; all patients had cystoscopy. Mean FU=11.3 months (range 3-24) Laparoscopic colposuspension with sutures Procedure as described by Tanagho 1976. Antibiotic prophylaxis given to all patients. Mean FU=13.48 months (range 3-24)</p>	<p>Results Objective cure at FU (subjectively dry, negative stress test and urodynamic evaluation) - n/N TVT: 19/23 Colposuspension: 19/23 Adverse events - bladder injury - n/N TVT: 2/23 Colposuspension: 1/23</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Laparoscopists, 10, 386-389, 2003</p> <p>Ref Id 674368</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type RCT</p> <p>Aim of the study To compare laparoscopic Burch colposuspension to TVT in women with genuine stress incontinence</p> <p>Study dates Unclear, not reported</p> <p>Source of funding Not reported</p>	<p>Colposuspension: 3 (range 0-5)</p> <p>Menopausal (%)</p> <p>TVT: 30</p> <p>Colposuspension: 35</p> <p>Inclusion criteria Women with proven genuine stress incontinence</p> <p>Exclusion criteria</p>				<p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (no missing data)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Ustun, Y., Engin-Ustun, Y., Gungor, M., Tezcan, S., Randomized comparison of Burch urethropexy procedures concomitant with gynecologic operations, Gynecologic and obstetric investigation, 59, 19-23, 2005 Ref Id 674369 Country/ies where the study was carried out Turkey Study type RCT</p>	<p>Sample size N=52 randomised Intervention, n=26 Control, n=26</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD Laparoscopic: 43.62 (9.09) Open: 47.27 (5.41) Median parity Laparoscopic: 3 (range 0–5) Open: 4 (range 0–6) Menopausal (%) Laparoscopic: 38 Open: 46 Concomitant POP surgery (%) Laparoscopic: 38 Open: 46</p> <p>Inclusion criteria Women with diagnosis of urinary stress incontinence based on</p>	<p>Interventions Intervention: Laparoscopic colposuspension Control: Open colposuspension</p>	<p>Details Laparoscopic colposuspension with sutures General anaesthesia used; Procedure as described by Tanagho 1976. Antibiotic prophylaxis given to all patients. Indwelling catheter removed and residual urine recorded within 24hrs of surgery. Discharged when &lt;75 ml residual and no difficulty voiding. Mean FU: 14.19 months. Open colposuspension with sutures Incision type/size based on planned surgery. Cooper ligaments visualised after retropubic space dissection. Two sutures placed in paravaginal fascia and tied to Cooper ligaments. Mean FU: 13.04</p>	<p>Results Objective cure at &gt;1 year to <math>\leq</math>5 years (subjectively dry, negative stress test and dry on urodynamic evaluation) - n/N Laparoscopic: 21/26 Open: 21/26 Adverse events - bladder injury - n/N Laparoscopic: 1/26 Open: 1/26 Complications - n/N De novo detrusor instability Laparoscopic: 2/26 Open: 3/26</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (consecutive sealed envelopes but no further details) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>n with concomitant gynaecologic procedures in treatment of women with genuine stress incontinence</p> <p>Study dates Unclear, not reported</p> <p>Source of funding None reported</p>	<p>history and urodynamic studies requiring additional gynaecological surgery</p> <p>Exclusion criteria Women with detrusor instability</p>				
<p>Full citation Wadie,B.S., Edwan,A., Nabeeh,A.M., Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study, Journal of Urology, 174, 990-993, 2005</p>	<p>Sample size N=53 randomised Intervention, n=28 Control, n=25</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD TVT: 44.9 (9) Fascial sling: 45.32 (6.3) BMI - mean <math>\pm</math>SD TVT: 29.7 (4.2)</p>	<p>Interventions Intervention: Synthetic sling Control: Autologous fascial sling</p>	<p>Details All patients received spinal anaesthesia. Follow up of at least 6 months. Synthetic sling (TVT) Procedure similar to that described by Ulmsten et al. 1998 Autologous rectus fascial sling Modified procedure based on that described by Blaivas &amp; Jacobs 1991.</p>	<p>Results Objective cure at 6-mo (complete dryness with no pad usage, anti-incontinence surgery response score=0, and negative stress test) - n/N TVT: 26/28 Fascial sling: 23/25 Adverse events - bladder injury - n/N TVT: 2/28 Fascial sling: 1/25</p>	<p>Limitations Random sequence generation: Unclear risk (reports closed envelopes but no further details about method) Allocation concealment: Unclear risk (reports closed envelopes kept in safe place but no further details) Blinding of participants/personnel: Unclear risk (blinding of</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Ref Id 100781</p> <p>Country/ies where the study was carried out Egypt</p> <p>Study type RCT</p> <p>Aim of the study To compare outcome of TVT to rectus fascia sling in women with SUI</p> <p>Study dates Unclear, not reported</p> <p>Source of funding Not reported</p>	<p>Fascial sling: 31.6 (4.2)</p> <p>Parity - mean <math>\pm</math>SD TVT: 4.1 (1.8) Fascial sling: 5.2 (2.6)</p> <p>Inclusion criteria Women &gt;21 years-old primary complaint of SUI willing to give informed consent Life expectancy&gt;1 year</p> <p>Normal upper tract and manual dexterity</p> <p>Exclusion criteria Women who had pelvic or vaginal surgery in last 6 months with predominant urge incontinence with cystocele&gt;grade 2</p>			<p>Complications at 6-mo - n/N</p> <p>Pain TVT: 2/28 Fascial sling: 7/25 Mesh erosion TVT: 0/28 Fascial sling: 0/25 Need for catheterisation: 3/28; 7/25 De novo detrusor overactivity TVT: 0/28 Fascial sling: 1/25</p>	<p>participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (no missing data)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	with associated urethral or bladder pathology with active UTI				
<p>Full citation Wadie, B. S., Elhefnawy, A. S., TVT versus TOT, 2-year prospective randomized study, World journal of urology, 31, 645-649, 2013 Ref Id 674383 Country/ies where the study was carried out Egypt Study type RCT</p> <p>Aim of the study To compare 2-year cure outcomes of TVT and TOT in women with SUI</p>	<p>Sample size N=87 randomised Intervention, n=45 Control, n=42</p> <p>Characteristics Data for TVT, n=36; TOT, n=35 Median age (years) TVT: 46.8 (SD 5) TOT: 45.8 (SD 7) Mean BMI TVT: 34 (SD 5) TOT: 32 (SD 5) Median parity TVT: 4 (SD 2) TOT: 32 (SD 5)</p> <p>Inclusion criteria Women &gt;18 years-old with stress-predominant UI and positive stress test</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details All patients had spinal anaesthesia and had cystoscopy. All patients included in study had follow up &gt;2 years. Retropubic sling (TVT) Gynecare TVT used. Transobturator sling (TOT) Aris (Coloplast) used.</p>	<p>Results Objective cure at ~1 years (Negative 1-hr pad test; increase of &gt;1g weight considered 'positive') - n/N TVT: 31/45 TOT: 28/42 Objective cure at ~2 years - n/N TVT: 29/45 TOT: 26/42 Adverse events - bladder injury TVT: 3/36 TOT: 1/35 Adverse events - severe bleeding requiring blood transfusion - n/N TVT: 1/36 TOT: 0/35 Complications at ~2 years - n/N Pain TVT: 0/36</p>	<p>Limitations Random sequence generation: Unclear risk (reported use of sealed envelopes but no further details) Allocation concealment: Unclear risk (reports sealed envelopes but no further details) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessor blinded to group assignment) Incomplete outcome data: Low risk (missing data balanced across groups for similar reasons) Selective reporting: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates 04/2006 to 10/2010</p> <p>Source of funding Not reported</p>	<p>willing to answer symptom scores and undergo urodynamic evaluation</p> <p>Exclusion criteria Women with suspected neuropathic bladder pelvic surgery &lt;6 months ago POP&gt;grade 2 (Baden- Walker)</p>			<p>TOT: 4/35 Need for catheterisation TVT: 3/36 TOT: 1/35 Mesh extrusion TVT: 0/36 TOT: 1/35 De novo urgency TVT: 0/36 TOT: 3/35</p>	<p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>
<p>Full citation Wadie,B.S., Mansour,A., El- Hefnawy,A.S., Nabeeh,A., Khair,A.A., Minimum 2-year follow-up of mid- urethral slings, effect on quality of life, incontinence impact and sexual function, International Urogynecology Journal, 21,</p>	<p>Sample size N=63 randomised Intervention, n=39 completers Control, n=24 completers</p> <p>Characteristics Mean Age (years) Fascial sling: 50.29 TVT: 46.08 Mean BMI Fascial sling: 33.49 TVT: 31.35 Mean Parity</p>	<p>Interventions Intervention: Fascial sling Control: Synthetic sling</p>	<p>Details All procedures performed by same surgeon. Only grade 2 or 3 rectocele or cystocele concomitant surgery allowed. Median FU=54 months (range 24-102). Autologous rectus fascial sling Harvested from anterior rectus sheath, 8-10cm long, suspended by zero polyglactin suture, with both ends teid in fron of anterior sheath after being closed. Synthetic sling (TVT) Gynecare TVT standard procedure used.</p>	<p>Results Objective cure at &gt;2 years (negative stress test) - n/N Fascial sling: 38/39 TVT: 22/24 Adverse events - severe bleeding requiring blood transfusion - n/N Fascial sling: 0/39 TVT: 1/24 Complications - n/N Mesh extrusion at &gt;2 years Fascial sling: 0/39 TVT: 1/24</p>	<p>Limitations Random sequence generation: Low risk (shuffled envelope method used) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>1485-1490, 2010 Ref Id 124691 Country/ies where the study was carried out Egypt Study type RCT  Aim of the study To compare impact on quality of life, bother and sexual life of pubovaginal sling and TVT in women with SUI  Study dates 03/2002 to 03/2006  Source of funding Not reported</p>	<p>Fascial sling: 4.81 TVT: 3.63 Cooncomitant POP surgery for whole sample (%): 43  Inclusion criteria Women with SUI willing to answer questionnaires minimum life expectancy of 2 years no associated disease that might affect responses to questionnaires  Exclusion criteria</p>				<p>Incomplete outcome data: High risk (uneven number of participants in each group likely from synthetic sling group) Selective reporting: Unclear risk (insufficient information) Other bias: Unclear risk (Appears to include some women who were in cohort reported in Wadie et al. 2005; uneven number of participants in each group)  Other information Unclear whether same participants/trial reported in Wadie et al. 2005.</p>
Full citation	Sample size	Interventions	Details	Results	Limitations

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Wai, C. Y., Curto, T. M., Zyczynski, H. M., Stoddard, A. M., Burgio, K. L., Brubaker, L., Rickey, L. M., Menefee, S. A., Patient satisfaction after midurethral sling surgery for stress urinary incontinence, Obstetrics and Gynecology, 121, 1009-1016, 2013 Ref Id 610731 Country/ies where the study was carried out USA Study type Multicentre RCT</p> <p>Aim of the study To report patient satisfaction outcomes at 12- months for</p>	<p>N=597 randomised Intervention, n=298 Control, n=299</p> <p>Characteristics See entry for Richter et al. 2010 for further details</p> <p>Inclusion criteria See entry for Richter et al. 2010 for further details</p> <p>Exclusion criteria See entry for Richter et al. 2010 for further details</p>	<p>Intervention: Retropubic sling Control: Transobturator sling</p>	<p>See entry for Richter et al. 2010 for further details</p>	<p>See entry for Richter et al. 2010 for further details</p>	<p>See entry for Richter et al. 2010 for further details</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>retropubic compared to transobturator slings in women with SUI</p> <p>Study dates 04/2006 to 06/2008</p> <p>Source of funding Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231, U01 DK60379, U01 DK60380, U01 DK60393, U01 DK60395, U01 DK60397, and U01 DK60401) from the National Institute of Diabetes and Digestive and Kidney Diseases and by</p>					

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
the National Institute of Child Health and Human Development. Partly funded by NIH grants to 4 authors.					
<p>Full citation Wang, A. C., Chen, M. C., Comparison of tension-free vaginal taping versus modified Burch colposuspension on urethral obstruction: A randomized controlled trial, Neurourology and Urodynamics, 22, 185-190, 2003 Ref Id 674386 Country/ies where the study was carried out</p>	<p>Sample size N=98 randomised Intervention, n=49 analysed Control, n=41 analysed</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD TVT: 51.65 (10.25) Colposuspension: 52.80 (8.89) Weight (kg) - mean <math>\pm</math>SD TVT: 45.73 (5.9) Colposuspension: 45.27 (6.63) Parity - mean <math>\pm</math>SD TVT: 2.51 (1.37)</p>	<p>Interventions Intervention: Synthetic sling/mesh Control: Colposuspension</p>	<p>Details Median 22-mo FU Synthetic sling/mesh (TVT) Performed in line with Ulmsten 1996 with participants under local anesthesia with sedation. Colposuspension Open Burch procedure performed in line with Stanton 1986 with participants under regional anaesthesia.</p>	<p>Results Objective cure at median 22-mo FU (<math>\leq</math>2g on 1-hour pad test) - n/N TVT: 40/49 Colposuspension: 31/49 Improvement at median 22-mo FU (50% decrease in loss from baseline or subjectively cured) - n/N TVT: 45/49 Colposuspension: 38/49 Reported no complications/adverse events in either arm.</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation) Allocation concealment: Unclear risk (reports allocated in sequential order but no further details) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (16% dropout rate in colposuspension group but not likely to affect effect estimate)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Taiwan Study type RCT  Aim of the study To compare effectiveness of TVT and modified Burch colposuspension in women with urodynamically-proven genuine stress incontinence  Study dates 07/1997 to 07/1999  Source of funding None reported	Colposuspension: 2.34 (1.35) Menopausal (%) TVT: 47 Colposuspension: 54  Inclusion criteria Women with urodynamically-proven stress incontinence  Exclusion criteria Women suffering from preoperative bladder outlet obstruction, defined as maximal flow rate of noninvasive uroflowmetry (freeQmax) of $\leq 12$ mL/sec in repeated free uroflow studies and detrusor pressure at maximal flow (PdetQmax) of $\geq 20$ cm H <sub>2</sub> O, or postvoid residual urine $\geq 100$ mL, or abdominal pressure increase of $\geq 10$ cm H <sub>2</sub> O compared				Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)  Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	with the baseline abdominal pressure in a pressure-flow study Women who had previous anti-incontinence surgery with pelvic organ prolapse				
Full citation Wang,A.C., Lin,Y.H., Tseng,L.H., Chih,S.Y., Lee,C.J., Prospective randomized comparison of transobturator suburethral sling (Monarc) vs suprapubic arc (Sparc) sling procedures for female urodynamic stress incontinence, International Urogynecology Journal, 17, 439-443, 2006	Sample size N=64 randomised Intervention, n=29 completers Control, n=31 completers  Characteristics Age (years) - mean ±SD SPARC: 51.4 (10.13) TOT: 50.49 (11.94) Parity - mean ±SD SPARC: 3.3 (3.1) TOT: 4 (2.1) Menopausal (%) SPARC: 69 TOT: 68  Inclusion criteria	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details One surgeon performed all procedures with spinal anaesthesia, with cystoscopy conducted in all cases. Patient discharged when post void residual volume <20% tha from self-voiding 4 consecutive times. Median FU=9 months (range 6-14). Retropubic sling (SPARC) SPARC (AMS) used, procedure as described by Plzak and Staskin 2002. Transobturator sling (TOT) Monarc TOT used, procedure as described by Dargent et al. 2002.	Results Adverse events - bladder injury - n/N SPARC: 1/29 TOT: 0/31 Complications - n/N Pain SPARC: 0/29 TOT: 4/31 Wound complications SPARC: 1/29 TOT: 0/31	Limitations Random sequence generation: Low risk (computer-generated randomisation code) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Low risk (participants blinded to group assignment) Blinding of outcome assessment: Low risk (assessor blinded to group assignment) Incomplete outcome data: Low risk (missing data not sufficient to have clinically-relevant impact on effect estimates)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Ref Id 100785</p> <p>Country/ies where the study was carried out Taiwan</p> <p>Study type RCT</p> <p>Aim of the study To compare complications and postoperative voiding function of SPARC and TOT procedures in women with SUI</p> <p>Study dates Unclear, 18-month recruitment period.</p> <p>Source of funding Not reported</p>	<p>Women with urodynamically-proven SUI</p> <p>Exclusion criteria Women with preoperative bladder outlet obstruction (any one the following: freeQmax of <math>\leq 12</math> ml/s in repeated free uroflow studies combined with PdetQmax of <math>\geq 20</math> cm H<sub>2</sub>O; postvoid residual urine <math>\geq 100</math> ml; Pabd increase <math>\geq 10</math> cm H<sub>2</sub>O compared to baseline abdominal pressure in pressure-flow study)</p> <p>who had previous anti-incontinence surgery POP&gt;stage 2 (ICS classification)</p>				<p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Full citation Wang,F., Song,Y., Huang,H., Prospective randomized trial of TVT and TOT as primary treatment for female stress urinary incontinence with or without pelvic organ prolapse in Southeast China, Archives of Gynecology and Obstetrics, 281, 279-286, 2010 Ref Id 100786 Country/ies where the study was carried out China Study type RCT Aim of the study</p>	<p>Sample size N=140 randomised Intervention, n=70 Control, n=70  Characteristics Age (years) - mean ±SD TVT: 60 (10.8) TOT: 58 (11.6) BMI - mean ±SD TVT: 24 (2.4) TOT: 24.6 (2.6) Previous SUI surgery - n/N TVT: 5/70 TOT: 3/70 Concomitant POP (%) TVT: 43 TOT: 31  Inclusion criteria Women with urodynamically- proven SUI  Exclusion criteria Women with</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details All procedures conducted by same surgeon with patients under local anaesthetic with iv sedation or spinal anaesthesia if concomitant vaginal hysterectomy or pelvic floor repair. Retropubic sling (TVT) Procedure as described by Ulmsten 1998. Two component needle and Ethicon prolene tape used. Transobturator sling (TOT) Procedure as described by Delorme 2001.</p>	<p>Results Negative cough stress test at 12-mo FU (with 300ml full bladder) - n/N TVT: 65/70 TOT: 64/70 Negative cough stress test at 12-mo FU - no concomitant POP - n/N TVT: 38/40 TOT: 45/48 Negative cough stress test at 12-mo FU - concomitant POP - n/N TVT: 27/30 TOT: 19/22 Objective cure at 12-mo FU (1-hr pad test &lt;2g) - n/N TVT: 66/70 TOT: 65/70 Objective cure at 12- mo FU - no concomitant POP - n/N TVT: 38/40 TOT: 46/48 Objective cure at 12- mo FU - concomitant POP TVT: 28/30</p>	<p>Limitations Random sequence generation: Unclear risk (insufficient information) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: High risk (not all outcomes that were stated in methods were reported in results) Other bias: Low risk (appears free from other sources of bias)  Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>To compare efficacy of TVT and TOT in women with SUI, with or without concomitant POP</p> <p>Study dates 10/2003 to 12/2007</p> <p>Source of funding None reported</p>	urge incontinence overactive bladder			<p>TOT: 19/22 Subjective cure at 12-mo FU (UDI-6 and IIQ-7 scores &lt;10) - n/N</p> <p>TVT: 63/70 TOT: 64/70</p> <p>Adverse events - bladder injury - n/N TVT: 3/70 TOT: 1/70</p> <p>Adverse events - bowel injury - n/N TVT: 0/70 TOT: 0/70</p> <p>Complications at 12-mo FU - n/N</p> <p>Pain TVT: 3/70 TOT: 8/70</p> <p>Mesh extrusion TVT: 1/70 TOT: 2/70</p> <p>Infection TVT: 0/70 TOT: 0/70</p>	
<p>Full citation Wang,W., Zhu,L., Lang,J.,</p>	<p>Sample size N=315 randomised Intervention, n=160</p>	<p>Interventions Intervention: Retropubic sling</p>	<p>Details All patients received prophylactic antibiotics with 1 preop dose of</p>	<p>Results</p>	<p>Limitations Random sequence generation: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Transobturator tape procedure versus tension-free vaginal tape for treatment of stress urinary incontinence, International Journal of Gynaecology and Obstetrics, 104, 113-116, 2009</p> <p>Ref Id 100787</p> <p>Country/ies where the study was carried out China</p> <p>Study type RCT</p> <p>Aim of the study To compare medium-term outcomes and complications of TVT and TVT-O in women with SUI</p>	<p>Control, n=155</p> <p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>TVT: 55.0 (11.9)</p> <p>TVT-O: 54.8 (12.5)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>TVT: 25.2 (3.0)</p> <p>TVT-O: 24.7 (3.3)</p> <p>Parity - mean <math>\pm</math>SD</p> <p>TVT: 2.2 (1.5)</p> <p>TVT-O: 1.9 (1.2)</p> <p>Postmenopausal (%)</p> <p>TVT: 57</p> <p>TVT-O: 60</p> <p>No POP (%)</p> <p>TVT: 21</p> <p>TVT-O: 21</p> <p>Concomitant anterior repair (%)</p> <p>TVT: 46</p> <p>TVT-O: 46</p> <p>Concomitant posterior repair (%)</p> <p>TVT: 12</p> <p>TVT-O: 15</p> <p>Inclusion criteria</p>	<p>Control: Transobturator sling</p>	<p>500mg iv levofloxacin, and all procedures performed under local anaesthesia with iv sedation or general/spinal anaesthesia if concomitant hysterectomy or pelvic floor repair. All procedures conducted by same surgeon. Gynecare (Ethicon) needles and woven polypropylene tape used in all procedures. Median FU: 20 months (range 6-48)</p> <p>Retropubic sling (TVT)</p> <p>Procedure as described in Ulmsten 1996. Cystoscopy performed in all patients after needle in place and before tape pulled upwards.</p> <p>Transobturator sling (TVT-O)</p> <p>Procedure as described in de Leval 2005</p>	<p>Cure at 12-mo FU (negative cough stress test) - n/N</p> <p>TVT: 103/160</p> <p>TVT-O: 106/155</p> <p>Cure at 2-year FU - n/N</p> <p>TVT: 68/160</p> <p>TVT-O: 75/155</p> <p>Cure at 3-year FU - n/N</p> <p>TVT: 29/160</p> <p>TVT-O: 25/155</p> <p>Improvement at 12-mo FU (number cured + decrease &gt;50% on both frequency of stress leakage and urine weight on 1-hr pad test) - n/N</p> <p>TVT: 113/160</p> <p>TVT-O: 115/155</p> <p>Improvement at 2-year FU - n/N</p> <p>TVT: 76/160</p> <p>TVT-O: 85/155</p> <p>Improvement at 3-year FU - n/N</p> <p>TVT: 34/160</p> <p>TVT-O: 29/155</p>	<p>(computer-generated randomisation)</p> <p>Allocation concealment: Unclear risk (insufficient information)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Low risk (assessors blinded to group assignment)</p> <p>Incomplete outcome data: Low risk (missing data similar across groups and for similar reasons)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Study dates 01/2004 to 12/2007</p> <p>Source of funding None reported</p>	<p>Women with demonstrable mild, moderate or severe SUI (defined as involuntary urine leakage without detrusor contraction on cough stress test with full bladder 300 ml saline) who have failed conservative treatment</p> <p>Exclusion criteria Women who were pregnant had urinary tract infection urge incontinence postvoid residual volume&gt;100 mL with past history of neurological disease, urogenital malignancy, fistula or pelvic radiotherapy</p>			<p>Adverse events - severe bleeding requiring transfusion - n/N TVT: 0/160 TVT-O: 0/154</p> <p>Adverse events - bladder injury - n/N TVT: 0/160 TVT-O: 0/154</p> <p>Complications - n/N Pain at 3-year FU TVT: 4/154 TVT-O: 12/146</p> <p>Mesh extrusion at 12- mo FU TVT: 3/154 TVT-O: 3/146</p> <p>De novo OAB at 3-year FU - de novo urge TVT: 9/154 TVT-O: 6/146</p> <p>Infection (wound) at 3- year FU TVT: 0/154 TVT-O: 0/146</p>	
<p>Full citation Wang,Y.J., Li,F.P.,</p>	<p>Sample size N=102 randomised</p>	Interventions	Details	<p>Results Cure at 1-year FU (negative cough stress</p>	<p>Limitations Random sequence generation: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Wang,Q., Yang,S., Cai,X.G., Chen,Y.H., Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up, International urogynecology journal and pelvic floor dysfunction, 22, 1369-1374, 2011</p> <p>Ref Id 188102</p> <p>Country/ies where the study was carried out China</p> <p>Study type Multicentre RCT</p> <p>Aim of the study</p>	<p>Intervention 1 (TVT-Secur), n=34</p> <p>Intervention 2 (TVT), n=32</p> <p>Intervention 3 (TVT-O), n=36</p> <p>Characteristics</p> <p>Age (years) - mean <math>\pm</math>SD</p> <p>Intervention 1: 57.3 (9.5)</p> <p>Intervention 2: 56.6 (9.6)</p> <p>Control: 56.0 (9.1)</p> <p>BMI - mean <math>\pm</math>SD</p> <p>Intervention 1: 26.6 (2.3)</p> <p>Intervention 2: 25.3 (2.0)</p> <p>Control: 27.3 (1.9)</p> <p>Parity - mean <math>\pm</math>SD</p> <p>Intervention 1: 2.7 (1.3)</p> <p>Intervention 2: 2.6 (1.0)</p> <p>Control: 2.3 (0.9)</p> <p>Number of women with pure SUI</p> <p>Intervention 1: 27</p>	<p>Intervention 1: Single-incision mini-sling</p> <p>Intervention 2: Other Synthetic (retropubic) sling (TVT)</p> <p>Intervention 3: Other Synthetic (transobturator) sling (TVT-O)</p>	<p>All procedures performed by surgeons with experience in both TVT and TVT-O procedures.</p> <p>Single-incision mini-sling (TVT-Secur)</p> <p>H position selected for women with abdominal leak point pressure <math>\geq</math>60cmH<sub>2</sub>O, otherwise U position was used. Procedure conducted in line with Tartaglia et al. 2009/Molden &amp; Lucente 2008. Cystoscopy conducted if needed during U-procedure.</p> <p>Other synthetic (retropubic) sling (TVT)</p> <p>Procedure conducted according to Ulmsten et al. 1996</p> <p>Other synthetic (transobturator) sling (TVT-O)</p> <p>Procedure conducted according to De Leval et al. 2003</p>	<p>test and self-reported absence of urine leakage) - n/N</p> <p>Intervention 1: 23/34</p> <p>Intervention 2: 30/32</p> <p>Control: 33/36</p> <p>Improvement at 1-year FU (number cured + number with self-reported reduction in urine leakage regardless of cough stress test result) - n/N</p> <p>Intervention 1: 30/34</p> <p>Intervention 2: 32/32</p> <p>Control: 36/36</p> <p>Adverse events - bladder injury - n/N</p> <p>Intervention 1: 1/34</p> <p>Intervention 2: 1/32</p> <p>Control: 0/36</p> <p>Complications - n/N</p> <p>Pain at &lt;6 months (includes pain in thigh, and mild dysuria)</p> <p>Intervention 1: 3/34</p> <p>Intervention 2: 3/32</p> <p>Control: 6/36</p> <p>Need for catheterisation at &lt;1 month</p>	<p>(computer-generated randomisation)</p> <p>Allocation concealment: Unclear risk (reports opaque, sealed envelopes but no further details provided)</p> <p>Blinding of participants/personnel: Unclear risk (blinding of participants not attempted)</p> <p>Blinding of outcome assessment: Unclear risk (insufficient information)</p> <p>Incomplete outcome data: Low risk (Dropout rate of 6%, not sufficient to make clinically relevant impact on effect estimates)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>To evaluate and compare 1-year outcomes of TVT-Secur, TVT, and TVT-O in women with pure SUI or stress-dominant mixed UI</p> <p>Study dates 10/2008 to 12/2009</p> <p>Source of funding Not reported</p>	<p>Intervention 2: 25 Control: 28 Number of women with mixed SUI Intervention 1: 7 Intervention 2: 7 Control: 8</p> <p>Inclusion criteria Women with stress-predominant urinary incontinence</p> <p>Exclusion criteria Women had previous SUI surgery with concomitant pelvic floor relaxation who had undergone previous surgical repair</p>			<p>Intervention 1: 1/34 Intervention 2: 4/32 Control: 1/36 De novo OAB - frequency, urge, or urge incontinence at 1-year Intervention 1: 12/34 Intervention 2: 5/32 Control: 6/36</p>	
<p>Full citation Ward, K., Hilton, P., Prospective multicentre randomised trial of tension-free vaginal tape and</p>	<p>Sample size N=344 randomised Intervention, n=175 Control, n=169</p> <p>Characteristics</p>	<p>Interventions Intervention: Synthetic sling/mesh Control: Colposus pension</p>	<p>Details All surgeons trained in TVT technique until satisfied with competence in it. Follow up: 6-months, 2 years (Ward &amp; Hilton, 2004), 5 years (Ward &amp; Hilton, 2008) Synthetic sling/mesh (TVT)</p>	<p>Results Note: 2-year FU data from Ward &amp; Hilton, 2004; 5-year FU data from Ward &amp; Hilton 2008.</p>	<p>Limitations Random sequence generation: Low risk (computer-generated randomisation)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>colposuspension as primary treatment for stress incontinence, British Medical Journal, 325, 67-70, 2002 Ref Id 619221 Country/ies where the study was carried out UK Study type Multicentre RCT Aim of the study To compare effectiveness of TVT and colposuspension in women with urodynamic stress incontinence Study dates 05/1998 to 08/1999</p>	<p>Age (years) - median TVT: 50 (range 42-56) Colposuspension: 50 (range 45-59) Parity - median TVT: 2 (range 2-3) Colposuspension: 2 (range 2-3) BMI - median TVT: 27 (range 24-30) Colposuspension: 27 (range 24-30) Menopause (%) TVT: 41 Colposuspension: 40 Previous hysterectomy (%) TVT: 30 Colposuspension: 32 Inclusion criteria Women with urodynamically-proven stress urinary incontinence failed pelvic floor muscle exercise training</p>		<p>Performed under local anaesthesia and sedation using TVT (Gynecare) as described by Ulmsten et al. 1996. Colposuspension Standard open Burch technique used by participating centre with all centres using either 2 or 3 sutures of polydioxanone (PDS) or braided polyester (Ethibond) to support paravaginal fascia from ileopectineal ligament on each side.</p>	<p>Objective cure at 6-mo FU (negative 1-hour pad test [<math>&lt;1g</math> change in weight]) - n/N TVT: 128/175 Colposuspension: 109/169 Objective cure at 2-year FU - n/N TVT: 111/175 Colposuspension: 86/169 Objective cure at 5-year FU TVT: 58/175; 44/169 Negative stress test at 6-mo FU - n/N TVT: 142/175 Colposuspension: 114/169 Subjective cure at 6-mo FU (self-reported continent according to response to Q7 on BFLUTS questionnaire) - n/N TVT: 103/175 Colposuspension: 90/169 Subjective cure at 2-year FU - n/N</p>	<p>Allocation concealment: Low risk (central allocation) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (missing data balanced across groups and for similar reasons at 6-mo, 2-year and 5-year follow up) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias) Other information 2-year follow up data reported in Ward &amp; Hilton 2004; 5-year follow-up data reported in Ward &amp; Hilton 2008</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding None	Exclusion criteria Women with detrusor overactivity vaginal prolapse requiring treatment previous surgery for prolapse or inconti- nence a major degree of voiding dysfunction (cystometry as a voiding pressure > 50 cm H <sub>2</sub> O, maximum flow < 15 ml/s, and residual urine volume > 100ml neurological disease allergy to local anaesthetic			TVT: 75/175; 63/169 Subjective cure at 5- year FU - n/N TVT: 62/175 Colposuspension: 55/169 Improvement at 6-mo FU - n/N TVT: 145/175 Colposuspension:119/1 69 Adverse events - bladder injury - n/N TVT: 15/170 Colposuspension: 3/146 Repeat surgery at 2 years - n/N TVT: 6/170 Colposuspension: 12/170 Repeat surgery at 5 years - n/N TVT: 7/170 Colposuspension: 16/146 Continence-specific health-related QoL - BFLUTS sex life spoilt by urinary symptoms at 6-mo FU (Number of	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				<p>women reporting symptom as a problem) - n/N</p> <p>TVT: 43/159</p> <p>Colposuspension: 33/127</p> <p>Continence-specific health-related QoL - BFLUTS sex life spoilt by urinary symptoms at 2-year FU - n/N</p> <p>TVT: 24/128</p> <p>Colposuspension: 21/102</p> <p>Continence-specific health-related QoL - BFLUTS sex life spoilt by urinary symptoms at 5-year FU - n/N</p> <p>TVT: 14/98</p> <p>Colposuspension: 7/79</p> <p>Complications - n/N</p> <p>Mesh extrusion at 6-mo FU</p> <p>TVT: 1/170</p> <p>Colposuspension: 0/146</p> <p>Mesh extrusion at 5-year FU</p> <p>TVT: 3/170</p> <p>Colposuspension: 0/146</p>	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Need for catheterisation at 2-year FU TVT: 0/170 Colposuspension: 4/170 Need for catheterisation at 5-year FU TVT: 1/170 Colposuspension: 0/170 Infection (recurrent UTI) at 6-week FU TVT: 38/170 Colposuspension: 46/146 Infection (recurrent UTI) at 2-year FU TVT: 10/170 Colposuspension: 3/146 Infection (wound) at 6-mo FU TVT: 4/170 Colposuspension: 10/146 De novo OAB - de novo urge at 5-year FU TVT: 2/98 Colposuspension: 4/79 De novo OAB - de novo urge incontinence at 5-year FU TVT: 1/98	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Colposuspension: 3/79	
<p>Full citation Ward,K.L., Hilton,P., A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up, American Journal of Obstetrics and Gynecology, 190, 324-331, 2004 Ref Id 143536 Country/ies where the study was carried out UK Study type Multicentre RCT</p>	<p>Sample size N=344 randomised Intervention, n=175 Control, n=169</p> <p>Characteristics See entry for Ward &amp; Hilton, 2002 for further details.</p> <p>Inclusion criteria See entry for Ward &amp; Hilton, 2002 for further details.</p> <p>Exclusion criteria See entry for Ward &amp; Hilton, 2002 for further details.</p>	<p>Interventions Intervention: Synthetic sling/mesh Control: Colposuspension</p>	<p>Details See entry for Ward &amp; Hilton, 2002 for further details.</p>	<p>Results See entry for Ward &amp; Hilton, 2002 for further details.</p>	<p>Limitations See entry for Ward &amp; Hilton, 2002 for further details.</p> <p>Other information Original study reported in Ward &amp; Hilton, 2002; 5-year FU data reported in Ward &amp; Hilton, 2008.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To compare 2-year follow up outcomes of TVT and colposuspension in women with urodynamic stress incontinence</p> <p>Study dates 05/1998 to 08/1999</p> <p>Source of funding None</p>					
<p>Full citation Ward,K.L., Hilton,P., Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-Year follow up,</p>	<p>Sample size N=344 randomised Intervention, n=175 Control, n=169</p> <p>Characteristics See entry for Ward &amp; Hilton, 2002 for further details.</p> <p>Inclusion criteria</p>	<p>Interventions Intervention: Synthetic sling/mesh Control: Colposuspension</p>	<p>Details See entry for Ward &amp; Hilton, 2002 for further details.</p>	<p>Results See entry for Ward &amp; Hilton, 2002 for further details.</p>	<p>Limitations See entry for Ward &amp; Hilton, 2002 for further details.</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>BJOG: An International Journal of Obstetrics and Gynaecology, 115, 226-233, 2008</p> <p>Ref Id 144192</p> <p>Country/ies where the study was carried out UK</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To compare 5-year follow up outcomes of TVT and colposuspension in women with urodynamic stress incontinence</p> <p>Study dates 05/1998 to 08/1999</p>	<p>See entry for Ward &amp; Hilton, 2002 for further details.</p> <p>Exclusion criteria See entry for Ward &amp; Hilton, 2002 for further details.</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding None					
<p>Full citation Xin, X., Song, Y., Xia, Z., A comparison between adjustable single-incision sling and tension-free vaginal tape-obturator in treating stress urinary incontinence, Archives of Gynecology &amp; Obstetrics, 293, 457-63, 2016 Ref Id 543154 Country/ies where the study was carried out China Study type RCT</p>	<p>Sample size N=368 randomised Intervention, n=184 Control, n=184</p> <p>Characteristics Age (years) - mean <math>\pm</math>SD Adjustable sling: 57.6 (6.8) TVT-O: 56.5 (5.7) BMI - mean <math>\pm</math>SD Adjustable sling: 26.5 (5.1) TVT-O: 27.4 (5.8) Number of women with SUI Adjustable sling: 162 TVT-O: 169 Number of women with mixed UI Adjustable sling: 22 TVT-O: 15</p>	<p>Interventions Intervention: Adjustable sling Control: Other synthetic sling</p>	<p>Details All surgeons each had experienced with more than 200 TVT-O and 20 Ajust procedures. In both arms, normal saline injected through anterior vaginal wall, which was then dissected longitudinally between inferior urethra and urethral lower ditch, and bilaterally dissected in urethral space till obturator. At end of proecdure after confirming no active bleeding, vagina filled with two pieces of Anerdian gauzes and removed 24 h later. Intraoperative epidural anaesthesia used. Follow up: 12 months post-op Adjustable sling Ajust SIMS used. Along tunnel on right side created by previous dissection, fixed anchor passed behind ischium pubic ramus, then pivoted through obturator internus muscle and membrane by rotating handle towards obturator internus muscle to align sling midline marker and middle urethra. Anchor then released by pushing release lever, inducer retracted, and</p>	<p>Results Objective cure at 12 months (no leakage on negative cough stress test) - n/N Adjustable sling: 175/184 TVT-O: 172/184 Subjective cure at 12 months (Response of 'very much improved' or 'much improved' on PGI-I) - n/N Adjustable sling: 170/184 TVT-O: 165/184 Continence-specific health-related QoL - Mean (SD) improvement in ICIQ-SF at 12 months Adjustable sling: 13.2 (5.43) TVT-O: 12.35 (4.87) Adverse events - bladder injury - n/N Adjustable sling: 0/184</p>	<p>Limitations Random sequence generation: Low risk (random number table used) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (missing data not sufficient to have relevant impact on effect size) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Aim of the study To compare cure rates, postoperative pain, complications and quality of life for Adjust sling versus TVT-O in women with SUI</p> <p>Study dates 01/2012 to 10/2013</p> <p>Source of funding Not reported</p>	<p>Number of women with previous hysterectomy Adjustable sling: 14 TVT-O: 18</p> <p>Inclusion criteria Women &gt;18 years-old with BMI&lt;35 kg/m<sup>2</sup> with corresponding clinical symptoms (leakage of urine at cough and sneeze) and urodynamically diagnosed with SUI received PFMT but failed to achieve efficacy or patients refused to receive PFMT (ineffective conservative therapy)</p> <p>Exclusion criteria Women POP-Q score≥2 history of urinary incontinence surgery (such as Burch surgery and mid-urethral sling surgery)</p>		<p>gentle sling traction applied to test for quality of anchoring. Adjustable anchor then introduced in contralateral side and sling adjusted. Flexible probe inserted into handle, sling lock pushed to adjustable anchor. Probe removed, excessive mesh cut off. Anterior vaginal incision continuously sutured using 2–0 absorbable strands.</p> <p>Other synthetic sling (TVT-O) Johnson &amp; Johnson TVT-O used. Left sling inserted under guidance of inducer, outlet located about 3 cm parallel to and 1 cm below urethra. Right sling inserted similarly and sling adjusted. Anterior vaginal wall continuously sutured using absorbable strands, then puncture incision also sutured.</p>	<p>TVT-O: 0/184 Adverse events - bowel injury - n/N Adjustable sling: 0/184 TVT-O: 0/184 Complications - n/N Need for catheterisation due to voiding dysfunction Adjustable sling: 4/184 TVT-O: 10/184 Mesh extrusion Adjustable sling: 0/184 TVT-O: 3/184</p>	Other information

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	or history of pelvic irradiation with mixed incontinence (SUI\urge urinary incontinence) who have received prolapse therapy with disseminated sclerosis and other neurologic diseases				
Full citation Zhang, Z., Zhu, L., Xu, T., Lang, J., Retropubic tension-free vaginal tape and inside-out transobturator tape: a long-term randomized trial, International Urogynecology Journal, 27, 103-11, 2016 Ref Id 541785	Sample size N=140 randomised Intervention, n=70 Control, n=70  Characteristics Age (years) - mean $\pm$ SD TVT: 55 (12) TVT-O: 51 (12) BMI - mean $\pm$ SD TVT: 25 (3) TVT-O: 25(4) Parity - times TVT: 2 (range 1-3) TVT-O: 1 (range 1-2) Menopausal (%)	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details Registered on Chinese clinical trial registry, ChiCTR-TRC-14004371. Procedures used Gynecare (Ethicon) needles and woven polypropylene tapes. Mean Follow up (n=120): 95 months Retropubic sling (TVT) Mean FU: 96 (11) months. Procedure as described by Ulmsten 1996. Transobturator sling (TVT-O) Mean FU: 94 (9) months. Procedure as described by De Leval 2003.	Results Objective cure at 8 years (negative cough stress test and negative 1-hr pad test (gain of <1g]) - n/N TVT: 58/70 TVT-O: 50/70 Objective improvement at 8 years (number objectively cured + number with decrease >50% on 1-hr pad test compared to preop) - n/N TVT: 67/70 TVT-O: 67/70 Subjective cure at 8 years (no SUI	Limitations Random sequence generation: Low risk (computer-generated randomisation table) Allocation concealment: Unclear risk (reports using sealed envelopes but no further information provided) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessor blinded to group assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out China</p> <p>Study type RCT</p> <p>Aim of the study To assess long-term complications, objective and subjective outcomes of TVT compared to TVT-O, and their effect on QoL and sexual function in women with SUI</p> <p>Study dates 08/2004 to 03/2008</p> <p>Source of funding None reported</p>	<p>TVT: 51 TVT-O: 49</p> <p>Inclusion criteria Women with SUI (symptoms, signs and urodynamic investigation according to ICS classification) aged between 26 and 81 years-old</p> <p>Exclusion criteria Women with SUI and intrinsic sphincter deficiency (Valsalva leak-point pressure of &lt;60 cm H<sub>2</sub>O) mixed urinary incontinence POP-Q Stage&gt;1 past history of hysterectomy and pelvic reconstruction surgery</p>			<p>retreatment and no reported stress leakage) - n/N</p> <p>TVT: 52/70 TVT-O: 44/70</p> <p>Subjective improvement (number subjectively cured + number of women who reported stress leakage and responded 'very much', 'much' or 'a little bit' better on PGII) - n/N</p> <p>TVT: 67/70 TVT-O: 63/70</p> <p>Adverse events - bladder injury - n/N</p> <p>TVT: 0/70 TVT-O: 0/70</p> <p>HR-related QoL PISQ-12 dyspareunia - mean (not clear whether range or IQR)</p> <p>TVT: 4 (4, 4), n=58 TVT-O: 4 (4, 4), n=62</p> <p>Complications - n/N</p> <p>Pain at 8 years</p> <p>TVT: 6/58 TVT-O: 5/62</p>	<p>Incomplete outcome data: Low risk (missing data similar across groups and for similar reasons)</p> <p>Selective reporting: Low risk (protocol available, all outcomes reported)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Dyspareunia at 8 years (preop + de novo) TVT: 5/58 TVT-O: 8/62 Mesh extrusion at 3 years TVT: 2/58 TVT-O: 5/62 Infection (wound) at ≤1 year TVT: 2/70 TVT-O: 0/69 Infection (recurrent UTI) at 8 years TVT: 5/58 TVT-O: 3/62 De novo OAB - de novo voiding symptoms TVT: 12/58 TVT-O: 6/62 De novo OAB - de novo storage symptoms TVT: 7/58 TVT-O: 6/62	
Full citation Zhu,L., Lang,J., Hai,N., Wong,F., Comparing vaginal tape and	Sample size N=55 randomised Intervention, n=28 Control, n=27	Interventions Intervention: Retropubic sling	Details One surgeon conducted all procedures using Gynecare products in all cases with patients under local anaesthetic plus iv	Results Subjective cure at ~2 years (no self-reported	Limitations Random sequence generation: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>transobturator tape for the treatment of mild and moderate stress incontinence, International Journal of Gynaecology and Obstetrics, 99, 14-17, 2007 Ref Id 100793 Country/ies where the study was carried out China Study type RCT</p> <p>Aim of the study To compare safety and efficacy of TVT and TVT-O in treatment of mild and moderate SUI</p> <p>Study dates</p>	<p>Characteristics Age (years) - mean <math>\pm</math>SD TVT: 56.2 (12.5) TVT-O: 53.3 (11.5) BMI - mean <math>\pm</math>SD TVT: 24.8 (3) TVT-O: 23.9 (2.6) Parity - mean <math>\pm</math>SD TVT: 2 (1.6) TVT-O: 1.7 (1.3) Concomitant POP surgery (%) (All patients had some form of POP) TVT: 100 TVT-O: 100</p> <p>Inclusion criteria Women with mild or moderate SUI (determined by 1-hr pad test; mild <math>\leq</math> 2g, moderate = 2-10g) who failed conservative treatment</p> <p>Exclusion criteria</p>	<p>Control: Transobturator sling</p>	<p>sedative unless patient also having hysterectomy (if so, then given general or spinal anaesthesia). Median FU=27.6 months (range 22-30) Retropubic sling (TVT) Procedure as described by Ulmsten et al. 1996. Cystoscopy performed in all patients. Transobturator sling (TVT-O) Procedure as described by de Leval 2003.</p>	<p>leakage on abdominal pressure) - n/N TVT: 26/28 TVT-O: 25/27 Improvement at ~2 years (number cured + number with 50% decrease in both frequency of leakage and 1-hr pad test weight) - n/N TVT: 28/28 TVT-O: 27/27 Adverse events- bladder injury - n/N TVT: 0/28 TVT-O: 0/27 Adverse events- bowel injury - n/N TVT: 0/28 TVT-O: 0/27 Complications - n/N Mesh extrusion at ~2 years TVT: 0/28 TVT-O: 0/27</p>	<p>(computer-generated randomisation) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Unclear risk (insufficient information) Incomplete outcome data: Low risk (no missing data) Selective reporting: Unclear risk (insufficient information) Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
01/2004 to 09/2005  Source of funding Not reported	Women who are pregnant with urinary tract infection with urge incontinence postvoid residual volume>100ml				
Full citation Zullo,M.A., Plotti,F., Calcagno,M., Marullo,E., Palaia,I., Bellati,F., Basile,S., Muzii,L., Angioli,R., Panici,P.B., One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a	Sample size N=72 randomised Intervention, n=35 Control, n=37  Characteristics Age (years) - mean ±SD TVT: 52.8 (11.8) TVT-O: 53.4 (10.7) BMI - mean ±SD TVT: 25.7 (2.9) TVT-O: 26.5 (2.7) Parity - mean ±SD TVT: 1.9 (1.1) TVT-O: 2.1 (0.7) Menopausal (%) TVT: 17 TVT-O: 22  Inclusion criteria	Interventions Intervention: Retropubic sling Control: Transobturator sling	Details Two experienced surgeons performed all procedures using lumbar epidural anaesthesia. Antibiotic prophylaxis administered 2hr before surgery. Median short-term FU=16 months (range 13-21); median long-term FU=60 months (range 13-69). Retropubic sling (TVT) Procedure as described by Ulmsten & Petros 1995. Cystoscopy performed in all cases. Transobturator sling (TVT-O) Procedure as described by De Leval 2003.	Results Note: 5-year followup data from Angioli et al. 2010. Objective cure at ~16 months (no leakage on stress test at urodynamic testing) - n/N TVT: 32/35 TVT-O: 33/37 Objective cure at ~60 months - n/N TVT: 25/35 TVT-O: 27/37 Improvement at ~60-months (satisfied or very satisfied) - n/N TVT: 21/35 TVT-O: 23/37 Adverse events - bladder injury - n/N	Limitations Random sequence generation: Low risk (computer-generated randomisation code) Allocation concealment: Unclear risk (insufficient information) Blinding of participants/personnel: Unclear risk (blinding of participants not attempted) Blinding of outcome assessment: Low risk (assessors blinded to group assignment) Incomplete outcome data: Low risk (no missing data on short-term follow up; missing data at long-term follow up not sufficient to have clinically-relevant

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>prospective randomised trial, European Urology, 51, 1376-1382, 2007</p> <p>Ref Id 100797</p> <p>Country/ies where the study was carried out Italy</p> <p>Study type RCT</p> <p>Aim of the study To assess complications and short-term efficacy of TVT compared to TVT-O in women with SUI</p> <p>Study dates 07/2004 to 05/2005</p> <p>Source of funding Not reported</p>	<p>Women with SUI with no contraindications to vaginal surgery providing signed informed consent</p> <p>Exclusion criteria Women with urogenital prolapse&gt;stage 1 detrusor overactivity overactive bladder symptoms intrinsic urethral sphincter deficiency urinary retention previous anti-incontinence surgery neurologic bladder psychiatric disease</p>			<p>TVT: 2/35 TVT-O: 0/37</p> <p>Adverse events - Bowel injury -n/N</p> <p>TVT: 0/35 TVT-O: 0/37</p> <p>Repeat surgery for mesh complications at ~60 months - n/N</p> <p>TVT: 1/35 TVT-O: 2/37</p> <p>Complications - n/N</p> <p>Pain at ~16 months TVT: 0/35 TVT-O: 1/37</p> <p>Pain at ~60 months TVT: 1/35 TVT-O: 2/37</p> <p>Mesh extrusion at ~16 months TVT: 0/35 TVT-O: 0/37</p> <p>Mesh extrusion at ~60 months TVT: 1/35 TVT-O: 2/37</p> <p>De novo urgency at ~60 months TVT: 1/35</p>	<p>impact on effect estimates)</p> <p>Selective reporting: Unclear risk (insufficient information)</p> <p>Other bias: Low risk (appears free from other sources of bias)</p> <p>Other information Five-year follow-up data reported in Angioli et al. 2010.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				TVT-O: 2/37 Infection at ~16 months TVT: 2/35 TVT-O: 1/37	
<p>Full citation Zyczynski, H. M., Rickey, L., Dyer, K. Y., Wilson, T., Stoddard, A. M., Gormley, E. A., Hsu, Y., Kusek, J. W., Brubaker, L., Urinary Incontinence Treatment, Network, Sexual activity and function in women more than 2 years after midurethral sling placement, American Journal of Obstetrics &amp; Gynecology, 207, 421.e1-6, 2012 Ref Id 541787</p>	<p>Sample size N=597 randomised Intervention, n=298 Control, n=299</p> <p>Characteristics See entry for Richter et al. 2010 for further details</p> <p>Inclusion criteria See entry for Richter et al. 2010 for further details</p> <p>Exclusion criteria See entry for Richter et al. 2010 for further details</p>	<p>Interventions Intervention: Retropubic sling Control: Transobturator sling</p>	<p>Details See entry for Richter et al. 2010 for further details</p>	<p>Results See entry for Richter et al. 2010 for further details</p>	<p>Limitations See entry for Richter et al. 2010 for further details</p> <p>Other information</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Country/ies where the study was carried out USA</p> <p>Study type Multicentre RCT</p> <p>Aim of the study To report 12- and 24-mo sexual function outcomes for retropubic compared to transobturator slings in women with SUI</p> <p>Study dates 04/2006 to 06/2008</p> <p>Source of funding Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231,</p>					

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
U01 DK60379, U01 DK60380, U01 DK60393, U01 DK60395, U01 DK60397, and U01 DK60401) from the National Institute of Diabetes and Digestive and Kidney Diseases and by the National Institute of Child Health and Human Development. Partly funded by NIH grants to 4 authors.					

**Evidence tables for observational studies included in long-term complications review**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<b>Full citation</b> Abougamrah, A., Ibrahim, M., Elsabaa, H., Ellaithy, M., Sweed, M., Treatment	<b>Sample size</b> N = 431	<b>Interventions</b> Monarc tape (American Medical Systems): N = 152 (35.3%)	<b>Details</b> All tape insertions performed in an outside-in	<b>Results</b> <u>Pain - number (%)</u> 42 (9.74)	<b>Limitations</b> <b>Confounding bias:</b> Low risk of bias

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>of stress urinary incontinence with a generic transobturator tape, International Journal of Gynaecology &amp; Obstetrics, 130, 226-9, 2015</p> <p><b>Ref Id</b></p> <p>542554</p> <p><b>Country/ies where the study was carried out</b></p> <p>Egypt</p> <p><b>Study type</b></p> <p>Prospective cohort</p> <p><b>Aim of the study</b></p> <p>To assess the short- and long-term efficacy and safety of a generic transobturator tape for the treatment of SUI.</p> <p><b>Study dates</b></p> <p>July 2004 to December 2013</p>	<p><b>Characteristics</b></p> <p><u>Age - mean <math>\pm</math> SD</u></p> <p>Monarc tape: 45 (9.6)</p> <p>Generic tape: 46.3 (12.1)</p> <p><u>BMI - (kg/m<sup>2</sup>) mean <math>\pm</math>SD</u></p> <p>Monarc tape: 27.9 (5.5)</p> <p>Generic tape: 28.5 (3.6)</p> <p><u>Menopausal - number (%)</u></p> <p>Monarc tape: 73 (48)</p> <p>Generic tape: 130 (46.6)</p> <p><u>Diabetes mellitus - number (%)</u></p> <p>Monarc tape: 23 (15.1)</p> <p>Generic tape: 29 (10.4)</p> <p><u>Hypertension - number (%)</u></p> <p>Monarc tape: 31 (20.4)</p> <p>Generic tape: 54 (19.4)</p> <p><u>Previous prolapse surgery - number (%)</u></p>	<p>Generic tape adapted from a monofilamentous, macroporous polypropylene mesh (Gynecare Gynemesh PS): N = 279 (64.7%)*</p>	<p>manner by the same team of surgeons.</p> <p>Monarc tape used initially, but then a generic tape was used.</p> <p>The edges of the generic tape were attached to suture by a surgical knot, and the other side of the thread was left to be attached to the eye of an adapted wide outside-in centred helical needle pair during the procedure. The same steps were repeated on the other side of the tape.</p> <p>Cystoscopy was performed where necessary. All patients received pre-operative chemoprophylaxis (1 g first-generation cephalosporin). All procedures were performed under general or regional anaesthesia.</p> <p><b>Statistical analyses</b></p> <p>The Shapiro-Wilk test was used to assess the normality of numerical outcomes. Where data were normally distributed,</p>	<p><u>Mesh extrusion/erosion - number (%)</u></p> <p>13 (3.0%)</p> <p><u>De novo OAB (urgency) - number (%)</u></p> <p>13 (3.0%)</p>	<p><b>Selection of participant's bias:</b> Serious risk of bias</p> <p><b>Classification of interventions bias:</b> Low risk of bias (not applicable as no comparator group)</p> <p><b>Deviations from intended interventions bias:</b> Low risk of bias</p> <p><b>Missing data bias:</b> Serious risk of bias</p> <p><b>Measurement of outcomes bias:</b> Serious risk of bias</p> <p><b>Selection of the reported results bias:</b> Low risk of bias</p> <p><b>Other information</b></p> <p><u>Follow-up</u></p> <p>Monarc tape: 87 months (range 79 to 105)</p> <p>Generic tape: 79 months (range 66 to 92)</p> <p>*Patients changed to generic tape to decrease the cost of surgery.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Source of funding</b></p> <p>None reported</p>	<p>Monarc tape: 20 (13.2)</p> <p>Generic tape: 53 (19.0)</p> <p><u>Previous SUI surgery - number (%)</u></p> <p>Monarc tape: 7 (4.6)</p> <p>Generic tape: 6 (2.2)</p> <p><u>Previous hysterectomy - number (%)</u></p> <p>Monarc tape: 16 (10.5)</p> <p>Generic tape: 26 (9.3)</p> <p><u>Urinary frequency - number (%)</u></p> <p>Monarc tape: 26 (17.1)</p> <p>Generic tape: 51 (18.3)</p> <p><u>Urinary urgency - number (%)</u></p> <p>Monarc tape: 23 (15.1)</p> <p>Generic tape: 26 (9.3)</p> <p><u>Associated genital prolapse - number (%)</u></p> <p>Monarc tape: 16 (10.5)</p> <p>Generic tape: 47 (16.8)</p>		<p>means and SDs were calculated, otherwise medians and IQRs were calculated.</p> <p>Categorical outcomes were presented as number (%) or as a ratio.</p> <p>The unpaired t test was used to compare normally distributed numerical outcomes. The Mann-Whitney U test was used to compare skewed data. The Pearson X<sup>2</sup> test (or Fisher exact test) was used to compare nominal data. Ordinal data were compared using linear-by-linear association. The Wilcoxon signed-rank test was used to compare paired numerical data.</p>		<p>**Outcomes are combined for both Monarc and Generic tape procedures as both procedures are transobturator.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><b>Inclusion criteria</b></p> <p>1] Women with SUI who were scheduled for treatment by TOT surgery using the outside-in technique).</p> <p><b>Exclusion criteria</b></p> <p>1] Pregnant women.</p> <p>2] Genital prolapse greater than stage 1 (according to the pelvic organ prolapse quantification system).</p> <p>3] Women with urge incontinence, intrinsic sphincter deficiency, neurogenic bladder, or urinary retention and/or receiving anticoagulant or antipsychotic therapy.</p>				
<p><b>Full citation</b></p> <p>Aigmuller,T., Trutnovsky,G., Tamussino,K., Kargl,J., Wittmann,A., Surtov,M., Kern,P., Frudinger,A.,</p>	<p><b>Sample size</b></p> <p>n=141</p>	<p><b>Interventions</b></p> <p>Retropubic TVT</p>	<p><b>Details</b></p> <p>Preoperative clinical and urodynamic assessment included relevant history, cystometry, midurethral</p>	<p><b>Results</b></p> <p><u>De novo OAB (Urgency) - n (%)</u></p> <p>17/83 (20%)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Riss,P., Bjelic-Radasic,V., Ten-year follow-up after the tension-free vaginal tape procedure, American journal of obstetrics and gynecology, 205, 496-5, 2011</p> <p><b>Ref Id</b></p> <p>188372</p> <p><b>Country/ies where the study was carried out</b></p> <p>Austria</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To evaluate objective and subjective results 10 years after TVT procedure</p> <p><b>Study dates</b></p> <p>1999 to 2001</p>	<p><b>Characteristics</b></p> <p><u>Age at surgery - mean (range)</u></p> <p>58.5 years (35 to 89)</p> <p><u>BMI</u></p> <p>28.2 (range 19.4 to 40.8)</p> <p><u>Previous surgery - n (%)</u></p> <p>Total: 36 (25.5)</p> <p>Hysterectomy only: 19 (13.5)</p> <p>Hysterectomy plus Burch colposuspension: 4 (2.8)</p> <p>Hysterectomy plus needle suspension: 2 (1.4)</p> <p>Hysterectomy plus needle suspension plus colporrhaphy: 6 (4.3)</p> <p>Needle suspension: 1 (0.7)</p> <p>Periurethral bulking agent injection: 1 (0.7)</p> <p>Radical hysterectomy plus radiation therapy: 2 (1.4)</p> <p>Staging procedure (ovarian cancer): 1 (0.7)</p>		<p>closure pressure, and cough stress test.</p> <p><b>Statistical analysis</b></p> <p>Not stated.</p>	<p><u>Urethral erosion</u></p> <p>n=1/117</p>	<p>Classification of interventions bias: Low risk of bias (no comparison group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (67% patients available for follow-up)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Mean 115.7 months (range 100 to 140)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Source of funding</b></p> <p>None stated</p>	<p><u>Concomitant surgeries - n (%)</u></p> <p>Total: 51 (36.2)</p> <p>Vaginal hysterectomy: 11 (7.8)</p> <p>Vaginal hysterectomy plus colporrhaphy: 34 (24.1)</p> <p>Colporrhaphy: 4 (2.8)</p> <p>Vaginal sacrospinous ligament fixation: 2 (1.4)</p> <p><b>Inclusion criteria</b></p> <p>Women who had clinically and urodynamically verified stress incontinence, included on the Austrian TVT registry.</p> <p><b>Exclusion criteria</b></p> <p>Not stated</p>				
<p><b>Full citation</b></p> <p>Ala-Nissila,S., Haarala,M., Makinen,J., Tension-free</p>	<p><b>Sample size</b></p>	<p><b>Interventions</b></p> <p>TVT</p>	<p><b>Details</b></p> <p>All operations were performed by experienced</p>	<p><b>Results</b></p> <p><u>POP occurrence - number (%)</u></p>	<p><b>Limitations</b></p> <p><b>Confounding bias:</b> Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>vaginal tape a suitable procedure for patients with recurrent stress urinary incontinence, Acta Obstetrica et Gynecologica Scandinavica, 89, 210-216, 2010</p> <p><b>Ref Id</b></p> <p>135794</p> <p><b>Country/ies where the study was carried out</b></p> <p>Finland</p> <p><b>Study type</b></p> <p>Prospective cohort</p> <p><b>Aim of the study</b></p> <p>To assess the efficacy and safety of TVT in patients with stress or mixed urinary incontinence, with and without previous anti-incontinence surgery.</p> <p><b>Study dates</b></p>	<p>N = 130 (n=60 women with recurrent UI; n=70 women with primary UI)</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>Recurrent UI: 61 (11)</p> <p>Primary UI: 55 (10)</p> <p><u>BMI - mean ±SD</u></p> <p>Recurrent UI: 27.7 (4.9)</p> <p>Primary UI: 26.6 (4.2)</p> <p><u>Previous gynaecological operation (other than for SUI) - number (%)</u></p> <p>Recurrent UI: 52 (87)</p> <p>Primary UI: 40 (57)</p> <p><u>No underlying disease - number (%)</u></p> <p>Recurrent UI: 27 (45)</p> <p>Primary UI: 37 (53)</p> <p><u>Rate of mixed urinary incontinence - number (%)</u></p> <p>Recurrent UI: 24 (40)</p>		<p>urogynaecologists and using local anaesthesia.</p> <p>TVT was performed in patients with recurrent UI with or without anterior and/or posterior repair, vaginal hysterectomy, sacrospinous fixation for vaginal vault prolapse.</p> <p>TVT was the only procedure performed in patients with primary UI.</p> <p>Suprapubic catheter was inserted only when needed.</p> <p><b>Statistical analyses</b></p> <p>Categorical outcomes were analysed using the chi-square test or Fischer's exact test.</p> <p>Continuous outcomes were assessed using the t-test. Logistic regression for repeated measurement data was used to assess urge symptoms and voiding difficulties.</p>	<p>Recurrent UI: 9 (15)</p> <p>Primary UI: 5 (7.14)</p>	<p><b>Selection of participant's bias:</b> Serious risk of bias</p> <p><b>Classification of interventions bias:</b> Low risk of bias</p> <p><b>Deviations from intended interventions bias:</b> Low risk of bias</p> <p><b>Missing data bias:</b> Serious risk of bias</p> <p><b>Measurement of outcomes bias:</b> Serious risk of bias</p> <p><b>Selection of the reported results bias:</b> Low risk of bias</p> <p><b>Other information</b></p> <p>Mean follow-up: 8 years (range 6 to 10 years)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>August 1998 to December 2002</p> <p><b>Source of funding</b></p> <p>None reported.</p>	<p>Primary UI: 29 (41)</p> <p><u>Urethral pressure - mean <math>\pm</math>SD (cm, H<sub>2</sub>O)</u></p> <p>Recurrent UI: 50 (16)</p> <p>Primary UI: 63 (20)</p> <p><b>Inclusion criteria</b></p> <p>1] Women attending for recurrent stress or mixed urinary incontinence.</p> <p>2] With or without previous anti-incontinence surgery.</p> <p><b>Exclusion criteria</b></p> <p>Not reported.</p>				
<p><b>Full citation</b></p> <p>Alcalay, M., Monga, A., Stanton, S. L., Burch colposuspension: A 10-20 year follow up, British Journal of Obstetrics and Gynaecology, 102, 740-745, 1995</p>	<p><b>Sample size</b></p> <p>n = 109</p> <p><b>Characteristics</b></p> <p><u>Age - mean (range)</u></p>	<p><b>Interventions</b></p> <p>Modified Burch colposuspension (Stanton, 1990)</p>	<p><b>Details</b></p> <p>Pre-operative assessment included a symptom-specific questionnaire, urogynaecological and neurological physical examination and urodynamic assessment (twin channel subtracted</p>	<p><b>Results</b></p> <p><u>De novo OAB (Urge Incontinence - n (% calculated))</u></p> <p>8 (7.3)</p> <p><u>De novo OAB (Urgency) - n (% calculated)</u></p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Ref Id</b></p> <p>768720</p> <p><b>Country/ies where the study was carried out</b></p> <p>UK</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To determine what factors affect long term success of women undergoing Burch colposuspension 10 to 20 years ago.</p> <p><b>Study dates</b></p> <p>1974 to 1983 (follow-up: 1994)</p> <p><b>Source of funding</b></p> <p>One author was supported by a grant from the Lewis Fellowship Fund.</p>	<p>46.6 years (29 to 70)</p> <p><u>Premenopausal - n (%)</u></p> <p>59 (54.1)</p> <p><u>Pre-operative weight - mean (range)</u></p> <p>68.3 kg (49 to 99)</p> <p><u>Symptoms at baseline - n (%)</u></p> <p>Stress incontinence: 109 (100)</p> <p>Urgency: 42 (38.5)</p> <p>Urge incontinence: 29 (26.6)</p> <p>Voiding difficulties: 6 (5.5)</p> <p>Aware of prolapse: 54 (49.5)</p> <p>Constipation: 15 (13.8)</p> <p>Frequency - mean (range):</p> <p>Day: 8.9 (3 to 18)</p> <p>Night: 1.4 (0 to 8)</p> <p><u>Signs at baseline - n (%)</u></p>		<p>cystometry or video-cystourethrography and uroflowmetry).</p> <p>All procedures were supervised by the senior author of the article.</p> <p><b>Statistical analysis</b></p> <p>Normally distributed numeric parameters compared using paired Student t tests. X<sup>2</sup> test used to compare proportions relating to women in different groups. Wilcoxon matched-pairs signed-rank test used for comparison within groups of non-parametric skewed variables. Correlation between non-parametric variables performed using Spearman's rank correlation coefficient.</p> <p>Women who required a further colposuspension between 1974 and 1983 were included in the sample only once.</p>	<p>9 (8.3)</p> <p><u>Recurrent urinary tract infections - n (% calculated)</u></p> <p>5 (4.6)</p> <p><u>POP occurrence - n (%)</u></p> <p>Second degree uterine descent: 2 (1.8)</p> <p>Marked rectocele: 19 (17.4)</p> <p>Marked enterocele: 2 (1.8)</p>	<p>of bias (no comparison group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (of 366 women invited to attend, 109 attended).</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Mean follow up: 13.8 years.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Stress incontinence: 17 (15.6) Marked cystourethrocele: 37 (33.9) 2nd degree uterine descent: 6 (5.5) Marked rectocele: 24 (22) Marked enterocele: 1 (0.9) <u>Previous continence operations in 33 patients - n (%)</u> Anterior repair: 40 (83.3) Anterior repairs (≥2): 7 (21.2) Manchester operation: 3 (6.3) Marshall Marchetti Krantz: 2 (4.2) Vesico-urethral fistula repair: 2 (4.2) Slings: 1 (2.1) <u>Previous bladder neck operations - n (%)</u> 33 (30.3)				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><u>Bladder neck operations per patient - mean (range)</u></p> <p>1.5 (1 to 4)</p> <p><b>Inclusion criteria</b></p> <p>1] Women who underwent colposuspension between 1974 and 1983.</p> <p>2] Complaint of stress incompetence, descent of the bladder neck and adequate vaginal capacity and mobility.</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>				
<p><b>Full citation</b></p> <p>Al-Zahrani, A. A., Gajewski, J., Long-term patient satisfaction after retropubic and transobturator mid-urethral slings for female stress urinary incontinence,</p>	<p><b>Sample size</b></p> <p>N = 330 (n=202 transobturator MUS; n=128 retropubic MUS)</p>	<p><b>Interventions</b></p> <p>MUS via transobturator or retropubic</p>	<p><b>Details</b></p> <p>For both techniques, knitted monofilament polypropylene tapes were used.</p> <p>Cystoscopic examination was routinely done during</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - number (%)</u></p> <p>Retropubic: 1 (0.8)</p> <p>Transobturator: 1 (0.5)</p>	<p><b>Limitations</b></p> <p><b>Confounding bias:</b> Low risk of bias</p> <p><b>Selection of participant's bias:</b> Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Journal of Obstetrics and Gynaecology Research, 42, 1180-1185, 2016</p> <p><b>Ref Id</b></p> <p>668839</p> <p><b>Country/ies where the study was carried out</b></p> <p>Canada</p> <p><b>Study type</b></p> <p>Retrospective cohort</p> <p><b>Aim of the study</b></p> <p>To assess the long-term patient outcomes in women with SUI after retropubic and transobturator midurethral slings.</p> <p><b>Study dates</b></p> <p>2000 to 2010</p> <p><b>Source of funding</b></p>	<p><b>Characteristics</b></p> <p><u>Age - mean <math>\pm</math> SD</u></p> <p>Retropubic: 54.8 (12.5)</p> <p>Transobturator: 54.7 (10.9)</p> <p><u>BMI - mean (kg/m<sup>2</sup>)</u></p> <p>Retropubic: 23.8</p> <p>Transobturator: 24.1</p> <p><u>Symptom duration - mean <math>\pm</math> SD (months)</u></p> <p>Retropubic: 44.9 (57.3)</p> <p>Transobturator: 49.3 (61.3)</p> <p><u>Hysterectomy - number (%)</u></p> <p>Retropubic: 62 (48.4)</p> <p>Transobturator: 77 (38.1)</p> <p><b>Inclusion criteria</b></p> <p>1] Patients undergoing MUS procedures for the treatment of female SUI.</p>		<p>the retropubic procedure. Urethral catheters were inserted routinely during surgery and removed after post-operative recovery from anaesthesia. Patients were discharged on the same day without catheters.</p> <p><b>Statistical analyses</b></p> <p>Percentages were calculated and compared using the chi-squared test or Fisher's exact test. For continuous outcomes, the t-test was used.</p>	<p><u>De novo OAB (urge incontinence) - number (%)</u></p> <p>Retropubic: 0</p> <p>Transobturator: 9 (4.5)</p> <p><u>De novo OAB (urgency) - number (%)</u></p> <p>Retropubic: 5 (3.9)</p> <p>Transobturator: 12 (5.9)</p>	<p><b>Classification of interventions bias:</b> Low risk of bias</p> <p><b>Deviations from intended interventions bias:</b> Low risk of bias</p> <p><b>Missing data bias:</b> Serious risk of bias</p> <p><b>Measurement of outcomes bias:</b> Serious risk of bias</p> <p><b>Selection of the reported results bias:</b> Low risk of bias</p> <p><b>Other information</b></p> <p><u>Follow-up</u></p> <p>MUS transobturator: 10.7 years</p> <p>MUS retropubic: 12.8 years</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
None.	<p>2] Patients with a minimum of 5 years' follow-up.</p> <p><b>Exclusion criteria</b></p> <p>1] Patients with associated pelvic prolapse or with a history of other continence surgeries.</p>				
<p><b>Full citation</b></p> <p>Antovska, V. S., Pleated colposuspension: Our modification of Burch colposuspension, Indian Journal of Urology, 29, 166-72, 2013</p> <p><b>Ref Id</b></p> <p>769350</p> <p><b>Country/ies where the study was carried out</b></p> <p>Macedonia</p> <p><b>Study type</b></p> <p>Prospective cohort</p>	<p><b>Sample size</b></p> <p>n= 145; modified pleated colposuspension (n = 97); standard Burch colposuspension (n = 48)</p> <p><b>Characteristics</b></p> <p>Age, BMI, parity not reported.</p> <p><b>Inclusion criteria</b></p> <p>Women with isolated SUI without coexisting genital prolapse (GP) requiring anti-SUI surgery.</p>	<p><b>Interventions</b></p> <p>Modified pleated colposuspension versus Standard Burch colposuspension</p> <p>Category: Laparoscopic (Lcol)?</p>	<p><b>Details</b></p> <p>All women completed a structured questionnaire based on the International Continence Society recommendation; Marshall's cough test in upright position, lithotomy position and during cervix reposition manoeuver after bladder filling with 300 ml; urodynamic studies including multichannel urethrocystometry, passive/dynamic urethral pressure profilometry, simple uroflowmetry, residual urine; POPf during rest position and Valsalva manoeuver after complete emptying of bladder and rectum.</p>	<p><b>Results</b></p> <p><u>Fistula - n (%)</u></p> <p>0</p> <p><u>Voiding dysfunction) - n (%)</u></p> <p>0</p> <p><u>Incomplete emptying (residual urine &gt;100 ml) - n (%)</u></p> <p>9 (6.2)</p> <p><u>Weak stream - n (%)</u></p> <p>10 (6.9)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Serious risk of bias</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias</p> <p>Measurement of outcomes bias: Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Aim of the study</b></p> <p>To describe and compare outcomes for the modified colposuspension and the standard Burch colposuspension procedures.</p> <p><b>Study dates</b></p> <p>January 2002 to December 2006</p> <p><b>Source of funding</b></p> <p>None</p>	<p><b>Exclusion criteria</b></p> <p>Presence of incomplete emptying (residual urine &gt; 100ml) and weak stream (maximum flow rates &lt;15ml/s with voided volume &gt;200ml)</p>		<p>All operations were performed by the author of the article.</p> <p><b>Statistical analysis</b></p> <p>Not stated.</p>		<p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Mean follow-up: 103 months</p>
<p><b>Full citation</b></p> <p>Athanasίου, S., Grigoriadis, T., Zacharakis, D., Skampardonis, N., Lourantou, D., Antsaklis, A., Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail?, International</p>	<p><b>Sample size</b></p> <p>n= 124</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>61 years (10)</p>	<p><b>Interventions</b></p> <p>TVT-O, TVT-O+PFR, TVT-O + VH + PFR, TVT-O + Lap SCP</p> <p>Category: Synthetic</p>	<p><b>Details</b></p> <p>Pre-operatively, women underwent medical history, clinical examination, urinalysis, and multichannel UDS. Women completed International Consultation no Incontinence Questionnaire for</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion</u></p> <p>0</p> <p><u>De novo OAB - Urge Incontinence - n/N (%)</u></p> <p>6/86 (7)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Urogynecology Journal, 25, 219-25, 2014	<u>BMI - mean <math>\pm</math>SD</u>		Evaluating Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) and the King's Health Questionnaire (KHQ). The degree of prolapse was graded using POP-Q.		Deviations from intended interventions bias: Low risk of bias
<b>Ref Id</b>	27.0 (3.7)				
542585	<u>Obese (BMI <math>\geq</math>30) - %</u>				Missing data bias: Low risk of bias (85.5%)
<b>Country/ies where the study was carried out</b>	19.4		All procedures were performed or supervised by a urogynaecologist and were carried out under epidural anaesthesia.		Measurement of outcomes bias: Serious risk of bias
Greece	<u>Parity - mean <math>\pm</math>SD</u>				Selection of the reported results bias: Low risk of bias
<b>Study type</b>	2 (1)				
Case series	<u>Previous abdominal hysterectomy - n (%)</u>		TVT-O placement was performed as described by de Leval, with minor modifications. Needles were inserted at the level of the midurethra, passed through the obturator membrane and directed 1 cm medially in relation to the genitofemoral fold. The TVT-O was placed after completion of prolapse surgery.		
	13 (10.5)				
<b>Aim of the study</b>	<u>Pre-operative International Continence Society score - mean <math>\pm</math>SD</u>				<b>Other information</b>
To assess long-term outcomes of tension-free vaginal tape-obturator (TVT-O) procedure for treating stress urinary incontinence (SUI), including possible risk factors for failure.	Aa: -0.06 (1.94)				Follow-up: 90.3 months (range 80 to 103)
	Ba: 1.06 (2.92)				
	Ap: -1.54 (1.42)				
	Bp: -1.26 (2.00)				
	C: -2.35 (4.64)		<b>Statistical analysis</b>		
	D: -5.15 (3.94)		Data presented as means $\pm$ SD, medians (quartiles), or percentages for normally and non-normally distributed continuous variables or categorical variables, respectively. Proportions		
<b>Study dates</b>	TVL: 8.66 (1.29)				
January 2004 to June 2006 (follow-up between	GH: 3.06 (0.75)				
	PB: 3.25 (0.68)				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>September 2012 and February 2013)</p> <p><b>Source of funding</b></p> <p>None stated</p>	<p><b>Inclusion criteria</b></p> <p>Women with SUI symptoms and had urodynamic stress incontinence on urodynamics.</p> <p><b>Exclusion criteria</b></p> <p>Women with a history of previous anti-incontinence procedures, radical pelvic surgery, and detrusor overactivity (DO) on UDS.</p>		<p>were compared using the z test, and comparisons of continuous variables between before and after surgery results done using the t test for paired data or Wilcoxon signed-rank test.</p>		
<p><b>Full citation</b></p> <p>Betschart,C., Scheiner,D., Hess,E., Seifert,B., Fink,D., Perucchini,D., Patient satisfaction after retropubic and transobturator slings: first assessment using the Incontinence Outcome Questionnaire (IOQ), International Urogynecology Journal, 22, 805-812, 2011</p>	<p><b>Sample size</b></p> <p>n=422; TVT (n=306); TOT (n=88); TVT-O (n=28)</p> <p><b>Characteristics</b></p> <p><u>Age at operation - mean ±SD</u></p> <p>TVT: 59.7 (12.2)</p> <p>TOT: 65.0 (12.9)</p>	<p><b>Interventions</b></p> <p>TOT</p> <p>TVT</p> <p>TVT-O</p> <p>Category: Transobturator and retropubic</p>	<p><b>Details</b></p> <p>Pre-operative women were evaluated through patient history, gynaecological examination with a positive cough test, and urine control (dipstick).</p> <p>10 surgeons performed the operations according to original methods, usually using local anaesthesia or</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - n</u></p> <p>TVT: 7</p> <p>TOT: 3</p> <p>TVT-O: 0</p> <p><u>Infection* - n</u></p> <p>TVT: 10</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Serious risk of bias</p> <p>Deviations from intended interventions bias: Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<b>Ref Id</b> 135505  <b>Country/ies where the study was carried out</b> Switzerland  <b>Study type</b> Retrospective cohort  <b>Aim of the study</b> To assess the quality of life and patient-reported outcome after midurethral slings.  <b>Study dates</b> January 1999 to December 2007  <b>Source of funding</b> No funding was received.	TVT-O: 62.2±13.8  <u>BMI - mean ±SD kg/m<sup>2</sup></u>  TVT: 26.8 (±4.9) TOT: 26.2 (4.4)  TVT-O: 27.7 (4.6)  <u>Parity - mean ±SD</u>  TVT: 2.5 (1.1) TOT: 2.6 (1.3)  TVT-O: 2.5 (1.0)  <u>Previous incontinence surgery - n</u>  <u>Abdominal colposuspension</u>  TVT: 11 TOT: 0  TVT-O: 3  <u>Vaginal colposuspension</u>  TVT: 5 TOT: 0  TVT-O: 3  <u>Sling insertion</u>		dependent on concomitant surgery.  <b>Statistical analyses</b>  Using Kruskal-Wallis, chi-square, or Fisher's exact test. Continuous data presented as mean ±SD.	TOT: 1  TVT-O: 1	Missing data bias: Serious risk of bias (69.1% completed questionnaires returned)  Measurement of outcomes bias: Serious risk of bias  Selection of the reported results bias: Low risk of bias  <b>Other information</b>  Follow-up: Mean 4.9 (2.3) years  TVT: 5.5 (2.4) years  TOT: 3.6 (1.1) years  TVT-O: 2.9 (1.0) years  *Complete tape excision due to bladder outlet obstruction, recurrent urinary tract infections, or de novo urge.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	TVT: 0 TOT: 1 TVT-O: 0 <u>Botulinum toxin intravesical</u> TVT: 1 TOT: 0 TVT-O: 0 <u>Sling and botulinum toxin</u> TVT: 0 TOT: 0 TVT-O: 1 <u>Concomitant prolapse surgery</u> <u>Hysterectomy</u> TVT: 19 TOT: 9 TVT-O: 2 <u>Colporrhaphia anterior</u> TVT: 28 TOT: 10				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	TVT-O: 4 <u>Colporrhaphia posterior</u> TVT: 23 TOT: 11 TVT-O: 2 <u>Sacrospinous ligament fixation</u> TVT: 4 TOT: 6 TVT-O: 0 <u>Botulinum toxin intravesical</u> TVT: 1 TOT: 3 TVT-O: 1  <b>Inclusion criteria</b> Women with a clinical SUI.  <b>Exclusion criteria</b>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Not stated.				
<p><b>Full citation</b></p> <p>Braga, A., Caccia, G., Sorice, P., Cantaluppi, S., Coluccia, A. C., Di Dedda, M. C., Regusci, L., Ghezzi, F., Uccella, S., Serati, M., Tension-free vaginal tape for treatment of pure urodynamic stress urinary incontinence: efficacy and adverse effects at 17-year follow-up, BJU International, 22, 22, 2018</p> <p><b>Ref Id</b></p> <p>866597</p> <p><b>Country/ies where the study was carried out</b></p> <p>Switzerland and Italy</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To assess the long-term efficacy and safety of retropubic tension-free</p>	<p><b>Sample size</b></p> <p>N = 52</p> <p><b>Characteristics</b></p> <p><u>Age - median (IQR)</u></p> <p>60 (51 to 72) years</p> <p><u>BMI - median (IQR) kg/m<sup>2</sup></u></p> <p>25.9 (25 to 28)</p> <p><u>Obese BMI ≥30 - number (%)</u></p> <p>6 (11.5)</p> <p><u>Menopausal - number (%)</u></p> <p>43 (82.3)</p> <p><u>Previous hysterectomy - number (%)</u></p> <p>12 (46.1)</p> <p><u>Urethral hypermobility - number (%)</u></p> <p>44 (84.6)</p>	<p><b>Interventions</b></p> <p>R-TVT procedure (Gynecare TVT System)</p>	<p><b>Details</b></p> <p>All procedures were performed according to the technique originally described by Ulmsten et al. General or spinal anaesthesia was used in accordance with the anaesthesiological requirements and/or the patient's preference.</p> <p><b>Statistical analyses</b></p> <p>Medians and interquartile range (IQR) were calculated for continuous outcomes. The chi-squared test and chi-squared test for trend were used to analyse and compare surgical outcomes during follow-up.</p> <p>The Cox proportional hazards model was used for univariate analysis to evaluate factors potentially affecting the risk of recurrence during the study period.</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - number (%)</u></p> <p>0</p> <p><u>De novo OAB (incontinence) - number with event/total (%)</u></p> <p>6/50 (12) at 5 years follow-up;</p> <p>9/47 (19.1) at 10 years follow-up;</p> <p>11/46 (23.9) at 15 years follow-up;</p> <p>15/46 (32.6) at 17 year follow-up; p=0.02</p> <p><u>POP occurrence - number (%)</u></p> <p>0</p>	<p><b>Limitations</b></p> <p><b>Confounding bias:</b> Low risk of bias</p> <p><b>Selection of participant's bias:</b> Low risk of bias</p> <p><b>Classification of interventions bias:</b> Low risk of bias (not applicable as no comparator group)</p> <p><b>Deviations from intended interventions bias:</b> Low risk of bias</p> <p><b>Missing data bias:</b> Serious risk of bias</p> <p><b>Measurement of outcomes bias:</b> Serious risk of bias</p> <p><b>Selection of the reported results bias:</b> Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: 17 years</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>vaginal tape (R-TVT) in women with pure stress urinary incontinence (SUI).</p> <p><b>Study dates</b> 1998 to 2000</p> <p><b>Source of funding</b> None</p>	<p><u>Valsalva leak-point pressure &lt;60 cm H<sub>2</sub>O - number (%)</u></p> <p>28 (53.8)</p> <p><b>Inclusion criteria</b></p> <p>1] Women complaining of pure SUI with urodynamically proven SUI.</p> <p>2] Eligible for surgical treatment and scheduled for an R-TVT procedure.</p> <p><b>Exclusion criteria</b></p> <p>1] Women with a history of radical pelvic surgery, psychiatric and neurological disorders.</p> <p>2] Concomitant vaginal prolapse greater than stage 1 according to the pelvic organ prolapse quantification system.</p> <p>3] OAB symptoms, urodynamically proven detrusor overactivity, and</p>		<p>Analysis of success data was undertaken to by plotting Kaplan-Meier survival curves and compared using the long-rank (Mantel-Cox) test.</p>		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	postvoid residual urine volume >100 mL.				
<p><b>Full citation</b></p> <p>Chevrot, A., Droupy, S., Coffin, G., Soustelle, L., Boukaram, M., Fattou, B., de Tayrac, R., Wagner, L., Costa, P., Long-term efficacy and safety of tension free vaginal tape in a historic cohort of 463 women with stress urinary incontinence, International urogynecology journal, 28, 827-833, 2017</p> <p><b>Ref Id</b></p> <p>650945</p> <p><b>Country/ies where the study was carried out</b></p> <p>France</p> <p><b>Study type</b></p> <p>Case series</p>	<p><b>Sample size</b></p> <p>n= 463</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>59.3 years (11.1)</p> <p><u>BMI (kg/m<sup>2</sup>) - mean ±SD</u></p> <p>25.6 (4.6)</p> <p><u>Postmenopausal - n/N (%)</u></p> <p>261/364 (71.7)</p> <p><u>Parity - n/N (%)</u></p> <p>Nulliparous = 13/439 (2.9)</p> <p>Multiparous = 351/439 (75.8)</p> <p><u>Previous surgery - n/N (%)</u></p> <p>Prolapse surgery: 36/462 (7.8)</p> <p>Incontinence surgery: 57/462 (12.3)</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>Pre-operative examinations: medical and obstetric history, physical examination including cough stress test (filling bladder with a volume of 200 to 300 ml using a urinary catheter), evaluation by operator opinion of urethral mobility, urethral support test, associated pelvic organ prolapse using POP-Q, and measurement of postvoid residual volume.</p> <p>Urodynamics were performed in all women. The procedure was performed by one of a group of nine experienced urologists or gynaecological surgeons using standard techniques (Ulmsten et al.) under general or spinal anaesthesia). After the procedure, a urinary catheter was placed and removed the following day.</p>	<p><b>Results</b></p> <p><u>Pelvic pain - n (%)</u></p> <p>62 (13.4)</p> <p><u>Mesh extrusion/erosion - n (%)</u></p> <p>4 (0.9)</p> <p><u>Infection - n (%)</u></p> <p>35 (7.6)</p> <p><u>De novo OAB - Urge Incontinence - n (%)</u></p> <p>59 (12.7)</p> <p><u>Need for catheterisation (voiding dysfunction) - n (%)</u></p> <p>10 (2.1)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (89.6%)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Mean 71 months</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Aim of the study</b></p> <p>To investigate the long-term safety and efficacy of the retropubic midurethral sling (MUS) in a large series of women with SUI.</p> <p><b>Study dates</b></p> <p>January 2005 to June 2012</p> <p><b>Source of funding</b></p> <p>None.</p>	<p>Hysterectomy: 66/462 (14.2)</p> <p><u>Urinary symptoms - n/N (%)</u></p> <p>SUI: 315/459 (68.6)</p> <p>MUI: 110/459 (23.9)</p> <p>Occult SUI: 34/459 (7.4)</p> <p><u>Physical examination - n/N (%)</u></p> <p>Positive cough stress test: 398/411 (98.8)</p> <p>Urethral hypermobility: 366/412 (88.8)</p> <p>Urethral low mobility or fixed urethra: 46/412 (11.2)</p> <p>Positive Ulmsten test: 390/407 (95.8)</p> <p><u>Urodynamic study</u></p> <p>Maximal urethral closure pressure (MUCP) (cm H<sub>2</sub>O) - mean ±SD: 35 (16)</p> <p>MUCP &lt;30 cm H<sub>2</sub>O - n/N (%): 71/434 (16.3)</p>		<p><b>Statistical analyses</b></p> <p>Data presented as mean ±SD, or number and percentage. The chi-squared test of Fisher's test was used for comparison between number (%).</p>		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><b>Inclusion criteria</b></p> <p>Women with SUI.</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>				
<p><b>Full citation</b></p> <p>Chun, J. Y., Song, M., Yoo, D. S., Han, J. Y., Hong, B., Choo, M. S., A Comparative Study of Outside-In and Inside-Out Transobturator Tape Procedures for Female Stress Urinary Incontinence: 7-Year Outcomes, Luts, 6, 145-50, 2014</p> <p><b>Ref Id</b></p> <p>542664</p> <p><b>Country/ies where the study was carried out</b></p> <p>South Korea</p>	<p><b>Sample size</b></p> <p>n=215 (TOT: n=129; TVT-O: n=86)</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>TOT: 53.6 (8.3)</p> <p>TVT-O: 54.4 (7.8)</p> <p><u>BMI - mean ±SD (kg/m<sup>2</sup>)</u></p> <p>TOT: 24.4 (2.6)</p> <p>TVT-O: 24.7 (2.9)</p> <p><u>Parity - (no.)</u></p> <p>TOT: 2.1 (1.1)</p>	<p><b>Interventions</b></p> <p>TOT, TVT-O</p> <p>Category: Transobturator</p>	<p><b>Details</b></p> <p>Pre-operatively women were assessed with medical history, physical examination, urodynamic study, uroflowmetry, filling/voiding cystometry, and urethral pressure profile.</p> <p>Procedures performed in standard manner by an experienced urologist, mainly taking place in day surgery under local anaesthesia. All patients received intraoperative prophylactic antibiotics, and cystoscopy was routinely performed.</p> <p><b>Statistical analyses</b></p>	<p><b>Results</b></p> <p><u>Pain - n (%)</u></p> <p>TOT: 0</p> <p>TVT-O: 1 (0.7)</p> <p><u>Infection - n (%)</u></p> <p>TOT: 6 (4.3)</p> <p>TVT-O: 3 (3.9)</p> <p><u>De novo OAB - Urge Incontinence - n (%)</u></p> <p>TOT: 11 (8.5)</p> <p>TVT-O: 3 (3.5)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (57.1% followed up)</p> <p>Measurement of outcomes bias: Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Study type</b></p> <p>Retrospective cohort</p> <p><b>Aim of the study</b></p> <p>To compare long-term surgical outcomes of the "inside out" (TVT-O) and "outside-in" (TOT) transobturator tape procedures for treating female stress urinary incontinence (SUI).</p> <p><b>Study dates</b></p> <p>January 2004 to December 2006</p> <p><b>Source of funding</b></p> <p>None reported.</p>	<p>TVT-O: 2.3 (1.3)</p> <p><u>Incontinence type - %</u></p> <p><u>SUI</u></p> <p>TOT: 66.7</p> <p>TVT-O: 47.7</p> <p><u>Mixed</u></p> <p>TOT: 33.3</p> <p>TVT-O: 52.3</p> <p><u>Urodynamic parameters</u></p> <p><u>Peak urinary flow - mL/sec</u></p> <p>TOT: 26.8 (10.2)</p> <p>TVT-O 26.0 (10.8)</p> <p><u>Voided volume - mL</u></p> <p>TOT: 233.8 (115.3)</p> <p>TVT-O: 224.0 (102.3)</p> <p><u>Post-voided residual - mL</u></p> <p>TOT: 28.2 (51.4)</p> <p>TVT-O: 25.1 (44.4)</p> <p><u>Maximum cystometric capacity - mL</u></p>		<p>Student's t tests, and chi-squared test used to compare outcomes between the two procedures. Univariate analysis performed by means of logistic regression analysis.</p>		<p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Median 85.2 months</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	TOT: 394.1 (72.4) TVT-O: 388.4 (88.4) <u>Valsala leak point pressure - cmH<sub>2</sub>O</u> TOT: 60.6 (31.0) TVT-O: 62.1 (27.0) <u>Maximum urethral closure pressure - cmH<sub>2</sub>O</u> TOT: 46.2 (16.7) TVT-O: 48.8 (17.8) <u>Detrusor overactivity - %</u> TOT: 33.6 TVT-O: 39.5 <u>Previous sling operation for SUI - %</u> TOT: 4.7 TVT-O: 1.2  <b>Inclusion criteria</b> Women with SUI treated with TOT or TVT-O procedures.				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<b>Exclusion criteria</b>				
<p><b>Full citation</b></p> <p>Doo,C.K., Hong,B., Chung,B.J., Kim,J.Y., Jung,H.C., Lee,K.S., Choo,M.S., Five-year outcomes of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence, European Urology, 50, 333-338, 2006</p> <p><b>Ref Id</b></p> <p>124253</p> <p><b>Country/ies where the study was carried out</b></p> <p>Korea</p> <p><b>Study type</b></p> <p>Case series</p>	<p><b>Sample size</b></p> <p>n= 134</p> <p><b>Characteristics</b></p> <p><u>Age - mean (range)</u></p> <p>52.3 years (35 to 78)</p> <p><u>BMI (kg/m<sup>2</sup>)- mean (range)</u></p> <p>24.2 (17 to 31)</p> <p><u>Parity - mean (range)</u></p> <p>3.2 (0 to 10)</p> <p><u>Grade 2 cystocele - n (%)</u></p> <p>6 (4.5)</p> <p><u>Associated urge incontinence - n (%)</u></p> <p>25 (18.7)</p> <p><u>Urgency - n (%)</u></p> <p>30 (22.4)</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>Pre-operative evaluation included medical history, physical examination, 3-day voiding diary, uroflowmetry, postvoid residual urine measurement, and complete multichannel urodynamic investigation.</p> <p>TVT procedure performed by experienced surgeons using light sedation and local anaesthesia, but general or spinal used if requested by patient or when concomitant pelvic or vaginal procedures performed.</p> <p><b>Statistical analyses</b></p> <p>Normally distributed variables compared with the Student <i>t</i> test.</p>	<p><b>Results</b></p> <p><u>Pain - n (%)</u></p> <p>3 (2.2)</p> <p><u>Need for catheterisation - n (%)</u></p> <p>9</p> <p><u>Infection - n (%)</u></p> <p>2 (1.5)</p> <p><u>De novo OAB - Urgency - n (%)</u></p> <p>16 (15.4)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (86%)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Aim of the study</b></p> <p>To evaluate the long-term efficacy and safety of a tension-free vaginal tape (TVT) procedure for the treatment of female stress urinary incontinence (SUI).</p> <p><b>Study dates</b></p> <p>March 1999 to June 2000</p> <p><b>Source of funding</b></p> <p>None stated.</p>	<p><u>Concomitant posterior repair - n (%)</u></p> <p>11 (8.2)</p> <p><u>Urodynamic parameters</u></p> <p>Peak urinary flow - ml/s (range): 25.8 (5 to 71)</p> <p>Voided volume - ml (range): 292.4 (55 to 578)</p> <p>Post-voided residual - ml (range): 13.6 (0 to 79)</p> <p>Maximum cystometric capacity - ml (range): 434.6 (220 to 652)</p> <p>Maximum detrusor pressure - cm H<sub>2</sub>O (range): 28.5 (10 to 76)</p> <p>Valsalva leak point - cm H<sub>2</sub>O (range): 79.5 (22 to 194)</p> <p>Maximal urethral closing pressure - cm H<sub>2</sub>O (range): 53.3 (9 to 113)</p> <p>Detrusor overactivity - n (%): 32 (23.9)</p> <p><u>Mean functional bladder capacity - ml (range):</u> 372.9 (200 to 600)</p>				<p>Follow-up: Mean 67 months (range 60 to 76)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><b>Inclusion criteria</b></p> <p>Women with complaints of SUI.</p> <p><b>Exclusion criteria</b></p> <p>Women who underwent concomitant surgery,</p>				
<p><b>Full citation</b></p> <p>Errando-Smet, C., Ruiz, C. G., Bertran, P. A., Mavrich, H. V., A re-adjustable sling for female recurrent stress incontinence and intrinsic sphincteric deficiency: Long-term results in 205 patients using the Remeex sling system, Neurourology &amp; UrodynamicsNeurourol Urodyn, 37, 1349-1355, 2018</p> <p><b>Ref Id</b></p> <p>866623</p> <p><b>Country/ies where the study was carried out</b></p>	<p><b>Sample size</b></p> <p>n=205</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>Total: 65.3 (10)</p> <p>rSUI: 63.2 (10)</p> <p>ISD: 66 (8)</p> <p><u>BMI - mean ±SD</u></p> <p>Total: 29 (5)</p> <p>rSUI: 29 (5)</p> <p>ISD: 30 (6)</p>	<p><b>Interventions</b></p> <p>Remeex re-adjustable sling</p> <p>Category: Re-adjustable Remeex sling</p>	<p><b>Details</b></p> <p>Pre-operative work-up included standard urogynaecological history and physical examination including Q-tip test. All patients underwent full urodynamic evaluation consisting of uroflowmetry, post-void residual measurement, cystometry, pressure/flow study, and urethral pressure profile.</p> <p>All procedures were performed by 3 surgeons under spinal anaesthesia in most cases. Device placed under the mid-urethra through a vaginal</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - n (%)</u></p> <p>4 (1.9)</p> <p><u>Need for catheterisation - n (%)</u></p> <p>3 (1.5)</p> <p><u>Infection - n (%)</u></p> <p>3 (1.5)</p> <p><u>De novo OAB - Urge Incontinence - n (%)</u></p> <p>49 (23.9)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (89.2% evaluable)</p> <p>Measurement of outcomes bias: Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Spain</p> <p><b>Study type</b></p> <p>Cohort study</p> <p><b>Aim of the study</b></p> <p>To evaluate the outcomes, complications, and quality of life of patients after a Remeex re-adjustable sling for recurrent stress urinary incontinence (SUI) and intrinsic sphincteric deficiency (ISD) indications.</p> <p><b>Study dates</b></p> <p>October 2000 to November 2006</p> <p><b>Source of funding</b></p> <p>None stated.</p>	<p><u>Abdominal hysterectomy - n (%)</u></p> <p>Total: 36 (17.5)</p> <p>rSUI: 16 (16.6)</p> <p>ISD: 20 (18.3)</p> <p><u>Vaginal hysterectomy - n (%)</u></p> <p>Total: 26 (12.6)</p> <p>rSUI: 12 (12.5)</p> <p>ISD: 14 (12.8)</p> <p><u>Previous SUI surgery - n (%)</u></p> <p>Total: 167 (81.4)</p> <p>rSUI: 96 (100)</p> <p>ISD: 71 (65.1)</p> <p><u>Retropubic (Burch/MMK) - n (%)</u></p> <p>Total: 73 (35.6)</p> <p>rSUI: 40 (41.6)</p> <p>ISD: 33 (30.3)</p> <p><u>Tension Free (TVT/TOT) - n (%)</u></p>		<p>incision. A second transverse incision made in the suprapubic region with needles then fixed to the Varitensor with a screw to rotating reel. The Foley catheter was removed the day after surgery after filling the bladder with 300 ml of saline.</p> <p><b>Statistical analyses</b></p> <p>Continuous variables assessed with mean (SD), median (range) and analysed with the Student <i>t</i>-test. Categorical variables assessed with number and proportion (%) of patients per category, and analysed with the chi-squared, Kruskal-Wallis or Fisher exact test.</p> <p>Intention-to-treat and per protocol analyses undertaken.</p>		<p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Mean 89 months (26 to 159)</p> <p>Patients classified as recurrent SUI (n=107) or ISD (n=123). Recurrent SUI women had a hypermobile urethra and at least one previous surgery (pubovaginal sling, TVT, TOT).</p> <p>Of 123 women with ISD 65% were also recurrent after an average of 3 previous surgeries.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Total: 69 (33.7) rSUI: 43 (44.8) ISD: 26 (23.9) <u>Pubovaginal sling - n (%)</u> Total: 25 (12.2) rSUI: 13 (13.5) ISD: 12 (11)  <b>Inclusion criteria</b> 1] Presence of SUI on examination or urodynamics.  <b>Exclusion criteria</b> 1] Presence of pelvic organ prolapse, history of neurogenic disorders, radical pelvic surgery, radiotherapy, bladder outlet obstruction or pure detrusor overactivity incontinence without SUI.				
<b>Full citation</b>	<b>Sample size</b>	<b>Interventions</b>	<b>Details</b>	<b>Results</b>	<b>Limitations</b>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Giberti, C., Gallo, F., Cortese, P., Visalli, F., Mid- to long-term results of the Remeex system for the treatment of female incontinence due to intrinsic sphincter deficiency: A retrospective analysis of the first 50 patients, <i>Neurourology and Urodynamics</i>, 36, 770-773, 2017</p> <p><b>Ref Id</b></p> <p>609729</p> <p><b>Country/ies where the study was carried out</b></p> <p>Italy</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To report mid to long term results following suburethral tension adjustable sling (Remeex system) implantation for</p>	<p>n= 50</p> <p><b>Characteristics</b></p> <p><u>Age - mean (range)</u></p> <p>67.8 (28 to 81)</p> <p><u>BMI (kg/m<sup>2</sup>) - mean (range)</u></p> <p>23.8 (23 to 29)</p> <p><u>Parity - mean (range)</u></p> <p>1.9 (0 to 4)</p> <p><u>Postmenopausal - n (%)</u></p> <p>49 (98)</p> <p><u>Associated grade 1 to 2 prolapse - n (%)</u></p> <p>8 (16)</p> <p><u>Previous anti-incontinence surgery - n</u></p> <p>Total: 19 (38%)</p> <p>Prolapse repair: 9</p> <p>Tension free suburethral sling positioning: 5</p> <p>Burch colposuspension: 2</p>	<p>Suburethral tension adjustable sling (Remeex system)</p> <p>Category: Adjustable Remeex re-adjustable sling</p>	<p>Women underwent physical examination and pad test.</p> <p>Sling tension readjustment performed under local anaesthesia in case of recurrent SUI with no urgency. Sling positioning combined with prolapse repair using vaginal approach, where required.</p> <p>All procedures performed by the same experienced surgeon in anti-incontinence procedure.</p> <p><b>Statistical analyses</b></p> <p>Chi -squared test used to compare the clinical outcomes between treatment groups. Mean values compared before and after surgery using the paired Student's <i>t</i>-test.</p>	<p><u>Infection - n (%)</u></p> <p>3 (6)</p> <p><u>Need for self-catheterisation - n (%)</u></p> <p>1 (2)</p> <p><u>De novo OAB - Urgency - n (%)</u></p> <p>5 (10)</p>	<p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Mean 83.8 months (range 30 to 160)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>SUI due to intrinsic sphincter deficiency (ISD).</p> <p><b>Study dates</b> May 2002 to March 2013</p> <p><b>Source of funding</b> None stated.</p>	<p>Bulking agents injection: 3</p> <p><u>Previous hysterectomy - n (%)</u> 11 (22)</p> <p><u>Detrusor overactivity - n (%)</u> 0</p> <p><u>Maximal urethral closure pressure - mean ±range (cmH<sub>2</sub>O)</u> 15.1 (2.3)</p> <p><u>Abdominal leak point pressure - mean ±range (cmH<sub>2</sub>O)</u> 43.5 (12.1)</p> <p><b>Inclusion criteria</b></p> <p>Women who had undergone suburethral tension adjustable sling positioning for SUI due to ISD, diagnosed with the following findings:</p> <p>1] History and physical examination with stress test (cough provocation)</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>showed severe SUI (more than four pads/day) for at least 1 year with no urgency or urethral hypermobility.</p> <p>2] Translabial ultrasonography confirmed the presence of a fixed urethra.</p> <p>3] Cystoscopy showed a wide open bladder neck at rest and a “lead pipe” urethra.</p> <p>4] Urodynamic measurements reported abdominal leak point pressure values &lt;60cm H<sub>2</sub>O and no instances of detrusor overactivity. Urethral pressure profilometry showed maximal urethral closure pressure values ≤20cm H<sub>2</sub>O.</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>				
<b>Full citation</b>	<b>Sample size</b>	<b>Interventions</b>	<b>Details</b>	<b>Results</b>	<b>Limitations</b>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Greenwell, T., Shah, P., Hamid, R., Shah, P. J., Ockrim, J., The Long-Term Outcome of the Turner-Warwick Vaginal Obturator Shelf Urethral Repositioning Colposuspension Procedure for Urodynamically Proven Stress Urinary Incontinence, Urologia Internationalis, 95, 352-6, 2015</p> <p><b>Ref Id</b></p> <p>542740</p> <p><b>Country/ies where the study was carried out</b></p> <p>UK</p> <p><b>Study type</b></p> <p>Retrospective cohort</p> <p><b>Aim of the study</b></p> <p>To analyse the long-term continence, voiding dysfunction and secondary prolapse rates following</p>	<p>n=96 (VOSURP n=50; Burch colposuspension n=46)</p> <p><b>Characteristics</b></p> <p><u>Age - mean (range)</u></p> <p>56.5 years (35 to 83)</p> <p><u>Previous surgery - n</u></p> <p><u>USUI - Burch</u></p> <p>VOSURP: 13</p> <p>Burch: 7</p> <p><u>USUI - TVT/O</u></p> <p>VOSURP: 6</p> <p>Burch: 1</p> <p><u>USUI - Stamey</u></p> <p>VOSURP: 2</p> <p>Burch: 2</p> <p><u>USUI - Macroplastique</u></p> <p>VOSURP: 0</p> <p>Burch: 2</p> <p><u>POP - TAH</u></p>	<p>Colposuspension (Vaginal Obturator Shelf Urethral Repositioning colposuspension)</p> <p>Burch colposuspension</p> <p>Category: Open (Ocol)?</p>	<p>VOSURP colposuspension procedure performed by placing 3 paired permanent sutures between the vaginal serosa and the tendinus arch of the obturator fascia with additional support provided by passing sutures through the pectineal ligament to avoid 'cut-out'. After surgery the bladder was temporarily drained by a suprapubic catheter or urethral catheter until woman mobile and able to resume voiding.</p>	<p><u>De novo OAB - Urge Incontinence - n (%)</u></p> <p>VOSURP: 4 (8)</p> <p>Burch: 4 (9)</p> <p><u>POP occurrence - n (%)</u></p> <p>VOSURP: 2 (4)</p> <p>Burch: 2 (4)</p> <p><u>Need for self-catheterisation - n (%)</u></p> <p>VOSURP: 2 (4)</p> <p>Burch: 2 (4)</p>	<p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Median 108.5 months (17 to 153)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>TurnerWarwick Vaginal Obturator Shelf Urethral Repositioning colposuspension (VOSURP) for urodynamically proven stress urinary incontinence (USUI).</p> <p><b>Study dates</b></p> <p>February 1997 to July 2008</p> <p><b>Source of funding</b></p> <p>None stated.</p>	<p>VOSURP: 13</p> <p>Burch: 11</p> <p><u>POP - sacrocolpopexy</u></p> <p>VOSURP: 0</p> <p>Burch: 1</p> <p><u>POP - anterior repair</u></p> <p>VOSURP: 1</p> <p>Burch: 5</p> <p><u>POP - posterior repair</u></p> <p>VOSURP: 2</p> <p>Burch: 3</p> <p><b>Inclusion criteria</b></p> <p>All women who had a VOSURP for videourodynamically confirmed USUI with significant urethral hypermobility (Blaivas type IIa and IIb).</p> <p><b>Exclusion criteria</b></p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Not stated.				
<b>Full citation</b>	<b>Sample size</b>	<b>Interventions</b>	<b>Details</b>	<b>Results</b>	<b>Limitations</b>
Han, J. Y., Park, J., Choo, M. S., Long-term durability, functional outcomes, and factors associated with surgical failure of tension-free vaginal tape procedure, International Urology & Nephrology, 46, 1921-7, 2014	n= 88	TVT	Preoperative evaluation included complete medical history, physical examination, completion of a 3-day voiding diary, uroflowmetry, post-void residual urine measurements, and a complete multichannel urodynamic study.	<u>Pain - n</u> 2	Confounding bias: Low risk of bias
<b>Ref Id</b>	<b>Characteristics</b>	Category: Retropubic TVT (retropubic)		<u>Need for catheterisation - n</u> 1	Selection of participant's bias: Serious risk of bias
542753	<u>Age - mean ±SD (range)</u> 54.2 ± 8.4 (38 to 78)		Procedures performed by one experienced surgeon under combined light sedation and local anaesthesia. Routine retropubic hydrodissection was performed using a mixture of local anaesthetic and normal saline. The tape was inserted via a 1-cm incision, 0.5 cm below the external urethral meatus, and was passed through the retropubic space to exit via two incisions above the symphysis pubis. Adjustment to tension-free was performed using curved scissors. Intraoperative	<u>De novo OAB - Urge Incontinence - n/N (%)</u> 10/58 (17.2)	Classification of interventions bias: Low risk of bias (no comparator group)
<b>Country/ies where the study was carried out</b>	<u>BMI - mean ± SD, kg/m<sup>2</sup> (range)</u> 25.1 ± 2.4 (19.6 to 32.0)			<u>De novo OAB - Urgency - n/N (%)</u> 15/37 (40.5)	Deviations from intended interventions bias: Low risk of bias
South Korea	<u>Parity - mean ± SD (range)</u> 3.4 ± 1.3 (1 to 7)				Missing data bias: Serious risk of bias (77.9% patients with complete data)
<b>Study type</b>	<u>SUI severity - n (%)</u>				Measurement of outcomes bias: Serious risk of bias
Case series	Slight: 9 (10.2)				Selection of the reported results bias: Low risk of bias
	Moderate: 49 (55.7)				
	Severe: 21 (23.9)				
<b>Aim of the study</b>	Very severe: 9 (10.2)				<b>Other information</b>
To evaluate the long-term durability and functional outcomes of TVT and	<u>Voiding diary parameters</u>				Follow-up: 144 months

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>identified the risk factors that may affect recurrence of SUI.</p> <p><b>Study dates</b></p> <p>March 1999 to December 2000</p> <p><b>Source of funding</b></p> <p>None stated</p>	<p>Micturition/24 hours - mean <math>\pm</math>SD (range): 9.6 <math>\pm</math> 3.2 (5 to 14)</p> <p>Nocturia - mean <math>\pm</math>SD (range): 1.0 <math>\pm</math> 0.8 (0 to 2.5)</p> <p>Associated urgency - n (%): 51 (57.9)</p> <p>Associated UUI - n (%): 30 (34.1)</p> <p><u>Urodynamic parameters</u></p> <p>Valsalva leak point pressure - cmH<sub>2</sub>O - mean <math>\pm</math>SD (range): 75.6 <math>\pm</math> 34.5 (22 to 263)</p> <p>Maximal urethral closing pressure - cmH<sub>2</sub>O - mean <math>\pm</math>SD (range): 44.8 <math>\pm</math> 15.8 (13 to 93)</p> <p>Detrusor overactivity - n (%): 17 (19.3)</p> <p><b>Inclusion criteria</b></p> <p>Women who underwent retropubic TVT sling for urodynamic SUI.</p>		<p>cystourethroscopy was performed routinely.</p> <p><b>Statistical analyses</b></p> <p>Univariate and multivariate logistic regression performed to assess associations between preoperative factors and occurrence of de novo OAB and cure of OAB. Normally distributed variables were compared using Student's <i>t</i>-test.</p>		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><b>Exclusion criteria</b></p> <p>Neurological disease or history of anti-incontinence surgery, or if they underwent concomitant surgery.</p>				
<p><b>Full citation</b></p> <p>Hawkins,E., Taylor,D., Hughes-Nurse,J., Long term follow up of the cruriate fascial sling for women with genuine stress incontinence, BJOG: An International Journal of Obstetrics and Gynaecology, 109, 327-338, 2002</p> <p><b>Ref Id</b></p> <p>143884</p> <p><b>Country/ies where the study was carried out</b></p> <p>UK</p> <p><b>Study type</b></p> <p>Case series</p>	<p><b>Sample size</b></p> <p>n = 103 at 6 years or more follow up</p> <p><b>Characteristics</b></p> <p><u>Age at the time of surgery - mean (range)</u></p> <p>51.3 years (36 to 75)</p> <p><u>BMI at time of follow-up (kg/m<sup>2</sup>) - mean (range)</u></p> <p>26 (18 to 49)</p> <p><u>Secondary surgery - mean (%)</u></p> <p>46* (26)</p> <p><u>Primary surgery - mean (%)</u></p> <p>132* (74)</p>	<p><b>Interventions</b></p> <p>Cruciate fascial sling</p> <p>Category: transobturator</p>	<p><b>Details</b></p> <p>Urodynamics were performed pre-operatively in all women.</p> <p>A betidine vaginal suppository and metronidazole was given on the evening before surgery and cefuroxime at induction and two doses at 8 and 16 hours post-operatively. On the fifth post-operative day the catheter was clamped.</p> <p><b>Statistical analyses</b></p> <p>Not stated for complications.</p>	<p><b>Results</b></p> <p>Pain = 22</p> <p>Need for catheterisation = 3</p> <p>Infection = 8</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparison group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (80% response rate to questionnaires).</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Aim of the study</b></p> <p>To determine the long term success of the cruriate fascial sling procedure for the treatment of genuine stress incontinence in women.</p> <p><b>Study dates</b></p> <p>1979 to 1996</p> <p><b>Source of funding</b></p> <p>None stated</p>	<p><u>Concomitant surgery - mean (%)</u></p> <p>Abdominal hysterectomy: 6 (3)</p> <p>Vaginal hysterectomy with or without repair: 21 (11)</p> <p>Posterior repair: 2 (1)</p> <p>Incisional hernia repair: 1 (0.5)</p> <p>*Data missing on 20 women.</p> <p><b>Inclusion criteria</b></p> <p>Women with genuine stress incontinence proven by pre-operative urodynamic studies.</p> <p><b>Exclusion criteria</b></p> <p>Not stated</p>				<p><b>Other information</b></p> <p>Median follow up 72 months (24-216)</p>
<p><b>Full citation</b></p> <p>Heinonen, P., Ala-Nissila, S., Raty, R., Laurikainen,</p>	<p><b>Sample size</b></p> <p>n= 138</p>	<p><b>Interventions</b></p> <p>TVT</p>	<p><b>Details</b></p> <p>All operations were performed by senior</p>	<p><b>Results</b></p> <p><u>Pain - n</u></p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>E., Kiilholma, P., Objective cure rates and patient satisfaction after the transobturator tape procedure during 6.5-year follow-up, Journal of Minimally Invasive Gynecology, 20, 73-8, 2013</p> <p><b>Ref Id</b></p> <p>542760</p> <p><b>Country/ies where the study was carried out</b></p> <p>Finland</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To evaluate the long-term outcome of the TVT procedure in women who did not undergo preoperative urodynamic examination.</p>	<p><b>Characteristics</b></p> <p>Age - median</p> <p>Evaluated cohort (n=128): 68</p> <p><u>BMI - median</u></p> <p>Evaluated cohort: 26</p> <p><u>Surgery after TVT operation - n</u></p> <p>Incontinence surgery: 6</p> <p>Bulking agent: 1</p> <p>Hysterectomy: 5</p> <p>Vaginal prolapse surgery: 5</p> <p><u>SUI - n (%)</u></p> <p>127 (66)</p> <p><u>MUI with SUI symptoms dominating - n (%)</u></p> <p>64 (34)</p>	<p>Category: Retropubic TVT</p>	<p>gynaecologists using local or spinal anaesthesia with perioperative cystoscopy. One dose of metronidazoles was given intravenously immediately before operation.</p> <p><b>Statistical analyses</b></p> <p>Not stated.</p>	<p>1</p> <p><u>Infection - n</u></p> <p>1</p> <p><u>De novo OAB - Urgency - n/N (%)</u></p> <p>6/37 women with MUI (6.6)</p>	<p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (72% patient evaluated at follow-up)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Mean 126.5 months (range 108 to 145)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Study dates</b></p> <p>January 1998 to May 2000</p> <p><b>Source of funding</b></p> <p>Corresponding author received a grant from Turku University</p>	<p><b>Inclusion criteria</b></p> <p>Women with a diagnosis of incontinence based on a history of leakage during stress.</p> <p><b>Exclusion criteria</b></p> <p>Not stated</p>				
<p><b>Full citation</b></p> <p>Holdo, B., Verelst, M., Svenningsen, R., Milsom, I., Skjeldestad, F. E., Long-term clinical outcomes with the retropubic tension-free vaginal tape (TVT) procedure compared to Burch colposuspension for correcting stress urinary incontinence (SUI), International Urogynecology Journal, 28, 1739-1746, 2017</p> <p><b>Ref Id</b></p> <p>702136</p>	<p><b>Sample size</b></p> <p>n= 307 (TVT n=180; Burch colposuspension n=127)</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>Burch group: 54.5 (11.5)</p> <p>TVT group: 55.2 (12.1)</p> <p><u>BMI (17.21 to 24.99 kg/m<sup>2</sup>) - n (%)</u></p> <p>Burch: 45 (35.4)</p> <p>TVT: 57 (31.7)</p> <p><u>BMI (25.0 to 29.99 kg/m<sup>2</sup>) - n (%)</u></p>	<p><b>Interventions</b></p> <p>Burch colposuspension, TVT</p> <p>Category: Ocol, retropubic TVT</p>	<p><b>Details</b></p> <p><b>Statistical analyses</b></p> <p>Data analysed using Chi-squared and <i>t</i> tests and survival analysis. For survival analysis of de novo OAB, women became 'cases' at the date of the first visit for bothersome symptoms, or were censored at the date of the last visit at which they were free of symptoms of OAB, or at the date of repeat incontinence/prolapse surgery, if surgery took place prior to the occurrence of bothersome symptoms.</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion -n</u></p> <p>5</p> <p><u>Need for catheterisation - n</u></p> <p>2</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Serious risk of bias</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (missing data censored)</p> <p>Measurement of outcomes bias: Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<b>Country/ies where the study was carried out</b>	Burch: 60 (47.2)				Selection of the reported results bias: Low risk of bias
Norway	TVT: 84 (46.7)				
<b>Study type</b>	<u>BMI (30.00 to 37.80 kg/m<sup>2</sup>) - n (%)</u>				<b>Other information</b> Follow-up: ≤144 months
Retrospective cohort	Burch: 15 (11.8) TVT: 32 (17.8)				
<b>Aim of the study</b>	<u>Parity - n (%)</u>				
To compare the short-term and long-term clinical outcomes of the Burch procedure with the retropubic TVT procedure.	Burch: 3.0 (1.2) TVT: 2.6 (1.2) <u>Premenopausal - n (%)</u>				
	Burch: 52 (40.9)				
<b>Study dates</b>	TVT: 64 (35.6)				
1994 to 2012	<u>Perimenopausal - n (%)</u>				
	Burch: 13 (10.2)				
<b>Source of funding</b>	TVT: 25 (13.9)				
Nordland Hospital, Bodø, Norway.	<u>Postmenopausal - n (%)</u>				
	Burch: 62 (48.8) TVT: 91 (50.6) <u>Hysterectomy - n (%)</u>				
	Burch: 12 (9.4)				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>TVT: 20 (11.1)</p> <p><u>Type of incontinence - n (%)</u></p> <p><u>Mixed</u></p> <p>Burch: 32 (25.2)</p> <p>TVT: 55 (30.6)</p> <p><u>Stress</u></p> <p>Burch: 95 (74.8)</p> <p>TVT: 125 (69.4)</p> <p><b>Inclusion criteria</b></p> <p>Women who underwent UI surgery during 1994 to 2012 at The Department of Gynecology at Norland Hospital, Norway.</p> <p><b>Exclusion criteria</b></p> <p>Women who had undergone earlier or concomitant prolapse surgery, earlier UI surgery, and surgical procedures for UI other than open</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Burch colposuspension or retropubic TVT surgery.				
<p><b>Full citation</b></p> <p>Holmgren,C., Nilsson,S., Lanner,L., Hellberg,D., Frequency of de novo urgency in 463 women who had undergone the tension-free vaginal tape (TVT) procedure for genuine stress urinary incontinence-A long-term follow-up, European Journal of Obstetrics Gynecology and Reproductive Biology, 132, 121-125, 2007</p> <p><b>Ref Id</b></p> <p>135243</p> <p><b>Country/ies where the study was carried out</b></p> <p>Sweden</p> <p><b>Study type</b></p> <p>Case series</p>	<p><b>Sample size</b></p> <p>n= 463</p> <p><b>Characteristics</b></p> <p><u>Age - mean (years)</u></p> <p>De novo urgency: 64.7</p> <p>Comparison group: 60.9</p> <p><u>Parity - mean</u></p> <p>De novo urgency: 2.6</p> <p>Comparison group: 2.3</p> <p><u>BMI - mean</u></p> <p>De novo urgency: 27.8</p> <p>Comparison group: 26.4</p> <p><u>Postmenopausal - n (%)</u></p> <p>De novo urgency: 45 (67.2)</p> <p>Comparison group: 240 (61.5)</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>Most TVT surgeons were performed by 3 surgeons using local anaesthesia. Small doses of sedatives were administered where required.</p> <p>Preoperatively, women underwent gynaecological history, physical examination, and stress test. Cystoscopy and cystometry were performed as appropriate.</p> <p><b>Statistical analyses</b></p> <p>Not stated.</p>	<p><b>Results</b></p> <p><u>Pain - n (%)</u></p> <p>66 (14.2)</p> <p><u>Infection - n (%)</u></p> <p>87 (18.8)</p> <p><u>De novo OAB - Urgency - N (%)</u></p> <p>67 (14.5)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (78.4% responded to questionnaire)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Aim of the study</b></p> <p>To determine risk factors for the appearance of de novo urgency symptoms, and subsequent accompanying problems, after TVT procedure in women with SUI.</p> <p><b>Study dates</b></p> <p>October 1995 to December 2001</p> <p><b>Source of funding</b></p> <p>None stated.</p>	<p><b>Inclusion criteria</b></p> <p>Women with SUI.</p> <p><b>Exclusion criteria</b></p> <p>Preoperative mixed incontinence and transient postoperative urgency symptoms were excluded.</p>				<p>Follow-up: Median 62.4 months</p>
<p><b>Full citation</b></p> <p>Kjohede,P., Long-term efficacy of Burch colposuspension: a 14-year follow-up study, Acta Obstetrica et Gynecologica</p>	<p><b>Sample size</b></p> <p>n= 192</p> <p><b>Characteristics</b></p> <p><u>Age at surgery</u></p>	<p><b>Interventions</b></p> <p>Burch colposuspension</p> <p>Category: Colposuspension</p>	<p><b>Details</b></p> <p><b>Statistical analyses</b></p> <p>Data presented as numbers and frequencies or median and range and analysed using non-parametrical statistics (Mann-Whitney <i>U</i>-test and Kruskal-Wallis test)</p>	<p><b>Results</b></p> <p>Infection: n= 19</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Scandinavica, 84, 767-772, 2005</p> <p><b>Ref Id</b></p> <p>124387</p> <p><b>Country/ies where the study was carried out</b></p> <p>Sweden</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To investigate the long-term efficacy of the Burch colposuspension and analyse the risk factors for an unsuccessful outcome at the long-term follow-up of more than 10 years.</p> <p><b>Study dates</b></p> <p>1980 to 1988</p>	<p>Urinary incontinent women: 49.0 (28.2 to 75.1)</p> <p>Urinary continent women: 48.0 (30.8 to 71.7)</p> <p><u>BMI at surgery (kg/m<sup>2</sup>)</u></p> <p>Urinary incontinent women: 25.8 (18.5 to 36.6)</p> <p>Urinary continent women: 24.5 (19.5 to 38.3)</p> <p><u>Parity</u></p> <p>Urinary incontinent women: 2.0 (0 to 8)</p> <p>Urinary continent women: 2.0 (0 to 7)</p> <p><b>Inclusion criteria</b></p> <p>Women with SUI operated upon with the Burch colposuspension.</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>				<p>of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (response rate 87%)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Median 168 months (120 to 216)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<b>Source of funding</b> Östergötland County Council					
<b>Full citation</b> Kuuva, N., Gustaf Nilsson, C., Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women, Acta obstetrica ET gynecologica scandinavica, 85, 482-487, 2006	<b>Sample size</b> n= 129  <b>Characteristics</b> <u>Age - median (range)</u> 55 years (35 to 81) <u>BMI (kg/m<sup>2</sup>) - median (range)</u> 25 (19 to 32) <u>Parity median (range)</u> Vaginal deliveries: 2 (0 to 9) CS: 0 (0 to 3) <u>Prior incontinence surgery - n (%)</u> One operation: 27 (20.9) Two operations: 3 (5.9) Three operations: 1 (0.8)	<b>Interventions</b> TVT Category: Retropubic TVT	<b>Details</b> Preoperative assessment included residual urine measurement by catheterisation, gynaecologic examination, multichannel urodynamic evaluation, a cough stress test, a 24 hour pad test, a micturition diary, and use of a visual analogue scale.  TVT procedures were performed by certified surgeons using local anaesthesia, cystoscopy after each retropubic passing of the needle, and cough-provocation test. One dose of metronidazole was used for infection prophylaxis. At the end of the operation, the bladder was emptied by single catheterisation in all women.  <b>Statistical analyses</b>	<b>Results</b> <u>Mesh extrusion/erosion - n (%)</u> 4 (3.1) <u>Infection - n (%)</u> 49 <u>De novo OAB - Urge Incontinence - n (%)</u> 6 (4.7)	<b>Limitations</b> Confounding bias: Low risk of bias Selection of participant's bias: Low risk of bias Classification of interventions bias: Low risk of bias (no comparator group) Deviations from intended interventions bias: Low risk of bias Missing data bias: Low risk of bias (80% women followed-up) Measurement of outcomes bias: Serious risk of bias Selection of the reported results bias: Low risk of bias  <b>Other information</b>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Aim of the study</b></p> <p>To examine the long-term effects and effectiveness of tension-free vaginal tape (TVT) procedure in women with stress incontinence.</p> <p><b>Study dates</b></p> <p>May 1995 to March 1999.</p> <p><b>Source of funding</b></p> <p>Finska Läkaresällskapet (Medical Society of Finland)</p>	<p><u>Duration of symptoms - median (range)</u></p> <p>10 years (1 to 50)</p> <p><u>Maximal urethral closure pressure at rest &lt;20 cm H<sub>2</sub>O - n (%)</u></p> <p>11 (8.5)</p> <p><u>Hormone-replacement treatment - n (%)</u></p> <p>Systemic: 66 (51.2)</p> <p>Local: 13 (10.1)</p> <p><b>Inclusion criteria</b></p> <p>Urodynamically proven stress incontinence with observed urinary leakage during the cough stress test, no need for additional concomitant surgery, no existing urogenital prolapse protruding beyond the vaginal introitus, and no urge-dominated mixed incontinence.</p>		<p>Data on continuous variables were compared using logistic regression analyses, and binary variables were compared using Fisher's exact test.</p>		<p>Follow-up: Median 72 months (57.6 to 104.4)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><b>Exclusion criteria</b></p> <p>TVT re-operation by the time of the long-term follow up visit.</p>				
<p><b>Full citation</b></p> <p>Ladwig, D., Miljkovic-Petkovic, L., Hewson, A. D., Simplified colposuspension: a 15-year follow-up, Australian &amp; New Zealand Journal of Obstetrics &amp; Gynaecology Aust N Z J Obstet Gynaecol, 44, 39-45, 2004</p> <p><b>Ref Id</b></p> <p>669628</p> <p><b>Country/ies where the study was carried out</b></p> <p>Australia</p> <p><b>Study type</b></p> <p>Case series</p>	<p><b>Sample size</b></p> <p>n= 374</p> <p><b>Characteristics</b></p> <p><u>Age - mean (range)</u></p> <p>49.7 years (27 to 88)</p> <p><u>Parity - mean (range)</u></p> <p>2.7 (0 to 8)</p> <p><u>Preoperative weight (kg) - mean (range)</u></p> <p>73.2 (48 to 148)</p> <p><u>Postmenopausal - n/N (%)</u></p> <p>135/354 (38.1)</p> <p><b>Inclusion criteria</b></p> <p>Patients who had a simplified Burch type</p>	<p><b>Interventions</b></p> <p>Burch type colposuspension</p> <p>Category: Ocol Burch colposuspension</p>	<p><b>Details</b></p> <p>All procedures were performed by one consultant or his supervised registrar.</p> <p>Preoperative assessment included history, examination and midstream urine specimen. Urodynamics were performed if there was doubt regarding diagnosis or complicated surgical history.</p> <p>The Cherney incision was used and a Foley catheter inserted. Antibiotics and cystoscopy were not standard. The drain and catheter were usually removed after 48 hours.</p> <p><b>Statistical analyses</b></p> <p>Not stated.</p>	<p><b>Results</b></p> <p><u>Infections - n/N (%)</u></p> <p>98/374 (26.2)</p> <p><u>De novo OAB - Frequency - n/N (%)</u></p> <p>35/94 (37.2)</p> <p><u>De novo OAB - Urgency - n/N (%)</u></p> <p>10/170 (6)</p> <p><u>De novo OAB - Nocturne - n/N (%)</u></p> <p>20/96 (20.8)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Aim of the study</b></p> <p>To investigate the long-term results of a simplified Burch type colposuspension, including the evaluation of patient satisfaction, cure rates, complications and postoperative morbidity.</p> <p><b>Study dates</b></p> <p>1985 to 1998</p> <p><b>Source of funding</b></p> <p>Not stated</p>	<p>colposuspension between 1985 and 1998</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>				<p><b>Other information</b></p> <p>Mean follow up = 9.2 years (range 2.1 to 15.8)</p>
<p><b>Full citation</b></p> <p>Lee,J.H., Cho,M.C., Oh,S.J., Kim,S.W., Paick,J.S., Long-term outcome of the tension-free vaginal tape procedure in female urinary incontinence: A 6-year follow-up, Korean Journal of Urology, 51, 409-415, 2010</p>	<p><b>Sample size</b></p> <p>n=141</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>55.8 (9.8)</p> <p><u>BMI (kg/m<sup>2</sup>) - mean ±SD</u></p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic</p>	<p><b>Details</b></p> <p>TVT procedures performed by 2 experienced surgeons with some modifications under local anaesthesia.</p> <p><b>Statistical analyses</b></p> <p>Data were analysed using the Fisher's exact test or chi-square test for categorical data and the</p>	<p><b>Results</b></p> <p><u>De novo OAB (urge incontinence) - n (%)</u></p> <p>29/107 (27.1)</p> <p><u>De novo OAB (urgency) - n (%)</u></p> <p>30/107 (28)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<b>Ref Id</b>	26.3 (1.8)		Student's t test for continuous data.		Deviations from intended interventions bias: Low risk of bias
135353	<u>Hysterectomy - n (%)</u>				
<b>Country/ies where the study was carried out</b>	26 (24.3)				Missing data bias: Serious risk of bias (51.3% followed)
South Korea	<u>Urgency - n (%)</u>				
<b>Study type</b>	11 (10.3)				Measurement of outcomes bias: Serious risk of bias
Case series	<u>Urgency incontinence - n (%)</u>				Selection of the reported results bias: Low risk of bias
	0				
<b>Aim of the study</b>	<u>SUI grade - n (%)</u>				<b>Other information</b>
To assess the long-term outcomes for the tension-free vaginal tape (TVT) procedure for the treatment of women with urinary incontinence.	1: 2 (1.9)				Mean follow-up: 85.5 months
	2: 43 (40.2)				
	3: 62 (57.9)				
	<u>Maximal urethral closure pressure (cmH<sub>2</sub>O) - mean ±SD</u>				
<b>Study dates</b>	60.1 (22.6)				
March 1999 to May 2003	<u>Valsalva leak point pressure (cmH<sub>2</sub>O) - mean ±SD</u>				
<b>Source of funding</b>	81.5 (28.9)				
None stated.	<u>Intrinsic sphincter deficiency - n (%)</u>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	21 (19.7) <u>Involuntary detrusor contraction - n (%)</u> 1 (0.9)  <b>Inclusion criteria</b> Women with SUI.  <b>Exclusion criteria</b> 1] Presence of UTI. 2] Urogynaecological malignancy. 3] Concomitant surgery (cystocele repair etc.) 4] Urogynaecological surgery during the postoperative follow-up period. 5] Postoperative follow-up of less than 6 years.				
<b>Full citation</b>	<b>Sample size</b> n=85	<b>Interventions</b>	<b>Details</b>	<b>Results</b> <u>Mesh erosion/extrusion - n</u>	<b>Limitations</b>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Lo, T. S., Chua, S., Kao, C. C., Uy-Patrimonio, M. C., Ibrahim, R., Tan, Y. L., Five-Year Outcome of MiniArc Single-Incision Sling Used in the Treatment of Primary Urodynamic Stress Incontinence, Journal of Minimally Invasive Gynecology, 25, 116-123, 2018</p> <p><b>Ref Id</b> 866653</p> <p><b>Country/ies where the study was carried out</b> China</p> <p><b>Study type</b> Retrospective case series</p> <p><b>Aim of the study</b> To assess the safety and efficacy of the MiniArc single-incision sling in the treatment of urodynamic stress incontinence (SUI).</p>	<p><b>Characteristics</b></p> <p>N=100 USI women</p> <p><u>Age - mean ±SD</u> 54.6 (10.9)</p> <p><u>BMI (kg/m<sup>2</sup>)</u> 25.0 (3.3)</p> <p><u>USI and intrinsic sphincter deficiency - n</u> 5</p> <p><u>Prior pelvic surgery - n</u> Vaginal hysterectomy plus Prolift total: 3 Vaginal hysterectomy plus Perigee: 5</p> <p><b>Inclusion criteria</b> Women with USI without needing concurrent procedures.</p>	<p>MiniArc single incision sling</p> <p>Category: SIMS</p>	<p>Women underwent preoperative medical history, physical examination, cough stress test, 72-hour voiding diary, urinalysis, and complete urodynamic testing including PVR.</p> <p>Surgery was performed under general anesthesia and carried out according to Moore et al using the MiniArc SIMS with the addition of a tension-releasing suture. Cystoscopy was performed on all patients. Urine was drained after evaluation with no indwelling catheter.</p> <p><b>Statistical analyses</b> Paired-samples t test and either the <math>\chi^2</math> or Fisher exact test were applied for comparison of pre- and postoperative continuous and categorical data, respectively.</p> <p><b>Power analysis</b> Assuming a failure rate of 25% at 5 years postoperatively with 80%</p>	<p>0 <u>De novo (OAB) - n</u> 4</p>	<p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Moderate risk of bias (85% evaluable)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b> Mean 74.1 months (60.8 to 85.1)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Study dates</b></p> <p>February 2010 to December 2011</p> <p><b>Source of funding</b></p> <p>None stated.</p>	<p><b>Exclusion criteria</b></p> <p>1] Women with pelvic organ prolapse quantification system &gt;1.</p> <p>2] Women with SUI in whom a urodynamic test did not show USI.</p> <p>3] Neurogenic bladder.</p> <p>4] Previous continence surgery.</p> <p>5] Psychiatric conditions.</p> <p>6] Previous radical pelvic surgery for malignancy.</p> <p>7] OAB symptoms such as urgency and urge urinary incontinence.</p> <p>8] Uroynamically proven detrusor overactivity.</p> <p>9] Postvoid bladder residual (PVR) &gt;100 mL.</p>		<p>statistical power and 95%confidence interval, a total of 56 subjects were required for the study.</p>		
<p><b>Full citation</b></p> <p>Montera, R., Miranda, A., Plotti, F., Terranova, C., Luvero, D., Capriglione, S., Scaletta, G., Zullo, M. A.,</p>	<p><b>Sample size</b></p> <p>N = 50</p> <p><b>Characteristics</b></p>	<p><b>Interventions</b></p> <p>TVT-O plus ultralateral anterior colphorrhaphy</p>	<p><b>Details</b></p> <p>Anterior colporrhaphy: midline anterior vaginal incision followed by paravaginal connective</p>	<p><b>Results</b></p> <p><u>Pain** - number with event/total (%)</u></p> <p>3/43 (6.98)</p>	<p><b>Limitations</b></p> <p><b>Confounding bias:</b> Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Buscarini, M., Lopez, S., Gatti, A., Schiro, T., De Cicco Nardone, C., Angioli, R., Anterior colporrhaphy plus inside-out tension-free vaginal tape for associated stress urinary incontinence and cystocele: 10-year follow up results, <i>Neurourology &amp; Urodynamics</i> Neurourol Urodyn, 37, 1144-1151, 2018</p> <p><b>Ref Id</b></p> <p>866659</p> <p><b>Country/ies where the study was carried out</b></p> <p>Italy</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To assess the long-term success rate and complications rate of combined ultralateral anterior colporrhaphy plus tension-free vaginal tape</p>	<p>Not reported</p> <p><b>Inclusion criteria</b></p> <p>1] Women with SUI associated with symptomatic cystocele greater than or equal to stage 1.</p> <p>2] No contraindications to vaginal surgery.*</p> <p><b>Exclusion criteria</b></p> <p>1] Uterine prolapse greater than or equal to stage 1.</p> <p>2] Rectocele greater than or equal to stage 1.</p> <p>3] OAB.*</p> <p>4] Intrinsic urethral sphincter deficiency.</p> <p>5] Previous anti incontinence and prolapse surgery.</p> <p>6] Neurologic bladder.</p> <p>7] Psychiatric disease.</p>		<p>tissue plication under tension in the midline with 3 cross-interrupted stitches.</p> <p>Urethral catheter left in place.</p> <p>Anterior vaginal wall incised 1 cm at a distance of 1 cm from the urethral meatus through a separate vaginal incision, then the synthetic tape passed from underneath the urethra, through the obturator foramens, toward the thigh folds.</p> <p>No concomitant procedures undertaken.</p> <p><b>Statistical analyses</b></p> <p>Changes from baseline were calculated using the Mann-Whitney and Fisher tests.</p>	<p><u>Mesh extrusion/erosion - number (%)</u></p> <p>2 (4)</p>	<p><b>Selection of participant's bias:</b> Low risk of bias</p> <p><b>Classification of interventions bias:</b> Low risk of bias (not applicable as no comparator group)</p> <p><b>Deviations from intended interventions bias:</b> Low risk of bias</p> <p><b>Missing data bias:</b> Low risk of bias</p> <p><b>Measurement of outcomes bias:</b> Serious risk of bias</p> <p><b>Selection of the reported results bias:</b> Low risk of bias</p> <p><b>Other information</b></p> <p>Median follow-up: 126 months (120 to 144)</p> <p>*Taken from previous study mentioned (Zullo MA, Ruggiero A, Plotti F, et al. Anterior colporrhaphy plus inside-out tension-free vaginal tape for associated stress urinary incontinence</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>(TVT-O) in patients with SUI and cystocele.</p> <p><b>Study dates</b> June 2004 to May 2006</p> <p><b>Source of funding</b> None</p>	<p>8] BMI greater than 30.</p> <p>9] Elevated intra abdominal pressure (chronic pulmonary disease and chronic constipation).</p>				<p>and cystocele. J Minim Invasive Gynecol. 2008;15:446-451).</p> <p>**Dyspareunia defined as pain during sexual intercourse, assessed with the following question "Did you experience pain during sexual intercourse?"</p> <p>Chronic pelvic pain defined as a non-menstrual pain lasting ≥6 months that was localised in the pelvis, lower abdominal wall, or lower back and was severe enough to require medical care.</p>
Full citation	Sample size	Interventions	Details	Results	Limitations
<p>Nilsson, C. G., Falconer, C., Rezapour, M., Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence, Obstetrics and Gynecology, 104, 1259-1262, 2004</p> <p><b>Ref Id</b></p>	<p>n= 80</p> <p><b>Characteristics</b></p> <p><u>Age at 7-year follow-up - median (range)</u> 60 (42 to 94)</p> <p><u>Parity - mean (range)</u></p>	<p>TVT</p> <p>Category: Retropubic TVT</p>	<p>Women underwent preoperative urodynamic studies, a stress test, a 24-hour pad-weighting test, a 2-day voiding diary, and residual urine measurements.</p> <p>All operations were performed under local infiltration anesthesia. The standard TVT set with a</p>	<p><u>Infection - n (%)</u> 6 (7.5)</p> <p><u>De novo OAB - Urge Incontinence - n (%)</u> 5 (6.3)</p> <p><u>POP occurrence - n/N (%)</u> 5/64 (7.8)</p>	<p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>640489</p> <p><b>Country/ies where the study was carried out</b></p> <p>Finland, Sweden.</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To investigate the long-term cure rates and late complication rates after treatment of female urinary stress incontinence with tension-free vaginal tape operation.</p> <p><b>Study dates</b></p> <p>January 1995 to October 1996.</p> <p><b>Source of funding</b></p> <p>Not stated.</p>	<p>2 (0 to 4)</p> <p><u>Menopausal at time of surgery - %</u></p> <p>58.8</p> <p><u>Urge symptoms at baseline - %</u></p> <p>27.7</p> <p><u>Duration of incontinence symptoms - mean (range)</u></p> <p>13 years (2 to 25)</p> <p><b>Inclusion criteria</b></p> <p>1] Primary cases of stress incontinence, with no prior incontinence surgery.</p> <p>2] Women with grade I cystocele not requiring surgical intervention.</p> <p><b>Exclusion criteria</b></p> <p>Women with detrusor instability on preoperative urodynamic studies and with intrinsic sphincter deficiency were excluded.</p>		<p>polypropylene tape was used (Gynecare TVT). Cystoscopy was performed twice during the operation, after each retropubic pass of the TVT needle to detect bladder injuries.</p> <p><b>Statistical analyses</b></p> <p>Not stated</p>		<p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (88% subjective evaluation; 71% clinical evaluation)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Mean 91 (78 to 100) months</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Full citation</b></p> <p>Nilsson,C.G., Palva,K., Rezapour,M., Falconer,C., Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence, International Urogynecology Journal, 19, 1043-1047, 2008</p> <p><b>Ref Id</b></p> <p>100711</p> <p><b>Country/ies where the study was carried out</b></p> <p>Finland &amp; Sweden</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To evaluate the long-term effectiveness and safety of the TVT procedure.</p>	<p><b>Sample size</b></p> <p>n= 69</p> <p><b>Characteristics</b></p> <p>Median age range of evaluated cohort (n=69) = 61-70</p> <p><b>Inclusion criteria</b></p> <p>History of stress incontinence, a positive cough stress test performed in a semilithotomy position with a comfortable filled bladder (200-300ml) and a urodynamically proven stress incontinence.</p> <p><b>Exclusion criteria</b></p> <p>1] Women with prior incontinence surgery or a need for concomitant surgery.</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>All operations were performed in local infiltration anesthesia using 0.25 % prilocaine with adrenaline (epinephrine).</p> <p>Cystoscopy was performed twice during the operation and after each retropubic pass of the TVT needle to detect bladder injury.</p> <p><b>Statistical analyses</b></p> <p>Continuous variables were assessed using paired-samples t test and the chi-square test was used for categorical variables.</p>	<p><b>Results</b></p> <p>Mesh extrusion/erosion, n= 0</p> <p>Need for catheterisation, n =0</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (77% evaluable)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Median 141 (127 to 160) months</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Study dates</b></p> <p>January 1995 to August 1996</p> <p><b>Source of funding</b></p> <p>None reported</p>	<p>2] Women showing detrusor activity during the urodynamic examination and women with a maximal urethral closure pressure less than 20 cm H<sub>2</sub>O.</p>				
<p><b>Full citation</b></p> <p>Nilsson, C. G., Palva, K., Aarnio, R., Morcos, E., Falconer, C., Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence, International Urogynecology Journal, 24, 1265-9, 2013</p> <p><b>Ref Id</b></p> <p>542951</p> <p><b>Country/ies where the study was carried out</b></p> <p>Sweden, Finland</p>	<p><b>Sample size</b></p> <p>n= 58</p> <p><b>Characteristics</b></p> <p>Mean age at time of 17 year follow-up (range) = 69±9 years (51-89)</p> <p><b>Inclusion criteria</b></p> <p>Women diagnosed with primary stress urinary incontinence with no prior incontinence surgery, with a positive stress test and urodynamically proven stress incontinence, with</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>The TVT operation was performed in a standard manner under local anesthesia using between 70 and 100 cc of 0.25 % prilocaine with epinephrine.</p> <p>Cystoscopy was performed twice after each retropubic pass of the trocar to detect bladder injuries.</p> <p><b>Statistical analyses</b></p> <p>Not stated</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - n</u></p> <p>1</p> <p><u>POP occurrence - n</u></p> <p>3</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (64.4% evaluable)</p> <p>Measurement of outcomes bias: Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To evaluate the long term effect of TVT and assess the continence status 17 years after surgery.</p> <p><b>Study dates</b></p> <p>January 1995 to August 1996</p> <p><b>Source of funding</b></p> <p>Funded by University-administered funds.</p>	<p>no detrusor over-activity and a urethral maximal closure pressure &gt;20cm H<sub>2</sub>O.</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>				<p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Mean 201 (185 to 213)</p>
<p><b>Full citation</b></p> <p>Olsson,I., Abrahamsson,A.K., Kroon,U.B., Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a</p>	<p><b>Sample size</b></p> <p>n= 124</p> <p><b>Characteristics</b></p> <p>Mean post-operative age (years) = 65.7±11.2</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>Pre-operatively, women underwent gynaecological examination and had a urine analysis and check of residual urine volume.</p> <p>TVT operations were performed under local</p>	<p><b>Results</b></p> <p><u>De novo OAB - Urge Incontinence, n</u></p> <p>21</p> <p><u>POP occurrence - n</u></p> <p>4</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>retrospective follow-up 11.5 years post-operatively, International Urogynecology Journal, 21, 679-683, 2010</p> <p><b>Ref Id</b></p> <p>124515</p> <p><b>Country/ies where the study was carried out</b></p> <p>Sweden</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To evaluate the long term cure rates and the late complications of TVT for the treatment of urinary incontinence.</p> <p><b>Study dates</b></p> <p>November 1994 to December 1997</p>	<p>Mean post-operative BMI (kg/m<sup>2</sup>) = 26.2±4.0</p> <p>Parity = 2 (0-7)</p> <p>Menopause post-operative - n (%) = 109 (90)</p> <p><b>Inclusion criteria</b></p> <p>Patients with a typical medical history of SUI (80%) or mixed incontinence, all had a positive cough test performed in a semilithotomy position with a saline filled bladder (300ml).</p> <p><b>Exclusion criteria</b></p> <p>Urodynamically proven detrusor overactivity.</p>		<p>anaesthesia by 4 urogynaecologists. Pre-operatively all women were given 1 g of metronidazole and 750 mg of ciprofloxacin.</p> <p><b>Statistical analyses</b></p> <p>Categorical variables were described using frequencies. Continuous variables were reported as means, standard deviations, medians, maximum and minimum.</p>		<p>of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (84% followed up)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Median 138 (120 to 156 months)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Source of funding</b></p> <p>None stated</p>					
<p><b>Full citation</b></p> <p>Punjani, N., Winick-Ng, J., Welk, B., Postoperative Urinary Retention and Urinary Tract Infections Predict Midurethral Sling Mesh Complications, Urology, 99, 42-48, 2017</p> <p><b>Ref Id</b></p> <p>866556</p> <p><b>Country/ies where the study was carried out</b></p> <p>Canada</p> <p><b>Study type</b></p> <p>Population-based, retrospective cohort study</p> <p><b>Aim of the study</b></p> <p>To determine whether post-operative urinary</p>	<p><b>Sample size</b></p> <p>N = 59,556</p> <p><b>Characteristics</b></p> <p><u>Age - Median ± IQR</u></p> <p>52 (45 to 63) years</p> <p><u>BMI (&gt;40) - number (%)</u></p> <p>2,819 (4.7)</p> <p><u>Diabetes mellitus - number (%)</u></p> <p>7,341 (12.3)</p> <p><u>Neurogenic disease - number (%)</u></p> <p>369 (0.6)</p> <p><u>UTI in the prior year - number (%)</u></p> <p>0: 56,656 (95.1)</p>	<p><b>Interventions</b></p> <p>MUS procedure</p>	<p><b>Details</b></p> <p>No further details provided.</p> <p><b>Statistical analyses</b></p> <p>Medians (interquartile range, IQR) or frequencies (count) were calculated. Baseline differences calculated using standardised differences (SDs).</p> <p>Univariate and multivariate Cox proportional hazard regressions were performed, accounting for time variance of primary and secondary risk factors. Hazard ratios (HRs) and 95% confidence intervals (CIs) were calculated.</p> <p>Patients were censored for death and emigration.</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - number (%)</u></p> <p>1,503 (2.5)</p> <p><u>Postoperative UTI - number (%)</u></p> <p>11,747 (19.7)</p> <p><u>Unadjusted analysis - HR (95% CI)</u></p> <p>Postoperative UTI: 2.55 (2.12 to 3.07); p&lt;0.01*</p>	<p><b>Limitations</b></p> <p><b>Confounding bias:</b> Low risk of bias</p> <p><b>Selection of participant's bias:</b> Serious risk of bias</p> <p><b>Classification of interventions bias:</b> Low risk of bias (not applicable as no comparator group)</p> <p><b>Deviations from intended interventions bias:</b> Low risk of bias</p> <p><b>Missing data bias:</b> Serious risk of bias</p> <p><b>Measurement of outcomes bias:</b> Serious risk of bias</p> <p><b>Selection of the reported results bias:</b> Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>retention and frequent urinary tract infections predict future mesh complications requiring surgical intervention in women after a midurethral sling (MUS).</p> <p><b>Study dates</b></p> <p>April 2002 to December 2013</p> <p><b>Source of funding</b></p> <p>Ontario Ministry of Health and Long-Term Care and the Academic Medical Organisation of South-western Ontario.</p>	<p>1: 2,472 (4.2)</p> <p>2: 325 (0.5)</p> <p>≥3: 103 (0.2)</p> <p><u>Previous procedures - number (%)</u></p> <p>Cystoscopy: 33,727 (56.6)</p> <p>Urodynamics: 23,394 (39.3)</p> <p><u>Hysterectomy - number (%)</u></p> <p>Previous: 5,145 (8.6)</p> <p>Combined: 7,688 (12.9)</p> <p><u>POP surgery - number (%)</u></p> <p>Previous: 3,385 (5.7)</p> <p>Combined: 17,510 (29.4)</p> <p><b>Inclusion criteria</b></p> <p>1] Women who underwent a MUS procedure.</p> <p><b>Exclusion criteria</b></p>				<p><b>Other information</b></p> <p>Median follow-up: 5.9 years (IQR 3.6 to 8.6)</p> <p>*Modeled as a continuous variable with stepwise increased from 0, 1, 2, ≥3 postoperative UTIs. Interpreted as each additional UTI (to a maximum of 3) increases the hazard of future mesh complications by 2.5-fold.</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p>1] Patients aged &lt;18 years of age.</p> <p>2] Male or missing gender.</p> <p>3] Not a resident of Ontario.</p> <p>4] Undergone a stress incontinence procedure in the 5 years prior to the study.</p> <p>5] Records missing the institution identification number.</p>				
<p><b>Full citation</b></p> <p>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</p> <p><b>Ref Id</b></p> <p>188202</p> <p><b>Country/ies where the study was carried out</b></p>	<p><b>Sample size</b></p> <p>n= 108</p> <p><b>Characteristics</b></p> <p><u>Age at the time of surgery, year (range)</u></p> <p>63 (44 to 86)</p> <p><u>BMI (kg/m<sup>2</sup>) mean (SD)</u></p> <p>27.95 (4.33)</p> <p><u>Stress incontinence grades - n</u></p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>One surgeon performed all procedures in accordance with Ulmsten et al.</p> <p><b>Statistical analysis</b></p> <p>Not stated.</p>	<p><b>Results</b></p> <p>Pain, n= 0</p> <p>Mesh extrusion/erosion, n= 0</p> <p>Infection, n = 0</p> <p>De novo OAB - Urge Incontinence, n = 26</p> <p>POP occurrence, n= 4</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Germany	I: 15				<p>Missing data bias: Serious risk of bias (68.8% evaluable at follow-up)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Median 102 (85 to 124) months</p>
<b>Study type</b>	II: 74				
Case series	III: 19				
	<u>Pre-existing mixed incontinence - n (%)</u>				
<b>Aim of the study</b>	27 (25)				
To evaluate the long-term effectiveness and late complications after treatment of female stress urinary incontinence with TVT.	<u>Previous gynaecological surgery - n</u>				
	Abdominal hysterectomy: 32				
	Vaginal hysterectomy: 40				
	Colporrhaphy: 48				
<b>Study dates</b>	Abdominal sacrocolpopexy: 3				
August 1998 to December 2001	Vaginal vault suspension: 2				
	<u>Previous incontinence surgery - n</u>				
<b>Source of funding</b>					
Not stated	Colposuspension: 15				
	Needle suspension: 1				
	<u>Additional prolapse repair surgery - n</u>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><u>Anterior prolapse repair surgery - n</u></p> <p>Anterior colporrhaphy: 11 Posterior colporrhaphy: 6 Colpocleisis:1</p> <p><b>Inclusion criteria</b></p> <p>Women with a history of SUI, a positive cough stress test, and a urodynamically proven SUI.</p> <p><b>Exclusion criteria</b></p> <p>Not stated</p>				
<p><b>Full citation</b></p> <p>Riggs, J. A., Retropubic cystourethropexy: A review of two operative procedures with long-term follow-up, <i>Obstetrics and Gynecology</i>, 68, 98-105, 1986</p>	<p><b>Sample size</b></p> <p>n=225</p> <p><b>Characteristics</b></p> <p><u>Age - mean</u></p> <p>49.3 years</p>	<p><b>Interventions</b></p> <p>Modified Peryera procedure</p> <p>Category: retropubic</p>	<p><b>Details</b></p> <p>Women underwent history and physical examination and urinary stress tests.</p> <p>Women with indications for vaginal surgery (cystourethrocele, rectocele, uterine prolapse) underwent</p>	<p><b>Results</b></p> <p><u>Infection - n (% calculated)</u></p> <p>5 (2.2)*</p> <p><u>Wound complications - n (% calculated)</u></p> <p>1 (0.4)**</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Ref Id</b></p> <p>702216</p> <p><b>Country/ies where the study was carried out</b></p> <p>USA</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To report long-term experience with transvaginal retropubic cystourethropexy (modified Pereyra procedure) plus anterior colporrhaphy in the management of stress urinary incontinence.</p> <p><b>Study dates</b></p> <p>January 1966 to December 1982</p> <p><b>Source of funding</b></p> <p>None stated.</p>	<p><u>Postmenopausal - n (%)</u></p> <p>113 (50)</p> <p><u>Previous abdominal or vaginal surgery for stress incontinence - n</u></p> <p>20</p> <p><b>Inclusion criteria</b></p> <p>1] Women with symptomatic stress urinary incontinence managed by retropubic cystourethropexy.</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>		<p>transvaginal retropubic cystourethropexy (modified Pereyra procedure). Sutures placed vertically through the stretched pubourethral ligaments, via a series of small bites, from the urethral meatus to the urethrovesical junction.</p>		<p>of bias (not applicable as no comparator)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (90% evaluable)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: 192 months</p> <p>*Wound collection +/- or infection</p> <p>** Wound separation +/- or dehiscence</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Full citation</b></p> <p>Schauer, I., Bock, H., Eredics, K., Wallis, M., Scholz, M., Madersbacher, S., Luftenegger, W., 10 years follow-up after mid-urethral sling implantation: high rate of cure yet a re-occurrence of OAB-symptoms, <i>Neurourology and Urodynamics</i>, 36, 614-619, 2017</p> <p><b>Ref Id</b></p> <p>610498</p> <p><b>Country/ies where the study was carried out</b></p> <p>Austria</p> <p><b>Study type</b></p> <p>Prospective database cohort</p> <p><b>Aim of the study</b></p> <p>To examine the long-term outcomes (urinary incontinence and lower urinary tract symptoms) in</p>	<p><b>Sample size</b></p> <p>N = 139 (54.3% of original total, N = 256 women)</p> <p><b>Characteristics</b></p> <p><u>Age - mean (range)</u></p> <p>63 (35 to 82) years</p> <p><u>BMI - mean ± SD</u></p> <p>28.2 (4.5)</p> <p><u>Pad usage at baseline - %</u></p> <p>0 to 1: 28.8</p> <p>2: 13.7</p> <p>3 to 4: 27.3</p> <p>&gt;4: 30.2</p> <p><u>Type of incontinence - %</u></p> <p>Pure stress UI: 63.3</p> <p>Mixed UI: 24.5</p> <p>Non specified: 1.4</p> <p>Previous UI surgery: 10.8</p>	<p><b>Interventions</b></p> <p>MUS</p>	<p><b>Details</b></p> <p>Procedures performed or supervised by a single surgeon using retropubic technique. All procedures were performed under general anaesthesia.</p> <p><b>Statistical analyses</b></p> <p>Descriptive statistics. Odds ratios (ORs) calculated for potential risk factors.</p>	<p><b>Results</b></p> <p><u>De novo OAB (urgency) - number (% calculated)</u></p> <p>20 (14.4)</p>	<p><b>Limitations</b></p> <p><b>Confounding bias:</b> Low risk of bias</p> <p><b>Selection of participant's bias:</b> Serious risk of bias</p> <p><b>Classification of interventions bias:</b> Low risk of bias (not applicable as no comparator group)</p> <p><b>Deviations from intended interventions bias:</b> Low risk of bias</p> <p><b>Missing data bias:</b> Serious risk of bias</p> <p><b>Measurement of outcomes bias:</b> Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>women who had a mid-urethral sling and to identify risk factors associated with unsatisfactory outcome.</p> <p><b>Study dates</b> 1999 to 2004</p> <p><b>Source of funding</b> Not reported</p>	<p><b>Inclusion criteria</b></p> <p>1] Women who underwent a mid-urethral sling procedure between 1999 and 2004 in whom a 10 years follow-up was available.</p> <p><b>Exclusion criteria</b> Not reported</p>				<p><b>Selection of the reported results bias:</b> Low risk of bias</p> <p><b>Other information</b> Follow-up: 10 years</p>
<p><b>Full citation</b></p> <p>Serati, M., Braga, A., Athanasiou, S., Tommaselli, G. A., Caccia, G., Torella, M., Ghezzi, F., Salvatore, S., Tension-free Vaginal Tape-Obturator for Treatment of Pure Urodynamic Stress Urinary Incontinence: Efficacy and Adverse Effects at 10-year Follow-up, European Urology, 71, 674-679, 2017</p> <p><b>Ref Id</b></p>	<p><b>Sample size</b> n= 160</p> <p><b>Characteristics</b></p> <p><u>Age - median (IQR)</u> 58 years (50 to 65)</p> <p><u>BMI (kg/m<sup>2</sup>) - median (IQR)</u> 25.3 (23 to 28)</p> <p><u>Menopausal - n (%)</u></p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Transobturator</p>	<p><b>Details</b></p> <p>Preoperative evaluation included medical history, physical examination, a voiding diary, urinalysis, and complete urodynamic testing.</p> <p>All procedures were performed according to De Leval, using the inside-out approach and using a polypropylene sling with two arms that are passed inside to outside through the obturator foramens, pulled to compress the bulbar urethra upward, and</p>	<p><b>Results</b></p> <p>Pain, n= 5</p> <p>Mesh extrusion/erosion, n= 0</p> <p>De novo OAB - Urge Incontinence, n = 23</p> <p>POP occurrence, n = 0</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (95% evaluable)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
641442	124 (74)		<p>ted to each other across the midline. General or spinal anaesthesia was used.</p> <p><b>Statistical analyses</b></p> <p>Continuous variables presented as median and IQR. Chi-square test and chi-square test for trend to analyse and compare the surgical outcomes during the follow-up were used.</p>		<p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: 132 months</p>
<p><b>Country/ies where the study was carried out</b></p> <p>Greece, Italy, Switzerland</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To assess the efficacy and safety of TVT-O 10 years after implantation for the treatment of female pure SUI.</p> <p><b>Study dates</b></p> <p>January 2004</p> <p><b>Source of funding</b></p> <p>None stated.</p>	<p><u>Previous POP or anti-incontinence surgery - n (%)</u></p> <p>12 (7.1)</p> <p><b>Inclusion criteria</b></p> <p>Women with pure SUI symptoms with urodynamically proven urodynamic stress incontinence (USI).</p> <p><b>Exclusion criteria</b></p> <p>Women with a history of radical pelvic surgery, psychiatric or neurologic disorders, concomitant vaginal prolapse greater than stage 1 according to the pelvic organ prolapse quantification system, OAB symptoms, urodynamically proven DO, and postvoid residual urine volume &gt; 100ml</p>				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Full citation</b></p> <p>Serati, M., Sorice, P., Bogani, G., Braga, A., Cantaluppi, S., Uccella, S., Caccia, G., Salvatore, S., Ghezzi, F., TVT for the treatment of urodynamic stress incontinence: Efficacy and adverse effects at 13-year follow-up, <i>Neurourology and Urodynamics</i>, 36, 192-197, 2017</p> <p><b>Ref Id</b></p> <p>619085</p> <p><b>Country/ies where the study was carried out</b></p> <p>Italy</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To assess long-term subjective, objective and urodynamic outcomes of</p>	<p><b>Sample size</b></p> <p>n=55</p> <p><b>Characteristics</b></p> <p>Age, BMI, parity not stated.</p> <p><b>Inclusion criteria</b></p> <p>Women with symptoms of pure SUI and proven urodynamic stress incontinence.</p> <p><b>Exclusion criteria</b></p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: retropubic</p>	<p><b>Details</b></p> <p>Preoperative evaluation included collection of medical history, physical examination, frequency-volume chart, urine analysis and complete urodynamic testing.</p> <p>All the TVT procedures were performed by the same, trained, surgeon according to the technique originally described by Ulmsten et al. General or spinal anaesthesia was used.</p> <p><b>Statistical analyses</b></p> <p>Continuous variables were reported as median and interquartile range (IQR). Chi-square and Fisher's exact test were used to analyze proportions, as appropriate. Student's t-test and the Mann-Whitney U-test were performed to compare continuous parametric and non-parametric variables, as appropriate. s</p>	<p><b>Results</b></p> <p>Pain, n= 0</p> <p>Mesh extrusion/erosion, n= 0</p> <p>De novo OAB - Urge Incontinence: n = 23</p> <p>POP occurrence, n = 0</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (87.3% evaluable)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: 156 months</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>retropubic mid-urethral slings at 13 year follow-up.</p> <p><b>Study dates</b></p> <p>January 2000 to June 2001</p> <p><b>Source of funding</b></p> <p>None stated.</p>					
<p><b>Full citation</b></p> <p>Song, P. H., Kwon, D. H., Ko, Y. H., Jung, H. C., The Long-Term Outcomes of the Tension-free Vaginal Tape Procedure for Treatment of Female Stress Urinary Incontinence: Data from Minimum 13Years of Follow-Up, LutsLow Urin Tract Symptoms, 9, 10-14, 2017</p> <p><b>Ref Id</b></p> <p>769766</p>	<p><b>Sample size</b></p> <p>n= 206</p> <p><b>Characteristics</b></p> <p><u>Age - mean (range)</u></p> <p>59.2 years (42 to 75)</p> <p><u>BMI (kg/m<sup>2</sup>) - mean (range)</u></p> <p>23.4 (18.4 to 29.1)</p> <p><u>Parity - mean (range)</u></p> <p>2.8 (0 to 9)</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>Preoperative evaluation included a medical history, obstetric history, physical examination including Q-tip and POP-Q, stress test, 3-day voiding diary, 1 hour pad test, uroflowmetry, post-void residual (PVT) urine measurement, and multichannel urodynamic test.</p> <p>TVT procedures were performed by experienced surgeons using the standard technique with some modifications. Procedures normally</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - n (%)</u></p> <p>1 (0.5)</p> <p><u>De novo OAB - Urgency - n (%)</u></p> <p>2 (1)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (56.6% evaluable at follow-up)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<b>Country/ies where the study was carried out</b>	<u>Urge incontinence - n (%)</u>		performed under a combination of light sedation and local anesthesia; but general or spinal anesthesia used when requested by the patients or when concomitant pelvic or vaginal procedures were performed.		Measurement of outcomes bias: Serious risk of bias
South Korea	41 (19.9)				Selection of the reported results bias: Low risk of bias
<b>Study type</b>	<u>Urgency - n (%)</u>				
Case series	59 (28.6)				
	<u>Concomitant surgeries - n (%)</u>				
	Cystocele repair: 7 (3.4)				
<b>Aim of the study</b>	Caruncle excision: 1 (0.5)		<b>Statistical analyses</b>		<b>Other information</b>
To evaluate the long-term outcomes of TVT for the treatment of women with stress urinary incontinence.	Posterior colporrhaphy: 8 (3.9)		Student's <i>t</i> -test was used for comparison of normally distributed variables.		Follow-up: Mean 162.4 (156-174)
	Urethral dilation: 1 (0.5)				
	<u>SUI Grade - n (%)</u>				
	I: 95 (46.1)				
<b>Study dates</b>	II: 103 (50.0)				
March 1999 to March 2001	III: 8 (3.9)				
	<u>Urodynamic parameters - mean (range)</u>				
<b>Source of funding</b>	Maximal urethral closing pressure (cmH <sub>2</sub> O): 66.1 (45 to 91)				
Supported by 2012 Yeungnam University Research Grant	Valsalva leak point pressure (cmH <sub>2</sub> O): 64.5 (35 to 191)				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	<p><b>Inclusion criteria</b></p> <p>Women with SUI.</p> <p><b>Exclusion criteria</b></p> <p>Women with neurologic disease, known bleeding diathesis or current anticoagulant therapy, or allergy to local anesthetic.</p>				
<p><b>Full citation</b></p> <p>Svenningsen, R., Staff, A. C., Schiotz, H. A., Western, K., Kulseng-Hanssen, S., Long-term follow-up of the retropubic tension-free vaginal tape procedure, International Urogynecology Journal, 24, 1271-8, 2013</p> <p><b>Ref Id</b></p> <p>543083</p> <p><b>Country/ies where the study was carried out</b></p>	<p><b>Sample size</b></p> <p>n= 327</p> <p><b>Characteristics</b></p> <p>Median age, years (range) = 64 (36 to 97)</p> <p>BMI = 26 (17 to 51)</p> <p><b>Inclusion criteria</b></p> <p>Women with SUI</p>	<p><b>Interventions</b></p> <p>TVT</p> <p>Category: Retropubic TVT</p>	<p><b>Details</b></p> <p>Tension-free vaginal tape from Gynecare used, and the procedures were performed as described by Ulmsten et al by 21 surgeons.</p> <p><b>Statistical analyses</b></p> <p>Categorical and continuous variables reported as percentage, median, and range. Differences in dichotomous variables were tested using McNemar's test for paired variables and Pearson's</p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - n/N (%)</u></p> <p>1/317 (0.3)</p> <p><u>De novo OAB - Urge Incontinence, n/N (%)</u></p> <p>15/101 (14.9)</p> <p><u>Infection - n/N (%)</u></p> <p>11/471 (2.3)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (89% evaluable)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Norway</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To evaluate the long-term objective and subjective outcomes in a non-selected patient population 10 years after the retropubic TVT procedure.</p> <p><b>Study dates</b></p> <p>September 1998 to December 2000</p> <p><b>Source of funding</b></p> <p>Grants from The Nordic Urogynaecologic Association (NUGA) and the Norwegian Urodynamic Discussion Group (UDYDIG)</p>	<p><b>Exclusion criteria</b></p> <p>Women having undergone repeat SUI surgery.</p>		<p>Chi-Squared test for unpaired variables. Differences in continuous variables were tested using the Mann–Whitney U test.</p>		<p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Median follow-up: 129 months (114 to 160)</p>
<b>Full citation</b>	<b>Sample size</b>	<b>Interventions</b>	<b>Details</b>	<b>Results</b>	<b>Limitations</b>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p>Tsivian,A., Neuman,M., Kessler,O., Mogutin,B., Korczak,D., Levin,S., Sidi,A.A., Does patient weight influence the outcome of the tension-free vaginal tape procedure? A long-term follow-up study, Gynecological Surgery, 3, 195-198, 2006</p> <p><b>Ref Id</b></p> <p>135144</p> <p><b>Country/ies where the study was carried out</b></p> <p>Israel</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To determine whether obesity affects the outcome of the tension-free vaginal tape (TVT) procedure.</p>	<p>n= 81</p> <p><b>Characteristics</b></p> <p><u>Age - mean (years)</u></p> <p>63.4</p> <p><u>Previous hysterectomy - n</u></p> <p>Transabdominal: 13</p> <p>Transvaginal: 4</p> <p><u>Previous anti-incontinence procedure - n</u></p> <p>Burch: 5</p> <p>Raz: 2</p> <p>MMK: 1</p> <p>Anterior colporrhaphy: 3</p> <p><b>Inclusion criteria</b></p> <p>Women who underwent a TVT procedure.</p> <p><b>Exclusion criteria</b></p> <p>Not stated.</p>	<p>TVT</p> <p>Category: Retropubic TVT (65% of cohort had concomitant procedures)</p>	<p>Preoperative examination included medical history and physical examinations with stress tests and urodynamic studies.</p> <p>TVT procedures were performed according to Ulmsten's method.</p> <p><b>Statistical analyses</b></p> <p>Inter-group outcome variables were compared using the Chi-squared test with 99% Monte Carlo confidence intervals or Fisher's exact test when expected frequencies were low.</p>	<p><u>Mesh extrusion/erosion - n</u></p> <p>5</p> <p><u>Infection - n</u></p> <p>0</p> <p><u>De novo OAB – Urgency - n</u></p> <p>17</p>	<p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias (90% evaluable)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: Median 65 (52 to 84)</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Study dates</b></p> <p>April 1998 to December 2000</p> <p><b>Source of funding</b></p> <p>Not stated.</p>					
<p><b>Full citation</b></p> <p>Tutolo, M., De Ridder, D. J. M. K., Montorsi, F., Castagna, G., Deprest, J., Schellart, R. P., Ammirati, E., Van Der Aa, F., A minimum of 1-year follow-up for MiniArc single incision slings compared to Monarc transobturator slings: An analysis to evaluate durability of continence and medium-term outcomes, <i>Neurourology and Urodynamics</i>, 36, 803-807, 2017</p> <p><b>Ref Id</b></p>	<p><b>Sample size</b></p> <p>Monarc Tape, n= 215</p> <p>MiniArc, n= 166</p> <p><b>Characteristics</b></p> <p><u>Age mean (range) - years</u></p> <p>Total: 59 (20 to 92)</p> <p>MiniArc: 59 (33 to 92)</p> <p>Monarc: 59 (20 to 87)</p> <p><u>BMI - mean (range)</u></p> <p>Total: 27 (17 to 47)</p> <p>MiniArc: 27 (17 to 47)</p>	<p><b>Interventions</b></p> <p>TOT</p> <p>Category: Transobturator (Monarc, MiniArc SIMS)</p>	<p><b>Details</b></p> <p>Preoperative assessment included medical history and assessment of symptoms, physical examination, a 3-day voiding diary, urinalysis, urine culture, uroflowmetry, and post-void residual urine (PVR) measurement. Where necessary, urodynamics were performed.</p> <p>Procedures were performed by experienced urologists and gynaecologists.</p> <p><b>Statistical analyses</b></p>	<p><b>Results</b></p> <p><u>Mesh extrusion/erosion - n/N</u></p> <p>Monarc Tape n= 6/145</p> <p>MiniArc: 1/48</p> <p><u>De novo OAB - Urge Incontinence</u></p> <p>Monarc: 4/117</p> <p>MiniArc: 3/32</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Serious risk of bias</p> <p>Classification of interventions bias: Serious risk of bias</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Low risk of bias</p> <p>Measurement of outcomes bias: Serious risk of bias</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
769771	Monarc: 27 (18 to 44)				
<b>Country/ies where the study was carried out</b>	<u>Mixed urinary incontinence - n (%)</u>				
Belgium, Italy, The Netherlands	Total: 127 (33)				
<b>Study type</b>	MiniArc: 62 (37.3)				
Retrospective cohort	Monarc: 65 (30.2)				
	<u>Previous hysterectomy - n (%)</u>				
	Total: 99 (26)				
<b>Aim of the study</b>	MiniArc: 38 (23)				
To compare the efficacy and safety of two commercially available single incision slings (SIS) and trans-obturator vaginal tapes (TOT) and report results at 5-year follow up.	Monarc: 61 (28)				
	<b>Inclusion criteria</b>				
	Women with SUI.				
<b>Study dates</b>	<b>Exclusion criteria</b>				
2003 to 2012	Women with neurogenic bladder or concomitant prolapse surgery.				
<b>Source of funding</b>					
None stated.					

Selection of the reported results bias: Low risk of bias

**Other information**

Follow-up: Mean 65 months (12 to 138)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Full citation</b></p> <p>Ulrich, D., Tammaa, A., Holbfer, S., Trutnovsky, G., Bjelic-Radisic, V., Tamussino, K., Aigmuller, T., Ten-Year Followup after Tension-Free Vaginal Tape-Obturator Procedure for Stress Urinary Incontinence, Journal of Urology, 196, 1201-6, 2016</p> <p><b>Ref Id</b></p> <p>769655</p> <p><b>Country/ies where the study was carried out</b></p> <p>Austria</p> <p><b>Study type</b></p> <p>Case series</p> <p><b>Aim of the study</b></p> <p>To evaluate subjective and objective cure rates 10 years after TVT-O procedure for stress urinary incontinence.</p>	<p><b>Sample size</b></p> <p>n= 71</p> <p><b>Characteristics</b></p> <p><u>Age - mean ±SD</u></p> <p>60 (7)</p> <p><u>BMI (kg/m<sup>2</sup>) - mean ±SD</u></p> <p>28 (5)</p> <p><u>Parity - median (range)</u></p> <p>2 (0 to 5)</p> <p><u>Hormonal status - n (%)</u></p> <p>Premenopausal: 39 (59)</p> <p>Menopausal: 18 (14)</p> <p><u>Recurrent urinary tract infections - n</u></p> <p>0</p> <p><u>MUCP (cm H<sub>2</sub>O) - mean ±SD</u></p> <p>43 (27)</p> <p><u>Previous surgery - n (%)</u></p>	<p><b>Interventions</b></p> <p>TVT-O</p> <p>Category: Transobturator</p>	<p><b>Details</b></p> <p>Preoperative clinical and urodynamic assessment included medical history, symptoms of lower urinary tract and pelvic floor dysfunction, clinical examination and urodynamics, MUCP and cough stress test.</p> <p>Procedures performed as described by de Leval with or without concomitant surgery by consultants experienced in urogynaecologic surgery.</p> <p><b>Statistical analyses</b></p> <p>Not stated for complications.</p>	<p><b>Results</b></p> <p><u>Pain - n</u></p> <p>11</p> <p><u>Mesh extrusion/erosion - n/N (%)</u></p> <p>4/55 (7)</p> <p><u>De novo OAB - Urge Incontinence - n/N (%)</u></p> <p>18/71 (26)</p>	<p><b>Limitations</b></p> <p>Confounding bias: Low risk of bias</p> <p>Selection of participant's bias: Low risk of bias</p> <p>Classification of interventions bias: Low risk of bias (no comparator group)</p> <p>Deviations from intended interventions bias: Low risk of bias</p> <p>Missing data bias: Serious risk of bias (57% available for follow-up)</p> <p>Measurement of outcomes bias: Serious risk of bias</p> <p>Selection of the reported results bias: Low risk of bias</p> <p><b>Other information</b></p> <p>Follow-up: 120 months</p>

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
<p><b>Study dates</b></p> <p>2004 to 2005</p> <p><b>Source of funding</b></p> <p>Not stated.</p> <p>One author had financial interest and/or other relationship with Covidien and Roci.</p>	<p>Hysterectomy: 21 (30)</p> <p>POP: 8 (12)</p> <p>Anti-incontinence: 4 (6)</p> <p><u>Concomitant surgery - n (%)</u></p> <p>Vaginal hysterectomy: 6 (10)</p> <p>Vaginal hysterectomy + colporrhaphy: 4 (6)</p> <p>Colporrhaphy ony: 4 (6)</p> <p>Hysteroscopy: 1 (1.5)</p> <p>Mesh: 2 (3)</p> <p><b>Inclusion criteria</b></p> <p>Patients who underwent TVT-O entered in the Austrian Transobturator Registry.</p> <p><b>Exclusion criteria</b></p> <p>No study exclusion criteria was applied.</p>				

**Evidence tables for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

**Table 19: Clinical evidence tables for surgery versus pelvic floor muscle training for stress urinary incontinence**

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Full citation Klarskov, P., Belving, D., Bischoff, N., Pelvic floor exercise versus surgery for female urinary stress incontinence, Urologia Internationalis, 41, 129-132, 1986</p> <p>Ref Id 763834</p> <p>Country/ies where the study was carried out Denmark</p> <p>Study type Prospective randomised controlled trial</p> <p>Aim of the study To test an optimal outpatient pelvic floor exercise program by urodynamic assessment and to compare the results with surgery in unselected females with genuine urinary stress incontinence</p> <p>Study dates</p>	<p>Sample size N=50</p> <p>Intervention, n=24 Control, n=26</p> <p>Characteristics Not reported</p> <p>Inclusion criteria Genuine stress incontinence. Informed consent. No previous surgery or systematic pelvic floor exercises</p> <p>No significant urge incontinence</p> <p>Exclusion criteria Surgery indicated for reasons other than incontinence (e.g. prolapse operation, hysterectomy)</p> <p>Patients who for mental reasons could not be expected to be able to follow the</p>	<p>Interventions Intervention: Pelvic floor muscle training (PFMT) Control: Surgery</p>	<p>Details PFMT: Physiotherapy-guided weekly group sessions leading to a home exercise program Surgery: Burch Colposuspension and/or vaginal repair on the basis of voiding colpocystourethrography</p>	<p>Results Change in number of incontinence episodes per 3 days (median, after procedure): 6-2; 6-0. Subjective cure (in number of women; after procedure): Cured - 3/24; 16/26 Improved - 14/24; 7/26 Unchanged - 7/24; 2/26 Worse - 0/24; 1/26</p>	<p>Limitations Random sequence generation: Unclear risk (no details of how randomisation was conducted) Allocation concealment: Unclear risk (no details of how concealment was conducted) Blinding of participants/personnel: Low risk (no details of blinding but as a surgical non-surgical intervention, blinding is difficult) Blinding of outcome assessment: Low risk (no details of blinding but as a surgical non-surgical intervention, blinding would have not influenced outcome measures) Incomplete outcome data: Low risk (no missing outcome data)</p>

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Not reported Source of funding Not reported	instructions of the training program				Selective reporting: Unclear risk (no published protocol) Other bias: Low risk (no further apparent bias) Other information At the final evaluation an objective and standardized 60-min continence test was applied. The continence test was not available when the study was initiated. Therefore, the patients were not tested before treatment.
Full citation Klarskov, P, Nielson, Kk, Kromann-Andersen, B, Maegaard, E, Long term results of pelvic floor training and surgery to female genuine stress incontinence, International Urogynecology Journal, 2, 132-135, 1991 Ref Id 763837 Country/ies where the study was carried out	Sample size N=30 Intervention, n=10 Control, n=20 Characteristics Age (y, median): 48 years (31-66) BMI kg/m2: not reported Parity: not reported Inclusion criteria Women with genuine SUI Exclusion criteria	Interventions Intervention: PFMT Control: Surgery	Details PFMT: Physiotherapy-guided weekly group sessions leading to a home exercise program. Surgery: Burch Colposuspension and/or vaginal repair on the basis of voiding colpocystourethrography.	Results Subjective judgement change from 1-y to 4-8-y FU (patients' judgements; reported in number of women): Improved=1/10; 3/20 Stable=6/10; 3/2 Worse=2/10; 2/20 Lost=1/10; 1/20  Subjective cure at 1-y FU (voiding chart. No. continence patients): 6/10 (1 lost FU); 19/20	Limitations Random sequence generation: Unclear risk (no details of how randomisation was conducted) Allocation concealment: Unclear risk (no details of how concealment was conducted)  Blinding of participants/personnel: Low risk (no details of blinding)

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
Denmark Study type Prospective randomised controlled trial Aim of the study To assess the long-term results of the treatments, especially those of the pelvic floor training program, as such information is not currently available in the medical literature Study dates 1983 to 1991 Source of funding Not reported	Not reported			Subjective cure at 4-8-y FU (voiding chart. No. continence patients): 5/10 (3 lost FU); 11/20 (6 lost FU)	but as a surgical non-surgical intervention, blinding is difficult) Blinding of outcome assessment: Low risk (no details of blinding but as a surgical non-surgical intervention, blinding would have not influenced outcome measures) Incomplete outcome data: Low risk (no missing outcome data) Selective reporting: Unclear risk (no published protocol) Other bias: Low risk (no further apparent bias) Other information
Full citation Labrie, J., Berghmans, B. L., Fischer, K., Milani, A. L., van der Wijk, I., Smalbraak, D. J., Vollebregt, A., Schellart, R. P., Graziosi, G. C., van der Ploeg, J. M., Brouns, J. F., Tiersma, E. S., Groenendijk, A. G., Scholten, P., Mol, B. W., Blokhuis, E. E.,	Sample size N=417 Intervention, n=202 Control, n=215 Characteristics Age (y, mean)= 50.0 (8.2); 50.2 (9.8). BMI (kg/m <sup>2</sup> )= 26.9 (5.0); 26.4 (5.0). Parity (median)= 2 (0-7); 2 (0-4).	Interventions Intervention: PFMT  Control: Midurethral-sling surgery	Details TRIAL REGISTRATION: Nederlands trial register: NTR 1248  PFMT Educational physiotherapist-lead PFMT tailored for each patient for a total of nine sessions over 9-18 weeks.	Results PGI-I improvement at 2-mo (7-point Likert scale; reported in number of women): 25/194; 175/201. PGI-S no symptoms at 2-mo (4-point Likert scale; reported in number of women): 25/193; 167/201. PGI-I improvement at 4-mo (7-point Likert scale;	Limitations Random sequence generation: Low risk (an independent data manager used computerised randomisation to produce random number table) Allocation concealment: High risk (no attempt to conceal assignments)

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Adriaanse, A. H., Schram, A., Roovers, J. P., Lagro-Janssen, A. L., van der Vaart, C. H., Surgery versus physiotherapy for stress urinary incontinence, <i>New England Journal of Medicine</i>, 369, 1124-33, 2013</p> <p>Ref Id 542845</p> <p>Country/ies where the study was carried out Netherlands</p> <p>Study type Multicentre randomised controlled trial</p> <p>Aim of the study To compare midurethral-sling surgery to PFMT as they had not been directly compared previously in an RCT</p> <p>Study dates Not reported</p> <p>Source of funding ZonMw, the Netherlands Organization for Health Research and Development</p>	<p>Inclusion criteria All women aged 35-80 years who present with symptoms of moderate to severe, predominant stress urinary incontinence.</p> <p>Moderate to severe stress incontinence according to the Sandvik severity index. The index is calculated by multiplying the reported frequency (four levels, 1 to 4) by the amount of leakage (two levels, 1 and 2). The resulting index value (1-8) is further categorized into slight (1-2), moderate (3-4) and severe (5-8)</p> <p>Objective confirmation of stress urinary incontinence by either examination,</p>		<p>Surgery Surgical procedures were performed by 49 gynecologists and urologists. Before participating in this trial, each surgeon had performed a minimum of 20 procedures. Both retropubic and transobturator midurethral-sling surgical techniques were allowed.</p>	<p>reported in number of women): 59/190; 182/200. PGI-S no symptoms at 4-mo (4-point Likert scale; reported in number of women): 59/189; 166/199. PGI-I improvement at 6-mo (7-point Likert scale; reported in number of women): 81/182; 180/203. PGI-S no symptoms at 6-mo (4-point Likert scale; reported in number of women): 76/182; 173/203. PGI-I improvement at 1-y (7-point Likert scale; reported in number of women): 112/174; 177/195. PGI-S no symptoms at 1-y (4-point Likert scale; reported in number of women): 114/174; 167/195. PGI-I improvement at 18-mo (7-point Likert scale; reported in number of women): 119/159; 163/178. PGI-S no symptoms at 18-mo (4-point Likert scale; reported in number of</p>	<p>Blinding of participants/personnel: Low risk (no details of blinding but as a surgical non-surgical intervention, blinding is difficult) Blinding of outcome assessment: Low risk (no details of blinding but as a surgical non-surgical intervention, blinding would have not influenced outcome measures) Incomplete outcome data: Low risk (no missing outcome data) Selective reporting: Low risk (published protocol and all study's pre-specified outcomes reported)</p> <p>Other bias: Low risk (no further apparent bias) Other information</p>

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	<p>stress-test or urodynamics.</p> <p>Exclusion criteria</p> <p>A post voiding bladder volume of more than 100 ml.</p> <p>History of anti-incontinence surgery.</p> <p>PFMT exercises by a specialised physiotherapist for urinary incontinence in the previous 6 months.</p> <p>Genital prolapse Stage 2 or more according to the POP-Q classification.</p> <p>Probability of future pregnancy and childbirth present.</p> <p>Co morbidity which is associated with increased surgical risks, for instance women with ASA 3 or 4 classification.</p> <p>History of recurrent lower urinary tract</p>			<p>women): 117/159; 152/177.</p> <p>Subjective cure at 1-y (a negative response to "Do you experience urine leakage related to physical activity, coughing, or sneezing?"; reported in number of women: 93/174; 167/196.</p> <p>Objective cure at 1-y (negative cough stress test; reported in number of women): 94/160; 140/183.</p> <p>Complications (reported in number of women)</p> <p>Serious adverse events</p> <p>Bladder perforation: 0/202; 6/215.</p> <p>Repeat surgery: 1/202; 6/215.</p> <p>de novo urinary incontinence: 5/202; 13/215.</p>	

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	infection (> 3 times/year). Insufficient knowledge or understanding of the Dutch language. Use of medication interacting in bladder function. History of or current major psychiatric illness. History of chronic neurological disease.				
Full citation Tapp, A. J. S., Hills, B., Cardozo, L. D., Randomised study comparing pelvic floor physiotherapy with the Burch colposuspension, <i>Neurourology and Urodynamics</i> , 8, 356-357, 1989 Ref Id 674337 Country/ies where the study was carried out UK Study type	Sample size N=45 Intervention=24 Control=21 Characteristics Not reported Inclusion criteria Women with urodynamically proven GSI with incontinence. Exclusion criteria Women with a history of urological or vaginal surgery	Interventions Intervention PMFT Control Burch colposuspension	Details PFMT With or without Faradic consisted of 14 session over 3 months	Results Objective cure rate 6-mo (reported in number of women): 2/21; 18/24 Subjective (symptomatic) improvement 6-mo (reported in number of women): 9/21; 23/24	Limitations Random sequence generation: Unclear risk (no details of randomisation given) Allocation concealment: Unclear risk (no details of concealment given) Blinding of participants/personnel: Unclear risk (no details of blinding given) Blinding of outcome assessment: Unclear risk (no details of blinding given)

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>Prospective randomised controlled trial</p> <p>Aim of the study</p> <p>To compare PFMT with PFMT and Faradic stimulation (PFMT+F), and with Burch colposuspension (BC) in the management of urodynamically proven GSI.</p> <p>Study dates</p> <p>Not reported</p> <p>Source of funding</p> <p>Not reported</p>	<p>Other urodynamic abnormality</p>				<p>Incomplete outcome data: Low risk (no missing data)</p> <p>Selective reporting: Unclear risk (no published protocol)</p> <p>Other bias: Low risk (no further apparent bias)</p> <p>Other information</p>
<p>Full citation</p> <p>ter Meulen Ph, H., Berghmans, L. C. M., Nieman, F. H. M., van Kerrebroeck Ph, E. V. A., Effects of Mmacroplastique Implantation System for stress urinary incontinence and urethral hypermobility in women, International Urogynecology Journal, 20, 177-183, 2009</p> <p>Ref Id</p>	<p>Sample size</p> <p>N=45</p> <p>PFMT, n=21</p> <p>MPQ, n=24</p> <p>Characteristics</p> <p>Age (y, mean): 55.6 (8.9); 54.7 (8.9)</p> <p>BMI (kg/m<sup>2</sup>): 28.3 (8.3); 26.6 (4.3)</p> <p>Parity (median): 2; 2</p> <p>Inclusion criteria</p> <p>Female and at least 18 years of age</p>	<p>Interventions</p> <p>Intervention:</p> <p>PFMT</p> <p>Control:</p> <p>Macroplastique® (MPQ) bulking agent</p>	<p>Details</p> <p>PFMT</p> <p>Participants were offered a written instruction material.</p> <p>MPQ</p> <p>Transurethral injection performed using the MIS in a day case setting.</p>	<p>Results</p> <p>I-QOL (overall, scores at baseline and 3 months):</p> <p>PFMT: 2.96 (0.62), 3.03 (0.66);</p> <p>Surgery: 2.59 (0.61), 3.20 (0.73)</p> <p>I-QOL (avoidance and limiting behaviour, score at baseline and 3 months):</p> <p>PFMT: 2.86 (0.72), 2.99 (0.71);</p> <p>Surgery: 2.55 (0.65), 3.26 (0.86)</p>	<p>Limitations</p> <p>Random sequence generation: Low risk (sealed envelopes and random number table for treatment assignment)</p> <p>Allocation concealment: Low risk (sealed envelopes)</p> <p>Blinding of participants/personnel: Unclear risk (not addressed but difficult to blind in a surgical vs non-surgical intervention with patients'</p>

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>763922</p> <p>Country/ies where the study was carried out Netherlands</p> <p>Study type Prospective randomised controlled trial</p> <p>Aim of the study To evaluate the efficacy and quality of life in women using the Macroplastique® Implantation System (MIS) as a procedure in adult women with stress urinary incontinence and urethral hypermobility</p> <p>Study dates April 2002 to May 2007</p> <p>Source of funding This study was funded by an unrestricted grant of Uroplasty BV</p>	<p>Urodynamic stress urinary incontinence and urethral hypermobility</p> <p>Urodynamic assessment of SUI and VLPP &gt;60-cm water</p> <p>SUI did not show defined improvement after PFME therapy</p> <p>No more than stage 0, 1, or 2 pelvic organ prolapse (Bump classification)</p> <p>Negative dipstick urinalysis</p> <p>Postvoid residual urine ≤100 ml</p> <p>Not pregnant or within 12 months postpartum</p> <p>Understanding of the Dutch language</p> <p>Written informed consent document</p> <p>Exclusion criteria Any prior solid particle UBA treatment or any surgical anti-</p>			<p>I-QOL (psychosocial impacts, scores at baseline and 3 months): PFMT: 3.27 (0.66), 3.31 (0.65); Surgery: 2.76 (0.70), 3.37 (0.74)</p> <p>I-QOL (social embarrassment, scores at baseline and 3 months): PFMT: 2.53 (0.66), 2.59 (0.87); Surgery: 2.31 (0.68), 2.95 (0.81)</p> <p>I-QOL (overall, scores at baseline and 12 months, successful surgeries only [n=18]): 2.58 (0.64), 3.85 (0.81)</p> <p>I-QOL (Avoidance and limiting behaviour, scores at baseline and 12 months, successful surgeries only [n=18]): 2.47 (0.58), 3.65 (0.73)</p> <p>I-QOL (Psychosocial impacts, scores at baseline and 12 months, successful surgeries only [n=18]): 2.76 (0.77), 3.94 (0.78)</p>	<p>subjective reporting as an outcome)</p> <p>Blinding of outcome assessment: Unclear risk (no details of outcome assessment blinding)</p> <p>Incomplete outcome data: High risk (6 participants dropped out in the MPQ arm; 5 for other treatment and 1 visit out of window. No dropouts in control arm)</p> <p>Selective reporting: Unclear risk (no published protocol)</p> <p>Other bias: High (study funded by an unrestricted grant of Uroplasty BV, who produce the Macroplastique device)</p> <p>Other information</p>

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	incontinence procedure A form of urinary incontinence other than SUI contributing substantially to their symptoms A neurogenic bladder Urinary incontinence due to an anatomical defect, fibrotic urethral mucosa (preventing Macroplastique® bolus formation), tissue damage due to injury, pelvic radiotherapy, or other therapy affecting the bladder neck and/or urethral tissues A history of intermittent or long-term use of intraurethral continence devices Voiding difficulties A history of unexplained hematuria			I-QOL (Social embarrassment, scores at baseline and 12 months, successful surgeries only [n=18]): 2.35 (0.71), 3.77 (0.97) Subjective cure at 3mo (final surgeon's rating): Cured - 2/21; 8/24 Markedly improved - 4/21; 9/24 Slightly improved - 4/21; 1/24 Unchanged - 11/21; 6/24 Subjective report at 3mo (patient self-assessment): Cured - 0/21; 7/24 Markedly improved - 4/21; 8/24 Slightly improved - 3/21; 2/24 Unchanged - 14/21; 7/24 Subjective cure at 12mo, MPQ only (final surgeon's rating): cured - 9/18 Markedly improved - 7/18 Slightly improved - 1/18 Unchanged - 1/18	

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	<p>Cystitis, urethritis, or evidence of possible infection, which would preclude safe penetration of the urethral wall with the implantation needle</p> <p>An incurable malignant disease or other form of disease that is advancing rapidly and causing deterioration of the patient's physical condition</p> <p>Any condition that could lead to serious postoperative complications (e.g., current infection or uncontrolled diabetes)</p> <p>Lactating within 12 months postpartum or planning to become pregnant in the next 12 months</p> <p>Morbidly obese (i.e., body mass index; BMI&gt;40 kg/m<sup>2</sup>)</p> <p>Unable or unwilling to perform clean</p>			<p>Subjective report at 12mo, MPQ only (patient self-assessment): cured - 6/17</p> <p>Markedly improved - 8/17</p> <p>Slightly improved - 2/17</p> <p>Unchanged - 1/17</p>	

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
	intermittent self-catheterization if the need arises (e.g., lack of manual dexterity, arthritic hands, dementia, etc.)				
<p>Full citation Yalcin, O. T., Hassa, H., Ozalp, S., Yildirim, A., Sener, T., Results of the anti-incontinence operations and Kegel exercises in patients with type II anatomic stress incontinence, Acta Obstetrica et Gynecologica Scandinavica, 77, 341-6, 1998</p> <p>Ref Id 763939</p> <p>Country/ies where the study was carried out Turkey</p> <p>Study type Prospective observational cohort</p> <p>Aim of the study To compare the subjective and objective</p>	<p>Sample size N=98</p> <p>Intervention, n=47 Control, n=51</p> <p>Characteristics Age (y, SD): 47.8 (9.2); 48.6 (9.9). BMI (kg/m<sup>2</sup>): not reported</p> <p>Parity (median, SD, range): 3.4 (1.7, 0-7); 3.7 (1.8, 1-8).</p> <p>Inclusion criteria No urinary fistula or diverticula No involuntary detrusor contraction detected by cystometry Urine loss &gt; 1g during 1-hour pad test Urine leakage simultaneously with</p>	<p>Interventions Intervention: Kegel exercises Control: Surgical treatments including Burch and modified Pereyra operations</p>	<p>Details Kegel exercises Taught as defined by Kegel in 1948 and pelvic floor anatomy taught. Exercises were conducted 5 times a day increasing to 10 for at least 8 weeks</p> <p>Surgery 27/51 undergoing surgery also had significant pelvic relaxation, which had to be corrected by vaginal surgery by modified Pereyra operations. 24/51 did not have significant pelvic relaxation and had Burch operations</p>	<p>Results Objective cure rate (combined pad and stress test): Complete success - 4/47; 46/51 Partial success - 17/47; 4/51 No success - 26/47; 1/51 Total success - 21/47; 50/51</p> <p>Subjective cure rate (combined 24-hour urinary diary and questionnaire): Complete success - 7/47; 48/51 Partial success - 18/47; 2/51 No success - 22/47; 1/51 Total success - 26/47; 1/51</p> <p>Objective cure rate, Burch only (combined pad and stress test): Complete success - 22/24 Partial success - 2/24</p>	<p>Limitations Random sequence generation: High risk (allocation of surgery based on whether the participant had significant pelvic relaxation necessitating vaginal Pereyra surgery). Allocation concealment: High risk (allocation of surgery based on whether the participant had significant pelvic relaxation necessitating vaginal Pereyra surgery). Blinding of participants/personnel: Low risk (no blinding reported but difficult to blind in surgical vs non-surgical intervention). Blinding of outcome assessment: Unclear (no details reported).</p>

Bibliographic details	Participants	Intervention	Methods	Outcomes and results	Comments
<p>cure rates for incontinence between Kegel exercise and anti-incontinence operations in patients with type II anatomic stress incontinence.</p> <p>Study dates Not reported</p> <p>Source of funding Not reported</p>	<p>stress during stress test</p> <p>Urinary incontinence with hypermobility of the bladder</p> <p>Exclusion criteria Intravesical pressure rise &gt; 15 cm H2O without any symptoms or &gt; 5 cm H2O with urgency during cystometry while patients' abdominal muscles were completely relaxed</p> <p>Urinary incontinence without bladder hypermobility was classified as Type I or II</p>			<p>No success - 0/24</p> <p>Total success - 24/24</p> <p>Objective cure rate, Pereya only (combined pad and stress test): Complete success - 2/27</p> <p>Partial success - 24/27</p> <p>No success - 1/27</p> <p>Total success - 26/27</p> <p>Complications Infections: 0/47; 5/51 (3 UTI; 2 wound)</p>	<p>Incomplete outcome data: Low risk (no missing data).</p> <p>Selective reporting: Unclear (no published protocol).</p> <p>Other bias: Low risk (no further apparent bias).</p> <p>Other information</p>

## Appendix E – Forest plots

Forest plots for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?

### Colposuspension versus synthetic mesh sling

Figure 3: Adverse events – Severe bleeding requiring blood transfusion

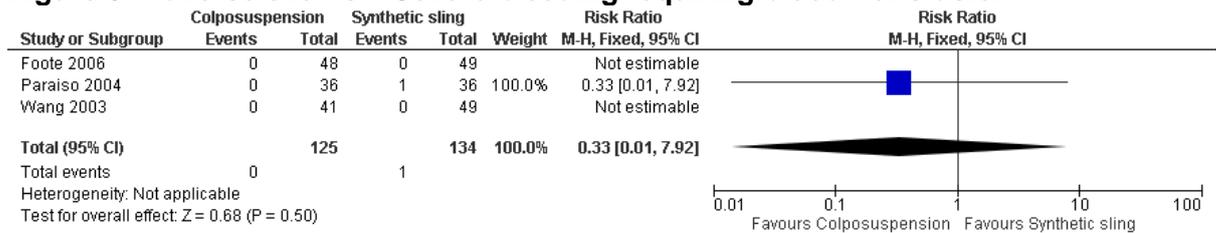


Figure 4: Adverse events – Bladder injury

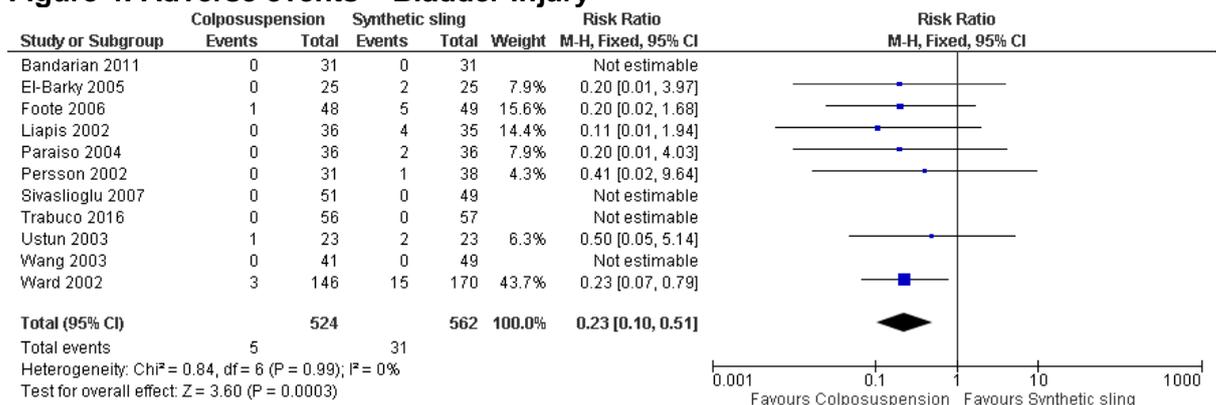
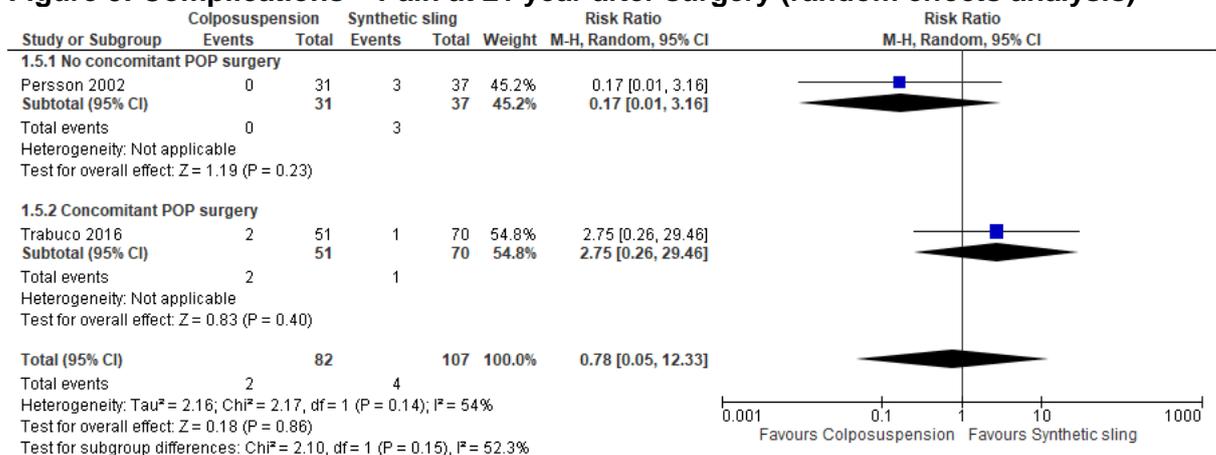
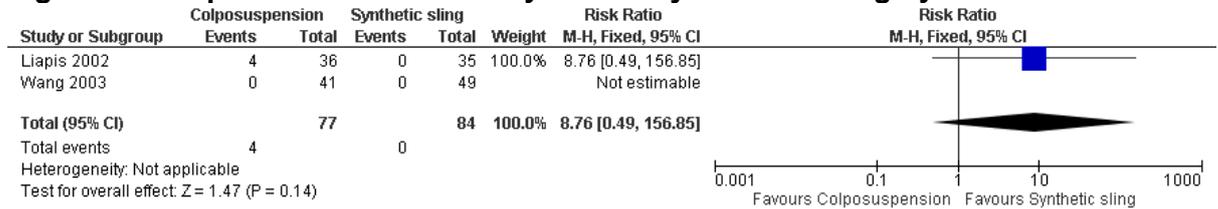


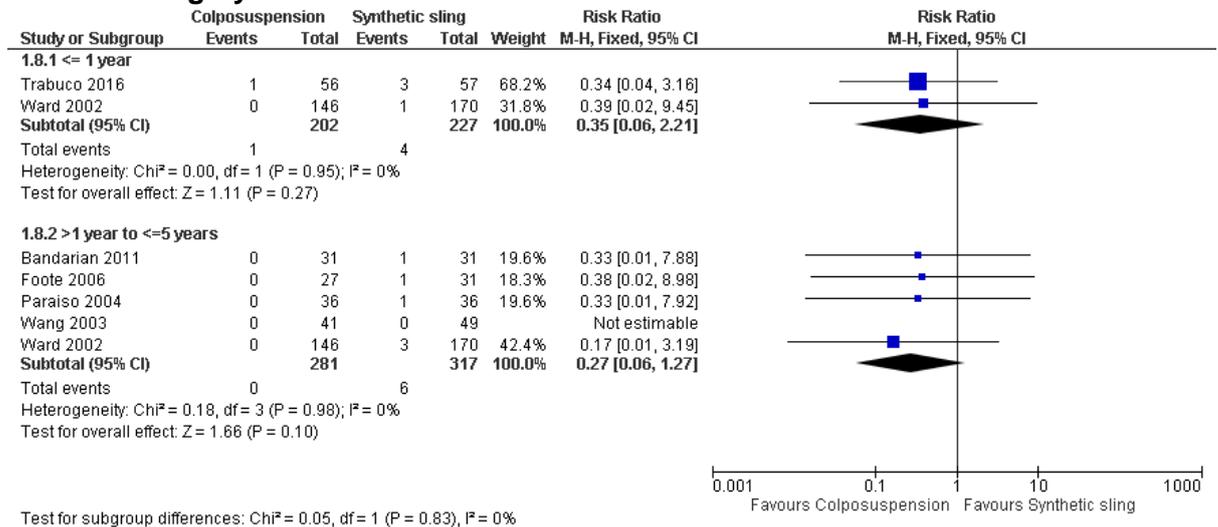
Figure 5: Complications – Pain at ≤1 year after surgery (random effects analysis)



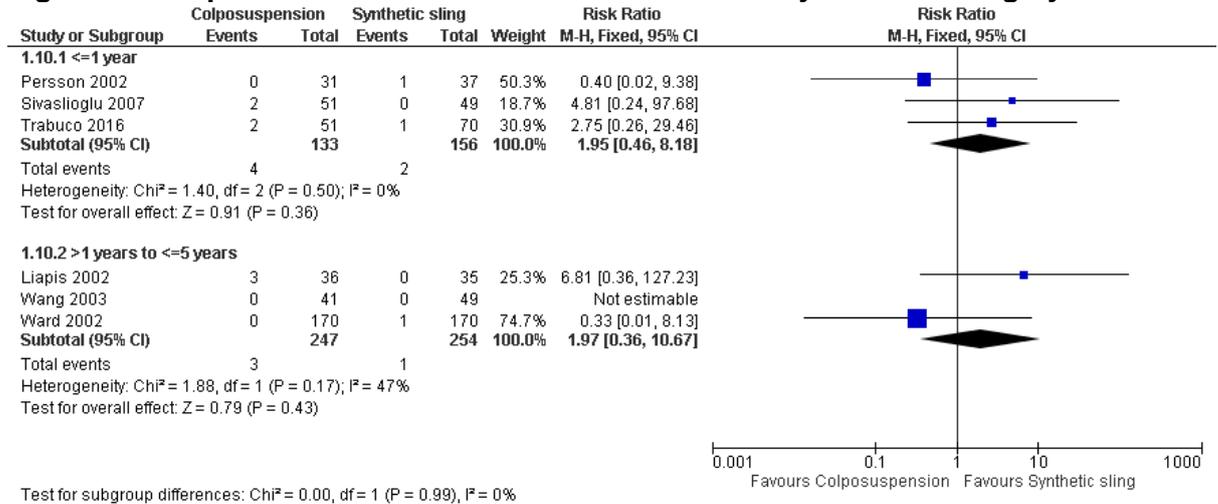
**Figure 6: Complications – Pain at >1 year to ≤5 years after surgery**



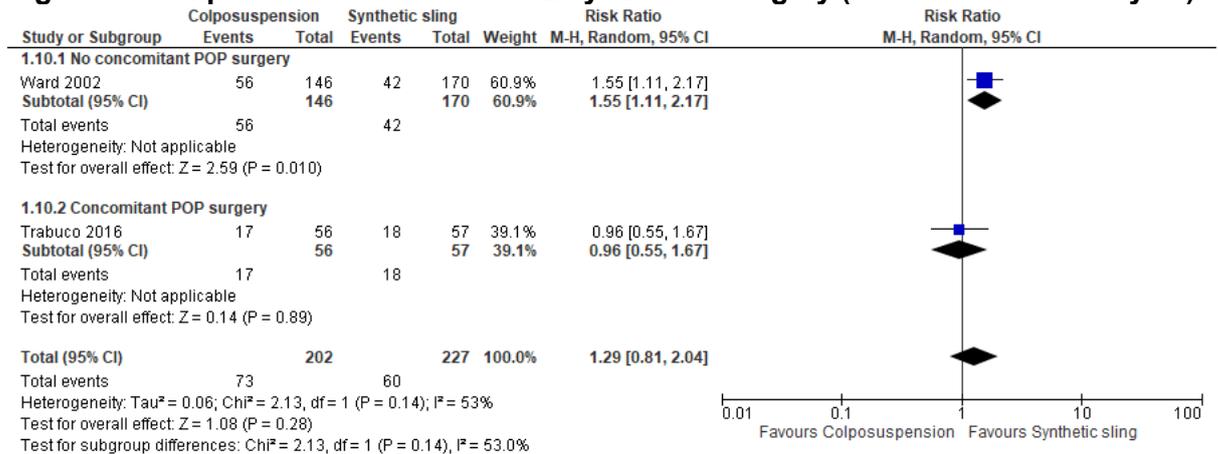
**Figure 7: Complications - Mesh extrusion at ≤1 year and >1 year to ≤5 years after surgery**



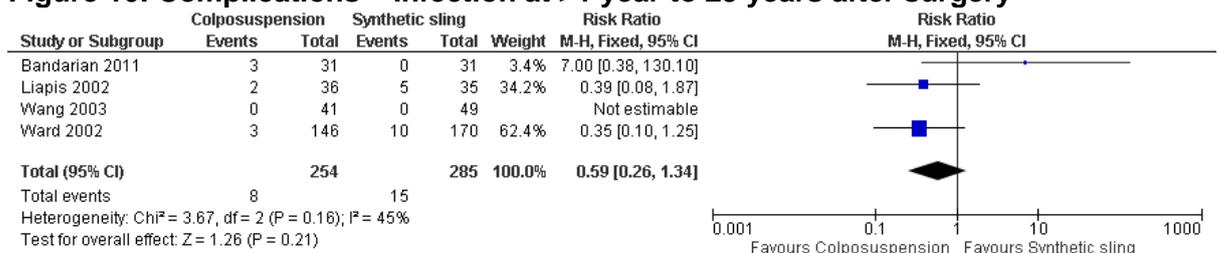
**Figure 8: Complications – Need for catheterisation at ≤5 years after surgery**



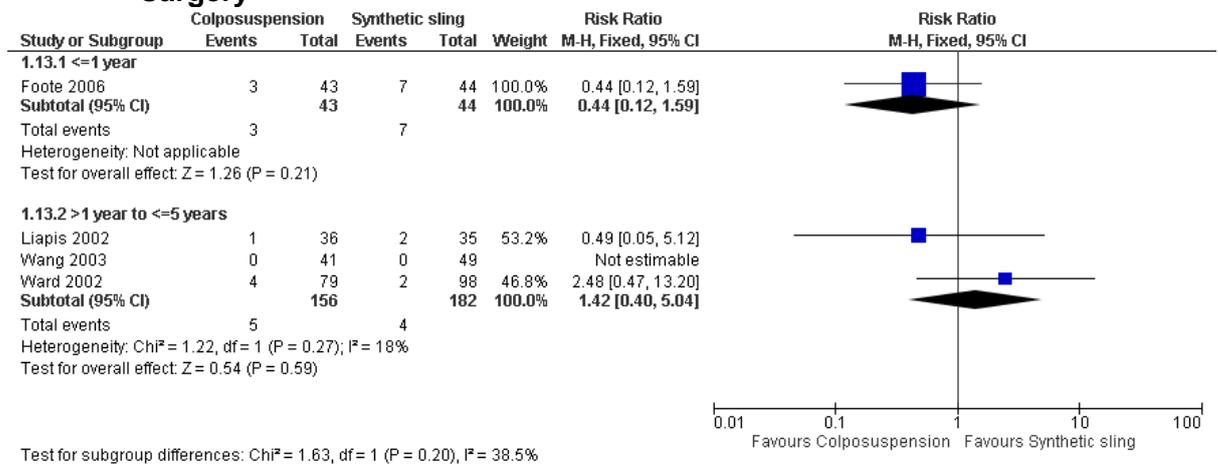
**Figure 9: Complications – Infection at ≤1 year after surgery (random effects analysis)**



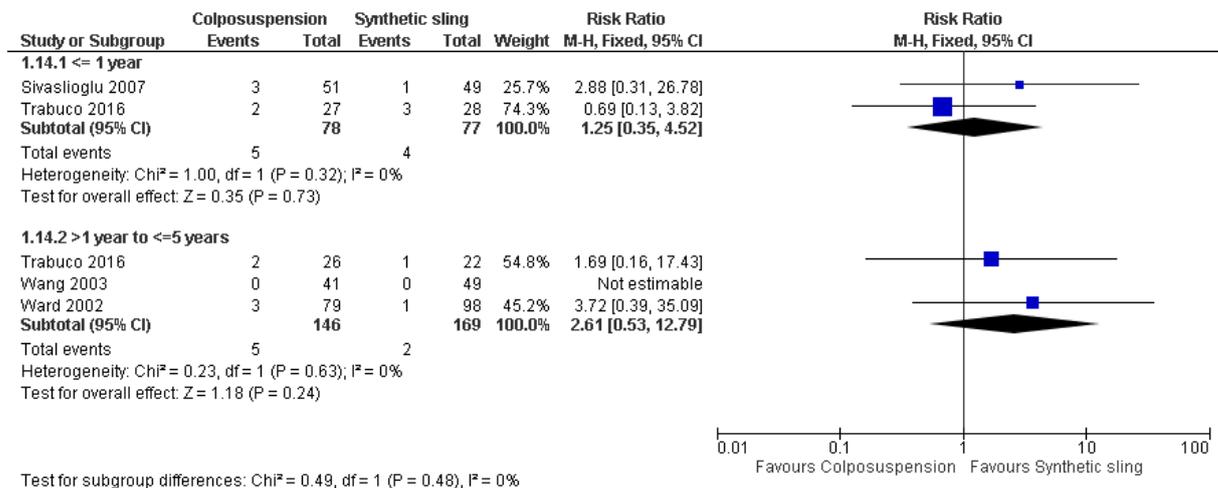
**Figure 10: Complications – Infection at >1 year to ≤5 years after surgery**



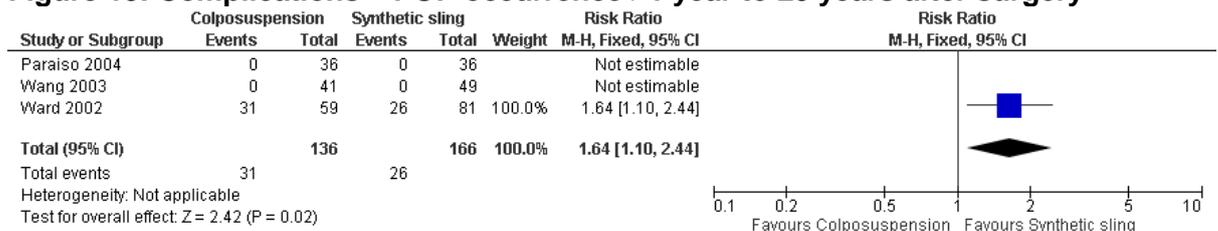
**Figure 11: Complications – De novo urgency at ≤1 year and >1 year to ≤5 years after surgery**



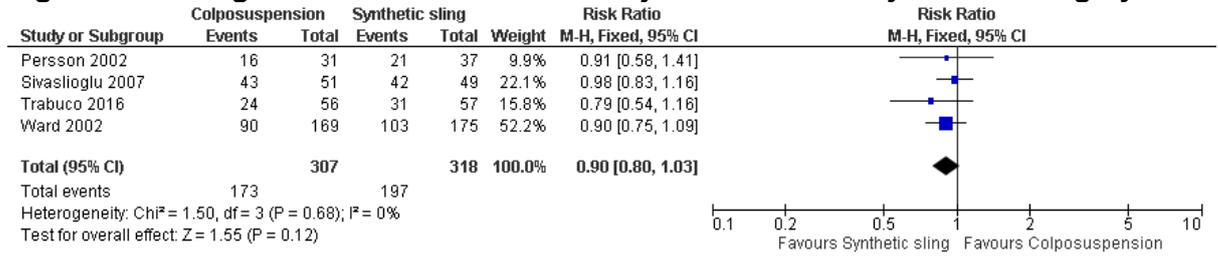
**Figure 12: Complications – De novo urge incontinence at ≤1 year and >1 year to ≤5 years after surgery**



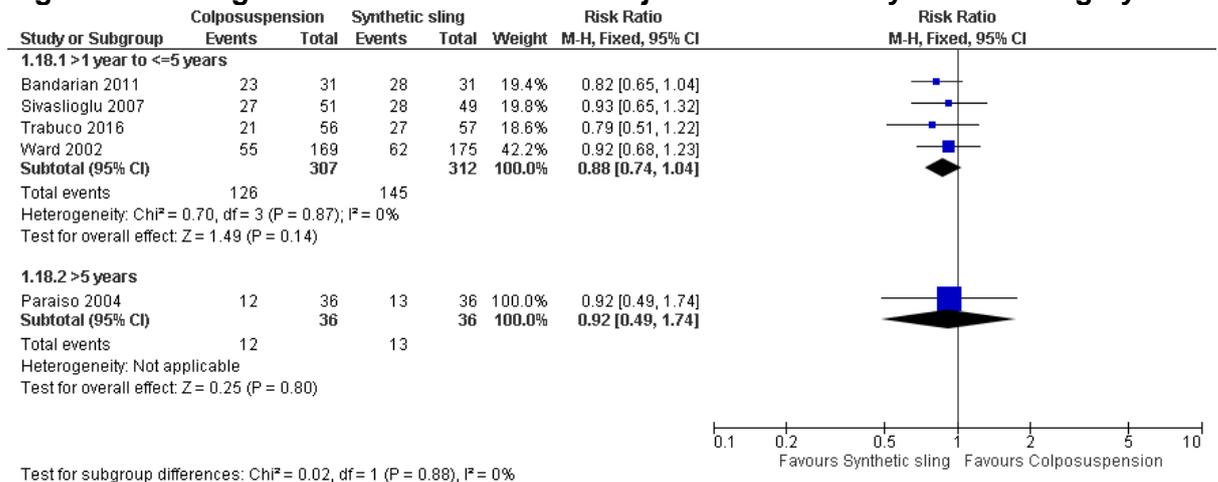
**Figure 13: Complications – POP occurrence >1 year to ≤5 years after surgery**



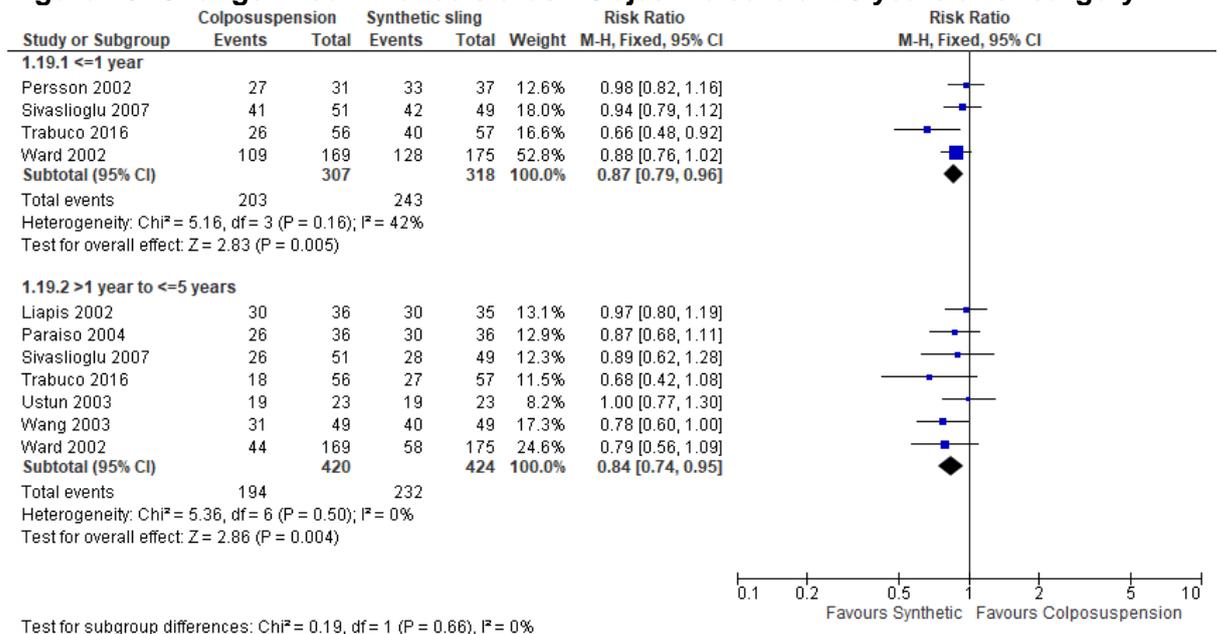
**Figure 14: Change in continence status - Subjective cure at ≤1 year after surgery**



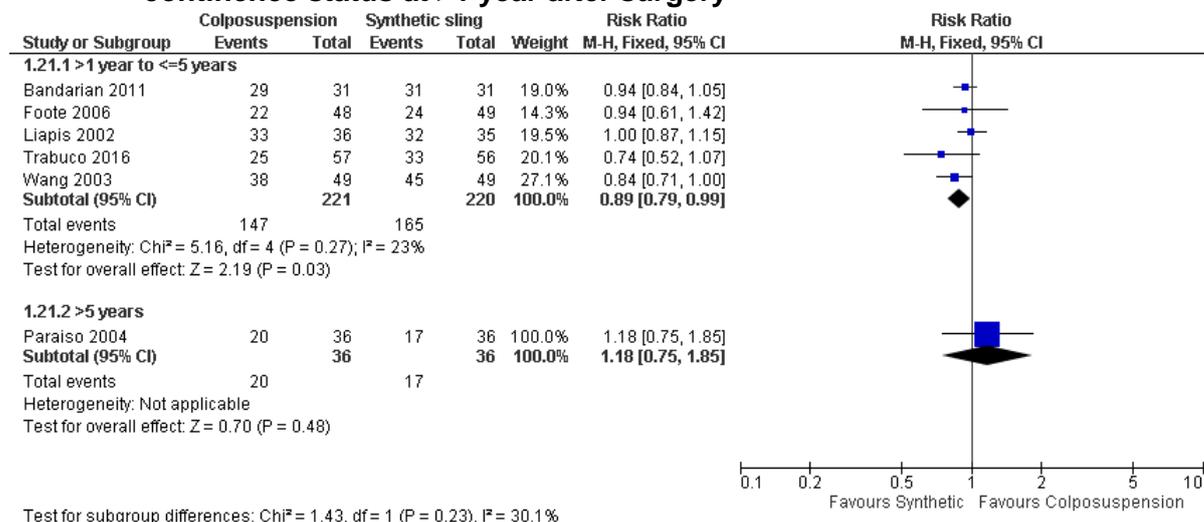
**Figure 15: Change in continence status - Subjective cure at >1 year after surgery**



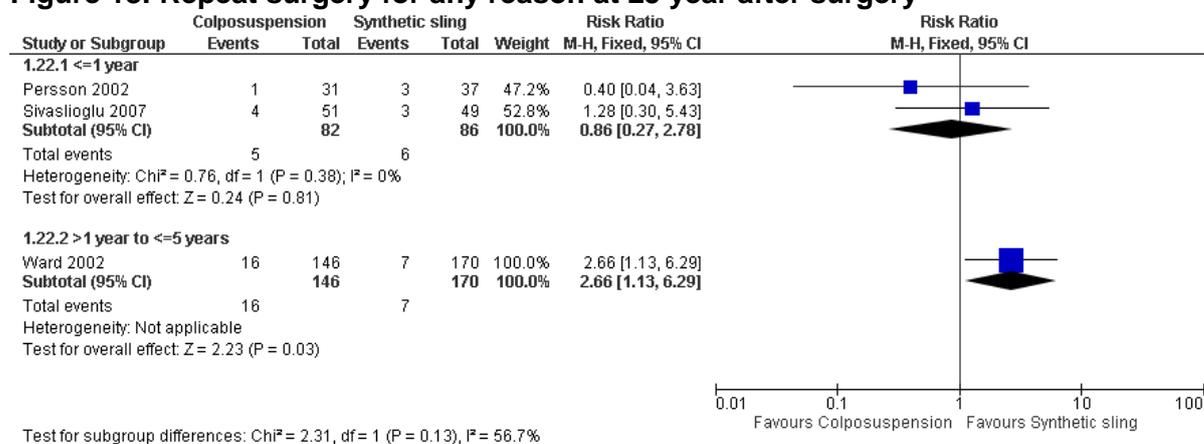
**Figure 16: Change in continence status - Objective cure at ≤5 years after surgery**



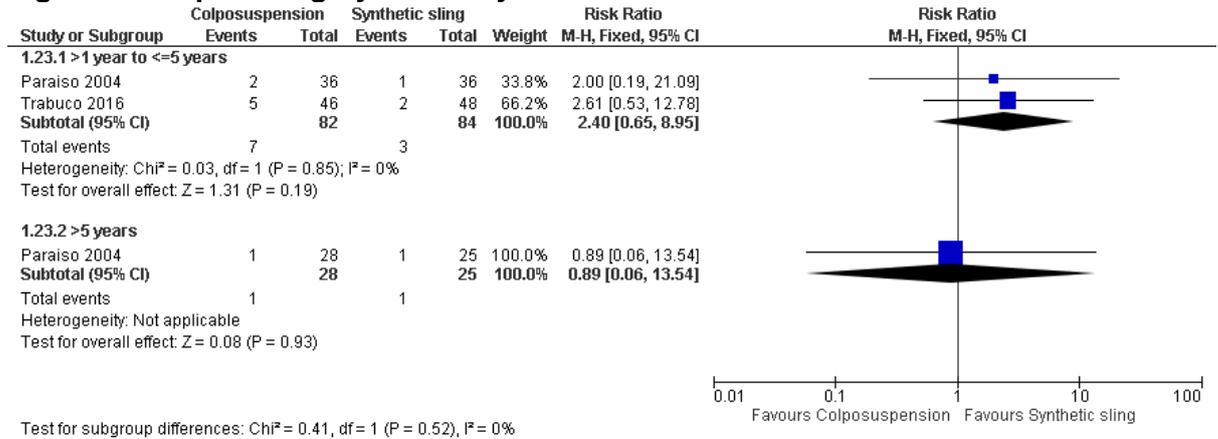
**Figure 17: Patient satisfaction/patient-reported improvement - Improvement in continence status at >1 year after surgery**



**Figure 18: Repeat surgery for any reason at ≤5 year after surgery**

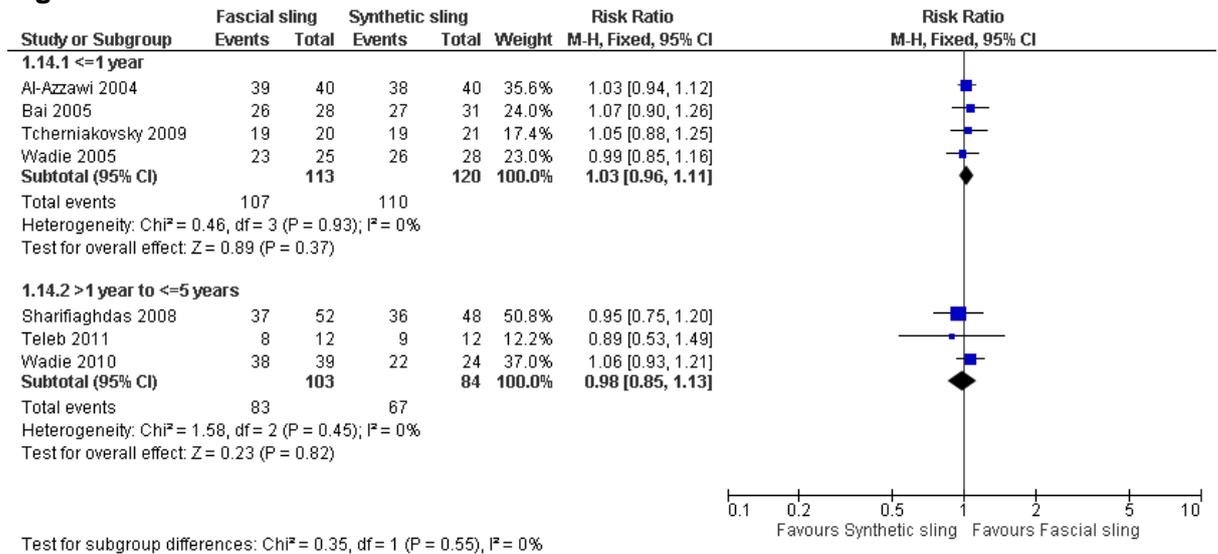


**Figure 19: Repeat surgery for SUI ry**

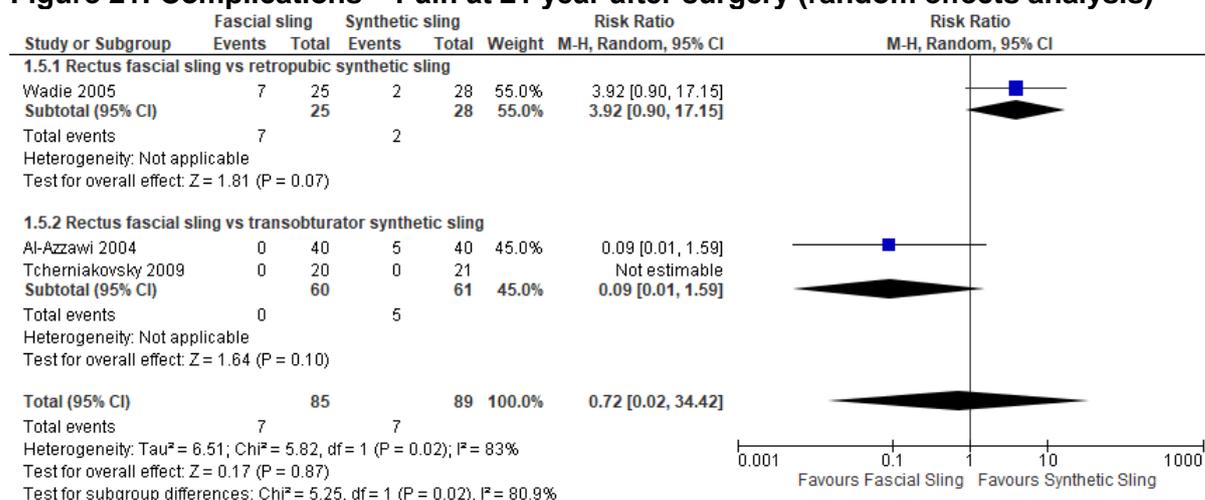


**Autologous rectus fascial sling versus synthetic mesh sling**

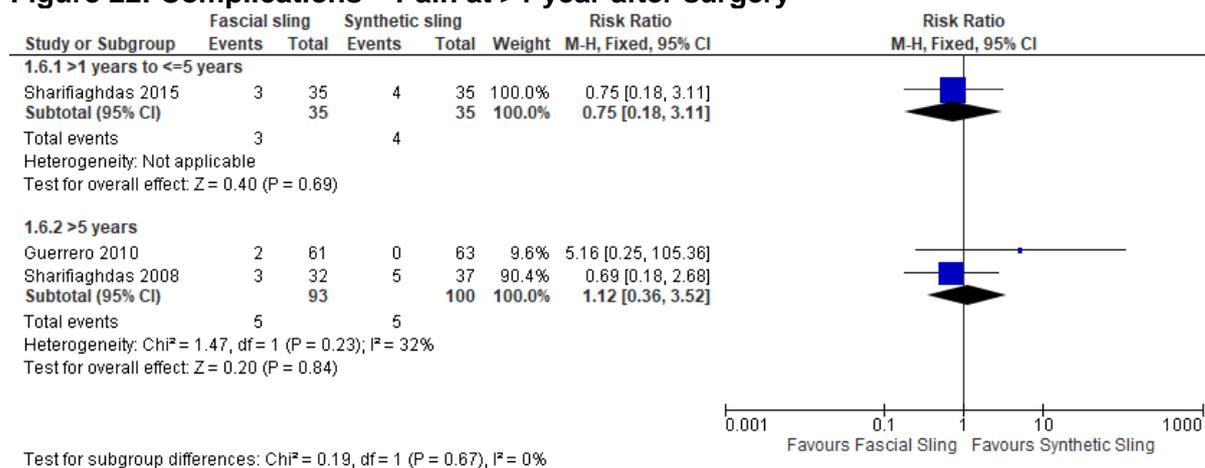
**Figure 20: Adverse events**



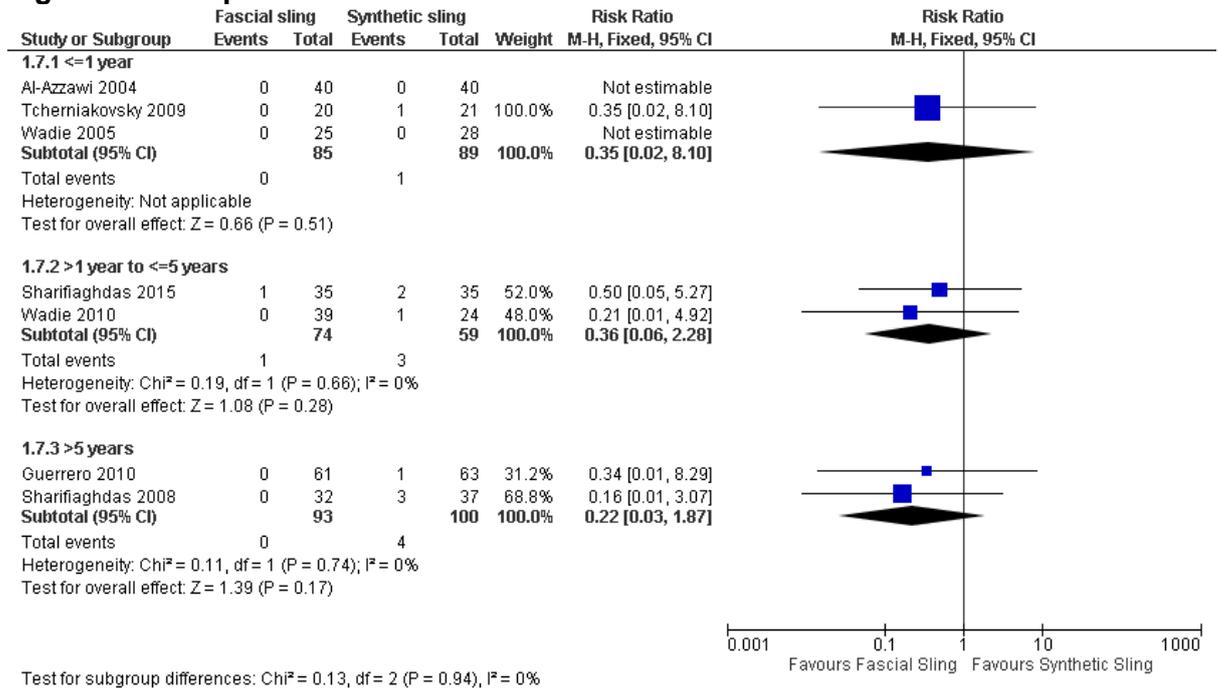
**Figure 21: Complications – Pain at ≤1 year after surgery (random effects analysis)**



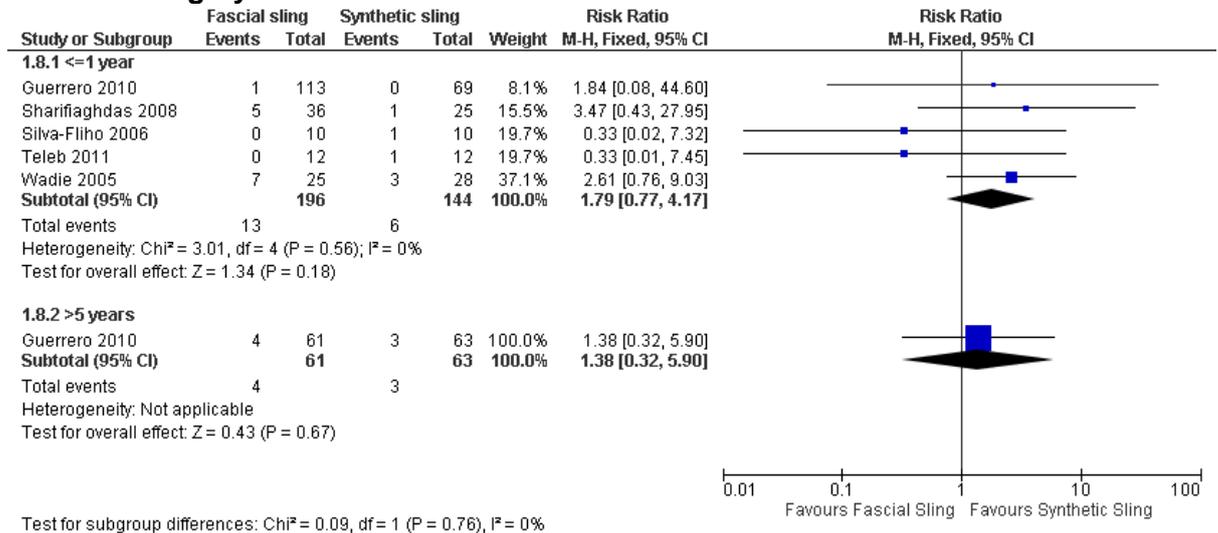
**Figure 22: Complications – Pain at >1 year after surgery**



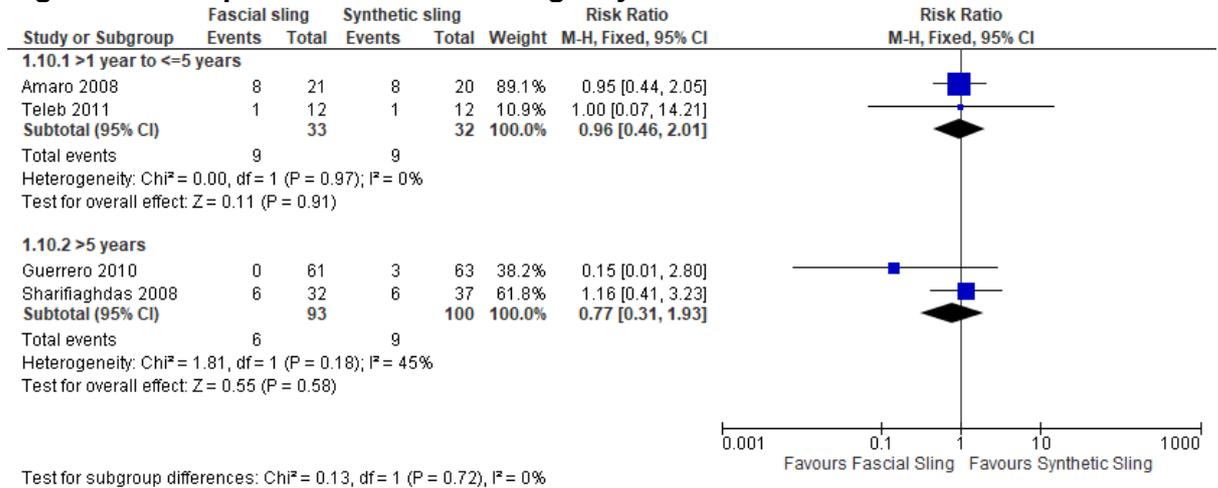
**Figure 23: Complications – Mesh extrusion**



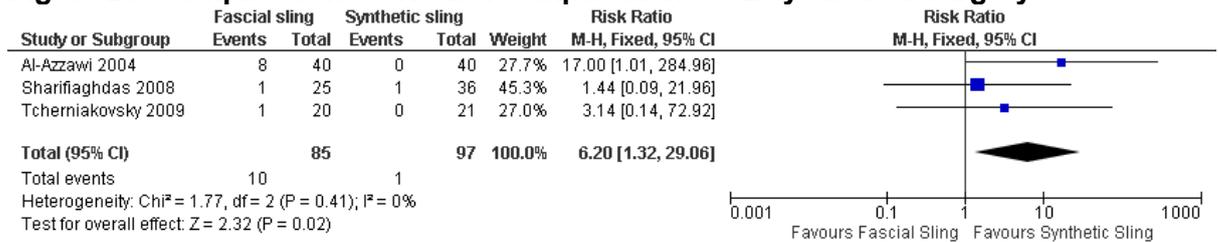
**Figure 24: Complications – Need for catheterisation at ≤1 year and >5 years after surgery**



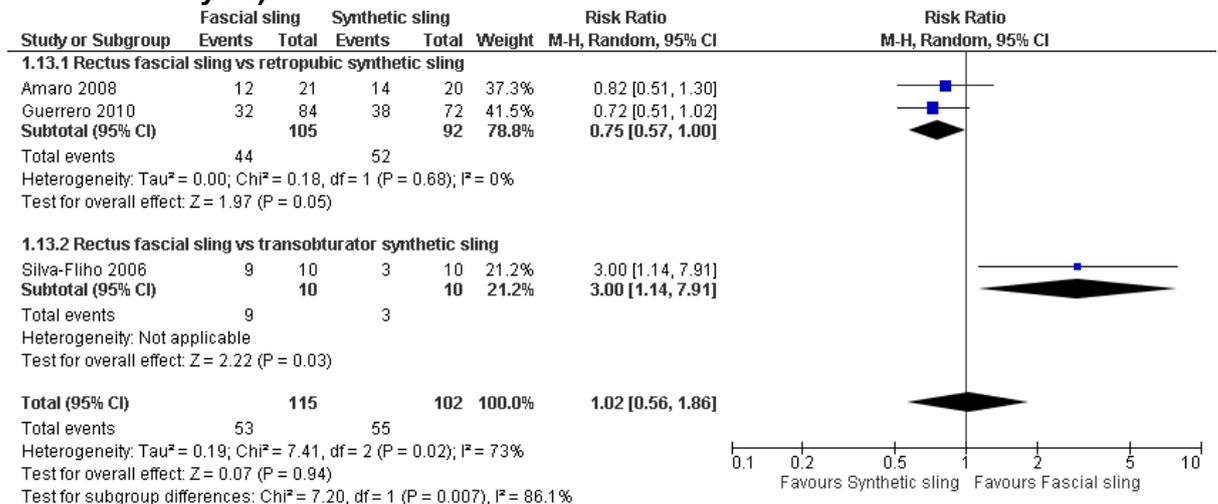
**Figure 25: Complications – De novo urgency**



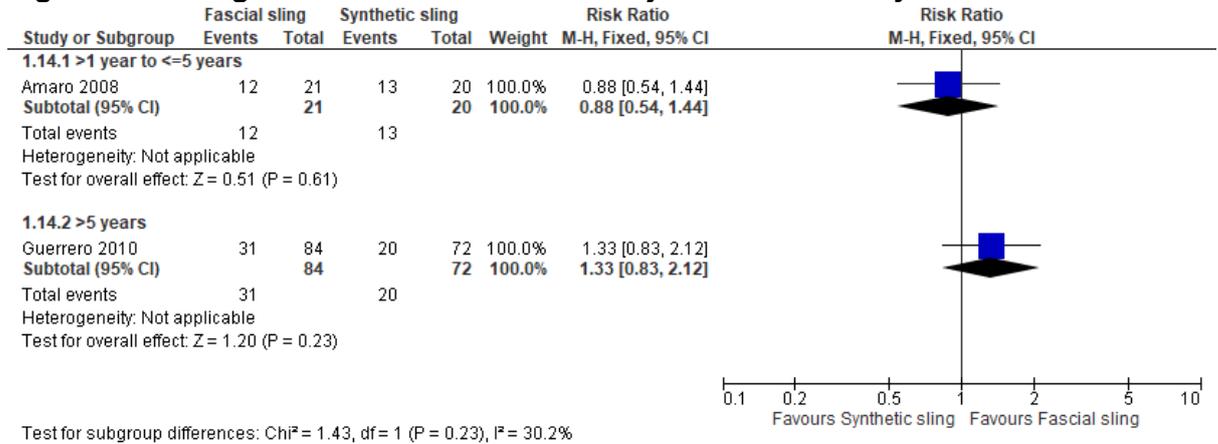
**Figure 26: Complications – Wound complications at ≤1 year after surgery**



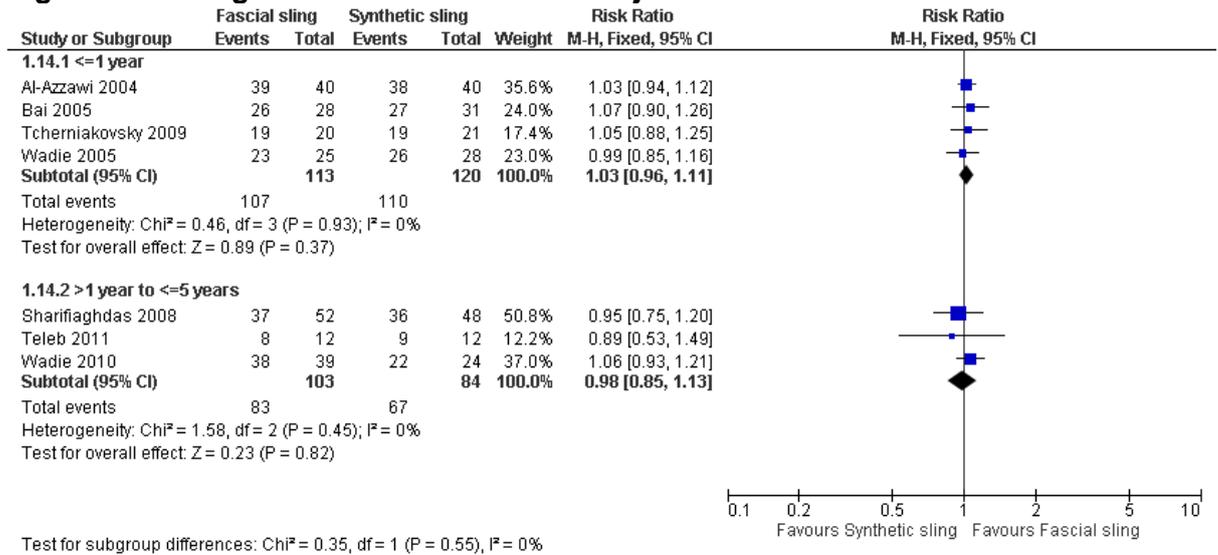
**Figure 27: Change in continence status – Subjective cure at ≤1 year (random effects analysis)**



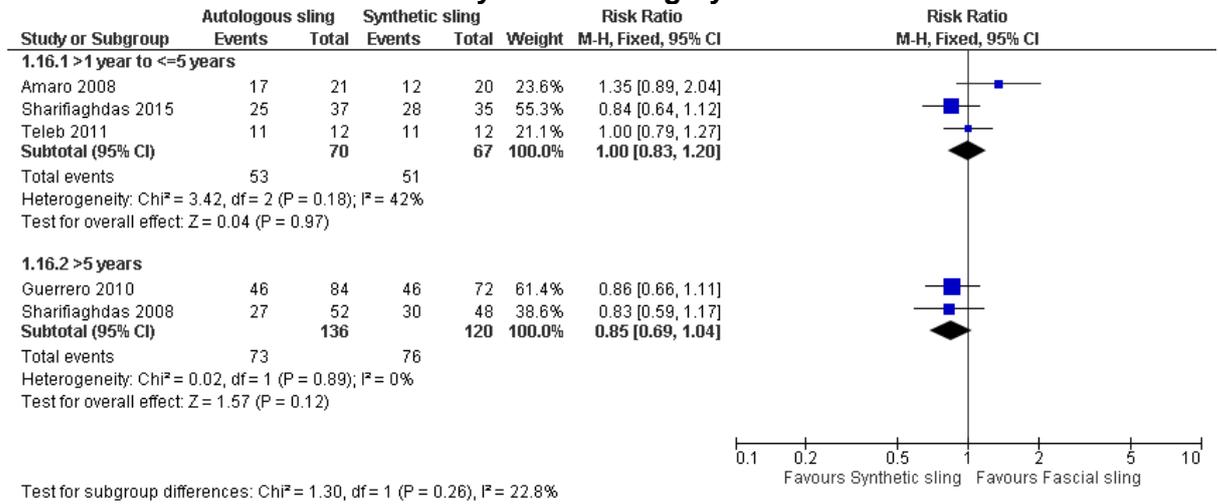
**Figure 28: Change in continence status – Subjective cure at >1 year**



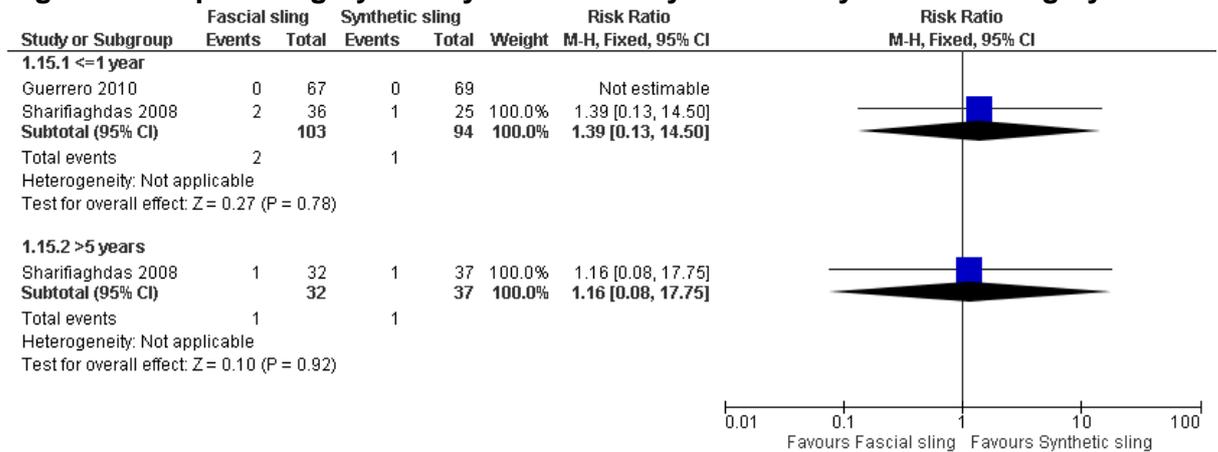
**Figure 29: Change in continence status – Objective cure**



**Figure 30: Patient satisfaction/patient-reported improvement – Improvement in continence status at >1 year after surgery**

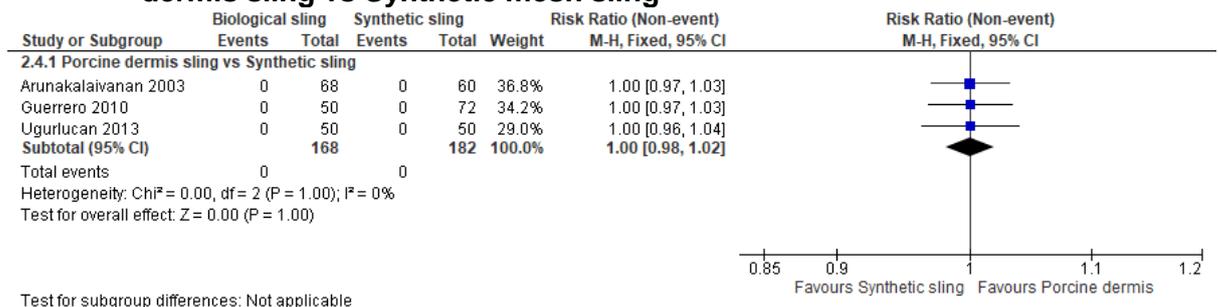


**Figure 31: Repeat surgery for any reason at ≤1 year and >5 years after surgery**



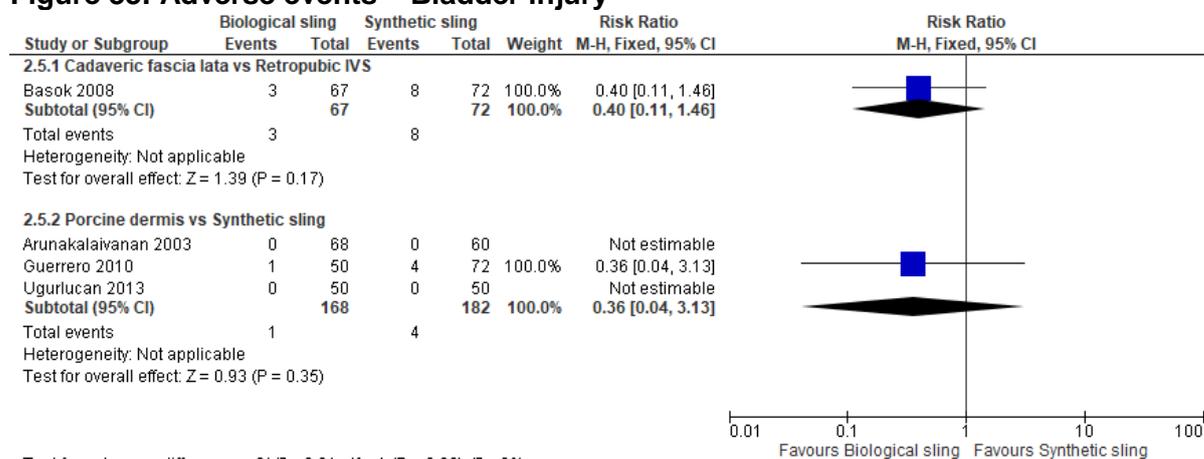
**Non-autologous biological sling versus synthetic mesh sling**

**Figure 32: Adverse events – Severe bleeding requiring blood transfusion – Porcine dermis sling vs Synthetic mesh sling**



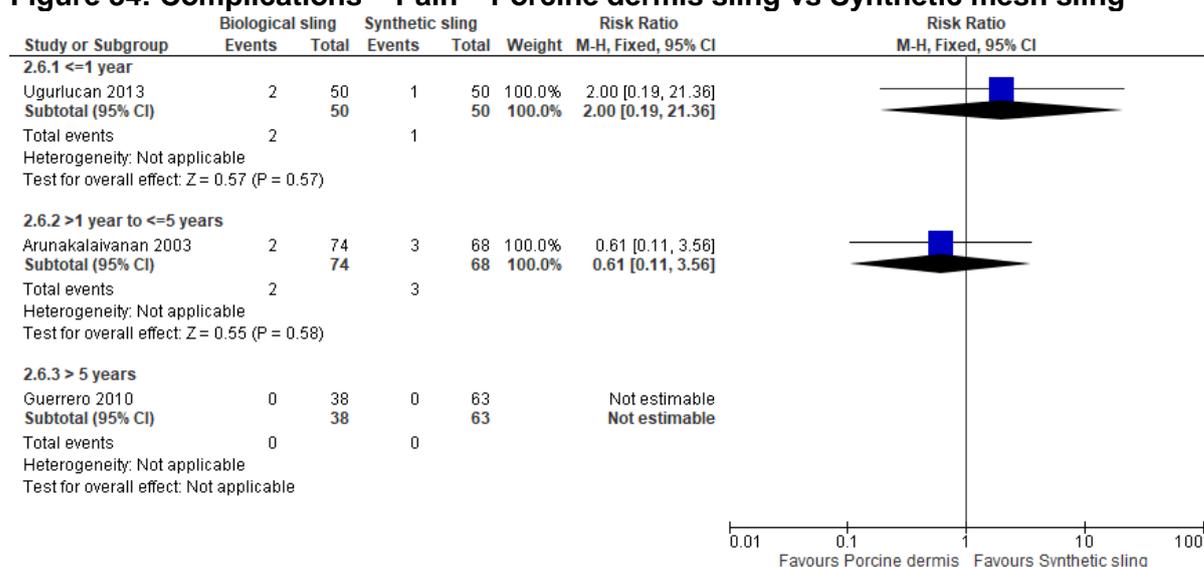
Note: forest plot shows non-events

**Figure 33: Adverse events – Bladder injury**



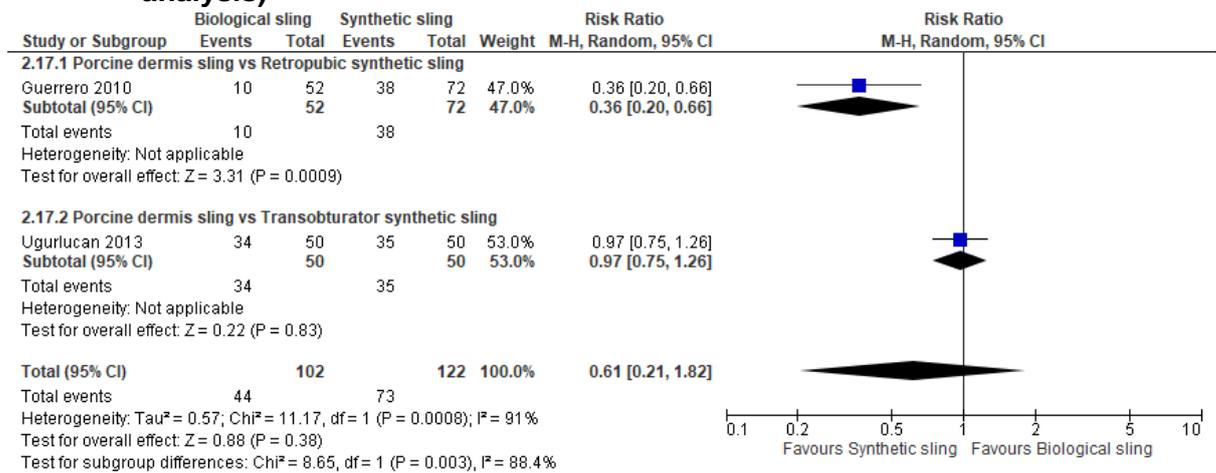
Test for subgroup differences: Chi<sup>2</sup> = 0.01, df = 1 (P = 0.93), I<sup>2</sup> = 0%

**Figure 34: Complications – Pain – Porcine dermis sling vs Synthetic mesh sling**

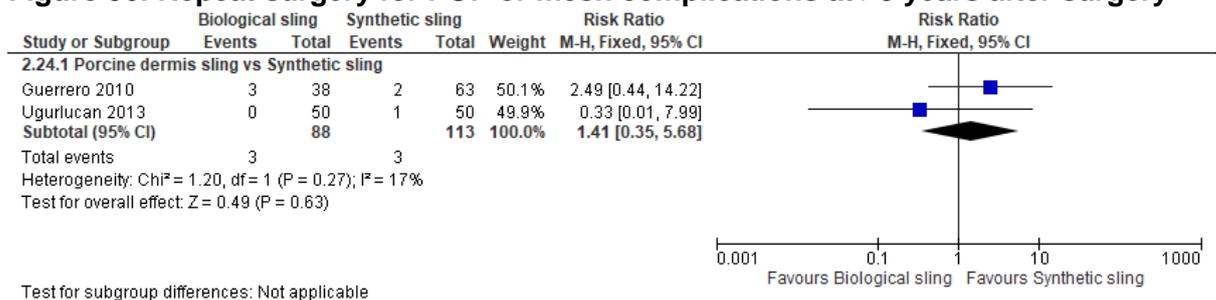


Test for subgroup differences: Chi<sup>2</sup> = 0.62, df = 1 (P = 0.43), I<sup>2</sup> = 0%

**Figure 35: Change in continence status – Subjective cure at ≤1 year (random effects analysis)**

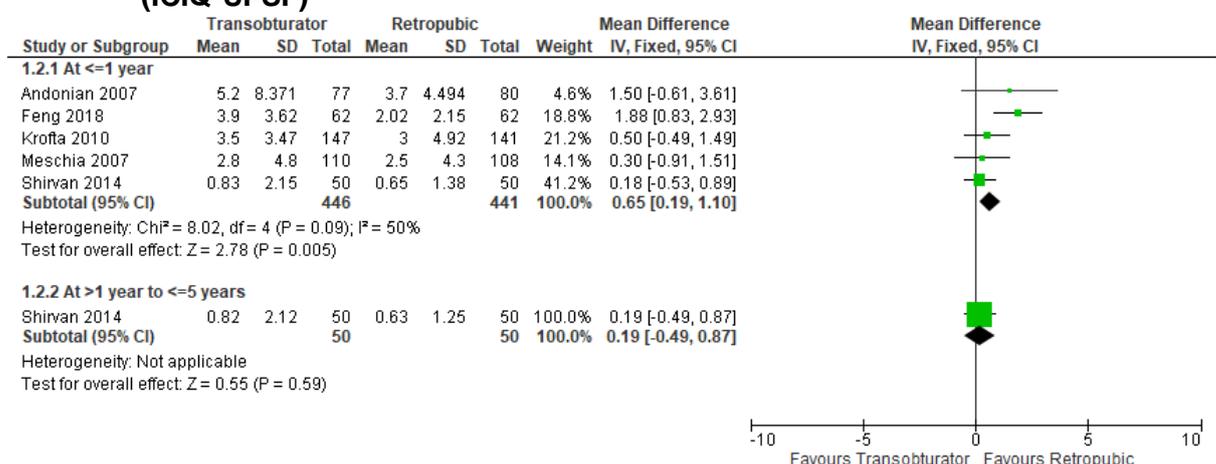


**Figure 36: Repeat surgery for POP or mesh complications at >5 years after surgery**



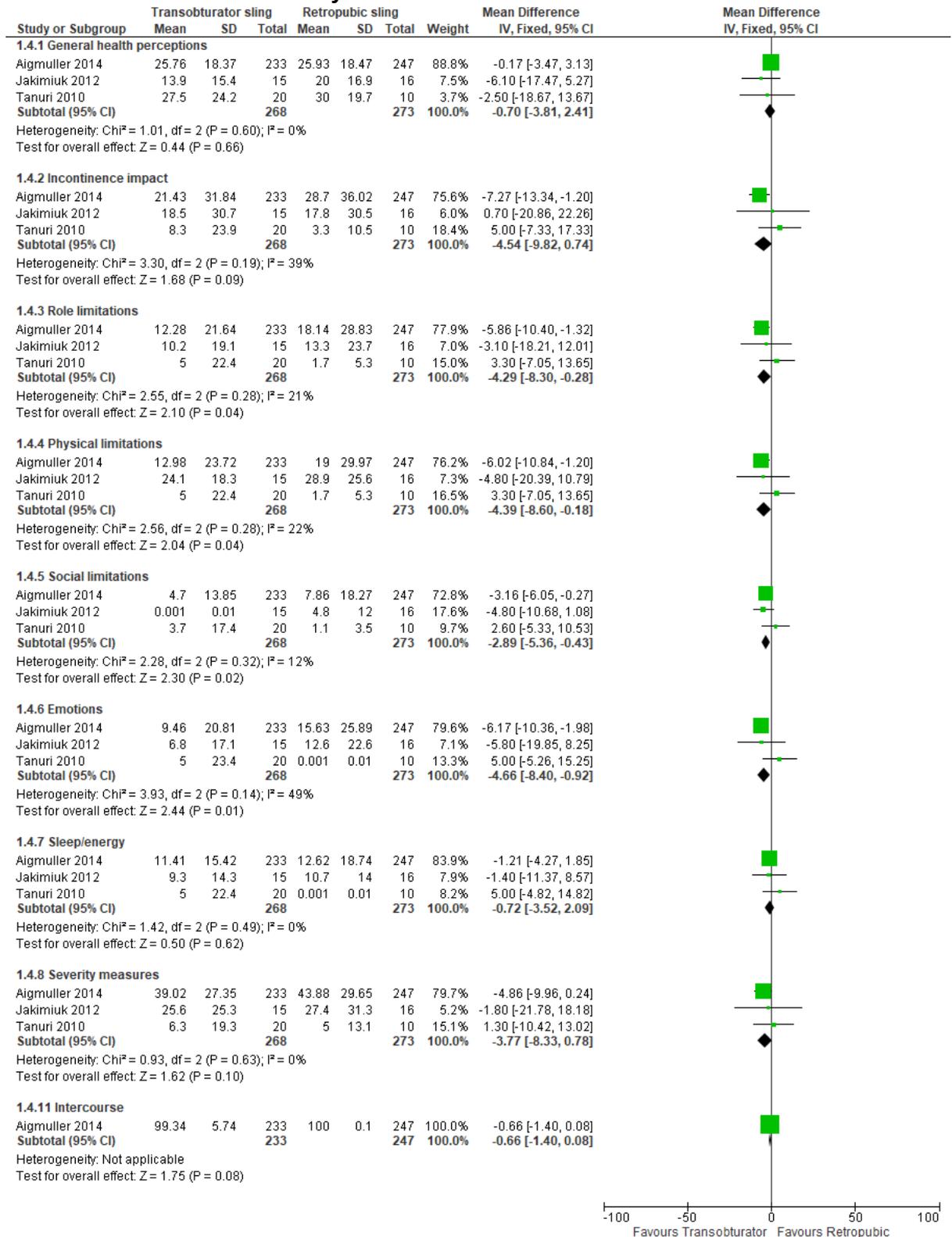
**Transobturator mesh sling versus retropubic mesh sling**

**Figure 37: Continence-specific health-related quality of life – International Consultation on Incontinence Questionnaire-Urinary Incontinence Form (ICIQ-UI-SF)**



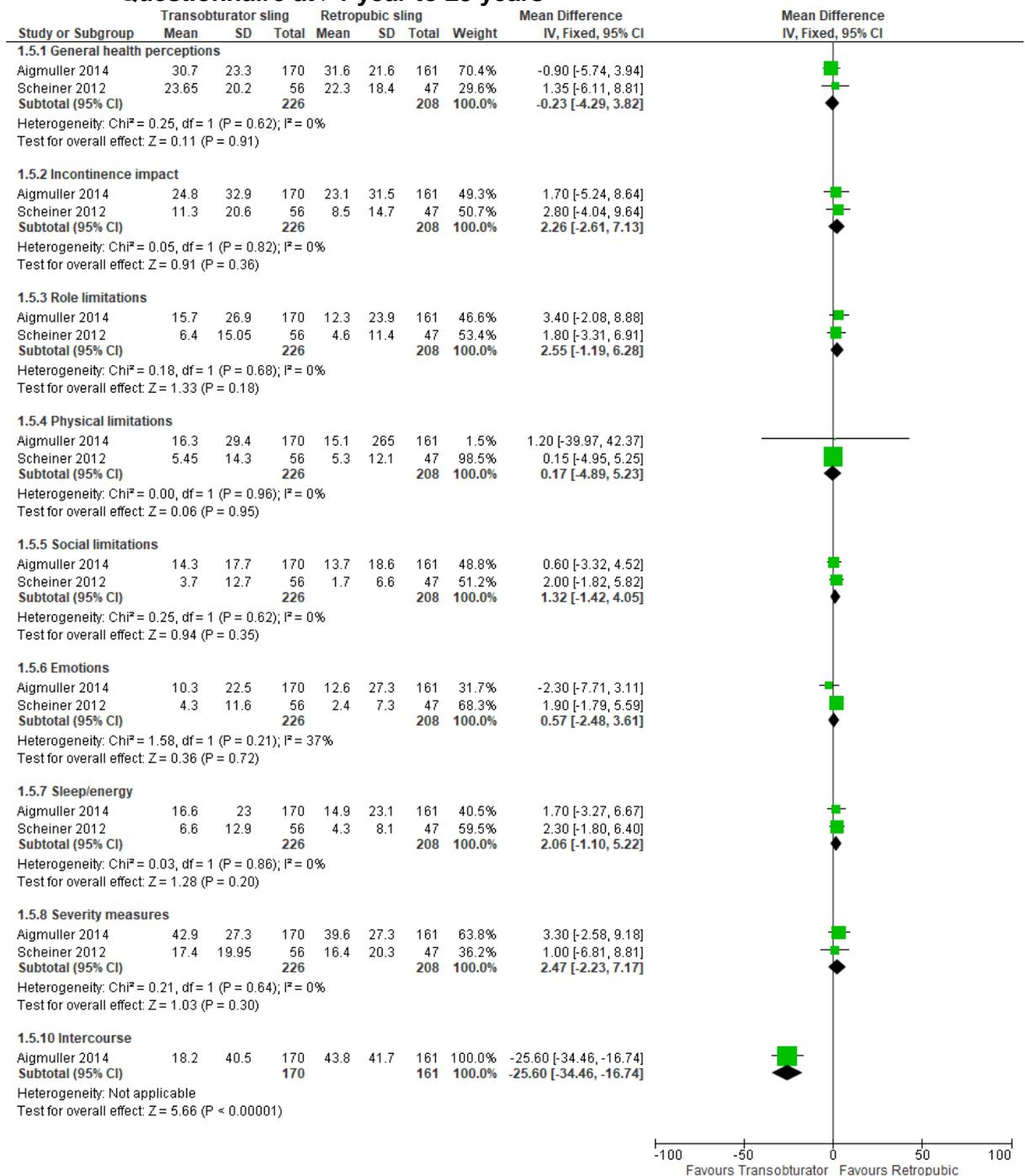


**Figure 38: Continence-specific health-related quality of life: King's Health Questionnaire at ≤1 year**



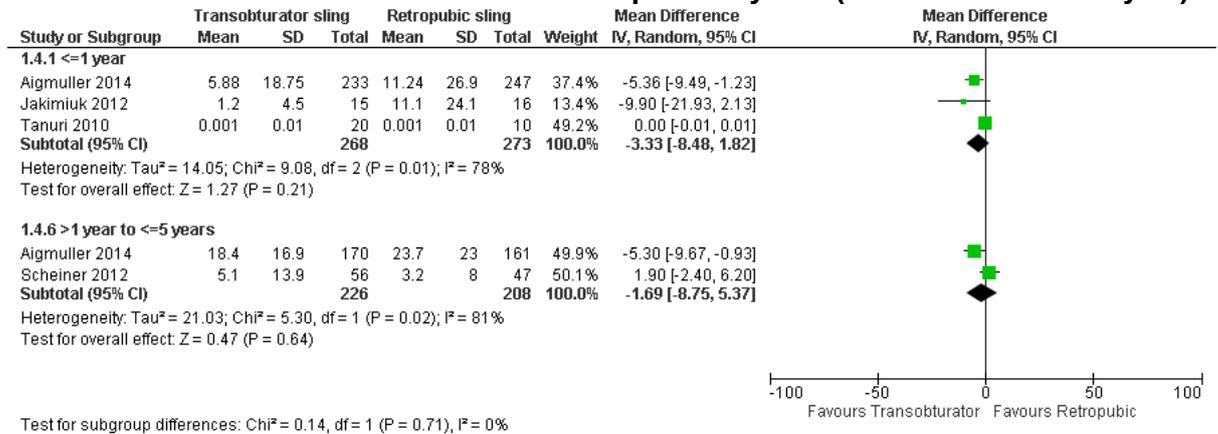
Note: Forest plot does not include personal relationships subscale (see below).

**Figure 39: Continence-specific health-related quality of life: King's Health Questionnaire at >1 year to ≤5 years**

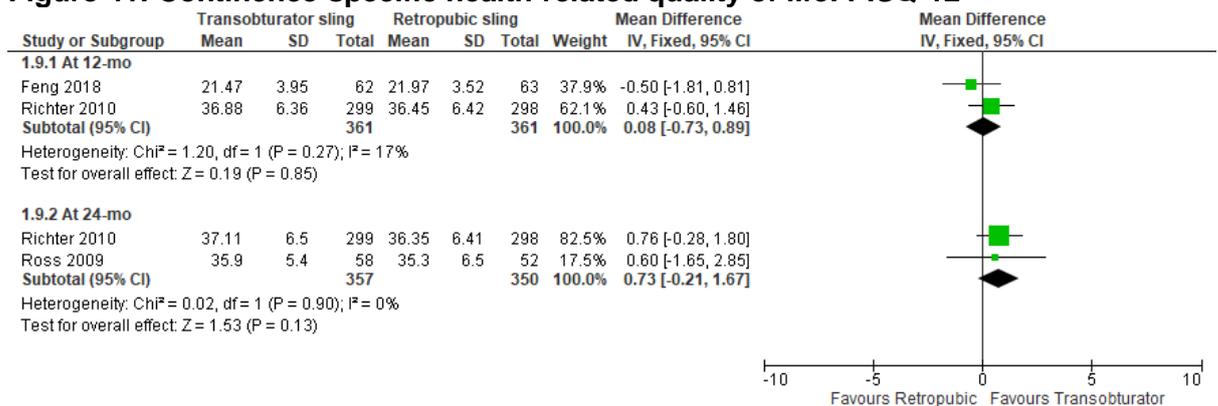


Note: For personal relationships subscale, see next forest plot.

**Figure 40: Continence-specific health-related quality of life: King's Health Questionnaire-Personal relationships at ≤5 years (random effects analysis)**

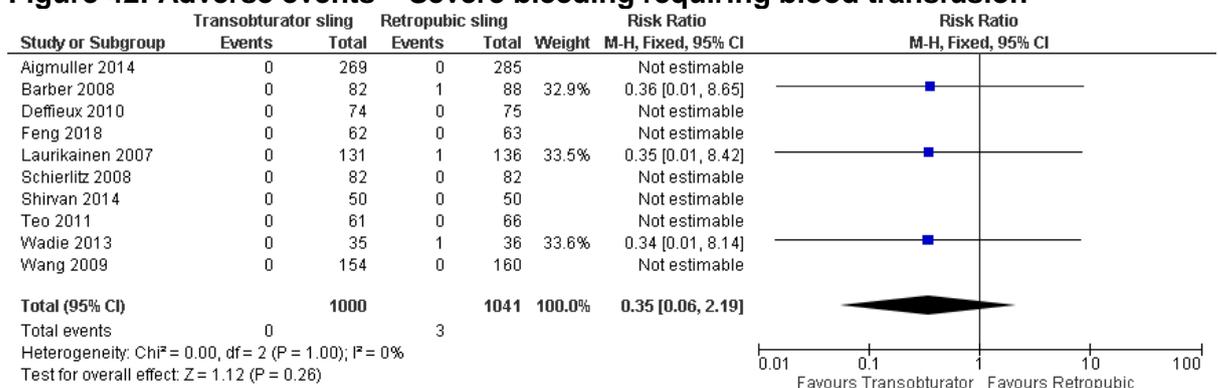


**Figure 41: Continence-specific health-related quality of life: PISQ-12**

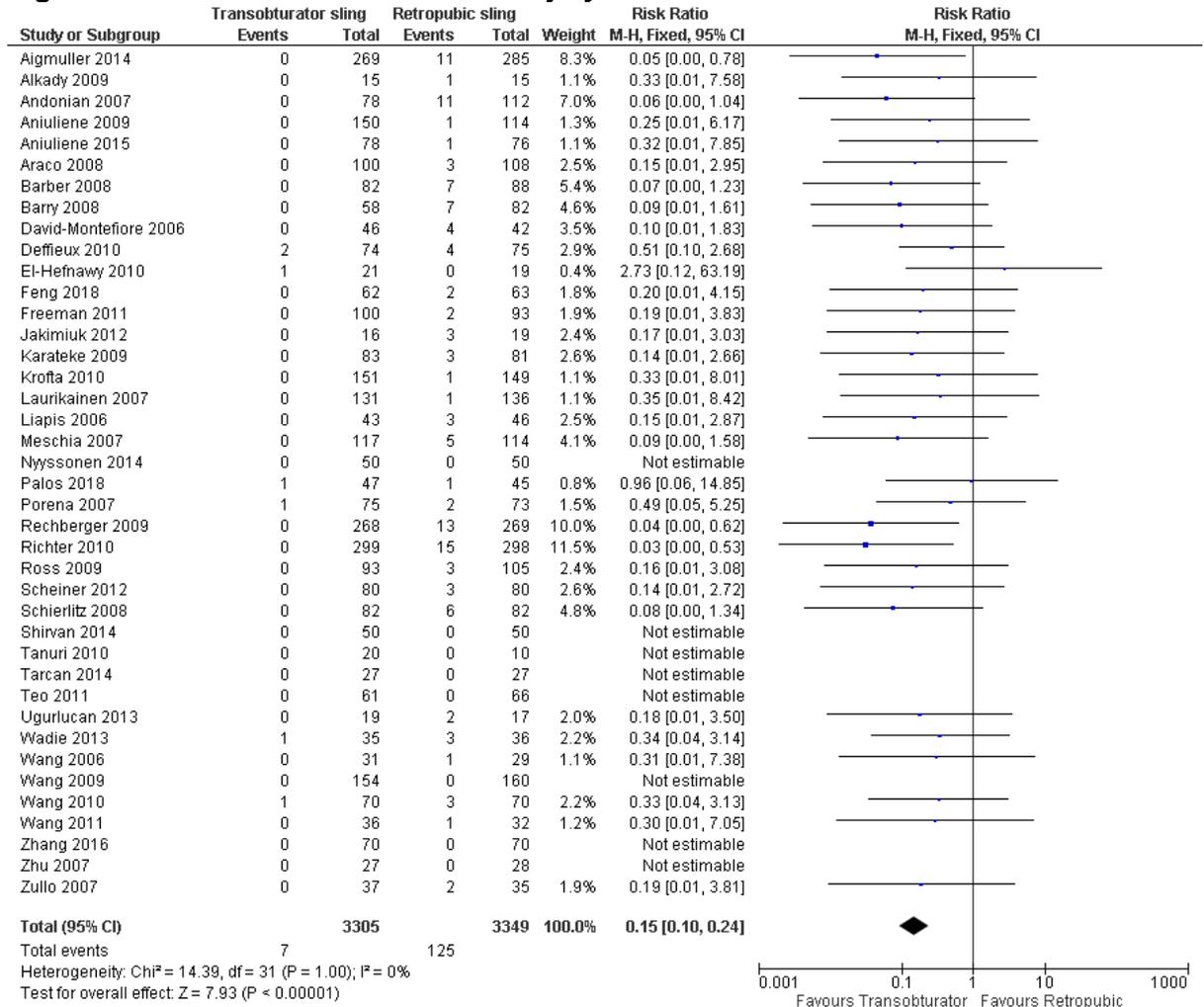


Abbreviations: PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire.

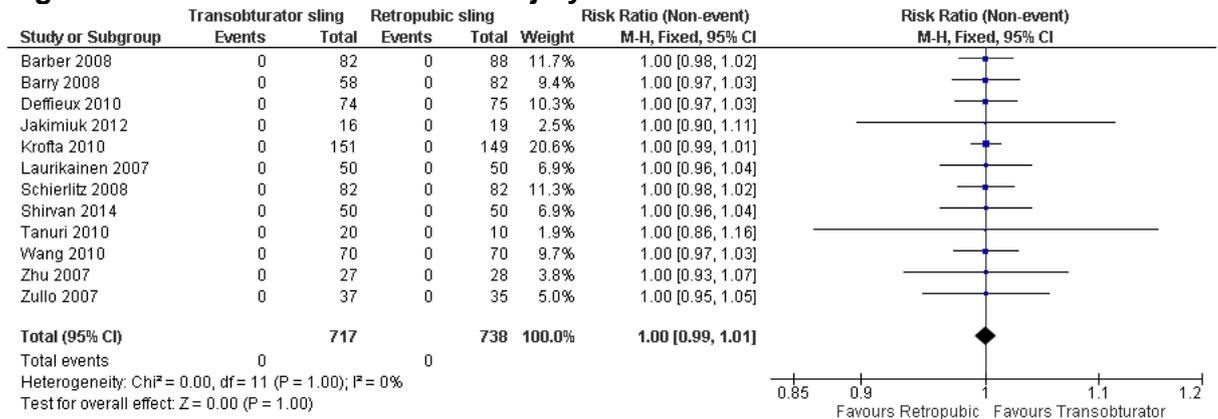
**Figure 42: Adverse events – Severe bleeding requiring blood transfusion**



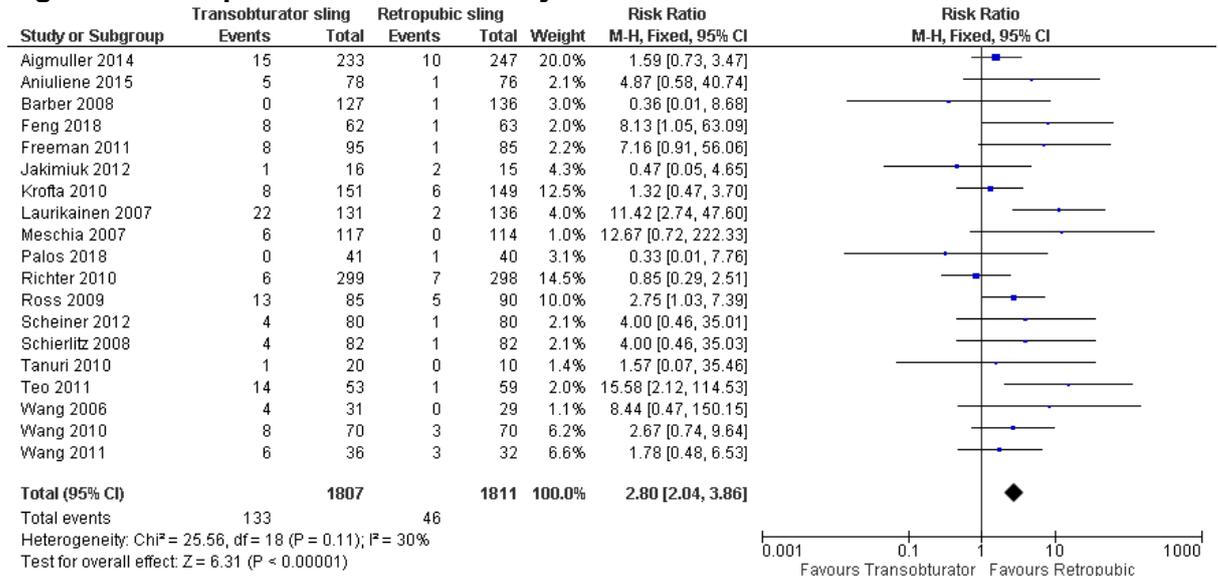
**Figure 43: Adverse events – Bladder injury**



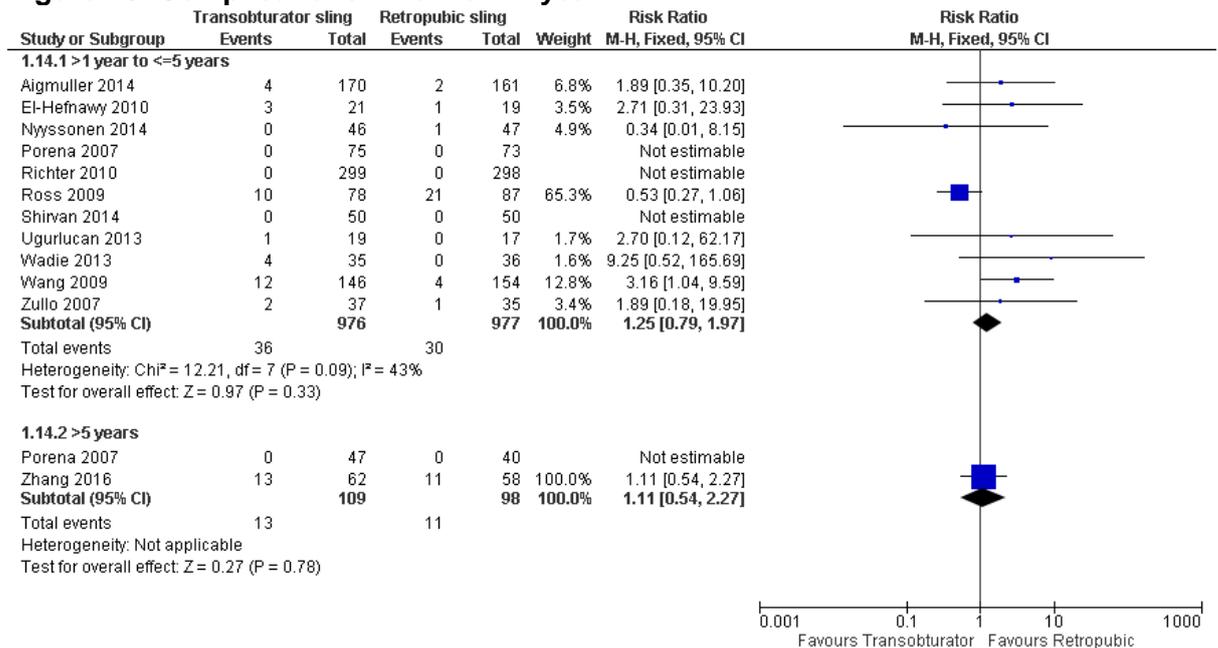
**Figure 44: Adverse events – Bowel injury**



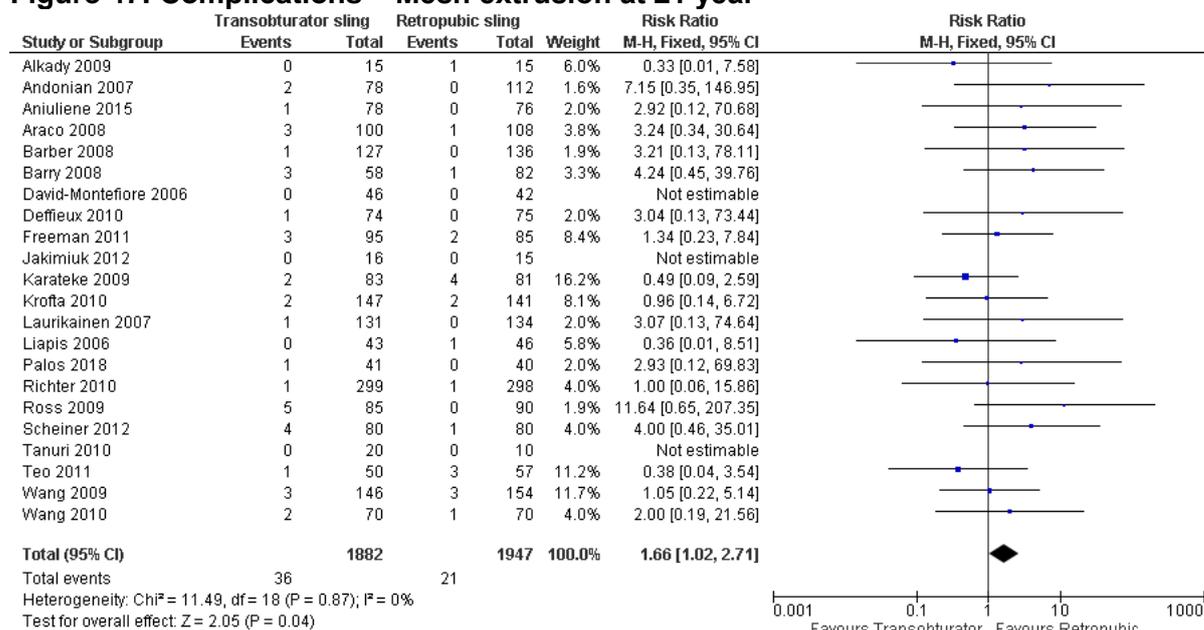
**Figure 45: Complications – Pain at ≤1 year**



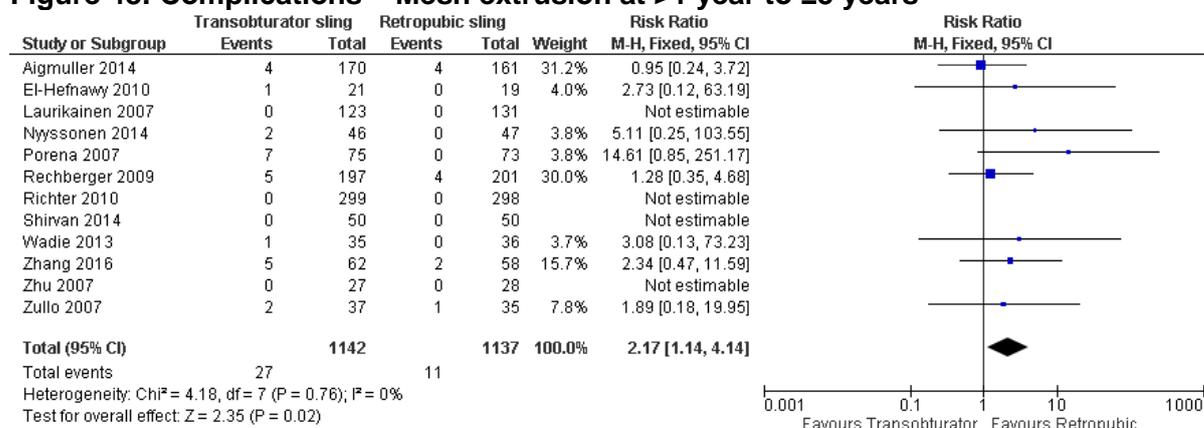
**Figure 46: Complications – Pain at >1 year**



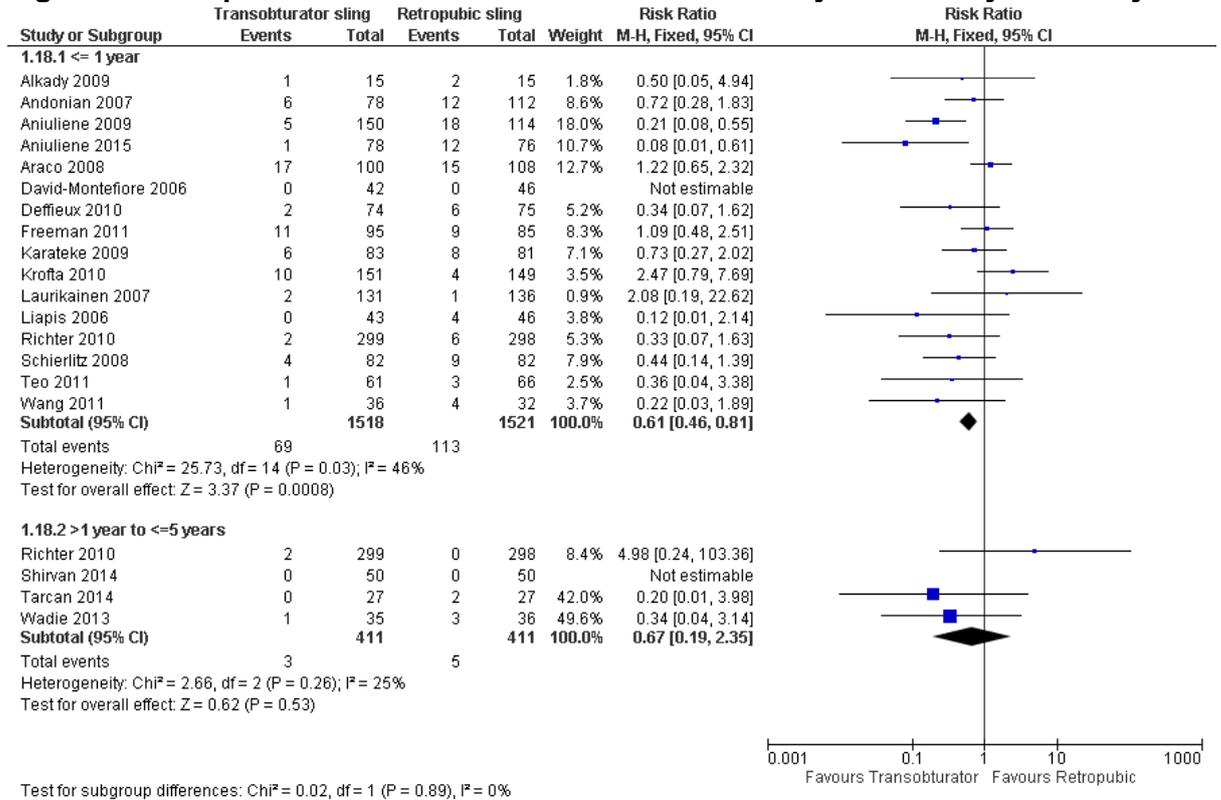
**Figure 47: Complications – Mesh extrusion at ≤1 year**



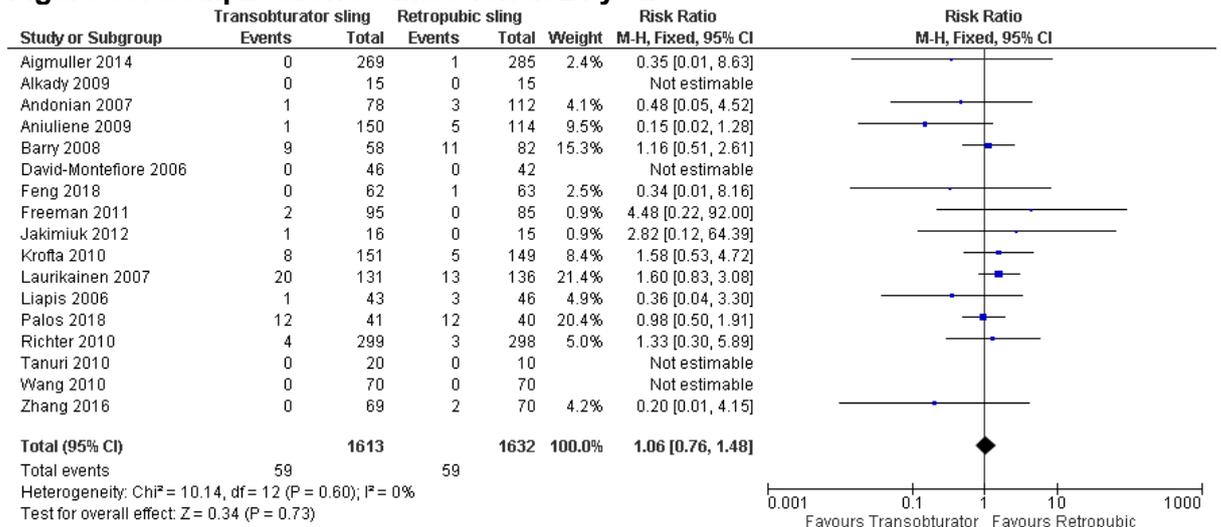
**Figure 48: Complications – Mesh extrusion at >1 year to ≤5 years**



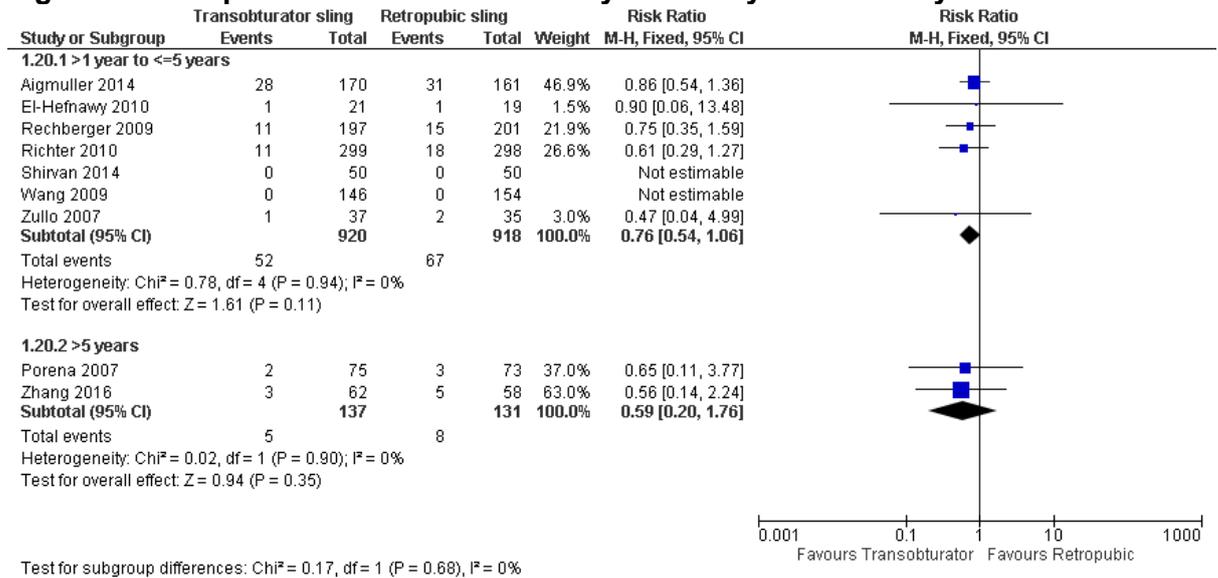
**Figure 49: Complications – Need for catheterisation at ≤1 year and >1 year to ≤5 years**



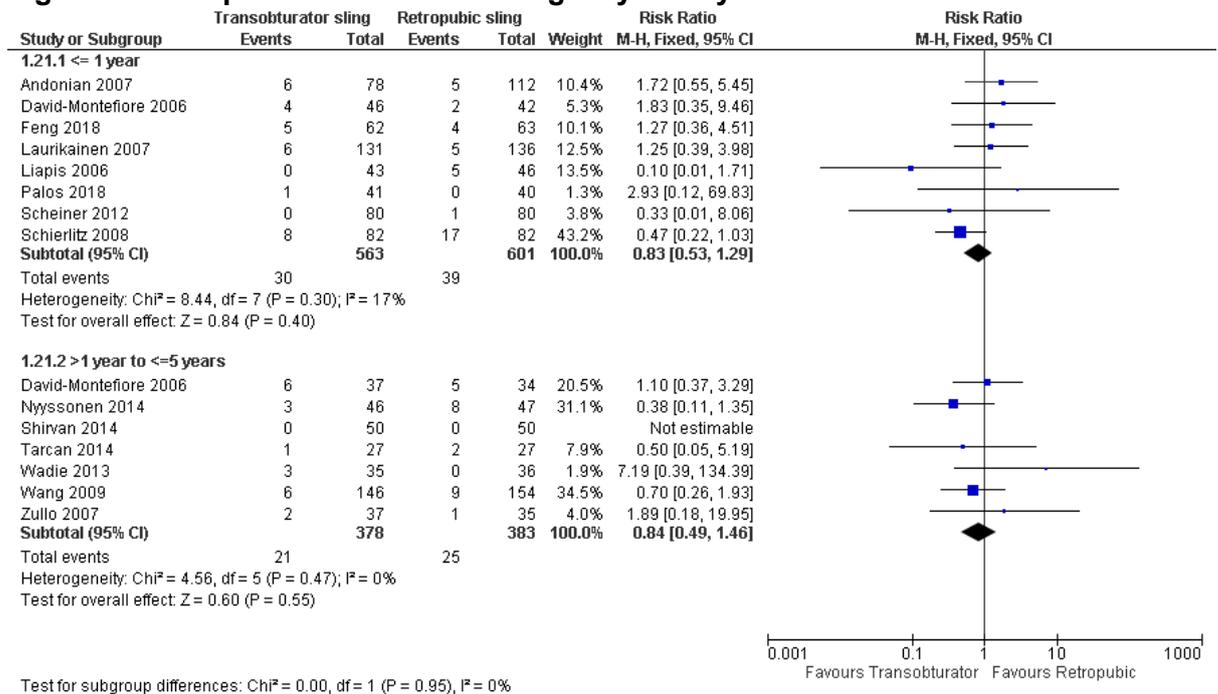
**Figure 50: Complications – Infection at ≤1 year**



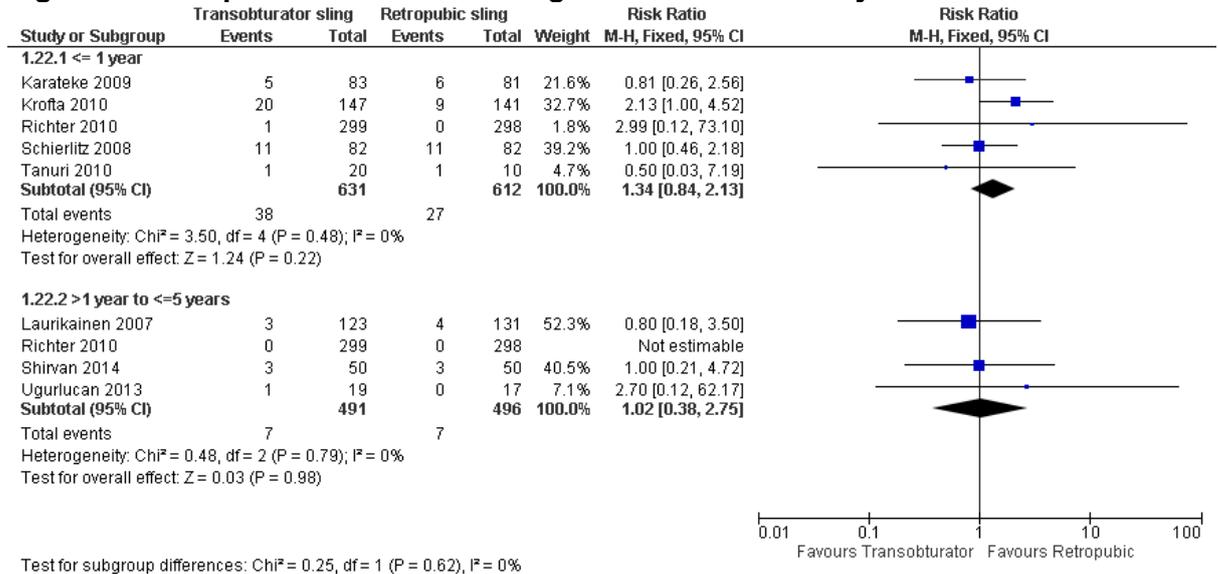
**Figure 51: Complications – Infection at >1 year to ≤5 years and >5 years**



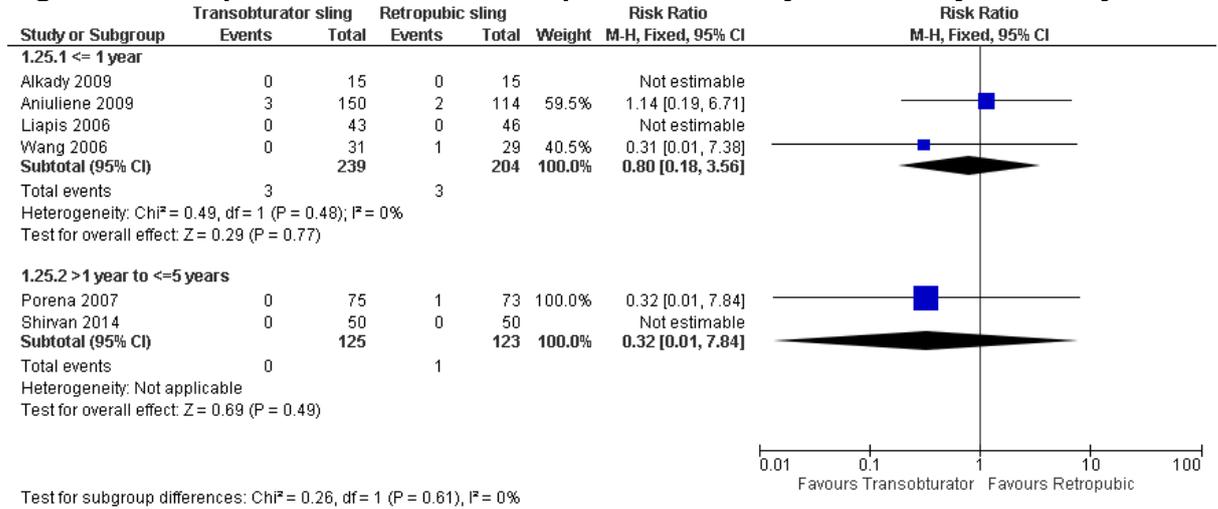
**Figure 52: Complications – De novo urgency at ≤5 years**



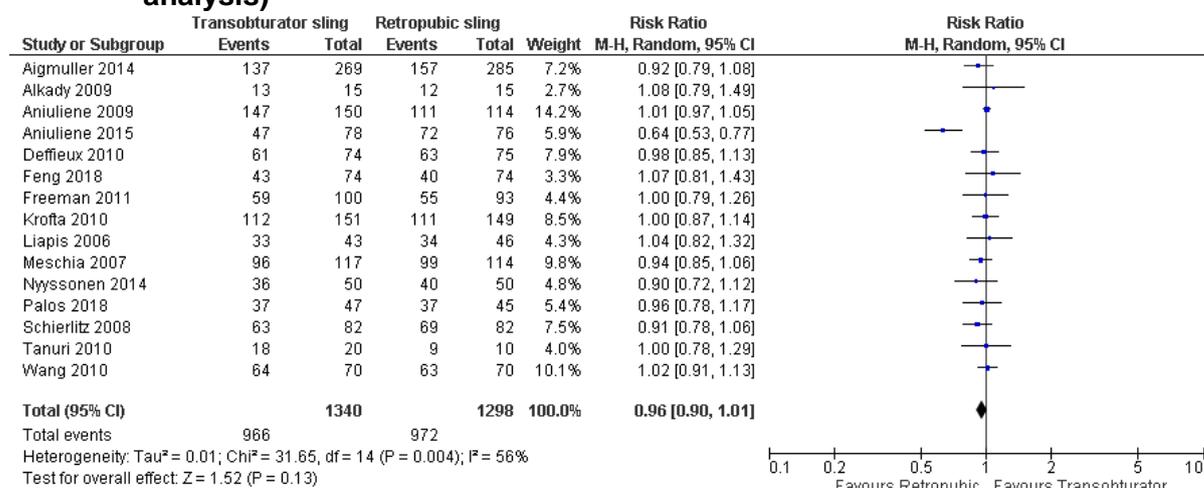
**Figure 53: Complications – De novo urge incontinence at ≤5 years**



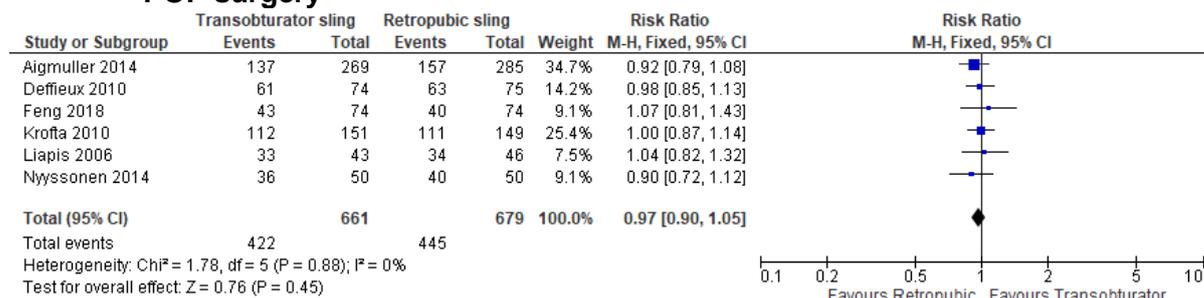
**Figure 54: Complications – Wound complications at ≤1 year and >1 year to ≤5 years**



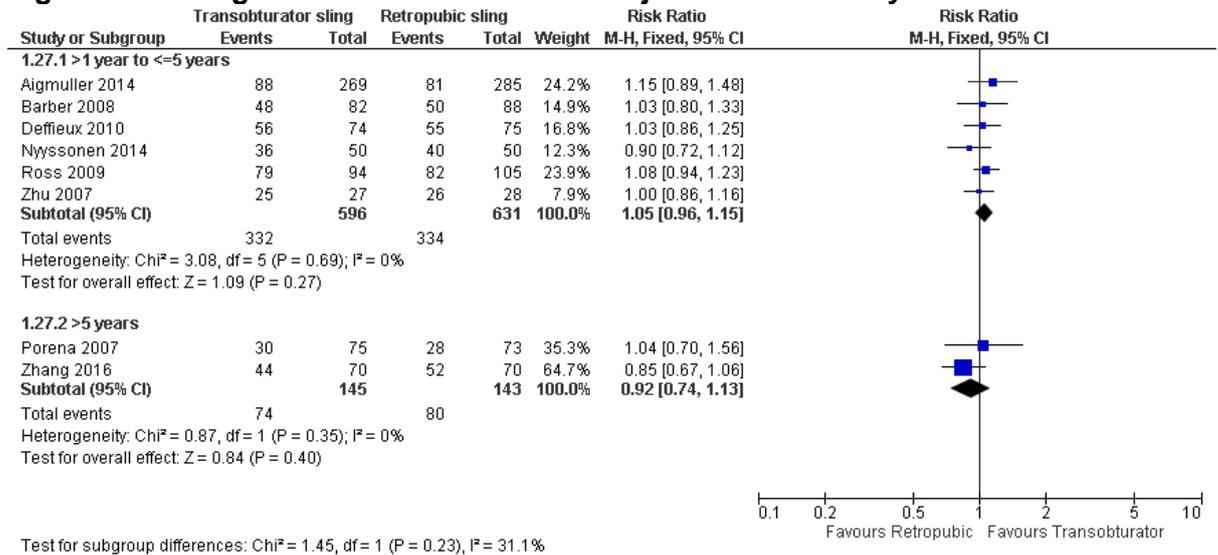
**Figure 55: Change in continence status – Subjective cure at ≤1 year (random effects analysis)**



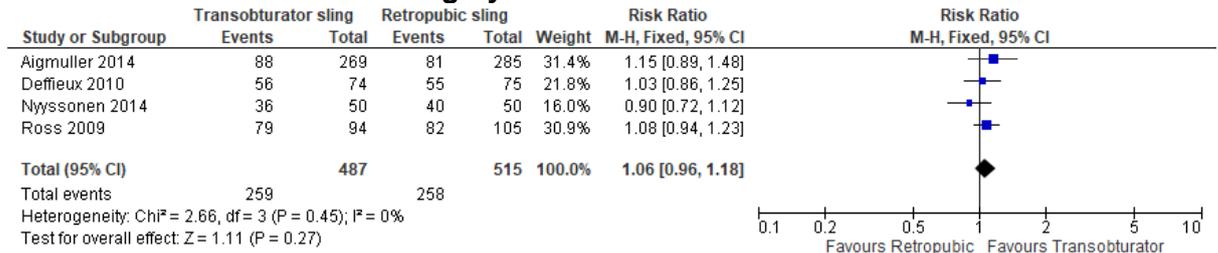
**Figure 56: Change in continence status – Subjective cure at ≤1 year: No concomitant POP surgery**



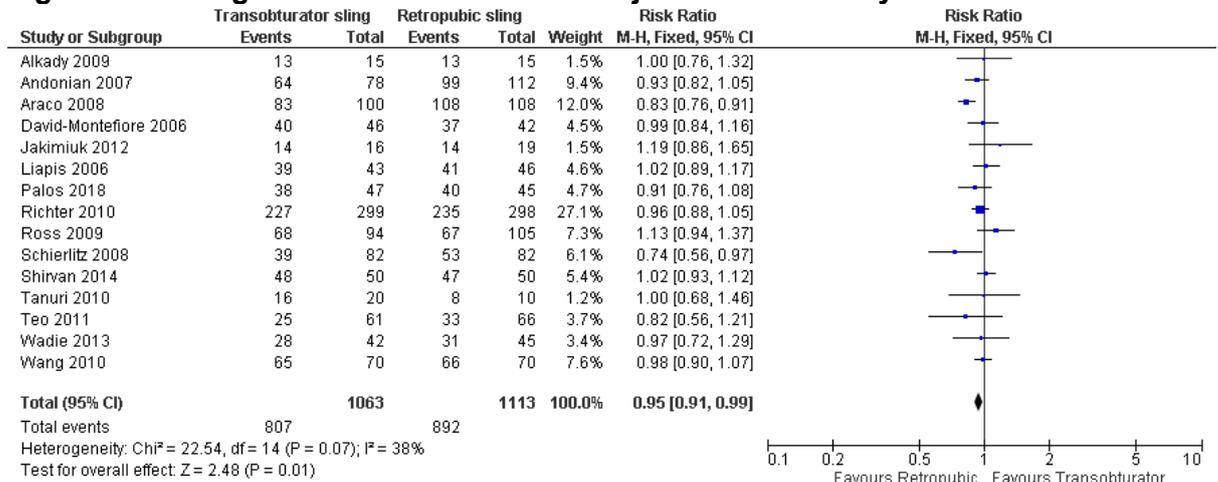
**Figure 57: Change in continence status - Subjective cure at >1 year**



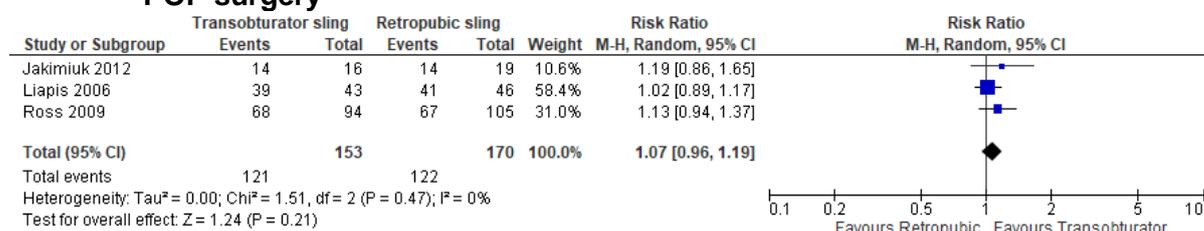
**Figure 58: Change in continence status - Subjective cure at >1 year to ≤5 years: No concomitant POP surgery**



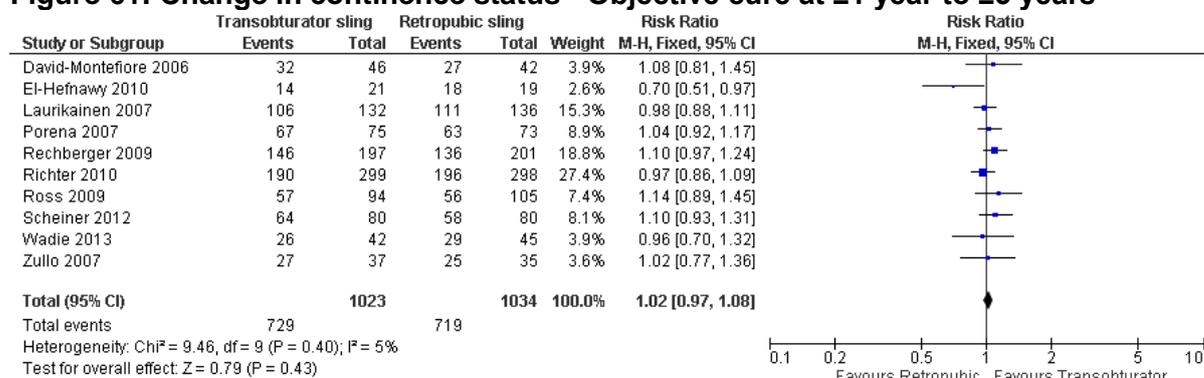
**Figure 59: Change in continence status – Objective cure at ≤1 year**



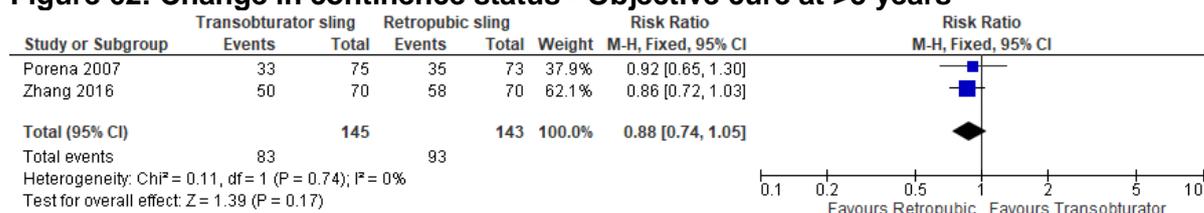
**Figure 60: Change in continence status – Objective cure at ≤1 year: No concomitant POP surgery**



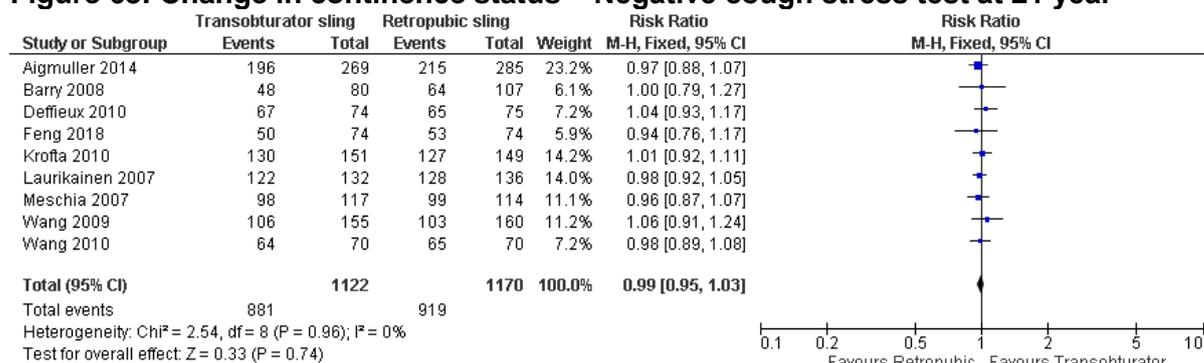
**Figure 61: Change in continence status - Objective cure at ≤1 year to ≤5 years**



**Figure 62: Change in continence status - Objective cure at >5 years**



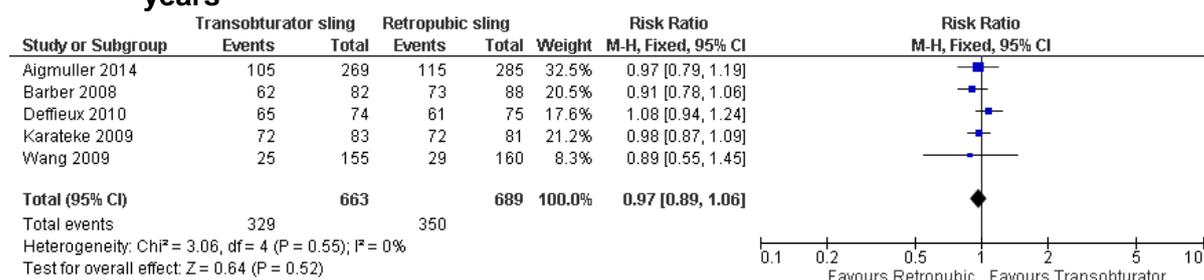
**Figure 63: Change in continence status – Negative cough stress test at ≤1 year**



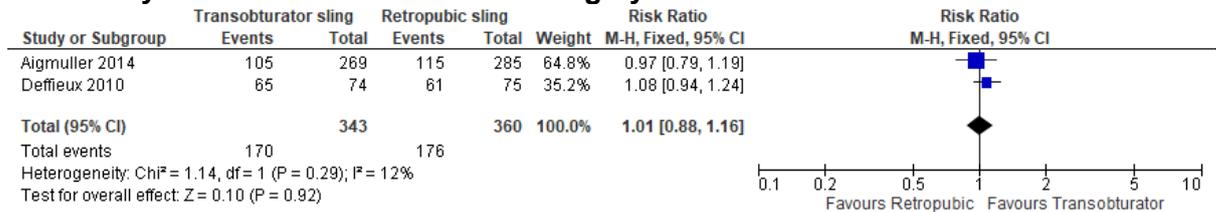
**Figure 64: Change in continence status – Negative cough stress test at ≤1 year: No concomitant POP surgery**



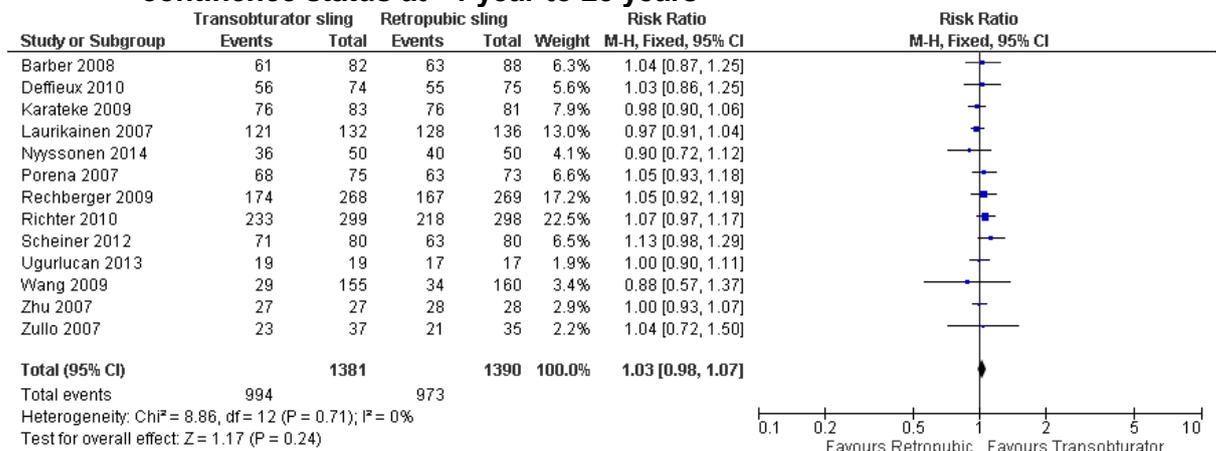
**Figure 65: Change in continence status - Negative cough stress test at >1 year to ≤5 years**



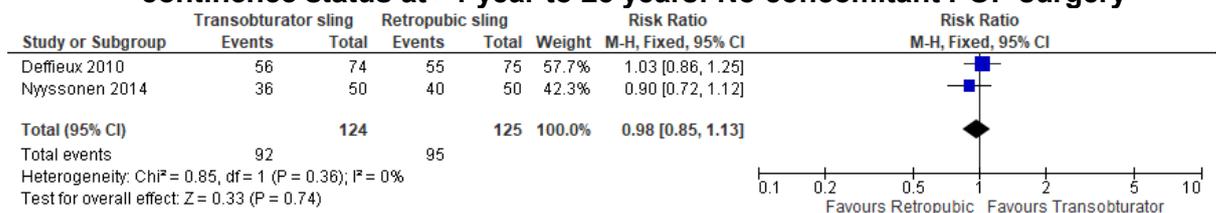
**Figure 66: Change in continence status - Negative cough stress test at >1 year to ≤5 years: No concomitant POP surgery**



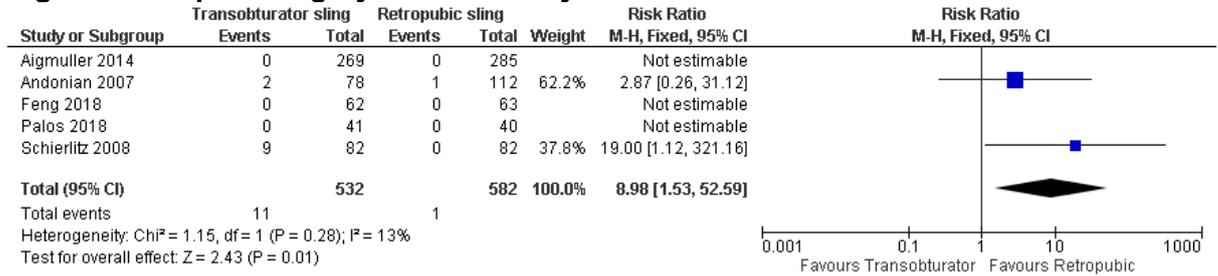
**Figure 67: Patient satisfaction/patient-report improvement – Improvement in continence status at >1 year to ≤5 years**



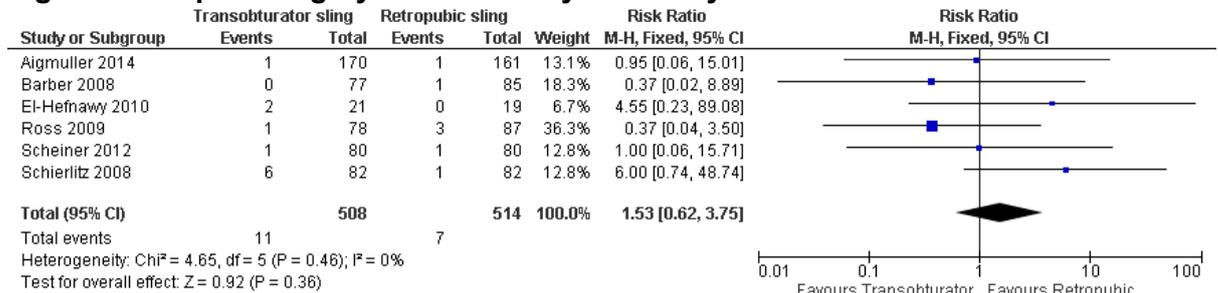
**Figure 68: Patient satisfaction/patient-report improvement – Improvement in continence status at >1 year to ≤5 years: No concomitant POP surgery**



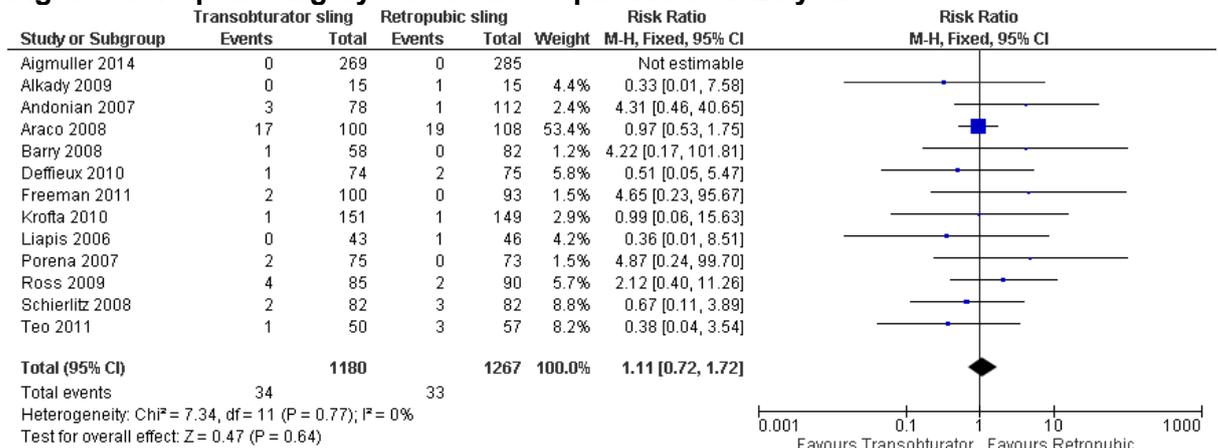
**Figure 69: Repeat surgery for SUI at ≤1 year**



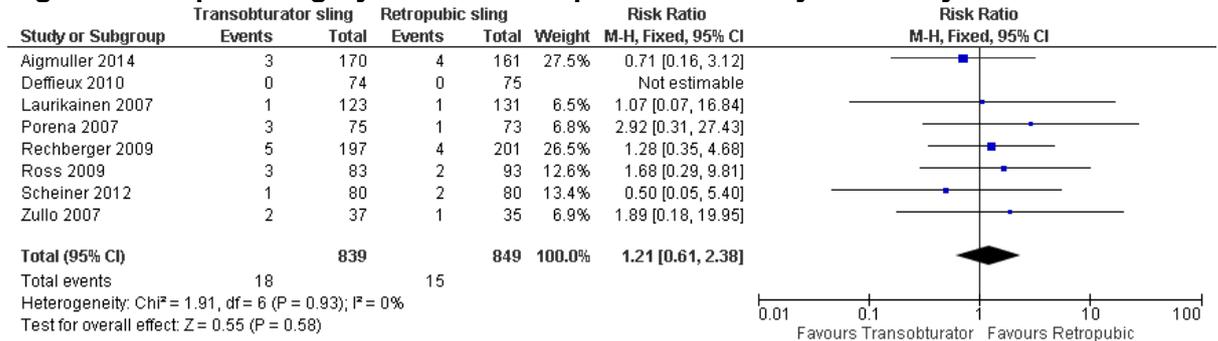
**Figure 70: Repeat surgery for SUI at >1 year to ≤5 years**



**Figure 71: Repeat surgery for mesh complications at ≤1 year**

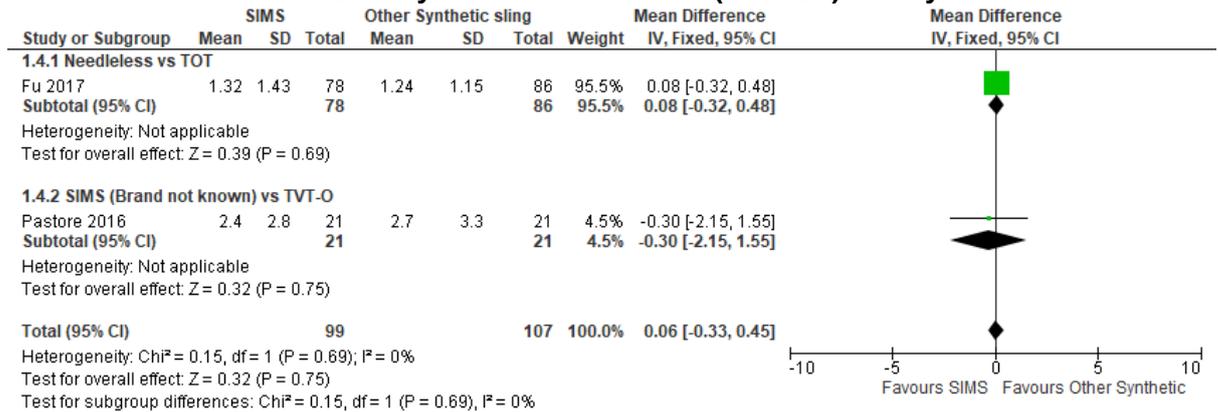


**Figure 72: Repeat surgery for mesh complications at >1 year to ≤5 years**

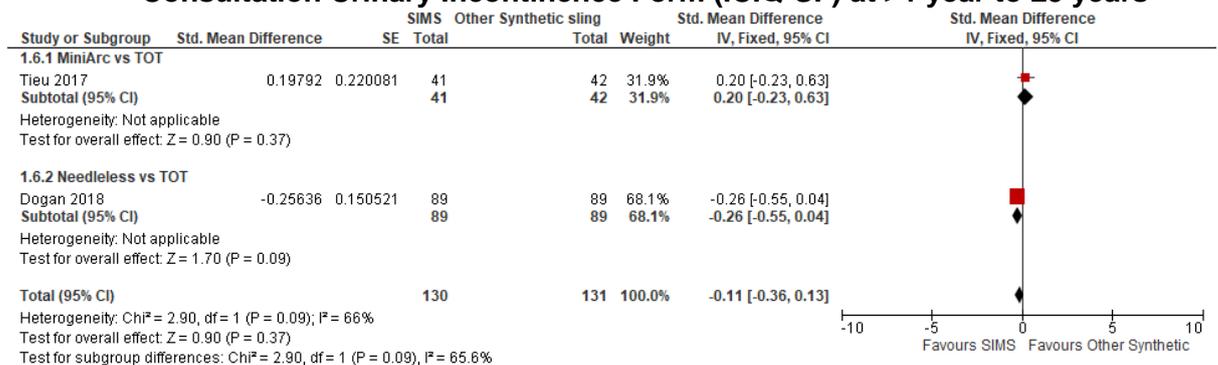


**Single-incision mini-sling versus other synthetic mesh sling**

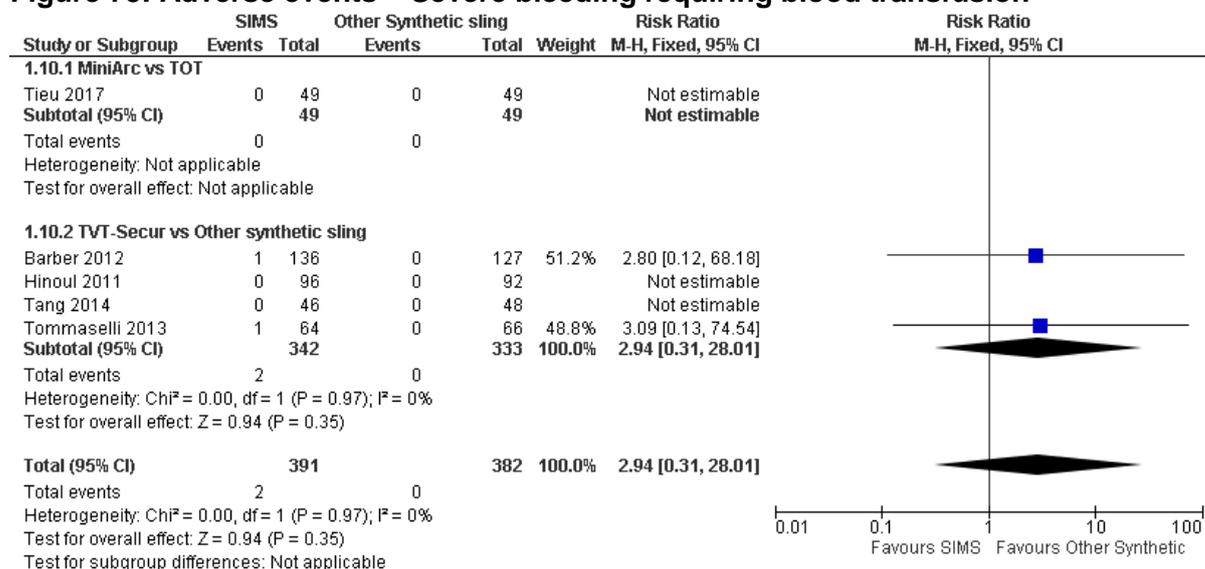
**Figure 73: Continence-specific health-related quality of life – International Consultation Urinary Incontinence Form (ICIQ-SF) at ≤1 year**



**Figure 74: Continence-specific health-related quality of life – International Consultation Urinary Incontinence Form (ICIQ-SF) at >1 year to ≤5 years**

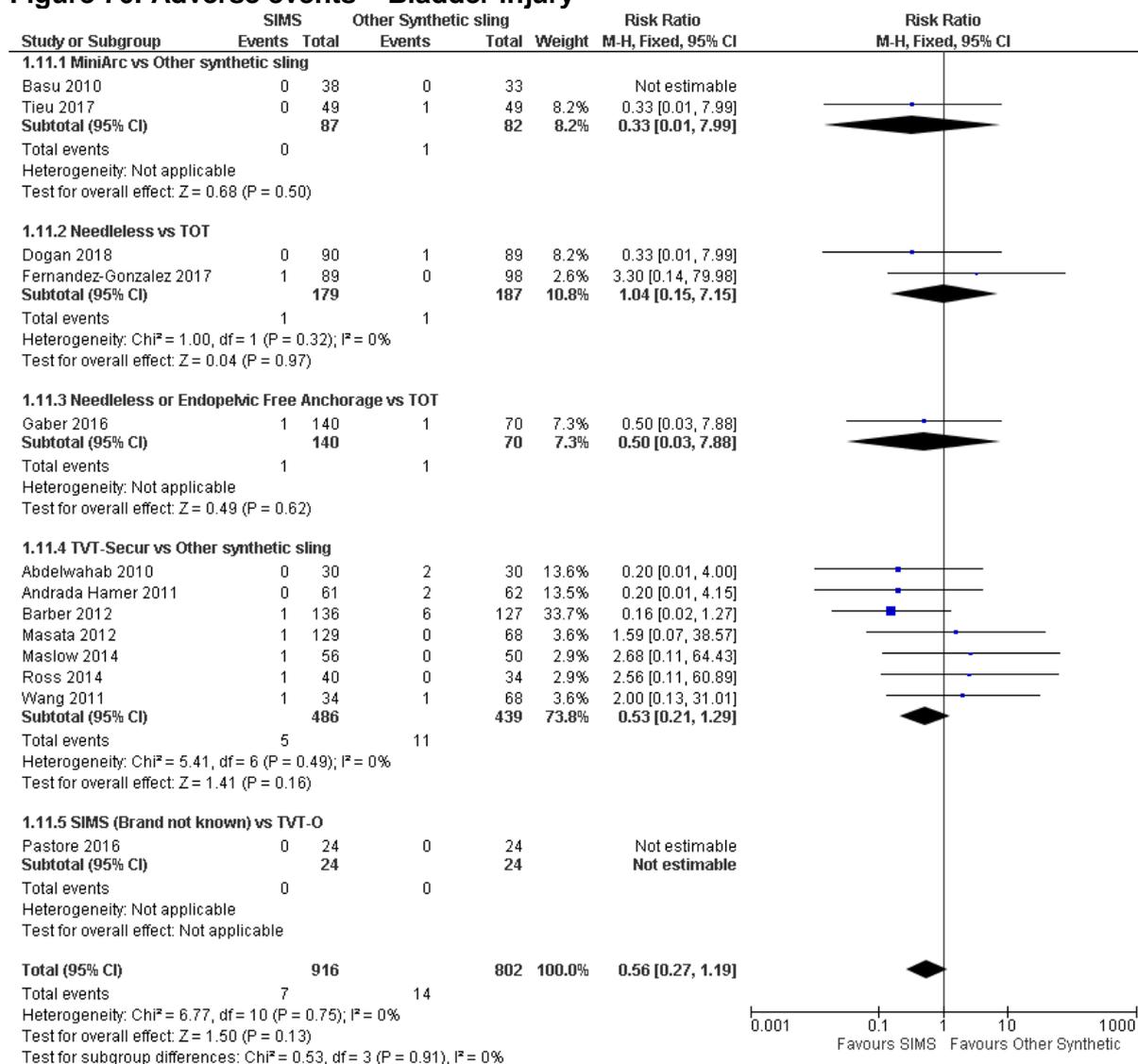


**Figure 75: Adverse events – Severe bleeding requiring blood transfusion**



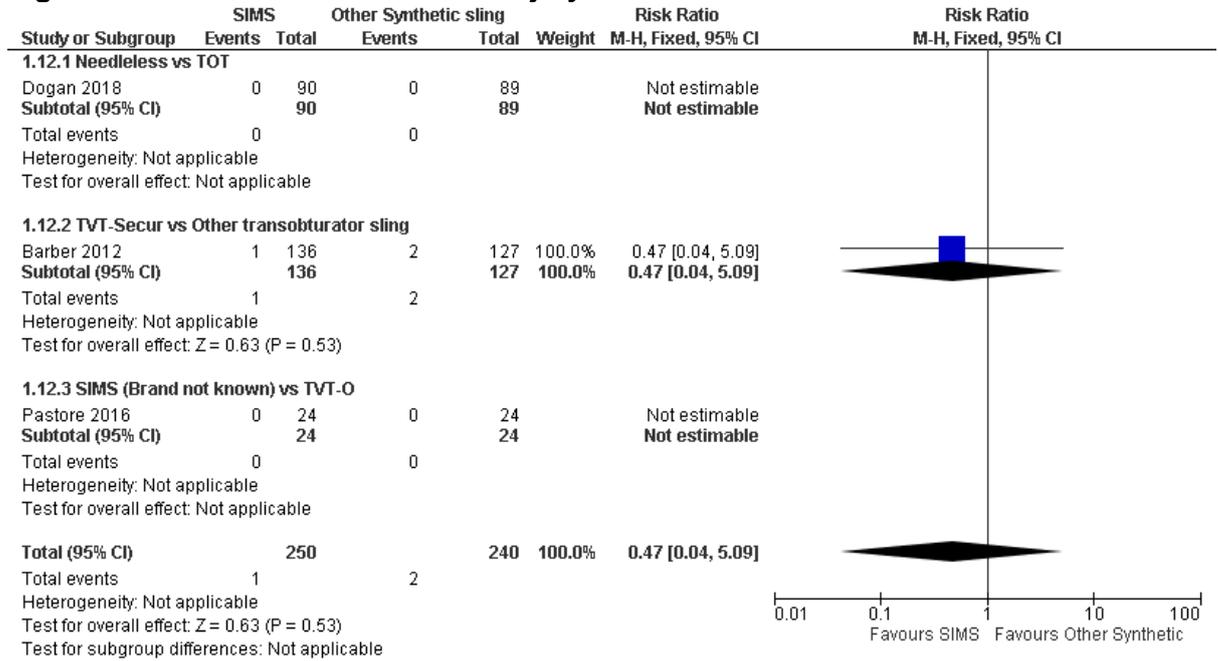
Abbreviations: SIMS, single-incision mini-sling.

**Figure 76: Adverse events – Bladder injury**



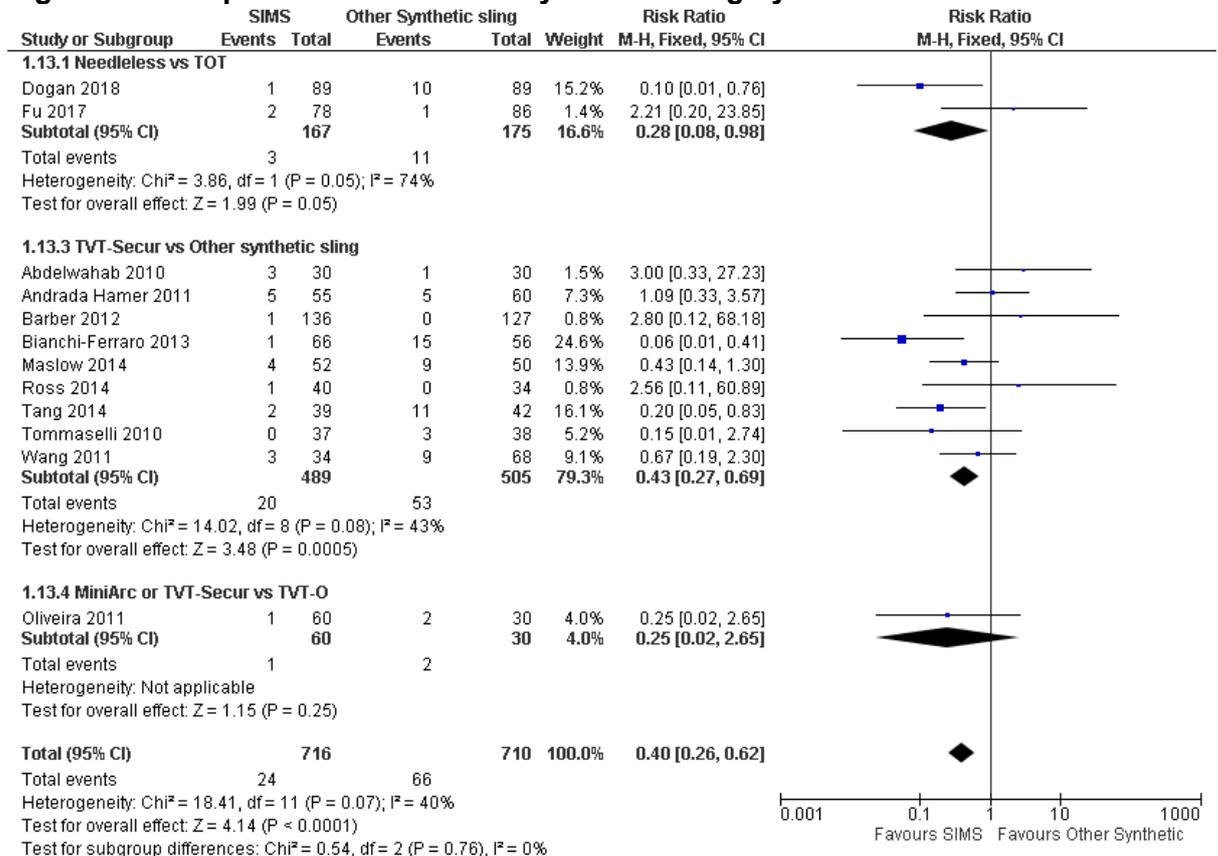
Abbreviations: NDL, Needleless; EFA, Endopelvic Free Anchorage; SIMS, single-incision mini-sling.

**Figure 77: Adverse events – Bowel injury**



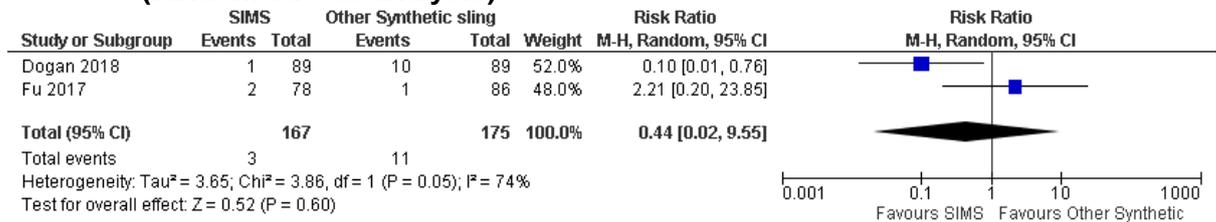
Abbreviations: SIMS, single-incision mini-sling.

**Figure 78: Complications – Pain at ≤1 year after surgery**



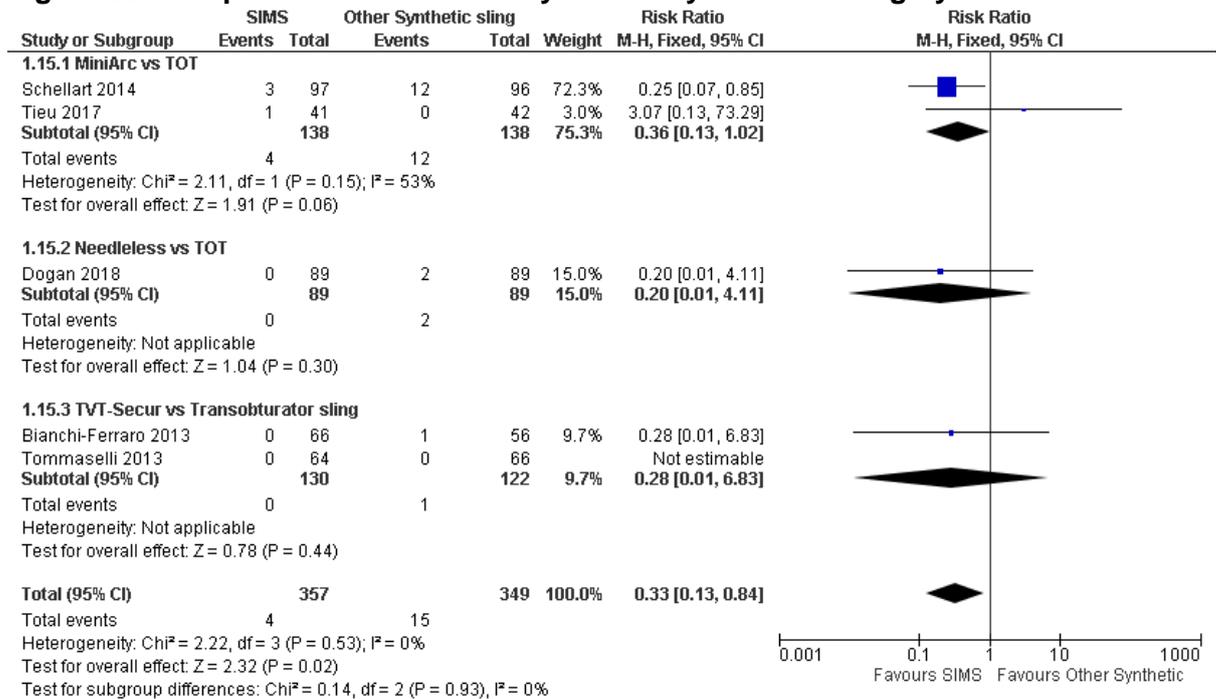
Abbreviations: SIMS, single-incision mini-sling;

**Figure 79: Complications – Pain for Needleless vs TOT at ≤1 year after surgery (random effects analysis)**



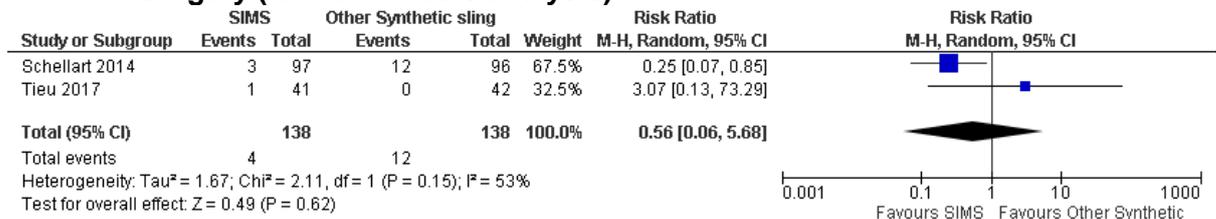
Abbreviations: SIMS, single-incision mini-sling;

**Figure 80: Complications – Pain at >1 year to ≤5 years after surgery**



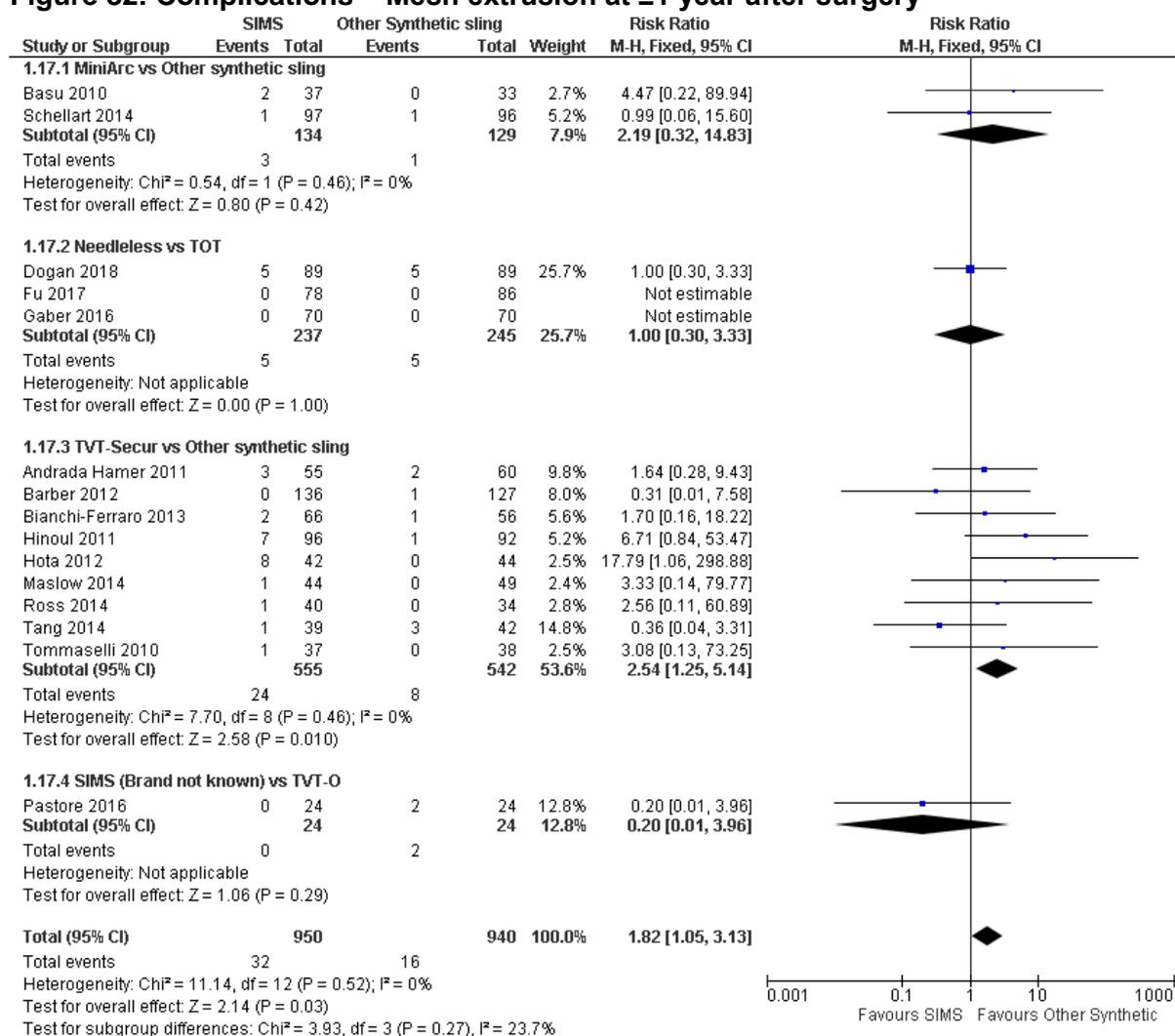
Abbreviations: SIMS, single-incision mini-sling.

**Figure 81: Complications – Pain for MiniArc vs TOT at >1 year to ≤5 years after surgery (random effects analysis)**



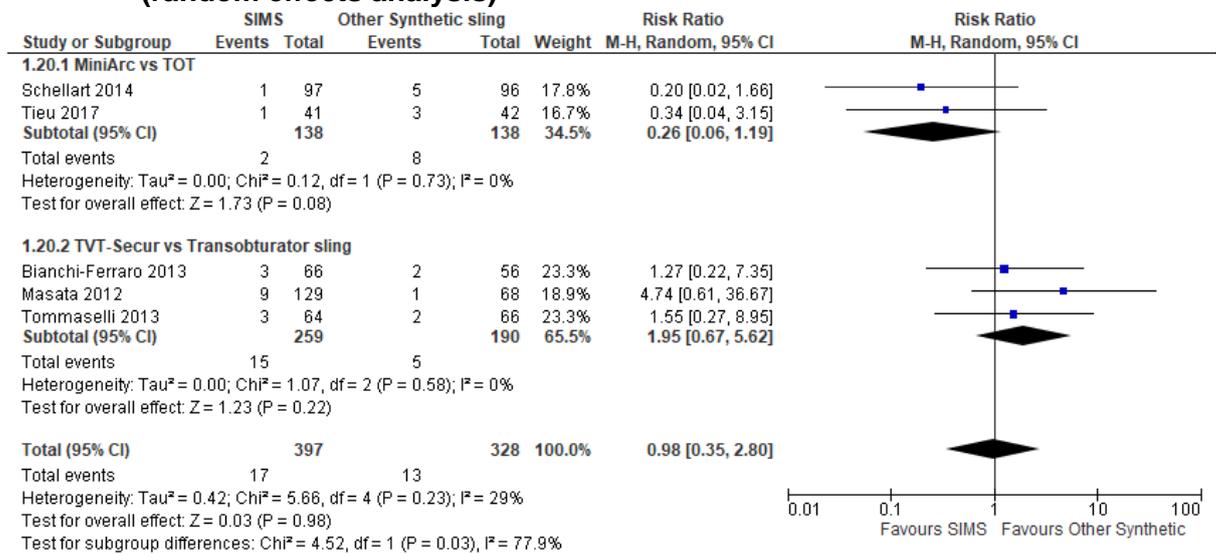
Abbreviations: SIMS, single-incision mini-sling.

**Figure 82: Complications – Mesh extrusion at ≤1 year after surgery**



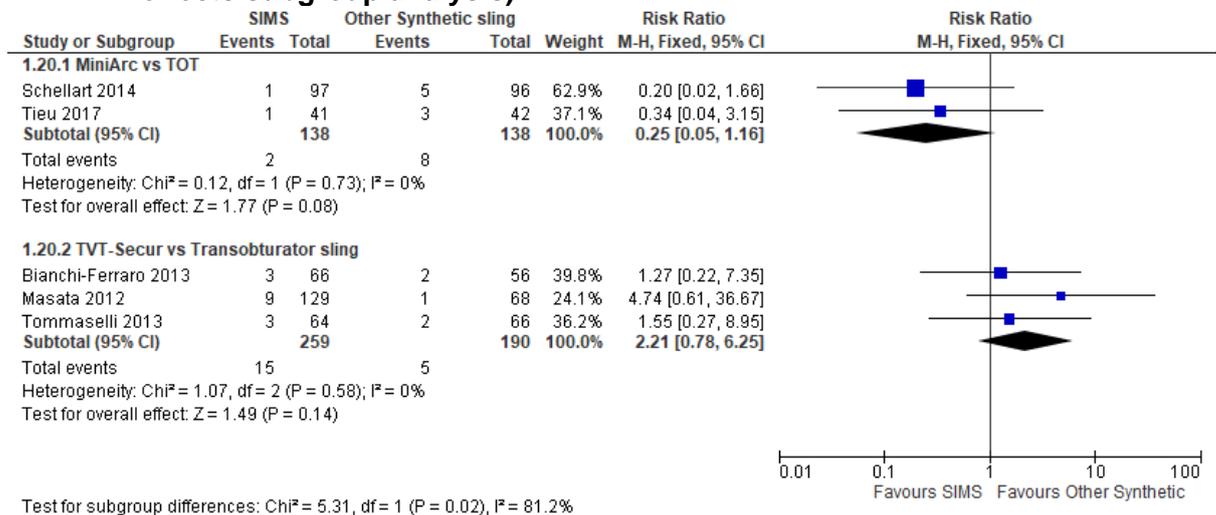
Abbreviations: SIMS, single-incision mini-sling.

**Figure 83: Complications - Mesh extrusion at >1 year to ≤5 years after surgery (random effects analysis)**



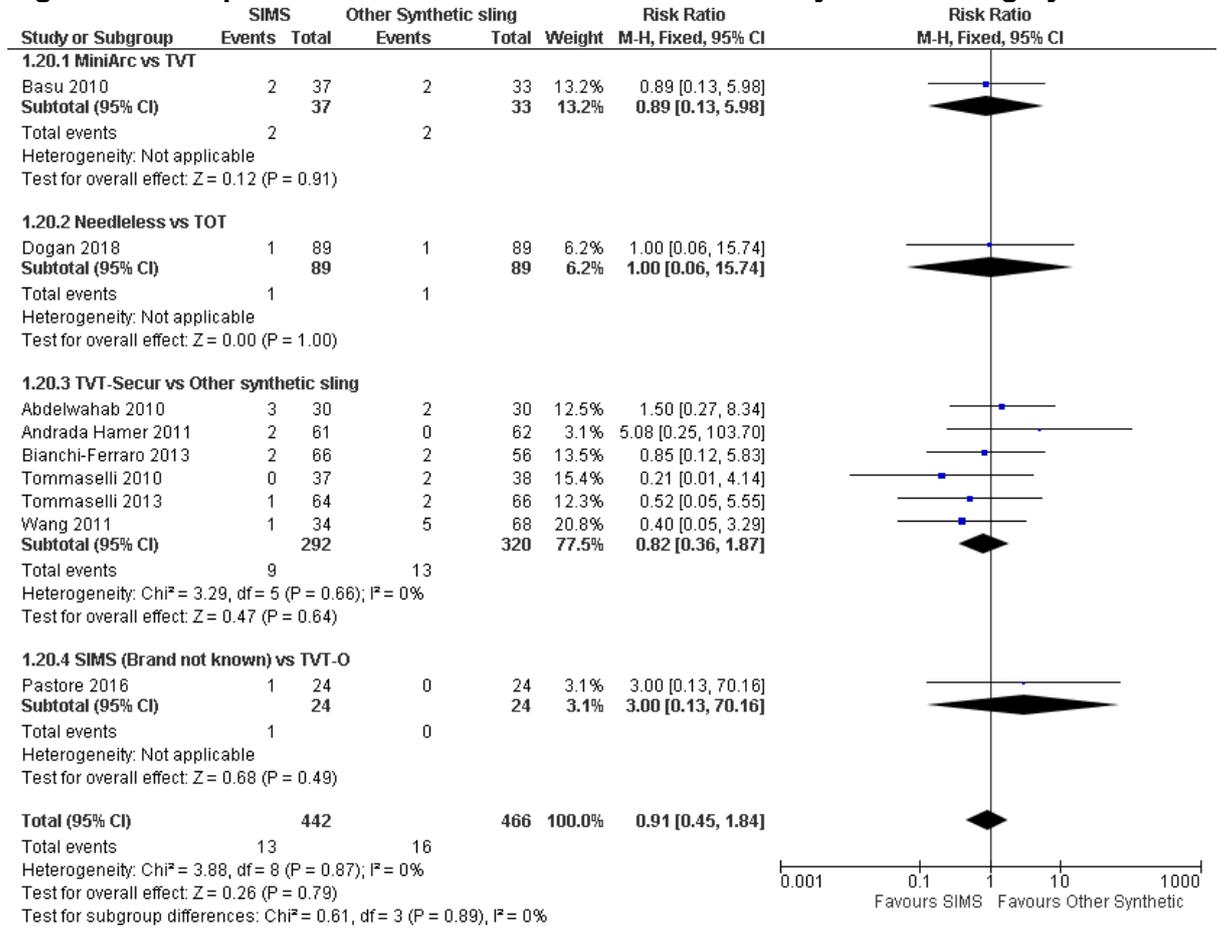
Abbreviations: SIMS, single-incision mini-sling.

**Figure 84: Complications - Mesh extrusion at >1 year to ≤5 years after surgery (fixed effects subgroup analysis)**



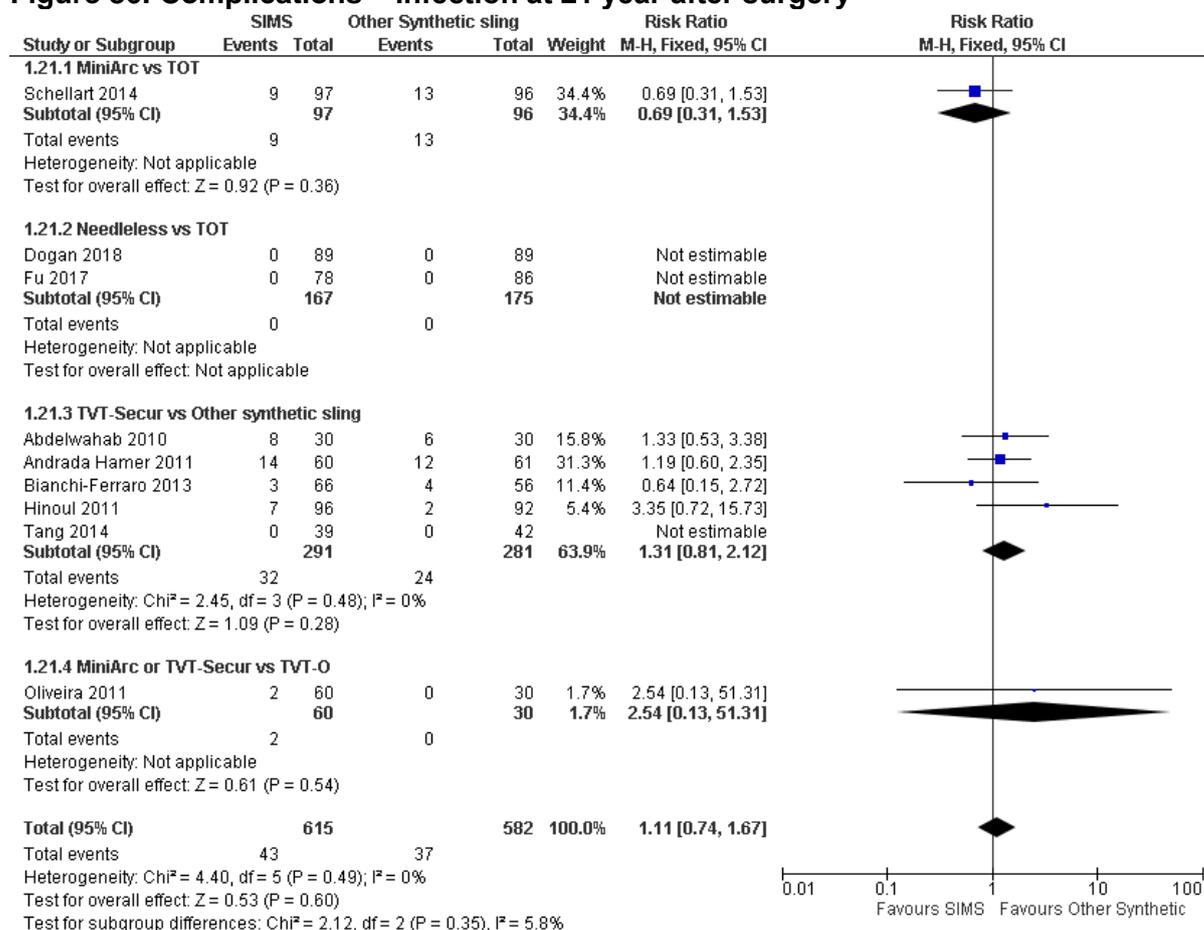
Abbreviations: SIMS, single-incision mini-sling.

**Figure 85: Complications – Need for catheterisation at ≤1 year after surgery**



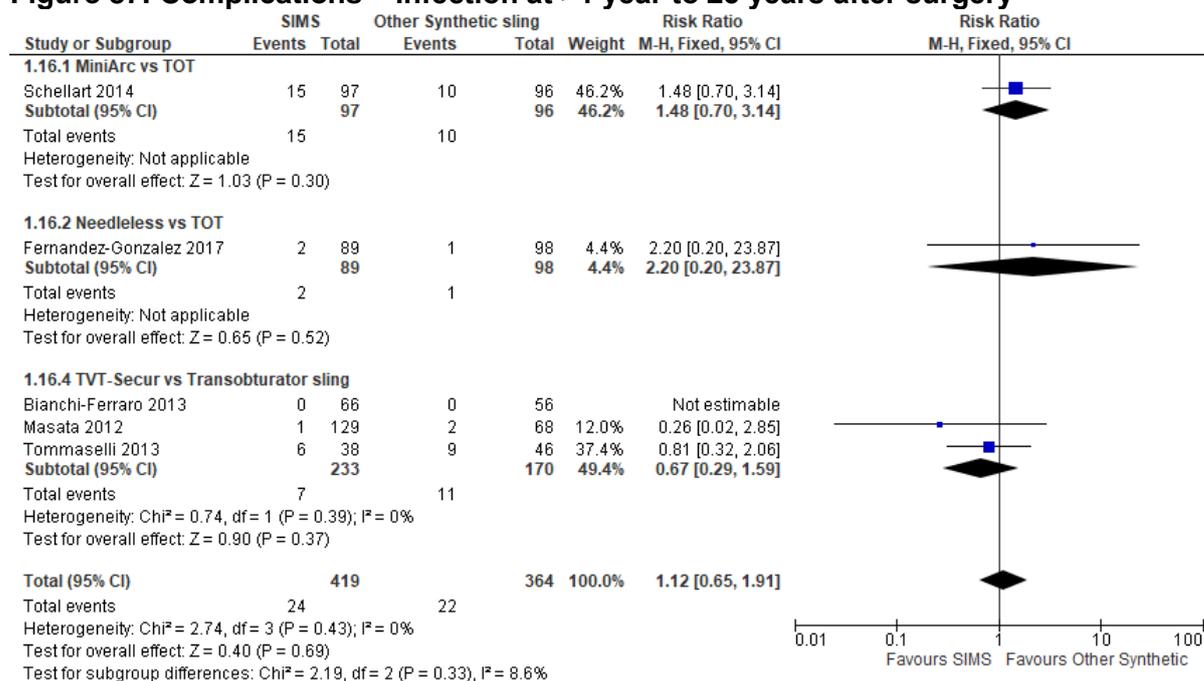
Abbreviations: SIMS, single-incision mini-sling.

**Figure 86: Complications – Infection at ≤1 year after surgery**



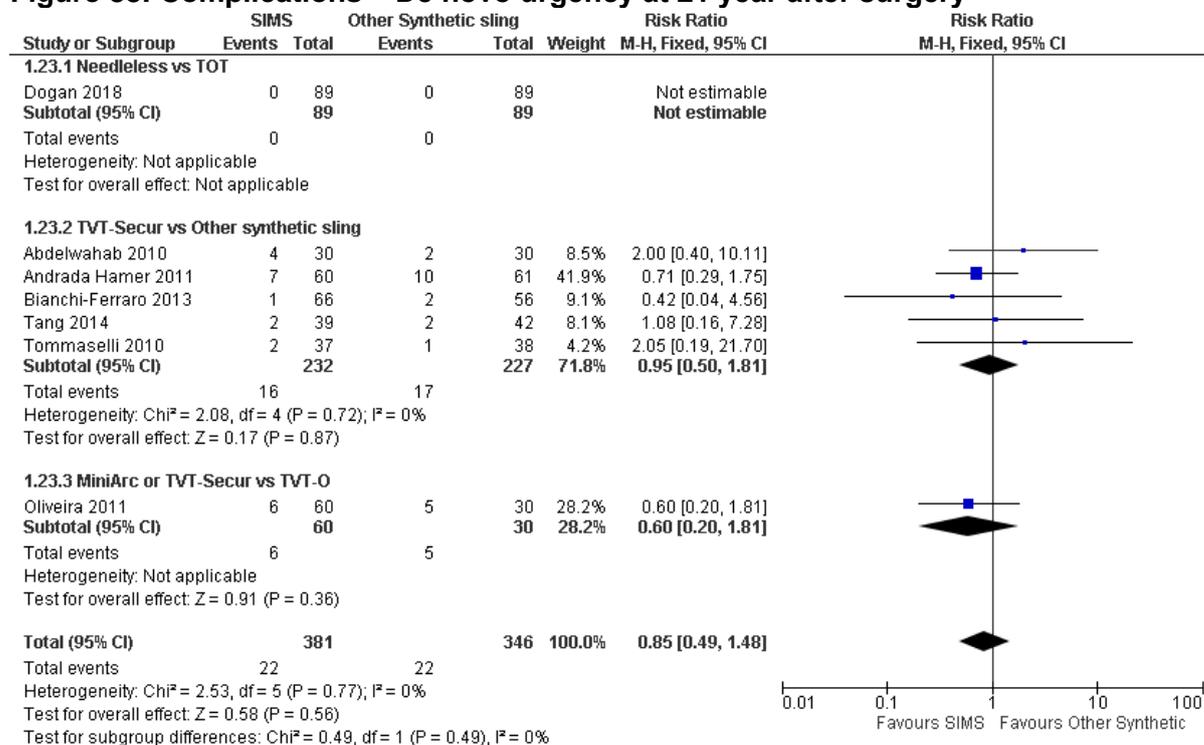
Abbreviations: SIMS, single-incision mini-sling.

**Figure 87: Complications – Infection at >1 year to ≤5 years after surgery**



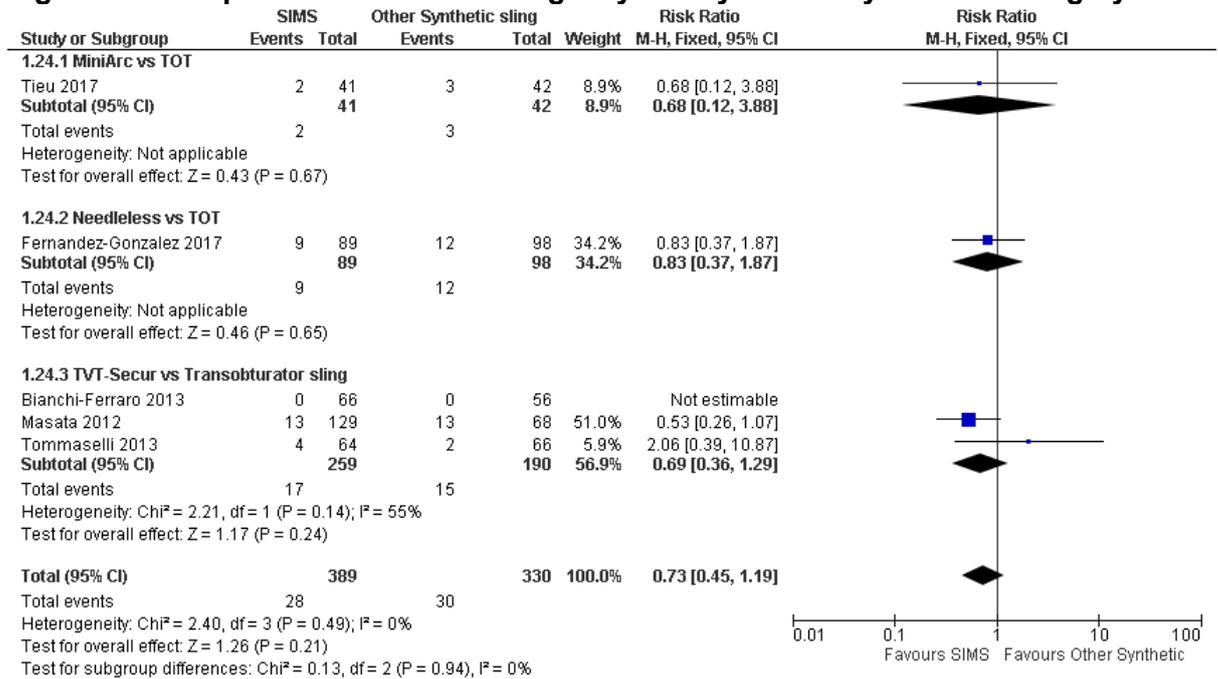
Abbreviations: SIMS, single-incision mini-sling.

**Figure 88: Complications – De novo urgency at ≤1 year after surgery**



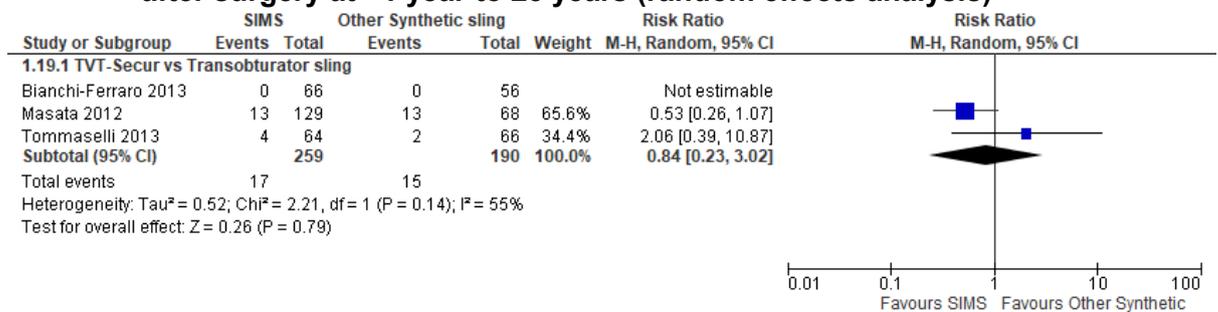
Abbreviations: SIMS, single-incision mini-sling.

**Figure 89: Complications – De novo urgency at >1 year to ≤5 years after surgery**



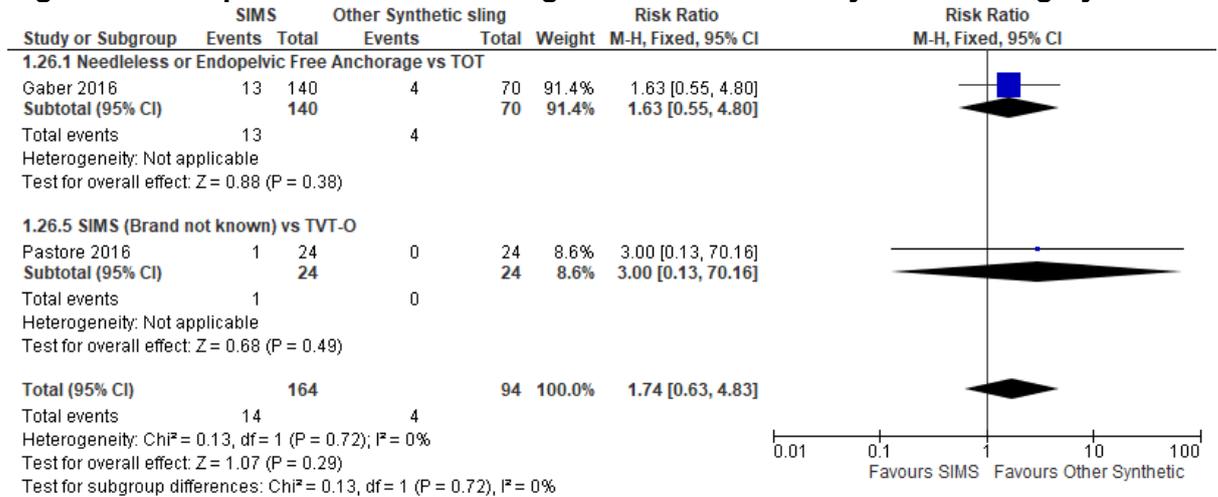
Abbreviations: SIMS, single-incision mini-sling.

**Figure 90: Complications – De novo urgency for TVT-Secur vs Transobturator sling after surgery at >1 year to ≤5 years (random effects analysis)**



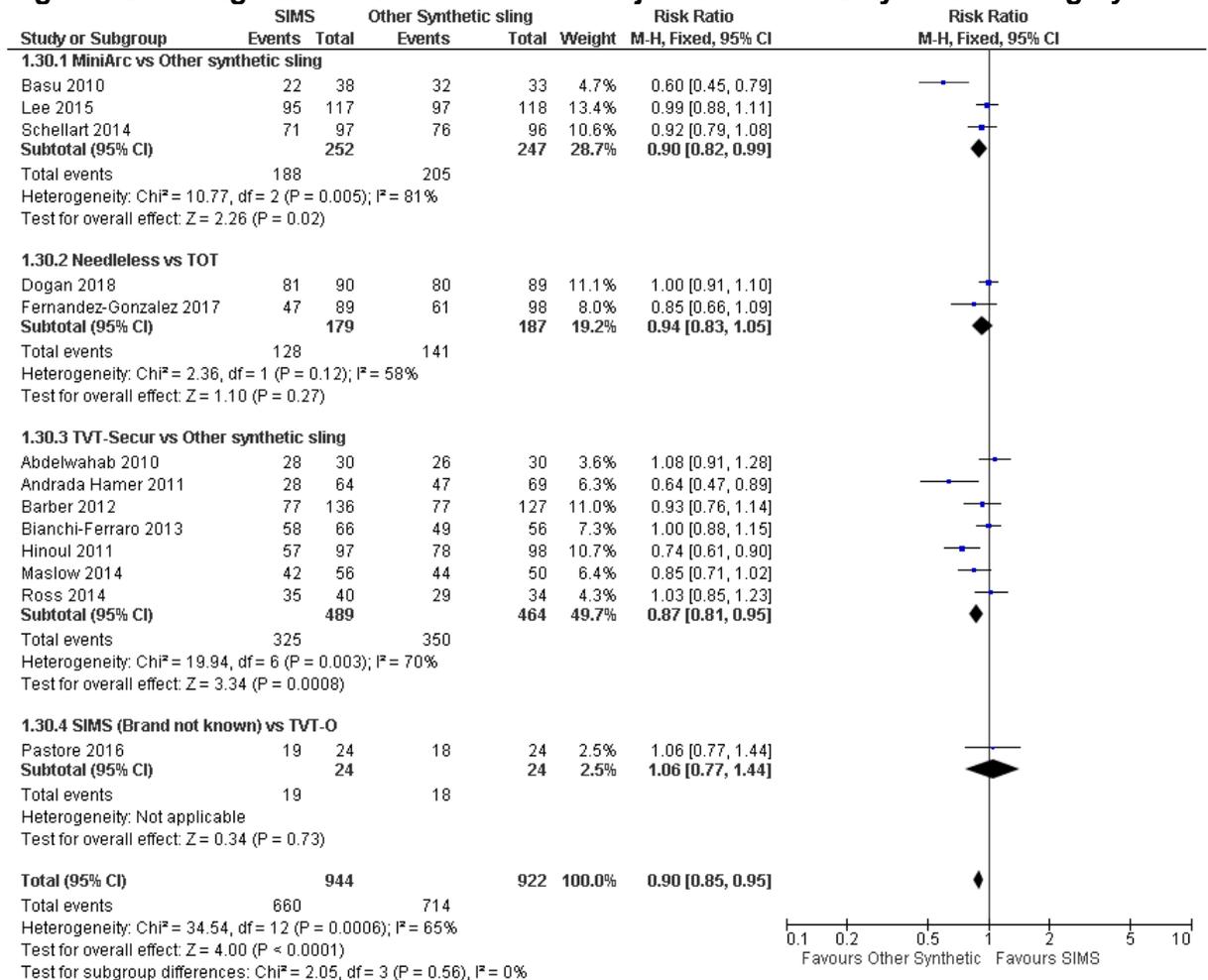
Abbreviations: SIMS, single-incision mini-sling.

**Figure 91: Complications - De novo urge incontinence at ≤1 year after surgery**



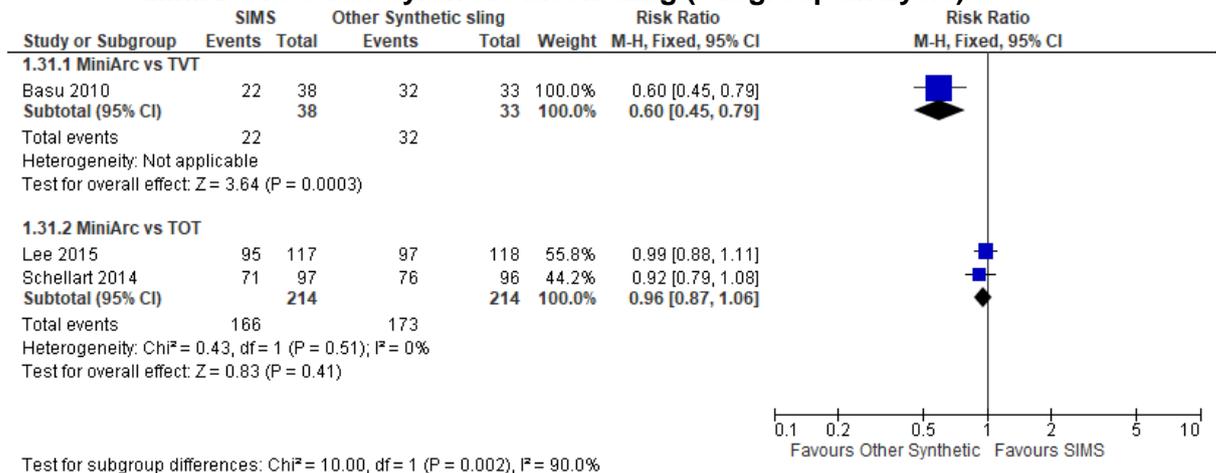
Abbreviations: SIMS, single-incision mini-sling.

**Figure 92: Change in continence status - Subjective cure at ≤1 year after surgery**



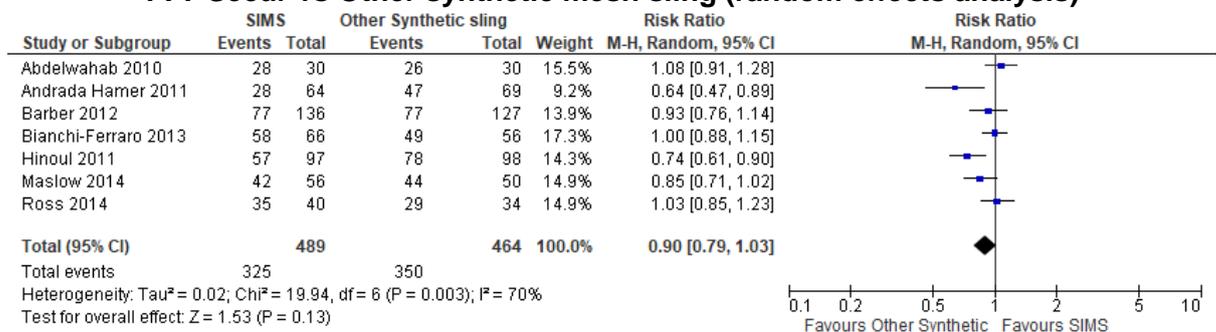
Abbreviations: SIMS, single-incision mini-sling.

**Figure 93: Change in continence status - Subjective cure at ≤1 year after surgery for MiniArc vs Other synthetic mesh sling (subgroup analysis)**



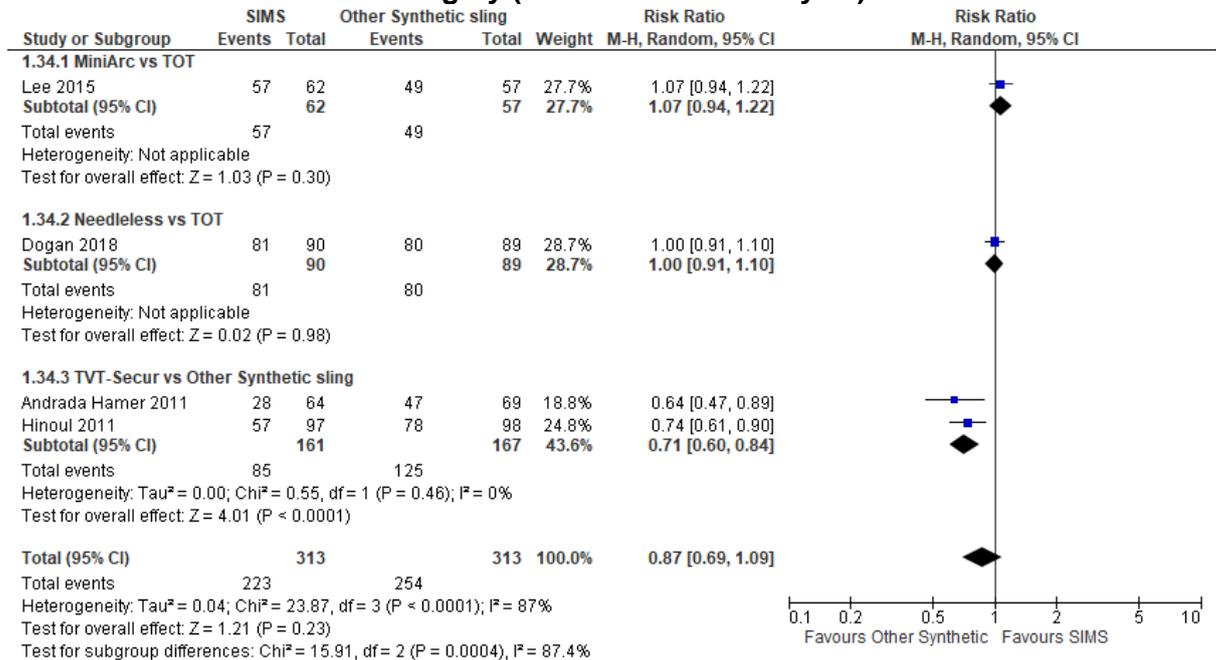
Abbreviations: SIMS, single-incision mini-sling.

**Figure 94: Change in continence status - Subjective cure at ≤1 year after surgery for TVT-Secur vs Other synthetic mesh sling (random effects analysis)**



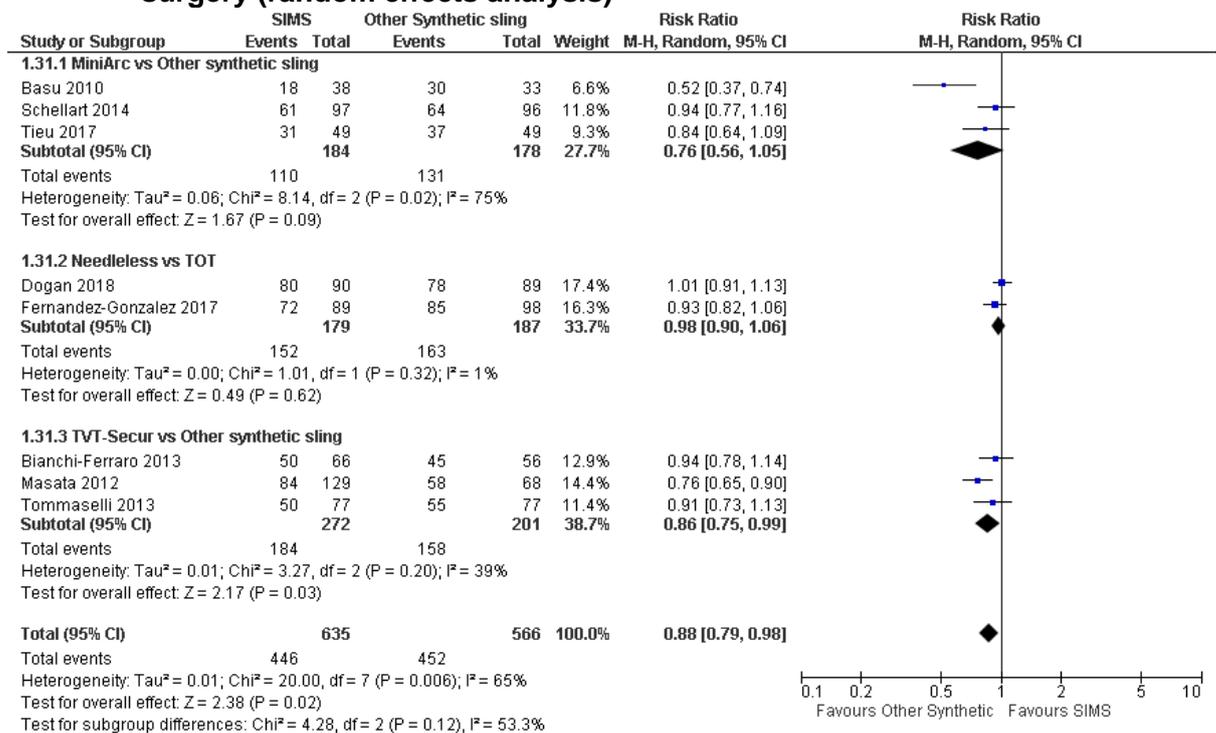
Note: Heterogeneity not explained by type of other (e.g. retropubic or transobturator) synthetic mesh sling used.  
Abbreviations: SIMS, single-incision mini-sling.

**Figure 95: Change in continence status - Subjective cure at ≤1 year after surgery: No concomitant POP surgery (random effects analysis)**



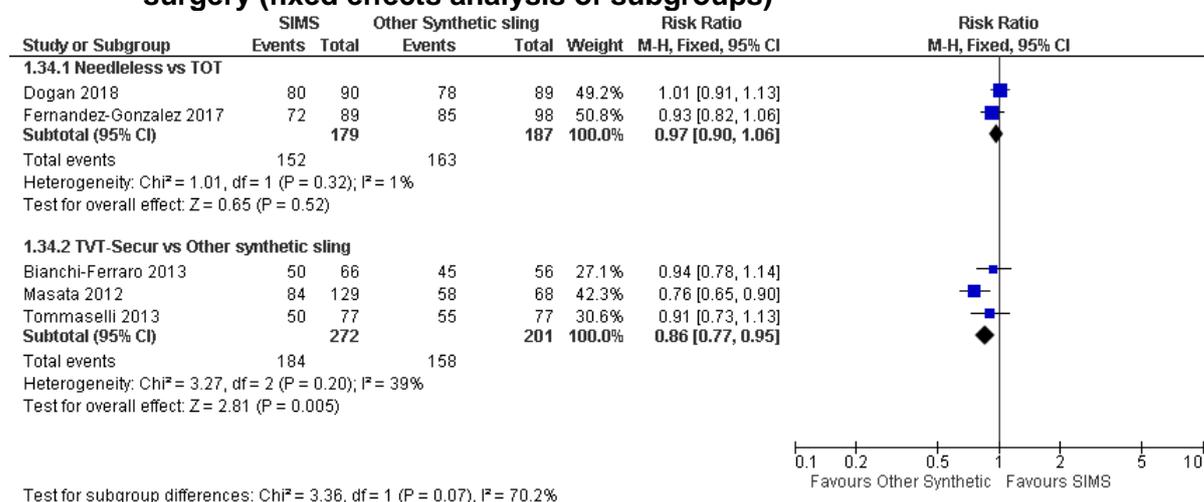
Abbreviations: SIMS, single-incision mini-sling.

**Figure 96: Change in continence status - Subjective cure at >1 year to ≤5 years after surgery (random effects analysis)**



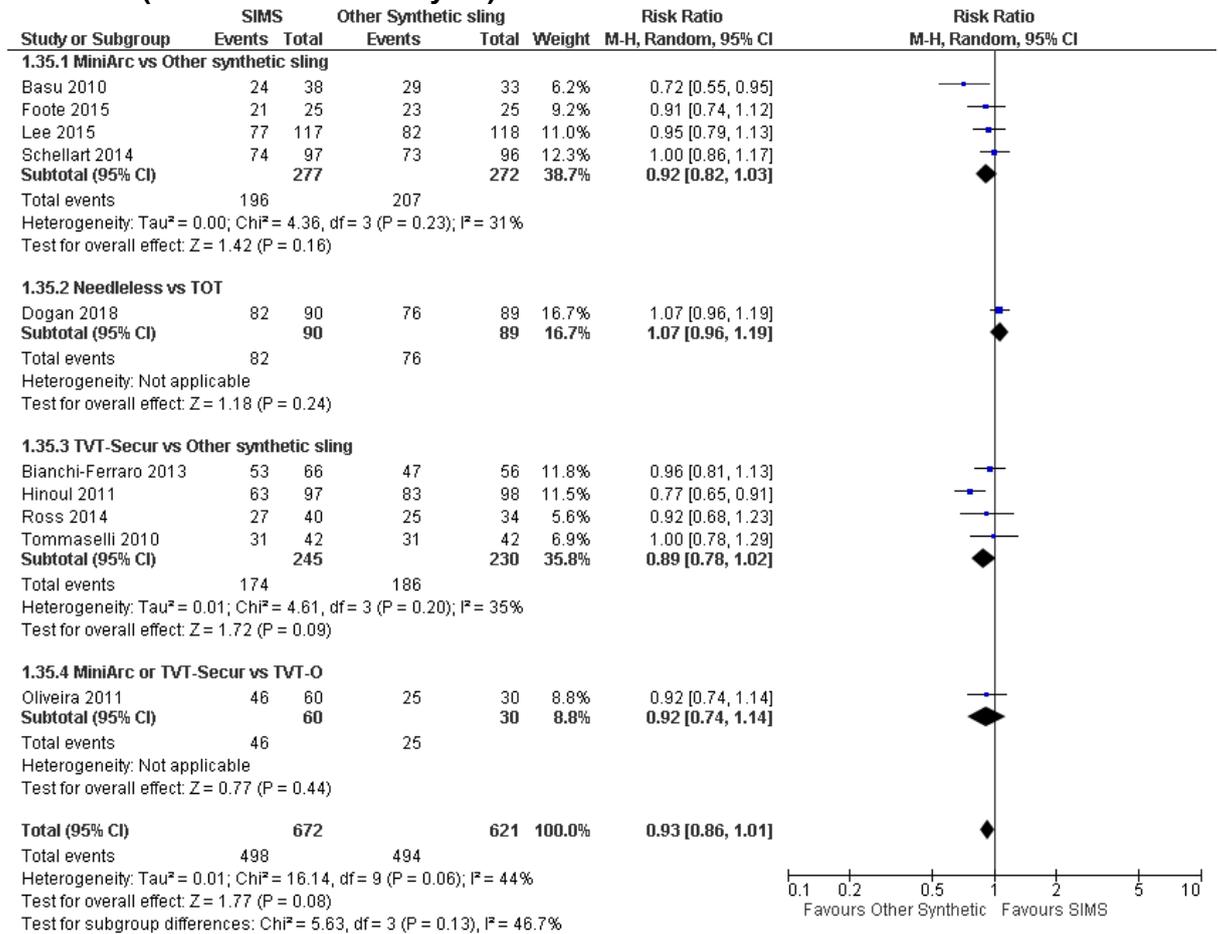
Note: Heterogeneity in MiniArc subgroup not explained by type of other synthetic (e.g. retropubic or transobturator) sling used. Abbreviations: SIMS, single-incision mini-sling.

**Figure 97: Change in continence status - Subjective cure at >1 year to ≤5 years after surgery (fixed effects analysis of subgroups)**



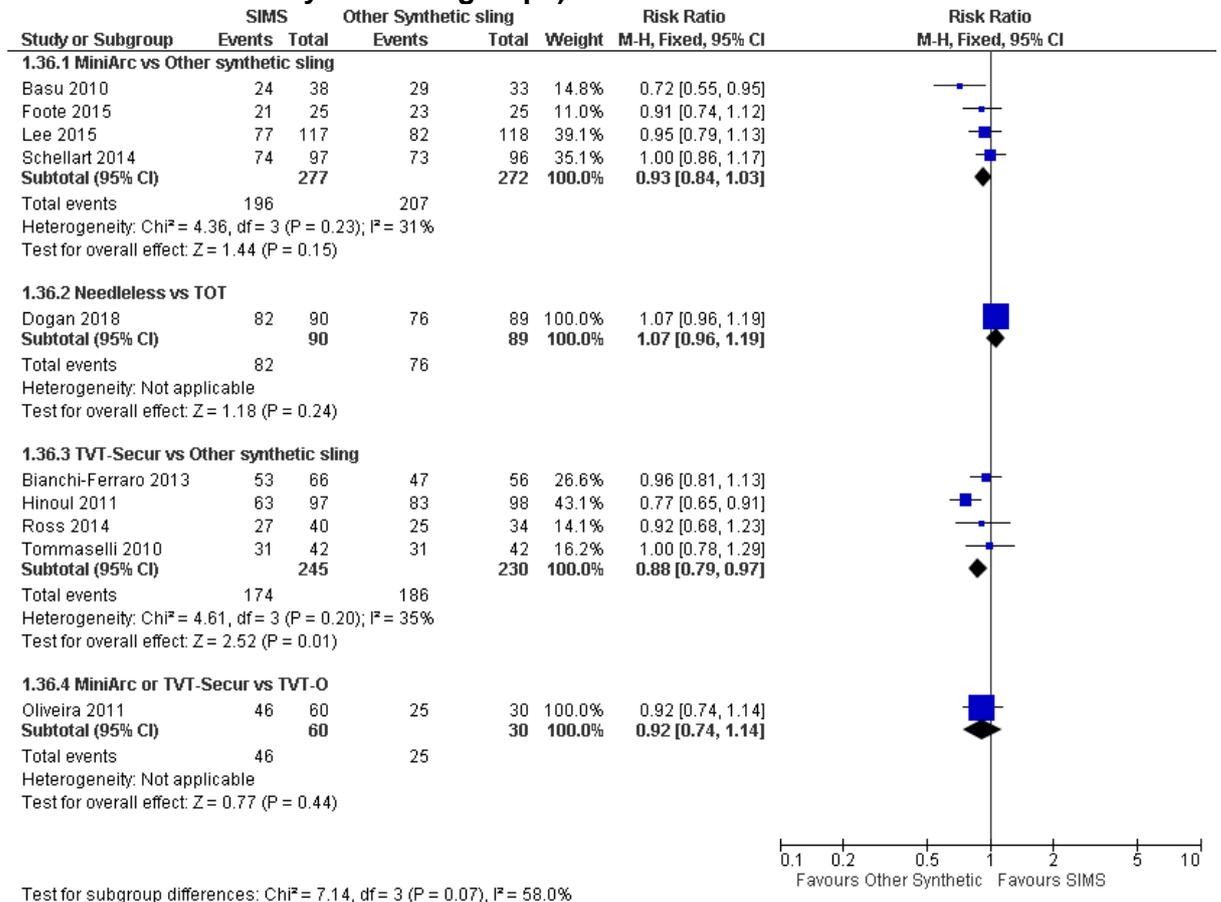
Abbreviations: SIMS, single-incision mini-sling.

**Figure 98: Change in continence status - Objective cure at ≤1 year after surgery (random effects analysis)**



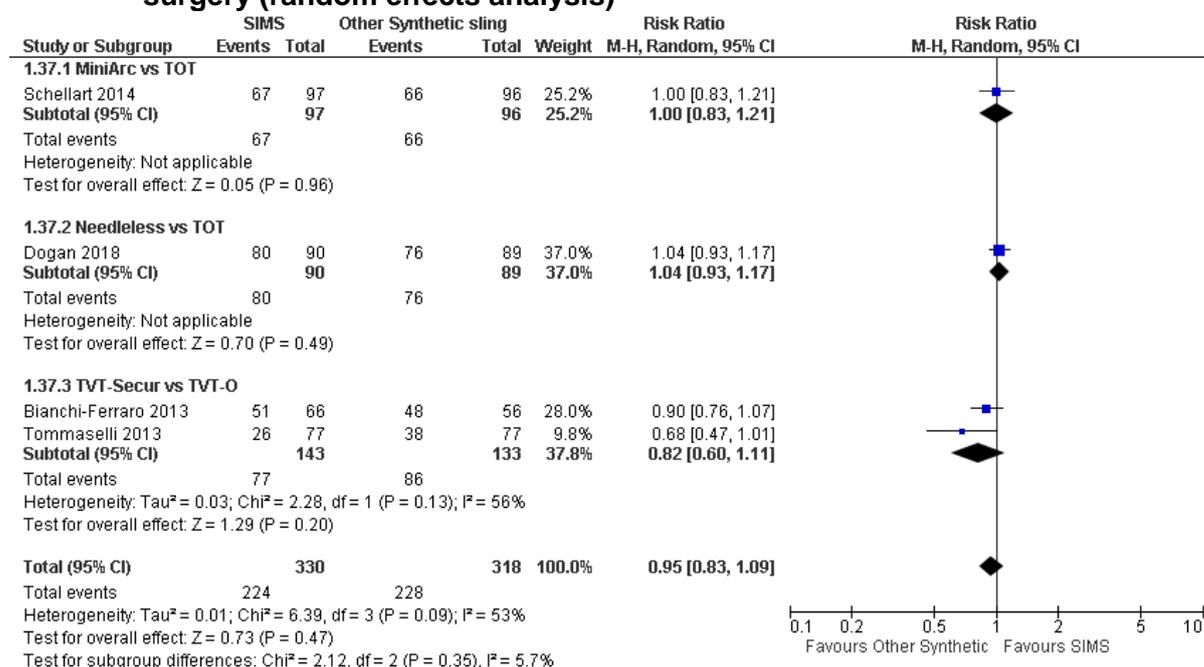
Abbreviations: SIMS, single-incision mini-sling.

**Figure 99: Change in continence status - Objective cure at ≤1 year after surgery (fixed effects analysis of subgroups)**



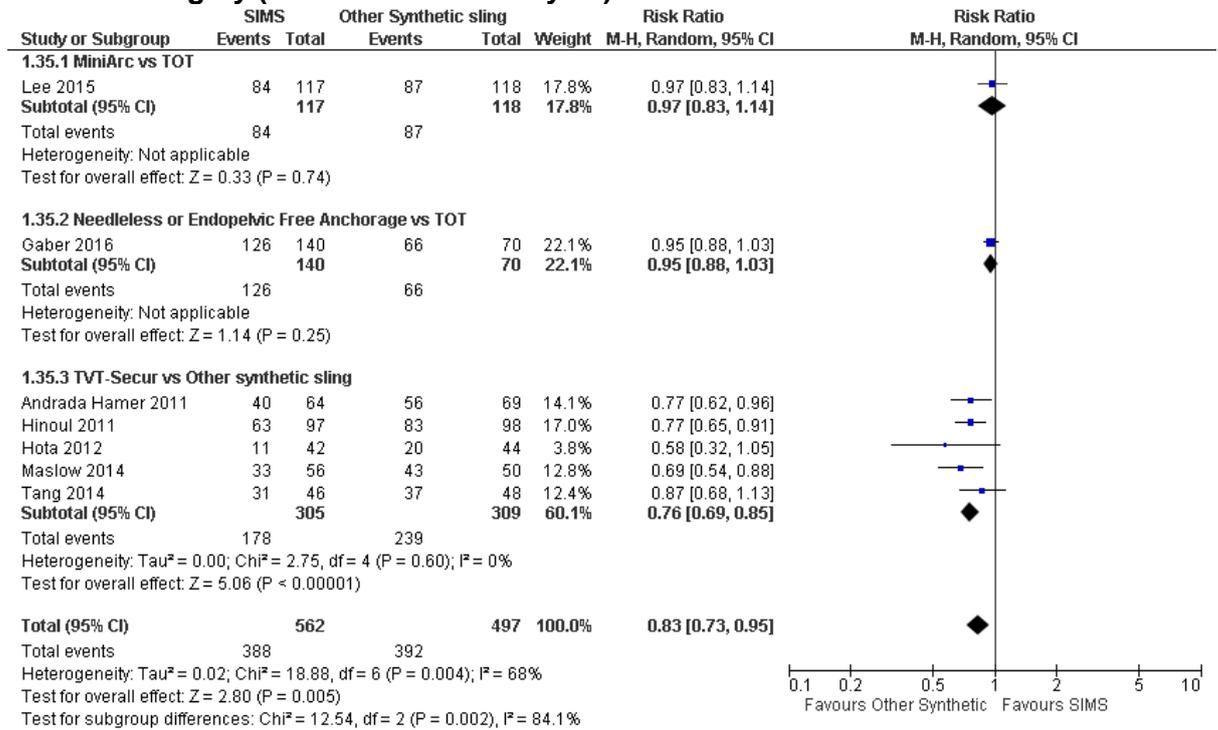
Abbreviations: SIMS, single-incision mini-sling.

**Figure 100: Change in continence status - Objective cure at >1 year to ≤5 years after surgery (random effects analysis)**



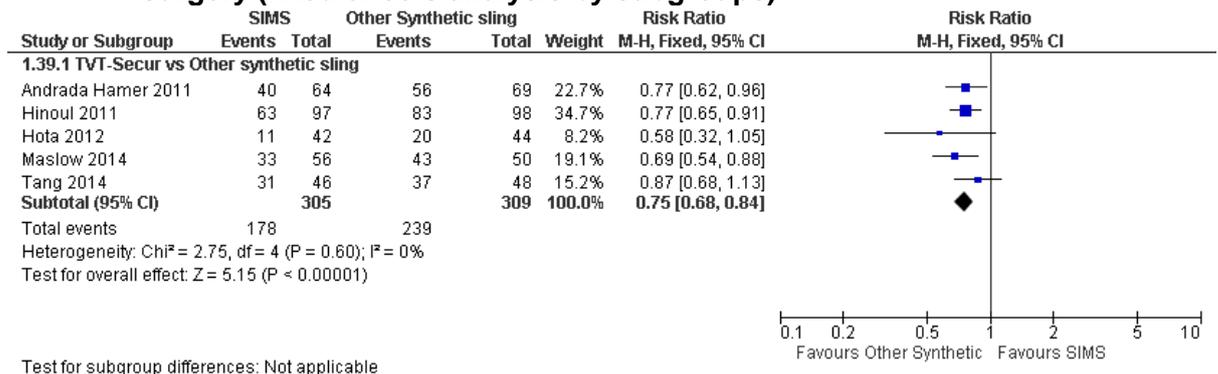
Abbreviations: SIMS, single-incision mini-sling.

**Figure 101: Change in continence status - Negative cough stress test at ≤1 year after surgery (random effects analysis)**



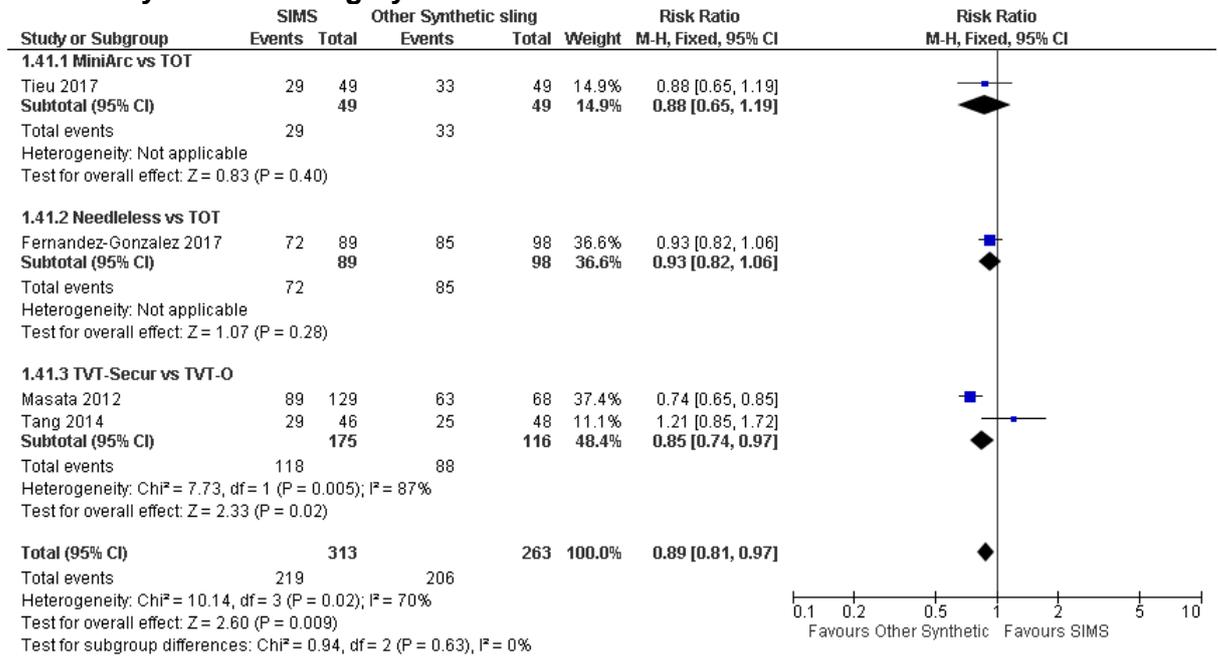
Abbreviations: SIMS, single-incision mini-sling.

**Figure 102: Change in continence status - Negative cough stress test at ≤1 year after surgery (fixed effects analysis by subgroups)**



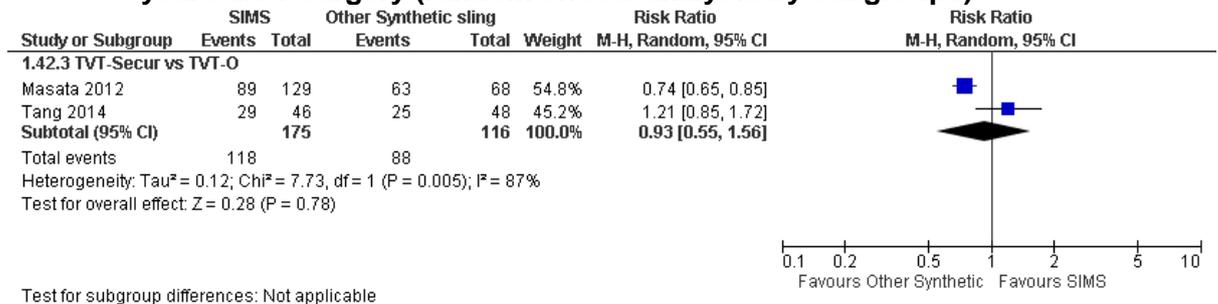
Abbreviations: SIMS, single-incision mini-sling.

**Figure 103: Change in continence status - Negative cough stress test at >1 year to ≤5 years after surgery**



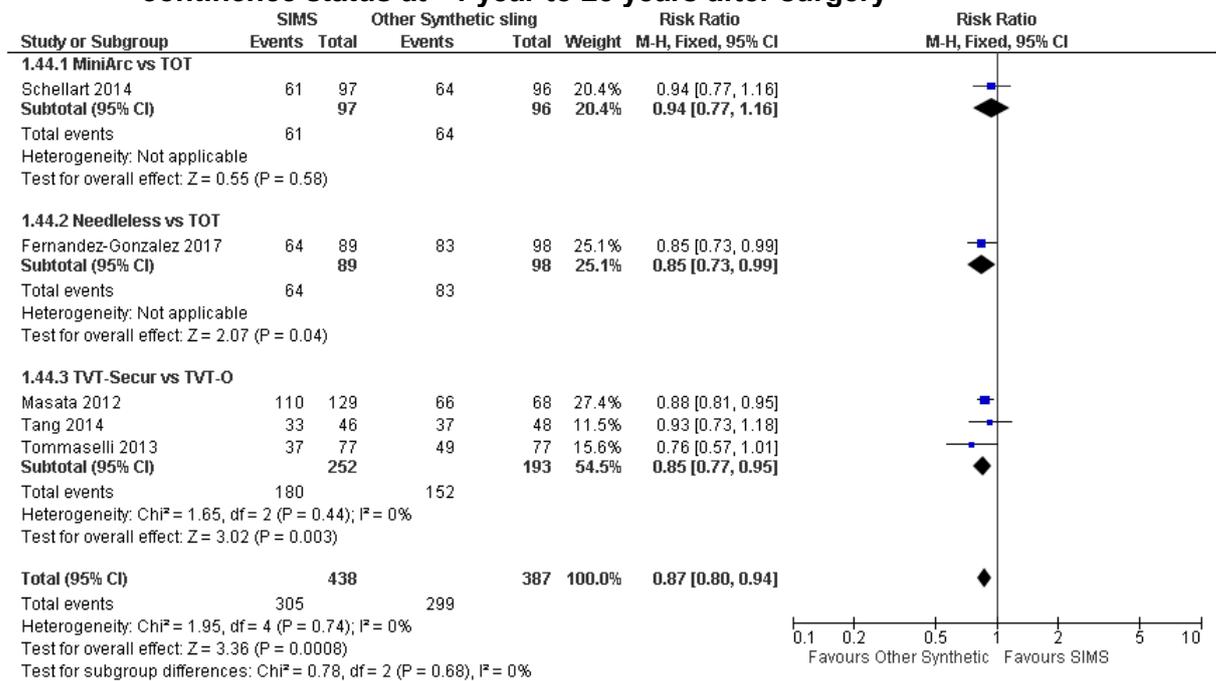
Abbreviations: SIMS, single-incision mini-sling.

**Figure 104: Change in continence status - Negative cough stress test at >1 year to ≤5 years after surgery (random effects analysis by subgroups)**



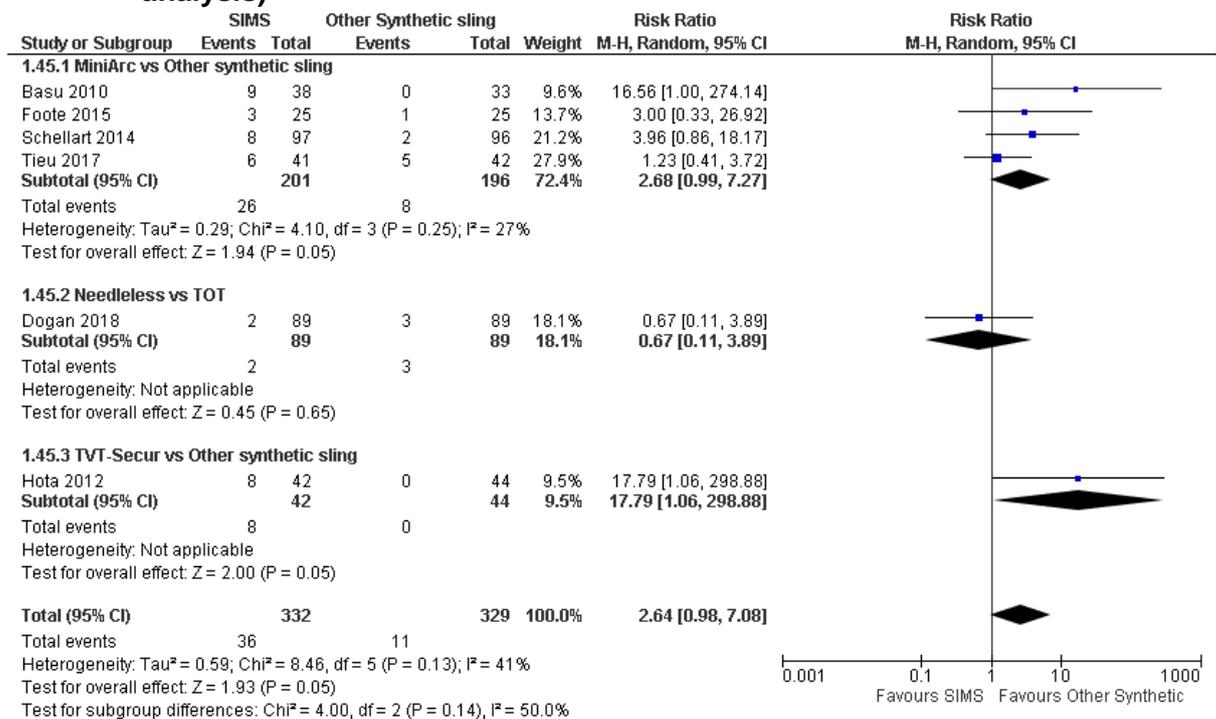
Abbreviations: SIMS, single-incision mini-sling.

**Figure 105: Patient satisfaction/patient-reported improvement - Improvement in continence status at >1 year to ≤5 years after surgery**



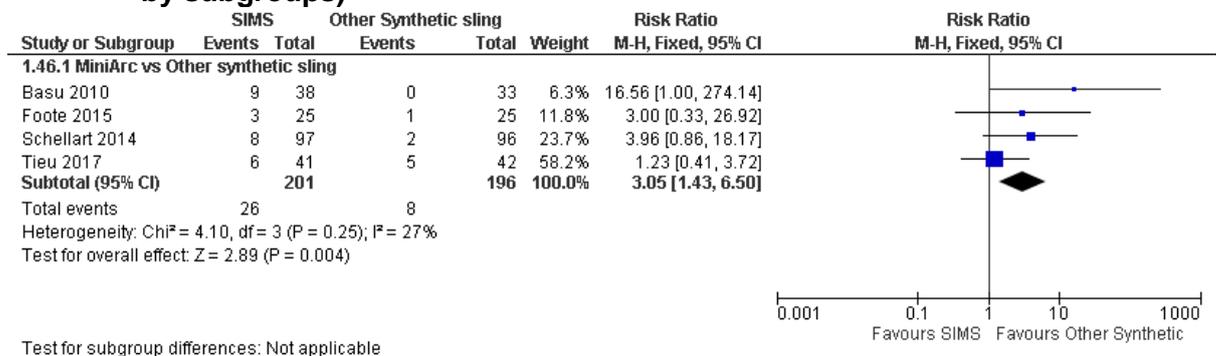
Abbreviations: SIMS, single-incision mini-sling.

**Figure 106: Repeat surgery for SUI up to 5 years after surgery (random effects analysis)**



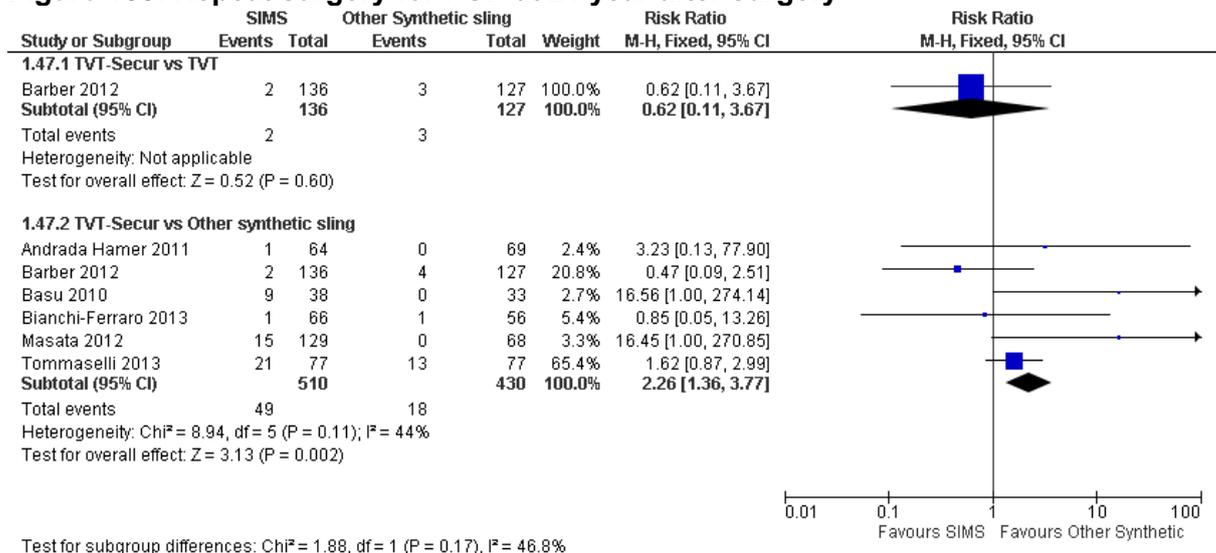
Abbreviations: SIMS, single-incision mini-sling.

**Figure 107: Repeat surgery for SUI up to 5 years after surgery (fixed effects analysis by subgroups)**



Abbreviations: SIMS, single-incision mini-sling.

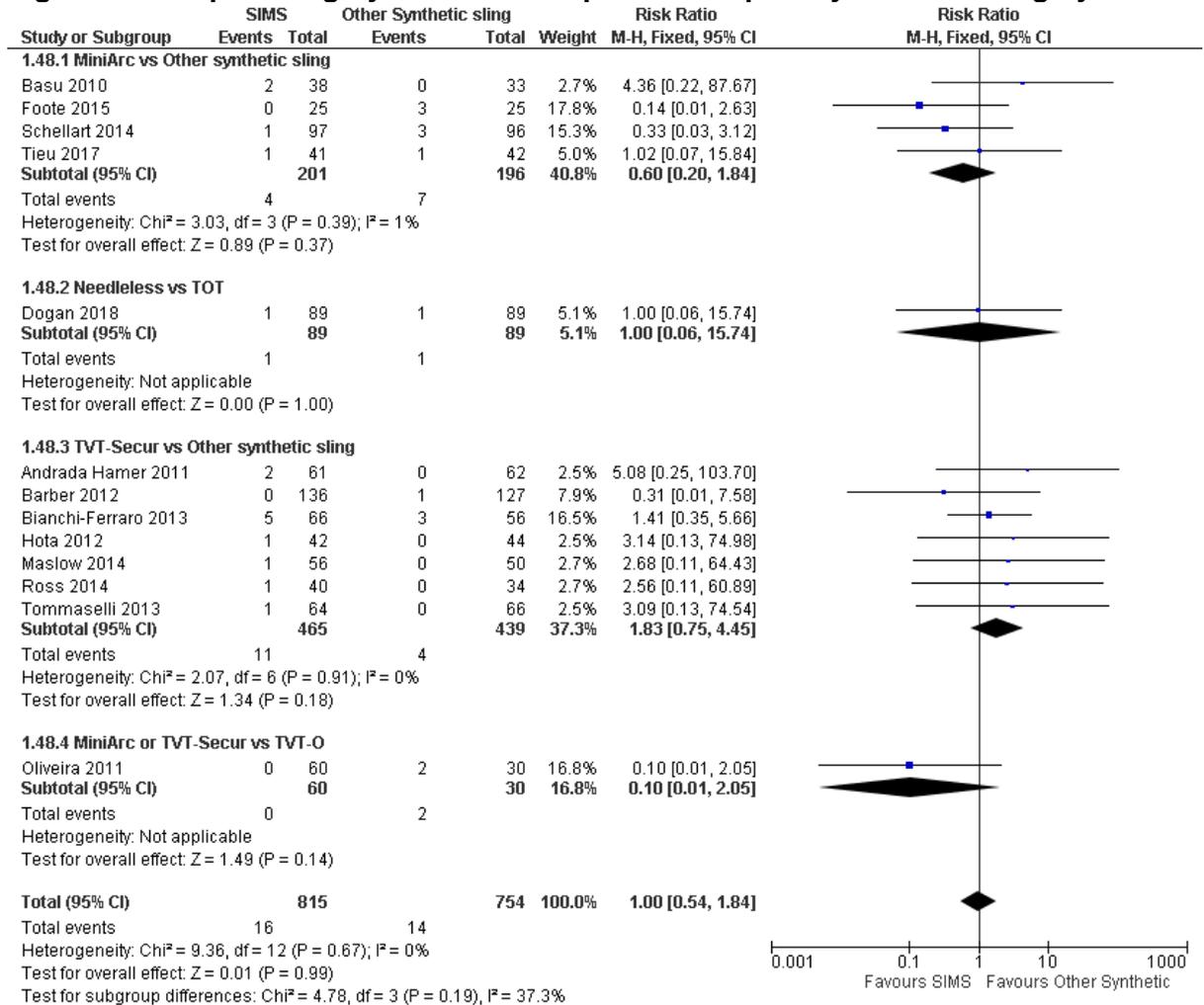
**Figure 108: Repeat surgery for POP at ≤1 year after surgery**



Note: Barber et al. 2012 is a 3-arm trial. The subgroups have therefore not been analysed together.

Abbreviations: SIMS, single-incision mini-sling.

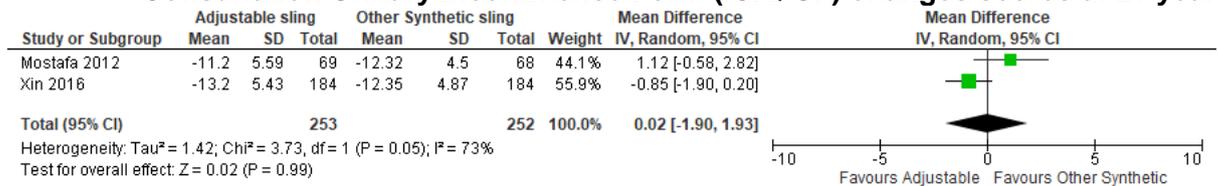
**Figure 109: Repeat surgery for mesh complications up to 5 years after surgery**



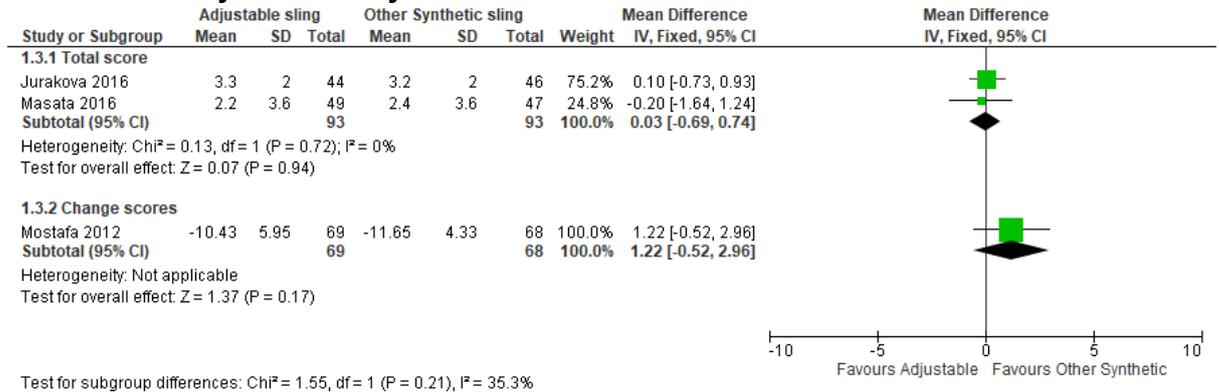
Abbreviations: SIMS, single-incision mini-sling.

## Adjustable mesh sling versus other synthetic mesh sling

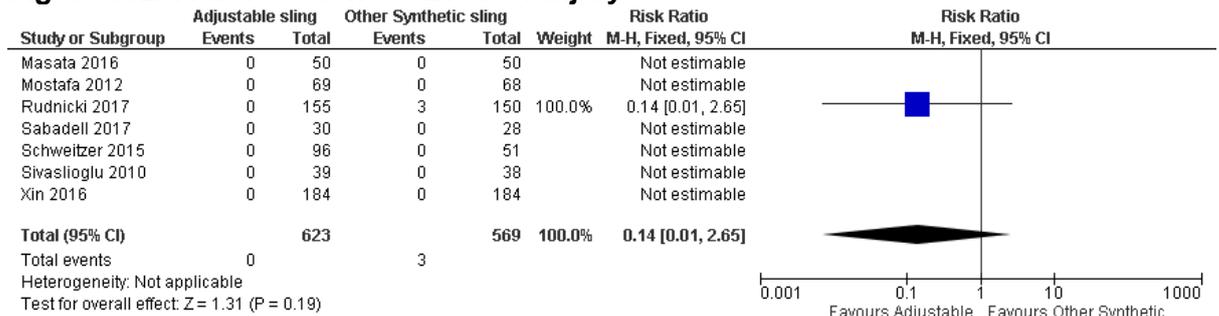
**Figure 110: Continence-specific health-related quality of life - International Consultation Urinary Incontinence Form (ICIQ-SF) changes scores at ≤1 year**



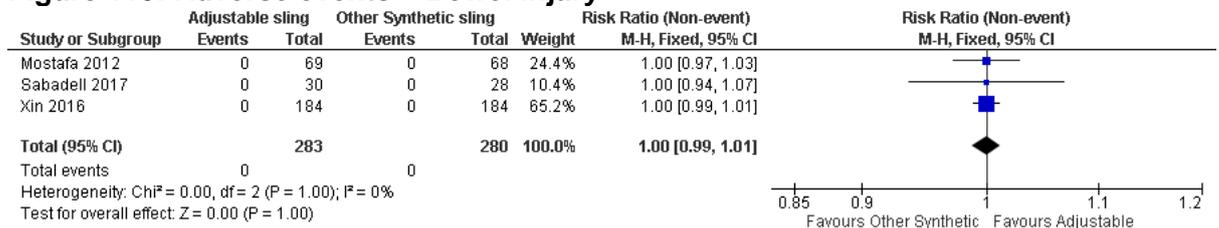
**Figure 111: Continence-specific health-related quality of life - International Consultation Urinary Incontinence Form (ICIQ-SF) total and changes scores at >1 year and ≤5 years**



**Figure 112: Adverse events – Bladder injury**

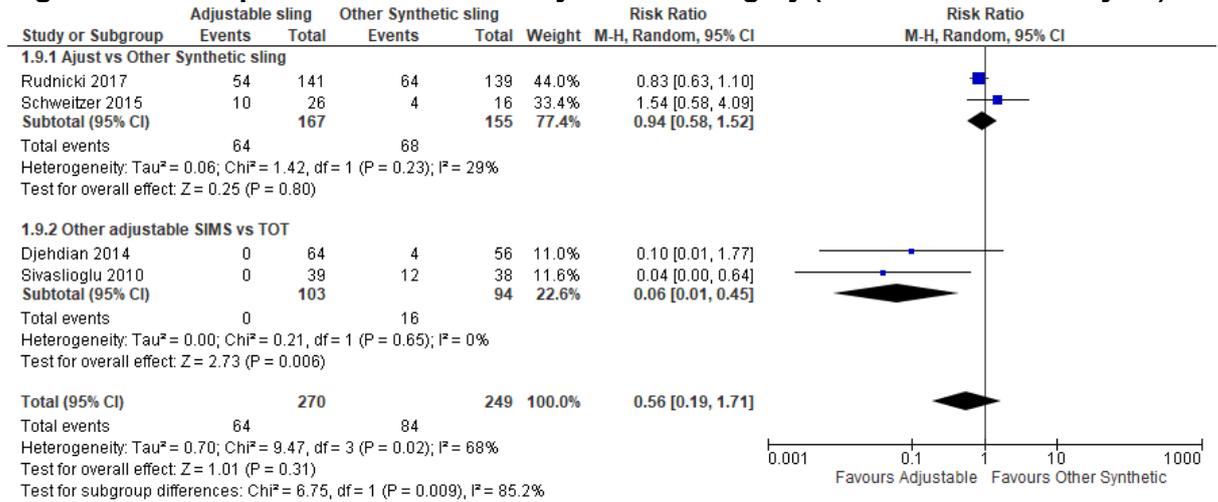


**Figure 113: Adverse events – Bowel injury**



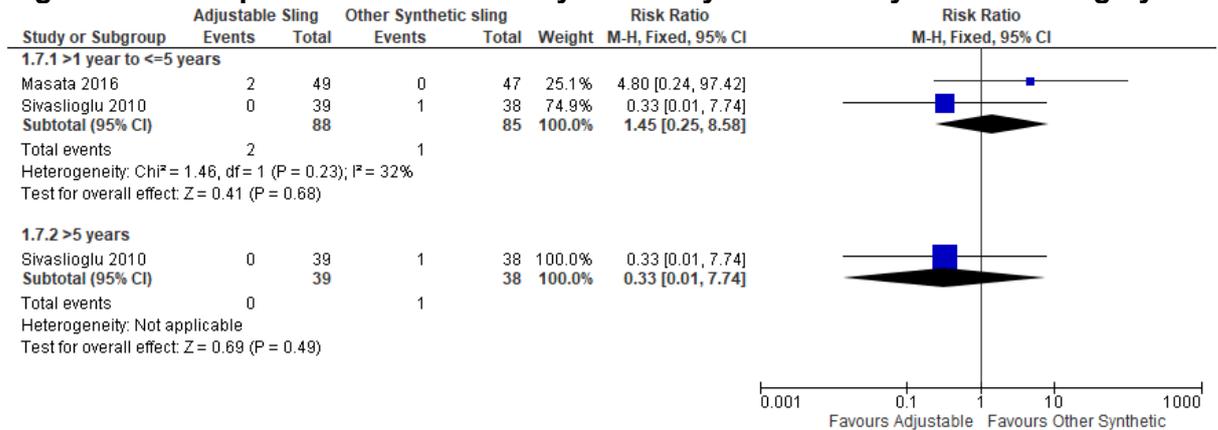
Note: Forest plot shows non-events

**Figure 114: Complications – Pain at ≤1 year after surgery (random effects analysis)**

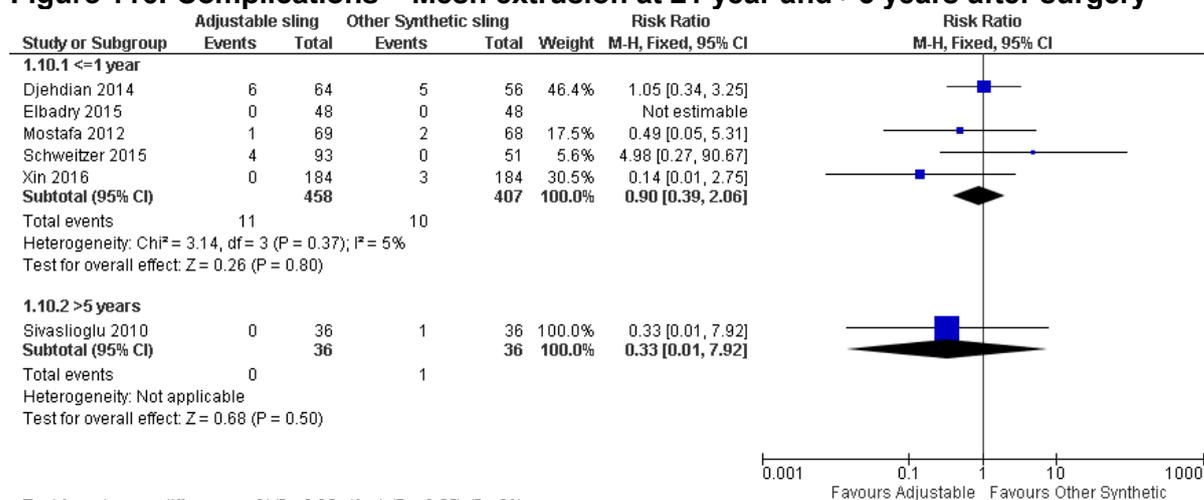


Note: Djehdian et al. 2014 compares Ophira single-incision mini-sling to TOT, whilst Sivaslioglu et al. 2010 compares (adjustable) Tissue Fixation System to TOT.

**Figure 115: Complications – Pain at >1 year to ≤5 years and >5 years after surgery**

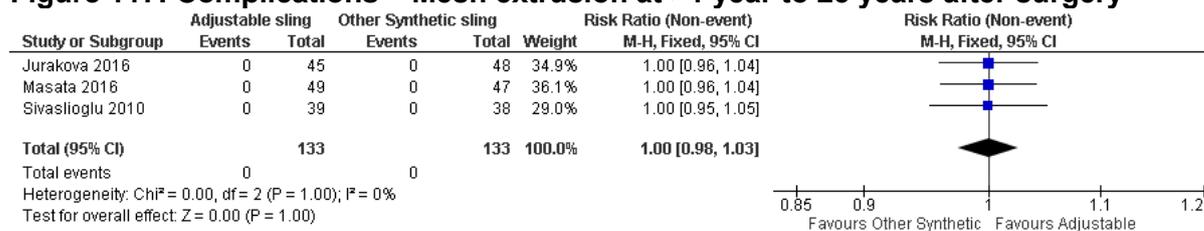


**Figure 116: Complications – Mesh extrusion at ≤1 year and >5 years after surgery**



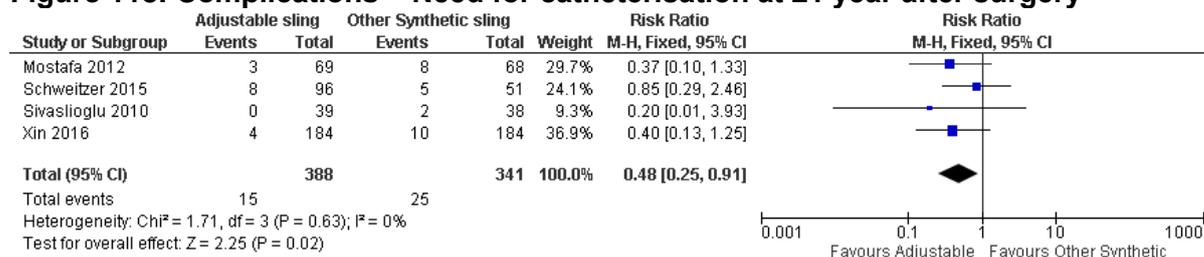
Test for subgroup differences: Chi<sup>2</sup> = 0.35, df = 1 (P = 0.55), I<sup>2</sup> = 0%

**Figure 117: Complications – Mesh extrusion at >1 year to ≤5 years after surgery**

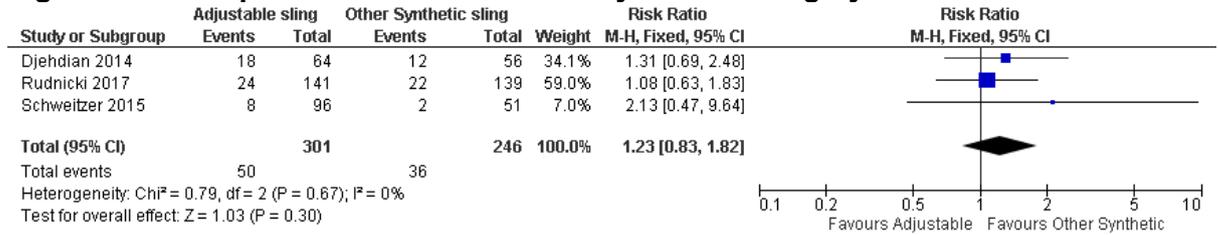


Note: Forest plot shows non-events

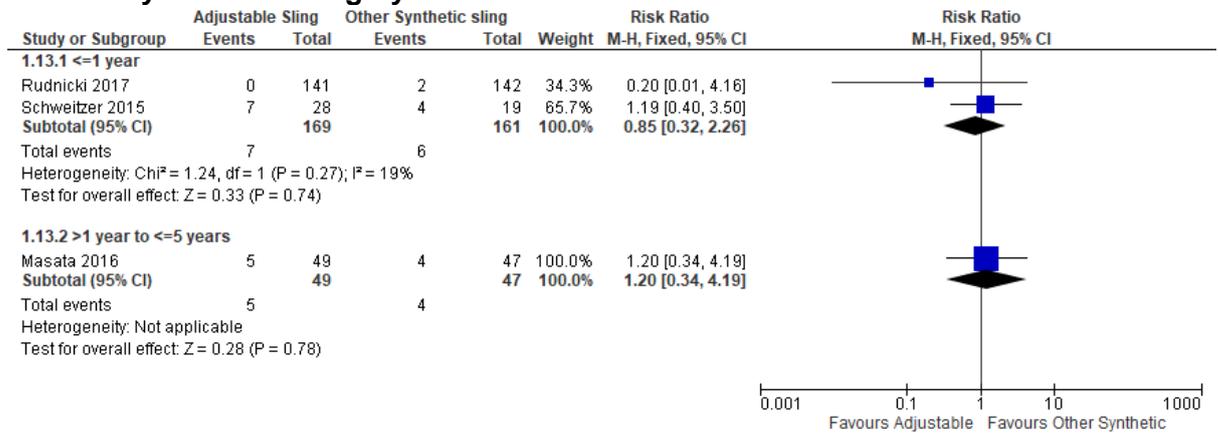
**Figure 118: Complications – Need for catheterisation at ≤1 year after surgery**



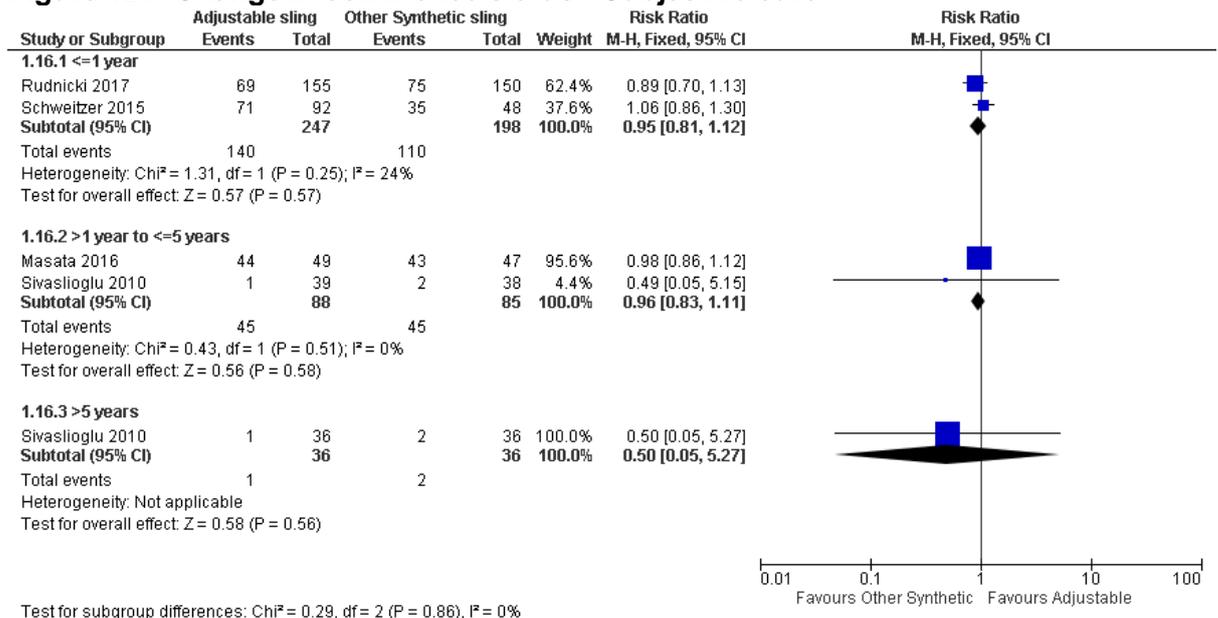
**Figure 119: Complications – Infection at ≤1 year after surgery**



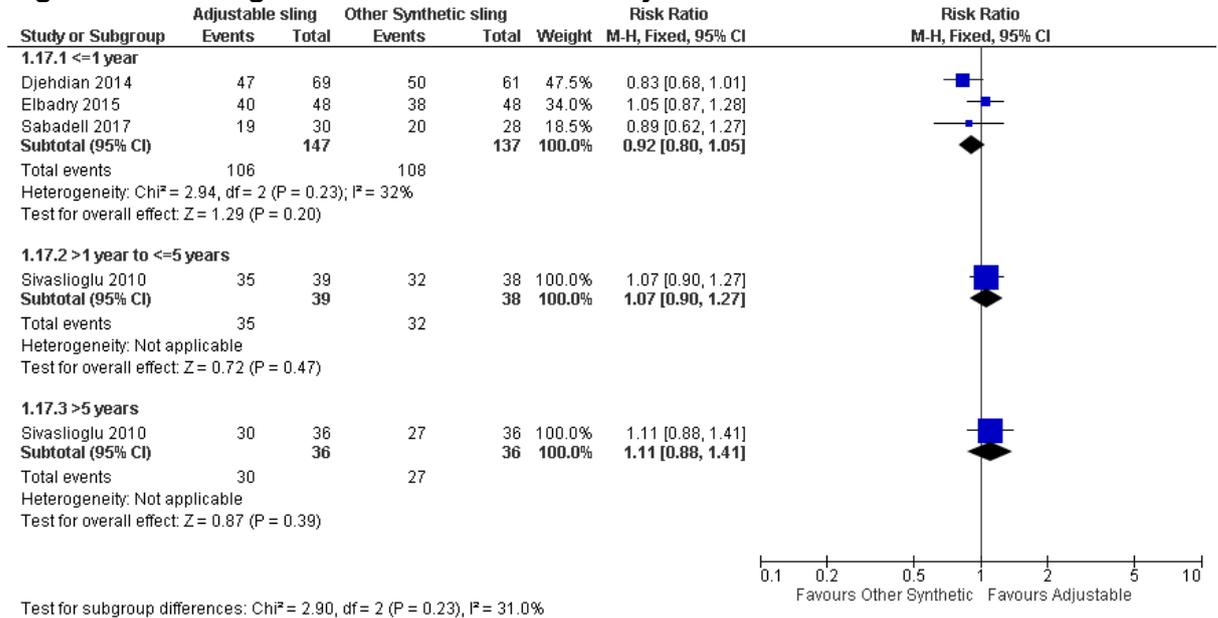
**Figure 120: Complications – De novo urge incontinence at ≤1 year and >1 year to ≤5 years after surgery**



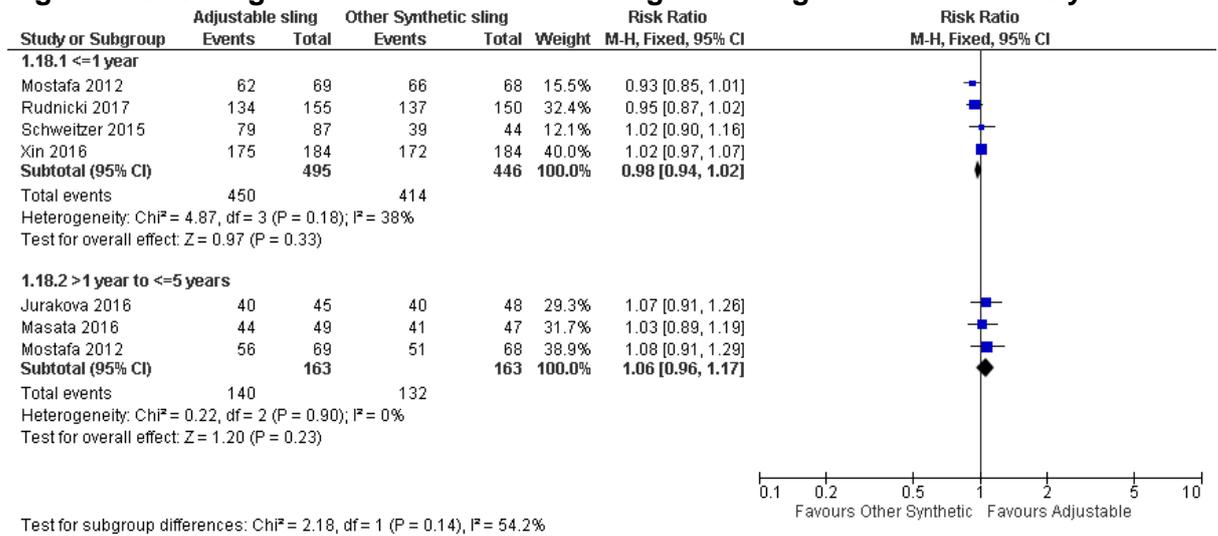
**Figure 121: Change in continence status - Subjective cure**



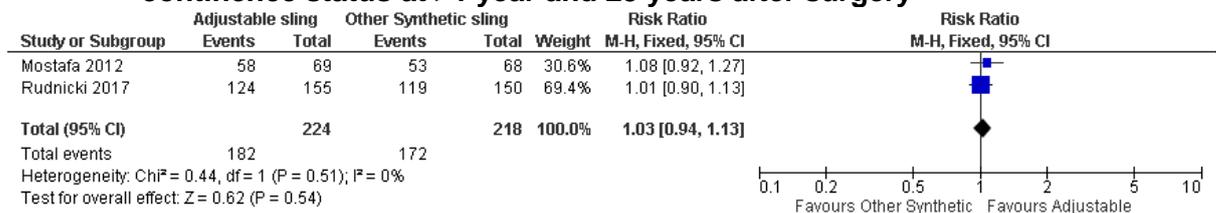
**Figure 122: Change in continence status - Objective cure**



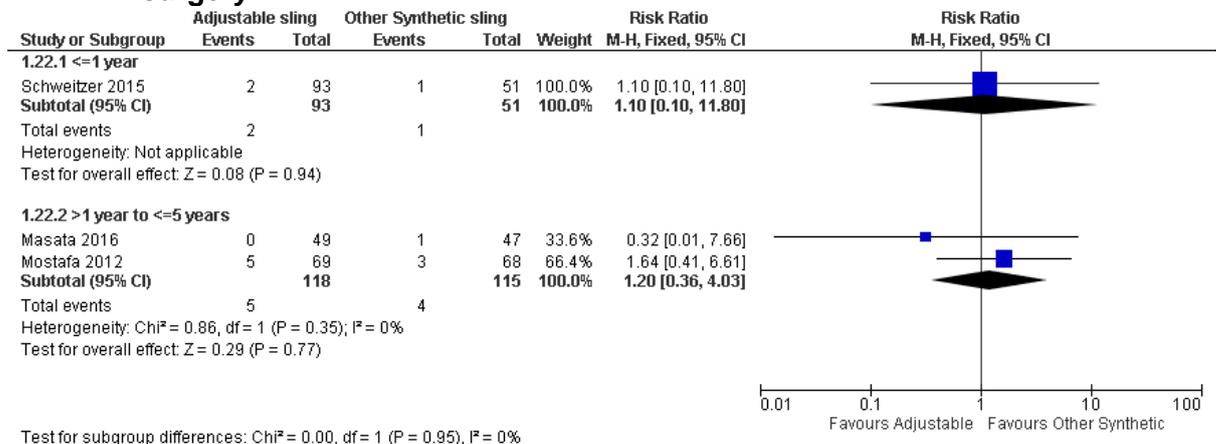
**Figure 123: Change in continence status – Negative cough stress test at ≤5 years**



**Figure 124: Patient satisfaction/patient-reported improvement - Improvement in continence status at >1 year and ≤5 years after surgery**

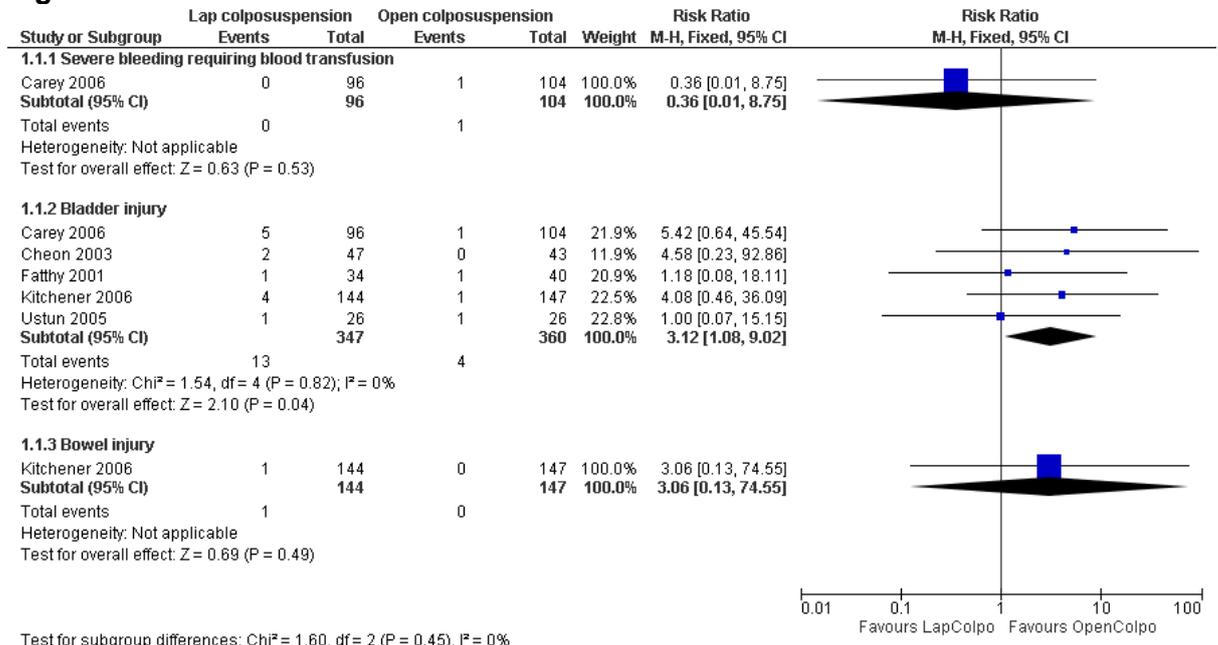


**Figure 125: Repeat surgery for SUI, POP or mesh complications at ≤5 years after surgery**



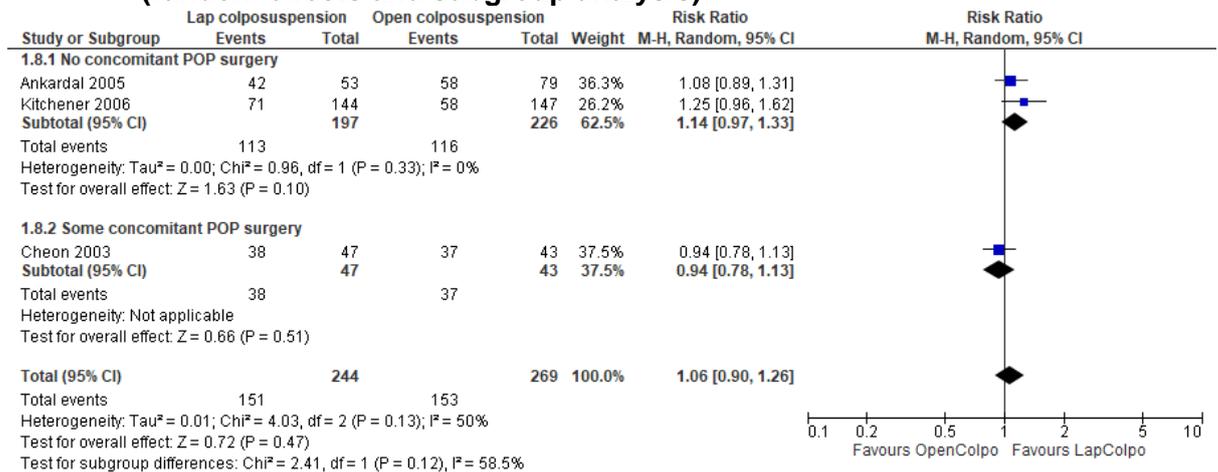
Laparoscopic colposuspension with sutures versus open colposuspension with sutures

Figure 126: Adverse events



Abbreviations: LapColpo, Laparoscopic colposuspension with sutures; OpenColpo, Open Colposuspension with sutures.

Figure 127: Change in continence status – Subjective cure at ≤1 year after surgery (random effects and subgroup analysis)



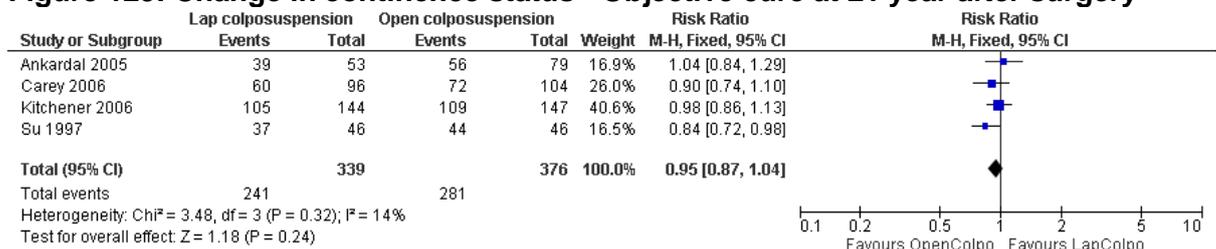
Abbreviations: LapColpo, Laparoscopic colposuspension with sutures; OpenColpo, Open Colposuspension with sutures.

**Figure 128: Change in continence status – Subjective cure at >1 year to ≤5 years after surgery**



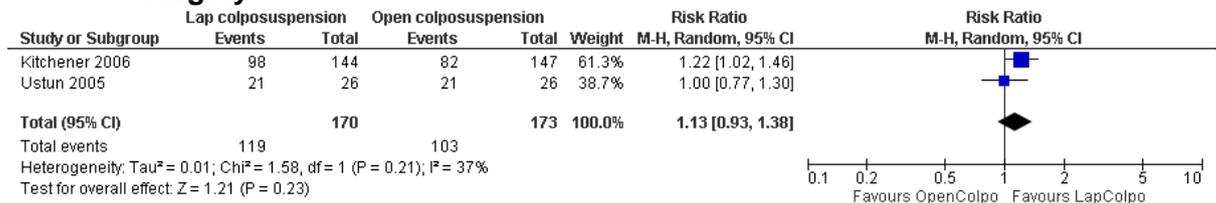
Abbreviations: *LapColpo*, Laparoscopic colposuspension with sutures; *OpenColpo*, Open Colposuspension with sutures.

**Figure 129: Change in continence status - Objective cure at ≤1 year after surgery**



Abbreviations: *LapColpo*, Laparoscopic colposuspension with sutures; *OpenColpo*, Open Colposuspension with sutures.

**Figure 130: Change in continence status - Objective cure at >1 year to ≤5 years after surgery**



Abbreviations: *LapColpo*, Laparoscopic colposuspension with sutures; *OpenColpo*, Open Colposuspension with sutures.

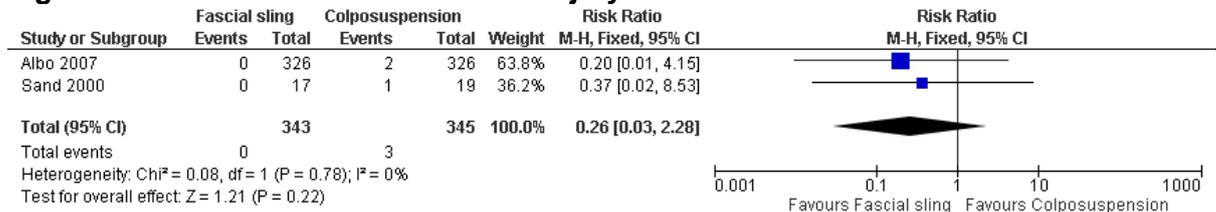
**Figure 131: Change in continence status – Negative cough stress test at ≤1 year after surgery**



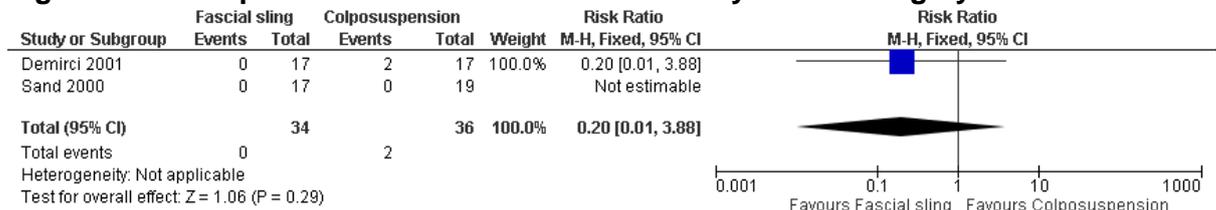
Abbreviations: *LapColpo*, Laparoscopic colposuspension with sutures; *OpenColpo*, Open Colposuspension with sutures.

## Autologous rectus fascial sling versus colposuspension

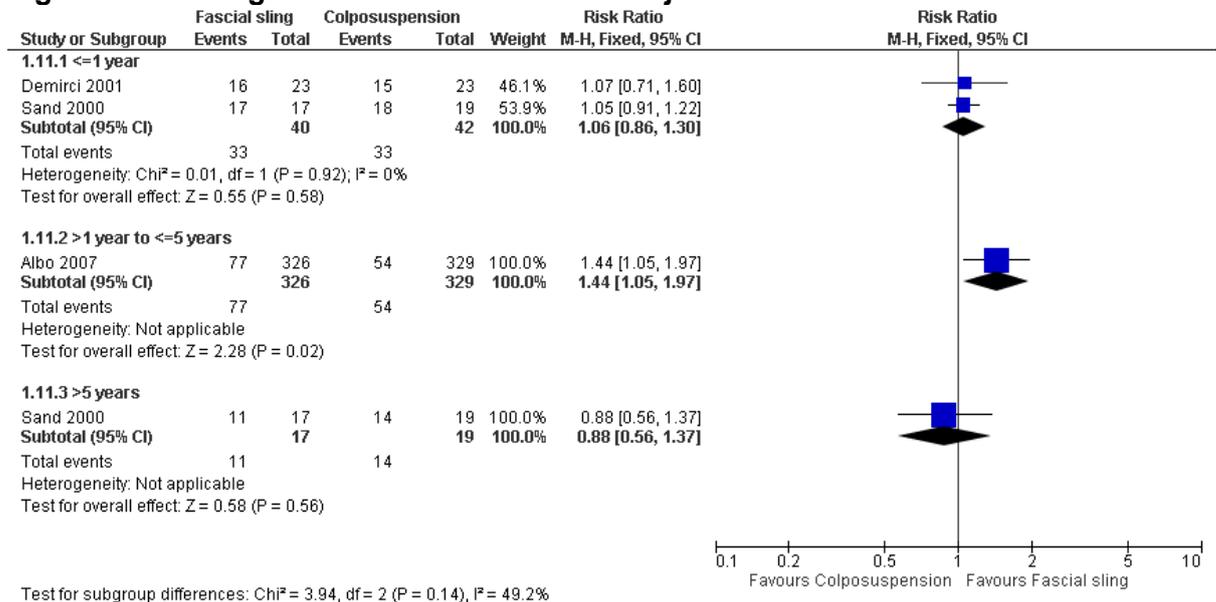
**Figure 132: Adverse events – Bladder injury**



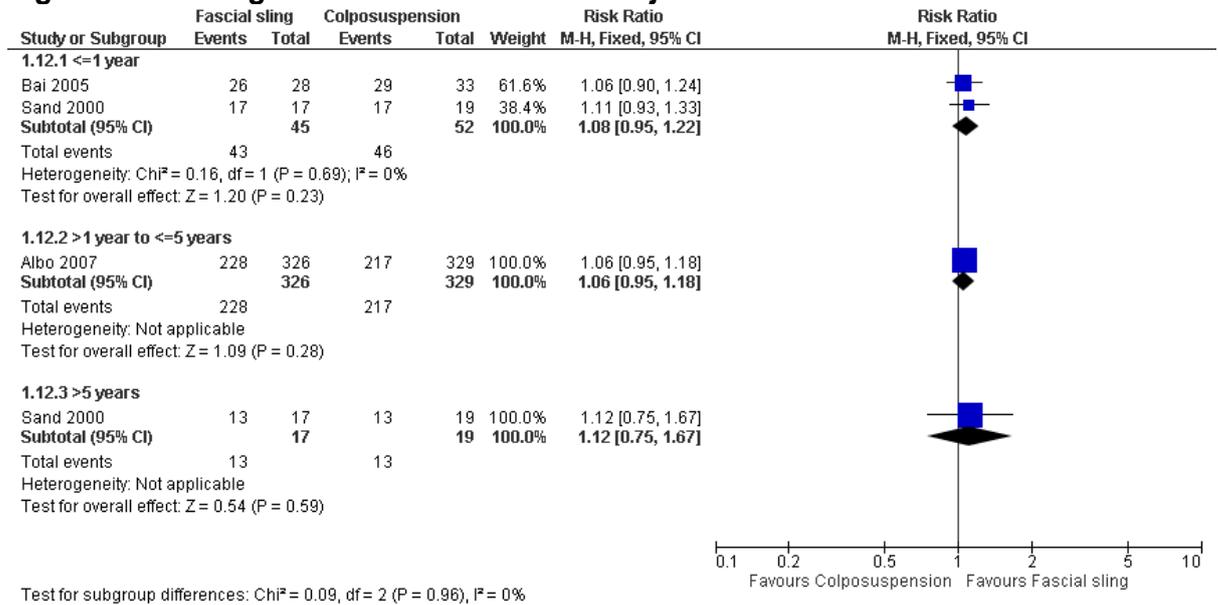
**Figure 133: Complications – POP occurrence at ≤ 1 year after surgery**



**Figure 134: Change in continence status – Subjective cure**

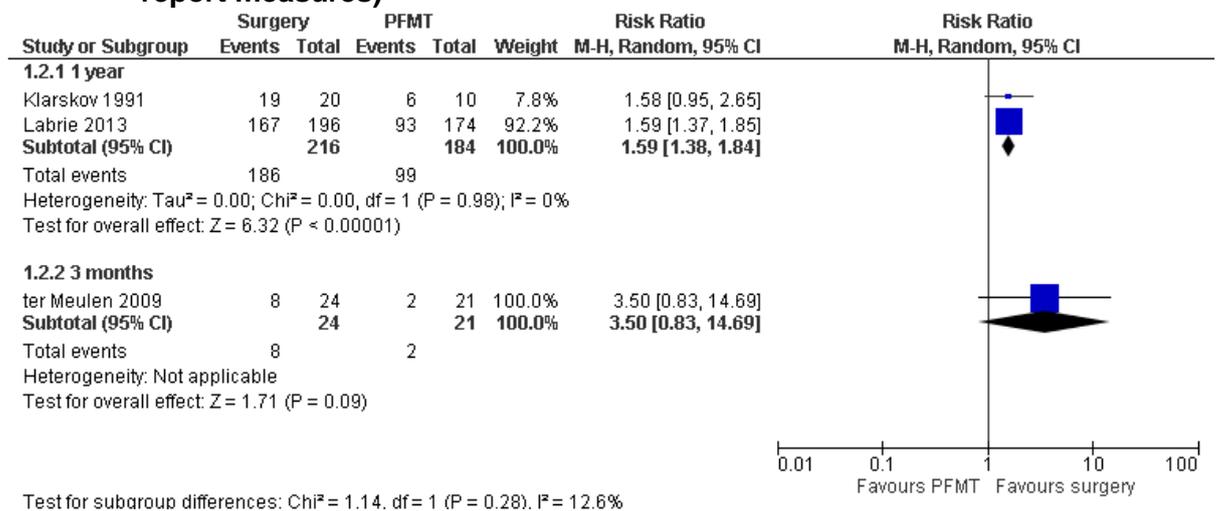


**Figure 135: Change in continence status – Objective cure**

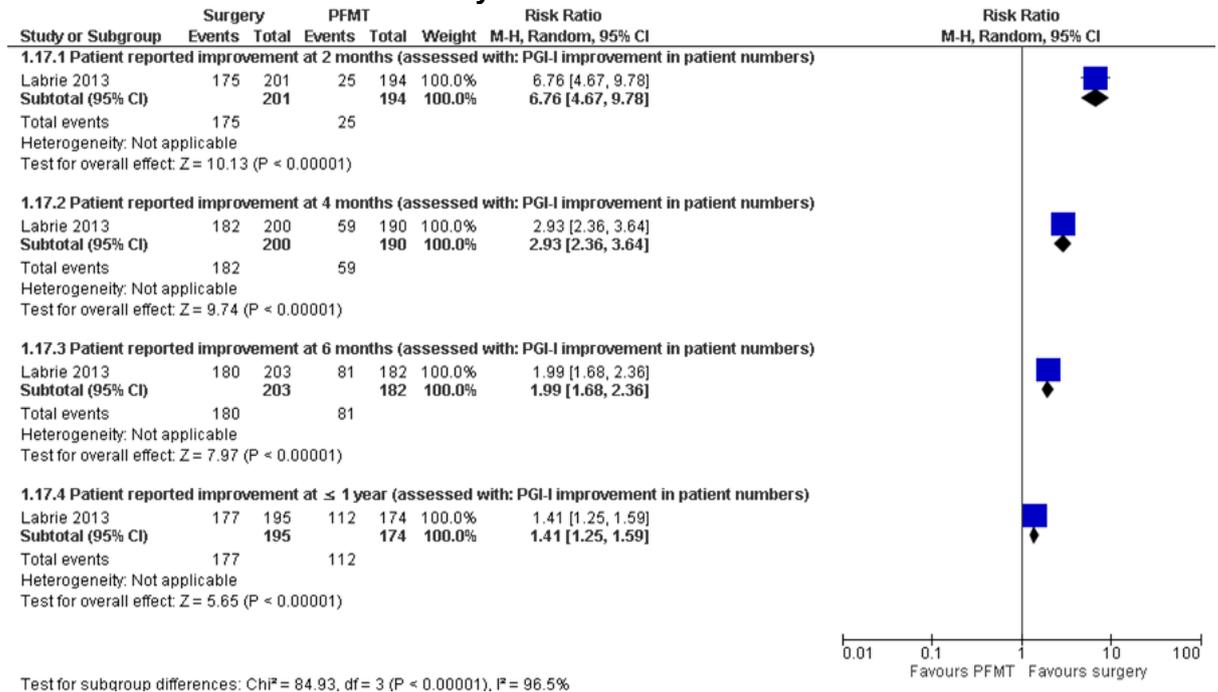


**Forest plots for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

**Figure 136: Change in continence status at ≤ 1 year - Subjective cure (various self-report measures)**



**Figure 137: Patient satisfaction/patient-reported improvement – Improvement in continence status at ≤1 year**



## Appendix F – GRADE tables

GRADE tables for the review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?

### Colposuspension versus synthetic mesh sling

Table 20: Clinical evidence profile for colposuspension versus synthetic mesh sling

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related quality of life - BFLUTS-SF sex life spoilt by urinary symptoms at 6 months (follow-up 6 months; assessed with: Bristol Female Lower Urinary Tract Symptoms Scored Form)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	33/127 (26%)	43/159 (27%)	RR 0.96 (0.65 to 1.42)	11 fewer per 1000 (from 95 fewer to 114 more)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related quality of life - BFLUTS-SF sex life spoilt by urinary symptoms at 60 months (follow-up 60 months; assessed with: Bristol Female Lower Urinary Tract Symptoms Scored Form)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	7/79 (8.9%)	14/98 (14.3%)	RR 0.62 (0.26 to 1.46)	54 fewer per 1000 (from 106 fewer to 66 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Severe bleeding requiring blood transfusion</b>												
3	randomised trials	serious <sup>3</sup>	no serious inconsistency	serious <sup>4,5</sup>	very serious <sup>2</sup>	none	0/125 (0%)	1/134 (0.75%)	RR 0.33 (0.01 to 7.92)	5 fewer per 1000 (from 7 fewer to 52 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Bladder injury</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
11	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	5/524 (0.95%)	31/562 (5.5%)	RR 0.23 (0.1 to 0.51)	42 fewer per 1000 (from 27 fewer to 50 fewer)	⊕⊕OO LOW	CRITICAL
<b>Adverse events - Bowel injury</b>												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	serious <sup>4,5</sup>	very serious <sup>2</sup>	none	1/36 (2.8%)	0/36 (0%)	RR 3 (0.13 to 71.28)	-	⊕OOO VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year (random effects analysis) (follow-up 12 months)</b>												
2	randomised trials	no serious risk of bias	serious <sup>6</sup>	serious <sup>4,7</sup>	very serious <sup>2</sup>	none	2/82 (2.4%)	4/107 (3.7%)	RR 0.78 (0.05 to 12.33)	8 fewer per 1000 (from 36 fewer to 424 more)	⊕OOO VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - subgroup analysis - No concomitant POP surgery (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	very serious <sup>2</sup>	none	0/31 (0%)	3/37 (8.1%)	RR 0.17 (0.01 to 3.16)	67 fewer per 1000 (from 80 fewer to 175 more)	⊕OOO VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - subgroup analysis - Concomitant POP surgery (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7</sup>	very serious <sup>2</sup>	none	2/51 (3.9%)	1/70 (1.4%)	RR 2.75 (0.26 to 29.46)	25 more per 1000 (from 11 fewer to 407 more)	⊕OOO VERY LOW	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years (follow-up 22-24 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
2	randomised trials	very serious <sup>8</sup>	no serious inconsistency	serious <sup>4,9</sup>	very serious <sup>2</sup>	none	4/77 (5.2%)	0/84 (0%)	RR 8.76 (0.49 to 156.85)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤ 1 year (follow-up 6-12 months)</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7</sup>	very serious <sup>2</sup>	none	1/202 (0.5%)	4/227 (1.8%)	RR 0.35 (0.06 to 2.21)	11 fewer per 1000 (from 17 fewer to 21 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion - &gt;1 year to ≤5 years (follow-up 12-60 months)</b>												
5	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>2</sup>	none	0/281 (0%)	6/317 (1.9%)	RR 0.27 (0.06 to 1.27)	14 fewer per 1000 (from 18 fewer to 5 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Fistula at &gt;1 year to ≤5 years (non-event) (follow-up median 22 months)</b>												
1	randomised trials	serious <sup>10</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	0/41 (0%)	0/49 (0%)	RR 1 (0.96 to 1.04)	-	⊕⊕○○ LOW	CRITICAL
								0%		-		
<b>Complications - Need for catheterisation at ≤1 year (follow-up 12 months)</b>												
3	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7</sup>	very serious <sup>2</sup>	none	4/133 (3%)	2/156 (1.3%)	RR 1.95 (0.46 to 8.18)	12 more per 1000 (from 7 fewer to 92 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at &gt;1 years to ≤5 years (follow-up 22-60 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>2</sup>	none	3/247 (1.2%)	1/254 (0.39%)	RR 1.97 (0.36 to 10.67)	4 more per 1000 (from 3 fewer to 38 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year (random effects analysis) (follow-up 6-12 months)</b>												
2	randomised trials	serious <sup>1</sup>	serious <sup>6</sup>	serious <sup>4,7</sup>	serious <sup>11</sup>	none	73/202 (36.1%)	60/227 (26.4%)	RR 1.29 (0.81 to 2.04)	77 more per 1000 (from 50 fewer to 275 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year - subgroup analysis - No concomitant POP surgery (follow-up 6 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>11</sup>	none	56/146 (38.4%)	42/170 (24.7%)	RR 1.55 (1.11 to 2.17)	136 more per 1000 (from 27 more to 289 more)	⊕⊕○○ LOW	CRITICAL
<b>Complications - Infection at ≤1 year - subgroup analysis - Concomitant POP surgery (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7</sup>	very serious <sup>2</sup>	none	17/56 (30.4%)	18/57 (31.6%)	RR 0.96 (0.55 to 1.67)	13 fewer per 1000 (from 142 fewer to 212 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 to ≤5 years (follow-up 22-24 months)</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>4,9</sup>	very serious <sup>2</sup>	none	8/254 (3.1%)	15/285 (5.3%)	RR 0.59 (0.26 to 1.34)	22 fewer per 1000 (from 39 fewer to 18 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at ≤1 year (follow-up 6 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>12</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>2</sup>	none	3/43 (7%)	7/44 (15.9%)	RR 0.44 (0.12 to 1.59)	89 fewer per 1000 (from 140 fewer to 94 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;1 year to ≤5 years (follow-up 22-60 months)</b>												
3	randomised trials	serious <sup>8</sup>	no serious inconsistency	serious <sup>4,9</sup>	very serious <sup>2</sup>	none	5/156 (3.2%)	4/182 (2.2%)	RR 1.42 (0.4 to 5.04)	9 more per 1000 (from 13 fewer to 89 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤ 1 year (follow-up 12 months)</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>7</sup>	very serious <sup>2</sup>	none	5/78 (6.4%)	4/77 (5.2%)	RR 1.25 (0.35 to 4.52)	13 more per 1000 (from 34 fewer to 183 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at &gt;1 year to ≤5 years (follow-up 22-60 months)</b>												
3	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7</sup>	very serious <sup>2</sup>	none	5/146 (3.4%)	2/169 (1.2%)	RR 2.61 (0.53 to 12.79)	19 more per 1000 (from 6 fewer to 140 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - POP occurrence at &gt;1 year to ≤5 years (follow-up 20-60 months)</b>												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>11</sup>	none	31/136 (22.8%)	26/166 (15.7%)	RR 1.64 (1.1 to 2.44)	100 more per 1000 (from 16 more to 226 more)	⊕⊕○○ LOW	CRITICAL
<b>Complications - Wound complications at &gt;1 year to ≤5 year (follow-up median 22 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>10</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	0/41 (0%)	0/49 (0%)	RR 1 (0.96 to 1.04)	-	⊕⊕○○ LOW	CRITICAL
								0%		-		
<b>Change in continence status - Subjective cure at ≤1 year (follow-up 6-12 months; assessed with: Self-reportedly continent; ICIQ score of 0)</b>												
4	randomised trials	serious <sup>1,13</sup>	no serious inconsistency	serious <sup>4,13</sup>	no serious imprecision	none	173/307 (56.4%)	197/318 (61.9%)	RR 0.9 (0.8 to 1.03)	62 fewer per 1000 (from 124 fewer to 19 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years (follow-up 24-60 months; assessed with: Self-reported continent; ICIQ score of 0)</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>4,7,13</sup>	serious <sup>11</sup>	none	126/307 (41%)	145/312 (46.5%)	RR 0.88 (0.74 to 1.04)	56 fewer per 1000 (from 121 fewer to 19 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;5 years (follow-up median 65 months; assessed with: Response of 'never' to Incontinence Severity Index Q1)</b>												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	serious <sup>4,5</sup>	very serious <sup>2</sup>	none	12/36 (33.3%)	13/36 (36.1%)	RR 0.92 (0.49 to 1.74)	29 fewer per 1000 (from 184 fewer to 267 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year (follow-up 6-12 months; assessed with: Negative pad test or composite (subjective and objective) measures)</b>												
5	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>4,7,13</sup>	serious <sup>11</sup>	none	233/340 (68.5%)	272/349 (77.9%)	RR 0.88 (0.8 to 0.96)	94 fewer per 1000 (from 31 fewer to 156 fewer)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years (follow-up 21-60 months; assessed with: Negative pad test or composite (subjective and objective) measures)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
7	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,5,7,9,13</sup>	serious <sup>11</sup>	none	194/420 (46.2%)	232/424 (54.7%)	RR 0.84 (0.74 to 0.95)	88 fewer per 1000 (from 27 fewer to 142 fewer)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at ≤1 year - No concomitant POP surgery (follow-up 6 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>11</sup>	none	114/169 (67.5%)	142/175 (81.1%)	RR 0.83 (0.73 to 0.94)	138 fewer per 1000 (from 49 fewer to 219 fewer)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at &gt;1 year to ≤5 years - Concomitant POP surgery (follow-up 24 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7</sup>	serious <sup>11</sup>	none	36/56 (64.3%)	44/57 (77.2%)	RR 0.83 (0.65 to 1.06)	131 fewer per 1000 (from 270 fewer to 46 more)	⊕⊕○○ LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years (follow-up 22-24 months; assessed with: Various measurements of improvement )</b>												
5	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7,9</sup>	serious <sup>11</sup>	none	147/221 (66.5%)	165/220 (75%)	RR 0.89 (0.79 to 0.99)	83 fewer per 1000 (from 7 fewer to 157 fewer)	⊕⊕○○ LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;5 years (follow-up median 65 months; assessed with: Patient Global Impression of Improvement (PGII))</b>												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	serious <sup>5</sup>	very serious <sup>2</sup>	none	20/36 (55.6%)	17/36 (47.2%)	RR 1.18 (0.75 to 1.85)	85 more per 1000 (from 118 fewer to 401 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for any reason at ≤1 year (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>10</sup>	no serious inconsistency	serious <sup>4,13</sup>	very serious <sup>2</sup>	none	5/82 (6.1%)	6/86 (7%)	RR 0.86 (0.27 to 2.78)	10 fewer per 1000 (from 51 fewer to 124 more)	⊖○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for any reason at &gt;1 year to ≤5 years - No concomitant POP surgery (follow-up 60 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>11</sup>	none	16/146 (11%)	7/170 (4.1%)	RR 2.66 (1.13 to 6.29)	68 more per 1000 (from 5 more to 218 more)	⊕⊕○○ LOW	IMPORTANT
<b>Repeat surgery for SUI - &gt;1 year to ≤5 years (follow-up 20-20.6 months)</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4,7</sup>	very serious <sup>2</sup>	none	7/82 (8.5%)	3/84 (3.6%)	RR 2.4 (0.65 to 8.95)	50 more per 1000 (from 13 fewer to 284 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for SUI - &gt;5 years (follow-up mean 65 months)</b>												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	serious <sup>4,5</sup>	very serious <sup>2</sup>	none	1/28 (3.6%)	1/25 (4%)	RR 0.89 (0.06 to 13.54)	4 fewer per 1000 (from 38 fewer to 502 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	very serious <sup>2</sup>	none	0/31 (0%)	1/37 (2.7%)	RR 0.4 (0.02 to 9.38)	16 fewer per 1000 (from 26 fewer to 226 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications at &gt;5 years (follow-up median 65 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Colposuspension	Synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	serious <sup>4,5</sup>	very serious <sup>2</sup>	none	0/36 (0%)	2/36 (5.6%)	RR 0.2 (0.01 to 4.03)	44 fewer per 1000 (from 55 fewer to 168 more)	⊕○○○ VERY LOW	IMPORTANT

1 Unclear risk of bias regarding blinding of participants, blinding of outcome assessment and selective reporting.

2 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

3 Unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting. Participants in colposuspension group has significantly more lysis of adhesions at baseline than those in synthetic sling group.

4 Unclear whether some or all participants had failed or declined conservative treatment.

5 Paraiso et al. 2004/Jelovsek et al. 2008: Some participants had concomitant POP surgery (percentage not reported).

6 High heterogeneity (i-squared ≥50% and <80%).

7 Trabuco et al. 2016/2018: All participants had concomitant abdominal sacrocolpopexy.

8 High risk of bias regarding random sequence generation; unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment and selective reporting.

9 Liapis et al. 2002: Some participants had concomitant POP surgery (percentage not reported).

10 Unclear risk regarding allocation concealment, blinding of participants, blinding of outcome assessment and selective reporting.

11 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

12 Unclear risk regarding allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data (40% dropout rate) and selective reporting.

13 Sivaslioglu et al. 2007: Unclear whether some or all participants had concomitant POP surgery.

## Autologous rectus fascial sling versus synthetic mesh sling

**Table 21: Clinical evidence profile for autologous rectus fascial sling versus synthetic mesh sling**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related quality of life - BFLUTS at 10 years (follow-up median 10 years; measured with: Bristol Female Lower Urinary Tract Symptoms questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	63	61	-	SMD 0.15 lower (0.5 lower to 0.21 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related quality of life - BFLUTS sexual function at 10 years (follow-up median 10 years; measured with: Bristol Female Lower Urinary Tract Symptoms questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	63	61	-	SMD 0.08 higher (0.28 lower to 0.43 higher)	⊕⊕○○ LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - General health perceptions (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>6</sup>	none	10	10	-	SMD 1.04 lower (1.97 to 0.11 lower)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - Incontinence impact (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>6</sup>	none	10	10	-	SMD 0.7 lower (1.6 lower to 0.2 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - Role limitations (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>6</sup>	none	10	10	-	SMD 1.39 lower (2.37 to 0.42 lower)	⊕○○○ VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - Physical and Social limitations (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>6</sup>	none	10	10	-	SMD 1.39 lower (2.37 to 0.42 lower)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - Personal relationships (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>7</sup>	none	10	10	-	SMD 0.03 higher (0.85 lower to 0.91 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - Emotions (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>6</sup>	none	10	10	-	SMD 1.19 lower (2.14 to 0.24 lower)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - Sleep/energy (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>6</sup>	none	10	10	-	SMD 0.54 lower (1.43 lower to 0.36 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at 6 months - Severity (follow-up 6 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>6</sup>	none	10	10	-	SMD 1.47 lower (2.46 to 0.49 lower)	⊕000 VERY LOW	CRITICAL
<b>Adverse Events - Severe bleeding requiring blood transfusion</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
5	randomised trials	very serious <sup>8</sup>	no serious inconsistency	serious <sup>9</sup>	very serious <sup>10</sup>	none	1/184 (0.54%)	2/152 (1.3%)	RR 0.4 (0.05 to 2.88)	8 fewer per 1000 (from 12 fewer to 25 more)	⊕000 VERY LOW	CRITICAL
<b>Adverse Events - Bladder injury</b>												
9	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>12</sup>	none	7/243 (2.9%)	16/228 (7%)	RR 0.36 (0.16 to 0.84)	45 fewer per 1000 (from 11 fewer to 59 fewer)	⊕000 VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - Rectus fascial sling vs synthetic sling (follow-up 6-12 months)</b>												
3	randomised trials	serious <sup>5</sup>	very serious <sup>13</sup>	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	7/85 (8.2%)	7/89 (7.9%)	RR 0.72 (0.02 to 34.42)	22 fewer per 1000 (from 77 fewer to 1000 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - Rectus fascial sling vs retropubic synthetic sling (follow-up 6 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>12</sup>	none	7/25 (28%)	2/28 (7.1%)	RR 3.92 (0.9 to 17.15)	209 more per 1000 (from 7 fewer to 1000 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - Rectus fascial sling vs transobturator synthetic sling (follow-up 12 months)</b>												
2	randomised trials	serious <sup>14</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	0/60 (0%)	5/61 (8.2%)	RR 0.09 (0.01 to 1.59)	75 fewer per 1000 (from 81 fewer to 48 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Pain at &gt;1 years to ≤5 years (follow-up mean 13.8 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	3/35 (8.6%)	4/35 (11.4%)	RR 0.75 (0.18 to 3.11)	29 fewer per 1000 (from 94 fewer to 241 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Pain at &gt;5 years (follow-up 120-126 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
2	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	5/93 (5.4%)	5/100 (5%)	RR 1.12 (0.36 to 3.52)	6 more per 1000 (from 32 fewer to 126 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year (follow-up 6-12 months)</b>												
3	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	0/85 (0%)	1/89 (1.1%)	RR 0.35 (0.02 to 8.1)	7 fewer per 1000 (from 11 fewer to 80 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;1 year to ≤5 years (follow-up 14-54 months)</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,9</sup>	very serious <sup>10</sup>	none	1/74 (1.4%)	3/59 (5.1%)	RR 0.36 (0.06 to 2.28)	33 fewer per 1000 (from 48 fewer to 65 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;5 years (follow-up 120-126 months)</b>												
2	randomised trials	very serious <sup>15</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	0/93 (0%)	4/100 (4%)	RR 0.22 (0.03 to 1.87)	31 fewer per 1000 (from 39 fewer to 35 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation - ≤1 year (follow-up 1-12 months)</b>												
5	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	13/196 (6.6%)	6/144 (4.2%)	RR 1.79 (0.77 to 4.17)	33 more per 1000 (from 10 fewer to 132 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at &gt;5 years (follow-up median 120 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	4/61 (6.6%)	3/63 (4.8%)	RR 1.38 (0.32 to 5.9)	18 more per 1000 (from 32 fewer to 233 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	3/20 (15%)	0/21 (0%)	RR 7.33 (0.4 to 133.57)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 year to ≤5 years (non-event)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	0/35 (0%)	0/35 (0%)	RR 1.0 (0.95 to 1.06)	-	⊕⊕○○ LOW	CRITICAL
								0%		-		
<b>Complications - De novo urgency at &gt;1 year to ≤5 years (follow-up 18-44 months)</b>												
2	randomised trials	serious <sup>16</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	9/33 (27.3%)	9/32 (28.1%)	RR 0.96 (0.46 to 2.01)	11 fewer per 1000 (from 152 fewer to 284 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;5 years (follow-up 120-126 months)</b>												
2	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	6/93 (6.5%)	9/100 (9%)	RR 0.77 (0.31 to 1.93)	21 fewer per 1000 (from 62 fewer to 84 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at &gt;1 year to ≤5 years (follow-up mean 39 months)</b>												
1	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	8/36 (22.2%)	1/25 (4%)	RR 5.56 (0.74 to 41.68)	182 more per 1000 (from 10 fewer to 1000 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at &gt;5 years (follow-up mean 126 months)</b>												
1	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	2/32 (6.3%)	3/37 (8.1%)	RR 0.77 (0.14 to 4.33)	19 fewer per 1000 (from 70 fewer to 270 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Wound complications at ≤1 year (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
3	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	10/85 (11.8%)	1/97 (1%)	RR 6.2 (1.32 to 29.06)	54 more per 1000 (from 3 more to 289 more)	⊕○○○ VERY LOW	CRITICAL
<b>Change of continence status - Subjective cure at ≤1 year (random effects analysis) (follow-up 12 months)</b>												
3	randomised trials	very serious <sup>17</sup>	very serious <sup>13</sup>	serious <sup>3,4</sup>	very serious <sup>12</sup>	none	53/115 (46.1%)	55/102 (53.9%)	RR 1.02 (0.56 to 1.86)	11 more per 1000 (from 237 fewer to 464 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - Rectus fascial sling vs retropubic synthetic sling (follow-up 12 months; assessed with: Various self-report measures)</b>												
2	randomised trials	very serious <sup>17</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>12</sup>	none	44/105 (41.9%)	52/92 (56.5%)	RR 0.75 (0.57 to 1)	141 fewer per 1000 (from 243 fewer to 0 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - Rectus fascial sling vs transobturator synthetic sling (follow-up 12 months; assessed with: Various self-report measures)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>12</sup>	none	9/10 (90%)	3/10 (30%)	RR 3.0 (1.14 to 7.91)	600 more per 1000 (from 42 more to 1000 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years (follow-up 12 months; assessed with: Various self-report measures)</b>												
1	randomised trials	serious <sup>16</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	12/21 (57.1%)	13/20 (65%)	RR 0.88 (0.54 to 1.44)	78 fewer per 1000 (from 299 fewer to 286 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;5 years (follow-up median 120 months; assessed with: Various self-report measures)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>12</sup>	none	31/84 (36.9%)	20/72 (27.8%)	RR 1.33 (0.83 to 2.12)	92 more per 1000 (from 47 fewer to 311 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year (follow-up 6-12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
4	randomised trials	serious <sup>14</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	107/113 (94.7%)	110/120 (91.7%)	RR 1.03 (0.96 to 1.11)	27 more per 1000 (from 37 fewer to 101 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years (follow-up 18-54 months)</b>												
3	randomised trials	very serious <sup>8</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	83/103 (80.6%)	67/84 (79.8%)	RR 0.98 (0.85 to 1.13)	16 fewer per 1000 (from 120 fewer to 104 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at &gt;1 year to ≤5 years (follow-up mean 13.8 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	33/37 (89.2%)	31/35 (88.6%)	RR 1.01 (0.86 to 1.19)	9 more per 1000 (from 124 fewer to 168 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at &gt;5 years (follow-up mean 126 months)</b>												
1	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	48/52 (92.3%)	43/48 (89.6%)	RR 1.03 (0.91 to 1.17)	27 more per 1000 (from 81 fewer to 152 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years (follow-up 18-44 months)</b>												
3	randomised trials	serious <sup>16</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	53/70 (75.7%)	51/67 (76.1%)	RR 1 (0.83 to 1.2)	0 fewer per 1000 (from 129 fewer to 152 more)	⊕⊕○○ LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;5 years (follow-up 120-126 months)</b>												
2	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>12</sup>	none	73/136 (53.7%)	76/120 (63.3%)	RR 0.85 (0.69 to 1.04)	95 fewer per 1000 (from 196 fewer to 25 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for any reason at ≤1 year (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Synthetic sling	Relative (95% CI)	Absolute		
2	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	2/103 (1.9%)	1/94 (1.1%)	RR 1.39 (0.13 to 14.5)	4 more per 1000 (from 9 fewer to 144 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for any reason at &gt;5 years (follow-up mean 126 months)</b>												
1	randomised trials	very serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	1/32 (3.1%)	1/37 (2.7%)	RR 1.16 (0.08 to 17.75)	4 more per 1000 (from 25 fewer to 453 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for SUI at &gt;5 years (follow-up median 120 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	4/61 (6.6%)	4/63 (6.3%)	RR 1.03 (0.27 to 3.95)	2 more per 1000 (from 46 fewer to 187 more)	⊕○○○ VERY LOW	CRITICAL
<b>Repeat surgery for POP or mesh complications at &gt;5 years - &gt;1 year to ≤5 years (follow-up mean 13.8 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	0/35 (0%)	2/35 (5.7%)	RR 0.2 (0.01 to 4.02)	46 fewer per 1000 (from 57 fewer to 173 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for POP or mesh complications at &gt;5 years - &gt;5 years (follow-up median 10 years)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	4/61 (6.6%)	2/63 (3.2%)	RR 2.07 (0.39 to 10.87)	34 more per 1000 (from 19 fewer to 313 more)	⊕○○○ VERY LOW	IMPORTANT

1 Outcome expressed as standardised mean difference because study only reported p-value.

2 High risk of bias regarding selective reporting (only reports quality of life data where TVT and fascial sling significantly better than porcine dermis sling); Unclear risk of bias regarding blinding of participants.

3 Unclear whether some or all of participants had failed or declined conservative treatment.

4 For all studies (with exception of Teleb et al. 2011 and Wadie et al. 2010), it is not reported whether or not participants had concomitant POP surgery.

5 Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment and selective reporting.

6 95% CI crosses 1 default MID for standardised mean difference (+/-0.5 or -0.5).

7 95% CI crosses 2 default MIDs for standardised mean difference (+/- 0.5).

8 High risk of bias regarding incomplete outcome data (data reported for uneven number of participants in each group, number randomised not reported in 1 study; >20% overall dropout rate at both follow-up points in 1 study); Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting.

9 Wadie et al. 2010: 43% of participants had concomitant POP surgery.

10 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

11 High risk regarding incomplete outcome data (>20% overall dropout rate at both follow-up points); unclear risk of bias regarding random sequence generation, allocation concealment, blinding of outcome assessment and selective reporting.

12 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

13 Very high heterogeneity (i-squared >=80%)

14 Unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting.

15 High/unclear risk of bias regarding selective reporting (1 study only reports quality of life data where TVT and fascial sling significantly better than porcine dermis sling) and incomplete outcome data (>20% overall dropout rate at both follow-up points in 1 study); unclear risk of bias regarding random sequence generation, allocation concealment, blinding of outcome assessment and selective reporting.

16 Unclear risk of bias regarding random sequence generation, blinding of participants, blinding of outcome assessment, and selective reporting.

17 High risk of bias regarding selective reporting (only reports quality of life data where TVT and fascial sling significantly better than porcine dermis sling); Unclear risk of bias regarding random sequence generation, blinding of participants, blinding of outcome assessment, and selective reporting.

## Non-autologous biological sling versus synthetic mesh sling

**Table 22: Clinical evidence profile for non-autologous biological sling versus synthetic mesh sling**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Biological sling	Synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related quality of life - BFLUTS at 10 years - Porcine dermis sling vs TVT (follow-up median 10 years; measured with: Bristol Female Lower Urinary Tract Symptoms questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>5</sup>	none	63	38	-	SMD 0.19 higher (0.21 lower to 0.59 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related quality of life - BFLUTS sexual function at 10 years - Porcine dermis sling vs TVT (follow-up median 10 years; measured with: Bristol Female Lower Urinary Tract Symptoms questionnaire; Better indicated by lower values)</b>												
1 <sup>1</sup>	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>5</sup>	none	63	38	-	SMD 0.31 higher (0.1 lower to 0.71 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related quality of life - King's Health Questionnaire-Total at 1 year - - Porcine dermis sling vs Align-TO (follow-up 12 months; measured with: King's Health Questionnaire; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Biological sling	Synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	serious <sup>6,7</sup>	none	50	50	-	MD 53.6 lower (136.34 lower to 29.14 higher)	⊕⊕⊕ LOW	CRITICAL
<b>Adverse Events - Severe bleeding requiring blood transfusion (non-event) - - Porcine dermis sling vs Synthetic sling</b>												
3	randomised trials	serious <sup>2,8</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	0/168 (0%)	0/182 (0%)	RR 1 (0.98 to 1.02)	-	⊕⊕⊕ LOW	CRITICAL
								0%		-		
<b>Adverse Events - Bladder injury - Cadaveric fascia lata sling vs Retropubic synthetic sling</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	3/67 (4.5%)	8/72 (11.1%)	RR 0.4 (0.11 to 1.46)	67 fewer per 1000 (from 99 fewer to 51 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Adverse Events - Bladder injury - Porcine dermis sling vs Synthetic sling</b>												
3	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	1/168 (0.6%)	4/182 (2.2%)	RR 0.36 (0.04 to 3.13)	14 fewer per 1000 (from 21 fewer to 47 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - Porcine dermis sling vs Synthetic sling (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	2/50 (4%)	1/50 (2%)	RR 2.0 (0.19 to 21.36)	20 more per 1000 (from 16 fewer to 407 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years - Porcine dermis sling vs Synthetic sling (follow-up 24. 36 months)</b>												
1	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	2/74 (2.7%)	3/68 (4.4%)	RR 0.61 (0.11 to 3.56)	17 fewer per 1000 (from 39 fewer to 113 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at &gt; 5 years - Porcine dermis sling vs Synthetic sling (non-event) (follow-up median 120 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	0/38 (0%)	0/63 (0%)	RR 1.0 (0.96 to 1.04)	-		CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Biological sling	Synthetic sling	Relative (95% CI)	Absolute		
								6.8%		0 fewer per 1000 (from 3 fewer to 3 more)	⊕000 VERY LOW	
<b>Complications - Mesh extrusion at ≤1 year - Cadaveric fascia lata sling vs Retropubic IVS (non-event) (follow-up 12 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	0/72 (0%)	0/67 (0%)	RR 1.0 (0.97 to 1.03)	-	⊕⊕00 LOW	CRITICAL
								1%		0 fewer per 1000 (from 0 fewer to 0 more)		
<b>Complications - Mesh extrusion at ≤1 year - Porcine dermis sling vs Align-TO (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	0/50 (0%)	1/50 (2%)	RR 0.33 (0.01 to 7.99)	13 fewer per 1000 (from 20 fewer to 140 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;5 years - Porcine dermis vs TVT (follow-up median 120 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	0/38 (0%)	1/63 (1.6%)	RR 0.55 (0.02 to 13.1)	7 fewer per 1000 (from 16 fewer to 192 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at ≤1 year - Cadaveric fascia lata sling vs Retropubic IVS (follow-up 12 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	8/67 (11.9%)	8/72 (11.1%)	RR 1.07 (0.43 to 2.7)	8 more per 1000 (from 63 fewer to 189 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at ≤1 year - Porcine dermis sling vs TVT (follow-up 1.4-12 months)</b>												
2	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	2/120 (1.7%)	3/137 (2.2%)	RR 0.61 (0.11 to 3.56)	9 fewer per 1000 (from 19 fewer to 56 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at &gt;5 years- Porcine dermis sling vs TVT (follow-up median 120 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	0/38 (0%)	3/63 (4.8%)	RR 0.23 (0.01 to 4.42)	37 fewer per 1000 (from 47 fewer to 163 more)	⊕000 VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Biological sling	Synthetic sling	Relative (95% CI)	Absolute		
<b>Complications - Infection at ≤1 year - Cadaveric fascia lata sling vs retropubic IVS (non-event) (follow-up 12 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	0/67 (0%)	0/72 (0%)	RR 1 (0.97 to 1.03)	-	⊕⊕⊕ LOW	CRITICAL
								0%		-		
<b>Complications - Infection at &gt;1 year to ≤5 years - Porcine dermis sling vs TVT (follow-up 24. 36)</b>												
1	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	0/74 (0%)	2/68 (2.9%)	RR 0.18 (0.01 to 3.77)	24 fewer per 1000 (from 29 fewer to 81 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;1 years to ≤5 years - Porcine dermis sling vs TVT (follow-up 24-36 months)</b>												
1	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	12/68 (17.6%)	9/60 (15%)	RR 1.18 (0.53 to 2.6)	27 more per 1000 (from 71 fewer to 240 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;5 years - Porcine dermis sling vs TVT (follow-up median 120 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	0/38 (0%)	1/63 (1.6%)	RR 0.55 (0.02 to 13.1)	7 fewer per 1000 (from 16 fewer to 192 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤1 year - Cadaveric fascia lata vs retropubic IVS (follow-up 12 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	45/67 (67.2%)	18/72 (25%)	RR 2.69 (1.74 to 4.15)	423 more per 1000 (from 185 more to 788 more)	⊕⊕⊕ LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤1 year - Porcine dermis sling vs TVT (follow-up 6 months)</b>												
1	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	4/74 (5.4%)	6/68 (8.8%)	RR 0.61 (0.18 to 2.08)	34 fewer per 1000 (from 72 fewer to 95 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - POP occurrence at ≤1 year - Porcine dermis sling vs Align-TO (non-event) (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Biological sling	Synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	0/50 (0%)	0/50 (0%)	RR 1 (0.96 to 1.04)	-	⊕⊕⊕⊕ MODERATE	CRITICAL
								0%		-		
<b>Complications - Wound complications at ≤1 year - Porcine dermis sling vs Align-TO</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	1/50 (2%)	0/50 (0%)	RR 3 (0.13 to 71.92)	-	⊕○○○ VERY LOW	CRITICAL
<b>Change of continence status - Subjective cure at ≤1 year - Porcine dermis sling vs Synthetic sling (random effects analysis) (follow-up 12 months; assessed with: Self-reported dry)</b>												
2	randomised trials	very serious <sup>2</sup>	very serious <sup>12</sup>	serious <sup>3,4</sup>	no serious imprecision	none	44/102 (43.1%)	73/122 (59.8%)	RR 0.61 (0.21 to 1.82)	233 fewer per 1000 (from 473 fewer to 491 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change of continence status - Subjective cure at ≤1 year - Porcine dermis sling vs retropubic synthetic sling (follow-up 12 months; assessed with: Self-reported dry)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	10/52 (19.2%)	38/72 (52.8%)	RR 0.36 (0.3 to 0.66)	338 fewer per 1000 (from 179 fewer to 369 fewer)	⊕○○○ VERY LOW	IMPORTANT
<b>Change of continence status - Subjective cure at ≤1 year - Porcine dermis sling vs transobturator synthetic sling (assessed with: Self-reported dry)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	very serious <sup>10</sup>	none	34/50 (68%)	35/50 (70%)	RR 0.97 (0.75 to 1.26)	21 fewer per 1000 (from 175 fewer to 182 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change of continence status - Subjective cure at &gt;5 years - Porcine dermis sling vs TVT (follow-up median 120 months; assessed with: Self-reported dry)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>13</sup>	none	6/52 (11.5%)	20/72 (27.8%)	RR 0.42 (0.18 to 0.96)	161 fewer per 1000 (from 11 fewer to 228 fewer)	⊕○○○ VERY LOW	IMPORTANT
<b>Change of continence status - Objective cure at ≤1 year - Cadaveric fascia lata sling vs retropubic synthetic sling (follow-up 12 months; assessed with: Negative pad test)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	35/67 (52.2%)	34/72 (47.2%)	RR 1.11 (0.79 to 1.55)	52 more per 1000 (from 99 fewer to 260 more)	⊕○○○ VERY LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Biological sling	Synthetic sling	Relative (95% CI)	Absolute		
<b>Change of continence status - Objective cure at ≤1 year - Porcine dermis sling vs transobturator synthetic sling (follow-up 12 months; assessed with: Negative pad test)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	47/50 (94%)	49/50 (98%)	RR 0.96 (0.89 to 1.04)	39 fewer per 1000 (from 108 fewer to 39 more)	⊕⊕⊕⊕ MODERATE	IMPORTANT
<b>Change of continence status - Objective cure at &gt;1 year to ≤5 years - Porcine dermis sling vs TV (follow-up 36 months; assessed with: No leakage cough stress test, QoL improvement ≥90% and reported continence status as dry)</b>												
1	randomised trials	serious <sup>11</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	56/74 (75.7%)	53/68 (77.9%)	RR 0.97 (0.81 to 1.16)	23 fewer per 1000 (from 148 fewer to 125 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;5 years - Porcine dermis sling vs TVT (follow-up median 120 months; assessed with: Self-reported improvement)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>13</sup>	none	22/52 (42.3%)	46/72 (63.9%)	RR 0.66 (0.46 to 0.95)	217 fewer per 1000 (from 32 fewer to 345 fewer)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for any reason at ≤1 year - Cadaveric fascia lata sling vs Retropubic IVS (follow-up 12 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	2/67 (3%)	0/72 (0%)	RR 5.37 (0.26 to 109.81)	-	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for any reason at ≤1 year - Porcine dermis sling vs TVT (follow-up 12 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	no serious imprecision	none	9/46 (19.6%)	0/69 (0%)	RR 28.3 (1.69 to 474.6)	-	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for SUI at &gt;5 years - Porcine dermis sling vs TVT (follow-up 120 months)</b>												
1	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	serious <sup>13</sup>	none	5/38 (13.2%)	2/63 (3.2%)	RR 4.14 (0.85 to 20.32)	100 more per 1000 (from 5 fewer to 613 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for POP/mesh complications at &gt;5 years - Porcine dermis sling vs Synthetic sling</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Biological sling	Synthetic sling	Relative (95% CI)	Absolute		
2	randomised trials	very serious <sup>2</sup>	no serious inconsistency	serious <sup>3,4</sup>	very serious <sup>10</sup>	none	3/88 (3.4%)	3/113 (2.7%)	RR 1.41 (0.35 to 5.68)	11 more per 1000 (from 17 fewer to 124 more)	⊕000 VERY LOW	IMPORTANT

1 Outcome expressed as standardised mean difference because study only reported p-value.

2 High risk of bias regarding selective reporting (only reports quality of life data where TVT and fascial sling significantly better than porcine dermis sling); Unclear risk of bias regarding blinding of participants.

3 Unclear whether some or all of participants had failed or declined conservative treatment.

4 For all studies (with exception of Ugurlucan et al. 2013 where 56% of participants had concomitant POP surgery), it is not reported whether or not participants had concomitant POP surgery.

5 95% CI crosses 1 default MID for standardised mean difference (+0.5 or -0.5).

6 MID for overall King's Health Questionnaire score, calculated as 0.5 times the standard deviation at baseline of the synthetic sling arm is +/-117.95.

7 95% CI crosses 1 MID for this outcome.

8 High risk of bias regarding selective reporting (1 study only reports quality of life data where TVT and fascial sling significantly better than porcine dermis sling); Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting.

9 Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting.

10 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

11 Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants/personnel, blinding of outcome assessment, and selective reporting.

12 Very high heterogeneity (i-squared >=80%).

13 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

**Transobturator mesh sling versus retropubic mesh sling**

**Table 23: Clinical evidence profile for transobturator mesh sling versus retropubic mesh sling**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - ICIQ-QoL - At ≤1 year (follow-up 12 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Quality of Life; range of scores: 22-110; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3,4</sup>	none	50	50	-	MD 6.37 lower (13.22 lower to 0.48 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-QoL - At &gt;1 year to ≤5 years (follow-up 18 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Quality of Life; range of scores: 22-110; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3,4</sup>	none	50	50	-	MD 8.34 lower (14.4 to 2.28 lower)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF - At ≤1 year (follow-up 6-12 months; measured with: International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; range of scores: 0-21; Better indicated by lower values)</b>												
5	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision <sup>6</sup>	none	446	441	-	MD 0.65 higher (0.19 to 1.1 higher)	⊕⊕○○ LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF - At &gt;1 year to ≤5 years (follow-up 18 months; measured with: International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; range of scores: 0-21; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	50	50	-	MD 0.19 higher (0.49 lower to 0.87 higher)	⊕⊕○○ LOW	CRITICAL
<b>Continence-specific health-related QoL - I-QoL at 1 year - TVT-ABBREVO vs TVT-EXACT (follow-up 12 months; measured with: Urinary Incontinence Quality of Life Scale; range of scores: 22-110; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>7</sup>	no serious inconsistency	serious <sup>5</sup>	serious <sup>4,8</sup>	none	62	63	-	MD 4.54 lower (7.43 to 1.65 lower)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - General health perceptions (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 0.7 lower (3.81 lower to 2.41 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Incontinence impact (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 4.54 lower (9.82 lower to 0.74 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Role limitations (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 4.29 lower (8.3 to 0.28 lower)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Physical limitations (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 4.39 lower (8.6 to 0.18 lower)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Social limitations (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 2.89 lower (5.36 to 0.43 lower)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Emotions (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 4.66 lower (8.4 to 0.92 lower)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Sleep/energy (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 0.72 lower (3.52 lower to 2.09 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Severity measures (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
3	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 3.77 lower (8.33 lower to 0.78 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Intercourse (follow-up 3 months; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	233	247	-	MD 0.66 lower (1.4 lower to 0.08 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - General health perceptions (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 0.23 lower (4.29 lower to 3.82 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Incontinence impact (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>12</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 2.26 higher (2.61 lower to 7.13 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Role limitations (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>12</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 2.55 higher (1.19 lower to 6.28 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Physical limitations (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 0.17 higher (4.89 lower to 5.23 higher)	⊕⊕00 LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Social limitations (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>12</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 1.32 higher (1.42 lower to 4.05 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Emotions (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>12</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 0.57 higher (2.48 lower to 3.61 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Sleep/energy (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>12</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 2.06 higher (1.1 lower to 5.22 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Severity measures (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	226	208	-	MD 2.47 higher (2.23 lower to 7.17 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Intercourse (follow-up 60 months; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	serious <sup>4,11</sup>	none	170	161	-	MD 25.6 lower (34.46 to 16.74 lower)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at ≤1 year - Personal relationships subscale (random effects analysis) - ≤1 year (follow-up 3-12 months; range of scores: 0-100; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
3	randomised trials	very serious <sup>14</sup>	serious <sup>15</sup>	serious <sup>5</sup>	no serious imprecision <sup>10</sup>	none	268	273	-	MD 3.33 lower (8.48 lower to 1.82 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - King's Health Questionnaire at &gt;1 year to ≤5 years - Personal relationships subscale (random effects analysis) - &gt;1 year to ≤5 years (follow-up 12.6-60 months; range of scores: 0-100; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>12</sup>	very serious <sup>16</sup>	serious <sup>2,5</sup>	no serious imprecision <sup>11</sup>	none	226	208	-	MD 1.69 lower (8.75 lower to 5.37 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - UISS Total at ≤1 year (follow-up 12 months; measured with: Urinary Incontinence Severity Score; range of scores: 0-20; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>17</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision <sup>18</sup>	none	131	134	-	MD 0.3 lower (0.65 lower to 0.05 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - UISS Total at &gt;1 year to ≤5 years (follow-up 60 months; measured with: Urinary Incontinence Severity Score; range of scores: 0-20; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>17</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	132	131	-	MD 0 higher (0.62 lower to 0.62 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - PISQ-12 at ≤1 year (follow-up 12 months; measured with: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; range of scores: 0-48; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>19</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision <sup>20</sup>	none	361	361	-	MD 0.08 higher (0.73 lower to 0.89 higher)	⊕000 VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - PISQ-12 at &gt;1 year to ≤5 years (follow-up 24-60 months; measured with: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; range of scores: 0-48; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>19</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	357	350	-	MD 0.73 higher (0.21 lower to 1.67 higher)	⊕000 VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - ICIQ-FLUTS-sexual function at 1 year (follow-up 12 months; assessed with: Response of 'not at all' to Q3 of International Consultation on Incontinence Modular Questionnaire-Female Sexual Matters associated with Lower Urinary Tract Symptoms)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2</sup>	serious <sup>21</sup>	none	60/95 (63.2%)	57/85 (67.1%)	RR 0.94 (0.76 to 1.17)	40 fewer per 1000 (from 161 fewer to 114 more)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Adverse events - severe bleeding requiring blood transfusion</b>												
10	randomised trials	very serious <sup>22</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	0/1000 (0%)	3/1041 (0.29%)	RR 0.35 (0.06 to 2.19)	2 fewer per 1000 (from 3 fewer to 3 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Adverse events - bladder injury</b>												
40	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	7/3305 (0.21%)	125/3349 (3.7%)	RR 0.15 (0.1 to 0.24)	32 fewer per 1000 (from 28 fewer to 34 fewer)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Adverse events - bowel injury (non-event)</b>												
12	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	0/717 (0%)	0/738 (0%)	RR 1 (0.99 to 1.01)	-	⊕⊕⊕⊕ MODERATE	
								0%		-		
<b>Complications - Pain at ≤1 year (follow-up 3-12 months)</b>												
19	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	133/1807 (7.4%)	46/1811 (2.5%)	RR 2.8 (2.04 to 3.86)	46 more per 1000 (from 26 more to 73 more)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years (follow-up 14-60 months)</b>												
11	randomised trials	serious <sup>24</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	36/976 (3.7%)	30/977 (3.1%)	RR 1.25 (0.79 to 1.97)	8 more per 1000 (from 6 fewer to 30 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at &gt;5 years (follow-up 95-100 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>25</sup>	no serious inconsistency	serious <sup>2.5</sup>	very serious <sup>23</sup>	none	13/109 (11.9%)	11/98 (11.2%)	RR 1.11 (0.54 to 2.27)	12 more per 1000 (from 52 fewer to 143 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤ 1 year (follow-up 3-12 months)</b>												
22	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2.5</sup>	serious <sup>21</sup>	none	36/1882 (1.9%)	21/1947 (1.1%)	RR 1.66 (1.02 to 2.71)	7 more per 1000 (from 0 more to 18 more)	⊕⊕○○ LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;1 year to ≤5 years (follow-up 14-60 months)</b>												
12	randomised trials	serious <sup>26</sup>	no serious inconsistency	serious <sup>2.5</sup>	serious <sup>21</sup>	none	27/1142 (2.4%)	11/1137 (0.97%)	RR 2.17 (1.14 to 4.14)	11 more per 1000 (from 1 more to 30 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation - ≤ 1 year (follow-up 6-12 months)</b>												
16	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2.5</sup>	serious <sup>21</sup>	none	69/1518 (4.5%)	113/1521 (7.4%)	RR 0.61 (0.46 to 0.81)	29 fewer per 1000 (from 14 fewer to 40 fewer)	⊕⊕○○ LOW	CRITICAL
<b>Complications - Need for catheterisation - &gt;1 year to ≤5 years (follow-up 18-48.5 months)</b>												
4	randomised trials	very serious <sup>27</sup>	no serious inconsistency	serious <sup>2.5</sup>	very serious <sup>23</sup>	none	3/411 (0.73%)	5/411 (1.2%)	RR 0.67 (0.19 to 2.35)	4 fewer per 1000 (from 10 fewer to 16 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year (follow-up 3-12 months)</b>												
17	randomised trials	serious <sup>28</sup>	no serious inconsistency	serious <sup>2.5</sup>	very serious <sup>23</sup>	none	59/1613 (3.7%)	59/1632 (3.6%)	RR 1.06 (0.76 to 1.48)	2 more per 1000 (from 9 fewer to 17 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 year to ≤5 years (follow-up 16-60 months)</b>												
7	randomised trials	serious <sup>29</sup>	no serious inconsistency	serious <sup>2.5</sup>	serious <sup>21</sup>	none	52/920 (5.7%)	67/918 (7.3%)	RR 0.76 (0.54 to 1.06)	18 fewer per 1000 (from 34 fewer to 4 more)	⊕○○○ VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
<b>Complications - Infection at &gt;5 years (follow-up 95-100 months)</b>												
2	randomised trials	serious <sup>30</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	5/137 (3.6%)	8/131 (6.1%)	RR 0.59 (0.2 to 1.76)	25 fewer per 1000 (from 49 fewer to 46 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at ≤ 1 year (follow-up 6-12 months)</b>												
8	randomised trials	serious <sup>31</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	30/563 (5.3%)	39/601 (6.5%)	RR 0.83 (0.53 to 1.29)	11 fewer per 1000 (from 30 fewer to 19 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;1 year to ≤5 years (follow-up 18-60 months)</b>												
7	randomised trials	serious <sup>32</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	21/378 (5.6%)	25/383 (6.5%)	RR 0.84 (0.49 to 1.46)	10 fewer per 1000 (from 33 fewer to 30 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤ 1 year (follow-up 6-12 months)</b>												
5	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2,5</sup>	serious <sup>21</sup>	none	38/631 (6%)	27/612 (4.4%)	RR 1.34 (0.84 to 2.13)	15 more per 1000 (from 7 fewer to 50 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at &gt;1 year to ≤5 years (follow-up 18-60 months)</b>												
4	randomised trials	very serious <sup>17</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	7/491 (1.4%)	7/496 (1.4%)	RR 1.02 (0.38 to 2.75)	0 more per 1000 (from 9 fewer to 25 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo nocturia at ≤1 year (follow-up mean 10 months)</b>												
1	randomised trials	very serious <sup>33</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	1/46 (2.2%)	3/42 (7.1%)	RR 0.3 (0.03 to 2.81)	50 fewer per 1000 (from 69 fewer to 129 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo nocturia at &gt;1 year to ≤5 years (follow-up mean 52.9 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
1	randomised trials	very serious <sup>33</sup>	no serious inconsistency	serious <sup>2,5</sup>	serious <sup>21</sup>	none	17/37 (45.9%)	6/34 (17.6%)	RR 2.6 (1.16 to 5.83)	282 more per 1000 (from 28 more to 852 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - POP occurrence at &gt;5 years (follow-up median 100 months)</b>												
1	randomised trials	very serious <sup>26</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	0/47 (0%)	1/40 (2.5%)	RR 0.28 (0.01 to 6.8)	18 fewer per 1000 (from 25 fewer to 145 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Wound complications at ≤ 1 year (follow-up 9-12 months)</b>												
4	randomised trials	serious <sup>28</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	3/239 (1.3%)	3/204 (1.5%)	RR 0.8 (0.18 to 3.56)	3 fewer per 1000 (from 12 fewer to 38 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Wound complications at &gt;1 year to ≤5 years (follow-up 18-35 months)</b>												
2	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>23</sup>	none	0/125 (0%)	1/123 (0.81%)	RR 0.32 (0.01 to 7.84)	6 fewer per 1000 (from 8 fewer to 56 more)	⊕○○○ VERY LOW	CRITICAL
<b>Change in continence status - Subjective cure at ≤1 year (random effects analysis) (follow-up 3-12 months; assessed with: Self-reported continent, no self-reported pad use, or various self-report questionnaires)</b>												
15	randomised trials	no serious risk of bias	serious <sup>15</sup>	serious <sup>2,5</sup>	no serious imprecision	none	966/1340 (72.1%)	972/1298 (74.9%)	RR 0.96 (0.9 to 1.01)	30 fewer per 1000 (from 75 fewer to 7 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year: No concomitant POP surgery (follow-up 3-12 months; assessed with: Self-reported continent, no self-reported pad use, or various self-report questionnaires)</b>												
6	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision	none	422/661 (63.8%)	445/679 (65.5%)	RR 0.97 (0.9 to 1.05)	20 fewer per 1000 (from 66 fewer to 33 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years (follow-up 14-60 months; assessed with: Self-reported continent, no self-reported pad use, or various self-report questionnaires)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
6	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	332/596 (55.7%)	334/631 (52.9%)	RR 1.05 (0.96 to 1.15)	26 more per 1000 (from 21 fewer to 79 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;5 years (assessed with: Voiding diary or no leakage)</b>												
2	randomised trials	serious <sup>25</sup>	no serious inconsistency	serious <sup>2,5</sup>	serious <sup>21</sup>	none	74/145 (51%)	80/143 (55.9%)	RR 0.92 (0.74 to 1.13)	45 fewer per 1000 (from 145 fewer to 73 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure &gt;1 year to ≤5 years: No concomitant POP surgery (follow-up 14-60; Various self-report measures)</b>												
4	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision	none	259/487 (53.2%)	258/515 (50.1%)	RR 1.06 (0.96 to 1.18)	30 more per 1000 (from 20 fewer to 90 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year (follow-up 6-12 months; assessed with: Negative pad test or composite (subjective + objective) measure)</b>												
15	randomised trials	serious <sup>19</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	807/1063 (75.9%)	892/1113 (80.1%)	RR 0.95 (0.91 to 0.99)	40 fewer per 1000 (from 8 fewer to 72 fewer)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year: No concomitant POP surgery (follow-up 6-12 months; assessed with: Negative pad test or composite (subjective + objective) measure)</b>												
3	randomised trials	serious <sup>28</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision	none	121/153 (79.1%)	122/170 (71.8%)	RR 1.07 (0.96 to 1.19)	50 more per 1000 (from 29 fewer to 136 more)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years (follow-up 12.6-60 months; assessed with: Negative pad test or composite (subjective + objective) measure)</b>												
10	randomised trials	serious <sup>19</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	729/1023 (71.3%)	719/1034 (69.5%)	RR 1.02 (0.97 to 1.08)	14 more per 1000 (from 21 fewer to 56 more)	⊕⊕⊕⊕ LOW	
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years: No concomitant POP surgery (follow-up 60 months; assessed with: Negative pad test)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>24</sup>	no serious inconsistency	serious <sup>5</sup>	serious <sup>21</sup>	none	57/94 (60.6%)	56/105 (53.3%)	RR 1.14 (0.89 to 1.45)	75 more per 1000 (from 59 fewer to 240 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years - Mixed UI subgroup (follow-up median 35 months; assessed with: Composite (subjective + objective) measure)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	34/41 (82.9%)	36/43 (83.7%)	RR 0.99 (0.82 to 1.2)	8 fewer per 1000 (from 151 fewer to 167 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years - Pure SUI subgroup (follow-up median 35 months; assessed with: Composite (subjective + objective) measure)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2,5</sup>	serious <sup>21</sup>	none	24/34 (70.6%)	14/27 (51.9%)	RR 1.36 (0.89 to 2.08)	187 more per 1000 (from 57 fewer to 560 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;5 years (follow-up 95-100 months; assessed with: Composite (subjective + objective) measure)</b>												
2	randomised trials	serious <sup>25</sup>	no serious inconsistency	serious <sup>2,5</sup>	serious <sup>21</sup>	none	83/145 (57.2%)	93/143 (65%)	RR 0.88 (0.74 to 1.05)	78 fewer per 1000 (from 169 fewer to 33 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at ≤1 year (follow-up 3-12 months)</b>												
9	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	881/1122 (78.5%)	919/1170 (78.5%)	RR 0.99 (0.95 to 1.03)	8 fewer per 1000 (from 39 fewer to 24 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at ≤1 year: No concomitant POP surgery (follow-up 3-12 months)</b>												
4	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision	none	443/568 (78%)	460/583 (78.9%)	RR 0.99 (0.93 to 1.05)	8 fewer per 1000 (from 55 fewer to 39 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at &gt;1 year to ≤5 years (follow-up 14-60 months)</b>												
5	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	329/663 (49.6%)	350/689 (50.8%)	RR 0.97 (0.89 to 1.06)	15 fewer per 1000 (from 56 fewer to 30 more)	⊕⊕○○ LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
<b>Change in continence status - Negative cough stress test at &gt;1 year to ≤5 years: No concomitant POP surgery (follow-up 24-60 months)</b>												
2	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision	none	170/343 (49.6%)	176/360 (48.9%)	RR 1.01 (0.88 to 1.16)	5 more per 1000 (from 59 fewer to 78 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Incontinence episodes per day at &gt;1 year to ≤5 years (follow-up mean 18.4 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>12</sup>	no serious inconsistency	serious <sup>5,35</sup>	no serious imprecision <sup>36</sup>	none	19	17	-	MD 0.3 lower (1.25 lower to 0.65 higher)	⊕⊕○○ LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years (follow-up 12.6-60 months)</b>												
13	randomised trials	serious <sup>19</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	994/1381 (72%)	973/1390 (70%)	RR 1.03 (0.98 to 1.07)	21 more per 1000 (from 14 fewer to 49 more)	⊕⊕○○ LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years: No concomitant POP surgery (follow-up 24-46 months)</b>												
2	randomised trials	serious <sup>24</sup>	no serious inconsistency	serious <sup>5</sup>	no serious imprecision	none	92/124 (74.2%)	95/125 (76%)	RR 0.98 (0.85 to 1.13)	15 fewer per 1000 (from 114 fewer to 99 more)	⊕⊕○○ LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years - Pure SUI subgroup (follow-up median 60 months)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2,5</sup>	no serious imprecision	none	36/41 (87.8%)	41/43 (95.3%)	RR 0.92 (0.81 to 1.05)	76 fewer per 1000 (from 181 fewer to 48 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years - Mixed UI subgroup (follow-up median 60 months)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2,5</sup>	serious <sup>21</sup>	none	32/34 (94.1%)	22/27 (81.5%)	RR 1.16 (0.95 to 1.41)	130 more per 1000 (from 41 fewer to 334 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;5 years (follow-up mean 95 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>25</sup>	no serious inconsistency	serious <sup>2.5</sup>	no serious imprecision	none	63/70 (90%)	67/70 (95.7%)	RR 0.94 (0.86 to 1.03)	57 fewer per 1000 (from 134 fewer to 29 more)	⊕⊕⊕ LOW	IMPORTANT
<b>Repeat surgery for SUI ≤1 year (follow-up 3-12 months)</b>												
5	randomised trials	serious <sup>26</sup>	no serious inconsistency	serious <sup>2.5</sup>	no serious imprecision	none	11/532 (2.1%)	1/582 (0.17%)	RR 8.98 (1.53 to 52.59)	14 more per 1000 (from 1 more to 89 more)	⊕⊕⊕ LOW	IMPORTANT
<b>Repeat surgery for SUI at &gt;1 year to ≤5 years (follow-up 12.6-60 months)</b>												
6	randomised trials	serious <sup>24</sup>	no serious inconsistency	serious <sup>2.5</sup>	very serious <sup>23</sup>	none	11/508 (2.2%)	7/514 (1.4%)	RR 1.53 (0.62 to 3.75)	7 more per 1000 (from 5 fewer to 37 more)	⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for SUI at &gt;5 years (follow-up median 100 months)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2.5</sup>	very serious <sup>23</sup>	none	4/47 (8.5%)	0/40 (0%)	RR 7.69 (0.43 to 138.58)	-	⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for POP at ≤1 year (non-event) (follow-up 3 months)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2.5</sup>	no serious imprecision	none	0/269 (0%)	0/285 (0%)	RR 1 (0.99 to 1.01)	-	⊕⊕⊕ VERY LOW	IMPORTANT
								0%		-		
<b>Repeat surgery for POP at &gt;5 years (follow-up median 100 months)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2.5</sup>	very serious <sup>23</sup>	none	2/47 (4.3%)	1/40 (2.5%)	RR 1.7 (0.16 to 18.08)	18 more per 1000 (from 21 fewer to 427 more)	⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications ≤1 year (follow-up 3-12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Transobturator sling	Retropubic sling	Relative (95% CI)	Absolute		
13	randomised trials	very serious <sup>37</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	34/1180 (2.9%)	33/1267 (2.6%)	RR 1.11 (0.72 to 1.72)	3 more per 1000 (from 7 fewer to 19 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications at &gt;1 year to ≤5 years (follow-up 12.6-60 months)</b>												
8	randomised trials	serious <sup>29</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	18/839 (2.1%)	15/849 (1.8%)	RR 1.21 (0.61 to 2.38)	4 more per 1000 (from 7 fewer to 24 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications &gt;5 years (follow-up median 100 months)</b>												
1	randomised trials	very serious <sup>34</sup>	no serious inconsistency	serious <sup>2,5</sup>	very serious <sup>23</sup>	none	7/47 (14.9%)	2/40 (5%)	RR 2.98 (0.66 to 13.54)	99 more per 1000 (from 17 fewer to 627 more)	⊕○○○ VERY LOW	IMPORTANT

1 Unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting.

2 Unclear whether some or all participants received concomitant POP surgery.

3 Published MID for ICIQ-QoL is +/- 3.71 (Nyström et al. ICIQ symptom and quality of life instruments measure clinically relevant improvements in women with stress urinary incontinence. *Neurourology and urodynamics*. 2015, 34(8):747-51.).

4 95% CI crosses 1 MID for this outcome.

5 Unclear whether some or all participants failed or declined conservative treatment.

6 Published MID for ICIQ-SF at 1 and 2 years is +/- 5 and +/- 4, respectively (Sirls et al. The minimum important difference for the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form in women with stress urinary incontinence. *Neurourology and urodynamics*. 2015, 34(2):183-7.).

7 High risk of bias regarding incomplete outcome data (23% dropout rate); Unclear risk of bias regarding allocation concealment, blinding of participants, and selective reporting.

8 Published MID for I-QoL is +/- 2.5 (Yalcin et al. Minimal clinically important differences in Incontinence Quality-of-Life scores in stress urinary incontinence. *Urology*. 2006, 67(6):1304-8.).

9 High/unclear risk of bias regarding blinding of outcome assessment (1 study assessors not blinded to group assignment); unclear risk of bias regarding blinding of participants, and incomplete outcome data at 5 year FU (1 study >40% dropout rate).

10 MID for King's Health Questionnaire subscales at 1 year, calculated as 0.5 times the SD (if 1 study) or 0.5 times the median SD (if more than 1 study) at baseline of the control arm studies, are as follows: General health perceptions (8.73), incontinence impact (+/- 11.15), role limitations (+/- 13.81), physical limitations (+/- 13.65), social limitations (+/- 13.65), personal relationships (+/- 14.85), emotions (+/- 15.63), sleep/energy (+/- 12.0), severity (+/- 10.07), and intercourse (+/- 17.68).

11 MID for King's Health Questionnaire subscales at between 1 and 5 years after surgery, calculated as 0.5 times the SD (if 1 study) or 0.5 times the median SD (if more than 1 study) the median SD at baseline of the control arm studies, are as follows: General health perceptions (+/-9.82), incontinence impact (+/- 13.01), role limitations (+/- 13.91), physical limitations (+/- 14.01), social limitations (+/- 14.49), personal relationships (+/- 18.51), emotions (+/- 15.86), sleep/energy (+/- 12.64), severity (+/- 10.43), and intercourse (+/- 17.68).

12 High risk of bias regarding blinding of outcome assessment (assessors not blinded to group assignment); Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, incomplete outcome data at 5 year FU (>40% dropout rate), and selective reporting.

- 13 High risk of bias regarding blinding of outcome assessment (assessors not blinded to group assignment); Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, and selective reporting.
- 14 High risk of bias regarding blinding of outcome assessment (assessors not blinded to group assignment); Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data at 5 year FU (>40% dropout rate) and selective reporting.
- 15 High heterogeneity ( $i$ -squared  $\geq 50\%$  and  $< 80\%$ ).
- 16 Very high heterogeneity ( $i$ -squared  $\geq 80\%$ ).
- 17 High risk of bias regarding blinding of outcome assessment (assessors not blinded to group assignment); Unclear risk of bias regarding blinding of participants.
- 18 MID for UISS, calculated as 0.5 times the SD at baseline of the control arm, is  $\pm 1.5$ .
- 19 Unclear risk of bias regarding blinding of participants, blinding of outcome assessment, and selective reporting. Participants in retropubic group had significantly lower Valsalva peak point pressure compared to those in transobturator group.
- 20 MID for PISQ-12 at 1 year, calculated as the median of the SDs at baseline of the control arm, is  $\pm 3.13$ . MID for PISQ-12 at between 1 and 5 years, calculated as the median of the SDs at follow up of the control arm, is  $\pm 3.23$ .
- 21 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).
- 22 High risk of bias regarding blinding of outcome assessment (1 study assessors not blinded to group assignment); Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants/personnel, and selective reporting.
- 23 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).
- 24 Unclear risk of bias regarding allocation concealment, blinding of participants, and blinding of outcome assessment.
- 25 Unclear risk of bias regarding allocation concealment and blinding of participants.
- 26 Unclear risk of bias regarding allocation concealment, blinding of participants, and selective reporting.
- 27 High/unclear risk of bias regarding selective reporting (1 study reports outcomes of interest for whole sample rather than by intervention group); Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, and blinding of outcome assessment.
- 28 Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants/personnel, blinding of outcome assessment, and selective reporting.
- 29 High risk of bias regarding blinding of outcome assessment (assessors not blinded to group assignment); unclear risk of bias regarding allocation concealment and incomplete outcome data at 5 year FU (1 study >40% dropout rate).
- 30 Significantly more participants in transobturator group at baseline had detrusor overactivity compared to those in retropubic group. Unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting.
- 31 Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, blinding of outcome assessment, and selective reporting.
- 32 Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, and selective reporting.
- 33 Participants in transobturator group demonstrated significantly higher urethral closure pressure at baseline than those in retropubic group. Unclear risk of bias regarding blinding of participants, blinding of outcome assessment, and selective reporting.
- 34 Significantly more participants in transobturator group at baseline had detrusor overactivity compared to those in retropubic group. Unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment, and selective reporting.
- 35 Ugurlucan et al. 2013: 81% of participants had concomitant POP surgery; sample also included participants with mixed urinary incontinence.
- 36 MID for incontinence episodes per day, calculated as 0.5 times the SD of the control arm at baseline, is  $\pm 1.75$ .
- 37 High risk regarding random sequence generation (group assignment chosen by choice of envelope by participants); unclear risk of bias regarding allocation concealment, blinding of participants/personnel, blinding of outcome assessment, and selective reporting.

### Single-incision mini-sling versus other synthetic mesh sling

**Table 24: Clinical evidence profile for single-incision mini-sling versus other synthetic mesh sling**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - ISI Total at 1 year - TVT-Secur vs TVT (follow-up 12 years; measured with: Incontinence Severity Index; range of scores: 0-12; Better indicated by lower values)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>3,4</sup>	none	134	126	-	MD 0.7 higher (0.14 to 1.26 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - I-QoL at 2 years - TVT-Secur vs TVT-O (follow-up 24 months; measured with: Urinary Incontinence Quality of Life scale; range of scores: 22-110; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>4,6</sup>	none	129	68	-	MD 6.24 lower (10.93 to 1.55 lower)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - I-QoL ≥20 point increase at 5 years - TVT-Secur vs TVT-O (follow-up 60 months; assessed with: Urinary Incontinence Quality of Life scale)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2</sup>	serious <sup>7</sup>	none	42/58 (72.4%)	52/62 (83.9%)	RR 0.86 (0.71 to 1.05)	117 fewer per 1000 (from 243 fewer to 42 more)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at ≤1 year (follow-up 12 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Scored Form; range of scores: 0-21; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>8</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>9</sup>	none	99	107	-	MD 0.06 higher (0.33 lower to 0.45 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at ≤1 year - Needleless vs TOT (follow-up 12 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Scored Form; range of scores: 0-21; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>8</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>9</sup>	none	78	86	-	MD 0.08 higher (0.32 lower to 0.48 higher)	⊕⊕⊕⊕ LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - ICIQ-UI-SF at ≤1 year - SIMS (Brand not known) vs TVT-O (follow-up median 12 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Score Form; range of scores: 0-21; Better indicated by lower values)</b>												
1	randomised trials	serious	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>9</sup>	none	21	21	-	MD 0.3 lower (2.15 lower to 1.55 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at &gt;1 year to ≤5 years (random effects analysis) (follow-up 15-24 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Score Form; range of scores: 0-21; Better indicated by lower values)</b>												
2 <sup>28</sup>	randomised trials	no serious risk of bias	serious <sup>10</sup>	serious <sup>2</sup>	serious <sup>11</sup>	none	130	131	-	SMD 0.11 lower (0.36 lower to 0.13 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up median 15 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Score Form; range of scores: 0-21; Better indicated by lower values)</b>												
1 <sup>28</sup>	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>11</sup>	none	41	42	-	SMD 0.2 higher (0.23 lower to 0.63 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at &gt;1 year to &lt;5 years - Needleless vs TOT (follow-up 24 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Score Form; range of scores: 0-21; Better indicated by lower values)</b>												
1 <sup>28</sup>	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>11</sup>	none	89	89	-	SMD 0.26 lower (0.55 lower to 0.04 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at &gt;1 year to &lt;5 years - TVT-Secur-H vs TVT-O (follow-up 24 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Score Form; range of scores: 0-21; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision <sup>9</sup>	none	64	68	-	MD 2.1 higher (0.44 to 3.76 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at &gt;1 year to &lt;5 years - TVT-Secur-U vs TVT-O (follow-up 24 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Score Form; range of scores: 0-21; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision <sup>9</sup>	none	65	68	-	MD 1.8 higher (0.33 to 3.27 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - General health perceptions (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 3.9 lower (12.64 lower to 4.84 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Incontinence impact (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 2.7 lower (14.11 lower to 8.71 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Role limitations (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 7 lower (20.44 lower to 6.44 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Physical limitations (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 8.8 lower (22.28 lower to 4.68 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Social limitations (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	37	38	-	MD 3.9 lower (13.72 lower to 5.92 higher)	⊕⊕⊕⊕ LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Personal relationships (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 10.4 higher (1.06 to 19.74 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Emotions (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 7.1 higher (1.59 lower to 15.79 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Sleep/energy (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 2.9 higher (6.62 lower to 12.42 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 1 year for TVT-Secur vs TVT-O - Severity measures (follow-up 12 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,12</sup>	none	37	38	-	MD 7.9 lower (20.08 lower to 4.28 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - General health perceptions (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 0.59 lower (6.98 lower to 5.8 higher)	⊕⊕○○ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Incontinence impact (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 1.04 higher (5.47 lower to 7.55 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Role limitations (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 0.15 higher (5.33 lower to 5.63 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Physical limitations (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 0.5 higher (3.67 lower to 4.67 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Social limitations (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 0.39 lower (2 lower to 1.22 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Personal relationships (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 0.42 lower (1.03 lower to 0.19 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Emotions (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 0.42 lower (5.99 lower to 5.15 higher)	⊕⊕⊕⊕ LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Sleep/energy (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 2.78 lower (6.81 lower to 1.25 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 2 years for TVT-Secur-U vs TVT-O - Severity measures (follow-up 24 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision <sup>14</sup>	none	61	54	-	MD 0.21 higher (5.24 lower to 5.66 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 3 years for MiniArc vs TVT - change scores - Role limitations (follow-up 36 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>16,17</sup>	none	35	26	-	MD 33.19 higher (96.59 lower to 162.97 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 3 years for MiniArc vs TVT - change scores - Physical limitations (follow-up 36 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>4,16</sup>	none	35	26	-	MD 40.5 higher (21.68 lower to 102.68 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 3 years for MiniArc vs TVT - change scores - Social limitations (follow-up 36 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>4,16</sup>	none	35	26	-	MD 6.8 higher (24.56 lower to 38.16 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 3 years for MiniArc vs TVT - change scores - Personal relationships (follow-up 36 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>4,16</sup>	none	35	26	-	MD 25.8 higher (28.99 lower to 80.59 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 3 years for MiniArc vs TVT - change scores - Emotions (follow-up 36 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>4,16</sup>	none	35	26	-	MD 7.1 higher (9.98 lower to 24.18 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 3 years for MiniArc vs TVT - change scores - Sleep/energy (follow-up 36 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>4,16</sup>	none	35	26	-	MD 3.5 higher (2.17 lower to 9.17 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ at 3 years for MiniArc vs TVT - change scores - Severity measures (follow-up 36 months; measured with: King's Health Questionnaire; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>4,16</sup>	none	35	26	-	MD 51 higher (2.89 to 99.11 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Continence-specific health-related QoL - 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 lower values)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	no serious indirectness	no serious imprecision <sup>19</sup>	none	39	42	-	MD 0 higher (1.94 lower to 1.94 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Continence-specific health-related QoL - PISQ-12 at 2 years (follow-up 24 months; measured with: Pelvic Organ Prolapse-Urinary Incontinence Sexual Questionnaire Short Form; range of scores: 0-48; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	no serious indirectness	no serious imprecision <sup>19</sup>	none	39	42	-	MD 0.2 higher (1.84 lower to 2.24 higher)	⊕⊕⊕○ MODERATE	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Adverse events - Severe bleeding requiring blood transfusion - Any brand of SIMS</b>												
5	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	2/391 (0.51%)	0/382 (0%)	RR 2.94 (0.31 to 28.01)	-	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Adverse events - Severe bleeding requiring blood transfusion - MiniArc vs TOT (non-event)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	0/49 (0%)	0/49 (0%)	RR 1.0 (0.96 to 1.04)	-	⊕⊕⊕⊕ LOW	
								0%		-		
<b>Adverse events - Severe bleeding requiring blood transfusion - TVT-Secur vs Other synthetic sling</b>												
4	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	2/342 (0.58%)	0/333 (0%)	RR 2.94 (0.31 to 28.01)	-	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Adverse events - Bladder injury - Any brand of SIMS</b>												
13	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	7/916 (0.76%)	14/802 (1.7%)	RR 0.56 (0.27 to 1.19)	8 fewer per 1000 (from 13 fewer to 3 more)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Adverse events - Bladder injury - MiniArc vs Other synthetic sling</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	0/87 (0%)	1/82 (1.2%)	RR 0.33 (0.01 to 7.99)	8 fewer per 1000 (from 12 fewer to 85 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Adverse events - Bladder injury - Needleless vs TOT</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>20</sup>	none	1/179 (0.56%)	1/187 (0.53%)	RR 1.04 (0.15 to 7.15)	0 more per 1000 (from 5 fewer to 33 more)	⊕⊕⊕⊕ LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Adverse events - Bladder injury - Needleless or Endopelvic Free Anchorage vs TOT</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	1/140 (0.71%)	1/70 (1.4%)	RR 0.5 (0.03 to 7.88)	7 fewer per 1000 (from 14 fewer to 98 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Bladder injury - TVT-Secur vs Other synthetic sling</b>												
7	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	5/486 (1%)	11/439 (2.5%)	RR 0.53 (0.21 to 1.29)	12 fewer per 1000 (from 20 fewer to 7 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Bladder injury - SIMS (Brand not known) vs TVT-O (non-event)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	0/24 (0%)	0/24 (0%)	RR 1.0 (0.92 to 1.08)	-	⊕⊕○○ LOW	CRITICAL
								0%		-		
<b>Adverse events - Bowel injury - Any brand of SIMS</b>												
3	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	1/250 (0.4%)	2/240 (0.83%)	RR 0.47 (0.04 to 5.09)	4 fewer per 1000 (from 8 fewer to 34 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Bowel injury - Needleless vs TOT (non-event)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/90 (0%)	0/89 (0%)	RR 1.0 (0.98 to 1.02)	-	⊕⊕⊕⊕ HIGH	CRITICAL
								0%		-		
<b>Adverse events - Bowel injury - TVT-Secur vs Other transobturator sling</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	1/136 (0.74%)	2/127 (1.6%)	RR 0.47 (0.04 to 5.09)	8 fewer per 1000 (from 15 fewer to 64 more)	⊕○○○ VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Adverse events - Bowel injury - SIMS (Brand not known) vs TVT-O (non-event)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	0/24 (0%)	0/24 (0%)	RR 1.0 (0.92 to 1.08)	-	⊕⊕⊕⊕ LOW	CRITICAL
								0%		-		
<b>Complications - Pain at ≤1 year - Any brand of SIMS (follow-up 9-12 months)</b>												
12	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	24/716 (3.4%)	66/710 (9.3%)	RR 0.4 (0.26 to 0.62)	56 fewer per 1000 (from 35 fewer to 69 fewer)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Complications - Pain at ≤1 year - Needleless vs TOT (random effects analysis) (follow-up 12 months)</b>												
2	randomised trials	very serious <sup>8</sup>	serious <sup>10</sup>	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	3/167 (1.8%)	11/175 (6.3%)	RR 0.44 (0.02 to 9.55)	35 fewer per 1000 (from 62 fewer to 537 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - TVT-Secur vs Other synthetic sling (follow-up 9-12 months)</b>												
9	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	20/489 (4.1%)	53/505 (10.5%)	RR 0.43 (0.27 to 0.69)	60 fewer per 1000 (from 33 fewer to 77 fewer)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Complications - Pain at ≤1 year - MiniArc or TVT-Secur vs TVT-O (follow-up 12 months)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	1/60 (1.7%)	2/30 (6.7%)	RR 0.25 (0.02 to 2.65)	50 fewer per 1000 (from 65 fewer to 110 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years - Any brand of SIMS (follow-up 15-36 months)</b>												
5	randomised trials	serious <sup>21</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	4/357 (1.1%)	15/349 (4.3%)	RR 0.33 (0.13 to 0.84)	29 fewer per 1000 (from 7 fewer to 37 fewer)	⊕⊕⊕⊕ VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
<b>Complications - Pain at &gt;1 year to ≤5 years - MiniArc vs TOT (random effects analysis) (follow-up 15-24)</b>												
2	randomised trials	serious <sup>21</sup>	serious <sup>10</sup>	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	4/138 (2.9%)	12/138 (8.7%)	RR 0.56 (0.06 to 5.68)	38 fewer per 1000 (from 82 fewer to 407 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years - Needleless vs TOT (follow-up 24 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>20</sup>	none	0/89 (0%)	2/89 (2.2%)	RR 0.2 (0.01 to 4.11)	18 fewer per 1000 (from 22 fewer to 70 more)	⊕⊕○○ LOW	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years - TVT-Secur vs Transobturator sling (follow-up 24-60 months)</b>												
2	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	0/130 (0%)	1/122 (0.82%)	RR 0.28 (0.01 to 6.83)	6 fewer per 1000 (from 8 fewer to 48 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year - Any brand of SIMS</b>												
15	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	32/950 (3.4%)	16/940 (1.7%)	RR 1.82 (1.05 to 3.13)	14 more per 1000 (from 1 more to 36 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year - MiniArc vs Other synthetic sling (follow-up 6-12 months)</b>												
2	randomised trials	serious <sup>21</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	3/134 (2.2%)	1/129 (0.78%)	RR 2.19 (0.32 to 14.83)	9 more per 1000 (from 5 fewer to 107 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year - Needleless vs TOT (follow-up 12 months)</b>												
3	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	5/237 (2.1%)	5/245 (2%)	RR 1 (0.3 to 3.33)	0 fewer per 1000 (from 14 fewer to 48 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year - TVT-Secur vs Other synthetic sling (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
9	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	24/555 (4.3%)	8/542 (1.5%)	RR 2.54 (1.25 to 5.14)	23 more per 1000 (from 4 more to 61 more)	⊕⊕⊕ LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year - SIMS (Brand not known) vs TVT-O (follow-up median 12 months)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	0/24 (0%)	2/24 (8.3%)	RR 0.2 (0.01 to 3.96)	67 fewer per 1000 (from 82 fewer to 247 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;1 year to ≤5 years - Any brand of SIMS (random effects analysis) (follow-up 15-60 months)</b>												
5	randomised trials	serious <sup>13</sup>	serious <sup>10</sup>	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	17/397 (4.3%)	13/328 (4%)	RR 0.98 (0.36 to 2.8)	1 fewer per 1000 (from 25 fewer to 71 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up 15-24 months)</b>												
2	randomised trials	serious <sup>21</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	2/138 (1.4%)	8/138 (5.8%)	RR 0.25 (0.05 to 1.16)	43 fewer per 1000 (from 55 fewer to 9 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;1 year to ≤5 years - TVT-Secur vs Transobturator sling (follow-up 24-60 months)</b>												
3	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	15/259 (5.8%)	5/190 (2.6%)	RR 2.21 (0.78 to 6.25)	32 more per 1000 (from 6 fewer to 138 more)	⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Fistula at ≤1 year - TVT-Secur vs TVT (non-event) (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	0/136 (0%)	0/127 (0%)	RR 1 (0.99 to 1.01)	-	⊕⊕⊕ MODERATE	CRITICAL
								0%		-		
<b>Complications - Need for catheterisation at ≤1 year - Any brand of SIMS (follow-up 6-12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
9	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	13/442 (2.9%)	16/466 (3.4%)	RR 0.91 (0.45 to 1.84)	3 fewer per 1000 (from 19 fewer to 29 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at ≤1 year - MiniArc vs TVT (follow-up 6 months)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>20</sup>	none	2/37 (5.4%)	2/33 (6.1%)	RR 0.89 (0.13 to 5.98)	7 fewer per 1000 (from 53 fewer to 302 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at ≤1 year - Needleless vs TOT</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>20</sup>	none	1/89 (1.1%)	1/89 (1.1%)	RR 1 (0.06 to 15.74)	0 fewer per 1000 (from 11 fewer to 166 more)	⊕⊕○○ LOW	CRITICAL
<b>Complications - Need for catheterisation at ≤1 year - TVT-Secur vs Other synthetic sling (follow-up 9-12 months)</b>												
6	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	9/292 (3.1%)	13/320 (4.1%)	RR 0.82 (0.36 to 1.87)	7 fewer per 1000 (from 26 fewer to 35 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at ≤1 year - SIMS (Brand not known) vs TVT-O</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	1/24 (4.2%)	0/24 (0%)	RR 3 (0.13 to 70.16)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year - Any brand of SIMS (follow-up 9-12 months)</b>												
9	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	43/615 (7%)	37/582 (6.4%)	RR 1.11 (0.74 to 1.67)	7 more per 1000 (from 17 fewer to 43 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year - MiniArc vs TOT (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	9/97 (9.3%)	13/96 (13.5%)	RR 0.69 (0.31 to 1.53)	42 fewer per 1000 (from 93 fewer to 72 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year - Needleless vs TOT (non-event) (follow-up 12 months)</b>												
2	randomised trials	serious <sup>8</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	0/167 (0%)	0/175 (0%)	RR 1.0 (0.98 to 1.02)	-	⊕⊕○○ LOW	CRITICAL
								0%		-		
<b>Complications - Infection at ≤1 year - TVT-Secur vs Other synthetic sling (follow-up 9-12 months)</b>												
5	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	32/291 (11%)	24/281 (8.5%)	RR 1.31 (0.81 to 2.12)	26 more per 1000 (from 16 fewer to 96 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year - MiniArc or TVT-Secur vs TVT-O (follow-up 12 months)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	2/60 (3.3%)	0/30 (0%)	RR 2.54 (0.13 to 51.31)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 year to ≤5 years - Any brand of SIMS (follow-up 24-60 months)</b>												
5	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	24/419 (5.7%)	22/364 (6%)	RR 1.12 (0.65 to 1.91)	7 more per 1000 (from 21 fewer to 55 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up 24 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	15/97 (15.5%)	10/96 (10.4%)	RR 1.48 (0.7 to 3.14)	50 more per 1000 (from 31 fewer to 223 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 year to ≤5 years - Needleless vs TOT (follow-up mean 28.5 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>22</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	2/89 (2.2%)	1/98 (1%)	RR 2.2 (0.2 to 23.87)	12 more per 1000 (from 8 fewer to 233 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 year to ≤5 years - TVT-Secur vs Transobturator sling (follow-up 24-60 months)</b>												
3	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2</sup>	very serious <sup>20</sup>	none	7/233 (3%)	11/170 (6.5%)	RR 0.67 (0.29 to 1.59)	21 fewer per 1000 (from 46 fewer to 38 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at ≤1 year - Any brand of SIMS (follow-up 9-12 months)</b>												
7	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	22/381 (5.8%)	22/346 (6.4%)	RR 0.85 (0.49 to 1.48)	10 fewer per 1000 (from 32 fewer to 31 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at ≤1 year - Needleless vs TOT (non-event) (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/89 (0%)	0/89 (0%)	RR 1.0 (0.98 to 1.02)	-	⊕⊕⊕⊕ HIGH	CRITICAL
								0%		-		
<b>Complications - De novo urgency at ≤1 year - TVT-Secur vs Other synthetic sling (follow-up 9-12 months)</b>												
5	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	16/232 (6.9%)	17/227 (7.5%)	RR 0.95 (0.5 to 1.81)	4 fewer per 1000 (from 37 fewer to 61 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at ≤1 year - MiniArc or TVT-Secur vs TVT-O (follow-up 12 months)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	6/60 (10%)	5/30 (16.7%)	RR 0.6 (0.2 to 1.81)	67 fewer per 1000 (from 133 fewer to 135 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;1 year to ≤5 years - Any brand of SIMS (follow-up 15-60 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
5	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	28/389 (7.2%)	30/330 (9.1%)	RR 0.73 (0.45 to 1.19)	25 fewer per 1000 (from 50 fewer to 17 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up median 15 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	2/41 (4.9%)	3/42 (7.1%)	RR 0.68 (0.12 to 3.88)	23 fewer per 1000 (from 63 fewer to 206 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;1 year to ≤5 years - Needleless vs TOT (follow-up mean 28.5 months)</b>												
1	randomised trials	serious <sup>22</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	9/89 (10.1%)	12/98 (12.2%)	RR 0.83 (0.37 to 1.87)	21 fewer per 1000 (from 77 fewer to 107 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - De novo urgency at &gt;1 year to ≤5 years - TVT-Secur vs Transobturator sling (random effects analysis) (follow-up 24 months)</b>												
3	randomised trials	serious <sup>5</sup>	serious <sup>10</sup>	serious <sup>2</sup>	very serious <sup>20</sup>	none	17/259 (6.6%)	15/190 (7.9%)	RR 0.84 (0.23 to 3.02)	13 fewer per 1000 (from 61 fewer to 159 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤1 year – Any brand of SIMS (follow-up 12 months)</b>												
2	randomised trials	serious <sup>23</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	14/164 (8.5%)	4/94 (4.3%)	RR 1.74 (0.63 to 4.83)	31 more per 1000 (from 16 fewer to 163 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤1 year - Needleless or Endopelvic Free Anchorage vs TOT (follow-up 12 months)</b>												
1	randomised trials	serious <sup>23</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	13/140 (9.3%)	4/70 (5.7%)	RR 1.63 (0.55 to 4.8)	36 more per 1000 (from 26 fewer to 217 more)	⊕000 VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤1 year - SIMS (Brand not known) vs TVT-O (follow-up median 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	1/24 (4.2%)	0/24 (0%)	RR 3 (0.13 to 70.16)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at &gt;1 year to ≤5 years - TVT-Secur vs Transobturator sling (follow-up 24 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	very serious <sup>20</sup>	none	29/129 (22.5%)	15/68 (22.1%)	RR 1.02 (0.59 to 1.77)	4 more per 1000 (from 90 fewer to 170 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - POP occurrence at &gt;1 year to ≤5 years - TVT-Secur vs Transobturator sling (follow-up 60 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>2</sup>	very serious <sup>20</sup>	none	0/38 (0%)	1/46 (2.2%)	RR 0.4 (0.02 to 9.59)	13 fewer per 1000 (from 21 fewer to 187 more)	⊕○○○ VERY LOW	CRITICAL
<b>Change in continence status - Subjective cure ≤1 year - Any brand of SIMS (follow-up 6-12 months; assessed with: Various self-report measures)</b>												
12	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	613/855 (71.7%)	653/824 (79.2%)	RR 0.9 (0.86 to 0.95)	79 fewer per 1000 (from 40 fewer to 111 fewer)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Change in continence status - Subjective cure ≤1 year - MiniArc vs Other Synthetic sling (random effects analysis) (follow-up 6 months; assessed with: Various self-report measures)</b>												
3	randomised trials	serious <sup>21</sup>	very serious <sup>24</sup>	serious <sup>2</sup>	no serious imprecision	none	188/252 (74.6%)	205/247 (83%)	RR 0.9 (0.82 to 0.99)	83 fewer per 1000 (from 8 fewer to 149 fewer)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure ≤1 year - MiniArc vs TVT (follow-up 6 months; assessed with: Various self-report measures)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	22/38 (57.9%)	32/33 (97%)	RR 0.6 (0.45 to 0.79)	388 fewer per 1000 (from 204 fewer to 533 fewer)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Subjective cure ≤1 year - MiniArc vs TOT (follow-up 12 months; assessed with: Various self-report measures)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	166/214 (77.6%)	173/214 (80.8%)	RR 0.96 (0.87 to 1.06)	32 fewer per 1000 (from 105 fewer to 49 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Subjective cure ≤1 year - Needleless vs TOT (follow-up 12 months; assessed with: Various self-report measures)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	81/90 (90%)	80/89 (89.9%)	RR 1.0 (0.91 to 1.1)	0 fewer per 1000 (from 81 fewer to 90 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
<b>Change in continence status - Subjective cure ≤1 year - TVT-Secur vs Other synthetic sling (random effects analysis) (follow-up 9-12 months; assessed with: Various self-report measures)</b>												
7	randomised trials	no serious risk of bias	serious <sup>10</sup>	serious <sup>1,2</sup>	serious <sup>7</sup>	none	325/489 (66.5%)	350/464 (75.4%)	RR 0.9 (0.79 to 1.03)	75 fewer per 1000 (from 158 fewer to 23 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure ≤1 year - SIMS (Brand not known) vs TVT-O (follow-up median 12 months; assessed with: Various self-report measures)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	19/24 (79.2%)	18/24 (75%)	RR 1.06 (0.77 to 1.44)	45 more per 1000 (from 173 fewer to 330 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - No concomitant POP surgery (random effects analysis) (follow-up 12 months; assessed with: Various self-report measures)</b>												
4	randomised trials	serious <sup>13</sup>	very serious <sup>24</sup>	serious <sup>1</sup>	no serious imprecision	none	223/313 (71.2%)	254/313 (81.2%)	RR 0.87 (0.69 to 1.09)	105 fewer per 1000 (from 252 fewer to 73 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - MiniArc vs TOT: No concomitant POP surgery (follow-up 12 months; assessed with: Various self-report measures)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	57/62 (91.9%)	49/57 (86%)	RR 1.07 (0.94 to 1.22)	60 more per 1000 (from 52 fewer to 189 more)	⊕⊕⊕⊕ MODERATE	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - Needleless vs TOT: No concomitant POP surgery (follow-up 12 months; assessed with: Various self-report measures)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	81/90 (90%)	80/89 (89.9%)	RR 1 (0.91 to 1.1)	0 fewer per 1000 (from 81 fewer to 90 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - TVT-Secur vs Other Synthetic sling: No concomitant POP surgery (follow-up 12 months; assessed with: Various self-report measures)</b>												
2	randomised trials	serious <sup>15</sup>	no serious inconsistency	no serious indirectness	serious <sup>7</sup>	none	85/161 (52.8%)	125/167 (74.9%)	RR 0.71 (0.6 to 0.84)	217 fewer per 1000 (from 120 fewer to 299 fewer)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years - Any brand of SIMS (random effects analysis) (follow-up 24-60 months; assessed with: Various self-report measures)</b>												
8	randomised trials	no serious risk of bias	serious <sup>10</sup>	serious <sup>1,2</sup>	serious <sup>7</sup>	none	446/635 (70.2%)	452/566 (79.9%)	RR 0.88 (0.79 to 0.98)	96 fewer per 1000 (from 16 fewer to 168 fewer)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years (random effects analysis) - MiniArc vs Other synthetic sling (follow-up 15-36 months; assessed with: Various self-report measures)</b>												
3	randomised trials	serious <sup>15</sup>	serious <sup>10</sup>	serious <sup>1,2</sup>	serious <sup>7</sup>	none	110/184 (59.8%)	131/178 (73.6%)	RR 0.76 (0.56 to 1.05)	177 fewer per 1000 (from 324 fewer to 37 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years - MiniArc vs TVT (follow-up 36 months; assessed with: Various self-report measures)</b>												
1	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	18/38 (47.4%)	30/33 (90.9%)	RR 0.52 (0.37 to 0.74)	436 fewer per 1000 (from 236 fewer to 573 fewer)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up 15-24 months; assessed with: Various self-report measures)</b>												
2	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	92/146 (63%)	101/145 (69.7%)	RR 0.9 (0.77 to 1.07)	70 fewer per 1000 (from 160 fewer to 49 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years - Needleless vs TOT (follow-up 24-28.5 months; assessed with: Various self-report measures)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>22</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	152/179 (84.9%)	163/187 (87.2%)	RR 0.97 (0.9 to 1.06)	26 fewer per 1000 (from 87 fewer to 52 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years - TVT-Secur vs Other synthetic sling (follow-up 24-60 months; assessed with: Various self-report measures)</b>												
3	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>7</sup>	none	184/272 (67.6%)	158/201 (78.6%)	RR 0.86 (0.77 to 0.95)	110 fewer per 1000 (from 39 fewer to 181 fewer)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure ≤1 year - Any brand of SIMS (random effects analysis) (follow-up 6-12 months; assessed with: Negative pad test or composite (objective and subjective) measures)</b>												
10	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	498/672 (74.1%)	494/621 (79.5%)	RR 0.93 (0.86 to 1.01)	56 fewer per 1000 (from 111 fewer to 8 more)	⊕⊕⊕⊕ MODERATE	IMPORTANT
<b>Change in continence status - Objective cure ≤1 year - MiniArc vs Other synthetic sling (follow-up 6-12 months)</b>												
4	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	196/277 (70.8%)	207/272 (76.1%)	RR 0.93 (0.84 to 1.03)	53 fewer per 1000 (from 122 fewer to 23 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Objective cure ≤1 year - Needleless vs TOT (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	82/90 (91.1%)	76/89 (85.4%)	RR 1.07 (0.96 to 1.19)	60 more per 1000 (from 34 fewer to 162 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
<b>Change in continence status - Objective cure ≤1 year - TVT-Secur vs Other synthetic sling (follow-up 12 months)</b>												
4	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	174/245 (71%)	186/230 (80.9%)	RR 0.88 (0.79 to 0.97)	97 fewer per 1000 (from 24 fewer to 170 fewer)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure ≤1 year - MiniArc or TVT-Secur vs TVT-O (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	46/60 (76.7%)	25/30 (83.3%)	RR 0.92 (0.74 to 1.14)	67 fewer per 1000 (from 217 fewer to 117 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure &gt;1 year to ≤5 years (random effects analysis) (follow-up 24-60 months)</b>												
4	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	224/330 (67.9%)	228/318 (71.7%)	RR 0.95 (0.83 to 1.09)	36 fewer per 1000 (from 122 fewer to 65 more)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Change in continence status - Objective cure &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up 24 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	67/97 (69.1%)	66/96 (68.8%)	RR 1 (0.83 to 1.21)	0 fewer per 1000 (from 117 fewer to 144 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Objective cure &gt;1 year to ≤5 years - Needleless vs TOT (follow-up 24 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	80/90 (88.9%)	76/89 (85.4%)	RR 1.04 (0.93 to 1.17)	34 more per 1000 (from 60 fewer to 145 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
<b>Change in continence status - Objective cure &gt;1 year to ≤5 years - TVT-Secur vs TVT-O (random effects analysis) (follow-up 24-60 months)</b>												
2	randomised trials	serious <sup>13</sup>	serious <sup>10</sup>	serious <sup>1,2</sup>	serious <sup>7</sup>	none	77/143 (53.8%)	86/133 (64.7%)	RR 0.82 (0.6 to 1.11)	116 fewer per 1000 (from 259 fewer to 71 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test ≤1 year (random effects analysis) (follow-up 12 months)</b>												
7	randomised trials	no serious risk of bias	very serious <sup>24</sup>	serious <sup>1,2</sup>	serious <sup>7</sup>	none	388/562 (69%)	392/497 (78.9%)	RR 0.83 (0.73 to 0.95)	134 fewer per 1000 (from 39 fewer to 213 fewer)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test ≤1 year - MiniArc vs TOT (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	84/117 (71.8%)	87/118 (73.7%)	RR 0.97 (0.83 to 1.14)	22 fewer per 1000 (from 125 fewer to 103 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test ≤1 year - Needleless or Endopelvic Free Anchorage vs TOT (follow-up 12 months)</b>												
1	randomised trials	serious <sup>23</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	126/140 (90%)	66/70 (94.3%)	RR 0.95 (0.88 to 1.03)	47 fewer per 1000 (from 113 fewer to 28 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test ≤1 year - TVT-Secur vs Other synthetic sling (follow-up 12 months)</b>												
5	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	178/305 (58.4%)	239/309 (77.3%)	RR 0.75 (0.68 to 0.84)	193 fewer per 1000 (from 124 fewer to 248 fewer)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test at ≤1 year - No concomitant POP surgery - Any brand of SIMS (follow-up 12 months)</b>												
4	randomised trials	serious <sup>15</sup>	very serious <sup>24</sup>	serious <sup>1</sup>	serious <sup>7</sup>	none	181/258 (70.2%)	218/260 (83.8%)	RR 0.85 (0.72 to 1.01)	126 fewer per 1000 (from 235 fewer to 8 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test at ≤1 year - MiniArc vs TOT: No concomitant POP surgery (follow-up 12 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	47/51 (92.2%)	42/45 (93.3%)	RR 0.99 (0.88 to 1.1)	9 fewer per 1000 (from 90 fewer to 93 more)	⊕⊕⊕⊕ MODERATE	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test at ≤1 year - TVT-Secur vs Other synthetic sling: No concomitant POP surgery (follow-up 12 months)</b>												
3	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>1</sup>	serious <sup>7</sup>	none	134/207 (64.7%)	176/215 (81.9%)	RR 0.79 (0.7 to 0.89)	172 fewer per 1000 (from 90 fewer to 246 fewer)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test &gt;1 year to ≤5 years (follow-up 15-28.5 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
4	randomised trials	serious <sup>5,18</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	219/313 (70%)	206/263 (78.3%)	RR 0.89 (0.81 to 0.97)	86 fewer per 1000 (from 23 fewer to 149 fewer)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up median 15 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	29/49 (59.2%)	33/49 (67.3%)	RR 0.88 (0.65 to 1.19)	81 fewer per 1000 (from 236 fewer to 128 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test &gt;1 year to ≤5 years - Needleless vs TOT (follow-up mean 28.5 months)</b>												
1	randomised trials	serious <sup>22</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	72/89 (80.9%)	85/98 (86.7%)	RR 0.93 (0.82 to 1.06)	61 fewer per 1000 (from 156 fewer to 52 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test &gt;1 year to ≤5 years - TVT-Secur vs Other synthetic sling (random effects analysis) (follow-up 24 months)</b>												
2	randomised trials	serious <sup>5</sup>	very serious <sup>24</sup>	no serious indirectness	very serious <sup>20</sup>	none	118/175 (67.4%)	88/116 (75.9%)	RR 0.93 (0.55 to 1.56)	53 fewer per 1000 (from 341 fewer to 425 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test &gt;1 year to ≤5 years - TVT-Secur vs TVT-O (follow-up 24 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>7</sup>	none	89/129 (69%)	63/68 (92.6%)	RR 0.74 (0.65 to 0.85)	241 fewer per 1000 (from 139 fewer to 324 fewer)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Negative Cough Stress Test &gt;1 year to ≤5 years - TVT-Secur vs TOT (follow-up 24 months)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	no serious indirectness	serious <sup>7</sup>	none	29/46 (63%)	25/48 (52.1%)	RR 1.21 (0.85 to 1.72)	109 more per 1000 (from 78 fewer to 375 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Number of incontinence episodes per day at &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up median 15 months; Better indicated by lower values)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>4,25</sup>	none	49	49	-	MD 0.56 higher (0.01 to 1.11 higher)	⊕○○○ VERY LOW	IMPORTANT
<b>Improvement in continence status at &gt;1 year to ≤5 years (follow-up 24-60 months)</b>												
5	randomised trials	serious <sup>5</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	305/438 (69.6%)	299/387 (77.3%)	RR 0.87 (0.8 to 0.94)	100 fewer per 1000 (from 46 fewer to 155 fewer)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Improvement in continence status at &gt;1 year to ≤5 years - MiniArc vs TOT (follow-up 24 months)</b>												
1	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>7</sup>	none	61/97 (62.9%)	64/96 (66.7%)	RR 0.94 (0.77 to 1.16)	40 fewer per 1000 (from 153 fewer to 107 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Improvement in continence status &gt;1 year to ≤5 years - Needleless vs TOT (follow-up 28.5 months)</b>												
1	randomised trials	serious <sup>22</sup>	no serious inconsistency	no serious indirectness	serious <sup>7</sup>	none	64/89 (71.9%)	83/98 (84.7%)	RR 0.85 (0.73 to 0.99)	127 fewer per 1000 (from 8 fewer to 229 fewer)	⊕⊕○○ LOW	IMPORTANT
<b>Improvement in continence status at &gt;1 year to ≤5 years - TVT-Secur vs TVT-O (follow-up 24-60 months)</b>												
3	randomised trials	serious <sup>5</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>7</sup>	none	180/252 (71.4%)	152/193 (78.8%)	RR 0.85 (0.77 to 0.95)	118 fewer per 1000 (from 39 fewer to 181 fewer)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for SUI up to 5 years (random effects analysis) (follow-up 0-60 months)</b>												
6	randomised trials	serious <sup>15</sup>	serious <sup>10</sup>	no serious indirectness	serious <sup>7</sup>	none	36/332 (10.8%)	11/329 (3.3%)	RR 2.64 (0.98 to 7.08)	55 more per 1000 (from 1 fewer to 203 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for SUI up to 5 years - subgroup (fixed effects) - MiniArc vs Other synthetic sling (follow-up 0-60 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
4	randomised trials	serious <sup>15</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	26/201 (12.9%)	8/196 (4.1%)	RR 3.05 (1.43 to 6.5)	84 more per 1000 (from 18 more to 224 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Repeat surgery for SUI up to 5 years - Needleless vs TOT (follow-up 12. 24 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>20</sup>	none	2/89 (2.2%)	3/89 (3.4%)	RR 0.67 (0.11 to 3.89)	11 fewer per 1000 (from 30 fewer to 97 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Repeat surgery for SUI up to 5 years - TVT-Secur vs TVT-O (follow-up 12 months)</b>												
1	randomised trials	serious <sup>26</sup>	no serious inconsistency	serious <sup>1,27</sup>	serious <sup>7</sup>	none	8/42 (19%)	0/44 (0%)	RR 17.79 (1.06 to 298.88)	-	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for POP at ≤1 year - TVT-Secur vs TVT (follow-up 12 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	2/136 (1.5%)	3/127 (2.4%)	RR 0.62 (0.11 to 3.67)	9 fewer per 1000 (from 21 fewer to 63 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for POP at ≤1 year - TVT-Secur vs Other synthetic sling</b>												
6	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	49/510 (9.6%)	18/430 (4.2%)	RR 2.26 (1.36 to 3.77)	53 more per 1000 (from 15 more to 116 more)	⊕⊕⊕⊕ MODERATE	IMPORTANT
<b>Repeat surgery for mesh complications up to 5 years (follow-up 0-60 months)</b>												
13	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	16/815 (2%)	14/754 (1.9%)	RR 1 (0.54 to 1.84)	0 fewer per 1000 (from 9 fewer to 16 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications up to 5 years - MiniArc vs Other synthetic sling (follow-up 0-36 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-incision mini-sling	Other synthetic sling	Relative (95% CI)	Absolute		
4	randomised trials	very serious <sup>26</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	4/201 (2%)	7/196 (3.6%)	RR 0.6 (0.2 to 1.84)	14 fewer per 1000 (from 29 fewer to 30 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications up to 5 years - Needleless vs TOT (follow-up 0-24 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>20</sup>	none	1/89 (1.1%)	1/89 (1.1%)	RR 1 (0.06 to 15.74)	0 fewer per 1000 (from 11 fewer to 166 more)	⊕⊕○○ LOW	IMPORTANT
<b>Repeat surgery for mesh complications up to 5 years - TVT-Secur vs Other synthetic sling (follow-up 0-60 months)</b>												
7	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	11/465 (2.4%)	4/439 (0.91%)	RR 1.83 (0.75 to 4.45)	8 more per 1000 (from 2 fewer to 31 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications up to 5 years - MiniArc or TVT-Secur vs TVT-O (follow-up 0-12 months)</b>												
1	randomised trials	serious <sup>18</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>20</sup>	none	0/60 (0%)	2/30 (6.7%)	RR 0.1 (0.01 to 2.05)	60 fewer per 1000 (from 66 fewer to 70 more)	⊕○○○ VERY LOW	IMPORTANT

1 Unclear or not reported whether some or all participants had failed or declined conservative treatment.

2 Unclear how many, or not reported whether some or all, participants had concomitant POP surgery.

3 MID for ISI, calculated as 0.5 times the standard deviation at follow up of the control arm, is +/- 0.95.

4 95% CI crosses 1 MID for this outcome.

5 Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, blinding of outcome assessment, and selective reporting.

6 Published MID for I-QoL is +/- 2.5 (Yalcin et al. Minimal clinically important differences in Incontinence Quality-of-Life scores in stress urinary incontinence. *Urology*. 2006 :1304-8.).

7 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

8 High risk of bias regarding allocation concealment (no appropriate safeguard of allocation schedule); unclear risk of bias regarding random sequence generation, blinding of participants, blinding of outcome assessment, and selective reporting.

9 Published MID for ICIQ-SF at 1 and 2 years is +/- 5 and +/-4, respectively (Sirls et al. The minimum important difference for the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form in women with stress urinary incontinence. *Neurourology and urodynamics*. 2015: 183-7).

10 High heterogeneity (*i*-squared  $\geq 50\%$  and  $< 80\%$ ).

11 95% CI crosses 1 default MID for standardised mean difference (+0.5 or -0.5).

- 12 MIDs for the King's Health Questionnaire subscales at 1 year, calculated as 0.5 times the standard deviation at baseline of the control arm, are as follows: General health perception (+/- 7.7), incontinence impact (+/- 10.25), role limitations (+/- 15.25), physical limitations (+/- 15.4), social limitations (+/- 14.5), personal relationships (+/- 16.75), emotions (+/- 15.1), sleep/energy (+/- 9.4), and severity measures (+/- 10).
- 13 Unclear risk of bias regarding blinding of participants/personnel, blinding of outcome assessment, and selective reporting.
- 14 MIDs for the King's Health Questionnaire subscales at 2 years, calculated as 0.5 times the standard deviation at baseline of the control arm, are as follows: General health perception (+/- 11.18), incontinence impact (+/- 14.48), role limitations (+/- 16.48), physical limitations (+/- 16.32), social limitations (+/- 11.44), personal relationships (+/- 16.93), emotions (+/- 16.61), sleep/energy (+/- 13.79), and severity measures (+/- 11.45).
- 15 Unclear risk of bias regarding allocation concealment, blinding of outcome assessment, and selective reporting.
- 16 MIDs for change scores of the King's Health Questionnaire subscales at 3 years, calculated as 0.5 times the standard deviation at follow up of the control arm, are as follows: role limitations (+/- 44.95), physical limitations (+/- 63.76), social limitations (+/- 28.66), personal relationships (+/- 63.08), emotions (+/- 18.71), sleep/energy (+/- 6.61), and severity measures (+/- 57.65).
- 17 95% CI crosses 2 MIDs for this outcome.
- 18 Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants/personnel, blinding of outcome assessment, and selective reporting.
- 19 Published MID for PISQ-12 is +/-6 (Mamik et al. The minimum important difference for the pelvic organ prolapse-urinary incontinence sexual function questionnaire. International urogynecology journal. 2014:1321-6).
- 20 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).
- 21 Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, and blinding of outcome assessment.
- 22 At baseline in 1 study, significantly higher perceptange of participants in Needleless group were smokers compared to TOT group. Unclear risk of bias regarding blinding of participants and selective reporting.
- 23 Unclear risk of bias regarding allocation concealment and selective reporting. One study originally 3 arm trial with approximately 33.3% of participants receiving Endopelvic Free Anchorage SIMS; at baseline, these participants had significantly higher parity and BMI compared to TVT-O group, and significantly higher BMI than participants in Needleless group.
- 24 Very high heterogeneity (i-squared  $\geq 80\%$ ).
- 25 MID for this outcome, calculated as 0.5 times the baseline SD of the TOT arm, is +/- 0.65.
- 26 1 study was at high risk of bias regarding blinding of outcome assessment; unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, and selective reporting.
- 27 Hota et al. 2012: 49% of participants had concomitant POP surgery
- 28 Outcome expressed as standardised mean difference because study or at least one included study only reported p-value.

**Adjustable mesh sling versus other synthetic mesh sling**

**Table 25: Clinical evidence profile for adjustable sling versus other synthetic mesh sling**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adjustable sling	Other Synthetic Sling	Relative (95% CI)	Absolute		
<b>Continence-specific health-related QoL - I-QoL at &gt;1 to ≤5 years (follow-up mean 14.9 months; measured with: Urinary Incontinence Quality of Life scale; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2,3</sup>	none	49	47	-	MD 3 lower (7.81 lower to 1.81 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - ICIQ-UI-SF at ≤1 year - Change scores (follow-up 4-12 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form; range of scores: 0-21; Better indicated by lower values)</b>												
2	randomised trials	serious <sup>4</sup>	serious <sup>5</sup>	serious <sup>6</sup>	no serious imprecision <sup>7</sup>	none	253	252	-	MD 0.02 higher (1.9 lower to 1.93 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Continence-specific health-related QoL - ICIQ-UI-SF at &gt;1 year to ≤5 years - Total scores (follow-up 13-14.9 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form; range of scores: 0-21; Better indicated by lower values)</b>												
2	randomised trials	serious <sup>8</sup>	no serious inconsistency	serious <sup>9</sup>	no serious imprecision <sup>10</sup>	none	93	93	-	MD 0.03 higher (0.69 lower to 0.74 higher)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Continence-specific health-related QoL - ICIQ-UI-SF at &gt;1 year to ≤5 years - Change scores (follow-up 12-18 months; measured with: International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form; range of scores: 0-21; Better indicated by lower values)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>6</sup>	serious <sup>3,11</sup>	none	69	68	-	MD 1.22 higher (0.52 lower to 2.96 higher)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Continence-specific health-related QoL - KHQ≥10 point improvement at ≤1 year (follow-up 4-6 months; measured with: King's Health Questionnaire)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>6</sup>	serious <sup>12</sup>	none	57/69 (82.6%)	60/64 (93.8%)	RR 0.88 (0.78 to 1)	113 fewer per 1000 (from 206 fewer to 0 more)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Continence-specific health-related QoL - KHQ≥18 point improvement at &gt;1 year to ≤5 years (follow-up 12-18 months; measured with: King's Health Questionnaire)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adjustable sling	Other Synthetic Sling	Relative (95% CI)	Absolute		
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>6</sup>	serious <sup>12</sup>	none	38/50 (76%)	43/50 (86%)	RR 0.88 (0.73 to 1.07)	103 fewer per 1000 (from 232 fewer to 60 more)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Adverse events - Severe bleeding requiring transfusion (non-event)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>9,14</sup>	no serious imprecision	none	0/30 (0%)	0/28 (0%)	RR 1 (0.94 to 1.07)	-	⊕⊕⊕⊕ LOW	CRITICAL
								0%		-		
<b>Adverse events - Bladder injury</b>												
7	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>6,9</sup>	very serious <sup>15</sup>	none	0/623 (0%)	3/569 (0.53%)	RR 0.14 (0.01 to 2.65)	5 fewer per 1000 (from 5 fewer to 9 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Adverse events - Bowel injury (non-event)</b>												
3	randomised trials	serious <sup>16</sup>	no serious inconsistency	serious <sup>6</sup>	no serious imprecision	none	0/283 (0%)	0/280 (0%)	RR 1 (0.99 to 1.01)	-	⊕⊕⊕⊕ LOW	CRITICAL
								0%		-		
<b>Complications - Pain at ≤1 year (random effects analysis) (follow-up 1-12 months)</b>												
4	randomised trials	serious <sup>17</sup>	very serious <sup>18</sup>	serious <sup>6,9</sup>	very serious <sup>15</sup>	none	64/270 (23.7%)	84/249 (33.7%)	RR 0.56 (0.19 to 1.71)	148 fewer per 1000 (from 273 fewer to 240 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - Ajust vs Other Synthetic sling (follow-up 12 months)</b>												
2	randomised trials	serious	no serious inconsistency	serious <sup>6,9</sup>	serious <sup>12</sup>	none	64/167 (38.3%)	68/155 (43.9%)	RR 0.88 (0.68 to 1.15)	53 fewer per 1000 (from 140 fewer to 66 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year - Other adjustable SIMS vs TOT (follow-up 1-12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adjustable sling	Other Synthetic Sling	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>19</sup>	no serious inconsistency	serious <sup>6,9</sup>	no serious imprecision	none	0/103 (0%)	16/94 (17%)	RR 0.06 (0.01 to 0.41)	160 fewer per 1000 (from 100 fewer to 169 fewer)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years (follow-up 14.9-36 months)</b>												
2	randomised trials	serious <sup>19</sup>	no serious inconsistency	serious <sup>6</sup>	very serious <sup>15</sup>	none	2/88 (2.3%)	1/85 (1.2%)	RR 1.45 (0.25 to 8.58)	5 more per 1000 (from 9 fewer to 89 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Pain at &gt;5 years (follow-up mean 64 months)</b>												
1	randomised trials	serious <sup>19</sup>	no serious inconsistency	serious <sup>6</sup>	very serious <sup>15</sup>	none	0/39 (0%)	1/38 (2.6%)	RR 0.32 (0.01 to 7.74)	18 fewer per 1000 (from 26 fewer to 177 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year (follow-up 4-12 months)</b>												
5	randomised trials	serious <sup>4</sup>	no serious inconsistency	serious <sup>6,9</sup>	very serious <sup>15</sup>	none	11/458 (2.4%)	10/407 (2.5%)	RR 0.9 (0.39 to 2.06)	2 fewer per 1000 (from 15 fewer to 26 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at &gt;1 year to ≤5 years (non-event) (follow-up 13-36 months)</b>												
3	randomised trials	serious <sup>4</sup>	no serious inconsistency	serious <sup>6</sup>	no serious imprecision	none	0/133 (0%)	0/133 (0%)	RR 1 (0.98 to 1.03)	-	⊕⊕⊕⊕ LOW	CRITICAL
								0%		-		
<b>Complications - Mesh extrusion at &gt;5 years (follow-up mean 64 months)</b>												
1	randomised trials	serious <sup>20</sup>	no serious inconsistency	serious <sup>6</sup>	very serious <sup>15</sup>	none	0/36 (0%)	1/36 (2.8%)	RR 0.33 (0.01 to 7.92)	19 fewer per 1000 (from 28 fewer to 192 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at ≤1 year (follow-up 4-12)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adjustable sling	Other Synthetic Sling	Relative (95% CI)	Absolute		
4	randomised trials	serious <sup>4</sup>	no serious inconsistency	no serious indirectness	serious <sup>12</sup>	none	15/388 (3.9%)	25/341 (7.3%)	RR 0.48 (0.25 to 0.91)	38 fewer per 1000 (from 7 fewer to 55 fewer)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Complications - Infection at ≤1 year (follow-up 12 months)</b>												
3	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>6,9</sup>	serious <sup>12</sup>	none	50/301 (16.6%)	36/246 (14.6%)	RR 1.23 (0.83 to 1.82)	34 more per 1000 (from 25 fewer to 120 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - De novo urgency at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>21</sup>	no serious inconsistency	serious <sup>6,9</sup>	very serious <sup>15</sup>	none	4/64 (6.3%)	4/56 (7.1%)	RR 0.88 (0.23 to 3.34)	9 fewer per 1000 (from 55 fewer to 167 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence at ≤1 year (follow-up 12 months)</b>												
2	randomised trials	serious <sup>22</sup>	no serious inconsistency	serious <sup>6,9</sup>	very serious <sup>15</sup>	none	7/169 (4.1%)	6/161 (3.7%)	RR 0.85 (0.32 to 2.26)	6 fewer per 1000 (from 25 fewer to 47 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Complications - De novo urge incontinence - &gt;1 year to ≤5 years (follow-up mean 14.9 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>15</sup>	none	5/49 (10.2%)	4/47 (8.5%)	RR 1.2 (0.34 to 4.19)	17 more per 1000 (from 56 fewer to 271 more)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Change in continence status - Subjective cure at ≤1 year (follow-up 12 months; Various self-report measures)</b>												
2	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>6,9</sup>	no serious imprecision	none	140/247 (56.7%)	110/198 (55.6%)	RR 0.95 (0.81 to 1.12)	28 fewer per 1000 (from 106 fewer to 67 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years (follow-up 14.9-36 months; Various self-report measures)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adjustable sling	Other Synthetic Sling	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>6</sup>	no serious imprecision	none	45/88 (51.1%)	45/85 (52.9%)	RR 0.96 (0.83 to 1.11)	21 fewer per 1000 (from 90 fewer to 58 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;5 years (follow-up mean 64 months; Various self-report measures)</b>												
1	randomised trials	serious <sup>20</sup>	no serious inconsistency	serious <sup>6</sup>	very serious <sup>15</sup>	none	1/36 (2.8%)	2/36 (5.6%)	RR 0.5 (0.05 to 5.27)	28 fewer per 1000 (from 53 fewer to 237 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year (follow-up 8.5-12 months; assessed with: Negative pad test or composite (subjective and objective) measure)</b>												
3	randomised trials	serious <sup>21</sup>	no serious inconsistency	serious <sup>6,9,14</sup>	no serious imprecision	none	106/147 (72.1%)	108/137 (78.8%)	RR 0.92 (0.8 to 1.05)	63 fewer per 1000 (from 158 fewer to 39 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years (follow-up mean 36 months; assessed with: Negative pad test or composite (subjective and objective) measure)</b>												
1	randomised trials	serious <sup>20</sup>	no serious inconsistency	serious <sup>6</sup>	serious <sup>12</sup>	none	35/39 (89.7%)	32/38 (84.2%)	RR 1.07 (0.9 to 1.27)	59 more per 1000 (from 84 fewer to 227 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;5 years (follow-up mean 64 months; assessed with: Composite (subjective and objective) measure)</b>												
1	randomised trials	serious <sup>20</sup>	no serious inconsistency	serious <sup>6</sup>	serious <sup>12</sup>	none	30/36 (83.3%)	27/36 (75%)	RR 1.11 (0.88 to 1.41)	83 more per 1000 (from 90 fewer to 307 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at ≤1 year (follow-up 4-12 months)</b>												
4	randomised trials	serious <sup>16</sup>	no serious inconsistency	serious <sup>6</sup>	no serious imprecision	none	450/495 (90.9%)	414/446 (92.8%)	RR 0.98 (0.94 to 1.02)	19 fewer per 1000 (from 56 fewer to 19 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test - &gt;1 year to ≤5 years (follow-up 12-18 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adjustable sling	Other Synthetic Sling	Relative (95% CI)	Absolute		
3	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>6,9</sup>	no serious imprecision	none	140/163 (85.9%)	132/163 (81%)	RR 1.06 (0.96 to 1.17)	49 more per 1000 (from 32 fewer to 138 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Change in continence status - No incontinence episodes per day at ≤1 year</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>6,9</sup>	serious <sup>12</sup>	none	74/155 (47.7%)	67/150 (44.7%)	RR 1.07 (0.84 to 1.36)	31 more per 1000 (from 71 fewer to 161 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years (follow-up 12-18 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>6</sup>	serious <sup>12</sup>	none	58/69 (84.1%)	53/68 (77.9%)	RR 1.08 (0.92 to 1.27)	62 more per 1000 (from 62 fewer to 210 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Repeat surgery for any reason at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>22</sup>	no serious inconsistency	serious <sup>6</sup>	very serious <sup>15</sup>	none	2/93 (2.2%)	1/51 (2%)	RR 1.1 (0.1 to 11.8)	2 more per 1000 (from 18 fewer to 212 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for any reason - &gt;1 year to ≤5 years (follow-up 12-18 months)</b>												
2	randomised trials	serious <sup>23</sup>	no serious inconsistency	serious <sup>6</sup>	very serious <sup>15</sup>	none	5/118 (4.2%)	4/115 (3.5%)	RR 1.2 (0.36 to 4.03)	7 more per 1000 (from 22 fewer to 105 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Repeat surgery for SUI at ≤1 year (non-event) (follow-up 12 months)</b>												
1	randomised trials	serious <sup>13</sup>	no serious inconsistency	serious <sup>14</sup>	no serious imprecision	none	0/30 (0%)	0/28 (0%)	Not estimable	-	⊕⊕⊕⊕ LOW	IMPORTANT

1 Unclear risk of bias regarding random sequence generation, blinding of participants, blinding of outcome assessment, and selective reporting.

2 Published MID for I-QoL is +/- 2.5 (Yalcin et al. Minimal clinically important differences in Incontinence Quality-of-Life scores in stress urinary incontinence. *Urology*. 2006;1304-8.).

3 95% CI crosses 1 MID for this outcome

4 Unclear risk of bias regarding allocation concealment, blinding of participants/personnel, and selective reporting.

- 5 High heterogeneity (*i*-squared  $\geq 50\%$  and  $< 80\%$ ).
- 6 Unclear how many, or not reported whether some or all, participants had concomitant POP surgery.
- 7 MID for ICIQ-SF change scores at  $\leq 1$  year, calculated as 0.5 times the median SD of the control arm studies at followup, is +/- 2.34.
- 8 Unclear risk of bias regarding random sequence generation, blinding of participants/personnel, and blinding of outcome assessors.
- 9 Unclear whether some or all participants failed or declined conservative treatment.
- 10 Published MID for ICIQ-SF at 2 years is +/- 4 (Sirls et al. The minimum important difference for the International Consultation on Incontinence Questionnaire—Urinary Incontinence Short Form in women with stress urinary incontinence. *Neurourology and urodynamics*. 2015: 183-7).
- 11 MID for ICIQ-SF change scores between 1 and 5 years, calculated as 0.5 times the SD of control arm at followup, is +/- 2.17.
- 12 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).
- 13 Unclear risk of bias regarding blinding of participants and blinding of outcome assessment.
- 14 Sabadell et al. 2017: 28% of participants had concomitant POP surgery.
- 15 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).
- 16 Unclear risk of bias regarding allocation concealment, blinding of participants, and selective reporting.
- 17 Unclear risk of bias regarding random sequence generation, blinding of participants/personnel, and blinding of outcome assessment.
- 18 Very high heterogeneity (*i*-squared  $\geq 80\%$ ).
- 19 Unclear risk of bias regarding blinding of outcome assessment, and selective reporting.
- 20 Unclear risk of bias regarding allocation concealment, blinding of outcome assessment, and selective reporting.
- 21 Unclear risk of bias regarding blinding of participants, blinding of outcome assessment, and selective reporting.
- 22 Unclear risk of bias regarding random sequence generation and blinding of outcome assessment.
- 23 Unclear risk of bias regarding blinding of participants/personnel and selective reporting.

**Laparoscopic colposuspension with sutures versus open colposuspension with sutures**

**Table 26: Clinical evidence profile for laparoscopic colposuspension with sutures versus open colposuspension with sutures**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopic colposuspension	Open Colposuspension	Relative (95% CI)	Absolute		
<b>Adverse events - Severe bleeding requiring blood transfusion</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>3</sup>	none	0/96 (0%)	1/104 (0.96%)	RR 0.36 (0.01 to 8.75)	6 fewer per 1000 (from 10 fewer to 75 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Bladder injury</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopic colposuspension	Open Colposuspension	Relative (95% CI)	Absolute		
5	randomised trials	serious <sup>4</sup>	no serious inconsistency	serious <sup>1,2</sup>	serious <sup>5</sup>	none	13/347 (3.7%)	4/360 (1.1%)	RR 3.12 (1.08 to 9.02)	24 more per 1000 (from 1 more to 89 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Bowel injury</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>3</sup>	none	1/144 (0.69%)	0/147 (0%)	RR 3.06 (0.13 to 74.55)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>7</sup>	very serious <sup>3</sup>	none	3/47 (6.4%)	4/43 (9.3%)	RR 0.69 (0.16 to 2.89)	29 fewer per 1000 (from 78 fewer to 176 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Pain at &gt;1 year to ≤5 years (follow-up 18 months)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>3</sup>	none	1/33 (3%)	5/40 (12.5%)	RR 0.24 (0.03 to 1.97)	95 fewer per 1000 (from 121 fewer to 121 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Need for catheterisation at &gt;1 year to ≤5 years (follow-up 18 months)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>3</sup>	none	2/34 (5.9%)	2/40 (5%)	RR 1.18 (0.17 to 7.91)	9 more per 1000 (from 42 fewer to 345 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2,8</sup>	very serious <sup>3</sup>	none	1/46 (2.2%)	1/46 (2.2%)	RR 1 (0.06 to 15.51)	0 fewer per 1000 (from 20 fewer to 315 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - De novo urge symptoms and urge incontinence at ≤1 year (follow-up 12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopic colposuspension	Open Colposuspension	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2,8</sup>	very serious <sup>3</sup>	none	3/46 (6.5%)	2/46 (4.3%)	RR 1.5 (0.26 to 8.56)	22 more per 1000 (from 32 fewer to 329 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - POP occurrence at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2,7</sup>	very serious <sup>3</sup>	none	1/47 (2.1%)	2/43 (4.7%)	RR 0.46 (0.04 to 4.87)	25 fewer per 1000 (from 45 fewer to 180 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - POP occurrence at &gt;1 year to ≤5 years (follow-up 18 months)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>1,2</sup>	very serious <sup>3</sup>	none	3/34 (8.8%)	4/40 (10%)	RR 0.88 (0.21 to 3.67)	12 fewer per 1000 (from 79 fewer to 267 more)	⊕○○○ VERY LOW	CRITICAL
<b>Change in continence status - Subjective cure at ≤1 year (random effects analysis) (follow-up 12 months; assessed with: Reports no leakage; never leaks)</b>												
3	randomised trials	serious <sup>9</sup>	serious <sup>10</sup>	serious <sup>1,2</sup>	serious <sup>5</sup>	none	151/244 (61.9%)	153/269 (56.9%)	RR 1.06 (0.9 to 1.26)	34 more per 1000 (from 57 fewer to 148 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - subgroup - No concomitant POP surgery (follow-up 12 months; assessed with: Reports no leakage; never leaks)</b>												
2	randomised trials	very serious <sup>9</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>5</sup>	none	113/197 (57.4%)	116/226 (51.3%)	RR 1.14 (0.97 to 1.33)	72 more per 1000 (from 15 fewer to 169 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at ≤1 year - subgroup - Some concomitant POP surgery (follow-up 12 months; assessed with: Reports no leakage; never leaks)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2,7</sup>	serious <sup>5</sup>	none	38/47 (80.9%)	37/43 (86%)	RR 0.94 (0.78 to 1.13)	52 fewer per 1000 (from 189 fewer to 112 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure - &gt;1 year to ≤5 years (random effects analysis) (follow-up 24 months; assessed with: Self-report no leakage; never leaks)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopic colposuspension	Open Colposuspension	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>6</sup>	serious <sup>10</sup>	serious <sup>1,2</sup>	serious <sup>5</sup>	none	119/240 (49.6%)	131/251 (52.2%)	RR 0.94 (0.73 to 1.21)	31 fewer per 1000 (from 141 fewer to 110 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year (follow-up 6-12 months; assessed with: Negative pad test; No urodynamic stress incontinence)</b>												
4	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>1,2</sup>	no serious imprecision	none	241/339 (71.1%)	281/376 (74.7%)	RR 0.95 (0.87 to 1.04)	37 fewer per 1000 (from 97 fewer to 30 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years (follow-up 12-24 months; assessed with: Dry on cough stress test and bouncing on urodynamic testing; Negative pad test; Subjectively dry, negative stress test and dry on urodynamic evaluation)</b>												
2	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2,11</sup>	serious <sup>5</sup>	none	119/170 (70%)	103/173 (59.5%)	RR 1.13 (0.93 to 1.38)	77 more per 1000 (from 42 fewer to 226 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at ≤1 year (follow-up 12 months)</b>												
2	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2,7</sup>	no serious imprecision	none	83/100 (83%)	92/122 (75.4%)	RR 1.08 (0.95 to 1.24)	60 more per 1000 (from 38 fewer to 181 more)	⊕⊕○○ LOW	IMPORTANT
<b>Patient satisfaction/Patient-reported improvement - Improvement in continence status at &gt;1 year to ≤5 years (follow-up 24 months; assessed with: Response of 'perfectly happy' or 'pleased' to item 33 of Bristol Female Lower Urinary Tract Symptoms questionnaire)</b>												
1	randomised trials	serious <sup>6</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>5</sup>	none	73/144 (50.7%)	71/147 (48.3%)	RR 1.05 (0.83 to 1.32)	24 more per 1000 (from 82 fewer to 155 more)	⊕○○○ VERY LOW	IMPORTANT

1 Unclear whether some or all participants had concomitant POP surgery.

2 Unclear whether some or all participants had failed or declined conservative treatment.

3 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

4 Unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment and selective reporting.

5 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

6 Unclear risk of bias regarding blinding of participants/personnel, blinding of outcome assessment, and selective reporting.

7 Cheon et al. 2003: 26% participants had concomitant hysterectomy.

8 Su et al. 1997: 30% participants had concomitant hysterectomy.

9 High risk of bias of incomplete outcome data (1 study had >20% dropout at both followup times); Unclear risk of bias regarding allocation concealment, blinding of participants, blinding of outcome assessment and selective reporting.

10 High heterogeneity ( $i\text{-squared} \geq 50\%$  and  $< 80\%$ ).

11 Ustun et al. 2005: 42% of participants had concomitant POP surgery.

## Autologous rectus fascial sling versus colposuspension

**Table 27: Clinical evidence profile for fascial sling versus colposuspension**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Colposuspension	Relative (95% CI)	Absolute		
<b>Adverse events - Severe bleeding requiring transfusion (non-event)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	no serious imprecision	none	0/17 (0%)	0/19 (0%)	RR 1 (0.9 to 1.11)	-	⊕○○○ VERY LOW	CRITICAL
								0%		-		
<b>Adverse events - Bladder injury</b>												
2	randomised trials	very serious <sup>1,4</sup>	no serious inconsistency	serious <sup>2,3,5</sup>	very serious <sup>6</sup>	none	0/343 (0%)	3/345 (0.87%)	RR 0.26 (0.03 to 2.28)	6 fewer per 1000 (from 8 fewer to 11 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events - Bowel injury</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	very serious <sup>6</sup>	none	0/17 (0%)	1/19 (5.3%)	RR 0.37 (0.02 to 8.53)	33 fewer per 1000 (from 52 fewer to 396 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Pain at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>7</sup>	no serious inconsistency	serious <sup>3,8</sup>	very serious <sup>6</sup>	none	4/17 (23.5%)	2/17 (11.8%)	RR 2 (0.42 to 9.5)	118 more per 1000 (from 68 fewer to 1000 more)	⊕○○○ VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Colposuspension	Relative (95% CI)	Absolute		
<b>Complications - Pain at &gt;1 year to ≤5 years (follow-up 24 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	very serious <sup>6</sup>	none	2/326 (0.61%)	0/329 (0%)	RR 5.05 (0.24 to 104.7)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Mesh extrusion at ≤1 year (follow-up 3 months)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	very serious <sup>6</sup>	none	2/17 (11.8%)	0/19 (0%)	RR 5.56 (0.29 to 108.16)	-	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Fistula at &gt;1 year to ≤5 years (follow-up 24 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	very serious <sup>6</sup>	none	0/326 (0%)	1/329 (0.3%)	RR 0.34 (0.01 to 8.23)	2 fewer per 1000 (from 3 fewer to 22 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>7</sup>	no serious inconsistency	serious <sup>3,8</sup>	very serious <sup>6</sup>	none	1/15 (6.7%)	2/14 (14.3%)	RR 0.47 (0.05 to 4.6)	76 fewer per 1000 (from 136 fewer to 514 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at &gt;1 year to ≤5 years (follow-up 24 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	no serious imprecision	none	305/326 (93.6%)	207/329 (62.9%)	RR 1.49 (1.36 to 1.62)	308 more per 1000 (from 227 more to 390 more)	⊕⊕○○ LOW	CRITICAL
<b>Complications - De novo urge incontinence at &gt;1 year to ≤5 years (follow-up 24 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	very serious <sup>6</sup>	none	11/326 (3.4%)	11/329 (3.3%)	RR 1.01 (0.44 to 2.3)	0 more per 1000 (from 19 fewer to 43 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - POP occurrence at ≤1 year (follow-up 3-12 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Colposuspension	Relative (95% CI)	Absolute		
2	randomised trials	serious <sup>7</sup>	no serious inconsistency	serious <sup>3,8</sup>	very serious <sup>6</sup>	none	0/34 (0%)	2/36 (5.6%)	RR 0.2 (0.01 to 3.88)	44 fewer per 1000 (from 55 fewer to 160 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Wound complications at &gt;1 year to ≤5 years (follow-up 24 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	very serious <sup>6</sup>	none	82/326 (25.2%)	82/329 (24.9%)	RR 1.01 (0.77 to 1.32)	2 more per 1000 (from 57 fewer to 80 more)	⊕○○○ VERY LOW	CRITICAL
<b>Change in continence status - Subjective cure at ≤1 year (follow-up 3-12 months; assessed with: Self-reported no leakage or completely dry)</b>												
2	randomised trials	very serious <sup>10</sup>	no serious inconsistency	serious <sup>3,8</sup>	serious <sup>11</sup>	none	33/40 (82.5%)	33/42 (78.6%)	RR 1.06 (0.86 to 1.3)	47 more per 1000 (from 110 fewer to 236 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;1 year to ≤5 years (follow-up 60 months; assessed with: No leakage on MESA questionnaire)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	serious <sup>11</sup>	none	77/326 (23.6%)	54/329 (16.4%)	RR 1.44 (1.05 to 1.97)	72 more per 1000 (from 8 more to 159 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;5 years (follow-up mean 72.6 months; assessed with: No incontinence episodes on 1 week voiding diary)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	very serious <sup>6</sup>	none	11/17 (64.7%)	14/19 (73.7%)	RR 0.88 (0.56 to 1.37)	88 fewer per 1000 (from 324 fewer to 273 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year (follow-up 3-12 months; assessed with: Composite (objective + subjective) measures)</b>												
2	randomised trials	serious <sup>12</sup>	no serious inconsistency	serious <sup>2,3,13</sup>	no serious imprecision	none	43/45 (95.6%)	46/52 (88.5%)	RR 1.08 (0.95 to 1.22)	71 more per 1000 (from 44 fewer to 195 more)	⊕○○○ LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;1 year to ≤5 years (follow-up 24 months; assessed with: Negative pad test)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Colposuspension	Relative (95% CI)	Absolute		
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	no serious imprecision	none	228/326 (69.9%)	217/329 (66%)	RR 1.06 (0.95 to 1.18)	40 more per 1000 (from 33 fewer to 119 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Objective cure at &gt;5 years (follow-up mean 72.6 months; assessed with: Composite (objective + subjective) measure)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	very serious <sup>6</sup>	none	13/17 (76.5%)	13/19 (68.4%)	RR 1.12 (0.75 to 1.67)	82 more per 1000 (from 171 fewer to 458 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Negative cough stress test at &gt;1 year to ≤5 years (follow-up 24 months)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	serious <sup>11</sup>	none	231/326 (70.9%)	181/329 (55%)	RR 1.29 (1.14 to 1.45)	160 more per 1000 (from 77 more to 248 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Stress incontinence episodes per day at &gt;5 years (follow-up mean 72.6 months; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	very serious <sup>14,15</sup>	none	13	15	-	MD 0.15 higher (0.28 lower to 0.58 higher)	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Urge incontinence episodes per day at &gt;5 years (follow-up mean 72.6 months; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	very serious <sup>15</sup>	none	13	15	-	MD 0.02 lower (1.97 lower to 1.93 higher)	⊕○○○ VERY LOW	IMPORTANT
<b>Patient satisfaction/patient-reported satisfaction - Improvement in continence status &gt;1 year to ≤5 years (follow-up 60 months; assessed with: Self-reported satisfied)</b>												
1	randomised trials	serious <sup>9</sup>	no serious inconsistency	serious <sup>3,5</sup>	serious <sup>11</sup>	none	148/326 (45.4%)	126/329 (38.3%)	RR 1.19 (0.99 to 1.42)	73 more per 1000 (from 4 fewer to 161 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery for mesh complications at ≤1 year (follow-up 3 months)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Autologous rectus fascial sling	Colposuspension	Relative (95% CI)	Absolute		
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2,3</sup>	very serious <sup>6</sup>	none	2/17 (11.8%)	0/19 (0%)	RR 5.56 (0.29 to 108.16)	-	⊕○○○ VERY LOW	IMPORTANT

- 1 High risk of bias regarding blinding of outcome assessment; also significantly more participants at baseline in colposuspension group had detrusor instability and higher average postvoid residual volume than those in fascial sling group. Unclear risk of bias regarding allocation concealment and selective reporting.
- 2 Sand et al. 2000/Culligan et al. 2003: 8.5% of participants had concomitant POP surgery.
- 3 Unclear whether some or all participants had failed or declined conservative treatment.
- 4 High/unclear risk of bias regarding blinding of outcome assessment; participants in colposuspension arm in 1 study had significantly more detrusor instability and higher average postvoid residual volume at baseline compared to those in fascial sling arm. Also unclear risk regarding allocation concealment, blinding of participants and blinding of outcome assessment and selective reporting.
- 5 Albo et al. 2007: 58% of participants had concomitant POP surgery.
- 6 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).
- 7 Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment and selective reporting.
- 8 Demirci et al. 2001: 37% of participants had concomitant POP surgery.
- 9 Unclear risk of bias regarding allocation concealment, blinding of participants/personnel and blinding of outcome assessment.
- 10 High risk of bias regarding blinding of outcome assessment; also in 1 study, significantly more participants at baseline in colposuspension group had detrusor instability and higher average postvoid residual volume than those in fascial sling group. Also unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment and selective reporting.
- 11 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).
- 12 High/unclear risk of bias regarding blinding of outcome assessment; also in 1 study significantly more participants at baseline in colposuspension group had detrusor instability and higher average postvoid residual volume than those in fascial sling group. Unclear risk of bias regarding random sequence generation, allocation concealment, blinding of participants, and selective reporting.
- 13 Bai et al. 2005: Unclear whether some or all participants had concomitant POP surgery.
- 14 MIDs for these outcomes, calculated as 0.5 times the SD of the control arm at followup, are as follows: stress incontinence episodes per day (+/- 0.29); urge incontinence episodes per day (+/- 1.32).
- 15 95% CI crosses 2 MIDs for this outcome.

## Bulking agent versus other surgical technique

**Table 28: Clinical evidence profile for bulking agent versus other surgical technique**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bulking agents	Other surgical techniques	Relative (95% CI)	Absolute		
<b>Complications - Need for catheterisation at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	0/22 (0%)	1/21 (4.8%)	RR 0.32 (0.01 to 7.42)	32 fewer per 1000 (from 47 fewer to 306 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Infection at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	2/22 (9.1%)	3/21 (14.3%)	RR 0.64 (0.12 to 3.44)	51 fewer per 1000 (from 126 fewer to 349 more)	⊕○○○ VERY LOW	CRITICAL
<b>Complications - Wound complications at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	0/22 (0%)	1/21 (4.8%)	RR 0.32 (0.01 to 7.42)	32 fewer per 1000 (from 47 fewer to 306 more)	⊕○○○ VERY LOW	CRITICAL
<b>Change in continence status - Subjective cure at ≤1 year (follow-up 12 months; assessed with: &lt;1 stress incontinence episodes per week)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	17/23 (73.9%)	19/22 (86.4%)	RR 0.86 (0.64 to 1.15)	121 fewer per 1000 (from 311 fewer to 130 more)	⊕⊕○○ LOW	IMPORTANT
<b>Change in continence status - Subjective cure at &gt;5 years (follow-up 5 years; assessed with: &lt;1 stress incontinence episodes per week)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	4/23 (17.4%)	0/22 (0%)	RR 8.62 (0.49 to 151.39)	-	⊕○○○ VERY LOW	IMPORTANT
<b>Change in continence status - Objective cure at ≤1 year (follow-up 12 months; assessed with: No urinary leakage due to SUI on repeat urodynamic testing)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/23 (8.7%)	17/22 (77.3%)	RR 0.11 (0.03 to 0.43)	688 fewer per 1000 (from 440 fewer to 750 fewer)	⊕⊕⊕○ MODERATE	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bulking agents	Other surgical techniques	Relative (95% CI)	Absolute		
<b>Patient satisfaction/patient-reported improvement - Improvement in continence status at &gt;5 years (follow-up 5 years; assessed with: Satisfied with procedure)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	4/23 (17.4%)	9/22 (40.9%)	RR 0.43 (0.15 to 1.18)	233 fewer per 1000 (from 348 fewer to 74 more)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Repeat surgery for SUI at ≤1 year (follow-up 12 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	2/23 (8.7%)	1/22 (4.5%)	RR 1.91 (0.19 to 19.63)	41 more per 1000 (from 37 fewer to 847 more)	⊕⊕⊕⊕ VERY LOW	IMPORTANT

1 High risk of bias due to significant difference at baseline (significantly less participants in bulking agent group had detrusor instability compared to those in synthetic sling group); unclear risk of bias regarding allocation concealment, blinding of outcome assessment and selective reporting.

2 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).

3 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

### GRADE tables for the review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures) compared to pelvic floor muscle training?

Table 3: Clinical evidence profile for surgical management versus pelvic floor muscle training

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pelvic floor muscle training	Surgery	Relative (95% CI)	Absolute		
<b>Continence-specific health-related quality of life (follow-up mean 3 months; measured with: I-QOL [higher numbers favour surgery]; range of scores: 0-5; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	21	24	-	MD 0.54 higher	⊕⊕⊕⊕ LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pelvic floor muscle training	Surgery	Relative (95% CI)	Absolute		
										(0.49 to 0.59 higher)		
<b>Change in continence status within 1 year - Subjective cure (assessed with: patients' judgements, voiding chart, questionnaire or question)</b>												
3	randomised trials	serious <sup>2</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	101/205 (49.3%)	194/240 (80.8%)	RR 1.61 (1.39 to 1.85)	493 more per 1000 (from 315 more to 687 more)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Change in continence status at &gt;5 years - Subjective cure (follow-up mean 6.5 years; assessed with: voiding chart)</b>												
1	randomised trial	serious <sup>2</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	11/20 (55%)	5/10 (50%)	RR 1.1 (0.53 to 2.3)	50 more per 1000 (from 235 fewer to 650 more)	⊕○○○ VERY LOW	CRITICAL
<b>Change in continence status within 1 year - Objective cure (follow-up mean 1 years; assessed with: negative stress test)</b>												
2	randomised trial	very serious <sup>4</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	96/181 (53%)	158/207 (76.3%)	RR 2.86 (0.44 to 18.61)	1000 more per 1000 (from 427 fewer to 1000 more)	⊕○○○ VERY LOW	CRITICAL
<b>Patient reported improvement within 1 year (follow-up mean 1 years; assessed with: PGI-I improvement in patient numbers)</b>												
1	randomised trials	no serious	no serious inconsistency	no serious indirectness	no serious imprecision	none	177/195	112/174	RR 1.41	264 more per 1000	⊕⊕⊕⊕ HIGH	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pelvic floor muscle training	Surgery	Relative (95% CI)	Absolute		
		risk of bias					(90.8%)	(64.4%)	(1.25 to 1.59)	(from 161 more to 380 more)		
<b>Patient reported improvement within 1 year (follow-up mean 2 months; assessed with: PGI-I improvement in patient numbers)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	25/194 (12.9%)	175/201 (87.1%)	RR 6.76 (4.67 to 9.78)	742 more per 1000 (from 676 more to 808 more)	⊕⊕⊕⊕ HIGH	CRITICAL
<b>Patient reported improvement within 1 year (follow-up mean 4 months; assessed with: PGI-I improvement in patient numbers)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	59/190 (31.1%)	182/200 (91%)	RR 2.93 (2.36 to 3.64)	599 more per 1000 (from 523 more to 676 more)	⊕⊕⊕⊕ HIGH	CRITICAL
<b>Patient reported improvement within 1 year (follow-up mean 6 months; assessed with: PGI-I improvement in patient numbers)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	81/182 (44.5%)	180/203 (88.7%)	RR 1.99 (1.68 to 2.36)	878 more per 1000 (from 603 more to 1000 more)	⊕⊕⊕⊕ HIGH	CRITICAL
<b>Patient reported improvement at 1-5 years (follow-up mean 18 months; assessed with: PGI-I improvement in patient numbers)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pelvic floor muscle training	Surgery	Relative (95% CI)	Absolute		
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>5</sup>	none	163/178 (91.6%)	119/159 (74.8%)	RR 1.22 (1.11 to 1.35)	165 more per 1000 (from 82 more to 262 more)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Patient satisfaction at &gt;5 years - Subjective improvement (follow-up mean 6.5 years; assessed with: number of women who are satisfied)</b>												
1	randomised trials	serious <sup>2</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	3/20 (15%)	1/10 (10%)	RR 1.5 (0.18 to 12.65)	50 more per 1000 (from 82 fewer to 1000 more)	⊕○○○ VERY LOW	CRITICAL
<b>Adverse events (follow-up mean 18 months; assessed with: bladder perforation)</b>												
1	randomised trials	no serious risk of bias serious	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	0/202 (0%)	6/215 (2.8%)	RR 0.08 (0 to 1.44)	26 fewer per 1000 (from 28 fewer to 12 more)	⊕⊕○○ LOW	IMPORTANT
<b>Long-term complications &gt; 12 months (follow-up mean 13.3 months; assessed with: recurrent UTI or wound infection)</b>												
1	observational studies	serious <sup>6</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	0/47 (0%)	5/51 (9.8%)	RR 0.1 (0 to 1.73).	88 fewer per 1000 (from 97 fewer to 72 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Repeat surgery (follow-up mean 18 months)</b>												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	1/202 (0.5%)	5/215 (2.3%)	RR 0.21 (0.03 to 1.81)	18 fewer per 1000 (from 23 fewer to 19 more)	⊕⊕○○ LOW	IMPORTANT

1 1 RCT had a high risk of bias: unclear blinding of participants/personnel and of the outcome assessment and selective reporting (no published protocol), high risk for incomplete outcome data (6 participants dropped out in MPQ arm; 5 for other treatment and 1 visit out of window) and the study funded by an unrestricted grant of Uroplasty BV, who produce the Macroplastique device.

2 3 RCTs presented over a serious risk of bias: unclear blinding of participants/personnel, randomisation, allocation concealment and selective outcome reporting (no published protocol) and outcome assessment; high risk of bias in incomplete outcome data (6 participants dropped out in MPQ arm; 5 for other treatment and 1 visit out of window) and 1 RCT funded by an unrestricted grant of Uroplasty BV, who produce the Macroplastique device . and selective reporting (no published protocol), high risk for.

3 95% CI crosses two default MIDs for dichotomous outcomes (0.8 and 1.25).

4 1 RCT had an overall high risk of bias: high risk for random sequence generation: unclear risk of allocation concealment, blinding of participants/personnel, blinding of outcome assessment and selective outcome reporting all had no details given.

5 95% CI crosses a default MID for dichotomous outcomes (0.8 or 1.25).

6 1 observational study had an overall high risk of bias: high risk of bias in random sequence generation and allocation concealment (allocation of surgery based on whether the participant had significant pelvic relaxation necessitating vaginal Perea surgery). Unclear risk for blinding of outcome assessment (no details reported).

## **Appendix G – Economic evidence study selection**

### **Economic evidence study selection for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?**

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 effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

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 is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?

Table 29: Economic evidence tables

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost- effectiveness	Comments

<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>

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost- effectiveness	Comments

<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>

<b>Study</b> <b>Country</b> <b>Study type</b>	<b>Intervention</b> <b>details</b>	<b>Study population</b> <b>Study design</b> <b>Data sources</b>	<b>Costs: description and values</b> <b>Outcomes: description and values</b>	<b>Results: Cost-</b> <b>effectiveness</b>	<b>Comments</b>

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost- effectiveness	Comments
Kunkle, C. M., Hallock, J. L., Hu, X., Blomquist, J., Thung, S. F., Werner, E. F., Cost utility analysis of urethral bulking agents versus	Interventions:  Urethral bulking agents (BA) in the office compared with mid-urethral slings (MUS) in the operating room	Adult women with stress urinary incontinence without urethral hypermobility  Economic modelling (decision tree)	Costs: managing complications (transient urinary retention, managing persistent urinary retention/sling take down, thigh pain, mesh erosion, recurrent SUI/repeat sling, dysuria, UTI), de novo urge incontinence, recurrent UTI, sling, BA  Mean cost per participant:	The ICER of MUS (versus BA): \$70,400 per QALY  Sensitivity analyses: The model is most sensitive to: • the cost of MUS placement,	Perspective: health care payer Currency: USD Cost year: 2013 Time horizon: 1 year Discounting: NA Applicability: partially applicable

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost- effectiveness	Comments
midurethral sling in stress urinary incontinence, Female pelvic medicine & reconstructive surgery, 21,154-159, 2015  USA  Cost-utility analysis  Conflict of interest: none. Funding: not reported.		Source of clinical effectiveness data: published literature (RCTs)  Source of resource use data: Medicare reimbursement data  Source of unit costs: national sources	<ul style="list-style-type: none"> <li>MUS resulted in a cost increase of \$4,364.65</li> </ul> Primary outcome measure: QALYs (utility weights based on expert opinion)  Mean QALYs per participant: MUS resulted in 6.2% improvement in QALYs	<ul style="list-style-type: none"> <li>the probability of being dry at 1 year after MUS,</li> <li>the probability of postoperative urinary retention,</li> <li>the probabilities of some long-term complications (SUI, recurrent urinary tract infection, thigh pain, and need for further treatment including rejection of BA).</li> </ul> When MUS costs less than \$5,132, it becomes a cost-effective first-line treatment, and when it costs less than \$2,035, it is cost saving <sup>a</sup>  According to the PSA BA is cost-effective in 47.6% and cost-saving in 51.8% of the replications, and MUS is cost-effective in less	Quality: minor limitations

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
				than 1% of the replications	
Boyers, D., Kilonzo, M., Mostafa, A., Abdel-Fattah, M., Comparison of an adjustable anchored single-incision mini-sling, Ajust®, with a standard mid-urethral sling, TVT-OTM: a health economic evaluation, BJU international, 112, 1169-1177, 2013  UK  Cost-utility analysis  Conflict of interest: two authors had some	Interventions:  Single-incision mini-sling (SIMS) versus standard mid-urethral sling (SMUS)	Adult women with SUI  RCT (Boyers 2013)  Source of clinical effectiveness data: RCT (N=137)  Source of resource use data: RCT (N=127)  Source of unit costs: local and national sources	Costs: surgery (operating time, staff requirements, anaesthesia, consumables), secondary care (hospital readmission, repeat surgery and outpatient care), primary care (GP, physiotherapist and nurse contact), further treatment (medications); productivity losses <sup>b</sup>  Mean cost per participant from healthcare perspective: <ul style="list-style-type: none"> <li>SIMS: £1,277.44 (SD: £462.07)</li> <li>SMUS: £1,461.98 (SD: £419.15)</li> <li>The difference: -£142.41 (95% CI: -£316.99; £32.17)</li> </ul> Primary outcome measure: QALYs (validated algorithm was used to map the King's Health Questionnaire data onto the EQ-5D, UK general population norms)  Mean QALYs per participant: <ul style="list-style-type: none"> <li>SIMS: 0.9775 (SD: 0.0196)</li> <li>SMUS: 0.9804 (SD: 0.0147)</li> </ul> The difference: (SIMS versus SMUS): -0.003 (95% CI: -0.008; 0.002)	The ICER of SIMS (versus SMUS): £48,419 per QALY saved  According to bootstrapping the probability that SIMS is cost effective is 80% at a threshold of £20,000 per QALY saved  The ICER of SIMS (versus SMUS): £54,732 per QALY saved when using imputed costs and QoL values for the missing data points  The ICER of SIMS (versus SMUS): £76,673 per QALY saved when all women in the SIMS group are assumed to receive local anaesthetic	Perspective: NHS; and societal Currency: UK£ Cost year: 2011 Time horizon: 1 year Discounting: NA Applicability: partially applicable Quality: minor limitations  Bootstrapping was undertaken to capture uncertainty with regard to estimates of costs and outcomes.

<sup>b</sup> From societal perspective only

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost-effectiveness	Comments
involvement with the manufacturers (i.e. consultant and travel grants). Funding: Henry Smith Charity.				The ICER of SIMS (versus SMUS): £162,056 per QALY saved from societal perspective	
Lier, D., Robert, M., Tang, S., Ross, S., Surgical treatment of stress urinary incontinence—trans-obturator tape compared with tension-free vaginal tape—5-year follow up: an economic evaluation, Bjog: An International Journal of Obstetrics & Gynaecology, 124, 1431-1439, 2017	Interventions: Transobturator tape (TOT) compared with tension-free vaginal tape (TVT)	Adult women with SUI  RCT (Ross 2016)  Source of clinical effectiveness data: RCT (N=104 complete case analysis for QALY outcome; N=146 for no SAE outcome; N=199 imputed data set)  Source of resource use data: RCT  Source of unit costs: national sources (that is,	Costs: TVT and TOT surgical procedures, inpatient and outpatient care (including A&E visits), clinician visits, prescription medication  Mean cost per woman (using imputed data set): <ul style="list-style-type: none"> <li>TOT: \$13,007</li> <li>TVT: \$16,081</li> <li>The difference: -\$2,368 (95% CI: -\$7,166; \$2,548)</li> </ul> Mean cost per woman (using complete case analysis) for QALY outcome: <ul style="list-style-type: none"> <li>TOT: \$13,513</li> <li>TVT: \$13,436</li> <li>The difference: \$898 (95% CI: -\$2,315; \$4,452).</li> </ul>	TOT dominant using both outcome measures when using imputed data set.  The probability of TOT being cost effective was 79% and above over the entire range of willingness-to-pay (WTP) values per QALY gained and an additional SAE case averted of up to \$100,000  Using complete case analysis the ICER of TOT (versus TVT): \$22,450 per QALY; TOT was dominant using SAE outcome	Perspective: health care payer Currency: CAD Cost year: 2011 Time horizon: 5 years Discounting: 3% for both cost and outcomes Applicability: partially applicable Quality: minor limitations  Incremental health effects were adjusted depending on the outcome used with QALYs adjusted for 15D baseline utility score and menopause status and SAE

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>Canada</p> <p>Cost-effectiveness and cost-utility analysis</p> <p>Conflict of interest: research grants from manufacturer</p> <p>Funding: Alberta Heritage Fund for Medical Research and Bostin Scientific (manufacturer).</p>		<p>physician payment records from Alberta)</p>	<p>Mean cost per woman (using complete case analysis) for SAE outcome:</p> <ul style="list-style-type: none"> <li>TOT: \$14,117</li> <li>TVT: \$15,901</li> <li>The difference: -\$1,247 (95% CI: -\$7,043; \$2,346)</li> </ul> <p>Primary outcome measure: QALYs (15D, Finnish general population norms), and at least on serious adverse event [SAE] defined as the presence of either tape erosion, urine retention requiring intervention, failure requiring repeat surgery for SUI, or debilitating pain.</p> <p>Mean QALYs per woman (imputed dataset):</p> <ul style="list-style-type: none"> <li>TOT: 4.31</li> <li>TVT: 4.23</li> <li>The adjusted difference: 0.04 (95% CI: -0.06; 0.13)</li> </ul> <p>Proportion of women without SAE (imputed dataset):</p> <ul style="list-style-type: none"> <li>TOT: 0.79</li> <li>TVT: 0.73</li> <li>The adjusted difference: 0.03 (95% CI: -0.10; 0.16)</li> </ul>	<p>A sensitivity analysis on the imputed dataset</p> <ul style="list-style-type: none"> <li>woman in TVT group with the most extreme total costs removed (TOT remained dominant);</li> <li>future costs and QALYs not discounted (TOT remained dominant) when compared with TVT)</li> </ul>	<p>outcome adjusted for 15D baseline utility score, age, smoking and menopause status.</p> <p>Bootstrapping was undertaken to capture uncertainty with regard to estimates of costs and outcomes.</p>

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 QALYs per woman (complete case analysis):</p> <ul style="list-style-type: none"> <li>TOT: 4.37</li> <li>TVT: 4.29</li> <li>The adjusted difference: 0.04 (95% CI: -0.05; 0.12)</li> </ul> <p>Proportion of women without SAE (complete case analysis):</p> <ul style="list-style-type: none"> <li>TOT: 0.80</li> <li>TVT: 0.78</li> <li>The adjusted difference: 0.02 (95% CI: -0.10; 0.16)</li> </ul>		
Seklehner S., Laudano, M. A., Te, A. E., Kaplan, S. A., Chughtai, B., Lee, R. K., A cost- effectiveness analysis of retropubic midurethral sling versus transobturator	Interventions: Retropubic midurethral sling (RMUS) versus transobturator midurethral sling (TMUS)	Adult women with pure SUI or predominantly SUI  Economic modelling (Markov chain decision model)  Source of clinical effectiveness data: literature review of	Costs: devices, anaesthesia, physician fees, operating room, hospital stay, absorbent pads and laundry costs, infections management, lower urinary tract symptoms management, treatment of bladder perforation, catheterisation, drainage of hematoma, management of neurological symptoms, sling excision, management of bleeding  Mean expected cost per woman: <ul style="list-style-type: none"> <li>RMUS: \$9,579</li> <li>TMUS: \$9,017</li> </ul>	ICER of RMUS (versus TMS): \$187,333 per QALY gained using both objective and subjective definitions of cure  Sensitivity analyses: TMUS is more cost effective than RMUS as long as the cost of the TMUS device do	Perspective: health care payer Currency: USD Cost year: 2012 Time horizon: 10 years Discounting: 2.26% for both costs and QALYs Applicability: partially applicable Quality: potentially serious limitations

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>midurethral sling for female stress urinary incontinence, Neurourology and urodynamics, 33, 1186-1192, 2014</p> <p>USA</p> <p>Cost-utility analysis</p> <p>Conflict of interest: none. Funding: not reported.</p>		<p>RCTs; and assumptions</p> <p>Source of resource use data: published literature, Medicare reimbursement data</p> <p>Source of unit costs: likely national sources (Medicare); unclear for costs obtained from published literature</p>	<ul style="list-style-type: none"> <li>The difference: \$562</li> </ul> <p>Primary outcome measure: QALYs (From Manca et al; 2003 EQ-5D, UK population norms, Cody et al., EQ-5D UK population norms)</p> <p>Mean QALYs per participant (using objective cure – stress test, pad test):</p> <ul style="list-style-type: none"> <li>RMUS: 6.275</li> <li>TMUS: 6.272</li> <li>The difference: 0.003</li> </ul> <p>Mean QALYs per participant (subjective cure – patients perception of improvement expressed via validated questionnaire or open interview):</p> <ul style="list-style-type: none"> <li>RMUS: 6.264</li> <li>TMUS: 6.261</li> <li>The difference: 0.003</li> </ul>	<p>not exceed \$1,852 (base case: \$1,295).</p> <p>RMUS is cost effective only if the cost of the device is &lt;\$603 (base case: \$1,170).</p> <p>TMUS is cost effective for surgeon fees &lt;\$2,800 (base case: \$2,324).</p> <p>TMUS remains cost effective for efficacy &gt;76.1% (base case 73-83%); RMUS needs to demonstrate efficacy of 94% or greater to be cost effective (base case 87-76%).</p> <p>TMUS surgery could take up to 35.7 min and remain cost effective; RMUS surgery time needs to be reduced to ≤ 14 min</p>	

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>for it to be cost effective.</p> <p>TMUS is cost effective if length of hospital stay is <math>\leq 2.7</math> days; RMUS is cost effective if length of stay is <math>\leq 2.3</math> days.</p> <p>Varying the retreatment rate and the relative utilities of being (in-) continent don't alter the relative cost effectiveness.</p> <p>If the cost of TMUS device is \$1,200 (base case: \$1,295), TMUS is cost effective for TMUS efficacy <math>&gt; 69\%</math> (base case: 83%).</p> <p>If the probability of cure with TMUS and RMUS are 0.8 and 0.6, respectively (base case 0.83 and 0.86), then TMS is cost</p>	

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost- effectiveness	Comments
				effective. However, if cure rates are reversed, then RMUS is cost effective.	
Lo, K., Marcoux, V., Grossman, S., Kung, R., Lee, P., Cost comparison of the laparoscopic burch colposuspension, laparoscopic two-team sling procedure, and the transobturator tape procedure for the treatment of stress urinary incontinence, Journal of Obstetrics and Gynaecology Canada, 35, 252-257, 2013	Interventions:  The transobturator tape (TOT), laparoscopic Burch colposuspension procedure, the laparoscopic two-team sling procedure	Adult women with SUI  Retrospective observational cohort study (n=18)  Source of resource use data: observational study participants (n=18) and associated administrative databases (i.e. patients' medical records)  Source of unit costs: local sources (finance department of the hospital; Ontario Ministry of Health)	Costs: equipment costs, surgeon, surgical assistant, anaesthesiologist, nursing costs, operating and recovery room costs, hospital stay  Mean cost per participant: <ul style="list-style-type: none"> <li>TOT: \$2,547 (95% CI: \$2,260; \$2,833)</li> <li>Laparoscopic Burch colposuspension \$4,354 (95% CI: \$3,465; \$5,244)</li> <li>Laparoscopic two team sling: \$5,393 (95% CI: \$4,959; \$5,826)</li> <li>The difference (TOT versus Burch): - \$1,807.88, p &lt; 0.001</li> <li>The difference (TOT versus sling): - \$2,834.73, p &lt; 0.001</li> </ul> The difference (Burch versus sling): - \$1,039, p < 0.001	TOT procedure is cost saving	Perspective: health care payer Currency: CAD Cost year: 2010 Time horizon: unclear, seems to be immediate postoperative period Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

Study Country Study type	Intervention details	Study population Study design Data sources	Costs: description and values Outcomes: description and values	Results: Cost- effectiveness	Comments
Canada  Cost analysis  Conflict of interest: none. Funding: not reported.					
Laudano and colleagues (2013)  USA  Cost-utility analysis  Conflict of interest: none. Funding: not reported.	Interventions:  Tension free vaginal tape (TVT) versus Burch colposuspension (BC)	Adult women with SUI  Economic modelling (Markov model)  Source of clinical effectiveness data: review of RCTs  Source of resource use data: published sources and assumptions  Source of unit cost data: Medicare reimbursement data	Costs: procedures, devices, cystoscopy, operating room, hospital stay, physician visits, treatment of UTI, and mesh revision surgery  Mean expected cost per woman: <ul style="list-style-type: none"> <li>• TVT: \$8,651</li> <li>• BC: \$10,545</li> <li>• The difference: -\$1,894</li> </ul> Primary outcome measure: QALYs (from RCT by Manca et al., 2003; EQ-5D-3L, UK general population norms)  Mean expected QALYs per woman: <ul style="list-style-type: none"> <li>• TVT: 5.79</li> <li>• BC: 5.78</li> </ul> The difference: 0.01	TVT is dominant  Sensitivity analyses: TVT remains cost effective as long as the cost of TVT device is <\$3,220 (base case: \$1,170)  BC becomes cost-effective when TVT efficacy is <42% (base case: 77%)  Regardless of the utility gain TVT remains cost effective  If the cost of TVT device is \$2,000 (base	Perspective: health care payer Currency: USD Cost year: likely 2012 Time horizon: 10 years Discounting: 4.54% Applicability: partially applicable Quality: minor limitations

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>case: \$1,170), TVT is more cost effective for TVT efficacy &gt;59% (base case: 77%)</p> <p>If the probability of cure with BC and TVT are 70% and 40%, respectively (base case 68% and 77%, respectively), then BC is more cost-effective. If the cure rates are reversed then TVT is cost effective.</p> <p>The probability that vaginal tape and Burch colposuspension is cost effective at any WTP value above \$20,000/QALY is 90% 10%, respectively</p>	

## Economic evidence tables for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?

**Table 30: 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., Sokol, E. R., A cost-effectiveness analysis of conservative versus surgical management for the initial treatment of stress urinary incontinence. American Journal of Obstetrics & Gynecology, 211, 565-e1, . 2014  USA  Cost-utility analysis	Interventions: Surgery (MUS) vs. conservative management. Conservative management options included pessary and pelvic floor muscle training (PFMT).	Adult women with uncomplicated de-novo SUI  Economic modelling (decision tree model)  Source of clinical effectiveness data: review of RCTs  Source of resource use data: published sources and authors' assumptions  Source of unit costs: national sources (Medicare reimbursement and physician fee schedules)	Costs: intervention costs including pessary, PFMT, MUS; and the management of complications including sling release, sling removal for mesh exposure, and anticholinergic medication.  Mean cost per participant: not reported  Primary outcome measure: QALYs  Mean QALYs per participant: not reported	ICER of surgery (vs. PFMT): \$32,132 per QALY  Sensitivity analyses: If subjective cure of SUI with PFMT was >44% (base case 0.329) then it would be the preferred scenario over MUS.  The cost for initial SUI treatment with MUS would need to be \$5,300 (base case \$3,938) for the ICER to be above \$50,000. Varying the QALYs did not change the findings. Similarly, varying the complications associated with MUS by 50% did not impact the conclusions.	Perspective: healthcare Currency: USD Cost year: likely 2013 Time horizon: 1 year Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

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>Conflict of interest: one of the authors owns stocks in Pelvilon.</p> <p>Funding: not reported.</p>					

## Appendix I – Economic evidence profiles

**Economic evidence profiles for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?**

**Table 31: Economic evidence profile for retropubic midurethral mesh sling, anterior vaginal repair, bladder neck needle suspensions, open abdominal retropubic colposuspension, laparoscopic retropubic colposuspension, traditional sub-urethral retropubic sling, transobturator midurethral mesh sling, single incision sling, and peri-urethral bulking agents injections**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty

1. Well conducted study with some of the resource use based on expert opinion

2. UK study, QALYs

**Table 32: Economic evidence profile for urethral bulking agents versus midurethral mesh sling**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Kunkle 2015  USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost utility analysis	\$4,364.65	6.2%	\$70,400/QALY	BA is cost-effective in 47.6% and cost-saving in 51.8% of the replications, and MUS is cost-effective in less than 1% of the replications.

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
			<p>Comparison: urethral bulking agents versus mid-urethral sling (MUS)</p> <p>Primary measure of outcome: QALYs</p>				<p>The model is sensitive to the cost of MUS placement; the probability of being dry at 1 year after MUS, the probability of postoperative urinary retention, the probabilities of some long-term complications (SUI, recurrent urinary tract infection, thigh pain, and need for further treatment including rejection of BA).</p> <p>When MUS costs less than \$5,132, it becomes a cost-effective first-line treatment, and when it costs less than \$2,035, it is cost saving</p>

1. Short time horizon

2. USA study, QALYs but with utility weights based on expert opinion

**Table 33: Economic evidence profile for single-incision mini-sling versus standard midurethral mesh sling**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Boyers 2013	Minor limitations <sup>1</sup>	Directly applicable <sup>2</sup>	Type of economic analysis: cost-utility analysis	-£142.41	-0.003	£48,419 /QALY	The difference in costs not significant (95% CI: -£316.99; £32.17).
UK			Comparison: single-incision mini-sling (SIMS)				

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
			<p>versus standard mid-urethral sling (SMUS)</p> <p>Primary measure of outcome: QALYs</p>				<p>The difference in QALYs not significant (95% CI: -0.008; 0.002).</p> <p>The probability that SIMS is cost effective is 80% at a threshold of £20,000 per QALY saved.</p> <p>The ICER of SIMS (versus SMUS): £54,732 per QALY saved when using imputed costs and QoL values for the missing data points</p> <p>The ICER of SIMS (versus SMUS): £76,673 per QALY saved when all women in the SIMS group are assumed to receive local anaesthetic</p> <p>The ICER of SIMS (versus SMUS): £162,056 per QALY saved from societal perspective</p>

1. Short time horizon, local unit cost for mesh kit

2. UK study, QALYs (King's Health Questionnaire data mapped onto EQ-5D)

**Table 34: Economic evidence profile for transobturator outside-in tape compared with retropubic bottom-up tension-free vaginal tape**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Lier 2017 Canada	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-effectiveness and cost utility analysis  Comparison: TOT versus TVT  Primary measure of outcome: QALYs and proportion with serious adverse event (SAE). SAE was defined as either tape erosion, urine retention requiring intervention, failure requiring repeat surgery for SUI, or debilitating pain	-\$2,368 (using imputed data set)	0.04 QALYs (using imputed data set)  0.03 proportion without SAE using imputed dataset	TOT dominant using complete case data set using QALYs and SAE outcomes	Using imputed data set the cost and outcome differences were not significant: Costs - 95% CI: -\$7,166; \$2,548) QALYs - 95% CI: -0.06; 0.13 SAE - 95% CI: -0.10; 0.16  The probability of TOT being cost effective 79% at any willingness-to-pay up to \$100,000
				\$898 (using complete case analysis for QALY outcome)	0.04 QALYs using complete case analysis	\$22,450/QALY	Using complete case analysis for QALY outcome the cost difference was not significant (95% CI: -\$2,315; \$4,452)
				-\$1,247 (using complete case analysis)	0.02 SAE using complete case analysis	TOT dominant	Using complete case analysis for SAE outcome the cost difference was not significant (95% CI: -\$7,043; \$2,346)

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
				case analysis for SAE outcome)	case analysis		Using imputed data set and removing a woman in TVT group with the most extreme total costs: TOT dominant; Using undiscounted future costs and QALYs: TOT dominant

1. Well conducted study

2. Canadian study, QALYs based on 15D (Finnish general population norms)

**Table 35: Economic evidence profile for retropubic midurethral mesh sling versus transobturator midurethral mesh slin**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Seklehner 2014  USA	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-utility analysis  Comparison: RMUS versus TMUS  Primary measure of outcome: QALYs	\$562	0.003 (QALYs using objective cure)  0.003 (QALYs using subjective cure)	\$187,333 /QALY	TMUS is more cost effective than RMUS as long as the cost of the TMUS device do not exceed \$1,852 (base case: \$1,295).  RMUS is cost effective only if the cost of the device is <\$603 (base case: \$1,170).  TMUS is cost effective for surgeon fees <\$2,800 (base case: \$2,324).  TMUS remains cost effective for efficacy >76.1% (base case 73-83%); RMUS needs to demonstrate efficacy of 94% or greater to be cost effective (base case 87-76%).  TMUS surgery could take up to 35.7 min and remain cost effective; RMUS surgery time

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
							<p>needs to be reduced to <math>\leq 14</math> min for it to be cost effective.</p> <p>TMUS is cost effective if length of hospital stay is <math>\leq 2.7</math> days; RMUS is cost effective if length of stay is <math>\leq 2.3</math> days.</p> <p>Varying the retreatment rate and the relative utilities of being (in-) continent don't alter the relative cost effectiveness.</p> <p>If the cost of TMUS device is \$1,200 (base case: \$1,295), TMUS is cost effective for TMUS efficacy <math>&gt; 69\%</math> (base case: 83%).</p> <p>If the probability of cure with TMUS and RMUS are 0.8 and 0.6, respectively (base case 0.83 and 0.86), then TMS is cost effective. However, if cure rates are reversed, then RMUS is cost effective.</p>

1. Some model inputs are based on authors' assumptions, unclear if national unit costs used

2. USA study, QALYS (EQ-5D, UK population norms)

**Table 36: Economic evidence profile for transobturator outside-in tape, laparoscopic Burch colposuspension procedure, and the laparoscopic two-team sling procedure**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Lo 2013 Canada	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost analysis  Comparison: TOT), laparoscopic Burch colposuspension procedure, the laparoscopic two-team sling procedure	-\$1,807.88 (TOT versus Burch)  -\$2,834.73 (TOT versus sling)  -\$1,039 (Burch versus sling)	NA	NA (TOT is cost saving)	All differences were statistically significant (p < 0.001)

1. Unclear time horizon, but seems to be immediate postoperative; hasn't considered costs associated with complication management; some local unit costs

2. Canadian study

**Table 37: Economic evidence profile for transobturator outside-in tape versus laparoscopic Burch colposuspension**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER	Uncertainty
Laudano 2013  USA	Minor limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-utility analysis  Comparison: TOT versus laparoscopic BC procedure	-\$1,894	0.01	TVT dominant	TVT remains cost effective as long as the cost of TVT device is <\$3,220 (base case: \$1,170)  BC becomes cost effective when TVT efficacy is <42% (base case: 77%)  Regardless of the utility gain TVT remains cost effective  If the cost of TVT device is \$2,000 (base case: \$1,170), TVT is more cost effective for TVT efficacy >59% (base case: 77%)  If the probability of cure with BC and TVT are 70% and 40%, respectively (base case 68% and 77%, respectively), then BC is more cost-effective. If the cure rates are reversed then TVT is cost effective.  The probability that vaginal tape and Burch colposuspension is cost effective at any WTP value above \$20,000/QALY is 90% 10%, respectively

1. Well conducted study with unclear source of resource use data

2. USA study, QALYs (EQ-5D, UK population norms)

**Economic evidence profiles for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures) compared to pelvic floor muscle training?**

**Table 38: Economic evidence profile for surgery versus PFMT for stress urinary incontinence**

Study and country	Limitations	Applicability	Other comments	Incremental costs	Incremental effects	ICER (cost per QALY)	Uncertainty
Richardson 2014  USA	Potentially serious limitations <sup>1</sup>	Partially applicable <sup>2</sup>	Type of economic analysis: cost-utility  Time horizon: 1 year  Primary measure of outcome: QALYs	NR	NR	\$32,132	If subjective cure of SUI with PFMT was >44% (base case 0.329) then it would be the preferred scenario over MUS. The cost for initial SUI treatment with MUS would need to be \$5,300 (base case \$3,938) for the ICER to be above \$50,000 per QALY. Varying the QALYs did not change the findings. Varying complications associated with MUS treatment by 50% did not impact the conclusions.

1. Short time horizon; has not reported absolute costs and outcomes  
2. USA study

## **Appendix J – Economic analysis**

**Economic analysis for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?**

No economic analysis was conducted for this review question.

**Economic analysis for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

No economic analysis was conducted for this review question.

## Appendix K – Excluded studies

### Excluded studies for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?

**Table 39: Clinical studies with reasons for exclusion**

Study	Reason for Exclusion
Abdel-Fattah, M., Cao, G., Mostafa, A., Long-term outcomes of transobturator tension-free vaginal tapes as secondary continence procedures, <i>World journal of urology</i> , 35, 1141-1148, 2017	No relevant comparison
Abdel-Fattah, M., Ford, J. A., Lim, C. P., Madhuvrata, P., Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: A meta-analysis of effectiveness and complications, <i>European urology</i> , 60, 468-480, 2011	No additional randomised controlled trials identified
Abdel-Fattah, M., Ramsay, I., Pringle, S., Hardwick, C., Ali, H., Young, D., Mostafa, A., Evaluation of transobturator tension-free vaginal tapes in management of women with recurrent stress urinary incontinence, <i>Urology</i> , , 1070-1075, 2011	No relevant comparison
Aberger, M., Gomelsky, A., Padmanabhan, P., Comparison of retropubic synthetic mid-urethral slings to fascia pubovaginal slings following failed sling surgery, <i>Neurourology and Urodynamics</i> , 35, 851-854, 2016	Not randomised controlled trial
Abou Hashem, S., Mohamed Mostafa, M., Elbrombely, W., Five-years follow-up of tension-free vaginal tape (TVT) versus rectus sheath sling for surgical treatment of female stress urinary incontinence: A comparative study, <i>European Urology, Supplements</i> , 16 (3), e1503, 2017	Conference abstract
Agur, W., Riad, M., Secco, S., Litman, H., Madhuvrata, P., Novara, G., Abdel-Fattah, M., Surgical treatment of recurrent stress urinary incontinence in women: a systematic review and meta-analysis of randomised controlled trials, <i>European Urology</i> , 64, 323-36, 2013	No additional randomised controlled trials identified
Ahn, C., Bae, J., Lee, K. S., Lee, H. W., Analysis of voiding dysfunction after transobturator tape procedure for stress urinary incontinence, <i>Korean Journal of Urology</i> , 56, 823-30, 2015	Not randomised controlled trial
Ala-Nissila, S., Haarala, M., Makinen, J., Tension-free vaginal tape - a suitable procedure for patients with recurrent stress urinary incontinence, <i>Acta obstetrica ET gynecologica scandinavica</i> , 89, 210-6, 2010	Not randomised controlled trial
Allahdin, S., McKinley, C. A., Mahmood, T. A., Tension free vaginal tape: A procedure for all ages, <i>Acta Obstetrica et Gynecologica Scandinavica</i> , 83, 937-940, 2004	Not randomised controlled trial
Alwaal, A., Tian, X., Huang, Y., Zhao, L., Ma, L., Lin, G., Deng, D., Female sexual function following mid-urethral slings for the treatment of stress urinary incontinence, <i>International Journal of Impotence Research</i> , 28, 121-6, 2016	No additional randomised controlled trials identified

Study	Reason for Exclusion
Amat i Tardiu, L., Franco, E. M., Vicens, J. M. L., Contasure-Needleless compared with transobturator-TVT for the treatment of stress urinary incontinence, <i>International Urogynecology Journal</i> , 22, 827-833, 2011	Not randomised controlled trial
Amaye-Obu, F. A., Drutz, H. P., Surgical management of recurrent stress urinary incontinence: A 12-year experience, <i>American Journal of Obstetrics &amp; Gynecology</i> Am J Obstet Gynecol, 181, 1296-307; discussion 1307-9, 1999	Not randomised controlled trial
Anderson, B. B., Pariser, J. J., Pearce, S. M., Volsky, J. G., Bales, G. T., Chung, D. E., Safety and Efficacy of Retropubic Mid-urethral Sling Placement in Women Who Void With Valsalva, <i>Urology</i> , 91, 52-7, 2016	Not randomised controlled trial
Andonian,S., Chen,T., St-Denis,B., Corcos,J., Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results, <i>European Urology</i> , 47, 537-541, 2005	No relevant comparison (compares 2 types of retropubic tape)
Anger,J.T., Litwin,M.S., Wang,Q., Pashos,C.L., Rodriguez,L.V., The effect of age on outcomes of sling surgery for urinary incontinence, <i>Journal of the American Geriatrics Society</i> , 55, 1927-1931, 2007	Not randomised controlled trial
Anger,J.T., Weinberg,A.E., Gore,J.L., Wang,Q., Pashos,C.L., Leonardi,M.J., Rodriguez,L.V., Litwin,M.S., Thromboembolic complications of sling surgery for stress urinary incontinence among female Medicare beneficiaries, <i>Urology</i> , 74, 1223-1226, 2009	Not randomised controlled trial
Ankardal, M., Ekerydh, A., Crafoord, K., Milsom, I., Stjernedahl, J. H., Engh, M. E., A randomised trial comparing open Burch colposuspension using sutures with laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence, 111, 974-81, 2004	Laparoscopic colposuspension with mesh and staples is not standardly used in the UK
Ascher-Walsh, C. J., Capes, T. L., Lo, Y., Idrissa, A., Wilkinson, J., Echols, K., Crawford, B., Genadry, R., Sling procedures after repair of obstetric vesicovaginal fistula in Niamey, Niger, <i>International urogynecology journal</i> , 21, 1385-1390, 2010	Not randomised controlled trial
Ashok, K., Petri, E., Failures and complications in pelvic floor surgery, <i>World Journal of Urology</i> , 30, 487-94, 2012	No additional randomised controlled trials identified
Ashok,K., Wang,A., Recurrent urinary stress incontinence: an overview, <i>Journal of Obstetrics and Gynaecology Research</i> , 36, 467-473, 2010	No additional randomised controlled trials identified
Asicioglu, O., Gungorduk, K., Besimoglu, B., Ertas, I. E., Yildirim, G., Celebi, I., Ark, C., Boran, B., A 5-year follow-up study comparing Burch colposuspension and transobturator tape for the surgical treatment of stress urinary incontinence, <i>International Journal of Gynaecology &amp; Obstetrics</i> , 125, 73-7, 2014	Not randomised controlled trial
Athanasίου, S., Grigoriadis, T., Giannoulis, G., Protopapas, A., Antsaklis, A., Midurethral slings for women with urodynamic mixed incontinence: what to expect?, <i>International Urogynecology Journal</i> , 24, 393-9, 2013	Not randomised controlled trial

Study	Reason for Exclusion
Atherton,M.J., Stanton,S.L., The tension-free vaginal tape reviewed: An evidence-based review from inception to current status, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 534-546, 2005	No additional randomised controlled trials identified
Aydin, S., ArioGlu Aydin, C., Ersan, F., Prediction of Mid-Urethral Sling Failure with Clinical Findings and Urodynamics, LUTS: Lower Urinary Tract Symptoms, 9, 89-93, 2017	Not randomised controlled trial
Bach, F., Toozs-Hobson, P., What can we learn from large data sets? An analysis of 19,000 retropubic tapes, International Urogynecology Journal, 28, 629-636, 2017	Not randomised controlled trial
Bafghi,A., Benizri,E.I., Trastour,C., Benizri,E.J., Michiels,J.F., Bongain,A., Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 376-378, 2005	Not randomised controlled trial
Bafghi,A., Valerio,L., Benizri,E.I., Trastour,C., Benizri,E.J., Bongain,A., Comparison between monofilament and multifilament polypropylene tapes in urinary incontinence, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 122, 232-236, 2005	Not randomised controlled trial
Bai, F., Chen, J., Zhang, Z., Zheng, Y., Wen, J., Mao, X., Zhang, N., Adjustable single-incision mini-slings (Ajust) versus other slings in surgical management of female stress urinary incontinence: A meta-analysis of effectiveness and complications, BMC Urology, 18 (1) (no pagination), 2018	Added Bai et al. 2016; no other additional RCTs identified
Bai, S. W., Kim, B. J., Kim, S. K., Park, K. H., Comparison of outcomes between Burch colposuspension with and without concomitant abdominal hysterectomy, Yonsei Medical Journal, 45, 2004	Not randomised controlled trial
Bai,S.W., Jung,Y.H., Jeon,M.J., Jung,D.J., Kim,S.K., Kim,J.W., Treatment outcome of tension-free vaginal tape in stress urinary incontinence: Comparison of intrinsic sphincter deficiency and nonintrinsic sphincter deficiency patients, International urogynecology journal and pelvic floor dysfunction, 18, 1431-1434, 2007	Not randomised controlled trial
Bakali, Evangelia, Buckley, Brian S, Hilton, Paul, Tincello, Douglas G, Treatment of recurrent stress urinary incontinence after failed minimally invasive synthetic suburethral tape surgery in women, Cochrane Database of Systematic Reviews, 2013	No randomised controlled trials identified
Balachandran, A., Duckett, J., Does the diagnosis of detrusor overactivity affect the long-term prognosis of patients treated with a retropubic midurethral sling?, International Urogynecology Journal, 10, 10, 2016	Not randomised controlled trial
Balakrishnan,S., Lim,Y.N., Barry,C., Corstiaans,A., Kannan,K., Rane,A., Sling distress: a subanalysis of the IVS tapes from the SUSPEND trial, Australian and New Zealand Journal of Obstetrics and Gynaecology, 47, 496-498, 2007	No relevant comparison

Study	Reason for Exclusion
Bano,F., Barrington,J.W., Dyer,R., Comparison between porcine dermal implant (Permacol) and silicone injection (Macropastique) for urodynamic stress incontinence, International urogynecology journal and pelvic floor dysfunction, 16, 147-150, 2005	No relevant comparison
Barbalias, G., Liatsikos, E., Barbalias, D., Use of slings made of indigenous and allogenic material (Goretex) in type III urinary incontinence and comparison between them, European Urology, 31, 394-400, 1997	No relevant comparison
Barber,M.D., Kleeman,S., Karram,M.M., Paraiso,M.F., Ellerkmann,M., Vasavada,S., Walters,M.D., Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings, American Journal of Obstetrics and Gynecology, 199, 666-667, 2008	Regression analysis of Barber et al. 2008/No relevant data
Barboglio, P. G., Ann Gormley, E., The fate of synthetic mid-urethral slings in 2013: A turning point, Arab Journal of Urology Print, 11, 117-26, 2013	No extractable data form review
Barr, S., Reid, F. M., North, C. E., Hosker, G., Smith, A. R., The long-term outcome of laparoscopic colposuspension: a 10-year cohort study, International Urogynecology Journal, 20, 443-5, 2009	Not randomised controlled trial
Barski, D., Deng, D. Y., Management of Mesh Complications after SUI and POP Repair: Review and Analysis of the Current Literature, BioMed Research International, 2015, 831285, 2015	Not randomised controlled trial
Basok,E.K., Yildirim,A., Atsu,N., Gurbuz,C., Tokuc,R., The surgical results of the pubovaginal sling procedure using Intravaginal Slingplasty (IVS) for stress urinary incontinence, International Urology and Nephrology, 38, 507-512, 2006	Not randomised controlled trial
Ben-Zvi, T., Moore, K., Haidar, N., Gregoire, M., An in-house ComposixTM-based pubovaginal sling trial for female stress urinary incontinence: Five-year comparative followup to tension-free and transobturator vaginal tapes, Canadian urological association journal, 11, 275-280, 2017	Not randomised controlled trial
Bergman, A., Ballard, C. A., Koonings, P. P., Comparison of three different surgical procedures for genuine stress incontinence: Prospective randomized study, American journal of obstetrics and gynecology, 160, 1102-1106, 1989	No relevant comparison
Bergman, A., Koonings, P. P., Ballard, C. A., Primary stress urinary incontinence and pelvic relaxation: prospective randomized comparison of three different operations, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 161, 97-101, 1989	No relevant comparison
Bicudo-Furst, M. C., Borba Leite, P. H., Araujo Glina, F. P., Baccaglini, W., de Carvalho Furst, R. V., Bezerra, C. A., Glina, S., Female Sexual Function Following Surgical Treatment of Stress Urinary Incontinence: Systematic Review and Meta-Analysis, Sexual Medicine Reviews, 6, 224-233, 2018	No additional RCTs identified
Birch, C., Fynes, M. M., The role of synthetic and biological prostheses in reconstructive pelvic floor	General non-systematic narrative review

Study	Reason for Exclusion
surgery, Current Opinion in Obstetrics & Gynecology, 14, 527-35, 2002	
Black, N. A., Downs, S. H., The effectiveness of surgery for stress incontinence in women: A systematic review, British journal of urology, 78, 497-510, 1996	No additional randomised controlled trials identified
Boyers, D., Kilonzo, M., Mostafa, A., Abdel-Fattah, M., Comparison of an adjustable anchored single-incision mini-sling, Ajust(), with a standard mid-urethral sling, TVT-O(TM) : a health economic evaluation, BJU International, 112, 1169-77, 2013	All relevant data already reported in Mostafa et al. 2012
Brito, L. G., Rodrigues, H. L., Carvalho, M. A., Magnani, P. S., Lopes, A. H., Sabino-de-Freitas, M. M., Comparison of the efficacy and safety of surgical procedures utilizing autologous fascial and transobturator slings in patients with stress urinary incontinence, Journal of Reproductive Medicine, 58, 19-24, 2013	Not randomised controlled trial
Brubaker, L., Chiang, S., Zyczynski, H., Norton, P., Kalinoski, D. L., Stoddard, A., Kusek, J. W., Steers, W., The impact of stress incontinence surgery on female sexual function, American journal of obstetrics and gynecology, 200, 562.e1-562.e7, 2009	Data not reported by treatment group
Bulent Tiras, M., Sendag, F., Dilek, U., Guner, H., Laparoscopic burch colposuspension: comparison of effectiveness of extraperitoneal and transperitoneal techniques, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 116, 79-84, 2004	Not randomised controlled trial
Cameron,A.P., Haraway,A.M., The treatment of female stress urinary incontinence: An evidenced-based review, Open Access Journal of Urology, 3, 109-120, 2011	No additional randomised controlled trials identified
Canel, V., Thubert, T., Wigniolle, I., Fernandez, H., Deffieux, X., Postoperative groin pain and success rates following transobturator midurethral sling placement: TVT ABBREVO system versus TVTTM obturator system, International Urogynecology Journal, 26, 1509-16, 2015	Not randomised controlled trial
Castillo-Pino,E., Sasson,A., Pons,J.E., Comparison of retropubic and transobturator tension-free vaginal implants for the treatment of stress urinary incontinence, International Journal of Gynaecology and Obstetrics, 110, 23-26, 2010	Not randomised controlled trial
Castroviejo-Royo, F., Martinez-Sagarra-Oceja, J. M., Marina-Garcia-Tunon, C., Conde-Redondo, C., Rodriguez-Toves, L. A., Gonzalez-Tejero, C., Treatment of female stress urinary incontinence using suburethral slings: comparative, retrospective, observational study of two surgical techniques, Actas Urologicas Espanolas, 37, 549-53, 2013	Not randomised controlled trial
Chae,H.D., Kim,S.R., Jeon,G.H., Kim,D.Y., Kim,S.H., Kim,J.H., Kim,C.H., Kim,Y.M., Kim,Y.T., Kang,B.M., Nam,J.H., A comparative study of outside-in and inside-out transobturator tape procedures for stress urinary	Not randomised controlled trial

Study	Reason for Exclusion
incontinence, Gynecologic and Obstetric Investigation, 70, 200-205, 2010	
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	Data not reported by treatment group/no relevant data
Chang, A., Kobashi, K. C., Stress Urinary Incontinence in the Elderly: Evaluation, Surgical Treatment, and Management of Postoperative Voiding Dysfunction, Current Bladder Dysfunction Reports, 9, 379-388, 2014	Non-systematic narrative review
Chang, C. P., Chang, W. H., Hsu, Y. M., Chen, Y. J., Wen, K. C., Chao, K. C., Yen, M. S., Horng, H. C., Wang, P. H., Task Force on Gyn-Urodynamic Research, Group, Comparison of single-incision mini-slings (Ajust) and standard transobturator midurethral slings (Align) in the management of female stress urinary incontinence: A 1-year follow-up, Taiwanese Journal of Obstetrics & Gynecology, 54, 726-30, 2015	Not randomised controlled trial
Chen, Z., Chen, Y., Du, G. H., Yuan, X. Y., Wu, J., Zeng, X. Y., Hu, Z. Q., Cai, D., Yang, W. M., Ye., Comparison of three kinds of mid-urethral slings for surgical treatment of female stress urinary incontinence, Urologia, 77, 37-41; discussion 42, 2010	Article not available
Cheung, R. Y., Chan, S. S., Yiu, K. W., Chung, T. K., Inside-out versus outside-in transobturator tension-free vaginal tape: a 5-year prospective comparative study, International Journal of Urology, 21, 74-80, 2014	Not randomised controlled trial
Chien, G. W., Tawadroas, M., Kaptein, J. S., Mourad, M. S., Tebyani, N., Aboseif, S. R., Surgical treatment for stress urinary incontinence with urethral hypermobility: what is the best approach?, World journal of urology, 20, 234-9, 2002	Not randomised controlled trial
Choe,J.M., Ogan,K., Battino,B.S., Antimicrobial mesh versus vaginal wall sling: A comparative outcomes analysis, Journal of Urology, 163, 1829-1834, 2000	No relevant comparison (compares synthetic sling with vaginal wall sling)
Choi, Ys, Park, Sy, Yum, Sh, Kim, Jb, Song, Sh, Doo, Ck, A Prospective Trial Comparing Tension-Free Vaginal Tape and Transobturator Vaginal Tape Inside-Out for the Surgical Treatment of Female Stress Urinary Incontinence: One-Year Follow up, Journal of the Korean Continence Society, 9, 108-14, 2005	Full text not in English
Cholhan,H.J., Lotze,P.M., Voiding function after a modified no-tension pubovaginal sling, International Urogynecology Journal, 15, 249-256, 2004	No relevant comparison
Cholhan,H.J., Lotze,P.M., Urodynamic changes after tension-free sling procedures: Mycromesh-Plus vs TVT sling, International Urogynecology Journal, 19, 217-225, 2008	Not randomised controlled trial
Chun, J. Y., Song, M., Yoo, D. S., Han, J. Y., Hong, B., Choo, M. S., A Comparative Study of Outside-In and Inside-Out Transobturator Tape Procedures for Female	Not randomised controlled trial

Study	Reason for Exclusion
Stress Urinary Incontinence: 7-Year Outcomes, Luts, 6, 145-50, 2014	
Chung, J. W., Yoo, E. S., Efficacy and safety of a readjustable midurethral sling (Remeex system) for stress urinary incontinence with female voiding dysfunction, Investigative and Clinical Urology, 58, 127-133, 2017	Not randomised controlled trial
Ciftci, S., Ozkurkcugil, C., Ustuner, M., Yilmaz, H., Yavuz, U., Gulecen, T., Comparison of transobturator tape surgery using commercial and hand made slings in women with stress urinary incontinence, Urology Journal, 12, 2090-4, 2015	Not randomised controlled trial
Cody, J., Wyness, L., Wallace, S., Glazener, C., Kilonzo, M., Stearns, S., McCormack, K., Vale, L., Grant, A., Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence, Health Technology Assessment (Winchester, England)Health Technol Assess, 7, iii, 1-189, 2003	No additional randomised controlled trials identified
Coroleuca, C., Ionescu, C. A., Dimitriu, M., Popescu, I., Coroleuca, C. A., Serbanescu, L., Sexual function and vaginal surgery, Gineco.eu, 13, 5-8, 2017	Selective literature review
Costantini, E., Lazzeri, M., Zucchi, A., Di Biase, M., Porena, M., Long-term efficacy of the transobturator and retropubic midurethral slings for stress urinary incontinence: single-center update from a randomized controlled trial, European Urology, 66, 599-601, 2014	Letter/data reported more recently in Costantini et al. 2016
Dainer, M., Hall, C.D., Choe, J., Bhatia, N.N., The Burch procedure: A comprehensive review, Obstetrical and Gynecological Survey, 54, 49-60, 1999	No relevant RCTs
Daneshgari, F., Kong, W., Swartz, M., Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials, Journal of Urology, 180, 1890-1897, 2008	No additional randomised controlled trials identified
Darai, E., Jeffry, L., Deval, B., Birsan, A., Kadoch, O., Soriano, D., Results of tension-free vaginal tape in patients with or without vaginal hysterectomy, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 103, 163-7, 2002	Not randomised controlled trial
Davis, N. F., Kheradmand, F., Creagh, T., Injectable biomaterials for the treatment of stress urinary incontinence: Their potential and pitfalls as urethral bulking agents, International Urogynecology Journal, 24, 913-919, 2013	No additional randomised controlled trials identified
De Leval, J., Thomas, A., Waltregny, D., The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial, International urogynecology journal, 22, 145-156, 2011	No relevant comparison (compares 2 types of TVT-O, original and 12cm version)
De Ridder, D., Berkers, J., Deprest, J., Verguts, J., Ost, D., Hamid, D., Van der Aa, F., Single incision mini-sling versus a transobutator sling: a comparative study on MiniArc and Monarc slings, International Urogynecology Journal, 21, 773-8, 2010	Not randomised controlled trial

Study	Reason for Exclusion
De Souza, A., Dwyer, P. L., Rosamilia, A., Hiscock, R., Lim, Y. N., Murray, C., Thomas, E., Conway, C., Schierlitz, L., Sexual function following retropubic TVT and transobturator Monarc sling in women with intrinsic sphincter deficiency: a multicentre prospective study, <i>International Urogynecology Journal</i> , 23, 153-8, 2012	Prospective observational study on sexually active participants (n=87) in Schierlitz et al. 2008
de Vries, A. M., Wadhwa, H., Huang, J., Farag, F., Heesakkers, Jpfa, Kocjancic, E., Complications of Urethral Bulking Agents for Stress Urinary Incontinence: An Extensive Review Including Case Reports, <i>Female Pelvic Medicine &amp; Reconstructive Surgery</i> Female pelvic med, 26, 26, 2017	No additional RCTs identified
Dean, Nicola, Ellis, Gaye, Herbison, G Peter, Wilson, Don, Mashayekhi, Atefeh, Laparoscopic colposuspension for urinary incontinence in women, <i>Cochrane Database of Systematic Reviews</i> , 2017	No additional relevant articles
Dean, N., Herbison, P., Ellis, G., Wilson, D., Laparoscopic colposuspension and tension-free vaginal tape: A systematic review, <i>BJOG: An International Journal of Obstetrics and Gynaecology</i> , 113, 1345-1353, 2006	No additional randomised controlled trials identified/Updated by systematic review by Dean et al. 2017
Debodinance, P., Delporte, P., Engrand, J. Bernard, Boulogne, M., Tension-free vaginal tape (TVT) in the treatment of urinary stress incontinence: 3 Years experience involving 256 operations, <i>European Journal of Obstetrics Gynecology and Reproductive Biology</i> , 105, 49-58, 2002	Not randomised controlled trial
Debodinance, P., Trans-obturator urethral sling for the surgical correction of female stress urinary incontinence: Outside-in (Monarc <sup>&lt;sup&gt;&lt;/sup&gt;</sup> ) versus inside-out (TVT-O <sup>&lt;sup&gt;&lt;/sup&gt;</sup> ). Are the two ways reassuring?, <i>European Journal of Obstetrics Gynecology and Reproductive Biology</i> , 133, 232-238, 2007	Not randomised controlled trial
del Canto, M., Bielsa, O., Lorente, J. A., Castillo, M., Carreras, R., Arango, O., The use of tension-free vaginal tape associated with pelvic floor reconstructive surgery, <i>Actas Urológicas Españolas/Actas Urol Esp</i> , 33, 1097-102, 2009	Not randomised controlled trial
DeTayrac, R., Deffieux, X., Droupy, S., Chauveaud-Lambling, A., Calvanese-Benamour, L., Fernandez, H., A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence (Retraction in: <i>American Journal of Obstetrics and Gynecology</i> (2005) 192:2 (339)), <i>American Journal of Obstetrics and Gynecology</i> , 190, 602-608, 2004	Article retracted from publication
Deval, B., Levardon, M., Samain, E., Rafii, A., Cortesse, A., Amarenco, G., Ciofu, C., Haab, F., A French multicenter clinical trial of SPARC for stress urinary incontinence, <i>European urology</i> , 44, 254-8; discussion 258-9, 2003	Not randomised controlled trial
Dietz, H.P., Wilson, P.D., Laparoscopic colposuspension versus urethropexy: a case-control series, <i>International Urogynecology Journal</i> , 16, 15-18, 2005	Not randomised controlled trial

Study	Reason for Exclusion
Dobberfuhr, A. D., De, E. J., Female stress urinary incontinence and the mid-urethral sling: is obstruction necessary to achieve dryness?, World Journal of Urology, 33, 1243-50, 2015	No relevant extractable data in review
Dogan, O., Basbug, A., Kaya, A. E., Pulatoglu, C., Yassa, M., A randomized prospective comparison of the needleless mini-sling "hammock" and "U-shape" configurations for management of stress urinary incontinence: 18 month follow-up results, Archives of gynecology and obstetrics, 297, 1483-1493, 2018	Compares 2 methods of single-incision mini-sling
Drahoradova, P, Martan, A, Svabik, K, Zvara, K, Otava, M, Masata, J, Longitudinal trends with improvement in quality of life after TVT, TVT O and burch colposuspension procedures, Medical science monitor, 17, Cr67-cr72, 2011	Not randomised controlled trial
Easton, W. A., Epp, A., Farrell, S. A., Flood, C. G., Girouard, L., Lajoie, F., Barry MacMillan, J., Mainprize, T. C., Robert, M., Choice of Surgery for Stress Incontinence, Journal of Obstetrics and Gynaecology Canada, 27, 964-971, 2005	Guidelines by SOGC based on Cochrane reviews/No additional randomised controlled trials identified
Elbadry, M., Essam, A., Hammady, A., Gamal, M., Abdelmalek, M., Minisling single incision tape for treatment of female stress incontinence, is it better?!, Journal of Endourology, 31 (Supplement 2), A350, 2017	Conference abstract
Elghamrawi, H, Abdelraouf, H, Elfayoumy, H, Elsheikh, Mg, Shannan, K, Salah, M, Predictive factors of bladder outlet obstruction following the tension-free vaginal tape obturator (TVTO) procedure in females treated surgically for stress urinary incontinence, African Journal of Urology, 21, 122-5, 2015	Not randomised controlled trial
El-Sayed, D., Desoky, E., Aly, M., Mostafa, M., Elbendary, L., Salem, H., Maarof, A., Abuo Hashem, S., Five-year outcomes of transobturator tape (TOT) compared with tension-free vaginal tape (TVT) in treatment of women with stress urinary incontinence, European Urology, Supplements, 17 (2), e1662, 2018	Conference abstract
EISheemy, M. S., Fathy, H., Hussein, H. A., Elsergany, R., Hussein, E. A., Surgeon-tailored polypropylene mesh as a tension-free vaginal tape-obturator versus original TVT-O for the treatment of female stress urinary incontinence: a long-term comparative study, International Urogynecology Journal, 26, 1533-40, 2015	Not randomised controlled trial
EISheemy, M. S., Fathy, H., Hussein, H. A., Hussein, E. A., Hassan, S. M., Surgeon-tailored polypropylene mesh as a needleless single-incision sling versus TVT-O for the treatment of female stress urinary incontinence: a comparative study, International Urology & Nephrology, 47, 937-44, 2015	Not randomised controlled trial
el-Toukhy, T.A., Davies, A.E., The efficacy of laparoscopic mesh colposuspension: results of a prospective controlled study, BJU International, 88, 361-366, 2001	Not randomised controlled trial
Enzelsberger, H., Helmer, H., Schatten, C., Comparison of Burch and Lyodura sling procedures for repair of	Lyodura sling withdrawn due to CJD infectino risk/not fascial sling

Study	Reason for Exclusion
unsuccessful incontinence surgery, <i>Obstetrics and Gynecology</i> , 88, 251-256, 1996	
Eriksen, B.C., Hagen, B., Eik-Nes, S.H., Molne, K., Mjølnerod, O.K., Romslo, I., Long-term effectiveness of the Burch colposuspension in female urinary stress incontinence, <i>Acta Obstetrica et Gynecologica Scandinavica</i> , 69, 45-50, 1990	Not randomised controlled trial
Esin, S., Salman, M.C., Ozyuncu, O., Durukan, T., Surgical outcome of transobturator tape procedure in obese and non-obese women, <i>Journal of Obstetrics and Gynaecology</i> , 31, 645-649, 2011	Not randomised controlled trial
Fan, Y., Huang, Z., Yu, D., Incontinence-specific quality of life measures used in trials of sling procedures for female stress urinary incontinence: a meta-analysis, <i>International Urology &amp; Nephrology</i> , 47, 1277-95, 2015	No relevant extractable data in review
Feifer, A., Corcos, J., The use of synthetic sub-urethral slings in the treatment of female stress urinary incontinence, <i>International urogynecology journal and pelvic floor dysfunction</i> , 18, 1087-1095, 2007	Non-systematic narrative review
Fischer-Rasmussen, W., Treatment of stress urinary incontinence, <i>Annals of Medicine</i> , 22, 455-465, 1990	No additional randomised controlled trials identified
Flynn, B.J., Yap, W.T., Pubovaginal sling using allograft fascia lata versus autograft fascia for all types of stress urinary incontinence: 2-year minimum followup, <i>Journal of Urology</i> , 167, 608-612, 2002	Not randomised controlled trial
Fong, E.D.M., Nitti, V.W., Mid-urethral synthetic slings for female stress urinary incontinence, <i>BJU International</i> , 106, 596-608, 2010	General non-systematic review
Ford, A. A., Ogah, J. A., Retropubic or transobturator mid-urethral slings for intrinsic sphincter deficiency-related stress urinary incontinence in women: a systematic review and meta-analysis, <i>International Urogynecology Journal</i> , 27, 19-28, 2016	No additional relevant articles
Ford, Abigail A, Rogerson, Lynne, Cody, June D, Aluko, Patricia, Ogah, Joseph A, Mid-urethral sling operations for stress urinary incontinence in women, <i>Cochrane Database of Systematic Reviews</i> , 2017	No additional relevant articles
Franzen, K., Andersson, G., Odeberg, J., Midlov, P., Samuelsson, E., Stenzelius, K., Hammarstrom, M., Surgery for urinary incontinence in women 65 years and older: a systematic review, <i>International Urogynecology Journal</i> , 26, 1095-102, 2015	No relevant articles identified
Freton, L., Tondut, L., Enderle, I., Hascoet, J., Manunta, A., Peyronnet, B., Comparison of adjustable continence therapy periurethral balloons and artificial urinary sphincter in female patients with stress urinary incontinence due to intrinsic sphincter deficiency, <i>International urogynecology journal</i> , 13, 13, 2018	Retrospective cohort study
Frigerio, M., Regini, C., Manodoro, S., Spelzini, F., Milani, R., Mini-sling efficacy in obese versus non-obese patients for treatment of stress urinary incontinence, <i>Minerva Ginecologica</i> , 09, 09, 2017	Not randomised controlled trial

Study	Reason for Exclusion
Frohme, C., Ludt, F., Varga, Z., Olbert, P. J., Hofmann, R., Hegele, A., TOT approach in stress urinary incontinence (SUI) - outcome in obese female, BMC Urology, 14, 20, 2014	Not randomised controlled trial
Fusco, F., Abdel-Fattah, M., Chapple, C. R., Creta, M., La Falce, S., Waltregny, D., Novara, G., Updated Systematic Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence, European urology, 72, 567-591, 2017	No additional RCTs identified
Futyma, K., Nowakowski, L., Galczynski, K., Miotla, P., Rechberger, T., Nonabsorbable urethral bulking agent - clinical effectiveness and late complications rates in the treatment of recurrent stress urinary incontinence after 2 years of follow-up, European Journal of Obstetrics, Gynecology, & Reproductive Biology Eur J Obstet Gynecol Reprod Biol, 207, 68-72, 2016	Not randomised controlled trial
Gaddi, A., Guaderrama, N., Bassiouni, N., Bebhuk, J., Whitcomb, E. L., Repeat midurethral sling compared with urethral bulking for recurrent stress urinary incontinence.[Erratum appears in Obstet Gynecol. 2014 Oct;124(4):842], Obstetrics & Gynecology, 123, 1207-12, 2014	Not randomised controlled trial
Gauruder-Burmester, A., Popken, G., The MiniArc sling system in the treatment of female stress urinary incontinence, International Braz J Urol, 35, 334-341, 2009	Not randomised controlled trial
German, K. A., Kynaston, H., Weight, S., Stephenson, T. P., A prospective randomized trial comparing a modified needle suspension procedure with the vagina/obturator shelf procedure for genuine stress incontinence, British journal of urology, 74, 188-190, 1994	No relevant comparison
Ghezzi, F., Cromi, A., Raio, L., Bergamini, V., Triacca, P., Serati, M., Kuhn, A., Influence of the type of anesthesia and hydrodissection on the complication rate after tension-free vaginal tape procedure, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 118, 96-100, 2005	Not randomised controlled trial
Ghielmetti, T., Kuhn, P., Dreher, E. F., Kuhn, A., Gynaecological operations: Do they improve sexual life?, European Journal of Obstetrics Gynecology and Reproductive Biology, 129, 104-110, 2006	No additional randomised controlled trials identified
Ghoniem, G. M., Miller, C. J., A systematic review and meta-analysis of Macroplastique for treating female stress urinary incontinence, International Urogynecology Journal and Pelvic Floor Dysfunction, 24, 27-36, 2013	No additional relevant articles
Giberti, C., Gallo, F., Cortese, P., Visalli, F., Mid- to long-term results of the Remeex system for the treatment of female incontinence due to intrinsic sphincter deficiency: A retrospective analysis of the first 50 patients, Neurourology and Urodynamics, 36, 770-773, 2017	Not randomised controlled trial
Giberti, C., Gallo, F., Cortese, P., ScheNo, M., The suburethral tension adjustable sling (REMEEX system)	Not randomised controlled trial

Study	Reason for Exclusion
in the treatment of female urinary incontinence due to 'true' intrinsic sphincter deficiency: Results after 5 years of mean follow-up, BJU International, 108, 1140-1144, 2011	
Gild, A., Schoenfisch, B., Huebner, M., Brucker, S., Wallwiener, D., Reisenauer, C., Does applying postoperative suprapubic catheterisation in urogynecology benefit patients?, Archives of Gynecology & Obstetrics, 293, 1039-42, 2016	Not randomised controlled trial
Gilja, I., Puskar, D., Mazuran, B., Radej, M., Comparative analysis of bladder neck suspension using Raz, Burch and transvaginal Burch procedures. A 3-year randomized prospective study, European Urology, 33, 298-302, 1998	No relevant comparison
Giri, S.K., Hickey, J.P., Sil, D., Mabadeje, O., Shaikh, F.M., Narasimhulu, G., Flood, H.D., The long-term results of pubovaginal sling surgery using acellular cross-linked porcine dermis in the treatment of urodynamic stress incontinence, Journal of Urology, 175, 1788-1792, 2006	Not randomised controlled trial
Glazener, Cathryn Ma, Cooper, Kevin, Mashayekhi, Atefeh, Bladder neck needle suspension for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	Systematic review of intervention not in protocol (bladder neck suspension)
Gomelsky, A., Coco, C. T., Dmochowski, R. R., Urinary incontinence in women: non-pharmacologic approaches and newer pharmacotherapies, Minerva Medica, 105, 263-74, 2014	Selective narrative review
Gordon, D., Gold, R., Pauzner, D., Lessing, J.B., Groutz, A., Tension-free vaginal tape in the elderly: is it a safe procedure?, Urology, 65, 479-482, 2005	Not randomised controlled trial
Gorton, E., Stanton, S., Monga, A., Wiskind, A. K., Lentz, G. M., Bland, D. R., Periurethral collagen injection: a long-term follow-up study, BJU International, 84, 966-71, 1999	Not randomised controlled trial
Grigoriadis, C., Bakas, P., Derpapas, A., Creatsa, M., Liapis, A., Tension-free vaginal tape obturator versus Ajust adjustable single incision sling procedure in women with urodynamic stress urinary incontinence, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 170, 563-6, 2013	Not randomised controlled trial
Groutz, A., Cohen, A., Gold, R., Pauzner, D., Lessing, J.B., Gordon, D., The safety and efficacy of the "inside-out" trans-obturator TVT in elderly versus younger stress-incontinent women: A prospective study of 353 consecutive patients, Neurourology and Urodynamics, 30, 380-383, 2011	Not randomised controlled trial
Guerrero, K., Watkins, A., Emery, S., Wareham, K., Stephenson, T., Logan, V., Lucas, M., A randomised controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up, International Urogynecology Journal, 18, 1263-1270, 2007	No relevant comparison

Study	Reason for Exclusion
Gungorduk,K., Celebi,I., Ark,C., Celikkol,O., Yildirim,G., Which type of mid-urethral sling procedure should be chosen for treatment of stress urinary incontinence with intrinsic sphincter deficiency? Tension-free vaginal tape or transobturator tape, Acta Obstetrica et Gynecologica Scandinavica, 88, 920-926, 2009	Not randomised controlled trial
Han, S. B., Kim, J. C., Lee, D. H., Kim, H. S., Koh, J. S., Hur, W. S., Cho, K. J., The Effect of Valsalva Leak Point Pressure on Outcomes of the Needleless System in Female Stress Urinary Incontinence, Urology Journal, 12, 2251-5, 2015	Not randomised controlled trial
Han,J.Y., Moon,K.H., Park,C.M., Choo,M.S., Management of recurrent stress urinary incontinence after failed midurethral sling: tape tightening or repeat sling?, International Urogynecology Journal, 23, 1279-1284, 2012	Not randomised controlled trial
Hana, D, Amir, I, Amel, K, Assessment of clinical effectiveness and economic viability of the obturator tension free vaginal tape method for the treatment of stress urinary incontinence by cost benefit analysis (Provisional abstract), European Journal of General Medicine, 9, 178-182, 2012	Not randomised controlled trial
Hassonah, S., Medel, S., Lovatsis, D., Drutz, H. P., Alarab, M., Outcome of the laparoscopic two-team sling procedure, tension-free vaginal tape insertion, and transobturator tape insertion in women with recurrent stress urinary incontinence, Journal of Obstetrics & Gynaecology Canada: JOGC, 35, 1004-9, 2013	Not randomised controlled trial
Health Quality, Ontario, Midurethral slings for women with stress urinary incontinence: an evidence-based analysis, Ontario Health Technology Assessment SeriesOnt Health Technol Assess Ser, 6, 1-61, 2006	No additional randomised controlled trials identified
Hilton, P., A clinical and urodynamic study comparison the Stamey bladder neck suspension and suburethral sling procedures in the treatment of genuine stress incontinence, British journal of obstetrics and gynaecology, 96, 213-220, 1989	No relevant comparison
Holroyd-Leduc, J. M., Straus, S. E., Management of Urinary Incontinence in Women: Scientific Review, Journal of the American Medical Association, 291, 986-995, 2004	No additional randomised controlled trials identified
Houwert,R.M., Renes-Zijl,C., Vos,M.C., Vervest,H.A., TVT-O versus Monarc after a 2-4-year follow-up: a prospective comparative study, International Urogynecology Journal, 20, 1327-1333, 2009	Not randomised controlled trial
Houwert,R.M., Roovers,J.P., Venema,P.L., Bruinse,H.W., Dijkgraaf,M.G., Vervest,H.A., Outcome and complications of retropubic and transobturator midurethral slings translated into surgical therapeutic indices, American Journal of Obstetrics and Gynecology, 202, 75-77, 2010	Not randomised controlled trial
Huang, W., Wang, T., Zong, H., Zhang, Y., Efficacy and safety of tension-free vaginal tape-secur mini- sling versus standard midurethral slings for female stress	No additional randomised controlled trials identified

Study	Reason for Exclusion
urinary incontinence: A systematic review and meta-analysis, International Neurourology Journal, 19, 246-258, 2015	
Hussain, M., Greenwell, T. J., Venn, S. N., Mundy, A. R., The current role of the artificial urinary sphincter for the treatment of urinary incontinence, Journal of Urology, 174, 418-424, 2005	No randomised controlled trials identified
Hwang, I.S., Yu, J.H., Chung, J.Y., Noh, C.H., Sung, L.H., One-year outcomes of mid-urethral sling procedures for stress urinary incontinence according to body mass index, Korean Journal of Urology, 53, 171-177, 2012	Not randomised controlled trial
Ignjatovic, I., Potic, M., Basic, D., Dinic, L., Medojevic, N., Laketic, D., Skacic, A., Mihajlovic, M., Self-created transobturator tape treatment of stress urinary incontinence without prior urodynamic investigation, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 182, 76-80, 2014	Not randomised controlled trial
Iliev, V. N., Andonova, I. T., Minimally invasive surgery for stress urinary incontinence - mesh complications, Prilozi Makedonska Akademija Na Naukite I Umetnostite Oddelenie Za Medicinski Nauki, 35, 105-10, 2014	Not randomised controlled trial
Jain, P., Jirschele, K., Botros, S.M., Latthe, P.M., Effectiveness of midurethral slings in mixed urinary incontinence: a systematic review and meta-analysis, International Urogynecology Journal, 22, 923-932, 2011	No additional randomised controlled trials identified
Jeffery, S, Acharyya, R, Algar, M, Makhene, M, Mini-sling procedures in stress urinary incontinence: A systematic review of efficacy and complications, International urogynecology journal and pelvic floor dysfunction, 21, S7-s8, 2010	Conference abstract
Jeon, M.J., Jung, H.J., Chung, S.M., Kim, S.K., Bai, S.W., Comparison of the treatment outcome of pubovaginal sling, tension-free vaginal tape, and transobturator tape for stress urinary incontinence with intrinsic sphincter deficiency, American Journal of Obstetrics and Gynecology, 199, 76-4, 2008	Not randomised controlled trial
Jeong, S. J., Lee, H. S., Lee, J. K., Jeong, J. W., Lee, S. C., Kim, J. H., Hong, S. K., Byun, S. S., Lee, S. E., The long-term influence of body mass index on the success rate of mid-urethral sling surgery among women with stress urinary incontinence or stress-predominant mixed incontinence: comparisons between retropubic and transobturator approaches, PLoS ONE [Electronic Resource] PLoS ONE, 9, e113517, 2014	Not randomised controlled trial
Jha, S., Ammenbal, M., Metwally, M., Impact of Incontinence surgery on Sexual Function: A Systematic Review and Meta-Analysis, Journal of Sexual Medicine, 9, 34-43, 2012	No additional randomised controlled trials identified
Jiang, Y. H., Wang, C. C., Chuang, F. C., Ke, Q. S., Kuo, H. C., Positioning of a suburethral sling at the bladder neck is associated with a higher recurrence rate of stress urinary incontinence, Journal of Ultrasound in Medicine, 32, 239-45, 2013	Not randomised controlled trial

Study	Reason for Exclusion
Jiao, B., Lai, S., Xu, X., Zhang, M., D. lao T, Zhang, G., A systematic review and meta-analysis of single-incision mini-slings (MiniArc) versus transobturator mid-urethral slings in surgical management of female stress urinary incontinence, <i>Medicine (United States)</i> , 97 (14) (no pagination), 2018	No additional identified RCTs
Joo, Y.M., Choe, J.H., Seo, J.T., One-year surgical outcomes and quality of life after minimally invasive sling procedures for the treatment of female stress urinary incontinence: TVT SECUR versus CureMesh, <i>Korean Journal of Urology</i> , 51, 337-343, 2010	Not randomised controlled trial
Karaman, U., Campbell, K. J., Frilot, C. F., 2nd, Gomelsky, A., The impact of obesity on outcomes and complications after top-down retropubic midurethral sling, <i>Neurourology &amp; Urodynamics/Neurourol Urodyn</i> , 36, 1330-1335, 2017	Not randomised controlled trial
Karantanis, E., Fynes, M.M., Stanton, S.L., The tension-free vaginal tape in older women, <i>BJOG: An International Journal of Obstetrics and Gynaecology</i> , 111, 837-841, 2004	Not randomised controlled trial
Karateke, A., Cam, C., Ince, S.B., Tug, N., Selcuk, S., Asoglu, M.R., Vatansver, D., Effects of single vaginal incision technique on quality of life in women with stress urinary incontinence, <i>Journal of Minimally Invasive Gynecology</i> , 18, 634-639, 2011	Not randomised controlled trial
Kasi, A. D., Pergialiotis, V., Perrea, D. N., Khunda, A., Doumouchtsis, S. K., Polyacrylamide hydrogel (Bulkamid) for stress urinary incontinence in women: a systematic review of the literature, <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 27, 367-375, 2016	No additional relevant articles
Kavanagh, A., Sanaee, M., Carlson, K. V., Bailly, G. G., Management of patients with stress urinary incontinence after failed midurethral sling, <i>Canadian Urological Association Journal</i> , 11, S143-S146, 2017	Non-systematic narrative review
Kiilholma, P., Makinen, J., Disappointing effect of endoscopic Teflon injection for female stress incontinence, <i>European urology</i> , 20, 197-9, 1991	Not randomised controlled trial
Killingsworth, L. B., Wheeler, T. L., 2nd, Burgio, K. L., Martirosian, T. E., Redden, D. T., Richter, H. E., One-year outcomes of tension-free vaginal tape (TVT) mid-urethral slings in overweight and obese women, <i>International Urogynecology Journal</i> , 20, 1103-8, 2009	Not randomised controlled trial
Kim, A., Kim, H. G., Han, J. Y., Choo, M. S., Long-term efficacy and safety of single-incision mini-slings except TVT-secur versus standard midurethral slings in surgical management of female stress urinary incontinence: An updated systemic review and meta- analysis, <i>Neurourology and urodynamics</i> , 37 (Supplement 1), S582-S583, 2018	Poster abstract
Kim, J., Lucioni, A., Govier, F., Kobashi, K., Worse long-term surgical outcomes in elderly patients undergoing SPARC retropubic midurethral sling placement, <i>BJU International</i> , 108, 708-12, 2011	Not randomised controlled trial

Study	Reason for Exclusion
Kim, Wt, Kim, Kt, Kim, Jw, Choe, Jh, Lee, Js, Seo, Jt, Comparative study of the tension-free vaginal tape (TVT) procedure and the suprapubic arc sling (SPARC) procedure for treating female stress urinary incontinence: a 1-year follow-up, Korean Journal of Urology, 47, 397-401, 2006	Article published in Korean/Not randomised controlled study
Kirby, A. C., Tan-Kim, J., Nager, C. W., Midurethral slings: which should I choose and what is the evidence for use?, Current Opinion in Obstetrics & Gynecology, 27, 359-65, 2015	General non-systematic review
Kirchin, Vivienne, Page, Tobias, Keegan, Phil E, Atiemo, Kofi Om, Cody, June D, McClinton, Samuel, Aluko, Patricia, Urethral injection therapy for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	No additional relevant articles
Kjohede, P., Wahlstrom, J., Wingren, G., Pelvic floor dysfunction after Burch colposuspension--a comprehensive study. Part I, Acta Obstetrica et Gynecologica Scandinavica, 84, 894-901, 2005	Not randomised controlled trial
Klan, R., Dieringer, J., Dieckmann, K. P., Influence of hysterectomy on the results of the Zodler sling procedure in stress incontinent women, International Urology & Nephrology/Int Urol Nephrol, 21, 299-303, 1989	Not randomised controlled trial
Kocjancic, E., Erickson, T., Tu, L. M., Gheiler, E., Van Drie, D., Two-year outcomes for the Altis adjustable single incision sling system for treatment of stress urinary incontinence, Neurourology & Urodynamics/Neurourol Urodyn, 36, 1582-1587, 2017	Not randomised controlled trial
Kocjancic, E., Tu, L. M., Erickson, T., Gheiler, E., Van Drie, D., The safety and efficacy of a new adjustable single incision sling for female stress urinary incontinence, Journal of Urology, 192, 1477-82, 2014	Not randomised controlled trial
Kondo, A., Isobe, Y., Kimura, K., Kamihira, O., Matsuura, O., Gotoh, M., Ozawa, H., Efficacy, safety and hospital costs of tension-free vaginal tape and pubovaginal sling in the surgical treatment of stress incontinence, Journal of Obstetrics and Gynaecology Research, 32, 539-544, 2006	Not randomised controlled study
Kowalik, C. G., Cohn, J. A., Gomelsky, A., Dmochowski, R. R., Urinary incontinence in women: Non pharmacologic approaches and newer pharmacotherapies. An update, Minerva Medica, 108, 255-267, 2017	Selective narrative review
Krhut, J., Martan, A., Jurakova, M., Nemecek, D., Masata, J., Zvara, P., Treatment of stress urinary incontinence using polyacrylamide hydrogel in women after radiotherapy: 1-year follow-up, International Urogynecology Journal, 27, 301-5, 2016	No relevant comparison
Krofta, L., Feyereis, J., Velebil, P., Otcenasek, M., Kasikova, E., Krcmar, M., TVT-S for surgical treatment of stress urinary incontinence: prospective trial, 1-year follow-up, International Urogynecology Journal, 21, 779-785, 2010	Not randomised controlled trial

Study	Reason for Exclusion
Kulseng-Hanssen,S., Husby,H., Schiotz,H.A., Follow-up of TVT operations in 1,113 women with mixed urinary incontinence at 7 and 38 months, International Urogynecology Journal, 19, 391-396, 2008	Not randomised controlled trial
Kumsar, S., Aydemir, H., Kose, O., Budak, S., Saglam, H. S., Adsan, O., Comparison of one-year results of transobturator tape method in the stress incontinence treatment according to body mass index, Turkish Journal of Urology, 41, 143-8, 2015	Not randomised controlled trial
Labrie, J., Berghmans, B. L. C. M., Fischer, K., Milani, A. L., Van Der Wijk, I., Smalbraak, D. J. C., Vollebregt, A., Schellart, R. P., Graziosi, G. C. M., Van Der Ploeg, J. M., Brouns, J. F. G. M., Tiersma, E. S. M., Groenendijk, A. G., Scholten, P., Mol, B. W., Blokhuis, E. E., Adriaanse, A. H., Schram, A., Roovers, J. W. R., Lagro-Janssen, A. L. M., Van Der Vaart, C. H., Surgery versus physiotherapy for stress urinary incontinence, New England journal of medicine, 369, 1124-1133, 2013	No relevant comparison
Labrie, J., Fischer, K., van der Vaart, C. H., Health-related quality of life. The effect of pelvic floor muscle training and midurethral sling surgery: a systematic review, International Urogynecology Journal, 23, 1155-62, 2012	No additional randomised controlled trials identified from review on midurethral sling surgery
Lalos, O, Berglund, Al, Bjerle, P, The long-term outcome of retropubic urethrocystopexy (sutures and fibrin sealant) and pubococcygeal repair, Acta obstetrica ET gynecologica scandinavica, 79, 135-139, 2000	Not randomised controlled trial
Lamin, E., Strother, M. C., Smith, A. L., The Evidence for Female Pelvic Medicine Interventions, Current Bladder Dysfunction Reports, 12, 8-14, 2017	Non-systematic narrative review
Langer,R., Golan,A., Ron-El,R., Neuman,M., Pansky,M., Bukovsky,I., Caspi,E., Colposuspension for urinary stress incontinence in premenopausal and postmenopausal women, Surgery, Gynecology and Obstetrics, 171, 13-16, 1990	Not randomised controlled trial
Lapitan, M. C. M., Cody, J. D., Grant, A., Open retropubic colposuspension for urinary incontinence in women: A short version cochrane review, Neurourology and Urodynamics, 28, 472-480, 2009	Short version of Lapitan et al. 2009/no additional randomised controlled trials identified
Lapitan, Marie Carmela M, Cody, June D, Mashayekhi, Atefeh, Open retropubic colposuspension for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	No additional relevant articles
Larouche, M., Merovitz, L., Correa, J. A., Walter, J. E., Outcomes of trocar-guided Gynemesh PSTM versus single-incision trocarless Polyform™ transvaginal mesh procedures, International Urogynecology Journal, 26, 71-7, 2015	Not randomised controlled trial
Larsson, B., Jonasson, A., Fianu, S., Retropubic urethrocystopexy with fibrin sealant: a long-term follow-up, Gynecologic & Obstetric Investigation Gynecol Obstet Invest, 26, 257-61, 1988	Not randomised controlled trial
Lathe,P.M., Review of transobturator and retropubic tape procedures for stress urinary incontinence, Current	General non-systematic review

Study	Reason for Exclusion
Opinion in Obstetrics and Gynecology, 20, 331-336, 2008	
Lathe,P.M., Foon,R., Tooze-Hobson,P., Transobturator and retropubic tape procedures in stress urinary incontinence: A systematic review and meta-analysis of effectiveness and complications, BJOG: An International Journal of Obstetrics and Gynaecology, 114, 522-531, 2007	No additional randomised controlled trials identified
Law, T. S., Cheung, R. Y., Chung, T. K., Chan, S. S., Efficacy and outcomes of transobturator tension-free vaginal tape with or without concomitant pelvic floor repair surgery for urinary stress incontinence: five-year follow-up, Hong Kong Medical Journal, 21, 333-8, 2015	Not randomised controlled trial
Lazarou, G., Miller, C., Gupta, N., Islam, S., Vetere, P., Intraoperative Crede maneuver for tape adjustment during transobturator sling placement: does it improve continence?, Female Pelvic Medicine & Reconstructive Surgery, 19, 369-73, 2013	Not randomised controlled trial
Leanza, V., Tension-free mini-invasive anti-incontinence procedures: Comparison among three main pathways, Open Women's Health Journal, 6, 30-35, 2012	No additional randomised controlled trials identified
Lebret, T., Lugagne, P. M., Herve, J. M., Barre, P., Orsoni, J. L., Yonneau, L., Saporta, F., Botto, H., Evaluation of tension-free vaginal tape procedure. Its safety and efficacy in the treatment of female stress urinary incontinence during the learning phase, European urology, 40, 543-7, 2001	Not randomised controlled trial
Lee, D., Murray, S., Bacsu, C. D., Zimmern, P. E., Long-term outcomes of autologous pubovaginal fascia slings: is there a difference between primary and secondary slings?, Neurourology & Urodynamics, 34, 18-23, 2015	Not randomised controlled trial
Lee, H. N., Lee, S. W., Lee, Y. S., Lee, S. Y., Lee, K. S., Tension-Free Vaginal Tape-SECUR Procedure for the Treatment of Female Stress Urinary Incontinence: 3-Year Follow-Up Results, Luts, 7, 9-16, 2015	Not randomised controlled trial
Lee, J. K., Rosamilia, A., Lim, Y. N., Thomas, E. A., Murray, C. J., Leitch, A., Dwyer, P. L., Miniarc monarc suburethral sling in women with stress urinary incontinence-an RCT-60M follow up, International Urogynecology Journal, 28 (1 Supplement 1), S80-S81, 2017	Conference abstract
Lee, K. S., Choo, M. S., Lee, Y. S., Han, J. Y., Kim, J. Y., Jung, B. J., Han, D. H., Prospective comparison of the 'inside - Out' and 'outside - In' transobturator-tape procedures for the treatment of female stress urinary incontinence, International Urogynecology Journal, 19, 577-582, 2008	Not randomised controlled trial
Lee,J.H., Cho,M.C., Oh,S.J., Kim,S.W., Paick,J.S., Long-term outcome of the tension-free vaginal tape procedure in female urinary incontinence: A 6-year follow-up, Korean Journal of Urology, 51, 409-415, 2010	Not randomised controlled trial
Lee,K.S., Han,D.H., Choi,Y.S., Yum,S.H., Song,S.H., Doo,C.K., Choo,M.S., A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape	Not randomised controlled trial

Study	Reason for Exclusion
inside-out for the surgical treatment of female stress urinary incontinence: 1-year followup, Journal of Urology, 177, 214-218, 2007	
Leone Roberti Maggiore, U., Alessandri, F., Medica, M., Gabelli, M., Venturini, P. L., Ferrero, S., Outpatient periurethral injections of polyacrylamide hydrogel for the treatment of female stress urinary incontinence: effectiveness and safety, Archives of Gynecology & Obstetrics Arch Gynecol Obstet, 288, 131-7, 2013	Not randomised controlled trial
Leone Roberti Maggiore, U., Bogani, G., Meschia, M., Sorice, P., Braga, A., Salvatore, S., Ghezzi, F., Serati, M., Urethral bulking agents versus other surgical procedures for the treatment of female stress urinary incontinence: a systematic review and meta-analysis, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 189, 48-54, 2015	No additional relevant articles
Leone Roberti Maggiore, U., Finazzi Agro, E., Soligo, M., Li Marzi, V., Digesu, A., Serati, M., Long-term outcomes of TOT and TVT procedures for the treatment of female stress urinary incontinence: a systematic review and meta-analysis, International Urogynecology Journal, 28, 1119-1130, 2017	No additional relevant articles
Liang, C. C., Hsieh, W. C., Huang, L., Outcome of coexistent overactive bladder symptoms in women with urodynamic urinary incontinence following anti-incontinence surgery, International Urogynecology Journal, 28, 605-611, 2017	Not randomised controlled trial
Liapis, A. E., Asimiadis, V., Loghis, C. D., Pyrgiotis, E., Zourlas, P. A., A randomized prospective study of three operative methods for genuine stress incontinence, Journal of gynecologic surgery, 12, 7-14, 1996	No relevant comparison
Liapis, A., Bakas, P., Creatsas, G., Assessment of TVT efficacy in the management of patients with genuine stress incontinence with the use of epidural vs intravenous anesthesia, International Urogynecology Journal, 18, 1197-1200, 2007	Not randomised controlled trial
Liapis, A., Bakas, P., Creatsas, G., Monarc vs TVT-O for the treatment of primary stress incontinence: a randomized study, International Urogynecology Journal, 19, 185-190, 2008	No relevant comparison (compares 2 types of transobturator slings)
Lim, Y. N., Muller, R., Corstiaans, A., Dietz, H. P., Barry, C., Rane, A., Suburethral slingplasty evaluation study in North Queensland Australia: The SUSPEND trial, Australian and New Zealand Journal of Obstetrics and Gynaecology, 45, 52-59, 2005	No relevant comparison (compares 3 types of retropubic tape)
Lim, P. H., Brown, A. D., Chisholm, G. D., The Burch Colposuspension operation for stress urinary incontinence, Singapore medical journal, 31, 242-246, 1990	Not randomised controlled trial
Lim, Y. N., Dwyer, P., Muller, R., Rosamilia, A., Lee, J., Stav, K., Do the Advantage slings work as well as the tension-free vaginal tapes?, International Urogynecology Journal and Pelvic Floor Dysfunction, 21, 1157-1162, 2010	Not randomised controlled trial

Study	Reason for Exclusion
Linder, B. J., El-Nashar, S. A., Carranza Leon, D. A., Trabuco, E. C., Predictors of vaginal mesh exposure after midurethral sling placement: a case-control study, <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 27, 1321-1326, 2016	Not randomised controlled trial
Lleberia-Juanos, J., Bataller-Sanchez, E., Pubill-Soler, J., Mestre-Costa, M., Ribot-Luna, L., Vizcaino, M.A., De novo urgency after tension-free vaginal tape versus transobturator tape procedure for stress urinary incontinence, <i>European Journal of Obstetrics, Gynecology, and Reproductive Biology</i> , 155, 229-232, 2011	Not randomised controlled trial
Lo, T. S., Tan, Y. L., Wu, P. Y., Cortes, E. F., Pue, L. B., Al-Kharabsheh, A., Ultrasonography and clinical outcomes following surgical anti-incontinence procedures (Monarc vs Miniarc), <i>European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology</i> , 182, 91-7, 2014	Not randomised controlled trial
Lo, T.S., Horng, S.G., Liang, C.C., Lee, S.J., Huang, H.J., Lin, C.T., Ultrasound and urodynamic comparison between caudocranial and craniocaudal tension-free vaginal tape for stress urinary incontinence, <i>Urology</i> , 66, 754-758, 2005	Not randomised controlled trial
Long, C. Y., Wu, M. P., Wang, C. L., Lin, K. L., Liu, C. M., Wu, S. H., Juan, Y. S., Modified prepubic TVT-obturator tape procedure versus the conventional method: a preliminary study, <i>European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology</i> , 171, 376-80, 2013	Not randomised controlled trial
Lord, H.E., Taylor, J.D., Finn, J.C., Tsokos, N., Jeffery, J.T., Atherton, M.J., Evans, S.F., Bremner, A.P., Elder, G.O., Holman, C.D.J., A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence, <i>BJU International</i> , 98, 367-376, 2006	No relevant comparison
Lorenzo Gomez, M. F., Collazos Robles, R. E., Virseda Rodriguez, A. J., Garcia Cenador, M. B., Miron Canelo, J. A., Padilla Fernandez, B., Urinary tract infections in women with stress urinary incontinence treated with transobturator suburethral tape and benefit gained from the sublingual polibacterial vaccine, <i>Therapeutic Advances in Urology</i> , 7, 180-5, 2015	Not randomised controlled trial
Low, S.J., Smith, K.M., Holt, E.M., Tension free vaginal tape: is the intra-operative cough test necessary?, <i>International Urogynecology Journal</i> , 15, 328-330, 2004	Not randomised controlled trial
Luo, D. Y., Wang, K. J., Zhang, H. C., Dai, Y., Yang, T. X., Shen, H., Different sling procedures for stress urinary incontinence: a lesson from 453 patients, <i>Kaohsiung Journal of Medical Sciences</i> , 30, 139-45, 2014	Not randomised controlled trial
MacDonald, S., Terlecki, R., Costantini, E., Badlani, G., Complications of Transvaginal Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence: Tips for	Article not available

Study	Reason for Exclusion
Prevention, Recognition, and Management, European Urology Focus, 2, 260-267, 2016	
Mackintosh, A, A pilot, randomised, prospective study of transobturator tape versus single incision sub-urethral tape in the management of female, urodynamic stress incontinence, 2010	Article not available
Madsen, A. M., El-Nashar, S. A., Woelk, J. L., Klingele, C. J., Gebhart, J. B., Trabuco, E. C., A cohort study comparing a single-incision sling with a retropubic midurethral sling, International Urogynecology Journal, 25, 351-8, 2014	Not randomised controlled trial
Magno-Azevedo, V., Silva, C., Cruz, F., Single Incision Slings: Is There a Role?, Current Bladder Dysfunction Reports, 8, 19-24, 2013	No additional randomised controlled trials identified
Mandron, E., Bryckaert, P. E., Papatsoris, A. G., Laparoscopic artificial urinary sphincter implantation for female genuine stress urinary incontinence: Technique and 4-year experience in 25 patients, BJU International, 106, 1194-1198, 2010	Not randomised controlled trial
Marcelissen, T., Van Kerrebroeck, P., Overactive bladder symptoms after midurethral sling surgery in women: Risk factors and management, Neurourology and Urodynamics., 2017	No relevant randomised controlled trials identified
Marinkovic, S. P., Mian, H., Evankovich, M., Poplawsky, D., Novi, J., Frey, C., Yap, W., Analysis of early outcome: Burch procedure versus pubovaginal sling.[Erratum appears in Int Urogynecol J Pelvic Floor Dysfunct. 2010 Aug;21(8):1043 Note: Marinkovic, S [corrected to Marinkovic, S P]], International Urogynecology Journal, 9, 94-9, 1998	Not randomised controlled trial
Martinez Franco, E., Amat Tardiu, L., Contasure-Needleless single incision sling compared with transobturator TVT-O for the treatment of stress urinary incontinence: long-term results, International Urogynecology Journal, 26, 213-8, 2015	Not randomised controlled trial
McAchrans, S.E., Retropubic versus transobturator midurethral synthetic slings: does one sling fit all?, Current Urology Reports, 11, 315-322, 2010	No additional relevant articles
McDougall, E. M., Heidorn, C. A., Portis, A. J., Klutke, C. G., Laparoscopic bladder neck suspension fails the test of time, Journal of Urology, 162, 2078-81, 1999	Not randomised controlled trial
McLennan, M. T., Bent, A. E., Fascia lata suburethral sling versus Burch retropubic urethropexy. A comparison of morbidity, Journal of reproductive medicine, 43, 488-94, 1998	Not randomised controlled trial
Medina, C. A., Costantini, E., Petri, E., Mourad, S., Singla, A., Rodriguez-Colorado, S., Ortiz, O. C., Doumouchtsis, S. K., Evaluation and surgery for stress urinary incontinence: A FIGO working group report, Neurourology and urodynamics, 36, 518-528, 2017	No extractable data
Mehdiyev, M, Itil, Im, Sendag, F, Akdemir, A, Askar, N, Comparing the Transvaginal Tape (TVT) and Transobturator Tape (TOT) in stress urinary incontinence for their efficiency and their effects on	Article not published in English

Study	Reason for Exclusion
quality of life, Turk jinekoloji ve obstetrik dernegi dergisi, 7, 117-124, 2010	
Melendez Munoz, J., Braverman, M., Rosamilia, A., Young, N. R., Leitch, A., Lee, J. K., Miniarc vs TVT abbrevo midurethral sling in womenwithstressurinaryincontinence. An RCT 6 and 12 month follow up, International urogynecology journal, 28 (1 Supplement 1), S18-S19, 2017	Conference abstract
Mengerink, B. B., Van Leijsen, S. A. L., Vierhout, M. E., Inthout, J., Mol, B. W. J., Milani, A. L., Roovers, J. P. W. R., Van Eijndhoven, H. W. F., Van Der Vaart, C. H., Van Gestel, I., Hartog, F. E., Heesakkers, J. F. A., Kluivers, K. B., The Impact of Midurethral Sling Surgery on Sexual Activity and Function in Women With Stress Urinary Incontinence, Journal of Sexual Medicine, 13, 1498-1507, 2016	No relevant comparison
Merlin, T., Arnold, E., Petros, P., MacTaggart, P., Tulloch, A., Faulkner, K., Maddern, G., A systematic review of tension-free urethropexy for stress urinary incontinence: Intravaginal slingplasty and the tension-free vaginal tape procedures, BJU International, 88, 871-880, 2001	No randomised controlled trials identified
Meschia, M., Rossi, G., Bertini, S., Sommacal, A., Foina, S., Sandretti, F., Barbacini, P., Single incision mid-urethral slings: impact of obesity on outcomes, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 170, 571-4, 2013	Not randomised controlled trial
Meschia, M., Barbacini, P., Ambrogi, V., Pifarotti, P., Ricci, L., Spreafico, L., TVT-secur: a minimally invasive procedure for the treatment of primary stress urinary incontinence. One year data from a multi-centre prospective trial, International Urogynecology Journal, 20, 313-317, 2009	Not randomised controlled trial
Meschia, M., Pifarotti, P., Bernasconi, F., Magatti, F., Viganò, R., Bertozzi, R., Barbacini, P., Tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for stress urinary incontinence: a multicenter randomized trial, American Journal of Obstetrics and Gynecology, 195, 1338-1342, 2006	No relevant comparison (compares 2 types of retropubic tape)
Meschia, M., Pifarotti, P., Buonaguidi, A., Gattei, U., Spennacchio, M., Tension-free vaginal tape (TVT) for treatment of stress urinary incontinence in women with low-pressure urethra, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 122, 118-121, 2005	Not randomised controlled trial
Miklos, J. R., Saye, W. B., A randomized comparison of Burch colposuspension and abdominal paravaginal defect repair, American journal of obstetrics and gynecology, 176, 255-256, 1997	Letter
Milanesi, M., Cocci, A., Cacciamani, G., Russo, G. I., Cerruto, M. A., Tosto, A., Artibani, W., Gacci, M., Li Marzi, V., Serni, S., Impact of preoperative patients' characteristics and flow rate on failure, early complications and voiding dysfunction after transobturator tape procedure: A retrospective	Not randomised controlled trial

Study	Reason for Exclusion
multicentre study, Neurourology and urodynamics, 36, S57-S58, 2017	
Mischinger, J., Amend, B., Reisenauer, C., Bedke, J., Naumann, G., Germann, M., Kruck, S., Arenas Desilva, L. F., Wallwiener, H., Koelbl, H., Nitti, V., Sievert, K. D., Different surgical approaches for stress urinary incontinence in women, <i>Minerva Ginecologica</i> , 65, 21-8, 2013	Selective narrative review
Mock, S., Angelle, J., Reynolds, W. S., Osborn, D. J., Dmochowski, R. R., Gomelsky, A., Contemporary comparison between retropubic midurethral sling and autologous pubovaginal sling for stress urinary incontinence after the FDA advisory notification, <i>Urology</i> , 85, 321-5, 2015	Not randomised controlled trial
Moehrer, B., Carey, M., Wilson, D., Laparoscopic colposuspension: A systematic review, <i>BJOG: An International Journal of Obstetrics and Gynaecology</i> , 110, 230-235, 2003	No additional randomised controlled trials identified
Moore, R. D., De Ridder, D., Kennelly, M. J., Two-year evaluation of the MiniArc in obese versus non-obese patients for treatment of stress urinary incontinence, <i>International Journal of Urology</i> , 20, 434-40, 2013	Not randomised controlled trial
Moore, R.D., Serels, S.R., Davila, G.W., Minimally invasive treatment for female stress urinary incontinence, <i>Expert Review of Obstetrics and Gynecology</i> , 3, 257-272, 2008	General non-systematic review
Morgan, D.M., Dunn, R.L., Fenner, D.E., Faerber, G., DeLancey, J.O.L., McGuire, E.J., Wei, J.T., Comparative Analysis of Urinary Incontinence Severity After Autologous Fascia Pubovaginal Sling, Pubovaginal Sling and Tension-Free Vaginal Tape, <i>Journal of Urology</i> , 177, 604-609, 2007	Not randomised controlled trial
Morton, H. C., Hilton, P., Urethral injury associated with minimally invasive mid-urethral sling procedures for the treatment of stress urinary incontinence: a case series and systematic literature search, 116, 1120-6, 2009	No additional randomised controlled trials identified
Mostafa, A., Lim, C. P., Hopper, L., Madhuvrata, P., Abdel-Fattah, M., Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications, <i>European Urology</i> , 65, 402-27, 2014	No additional randomised controlled trials identified
Murphy, M., van Raalte, H., Mercurio, E., Haff, R., Wiseman, B., Lucente, V. R., Incontinence-related quality of life and sexual function following the tension-free vaginal tape versus the "inside-out" tension-free vaginal tape obturator, <i>International Urogynecology Journal</i> , 19, 481-7, 2008	Not randomised controlled trial
Naidu, M., Thakar, R., Sultan, A. H., Outcomes of minimally invasive suburethral slings with and without concomitant pelvic organ prolapse surgery, <i>International Journal of Gynaecology &amp; Obstetrics</i> , 127, 69-72, 2014	Not randomised controlled trial
Nambiar, Arjun, Cody, June D, Jeffery, Stephen T, Aluko, Patricia, Single-incision sling operations for	No additional relevant articles

Study	Reason for Exclusion
urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	
Nerli,R.B., Kumar,A.G., Koura,A., Prabha,V., Alur,S.B., Transobturator vaginal tape in comparison to tension-free vaginal tape: A prospective trial with a minimum 12 months follow-up, Indian Journal of Urology, 25, 321-325, 2009	Not randomised controlled trial
Neuman,M., TVT and TVT-Obturator: comparison of two operative procedures, European Journal of Obstetrics, Gynecology, and Reproductive Biology, 131, 89-92, 2007	Not randomised controlled trial
Neuman,M., Perioperative complications and early follow-up with 100 TVT-SECUR procedures, Journal of Minimally Invasive Gynecology, 15, 480-484, 2008	Not randomised controlled trial
Neuman,M., Sosnovski,V., Goralnik,S., Diker,B., Bornstein,J., Comparison of two inside-out transobturator suburethral sling techniques for stress incontinence: Early postoperative thigh pain and 3-year outcomes, International Journal of Urology, 19, 1103-1107, 2012	Not randomised controlled trial
Neuman,M., Sosnovski,V., Kais,M., Ophir,E., Bornstein,J., Transobturator vs Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-Year Follow-up, Journal of Minimally Invasive Gynecology, 18, 769-773, 2011	Not randomised controlled trial
Nichols, D. H., The Mersilene mesh gauze-hammock for severe urinary stress incontinence, Obstetrics & Gynecology, 41, 88-93, 1973	Not randomised controlled trial
Nikolopoulos, K. I., Betschart, C., Doumouchtsis, S. K., The surgical management of recurrent stress urinary incontinence: a systematic review, Acta Obstetrica et Gynecologica Scandinavica, 94, 568-76, 2015	No extractable data in review
Norton, P. A., Nager, C. W., Chai, T. C., Mueller, E., Stoddard, A., Lowder, J., Varner, E., Lemack, G., Urinary Incontinence Treatment, Network, Risk factors for incomplete bladder emptying after midurethral sling, Urology, 82, 1038-41, 2013	Regression analysis of Richter et al. 2010/no relevant data
Novara,G., Artibani,W., Barber,M.D., Chapple,C.R., Costantini,E., Ficarra,V., Hilton,P., Nilsson,C.G., Waltregny,D., Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence, European Urology, 58, 218-238, 2010	No additional relevant RCTs identified
Novara,G., Ficarra,V., Boscolo-Berto,R., Secco,S., Cavalleri,S., Artibani,W., Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-analysis of Randomized Controlled Trials of Effectiveness, European Urology, 52, 663-679, 2007	Updated by Novara et al. 2010/No additional randomised controlled trials identified
Novara,G., Galfano,A., Boscolo-Berto,R., Secco,S., Cavalleri,S., Ficarra,V., Artibani,W., Complication Rates of Tension-Free Midurethral Slings in the Treatment of	Updated by Novara et al. 2010/No additional randomised controlled trials identified

Study	Reason for Exclusion
Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices, <i>European Urology</i> , 53, 288-309, 2008	
Novi, J.M., Mulvihill, B.H., Surgical intervention for stress urinary incontinence: comparison of midurethral sling procedures, <i>Journal of the American Osteopathic Association</i> , 108, 634-638, 2008	Not randomised controlled trial
Nwabine, N. J., Mittal, S., Legge, F., Outcome of midurethral tape Incontinence surgery in patients with and without urodynamically confirmed stress incontinence, <i>European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology</i> , 165, 357-60, 2012	Not randomised controlled trial
Nwabine, N.J., Mittal, S., Russell, M., Coleman, S., Long-term results of urinary stress incontinence treated with mid-urethral tape as a standalone operation or in combination with pelvic floor reconstruction, <i>Journal of Obstetrics and Gynaecology</i> , 32, 773-777, 2012	Not randomised controlled trial
Nyssonen, V., Talvensaari-Mattila, A., Santala, M., Intravaginal slingplasty sling is associated with increased risk of vaginal erosion, <i>Acta Obstetrica et Gynecologica Scandinavica</i> , 88, 1222-1226, 2009	Not randomised controlled trial
Ogah, J., Cody, D.J., Rogerson, L., Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: A short version cochrane review, <i>Neurourology and Urodynamics</i> , 30, 284-291, 2011	Updated by more recent Cochrane reviews/no additional relevant randomised controlled trials
Ogundipe, A., Rosenzweig, B.A., Karram, M.M., Blumenfeld, D., Bhatia, N.N., Modified suburethral sling procedure for treatment of recurrent or severe stress urinary incontinence, <i>Surgery, Gynecology and Obstetrics</i> , 175, 173-176, 1992	Not randomised controlled trial
Oliveira, R, Resende, A, Silva, C, Dinis, P, Cruz, F, Mini-arc for the treatment of female stress urinary incontinence: Long-term prospective evaluation by patient reported outcomes, <i>ISRN Urology</i> , 2014, 2014	Not randomised controlled trial
Onur, R., Singla, A., Kobashi, K. C., Comparison of solvent-dehydrated allograft dermis and autograft rectus fascia for pubovaginal sling: questionnaire-based analysis, <i>International Urology &amp; Nephrology/Int Urol Nephrol</i> , 40, 45-9, 2008	Not randomised controlled trial
Onwude, J.L., Stress incontinence, <i>Clinical Evidence</i> , 2009, 2009., -, 2009	No additional randomised controlled trials identified
O'Shea, R. T., Seman, E., Taylor, J., Laparoscopic Burch Colposuspension for Urinary Stress Incontinence, <i>Journal of the American Association of Gynecologic Laparoscopists</i> , 3, S36, 1996	Not randomised controlled trial
Pace, G., Guala, L., Paradiso, G.G., Vicentini, C., Tension-free vaginal and transobturator suburethral-tape positioning in stress urinary incontinence treatment: Effectiveness and management of complications, <i>Journal of Gynecologic Surgery</i> , 24, 135-144, 2008	Not randomised controlled trial

Study	Reason for Exclusion
Paick, S. H., Park, Y. J. P., Kim, A., Choi, W. S., Park, H. K., Kim, H. G., Long-term efficacy and safety of single-incision minislings excluding TVT-Secur versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systemic review and meta-analysis, <i>Journal of urology</i> , 199 (4 Supplement 1), e1010, 2018	Conference abstract
Palma, P. C. R., Riccetto, C. L. Z., Dambros, M., Herrmann, V., Thiel, M., Netto Jr, N. R., Tension-free vaginal tape (TVT): Minimally invasive technique for stress urinary incontinence (SUI), <i>International braz j urol</i> , 28, 458-463, 2002	Not randomised controlled trial
Palma, P., Riccetto, C., Herrmann, V., Dambros, M., Thiel, M., Bandiera, S., Netto, N. R., Jr., Transobturator SAFYRE sling is as effective as the transvaginal procedure, <i>International Urogynecology Journal</i> , 16, 487-491, 2005	Not randomised controlled trial
Palma, P. C., Dambros, M., Riccetto, C. Z., Thiel, M., Netto, N. R., Jr., The Ibero-American experience with a re-adjustable minimally invasive sling, <i>BJU International</i> , 95, 341-345, 2005	Not randomised controlled trial
Palomba, S., Falbo, A., Oppedisano, R., Torella, M., Materazzo, C., Maiorana, A., Tolino, A., Mastrantonio, P., La Sala, G. B., Alio, L., Colacurci, N., Zullo, F., A randomized controlled trial comparing three single-incision minislings for stress urinary incontinence, <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 25, 1333-1341, 2014	No relevant comparison
Palomba, S., Oppedisano, R., Falbo, A., Torella, M., Maiorana, A., Materazzo, C., Tolino, A., Mastrantonio, P., La Sala, G. B., Alio, L., Colacurci, N., Zullo, F., Sims Italian Group, Single-incision mini-slings versus retropubic tension-free vaginal tapes: a multicenter clinical trial, <i>Journal of Minimally Invasive Gynecology</i> , 21, 303-10, 2014	Not randomised controlled trial
Palva, K., Nilsson, C. G., Prevalence of urinary urgency symptoms decreases by mid-urethral sling procedures for treatment of stress incontinence, <i>International urogynecology journal and pelvic floor dysfunction</i> , 22, 1241-1247, 2011	Three-year follow up study of Laurikainen et al. 2014 examining prevalence of post-operative urge symptoms; more recent 5-year results reported in Laurikainen et al. 2014.
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, <i>International urogynecology journal and pelvic floor dysfunction</i> , 21, 1049-1055, 2010	Longer-term 5-year results reported in Laurikainen et al. 2014
Park, Y. J., Kim, D. Y., Randomized controlled study of MONARC versus tension-free vaginal tape obturator (TVT-O) in the treatment of female urinary incontinence: comparison of 3-year cure rates, <i>Korean Journal of Urology</i> , 53, 258-62, 2012	Compares 2 types of synthetic transobturator slings
Pereira, I., Valentim-Lourenco, A., Castro, C., Martins, I., Henriques, A., Ribeirinho, A. L., Incontinence surgery in obese women: comparative analysis of short- and	Not randomised controlled trial

Study	Reason for Exclusion
long-term outcomes with a transobturator sling, International Urogynecology Journal, 27, 247-53, 2016	
Pergialiotis, V., Mudiaga, Z., Perrea, D. N., Doumouchtsis, S. K., De novo overactive bladder following midurethral sling procedures: a systematic review of the literature and meta-analysis, International Urogynecology Journal, 05, 05, 2017	No additional relevant articles
Petri, E., Ashok, K., Comparison of late complications of retropubic and transobturator slings in stress urinary incontinence, International urogynecology journal and pelvic floor dysfunction, 23, 321-325, 2012	Not randomised controlled trial
Phe, V., Nguyen, K., Roupret, M., Cardot, V., Parra, J., Chartier-Kastler, E., A systematic review of the treatment for female stress urinary incontinence by ACT balloon placement (Uromedica, Irvine, CA, USA), World journal of urology, 32, 495-505, 2014	No randomised controlled trials identified
Pirincci, N., Kamberoglu, H., Kaya, C., Kaba, M., Gecit, I., Gunes, M., Ceylan, K., Karaman, M. I., Modified Raz operation backed with periurethral roll mesh in female stress urinary incontinence, European Review for Medical & Pharmacological Sciences, 16, 2006-13, 2012	Not randomised controlled trial
Pow-Sang, J.M., Lockhart, J.L., Suarez, A., Lansman, H., Politano, V.A., Female urinary incontinence: preoperative selection, surgical complications and results, Journal of Urology, 136, 831-833, 1986	Not randomised controlled trial
Pradhan, A., Jain, P., Latthe, P.M., Effectiveness of midurethral slings in recurrent stress urinary incontinence: a systematic review and meta-analysis, International Urogynecology Journal, 23, 831-841, 2012	No additional randomised controlled trials identified
Prezioso, D., Iacono, F., Di Lauro, G., Illiano, E., Romeo, G., Ruffo, A., Russo, N., Amato, B., Stress urinary incontinence: long-term results of laparoscopic Burch colposuspension, BMC surgery, 13 Suppl 2, S38, 2013	Article retracted from publication
Pugsley, H., Barbrook, C., Mayne, C.J., Tincello, D.G., Morbidity of incontinence surgery in women over 70 years old: a retrospective cohort study, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 786-790, 2005	Not randomised controlled trial
Pushkar, D., Kasyan, G., Gvozdev, M., Sosnowski, R., Analysis of 1,000 cases of synthetic midurethral slings used for treatment of female urinary incontinence - a single-center experience, Central European Journal of Urology, 64, 243-51, 2011	Not randomised controlled trial
Rapp, D.E., Govier, F.E., Kobashi, K.C., Outcomes following mid-urethral sling placement in patients with intrinsic sphincteric deficiency: comparison of Sparc and Monarc slings, International Braz J Urol, 35, 68-75, 2009	Not randomised controlled trial
Rardin, C. R., Kohli, N., Rosenblatt, P. L., Miklos, J. R., Moore, R., Strohsnitter, W. C., Tension-free vaginal tape: outcomes among women with primary versus recurrent stress urinary incontinence, Obstetrics & Gynecology, 100, 893-7, 2002	Not randomised controlled trial
Rechberger, T., Rzezniczuk, K., Skorupski, P., Adamiak, A., Tomaszewski, J., Baranowski, W., Jakowicki, J. A., A	No relevant comparison (compares 2 types of retropubic tape)

Study	Reason for Exclusion
randomized comparison between monofilament and multifilament tapes for stress incontinence surgery, International Urogynecology Journal, 14, 432-6, 2003	
Rechberger, T., Futyma, K., Jankiewicz, K., Adamiak, A., Bogusiewicz, M., Skorupski, P., Body mass index does not influence the outcome of anti-incontinence surgery among women whereas menopausal status and ageing do: a randomised trial, International Urogynecology Journal, 21, 801-806, 2010	All relevant results already reported in Rechberger et al. 2009
Rehman, Haroon, Bezerra, Carlos A, Bruschini, Homero, Cody, June D, Aluko, Patricia, Traditional suburethral sling operations for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	No additional relevant articles
Richter, H.E., Goode, P.S., Brubaker, L., Zyczynski, H., Stoddard, A.M., Dandreo, K.J., Norton, P.A., Two-year outcomes after surgery for stress urinary incontinence in older compared with younger women, Obstetrics and Gynecology, 112, 621-629, 2008	Not randomised controlled trial
Riemsma, R., Hagen, S., Kirschner-Hermanns, R., Norton, C., Wijk, H., Andersson, K. E., Chapple, C., Spinks, J., Wagg, A., Hutt, E., Misso, K., Deshpande, S., Kleijnen, J., Milsom, I., Can incontinence be cured? A systematic review of cure rates, BMC Medicine, 15 (1) (no pagination), 2017	No extractable data in review (Includes men in reporting of results)
Rodrigues, P., Hering, F., The role of a surgical learning curve in urethral obstruction following autologous fascial sling: A case-series study, International urogynecology journal and pelvic floor dysfunction, 23, 211-216, 2012	Not randomised controlled trial
Rodrigues, P., Hering, F., Meler, A., Campagnari, J.C., D'Imperio, M., Pubo-fascial versus vaginal sling operation for the treatment of stress urinary incontinence: A prospective study, Neurourology and Urodynamics, 23, 627-631, 2004	Not randomised controlled trial
Rodriguez, L. V., de Almeida, F., Dorey, F., Raz, S., Does Valsalva leak point pressure predict outcome after the distal urethral polypropylene sling? Role of urodynamics in the sling era, The Journal of urology, 172, 210-214, 2004	Not randomised controlled trial
Rogers, R.G., Lebkuchner, U., Kammerer-Doak, D.N., Thompson, P.K., Walters, M.D., Nygaard, I.E., Obesity and retropubic surgery for stress incontinence: is there really an increased risk of intraoperative complications?, American Journal of Obstetrics and Gynecology, 195, 1794-1798, 2006	Not randomised controlled trial
Rondini, C., Urzua, M., Garate, M., Monroy, M., Storme, O., Alvarez, J., Retropubic versus transobturator mid urethral sling and its impact on the overactive bladder component of mixed urinary incontinence: A prospective randomized study, International urogynecology journal, 28 (1 Supplement 1), S219-S220, 2017	Conference abstract
Rudnicki, M., von Bothmer-Ostling, K., Holstad, A., Magnusson, C., Majida, M., Merkel, C., Prien, J., Jakobsson, U., Teleman, P., Adjustable mini-sling compared with conventional mid-urethral slings in	Duplicate article

Study	Reason for Exclusion
women with urinary incontinence. A randomized controlled trial, <i>Acta Obstetrica et Gynecologica Scandinavica</i> , 96, 1347-1356, 2017	
Sabadell, J, Luis, Poza J, Sanchez-Iglesias, JI, Martinez-Gomez, X, Pla, F, Xercavins, J, Comparison of the outside-in and inside-out routes in the use of transobturator tapes for the treatment of stress urinary incontinence, <i>Progresos en obstetricia y ginecologia</i> , 51, 464-470, 2008	Not randomised controlled trial
Sabadell, J., Larrain, F., Gracia-Perez-Bonfils, A., Montero-Armengol, A., Salicru, S., Gil-Moreno, A., Poza, J. L., Comparative study of polyvinylidene fluoride and polypropylene suburethral slings in the treatment of female stress urinary incontinence, <i>Journal of obstetrics and gynaecology research</i> , 42, 291-296, 2016	Not randomised controlled trial
Samiee, H, Tavoli, Z, Ghanbari, Z, Poormand, Gh, Taslimi, Sh, Eslami, B, Tavoli, A, Treatment of urinary stress incontinence: laparoscopic Burch colposuspension versus transobturator tape procedure, <i>Tehran university medical journal</i> , 67, 629-636, 2009	Article not published in English
Schellart, R. P., Zwolsman, S. E., Lucot, J. P., de Ridder, D. J. M. K., Dijkgraaf, M. G. W., Roovers, J. P. W. R., A randomized, nonblinded extension study of single-incision versus transobturator midurethral sling in women with stress urinary incontinence, <i>International urogynecology journal</i> , 29, 37-44, 2018	Duplicate article
Schimpf, M. O., Rahn, D. D., Wheeler, T. L., Patel, M., White, A. B., Orejuela, F. J., El-Nashar, S. A., Margulies, R. U., Gleason, J. L., Aschkenazi, S. O., Mamik, M. M., Ward, R. M., Balk, E. M., Sung, V. W., Sling surgery for stress urinary incontinence in women: A systematic review and metaanalysis, <i>American journal of obstetrics and gynecology</i> , 211, 71.e1-71.e27, 2014	No additional randomised controlled trials identified
Schulte-Baukloh, H., Thalau, F., Sturzebecher, B., Knispel, H. H., Pubovaginal bone anchor fixation with polyethylene versus fascia lata slings in the treatment of female stress incontinence: sling material and processing are predominant factors in success, <i>Canadian Journal of Urology</i> , 12, 2581-2587, 2005	Not randomised controlled trial
Scotti, R. J., Angell, G., Flora, R., Greston, W. M., Antecedent history as a predictor of surgical cure of urgency symptoms in mixed incontinence, <i>Obstetrics and Gynecology</i> , 91, 51-54, 1998	Not randomised controlled trial
Seklehner, S., Laudano, M. A., Xie, D., Chughtai, B., Lee, R. K., A meta-analysis of the performance of retropubic mid urethral slings versus transobturator mid urethral slings, <i>Journal of Urology</i> , 193, 909-15, 2015	No additional randomised controlled trials identified
Serati, M, Braga, A, Athanasiou, S, Tommaselli, Ga, Caccia, G, Torella, M, Ghezzi, F, Salvatore, S, Tension-free Vaginal Tape-Obturator for Treatment of Pure Urodynamic Stress Urinary Incontinence: efficacy and Adverse Effects at 10-year Follow-up, <i>European urology</i> , 71, 674-679, 2017	Not randomised controlled trial

Study	Reason for Exclusion
Serati, M., Braga, A., Cattoni, E., Siesto, G., Cromi, A., Ghezzi, F., Salvatore, S., Transobturator vaginal tape for the treatment of stress urinary incontinence in elderly women without concomitant pelvic organ prolapse: is it effective and safe?, <i>European Journal of Obstetrics, Gynecology, &amp; Reproductive Biology</i> , 166, 107-10, 2013	Not randomised controlled trial
Serati, M., Ghezzi, F., Cattoni, E., Braga, A., Siesto, G., Torella, M., Cromi, A., Vitobello, D., Salvatore, S., Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up, <i>European Urology</i> , 61, 939-946, 2012	Not randomised controlled trial
Serati, M., Salvatore, S., Uccella, S., Zanirato, M., Cattoni, E., Nappi, R.E., Bolis, P., The impact of the mid-urethral slings for the treatment of stress urinary incontinence on female sexuality, <i>Journal of Sexual Medicine</i> , 6, 1534-1542, 2009	No additional randomised controlled trials identified
Shah, H. N., Badlani, G. H., Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review, <i>Indian Journal of Urology</i> , 28, 129-53, 2012	No additional randomised controlled trials identified
Sharifiaghdas, F., Surgical management of stress urinary incontinence, <i>Urology Journal</i> , 2, 175-82, 2005	General non-systematic review
Sharma, J. B., Tomar, S., Kumar, S., Seth, A., Sharma, A., Roy, K. K., Singh, N., Kumari, R., Kriplani, A., A comparative study of burch colposuspension and transobturator vaginal tape procedure in women with stress urinary incontinence, <i>International urogynecology journal</i> , 28 (1 Supplement 1), S218-S219, 2017	Conference abstract
Sharp, V.J., Bradley, C.S., Kreder, K.J., Incontinence surgery in the older woman, <i>Current Opinion in Urology</i> , 16, 224-228, 2006	General non-systematic review/No randomised controlled trials identified
Shaw, J. S., Jeppson, P. C., Rardin, C. R., Decreasing transobturator sling groin pain without decreasing efficacy using TVT-Abbrevio, <i>International Urogynecology Journal</i> , 26, 1369-72, 2015	Not randomised controlled trial
Shin, J.H., Lim, J.S., Song, K.H., Sul, C.K., Na, Y.G., Prospective study comparing the suprapubic arc (Sparc) procedure and the transobturator (Monarc) procedure for treating female stress urinary incontinence, <i>LUTS: Lower Urinary Tract Symptoms</i> , 2, 37-42, 2010	Not randomised controlled trial
Siddiqui, Z. A., Abboudi, H., Crawford, R., Shah, S., Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review, <i>International urogynecology journal</i> , 1-10, 2017	No additional relevant articles
Silva-Filho, A. L., Triginelli, S. A., Noviello, M. B., Santos-Filho, A. S., Pires, C. R., Cunha-Melo, J. R., Pubovaginal sling in the treatment of stress urinary incontinence for urethral hypermobility and intrinsic sphincteric deficiency, <i>International braz j urol</i> , 29, 540-4, 2003	Not randomised controlled trial
Sirls, L.T., Tennstedt, S., Lukacz, E., Rickey, L., Kraus, S.R., Markland, A.D., Kenton, K., Moalli, P., Hsu, Y., Huang, L., Stoddard, A.M., Condition-specific quality of life 24 months after retropubic and transobturator sling	Data not reported by treatment group/no relevant data

Study	Reason for Exclusion
surgery for stress urinary incontinence, Female Pelvic Medicine and Reconstructive Surgery, 18, 291-295, 2012	
Sivanesan,K., Sathiyathan,S., Ghani,R., Transobturator tension free vaginal tapes and bladder injury, Archives of Gynecology and Obstetrics, 279, 5-7, 2009	No additional randomised controlled trials identified
Skriapas, K., Poulakis, V., Dillenburg, W., De Vries, R., Witzsch, U., Melekos, M., Becht, E., Tension-free vaginal tape (TVT) in morbidly obese patients with severe urodynamic stress incontinence as last option treatment, European urology, 49, 544-550, 2006	Not randomised controlled trial
Smith, A. L., Karp, D. R., Aguilar, V. C., Davila, G. W., Repeat versus primary slings in patients with intrinsic sphincter deficiency, International Urogynecology Journal, 24, 963-8, 2013	Not randomised controlled trial
Sohbati, S., Salari, Z., Eftekhari, N., Comparison Between the Transobturator Tape Procedure and Anterior Colporrhaphy With the Kelly's Plication in the Treatment of Stress Urinary Incontinence: a Randomized Clinical Trial, Nephrourology MonthlyNephrourol Mon, 7, e32046, 2015	No relevant comparison
Song, P., Wen, Y., Huang, C., Wang, W., Yuan, N., Lu, Y., Wang, Q., Zhang, T., Wen, J., The efficacy and safety comparison of surgical treatments for stress urinary incontinence: A network meta-analysis, Neurourology and urodynamics, 37, 1199-1211, 2018	Network meta-analysis restricting analysis to only TVT-Secur and Ajust brands of SIMS; the NMAs undertaken by [redacted] are more comprehensive and inclusive
Song, Ph, Hyun, Ch, Lim, Hs, Jung, Hc, Five-year outcomes of the IRIS procedure for the treatment of female stress urinary incontinence: comparison with the TVT procedure, Korean Journal of Urology, 50, 767-773, 2009	Not randomised controlled trial
Spencer, J. R., O'Connor, V. J., Jr., Schaeffer, A. J., A comparison of endoscopic suspension of the vesical neck with suprapubic vesicourethropexy for treatment of stress urinary incontinence, Journal of Urology, 137, 411-5, 1987	Not randomised controlled trial
Stav, K., Dwyer, P. L., Rosamilia, A., Schierlitz, L., Lim, Y. N., Chao, F., De Souza, A., Thomas, E., Murray, C., Conway, C., Lee, J., Repeat Synthetic Mid Urethral Sling Procedure for Women With Recurrent Stress Urinary Incontinence, Journal of Urology, 183, 241-246, 2010	Not randomised controlled trial
Stav,K., Dwyer,P.L., Rosamilia,A., Schierlitz,L., Lim,Y.N., Lee,J., Midurethral sling procedures for stress urinary incontinence in women over 80 years, Neurourology and Urodynamics, 29, 1262-1266, 2010	Not randomised controlled trial
Sun, M. J., Sun, R., Li, Y. I., A comparative study of a single-incision sling and a transobturator sling: clinical efficacy and urodynamic changes, International Urogynecology Journal, 24, 823-9, 2013	Not randomised controlled trial
Sun, X., Yang, Q., Sun, F., Shi, Q., Comparison between the retropubic and transobturator approaches in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of effectiveness	No additional randomised controlled trials identified

Study	Reason for Exclusion
and complications, International Braz J Urol, 41, 220-9, 2015	
Sung, V. W., Schleinitz, M. D., Rardin, C. R., Ward, R. M., Myers, D. L., Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis, American journal of obstetrics and gynecology, 197, 3-11, 2007	No additional randomised controlled trials identified
Surkont, G., Wlazlak, E., Petri, E., Suzin, J., Standardized modified colposuspension - Midterm results of prospective studies in one centre, Annals of Agricultural and Environmental Medicine, 22, 293-296, 2015	Not randomised controlled trial
Suskind, A. M., Clemens, J. Q., Dunn, R. L., Zhang, Y., Stoffel, J. T., Hollenbeck, B. K., Effectiveness of mesh compared with nonmesh sling surgery in Medicare beneficiaries, Obstetrics & Gynecology, 122, 546-52, 2013	Not randomised controlled trial
Swartz, M., Ching, C., Gill, B., Li, J., Rackley, R., Vasavada, S., Goldman, H. B., Risk of infection after midurethral synthetic sling surgery: are postoperative antibiotics necessary?, Urology, 75, 1305-1308, 2010	Not randomised controlled trial
Szell, N., Komisaruk, B., Goldstein, S. W., Qu, X. H., Shaw, M., Goldstein, I., A Meta-Analysis Detailing Overall Sexual Function and Orgasmic Function in Women Undergoing Midurethral Sling Surgery for Stress Incontinence, Sexual Medicine, 5, e84-e93, 2017	No additional relevant articles
Szell, N., Qu, H., Shaw, M., Goldstein, S. W., Komisaruk, B. R., Rubin, R. S., Winter, A. G., Goldstein, I., Anterior vaginal wall periurethral tissue: An extensive literature review and metaanalysis of orgasmic and overall sexual function post mid-urethral sling surgery, Journal of Sexual Medicine, 14 (2 Supplement 1), e93-e94, 2017	Conference abstract
Tahseen, S., Reid, P., Effect of transobturator tape on overactive bladder symptoms and urge urinary incontinence in women with mixed urinary incontinence, Obstetrics and Gynecology, 113, 617-623, 2009	Not randomised controlled trial
Tammaa, A., Aigmuller, T., Hanzal, E., Umek, W., Kropshofer, S., Lang, P. F. J., Ralph, G., Riss, P., Koelle, D., Jundt, K., Tamussino, K., Bjelic-Radisic, V., Retropubic versus transobturator tension-free vaginal tape (TVT vs TVT-O): Five-year results of the Austrian randomized trial, Neurourology and urodynamics, 37, 331-338, 2018	Duplicate article
Tan, E., Tekkis, P. P., Cornish, J., Teoh, T. G., Darzi, A. W., Khullar, V., Laparoscopic versus open colposuspension for urodynamic stress incontinence, Neurourology and Urodynamics, 26, 158-169, 2007	No additional randomised controlled trials identified
Tan, P. F., Yang, L. L., Ou, R. B., Tang, P., Yang, W. J., Huang, J. B., Wei, W., Wei, X. H., Wang, B., Xie, K. J., Effectiveness and complication rates of tension-free vaginal tape, transobturator tape, and tension-free vaginal tape-obturator in the treatment of female stress	No additional randomised controlled trials identified

Study	Reason for Exclusion
urinary incontinence in a medium- to long-term follow up, Saudi Medical Journal, 35, 20-32, 2014	
Tantanasis, T., Daniilidis, A., Pantelis, A., Chatzis, P., Vrachnis, N., Minimally invasive techniques for female stress urinary incontinence, how, why, when, Archives of Gynecology & Obstetrics, 288, 995-1001, 2013	No extractable data in review
Tchey,D.U., Kim,W.T., Kim,Y.J., Yun,S.J., Lee,S.C., Kim,W.J., Influence of Obesity on Short-term Surgical Outcome of the Transobturator Tape Procedure in Patients with Stress Urinary Incontinence, International neurourology journal, 14, 13-19, 2010	Not randomised controlled trial
Tellez Martinez-Fornes, M., Fernandez Perez, C., Fouz Lopez, C., Fernandez Lucas, C., Borrego Hernando, J., A three year follow-up of a prospective open randomized trial to compare tension-free vaginal tape with Burch colposuspension for treatment of female stress urinary incontinence, Actas urologicas espanolas, 33, 1088-96, 2009	Article not published in English
Tennstedt, S. L., Litman, H. J., Zimmern, P., Ghetti, C., Kusek, J. W., Nager, C. W., Mueller, E. R., Kraus, S. R., Varner, E., Urinary Incontinence Treatment, Network, Quality of life after surgery for stress incontinence, International Urogynecology Journal, 19, 1631-8, 2008	No relevant data/uses quality of life measure (IIQ) not listed in protocol
ter Meulen, H., van Kerrebroeck, E., Injection therapy for stress urinary incontinence in adult women, Expert Review of Medical DevicesExpert Rev Med Devices, 1, 205-13, 2004	No additional randomised controlled trials identified
Thakar, R., Stanton, S., Prodigalidad, L., Den Boon, J., Secondary colposuspension: Results of a prospective study from a tertiary referral centre, BJOG: An International Journal of Obstetrics and Gynaecology, 109, 1115-1120, 2002	Not randomised controlled trial
Thomas, T. N., Siff, L. N., Jelovsek, J. E., Barber, M., Surgical Pain after Transobturator and Retropubic Midurethral Sling Placement, Obstetrics and gynecology, 130, 118-125, 2017	Not randomised controlled trial
Thomas, T. N., Siff, L. N., Jelovsek, J. E., Barber, M. D., Surgical pain after transobturator versus retropubic midurethral sling-a secondary analysis of the tomus trial, Female Pelvic Medicine and Reconstructive Surgery, 22 (5 Supplement 1), S4-S5, 2016	Conference abstract
Thubert, T., Canel, V., Vinchant, M., Wigniolle, I., Fernandez, H., Deffieux, X., Bladder injury and success rates following retropubic mid-urethral sling: TVT EXACTTM versus TVTTM, European Journal of Obstetrics, Gynecology, & Reproductive BiologyEur J Obstet Gynecol Reprod Biol, 198, 78-83, 2016	Not randomised controlled trial
Tommaselli, G. A., Di Carlo, C., Formisano, C., Fabozzi, A., Nappi, C., Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis, International Urogynecology Journal, 26, 1253-68, 2015	No additional relevant articles

Study	Reason for Exclusion
Tong, JI, Zhu, L, Lang, Jh, Effects of laparoscopic Burch colposuspension and tension-free vaginal tape in treatment of female stress urinary incontinence: a comparative study, Zhonghua yi xue za zhi, 88, 3192-3194, 2008	Not randomised controlled trial
Tooze-Hobson, P., Al-Singary, W., Fynes, M., Tegerstedt, G., Lose, G., Two-year follow-up of an open-label multicenter study of polyacrylamide hydrogel (Bulkamid) for female stress and stress-predominant mixed incontinence, International Urogynecology Journal, 23, 1373-8, 2012	Not randomised controlled trial
Tooze-Hobson, P., Devani, P., Pick, J., Moran, P. A., Assassa, P., Burton, C., Does age affect the outcome of suburethral tape surgery? The importance of national registries in answering bigger questions, International Urogynecology Journal, 27, 1541-5, 2016	Not randomised controlled trial
Tseng, L.H., Wang, A.C., Lin, Y.H., Li, S.J., Ko, Y.J., Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women, International Urogynecology Journal, 16, 230-235, 2005	No relevant comparison (compares 2 types of retropubic tape)
Tutolo, M., De Ridder, D. J., Montorsi, F., Castagna, G., Deprest, J., Schellart, R. P., Ammirati, E., Van Der Aa, F., A minimum of 1-year follow-up for MiniArc single incision slings compared to Monarc transobturator slings: An analysis to evaluate durability of continence and medium-term outcomes, Neurourology & Urodynamics, 36, 803-807, 2017	Not randomised controlled trial
Tuygun, C, Bakirtas, H, Eroglu, M, Alisir, I, Zengin, K, Imamoglu, A, Comparison of two different surgical approaches in the treatment of stress urinary incontinence: open and laparoscopic burch colposuspension, Turk uroloji dergisi, 32, 248-253, 2006	Article published in Turkish
Ulmsten, U., Falconer, C., Johnson, P., Jomaa, M., Lanner, L., Nilsson, C.G., Olsson, I., A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence, International urogynecology journal and pelvic floor dysfunction, 9, 210-213, 1998	Not randomised controlled trial
Ulrich, D., Bjelic-Radisic, V., Grabner, K., Avian, A., Trutnovsky, G., Tamussino, K., Aigmuller, T., Objective outcome and quality-of-life assessment in women with repeat incontinence surgery, Neurourology and urodynamics, 36, 1543-1549, 2017	Not randomised controlled trial
Ulubay, M., Ozturk, M., Keskin, U., Fidan, U., Firatligil, F. B., Alanbay, I., Yenen, M. C., Long Term Patient Satisfaction of Burch Colposuspension with or Without Concomitant Total Abdominal Hysterectomy, Journal of Clinical and Diagnostic Research JCDRJ Clin Diagn Res, 9, QC01-3, 2015	Not randomised controlled trial
Valpas, A, Kivela, A, Penttinen, J, Kauko, M, Kujansuu, E, Tomas, E, Haarala, M, Meltomaa, S, Nilsson, Cg, Intra-operative and immediate post-operative results comparing tensionfree vaginal tape (TVT) and laparoscopic colposuspension (LC) in the treatment of female stress urinary incontinence (SUI) - A randomized	Article not available

Study	Reason for Exclusion
clinical trial (Preliminary results), Proceedings of the 10th congress of the european society for gynaecological endoscopy, proceedings, 21-24 nov 2001, lisbon, portugal, 355-358, 2001	
Valpas, A., Ala-Nissila, S., Tomas, E., Nilsson, C. G., TVT versus laparoscopic mesh colposuspension: 5-year follow-up results of a randomized clinical trial, International urogynecology journal and pelvic floor dysfunction, 26, 57-63, 2014	Uses mesh and staples in laparoscopic colposuspension arm, which is not standard UK practice
Valpas, A., Kivela, A., Penttinen, J., Kauko, M., Kujansuu, E., Tomas, E., Haarala, M., Meltomaa, S., Nilsson, C. K., Tension-free vaginal tape and laparoscopic mesh colposuspension in the treatment of stress urinary incontinence: Immediate outcome and complications - A randomized clinical trial, Acta Obstetricia et Gynecologica Scandinavica, 82, 665-671, 2003	Uses mesh and staples in laparoscopic colposuspension arm, which is not standard UK practice
Valpas, A., Kivela, A., Penttinen, J., Kujansuu, E., Haarala, M., Nilsson, C. G., Tension-free vaginal tape and laparoscopic mesh colposuspension for stress urinary incontinence, Obstetrics and Gynecology, 104, 42-49, 2004	Uses mesh and staples in laparoscopic colposuspension arm, which is not standard UK practice
Valpas, A., Nilsson, C. G., Tension-free vaginal tape procedure and laparoscopic colposuspension in the treatment of stress urinary incontinence, Current Opinion in Obstetrics and Gynecology, 16, 319-323, 2004	General non-systematic narrative review
Valpas, A., Rissanen, P., Kujansuu, E., Nilsson, C. G., A cost-effectiveness analysis of tension-free vaginal tape versus laparoscopic mesh colposuspension for primary female stress incontinence, Acta Obstetricia et Gynecologica Scandinavica, 85, 1485-1490, 2006	Clinical results already reported in Valpas et al. 2003/2004.
Vianello, A., Costantini, E., Del Zingaro, M., Porena, M., Mini-invasive techniques for the treatment of female stress urinary incontinence, Minerva Ginecologica, 59, 557-69, 2007	No additional relevant RCTs identified
Viseshsindh, W., Waikakul, W., Siripornpinyo, N., Kochakarn, W., Roongruangsilp, U., Viseshsindh, V., A randomized controlled trial of Pubovaginal sling versus vaginal wall sling for stress urinary incontinence, Journal of the Medical Association of Thailand, 86, 308-315, 2003	Compares 2 types of biological sling
Vries, Am, Breda, Hmk, Fernandes, Jg, Venema, Pi, Heesakkers, Jpfa, Para-Urethral Injections with Urolastic for Treatment of Female Stress Urinary Incontinence: subjective Improvement and Safety, Urologia internationalis, (no pagination), 2017	Not randomised controlled trial
Wallwiener, D., Grischke, E. M., Rimbach, S., Maleika, A., Bastert, G., Endoscopic retropubic colposuspension: "Retziusscopy" versus laparoscopy--a reasonable enlargement of the operative spectrum in the management of recurrent stress incontinence?, Endoscopic Surgery and Allied Technologies, 3, 115-118, 1995	Article published in German

Study	Reason for Exclusion
Walsh,C.A., TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months, <i>BJU International</i> , 108, 652-657, 2011	No additional randomised controlled trials identified
Waltregny, D., de Leval, J., New surgical technique for treatment of stress urinary incontinence TVT-ABBREVO from development to clinical experience, <i>Surgical Technology International</i> , 22, 149-57, 2012	No relevant comparison (compares 2 types of TVT-O, original and 12cm version)
Waltregny, D., Reul, O., Mathantu, B., Gaspar, Y., Bonnet, P., de Leval, J., Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum followup, <i>Journal of Urology</i> , 175, 2191-5, 2006	Not randomised controlled trial
Wang, Wy, Zhu, L, Lang, Jh, Li, B, A prospective randomized trial of comparing the clinical outcome of tension-free vaginal tape and transobturator tape for stress urinary incontinence, <i>Zhonghua yi xue za zhi</i> , 91, 898-901, 2011	Article not published in English
Wang,A.C., Lee,L.Y., Lin,C.T., Chen,J.R., A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: A prospective case-controlled pilot study, <i>American Journal of Obstetrics and Gynecology</i> , 191, 1868-1874, 2004	Not randomised controlled trial
Wehbe,S.A., Kellogg,S., Whitmore,K., Urogenital Complaints and Female Sexual Dysfunction (Part 2) (CME), <i>Journal of Sexual Medicine</i> , 7, 2305-2317, 2010	No additional randomised controlled trials identified
Wilson,W.J., Winters,J.C., Is there still a place for the pubovaginal sling at the bladder neck in the era of the midurethral sling?, <i>Current Urology Reports</i> , 6, 335-339, 2005	No randomised controlled trials identified
Winckler,J.A., Ramos,J.G., Dalmolin,B.M., Winckler,D.C., Doring,M., Comparative study of polypropylene and aponeurotic slings in the treatment of female urinary incontinence, <i>International Braz J Urol</i> , 36, 339-347, 2010	Not randomised controlled trial
Wu,J.Y., He,H.C., Chen,S.W., Jin,X.D., Zhou,Y.X., Surgical therapies of female stress urinary incontinence: experience in 228 cases, <i>International Urogynecology Journal</i> , 21, 645-649, 2010	Not randomised controlled trial
Yang, M G, Zhao, X K, Wu, Z P, Xiao, N, Lv, C, Hou, Y, Effectiveness and safety of tension-free vaginal tapes versus Burch colposuspension for female stress urinary incontinence: a systematic review and meta-analyses of randomized controlled trials (Provisional abstract), <i>Chinese Journal of Evidence-Based Medicine</i> , 8, 237-243, 2008	Article published in Chinese
Yang,X., Jiang,M., Chen,X., Tong,X., Li,H., Qiu,J., Shao,L., TVT-O versus TVT for the treatment of SUI: a non-inferiority study, <i>International Urogynecology Journal</i> , 23, 99-104, 2012	Not randomised controlled study
Yasa, C., Gungor Ugurlucan, F., Dural, O., Yumru, H., Gunaydin, C., Yalcin, O., Transobturator Tape Operation for the Treatment of Stress Urinary Incontinence in	Not randomised controlled trial

Study	Reason for Exclusion
Postmenopausal Women Aged Over 65Years, Luts, 06, 06, 2017	
Yavuzcan, A., Yildiz, G., Ustun, Y., Altintas, R., Caglar, M., Yildiz, P., Sert, H., Dilbaz, S., Kumru, S., Influence of age, menopause, pelvic muscle exercises, urethral hypermobility and concomitant surgery on the outcomes after the transobturator tape procedure (factors effecting TOT outcomes), <i>Przegląd Menopauzalny</i> , 17, 105-110, 2013	Not randomised controlled trial
Yonguc, T., Degirmenci, T., Bozkurt, I. H., Aydogdu, O., Gunlusoy, B., Sen, V., Polat, S., Effectiveness of Transobturator Tape Procedure in Obese and Severely Obese Women: 3-Year Follow-up, <i>Urology</i> , 86, 244-8, 2015	Not randomised controlled trial
Yonguc, T., Gunlusoy, B., Degirmenci, T., Kozacioglu, Z., Bozkurt, I. H., Arslan, B., Minareci, S., Yilmaz, Y., Are the outcomes of transobturator tape procedure for female stress urinary incontinence durable in long-term follow-up?, <i>International Urology &amp; Nephrology</i> , 46, 1295-300, 2014	Not randomised controlled trial
Yurteri-Kaplan, L. A., Gutman, R. E., The use of biological materials in urogynecologic reconstruction: a systematic review, <i>Plastic &amp; Reconstructive Surgery</i> , 130, 242S-53S, 2012	No additional randomised controlled trials identified
Zengin, K., Kara, M., Tanik, S., Sertcelik, M. N., Eraslan, A., Comparison of Transobturator Tape and Mini-Sling Tissue Fixation in Female Patients Who Had Stress Urinary Incontinence, <i>Advances in Clinical &amp; Experimental Medicine</i> , 24, 851-5, 2015	Not randomised controlled trial
Zhang, P., Fan, B., Zhang, P., Han, H., Xu, Y., Wang, B., Zhang, X., Meta-analysis of female stress urinary incontinence treatments with adjustable single-incision mini-slings and transobturator tension-free vaginal tape surgeries, <i>BMC Urology</i> , 15, 64, 2015	No additional relevant articles
Zhang, Y., Jiang, M., Tong, X.W., Fan, B.Z., Li, H.F., Chen, X.L., The comparison of an inexpensive-modified transobturator vaginal tape versus TVT-O procedure for the surgical treatment of female stress urinary incontinence, <i>Taiwanese Journal of Obstetrics and Gynecology</i> , 50, 318-321, 2011	No relevant comparison (compares 2 types of transobturator tape)
Zhou, Q, Song, Yf, Chen, J, Qiu, LI, Yuan, Xd, Meta-analysis of clinical efficacy of TVT-S versus TVT-O/TOT in the treatment of stress urinary incontinence (Provisional abstract), <i>National Medical Journal of China</i> , 92, 2632-2635, 2012	Article not published in English
Zhu, L, Lang, J, Liu, Z, Comparison of different surgical procedures for urinary stress incontinence, <i>Zhonghua yi xue za zhi</i> , 78, 601-603, 1998	Published in Chinese
Zhu, Y.F., Gao, G.L., He, L.S., Tang, J., Chen, Q.K., Inside out transobturator vaginal tape versus tension-free vaginal tape for primary female stress urinary incontinence: Meta-analysis of randomized controlled trials, <i>Chinese Medical Journal</i> , 125, 1316-1321, 2012	Article published in Chinese

Study	Reason for Exclusion
Zyczynski, H. M., Albo, M. E., Goldman, H. B., Wai, C. Y., Sirls, L. T., Brubaker, L., Norton, P., Varner, R. E., Carmel, M., Kim, H. Y., Change in Overactive Bladder Symptoms after Surgery for Stress Urinary Incontinence in Women, <i>Obstetrics and gynecology</i> , 126, 423-430, 2015	Not randomised controlled trial

### Economic studies

No economic evidence was identified for this review question. See supplementary material D for further information.

### Excluded studies for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures) compared to pelvic floor muscle training?

**Table 40: Clinical studies with reasons for exclusion**

Study	Reason for Exclusion
A randomised controlled trial comparing the cost-effectiveness of pelvic floor muscle exercise versus the TVT (O) procedure for female moderate to severe stress urinary incontinence (Project record), <i>Health Technology Assessment Database</i> , 2007	Unable to obtain full text article
Allahdin, S., Kambhampati, L., Review Stress urinary incontinence in continent primigravidas, <i>Journal of Obstetrics and Gynaecology</i> , 32, 2-5, 2012	Non-systematic review
Al-Singary, W., Arya, M., Patel, H. R. H., Tension-free vaginal tape: Avoiding failure, <i>International Journal of Clinical Practice</i> , 59, 522-525, 2005	The comparator was not relevant to the protocol
Ames, D., Hastie, I. R., Urinary incontinence, <i>Postgraduate Medical Journal</i> <i>Postgrad Med J</i> , 71, 195-7, 1995	Non-systematic review
Anonymous,, Urinary incontinence in women, <i>Obstetrics and Gynecology</i> , 126, e66-e81, 2015	Non-systematic review
Aoki, Y., Brown, H. W., Brubaker, L., Cornu, J. N., Daly, J. O., Cartwright, R., Urinary incontinence in women, <i>Nature Reviews Disease Primers</i> , 3 (no pagination), 2017	Non-systematic review
Bakali, Evangelia, Buckley, Brian S, Hilton, Paul, Tincello, Douglas G, Treatment of recurrent stress urinary incontinence after failed minimally invasive synthetic suburethral tape surgery in women, <i>Cochrane Database of Systematic Reviews</i> , 2013	Systematic review - references checked for inclusion
Bandukwala, N. Q., Gousse, A. E., Mixed Urinary Incontinence: What First?, <i>Current Urology Reports</i> , 16, 2015	Non-systematic review
Cameron, A.P., Haraway, A.M., The treatment of female stress urinary incontinence: An evidenced-based review, <i>Open Access Journal of Urology</i> , 3, 109-120, 2011	Non-systematic review

Study	Reason for Exclusion
Capobianco, G., Madonia, M., Morelli, S., Dessole, F., De Vita, D., Cherchi, P. L., Dessole, S., Management of female stress urinary incontinence: A care pathway and update, <i>Maturitas</i> , 109, 32-38, 2018	Systematic review - references checked for inclusion
Chapple, C.R., Wein, A.J., Brubaker, L., Dmochowski, R., Pons, M.E., Haab, F., Hill, S., Stress incontinence injection therapy: What is best for our patients?, <i>European Urology</i> , 48, 552-565, 2005	Systematic review - references checked for inclusion
Corcos, J., Gajewski, J., Heritz, D., Patrick, A., Reid, I., Schick, E., Stothers, L., Canadian Urological Association guidelines on urinary incontinence, <i>The Canadian journal of urology</i> , 13, 3127-3138, 2006	Guideline - references checked for inclusion
Dannecker, C., Wolf, V., Raab, R., Hepp, H., Anthuber, C., EMG-biofeedback assisted pelvic floor muscle training is an effective therapy of stress urinary or mixed incontinence: A 7-year experience with 390 patients, <i>Archives of Gynecology and Obstetrics</i> , 273, 93-97, 2005	Intervention did not meet the inclusion criteria
Davila, G. W., Nonsurgical outpatient therapies for the management of female stress urinary incontinence: long-term effectiveness and durability, <i>Advances in Urology Adv</i> , 2011, 176498, 2011	The comparator was not relevant to the protocol
Duckett, J. R. A., The use of periurethral injectables in the treatment of genuine stress incontinence, <i>British Journal of Obstetrics and Gynaecology</i> , 105, 390-396, 1998	Non-systematic review
Duckett, J., Baranowski, A., Pain after suburethral sling insertion for urinary stress incontinence, <i>International Urogynecology Journal</i> , 24, 195-201, 2013	Non-systematic review
Ellington, D. R., Ballard, A. C., Surgical Treatment and Outcomes for the Management of Stress Urinary Incontinence in the Older Woman, <i>Current Geriatrics Reports</i> , 6, 90-97, 2017	Non-systematic review
Fischer-Rasmussen, W., Treatment of stress urinary incontinence, <i>Annals of Medicine</i> , 22, 455-465, 1990	Non-systematic review
Fritel, X., Dumoulin, C., Incontinence: Stress urinary incontinence treatment - Surgery first?, <i>Nature Reviews Urology</i> , 11, 10-11, 2014	Non-systematic review
Gillera, J.P., Zimmern, P., An evidence-based approach to the evaluation and management of stress incontinence in women, <i>Current Opinion in Urology</i> , 15, 236-243, 2005	Non-systematic review
Glazener, Cathryn Ma, Cooper, Kevin, Mashayekhi, Atefeh, Bladder neck needle suspension for urinary incontinence in women, <i>Cochrane Database of Systematic Reviews</i> , 2017	Systematic review - references checked for inclusion
Goel, M.C., Roberts, J.G., Dynamic rectus abdominis tendon colposuspension for female stress urinary incontinence: A new procedure and its follow-up, <i>Urologia Internationalis</i> , 71, 45-50, 2003	The comparator was not relevant to the protocol
Gomelsky, A., Coco, C. T., Dmochowski, R. R., Urinary incontinence in women: non-pharmacologic approaches and newer pharmacotherapies, <i>Minerva Medica</i> , 105, 263-74, 2014	Non-systematic review
Gomelsky, A., Dmochowski, R. R., Treatment of mixed urinary incontinence, <i>Central European Journal of Urology</i> , 64, 120-6, 2011	Non-systematic data extraction

Study	Reason for Exclusion
Gomelsky,A., Dmochowski,R.R., Treatment of mixed urinary incontinence in women, Current Opinion in Obstetrics and Gynecology, 23, 371-375, 2011	Non-systematic review
Greer, J. A., Arya, L. A., Smith, A. L., Urinary Incontinence: Diagnosis and Treatment in the Elderly, Current Translational Geriatrics and Gerontology Reports, 2, 66-75, 2013	Non-systematic review
Gungor Ugurlucan, F., Yasa, C., Erturk, E., Demir, O., Capan, N., Yalcin, O., What happens to coital incontinence after treatment? The effect of conservative treatment and surgery on coital incontinence and quality of life, Neurourology and Urodynamics, 36, S269-S270, 2017	Conference abstract
Hamed, A. H., Bekarma, H., Rewhorn, M., Nair, B., Transurethral injections of polyacrylamide hydrogel (Bulkamid) for treatment of female stress urinary incontinence (SUI) in DGH settings, European Urology, Supplements, 16 (3), e1508, 2017	Conference abstract
Holroyd-Leduc, J. M., Straus, S. E., Management of Urinary Incontinence in Women: Scientific Review, Journal of the American Medical Association, 291, 986-995, 2004	The intervention was not relevant to the protocol
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
Keegan, P. E., Atiemo, K., Cody, J., McClinton, S., Pickard, R., Periurethral injection therapy for urinary incontinence in women, Cochrane Database of Systematic Reviews, CD003881, 2007	Systematic review - reference checked for inclusion
Kirchin, Vivienne, Page, Tobias, Keegan, Phil E, Atiemo, Kofi Om, Cody, June D, McClinton, Samuel, Aluko, Patricia, Urethral injection therapy for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	The comparator was not relevant to the protocol
Klarskov, P, Belving, D, Bischoff, N, Dorph, S, Gerstenberg, T, Hald, T, Pelvic floor exercise versus surgery for female urinary stress incontinence: preliminary results, Proceedings of the international continence society (ICS), 14th annual meeting, 1984 sep 13-15, innsbruck, austria, 159-161, 1984	Conference abstract
Klarskov, P., Kroyer, K., Kromann, B., Maegaard, E., Long term results of pelvic floor training and surgery for female genuine stress incontinence, Neurourology and Urodynamics, 8, 357-359, 1989	Conference abstract
Klarskov, P., Vedel Jepsen, P., Dorph, S., Reliability of voiding colpo-cysto-urethrography in female urinary stress incontinence before and after treatment, Acta Radiologica, 29, 685-688, 1988	The intervention and comparator were not relevant to the protocol
Kobashi, K. C., Kobashi, L. I., Female stress urinary incontinence: Review of the current literature, Minerva Ginecologica, 58, 265-282, 2006	Non-systematic review
Kurien, A., Narang, S., Han, H. C., Tension-free vaginal tape-Abbrevio procedure for female stress urinary	No relevant comparator

Study	Reason for Exclusion
incontinence: a prospective analysis over 22 months, Singapore Medical Journal, 58, 338-342, 2017	
Labrie, J, Berghmans, Lcm, Fischer, K, Lagro-Janssen, Alm, Vaart, Ch, Surgery or physiotherapy for urinary stress incontinence; What is the preferred treatment in women?, Nederlands tijdschrift voor geneeskunde, 158, 2014	Unable to obtain full text article
Labrie, J., Fischer, K., van der Vaart, C. H., Health-related quality of life. The effect of pelvic floor muscle training and midurethral sling surgery: a systematic review, International Urogynecology Journal, 23, 1155-62, 2012	Study design did not meet the inclusion criteria - non-comparative data
Lapitan, M. C., Cody, J. D., Grant, A., Open retropubic colposuspension for urinary incontinence in women: a short version Cochrane review, Neurourology & Urodynamics, 28, 472-80, 2009	Systematic review - references checked for inclusion
Lapitan, Marie Carmela M, Cody, June D, Mashayekhi, Atefeh, Open retropubic colposuspension for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	No relevant comparator
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	Guideline - references checked for inclusion
Lau, H. H., Su, T. H., Huang, W. C., Hsieh, C. H., Su, C. H., Chang, R. C., A prospective study of transobturator tape as treatment for stress urinary incontinence after transvaginal mesh repair, International Urogynecology Journal, 24, 1639-44, 2013	No relevant comparator
Markun, S, Stress incontinence: first pelvic floor training or direct surgery?, PraxisPraxis (Bern 1994), 103, 173-174, 2014	The study was not reported in English
Min, L, Zhao, X, Comparison of the efficacy and safety between TVT-O and TVT-O with biofeedback pelvic floor electrical stimulation on female stress urinary incontinence, Sichuan da xue xue bao. Yi xue ban [Journal of Sichuan University. Medical science edition], 46, 149-152, 2015	The study was not reported in English
Mischinger, J., Amend, B., Reisenauer, C., Bedke, J., Naumann, G., Germann, M., Kruck, S., Arenas Desilva, L. F., Wallwiener, H., Koelbl, H., Nitti, V., Sievert, K. D., Different surgical approaches for stress urinary incontinence in women, Minerva Ginecologica, 65, 21-8, 2013	Systematic review - references checked for inclusion
Morsi, S, Hussein, H, Yehia, Abdelaziz A, Habib, E, Abozamel, A, Torad, H, Abdelrasoul, M, Elghamarawy, H, Abdelazeim, M, Different approaches for management of female pelvic floor dysfunction: a randomized study of 53 cases, European urology, supplements. Conference: 32nd annual european association of urology congress, EAU 2017. United kingdom, 16, e1744-e1745, 2017	Conference abstract
Myers, D. L., Female mixed urinary incontinence a clinical review, JAMA - Journal of the American Medical Association, 311, 2007-2014, 2014	No relevant comparator
Onwude, J.L., Stress incontinence, Clinical Evidence, 2009, 2009., -, 2009	Systematic review - references checked for inclusion

Study	Reason for Exclusion
Ordorica,R., Rodriguez,A.R., Coste-Delvecchio,F., Hoffman,M., Lockhart,J., Disabling complications with slings for managing female stress urinary incontinence, BJU International, 102, 333-336, 2008	The comparator was not relevant to the protocol
Rehman, H., Bezerra, C. A., Bruschini, H., Cody, J. D., Aluko, P., Traditional suburethral sling operations for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017, 1-134, 2017	Systematic review - references checked for inclusion
Riemsma, R., Hagen, S., Kirschner-Hermanns, R., Norton, C., Wijk, H., Andersson, K. E., Chapple, C., Spinks, J., Wagg, A., Hutt, E., Misso, K., Deshpande, S., Kleijnen, J., Milsom, I., Can incontinence be cured? A systematic review of cure rates, BMC Medicine, 15 (1) (no pagination), 2017	Systematic review - references checked for inclusion
Shirvan, M. K., Noughabi, S. A. S., Rahimi, H. R., Tension-free vaginal tape plus intradetrusor botox<sup></sup> injection versus tension-free vaginal tape versus intradetrusor botox injection in equal-weight mixed urinary incontinence: A prospective randomized study, Journal of gynecologic surgery, 29, 235-240, 2013	The comparator was not relevant to the protocol
Simsek, A., Ozgor, F., Kirecci, S. L., Akbulut, M. F., Sonmezay, E., Yuksel, B., Kucuktopcu, O., Gurbuz, Z. G., Results of tension-free vaginal tape for recurrent stress urinary incontinence after unsuccessful transobturator tape surgery, Journal of Obstetrics & Gynaecology Research, 40, 1764-9, 2014	The comparator was not relevant to the protocol
Tapp, Ajs, Hills, B, Cardozo, L, Pelvic floor physiotherapy compared with the Burch colposuspension in the treatment of genuine stress incontinence, Proceedings of the silver jubilee british congress of obstetrics and gynaecology, 1989 jul 4-7, london, UK, 65, 1989	Conference abstract
Tincello, D., Bach, F., Toozs-Hobson, P., Surgery for recurrent stress incontinence in the UK 2007-2015, Neurourology and Urodynamics, 36, S200-S201, 2017	The comparator was not relevant to the protocol
Trabuco, Ec, Klingele, Cj, Occhino, J, Blandon, Re, McGree, Me, Weaver, A, Gebhart, J, Treatment success of burch and midurethral sling 2 years following combined procedure with sacrocolpopexy, 27, S46, 2016	Conference abstract
Wein, A. J., Re: Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial, Journal of Urology, 193, 943-4, 2015	The comparator was not relevant to the protocol
Zhang, L., Zhu, L., Xu, T., Liang, S., Lang, J., Postoperative voiding difficulty and mesh-related complications after Total Prolift System surgical repair for pelvic organ prolapse and predisposing factors, Menopause, 22, 885-892, 2015	The comparator was not relevant to the protocol
Zhao, Y., Guo, X., Lobodasch, K., Liu, B., Wang, S., Lin, Q., Yu, Y., Su, F., Bulking agents - An analysis of 500 cases and review of the literature, Clinical and Experimental Obstetrics and Gynecology, 43, 666-672, 2016	No relevant comparator

## Economic studies

**Table 41: Excluded economic study with reason for exclusion**

Study	Reason for Exclusion
Von Barga, E., Patterson D., Cost utility of the treatment of stress urinary incontinence, Female pelvic medicine & reconstructive surgery; 21, 150-153, 2015	Doesn't report absolute costs, outcomes, or relevant incremental cost effectiveness ratios (ICER). The study reports only cost-effectiveness acceptability curves which makes it impossible to deduce the ICER of interventions of interest.

## Appendix L – Research recommendations

### Research recommendations for review question: What is the most effective surgical management of stress urinary incontinence, including mesh and non-mesh procedures?

What are the long-term risks of mesh surgery compared with non-mesh surgery for stress urinary incontinence in women?

#### Why this is important?

Mesh has been extensively used in continence surgery over the last 20 years but there is little 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 42: Research recommendation rationale**

Research question	What are long term risks of surgery with mesh for SUI 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 SUI. 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 stress urinary incontinence 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 long term data
Equality	None known

**Table 43: Research recommendation modified PICO table**

Criterion	Explanation
Population	Women who have had surgery for SUI (including non-mesh).
Intervention	Continence surgery with mesh 1. Retropubic 2. Transobturator 3. Single incision
Comparator	Continence surgery without mesh (1. colposuspension 2. Autologous fascial sling).
Outcome	Quality of life (e.g. dyspareunia); cure of SUI; complications; pain; adverse events; reoperation for mesh exposure; reoperation for SUI
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 effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

No research recommendation was made for this review question.





		<i>office compared with mid-urethral slings (MUS) in the operating room</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>US 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?	NA	<i>Time horizon: 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).	Yes	<i>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?	NA	<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: 1 year</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>A mix of published literature including RCTs and cohort studies</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Yes	<i>Published literature (RCTs)</i>
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if included primary care costs. However, these costs 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>Medicare reimbursement data</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

**Other comments:****Table 46: Economic methodology checklist for Boyers 2013**

<b>Study identification</b>		
<b>Boyers, D., Kilonzo, M., Mostafa, A., Abdel-Fattah, M., Comparison of an adjustable anchored single-incision mini-sling, Ajust®, with a standard mid-urethral sling, TVT-OTM: a health economic evaluation, BJU international, 112, 1169-1177, 2013</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for stress urinary incontinence</b>		<b>Review question no: 5.1</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 SUI</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Single-incision mini-sling (SIMS) or standard mid-urethral sling (SMUS)</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>UK study</i>
1.4 Are the perspectives clearly stated and are they appropriate for the review question?	Yes	<i>NHS; societal</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?	NA	<i>Time horizon: 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).	Yes	<i>Validated algorithm was used to map KHQ data onto the EQ-5D, UK general population norms</i>
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	Unclear	<i>Unclear how earlier return to work was valued</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?	NA	<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: 1 year</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 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?	Partly	<i>Local unit cost was used for mesh kit only.</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; and bootstrapping</i>
2.11 Is there any potential conflict of interest?	Yes	<i>Two authors had some involvement with the manufacturers (i.e. consultant and travel grants). Funded by Henry Smith Charity.</i>
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Table 47: Economic evidence methodology checklist for Lier 2017**

<b>Study identification</b>		
<b>Lier, D., Robert, M., Tang, S., Ross, S., Surgical treatment of stress urinary incontinence—trans-obturator tape compared with tension-free vaginal tape—5-year follow up: an economic evaluation, <i>Bjog: An International Journal of Obstetrics &amp; Gynaecology</i>, 124, 1431-1439, 2017</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for stress urinary incontinence</b>	<b>Review question no: 5.1</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 SUI</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Transobturator tape compared with tension-free vaginal tape</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Yes	<i>Canadian 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?	Yes	<i>3% 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).	Partly	<i>15D, Finnish 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>		
<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 RCT</i>
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	<i>Time horizon: 5 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>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>Hasn't considered primary care costs, laboratory tests. However, these are likely to account only for a small proportion of total health care 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?	Yes	<i>National sources (Alberta province of Canada)</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 analyses; deterministic sensitivity analyses; bootstrapping</i>
2.11 Is there any potential conflict of interest?	Yes	<i>None reported. The original trial and 12 month follow-up funded by the Alberta Heritage Fund for Medical Research and grant in aid from Boston Scientific (the manufacturer).</i>
2.12 Overall assessment: Minor limitations		
<b>Other comments:</b>		

**Table 48: Economic evidence methodology checklist for Seklehner 2014****Study identification**

**Seklehner S., Laudano, M. A., Te, A. E., Kaplan, S. A., Chughtai, B., Lee, R. K., A cost-effectiveness analysis of retropubic midurethral sling versus transobturator midurethral**

sling for female stress urinary incontinence, <i>Neurourology and urodynamics</i> , 33, 1186-1192, 2014		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for stress urinary incontinence</b>		<b>Review question no: 5.1</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 pure SUI or predominantly SUI</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Retropubic midurethral sling, transobturator midurethral sling</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>US 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?	NA	<i>Time horizon: 10 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).	Yes	<i>Utility weights based on EQ-5D-3L, UK 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>		
<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: 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>From RCTs</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Partly	<i>Review of RCTs; assumptions</i>
2.6 Are all important and relevant costs included?	Yes	<i>Unclear if included primary care costs. However, these costs 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 published literature, Medicare reimbursement data</i>

2.8 Are the unit costs of resources from the best available source?	Unclear	<i>Likely national sources (Medicare); unclear for costs obtained from published literature</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 analysis</i>
2.11 Is there any potential conflict of interest?	No	<i>None declared. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 49: Economic evidence methodology checklist for Lo 2013**

<b>Study identification</b>		
<b>Lo, K., Marcoux, V., Grossman, S., Kung, R., Lee, P., Cost comparison of the laparoscopic burch colposuspension, laparoscopic two-team sling procedure, and the transobturator tape procedure for the treatment of stress urinary incontinence, Journal of Obstetrics and Gynaecology Canada, 35, 252-257, 2013</b>		
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for stress urinary incontinence</b>		<b>Review question no: 5.1</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 SUI</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Laparoscopic Burch colposuspension procedure, the laparoscopic two-team sling procedure, and the transobturator tape</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>Canadian 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?	Unclear	<i>Time horizon was not reported. 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>	<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 unclear. However, seems to be immediate postoperative period</i>
2.3 Are all important and relevant outcomes included?	Partly	<i>Haven't considered primary care costs; complication management</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?	Partly	<i>Haven't considered primary care costs; complication management</i>
2.7 Are the estimates of resource use from the best available source?	Partly	<i>From a small cohort study (N=18)</i>
2.8 Are the unit costs of resources from the best available source?	Partly	<i>Some unit costs from local 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?	No	<i>None declared. Funding is not reported.</i>
2.12 Overall assessment: Potentially serious limitations		
<b>Other comments:</b>		

**Table 50: Economic evidence methodology checklist for Laudano 2013**

<b>Study identification</b>	
Laudano, M. A., Seklehner, S., Chughtai, B., Lee, U., Tyagi, R., Kavalier, E., Te, A. E., Kaplan, S. A., Lee, R. K., Cost-effectiveness analysis of tension-free vaginal tape vs burch colposuspension for female stress urinary incontinence in the USA, BJU international, 112, e151-158, 2013	
<b>Guidance topic: surgical management options (including mesh and non-mesh procedures) for stress urinary incontinence</b>	<b>Review question no: 5.1</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 SUI</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>Tension free vaginal tape (TVT), Burch colposuspension (BC)</i>
1.3 Is the system in which the study was conducted sufficiently similar to the current UK context?	Partly	<i>US 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?	Partly	<i>4.54% discount rate 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, UK 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>		
<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?	Yes	<i>Time horizon: 10 years</i>
2.3 Are all important and relevant outcomes included?	Yes	
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?	Yes	<i>From a review of RCT</i>
2.6 Are all important and relevant costs included?	Yes	<i>Primary care costs are not included; however these are likely to account only for a small proportion of costs.</i>
2.7 Are the estimates of resource use from the best available source?	Unclear	<i>Seems to be published sources and assumptions</i>
2.8 Are the unit costs of resources from the best available source?	Yes	<i>Medicare reimbursement data</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 analyses; PSA</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>		

**Economic methodology checklist for review question: What is the effectiveness of surgical management of stress urinary incontinence (including mesh and non-mesh procedures), compared to pelvic floor muscle training?**

**Table 51: Economic methodology checklist for Richardson 2014**

<b>Study identification</b>		
<b>Richardson ML, Sokol ER. A cost-effectiveness analysis of conservative versus surgical management for the initial treatment of stress urinary incontinence. American Journal of Obstetrics &amp; Gynecology. 2014;211(5):565-e1.</b>		
Guidance topic: surgical management versus pelvic floor muscle training (PFMT) for stress urinary incontinence		Review question no: 5.2
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 uncomplicated de-novo SUI
1.2 Are the interventions appropriate for the review question?	Yes	Surgery (MUS) vs. conservative management. Conservative management options included pessary and pelvic floor muscle therapy (PFMT)
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	Healthcare
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	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 (HUI-Mark-III, Canadian population norms)
1.8 Are costs and outcomes from other sectors fully and appropriately measured and valued?	NA	

<b>Study identification</b>		
<b>Richardson ML, Sokol ER. A cost-effectiveness analysis of conservative versus surgical management for the initial treatment of stress urinary incontinence. American Journal of Obstetrics &amp; Gynecology. 2014;211(5):565-e1.</b>		
1.9 Overall judgement: Partially 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	Decision tree model
2.2 Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Partly	Time horizon: 1 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?	Unclear	Seem to be from RCTs
2.5 Are the estimates of relative intervention effects from the best available source?	Unclear	Seem to be from 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	Various published sources and authors' assumptions
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?	Partly	
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	One of the authors owns stocks in Pelvilon.
2.12 Overall assessment: Potentially serious limitations		
Other comments: Absolute costs and outcomes are not reported however the ICER of surgery vs. PFMT is reported		

**Table 52: Economic methodology checklist for von Bargaen 2015**

<b>Study identification</b>		
<b>Von Bargaen, E., Patterson D., Cost utility of the treatment of stress urinary incontinence, Female pelvic medicine &amp; reconstructive surgery; 21, 150-153, 2015</b>		
<b>Guidance topic: surgical management versus pelvic floor muscle training (PFMT) for stress urinary incontinence</b>	<b>Review question no: 5.2</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 SUI</i>
1.2 Are the interventions appropriate for the review question?	Yes	<i>PFMT and surgical treatment</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>Healthcare</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: lifetime</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).	Partly	<i>QALYs (utility weights from various published sources supplemented with 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?	Yes	<i>Time horizon: lifetime</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?	Unclear	<i>Probabilities obtained from various published sources</i>
2.5 Are the estimates of relative intervention effects from the best available source?	Unclear	<i>Probabilities obtained from various published sources</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>Various published sources and authors' assumptions</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?	No	<i>Absolute costs and outcomes are not reported and it is impossible to derive the incremental cost effectiveness ratio for the comparison of interest</i>
2.10 Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Yes	<i>Probabilistic sensitivity analysis</i>
2.11 Is there any potential conflict of interest?	No	
2.12 Overall assessment: <i>Very serious limitations</i>		
<b>Other comments:</b>		











