NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of infracoccygeal sacropexy using mesh to repair vaginal vault prolapse

The vaginal vault is formed at the top of the vaginal canal after surgery to remove the womb and cervix. Vaginal vault prolapse happens when the upper part of the vagina slips down from its usual position. Infracoccygeal sacropexy involves inserting a mesh through a small cut in 1 buttock. The mesh is passed up the side of the vagina, across the top, down the other side of the vagina and then out through a cut in the other buttock. Both ends of the mesh are cut so that they end just below the surface of the skin. The mesh is attached to the top of the vagina. It acts like a sling to support the vaginal vault.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in September 2016 and updated in March 2017.

Procedure name

- Infracoccygeal sacropexy using mesh to repair vaginal vault prolapse
- Posterior intravaginal slingplasty for vaginal vault prolapse repair

Specialist societies

- Royal College of Obstetricians and Gynaecologists (RCOG)
- British Society of Urogynaecology (BSUG)

- British Association of Urological Surgeons (BAUS).

Description

Indications and current treatment

Vaginal vault prolapse is when the upper part of the vagina descends from its usual position, sometimes out through the vaginal opening. It is common after hysterectomy and can affect quality of life by causing pressure and discomfort, and by its effect on urinary, bowel and sexual function.

Vaginal vault prolapse may occur on its own or together with a cystocele (when the bladder sags into the vagina), rectocele (when the front wall of the rectum bulges into the lower wall of the vagina) or enterocele (when the intestine bulges into the upper wall of the vagina).

Treatment options for vaginal vault prolapse depend on the severity of the symptoms. Treatment is rarely indicated if there are no symptoms. Mild-to-moderate prolapse may be treated with conservative measures such as pelvic-floor muscle training, electrical stimulation and biofeedback. Topical oestrogens and mechanical measures such as pessaries may also be used.

Surgery may be needed when the prolapse is severe. Different surgical procedures are available using vaginal or abdominal (open, laparoscopic or robotic) approaches. Some procedures involve the use of mesh, with the aim of providing additional support.

What the procedure involves

Infracoccygeal sacropexy is done with the patient under general or regional anaesthesia. An incision is made in the posterior wall of the vagina and a small puncture incision is made in each buttock. A mesh tape is introduced through 1 buttock and, using a tunnelling device, guided by a finger through the vaginal incision, the tape is passed around the rectum. The mesh is then passed up the side of the vagina, across the top, and down the other side, and out through the incision in the other buttock. Both ends are cut so that they end just below the surface of the skin. The mesh is sutured to the top of the vagina to act as a tension-free sling that aims to support the vaginal vault. The procedure is sometimes described as posterior intravaginal slingplasty.

This procedure can be combined with surgery for stress urinary incontinence, such as a sub-urethral sling placement.

Several different types of synthetic and biological mesh are available that vary in structure and in physical properties such as absorbability.

Outcome measures and disease classification

The 2 main systems for staging the degree of pelvic organ prolapse are the Baden–Walker halfway scoring system and pelvic organ prolapse–quantification (POP-Q). Both systems measure the most distal portion of the prolapse during straining or Valsalva manoeuvre.

In the Baden–Walker halfway system, pelvic organ prolapse is classified as grade 0 (no prolapse), grade 1 (halfway to hymen), grade 2 (to hymen), grade 3 (halfway past hymen) or grade 4 (maximum descent).

The Pelvic Organ Prolapse Quantification system (POP–Q) classifies pelvic organ prolapse from stage 0 to stage 4, as follows:

Stage 0	no prolapse is demonstrated
Stage 1	the most distal portion of the prolapse is more than 1 cm above the level of the hymen
Stage 2	the most distal portion of the prolapse is 1 cm or less proximal or distal to the hymenal plane
Stage 3	the most distal portion of the prolapse protrudes more than 1 cm below the hymen but protrudes no further than 2 cm less than the total vaginal length (for example, not all of the vagina has prolapsed)
Stage 4	vaginal eversion is essentially complete

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to infracoccygeal sacropexy using mesh to repair vaginal vault prolapse. The following databases were searched, covering the period from their start to 24 January 2017: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with vaginal vault prolapse.
Intervention/test	Infracoccygeal sacropexy (also known as posterior intravaginal slingplasty) using mesh.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on approximately 2,400 patients treated by infracoccygeal sacropexy from 2 systematic reviews, 2 randomised controlled trials (1 of which was also included in the systematic reviews), 1 non-randomised comparative study and 4 case series[1–9].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on infracoccygeal sacropexy using mesh to repair vaginal vault prolapse

Study 1 Jia X (2010) – based on the systematic review commissioned for 2008 NICE interventional procedure guidance

Details

Study type	**Systematic review**
Country	Not reported for individual studies
Recruitment period	Search date: 2008
Study population and number	**n=7,054 (54 studies); n=976 (14 studies) for infracoccygeal sacropexy [2 randomised controlled trials]; 1 uterine prolapse, 5 vaginal vault prolapse, 1 uterine and vaginal vault prolapse reported separately, 7 uterine and vaginal vault prolapse reported together)** Women with vaginal vault or uterine prolapse.
Age	Median 64 years (range 54 to 73)
Patient selection criteria	Studies on women undergoing uterine or vault prolapse surgery were included. Studies of women with cancer or with prolapse caused by congenital anomalies, inherited conditions or creation of a neovagina were excluded. Studies with women undergoing other concomitant operations, such as anterior or posterior vaginal wall prolapse repair or anti-incontinence procedures, were included providing that the main indication for surgery was uterine or vault prolapse.
Technique	Infracoccygeal sacropexy using mesh.
Follow-up	**Median 13 months (range 5 to 30) for infracoccygeal sacropexy**
Conflict of interest/source of funding	No conflicts of interest. The manuscript was based on a systematic review commissioned and funded by NICE through its interventional procedures programme.

Analysis

Study design issues:

- The 14 studies on infracoccygeal sacropexy included 2 randomised controlled trials (RCTs), both of which were reported as conference abstracts only. There was 1 non-randomised comparative study, 2 case series with 100 or more patients and 9 case series with fewer than 100 patients. Case series with a mean follow-up of at least 1 year were included for both efficacy and safety. Case series with a mean follow-up of less than 1 year were included for safety outcomes only.
- The primary outcomes for efficacy were patient-reported persistent prolapse symptoms and clinician-reported recurrence of prolapse at the original site measured with a validated quantitative tool. Secondary outcomes for efficacy included de novo prolapse at other sites that were free of prolapse before surgery, the need for repeat surgery for prolapse (both recurrent at the same site and de novo), persistent urinary symptoms, persistent bowel symptoms and persistent sexual symptoms. For urinary, bowel and sexual symptoms, only women who reported these symptoms at baseline were counted. If possible, only women who were sexually active were considered for sexual function outcomes.
- The primary outcome for safety was mesh erosion. Secondary outcomes included blood loss; damage to surrounding organs during the operation; an operation for mesh erosion or removal; new urinary, bowel or sexual symptoms; and infection. For new urinary, bowel or sexual symptoms, only women who were free of these symptoms at baseline were considered for these outcomes.
- Meta-analysis was not possible, because the comparative studies used different comparators.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **976** ***All studies on infracoccygeal sacropexy (including patients with uterine or vaginal vault prolapse)*** Persistent prolapse symptoms after infracoccygeal sacropexy (patient reported)=2–21% (median 8.8%, n=262, 3 studies) Prolapse recurrence (clinician reported)=0% to 25% (median 4.8%, 9 studies, n=402). In 3 studies (n=288), the re-operation rate varied from none to 30% (median 7.9%). ***Vaginal vault prolapse only*** Patient reported persistent prolapse symptoms=8.8% (8/91; 1 case series) Clinician reported recurrent prolapse at original site=6.7% (4/60; 2 case series) ***Uterine or vaginal vault prolapse*** Patient reported persistent prolapse symptoms=16.4% (28/171; 2 case series) Clinician reported recurrent prolapse at original site=4.8% (1/21; 1 RCT); 7.3% (17/232; 4 case series)	***Complications – all studies*** • Mesh erosion=0% to 21% (median 6.7%, 11 studies, n=889). All studies reporting mesh erosion used non-absorbable synthetic mesh. • Operation for mesh erosion=0.3% to 17% (median 7.2%, 6 studies, n=678). • Blood transfusion=0% to 2% (7 studies, n=383). • Organ damage=0% to 2.7% (median 0%, 9 studies, n=684). • Infection=0% to 9% (8 studies, n=698) Little evidence was available for new urinary symptoms, bowel symptoms and sexual symptoms in women who did not have these symptoms at baseline. ***Vaginal vault prolapse only*** • Mesh erosion=6.7% (2/30; 1 RCT); 9.4% (22/235; 4 case series) ***Uterine or vaginal vault prolapse*** • Mesh erosion=0% (0/21; 1 RCT); 6.3% (33/524; 4 case series)

Study 2 Feiner B (2009)

Details

Study type	**Systematic review**
Country	Not reported for individual studies
Recruitment period	Search date: December 2007
Study population and number	**n=2,653** (655 for posterior intravaginal slingplasty [10 studies, including 2 RCTs]; 525 for Apogee [8 studies, including 1 RCT]; 1,295 for Prolift [8 studies]; 178 for self-styled polypropylene mesh [4 studies]) Women with vaginal vault or uterine prolapse.
Age	Not reported
Patient selection criteria	Studies were included if women had vaginal surgery for uterine or post-hysterectomy vaginal vault prolapse and had graft material vaginally placed to surgically reinforce the apical portion of the repair. Studies were excluded if they described the use of mesh to support either the anterior or posterior vaginal compartment alone, used mesh for incontinence or fistula repair or did not address the upper vaginal compartment. If it could not be established whether mesh was used for apical vaginal support, then the study was excluded. The type of study designs used included cross-sectional, case series, case–control, any design with historical controls, cohort or controlled trials. Case reports were excluded.
Technique	Vaginal mesh kits: Posterior Intravaginal Slingplasty (PIVS)/Infracoccygeal Sacropexy (Tyco Healthcare, US); Apogee system for apical and posterior vaginal prolapse (American Medical Systems, US); Prolift (Ethicon Women's Health and Urology, US); self-styled polypropylene mesh.
Follow-up	**Mean 46 weeks (range 3 to 120) for PIVS, 26 weeks for Apogee, 30 weeks for Prolift and 78 weeks for polypropylene mesh**
Conflict of interest/source of funding	None

Analysis

Study design issues:

- Of the 10 included studies for PIVS, 6 were reported only as conference abstracts (including the 2 RCTs).
- Outcomes included both objective and subjective outcomes relating to prolapse, urinary, bowel, sexual function, pain, mesh erosion and perioperative surgical complications.
- Objective success was defined as any description of vaginal support symptomatic or asymptomatic prolapse less than stage 2 of the Pelvic Organ Prolapse Quantification (POP-Q) system or grade 2 of the Baden–Walker Halfway System.
- Complications were categorised from Grade 1 to 5, using the previously validated Dindo system for classifying surgical complications (Grade I: any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions; Grade II: needing pharmacological treatment with drugs other than those allowed for grade I complications; Grade III: needing surgical, endoscopic or radiological intervention; Grade IV: life-threatening complication needing intensive care management; Grade V: death). Study quality was not formally assessed.

Other issues:

- There is some patient overlap with Jia X et al., 2010. The 2 RCTs and 1 case series are common to both reviews (n=106).
- The evidence included some women with uterine prolapse; 5 of the 10 studies on PIVS only included patients with vaginal vault prolapse.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: 2,653 (**655 for PIVS)** **Mean objective success (weighted averages analysis):** • **PIVS=88.2% (range 37–99; 95% CI: 87.2 to 89.1)** • **Apogee=95.4% (range 81–100; 95% CI: 95.1 to 95.7)** • **Prolift=86.8% (range 75–94; 95% CI: 86.4 to 87.3)** • **Polypropylene=91.6% (95% CI: 90.9 to 92.3)** The 2 RCTs on PIVS included 107 women randomised to either PIVS or sacrospinous fixation; 1 trial reported 82% objective success rate with PIVS compared with 88% with the sacrospinous fixation at 24 months follow up, and the other reported 95% success with PIVS at a mean follow up of 10.5 months compared with 100% success rate with the sacrospinous fixation at a mean follow up of 15.5 months. Exceptionally poor outcomes were reported from a study on 21 older women (mean age 70) treated by PIVS (objective success rate 37%). The authors noted that there were stringent criteria of primary failure used in this study and that some women with POP-Q stage 1 could have been considered as having an unsuccessful outcome.	**Complications (weighted averages analysis)** For PIVS, the complication rate ranged from 2% to 21% Other complications for PIVS included prolonged pain (n=4), blood transfusion (n=2), proctotomy (n=1), pararectal abscess (n=1), fistula (n=1). Haematoma was reported in 1% of patients. The paper also describes 2 case reports of adverse events associated with PIVS: 1 gluteovaginal sinus formation 3 months after a posterior intravaginal slingplasty procedure and 1 rectocutaneous fistula 2 months postoperatively. In the Apogee studies, the only severe intraoperative complication was proctotomy (n=2). In the Prolift group, there was 1 rectal injury and cystotomy occurred in 16 women (1%) with 3 women having fistula formation and 10 receiving a blood transfusion. One woman had necrotising fasciitis (considered as Dindo grade IVb), which was treated by removal of the mesh, extensive perineal debridement, laparotomy and colostomy followed by a prolonged stay in the intensive care unit.

	PIVS % (95% CI) n=655	**Apogee % (95% CI) n=525**	**Prolift % (95% CI) n=1295**	**Polypropylene % (95% CI) n=178**
Total complication rate	12.1 (11.6 to 12.5)	17.6 (16.7 to 18.5)	16.5 (15.9 to 17.1)	6.9 (6.8 to 6.9)
Dindo grade I	3.2 (2.9 to 3.6)	4.8 (4.4 to 5.3)	6.0 (5.6 to 6.2)	1.5 (1.3 to 1.8)
Dindo grade II	3.2 (3.0 to 3.5)	6.5 (6.0 to 7.0)	4.1 (3.7 to 4.5)	1.5 (1.2 to 1.8)
Dindo grade III	5.7 (5.3 to 6.1)	6.3 (5.9 to 6.7)	6.4 (6.3 to 6.6)	3.8 (3.8 to 3.8)
Dindo grade IIIa	0.6 (0.5 to 0.7)	0.4 (0.3 to 0.5)	0.5 (0.4 to 0.5)	2.3 (2.1 to 2.5)
Dindo grade IIIb	5.5 (4.6 to 5.5)	5.9 (5.5 to 6.2)	6.0 (5.8 to 6.1)	1.5 (1.3 to 1.8)
Dindo grade IV	0	0	0.1	0
Mesh erosion	7.8 (7.2 to 8.3)	10.7 (10.1 to 11.3)	5.7 (5.5 to 6.0)	4.6 (4.2 to 5.0)
Dyspareunia	1.7 (1.5 to 1.9)	2.7 (2.4 to 3.0)	2.1 (2.0 to 2.2)	5.5 (4.7 to 6.3)

Abbreviations used: PIVS, posterior intravaginal slingplasty

Study 3 de Tayrac (2008)

Details

Study type	**Randomised controlled trial**
Country	France
Recruitment period	2003–05
Study population and number	**n=49 (24 infracoccygeal sacropexy versus 25 sacrospinous suspension)** Women with symptomatic uterine or vaginal vault prolapse (stage 2 or higher).
Age	Mean 62 years (infracoccygeal sacropexy); 60 years (sacrospinous suspension), p=0.48
Patient selection criteria	Symptomatic uterine or vaginal vault prolapse (stage 2 or higher). Exclusion criteria were isolated cystocele, stage 1 prolapse, rectal prolapse, and intestinal inflammatory disease.
Technique	Infracoccygeal sacropexy was done using the IVS tunneller (Tyco Healthcare, France) with a 10-mm multifilament polypropylene tape. Sacrospinous suspension involved fixing the vaginal vault, uterosacral ligaments or a vaginal flap to 1 sacrospinous ligament with 2 monofilament nonabsorbable threads. Associated procedures were cystocele repair, hysterectomy, sub-urethral tape and posterior repair.
Follow-up	**Mean 16.8 months (range 1.5 to 32)**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues:

- The records of 2 patients in the infracoccygeal sacropexy group were missing and 1 patient was lost to follow-up in each group.

Study design issues:

- Multicentre, randomised study (randomisation was done centrally).
- The primary outcome measure was postoperative pain level 1 day after surgery, measured by a visual analogue scale (VAS) from 0 (no pain) to 10 (maximum pain).
- Secondary outcome measures were duration of procedure, intraoperative and postoperative morbidity, duration of hospital stay, patient satisfaction, quality of life, sexual activity, anatomical results, and rate of vaginal or rectal erosions. Global quality of life was assessed on a VAS. The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) were translated into French and used to measure symptoms and quality of life directly related to the prolapse. The Pelvic Organ Prolapse-Urinary Incontinence-Sexual Function questionnaire was also translated into French to measure sexual activity.
- The simplicity of the procedure was measured by the surgeon using a VAS from 0 (very easy) to 10 (very difficult).
- The study did not reach the calculated sample size of 154 because patient enrolment was stopped when multifilament tape was replaced by monofilament tape at the study centre.

Study population issues:

- Patient characteristics were similar in the 2 groups, with the exception of body mass index (mean 27.9 for infracoccygeal sacropexy versus 25.0 for sacrospinous suspension, p=0.01).

Other issues:

- This study, reported as an abstract, was included in the Jia X et al. (2010) and Feiner B et al. (2009) reviews.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **45 (21 versus 24)**

Comparison of surgical data (mean±standard deviation)

	Infracoccygeal sacropexy n=21	Sacrospinous suspension n=24	p value
Epidural anaesthesia	66.7% (14/21)	62.5% (15/24)	0.98
Mean duration of intervention, mins	13.2±5.2	20±8.1	0.002
Mean operative difficulty (0 to 10)	1.2±1.6	3.1±2.3	0.002
Mean duration of hospital stay, days	4.9±1.8	3.9±1.2	0.06

Comparison of anatomical results (mean±standard deviation)

	Infracoccygeal sacropexy n=21	Sacrospinous suspension n=24	p value
C* or D** point before surgery, cm	0.2±1.5	0.4±1.6	0.98
C or D point after surgery, cm	−6.4±2.2	−6.4±1.7	0.98
Postoperative uterine prolapse >1	4.8% (1/21)	0	0.94
Anatomical success	95.2% (20/21)	100% (24/24)	0.94
Postoperative cystocele >1	4.8% (1/21)	25% (6/24)	0.14
Postoperative rectocele >1	0	4.2% (1/24)	0.94

*C point: cervix in POP-Q classification (cm from hymen)
**D point: posterior vaginal fornix in POP-Q classification (cm from hymen)

Patient satisfaction (proportion of patients satisfied or very satisfied):

- Infracoccygeal sacropexy=85.7%
- Sacrospinous suspension=79.2%, p=0.85

Intensity of symptoms after procedure (VAS 0=no symptoms to 10=very severe symptoms):

- Infracoccygeal sacropexy=0.7±1.5
- Sacrospinous suspension=1.1±1.7 p=0.57

Reoperation

- 1 of the 3 patients treated by infracoccygeal sacropexy without hysterectomy had further surgery 3 months later for uterine prolapse recurrence.
- 1 patient treated by sacrospinous suspension who had a concomitant anterior colporrhaphy had a subsequent operation for a cystocele recurrence.

Preoperative, postoperative and *de novo* comparison of urinary, recto-anal and sexual function

	Infracoccygeal sacropexy (n=21)			Sacrospinous suspension (n=24)			p value (between groups)
	Preoperative	Postoperative	*de novo*	Preoperative	Postoperative	*de novo*	
Stress urinary incontinence	52% (11/21)	0	0	29.1% (7/24)	8.3% (2/24)	4.2% (1/24)	not significant
Urgency	52% (11/21)	14.3% (3/21)	0	50% (12/24)	25% (6/240	4.2% (1/24)	not significant
Voiding difficulty	38% (8/21)	14.3% (3/21)	9.5% (2/21)	33.3% (8/24)	33.3% (p=0.2508/24)	16.7% (4/24)	not significant
Constipation	9.5% (2/21)	4.8% (1/21)	0	25% (6/24)	29.2% (7/24)	16.7% (4/24)	not significant

Efficacy (continued)

Self-questionnaire scores on symptoms and quality of life

	Infracoccygeal sacropexy (n=21)			Sacrospinous suspension (n=24)			p value (between groups)
	Preoperative	Improved ≥50%	Worsened	Preoperative	Improved ≥50%	Worsened	
UDI	89.7±63	87.5%	12.5%	95.7±46.7	65%	10%	not significant
CRADI	63.7±55.8	62.5%	6.3%	87.8±84.1	50%	22.2%	not significant
POPDI	86.9±47.6	75%	6.3%	123.8±61	65%	10%	0.02
UIQ	66.1±58	68.8%	25%	83.3±72.6	73.7%	5.7%	not significant
CRAIQ	13.7±23.5	53.3%	6.7%	38.7±70.5	42.1%	15.8%	not significant
POPIQ	42.7±53.3	73.3%	0%	69.4±76.4	42.1%	5.3%	not significant

The UDI, CRADI, POPDI are scored from 0 (none) to 300 (very disturbing symptoms) ; the UIQ, CRAIQ and POPIQ are scored from 0 (no impact) to 300 (major impact)

Safety

Postoperative pain, VAS (0=no pain, 10=maximum pain)

	Infracoccygeal sacropexy n=21	Sacrospinous suspension n=24	p value
Mean VAS immediately after procedure	2.2±2.4	1.4±2.1	0.30
Mean VAS at day 1	1.3±1.6	3.2±2.7	0.005
VAS>5 at day 1	4.8% (1/21)	29.2% (7/24)	0.08
VAS at day 2	1.0±1.3	2.0±2.7	0.13
VAS at follow-up	0.7±2.2	1.2±2.5	0.46
VAS>5 at follow-up	4.8% (1/21)	12.5% (3/24)	0.70

Complications

	Infracoccygeal sacropexy n=21	Sacrospinous suspension n=24	p value
Intraoperative haemorrhage >300 ml	4.8% (1/21)	12.5% (3/24)*	0.70
Bladder injury	9.5% (2/21)	4.2% (1/24)	0.93
Rectal injury	0	0	
Nerve injury	0	0	
Postoperative haematoma	9.5% (2/21)	0	0.41

* The paper reports 2 cases of intraoperative haemorrhage but the percentage reported equates to 3 cases.

Reoperation

There were 2 re-interventions in each group for anterior vaginal wall erosion.

Abbreviations used: CRADI, Colo-Recto-Anal Distress Inventory; CRAIQ, Colo-Recto-Anal Impact Questionnaire; POPDI, Pelvic Organ Prolapse Distress Inventory; POPIQ, Pelvic Organ Prolapse Impact Questionnaire; UDI, Urinary Distress Inventory; UIQ, Urinary Impact Questionnaire; VAS, visual analogue scale

Study 4 Heinonen PK (2011)

Details

Study type	**Randomised controlled trial**
Country	Finland
Recruitment period	2003–05
Study population and number	**n=22 (14 posterior intravaginal slingplasty [PIVS] versus 8 sacrospinous ligament fixation [SSLF])** Women with symptomatic uterovaginal or vaginal vault prolapse.
Age	Mean 73 years (range 65–86) for PIVS and 68 years (range 51–86) for SSLF
Patient selection criteria	Symptomatic vaginal vault prolapse or uterine procidentia. Exclusion criteria were gynaecological tumour or malignancy needing laparotomy or laparoscopy, untreated vaginal infection, or unavailable for 3-year follow-up.
Technique	PIVS was done using the IVS tunneller (Tyco Healthcare, USA), with a multifilament polypropylene tape. All procedures were done with concomitant anterior repair. An absorbable polyglactin 910 and non-absorbable multifilament polypropylene composite mesh was used to reinforce the anterior colporrhaphy. All procedures except 1 were done under spinal block.
Follow-up	**3 years**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues:

- 79% (11/14) of patients in the PIVS group and 89% (7/8) of patients in the SSLF group completed the 3-year follow-up. Three patients did not complete follow-up, 2 because of other diseases and 1 refused examination without specifying a reason.

Study design issues:

- A computer-generated randomisation list was used and preoperative randomisation was done by an independent nurse taking a card from an opaque envelope.
- The calculated sample size assuming the type I error to be 5% and power 80% was 55 in each group. Patient enrolment was stopped before this number was reached because recruitment was slow and there were reported risks of erosion and infection associated with multifilament intravaginal slingplasty (IVS) tape; the study centre decided to use a monofilament mesh kit instead. The study is, therefore, underpowered to detect a difference between the groups.
- The primary endpoint was anatomic recurrence of prolapse at any site of the vaginal wall within 3 years after repair. Failure was defined as stage 2 or beyond on the POP-Q system.
- Secondary outcomes included perioperative and postoperative complications, symptom resolution, reoperation and mesh exposure.
- A validated quality of life questionnaire was not used because none was available in Finnish.
- Blinding of outcome assessment was not done.
- An intention to treat analysis was done.

Study population issues:

- All patients had stage 3–4 apical prolapse at baseline.
- There were no statistically significant differences between the groups with regard to baseline demographic and clinical data.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **22 (14 versus 8)**

Stage of pelvic organ prolapse and POP-Q values before and 3 years after procedure

Stage	Posterior intravaginal slingplasty n=14		Sacrospinous ligament fixation n=8	
	Preoperative	Postoperative	Preoperative	Postoperative
0	0	57% (8/14)	0	63% (5/8)
1	0	22% (3/14)	0	25% (2/8)
2	0	7% (1/14)	0	12% (1/8)
3	64% (9/14)	14% (2/14)	50% (4/8)	0
4	36% (5/14)	0	50% (4/8)	0
POP-Q value (cm)				
Point Ba*	4.4±3.9	−2.27±1.7	5.5±4.7	−2.5±0.7
Point C^	5.5±3.6	−5.6±2.7	6.7±3.8	−7.8±1.4
Point Bp*	3.9±3.7	−2.34±1.4	5.4±3.7	−3.0±0.0
Total vaginal length	10.4±1.2	7.6±1.1	10.8±1.0	9.4±2.1

* The values within groups are statistically significant (p<0.05) when comparing pre- and postoperative values, but not between the groups.

^ The values within groups are statistically significant (p<0.05) when comparing pre- and postoperative values and also between the groups.

Anatomic recurrence of prolapse at 3-year follow-up

- Posterior intravaginal slingplasty=21% (3/14)
- Sacrospinous ligament fixation=13% (1/8)

Symptoms before and 3 years after procedure (n)

Symptoms	Posterior intravaginal slingplasty n=14		Sacrospinous ligament fixation n=8	
	Preoperative	Postoperative	Preoperative	Postoperative
All prolapse symptoms	14	3	8	1
Pelvic pressure	10	1	7	0
Vaginal bulge	14	1	8	0
Difficulties in voiding the bladder	10	0	4	0
Stress urinary incontinence	1	0	0	1
Difficulties in rectal voiding	4	1	2	0

The differences between the groups were not statistically significant.

Safety

Complications

	Posterior intravaginal slingplasty	Sacro-spinous ligament fixation
Total	57% (8/14)	38% (3/8)
Infection at operative site	7% (1/14)	13% (1/8)
Haematoma	7% (1/14)	0
Urinary tract infection	43% (6/14)	25% (2/8)
De novo dyspareunia	25% (1/4) sexually active patients	0

Study 5 Sivaslioglu AA (2011)

Details

Study type	**Non-randomised comparative study (retrospective)**
Country	Turkey
Recruitment period	2002–10
Study population and number	**n=190 (92 posterior intravaginal slingplasty [PIVS] versus 98 abdominal sacrocolpopexy [ASCP])** Women with vaginal vault prolapse
Age	Mean 60 years (PIVS) and 59 years (ASCP)
Patient selection criteria	Grade 3 or 4 vaginal vault prolapse, according to the Baden-Walker classification system.
Technique	Posterior intravaginal slingplasty (infracoccygeal sacropexy) or abdominal sacrocolpopexy (with concomitant Burch procedure).
Follow-up	**mean 60 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues:

- An additional 34 patients were treated during the study period but were lost to follow-up and were excluded from the analysis.
- Patients were invited for follow-up visits at 6 weeks, 6 months, 1 year, and annually thereafter.

Study design issues:

- Retrospective, non-randomised comparative study.
- The Baden-Walker classification system was used to quantify the degree of prolapse before and after the procedure. A postoperative grade 0, 1 or 2 prolapse of the anterior, apex, or posterior compartments were accepted as cure.
- Lower urinary tract symptoms were assessed using a short form of validated Turkish version of the urogenital distress inventory (UDI-6).

Study population issues:

- There were no statistically significant differences between the 2 groups with regard to follow-up period, age, body mass index, and parity.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **190 (92 versus 98)**

Success rates by follow-up period (***postoperative grade 0, 1 or 2 prolapse of the anterior, apex, or posterior compartments)***

Follow-up	Posterior intravaginal slingplasty (PIVS) (n=92)	Abdominal sacrocolpopexy (ASCP) (n=98)	p value
6 weeks	91.3%	90.8%	0.408
6 months	85.9%	89.8%	0.906
1 year	83.7%	88.8%	0.310
2 years	80.4%	84.7%	0.440
p value	<0.001	0.004	

Improvement in lower urinary tract symptoms and anatomical restoration at 2 year follow-up, % (n)

	PIVS (n=92)			ASCP (n=98)		
	Preoperative	Postoperative	p value	preoperative	postoperative	p value
Stress urinary incontinence	15.2% (14)	4.3% (4)	0.002	16.3% (16)	8.2% (8)	0.039
Nocturia	23.9% (22)	14.1% (13)	0.004	24.5% (24)	21.4% (21)	0.250
Urgency	18.5% (17)	15.2% (14)	0.250	18.4% (18)	16.3% (16)	0.500
Abnormal emptying	13% (12)	7.6% (7)	0.063	13.3% (13)	13.3% (13)	1.000
Pelvic pain	25% (23)	13% (12)	0.001	25.5% (25)	21.4% (21)	0.125
Paravaginal defect	10.9% (10)	9.8% (9)	1.000	11.2% (11)	11.2% (11)	1.000
Rectocele	77.2% (71)	32.6% (30)	<0.001	78.6% (77)	35.7% (35)	<0.001
Enterocele	15.2% (14)	8.7% (8)	0.031	12.2% (12)	8.2% (8)	0.125
Cystocele	73.9% (68)	35.9% (33)	<0.001	75.5% (74)	41.8% (41)	<0.001

Mean operation time (minutes):

- PIVS=53 (range 25–90)
- ASCP=94.5 (range 40–150), p<0.001

Mean hospital stay (days):

- PIVS=2.1 (range 2–6)
- ASCP=3.1 (range 2–8), p<0.001

Safety

Complications, % (n)

	PIVS (n=92)	ASCP (n=98)	p value
Transfusion	0	8.1% (8)	Not reported
Urinary retention	0	4% (4)	Not reported
Fever	2.1% (2)	7.1% (7)	0.038
Surgical site infection	0	3.1% (3)	0.092
Constipation	2.1% (2)	9.1% (9)	0.039
Bladder injury	0	2% (2)	Not reported
Intramuscular haematoma	1% (1)	0	Not reported
Retroperitoneal haematoma	0	1% (1)	Not reported

Mean blood loss was significantly lower in the PIVS group than the ASCP group (275 versus 537 ml, p<0.001).

Abbreviations: ASCP, abdominal sacrocolpopexy; PIVS, posterior intravaginal slingplasty

Study 6 Cosma S (2011)

Details

Study type	**Case series**
Country	Italy
Recruitment period	2003–07
Study population and number	**n=118** (25 stage 3 or 4 vaginal cuff prolapse; 93 utero-vaginal prolapse) Women with stage 3 or 4 vaginal apical prolapse.
Age	mean 65 years
Patient selection criteria	Stage 3 or 4 vaginal apical prolapse diagnosed clinically according to the International Continence Society Pelvic Organ Prolapse Quantification (POP-Q) standard scoring system. Exclusion criteria were age less than 45 years, clotting disorders, and desire to preserve fertility.
Technique	All procedures were done under regional spinal anaesthesia. During the first period of the study, a multifilament polypropylene intravaginal slingplasty tape was used (posterior IVS, Tyco). By March 2006, the company withdrew the multifilament tape and substituted it with a monofilament one, which was used for the last 16 patients. Other concomitant procedures to correct anterior and posterior defects were done at the discretion of the surgeon.
Follow-up	**Mean 58.6 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues:

- All 188 patients were seen at 1–6 and 12–24 months; 115 patients (97%) at 36 months; 111 patients (94%) at 48 months; 84 patients (71%) at 60 months; 55 patients (47%) at 72 months and 14 patients (12%) at 84 months.

Study design issues:

- Objective postoperative assessment was done using the POP-Q staging system. Pelvic relaxation of up to stage 1 was accepted as cured, and relaxation of stage 2 or higher was considered to be a recurrence.
- Quality of life was assessed using 1 questionnaire for prolapse (King Health Questionnaire) that is also validated in Italian and 2 validated questionnaires that were translated into Italian (Pelvic Floor Impact Questionnaire-7 [PFIQ-7] and Agachan–Wexner constipation scoring system). A sexuality non-validated score and visual analogue scale were also completed by the patients.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **118**

Anatomical and symptomatic results

	All patients n=118	vaginal cuff prolapse n=25	utero-vaginal prolapse n=93	p value
Mean follow-up (months)	58.6	60.1	58.1	Not significant
Anatomical results				
Recurrence of vault prolapse	3.4% (4/118)	4% (1/25)	3.2% (3/93)	Not significant
Cystocele recurrence	14.7% (14/95)	20% (3/15)	13.7% (11/80)	Not significant
de novo cystocele formation	26% (6/23)	20% (2/10)	30.7% (4/13)	Not significant
Rectocele recurrence	13.8% (4/29)	28.5% (2/7)	9% (2/22)	Not significant
de novo rectocele formation	4.5% (4/89)	11.1% (2/18)	2.8% (2/71)	Not significant
Symptomatic results				
Persistent vaginal bulge	9.3% (11/118)	12% (3/25)	8.6% (8/93)	Not significant
Persistent stress urinary incontinence	2.5% (3/118)	4% (1/25)	2.1% (2/93)	Not significant
Persistent urge urinary incontinence	3.4% (4/118)	4% (1/25)	3.2% (3/93)	Not significant
Persistent bladder overactivity symptoms	4.2% (5/118)	4% (1/25)	4.3% (4/93)	Not significant

The vault prolapse recurrences were all seen at 24 month follow-up.

Quality of life questionnaire scores

Questionnaire	Baseline	After surgery	p value
UIQ	134.6	115.7	<0.05
POPIQ	164.3	108.4	<0.05
CRAIQ	107.5	114.11	not significant
Agachan-Wexner constipation scoring system*	4.6	5.5	NS

*Range 0-30, with lower scores indicating less bowel dysfunction.

Safety

Complications

	All patients n=118	vaginal cuff prolapse n=25	utero-vaginal prolapse n=93	p value
Early complications				
Haematoma	3.4% (4/118)	4% (1/25)	3.2% (3/93)	Not significant
Hyperthermia*	1.7% (2/118)	4% (1/25)	1% (1/93)	Not significant
Pain	2.5% (3/118)	0% (0/25)	3.2% (3/93)	Not significant
Urinary retention >100 ml	8.5% (10/118)	4% (1/25)	9.7% (9/93)	Not significant
Late complications				
Erosion	8.5% (10/118)	20% (5/25)	5.4% (5/93)	<0.05
Abscess or fistula	2.5% (3/118)	4% (1/25)	2.1% (2/93)	Not significant
De novo urge urinary incontinence or bladder overactivity symptoms	8.5% (10/118)	8% (2/25)	8.6% (8/93)	Not significant
De novo stress urinary incontinence	5.9% (7/118)	4% (1/25)	6.4% (6/93)	Not significant
De novo constipation	5.9% (7/118)	8% (2/25)	5.4% (5/93)	Not significant

*Reported in the text as ''Ipertermy''.

NB: all patients with urinary retention had an anti-incontinence procedure (sub-urethral sling)

1 of the 4 patients with haematoma needed surgical evacuation and blood transfusion.

3 patients had buttock pain, which resolved spontaneously within a few days.

Mesh erosions occurred at 1 month (n=1), 6 months (n=4), 18 months (n=2), 24 months (n=2) and 30 months (n=1).

There were no rectal injuries.

Overall reoperation rate=5.9% (2 patients with recurrence of prolapse, 2 with erosion and 3 with fistula).

Abbreviations used: CRAIQ, colorectal anal impact questionnaire; POPIQ, pelvic organ prolapse impact questionnaire; UIQ, Urinary impact questionnaire

Study 7 Bjelic-Radisic V (2009)

Details

Study type	**Case series – registry data**
Country	Austria
Recruitment period	2001–05
Study population and number	**n=577** Patients treated by posterior intravaginal slingplasty.
Age	Mean 64 years (range 30–86)
Patient selection criteria	Patients with pelvic organ prolapse treated by posterior intravaginal slingplasty. All patients had clinically evident prolapse, which was staged according to the ICS classification.
Technique	Posterior intravaginal slingplasty was done using the IVS tunneller (Tyco Healthcare) with the original multifilament tape.
Follow-up	**Median 7 weeks (range 1-156)**
Conflict of interest/source of funding	One of the authors served as an instructor and speaker and a second one as a speaker for Gynecare.

Analysis

Follow-up issues:

- The registry was not set up to record long term problems; therefore it is likely that the long-term safety events have been underestimated.

Study design issues:

- The centres were asked to complete a 20-item questionnaire for every posterior intravaginal slingplasty procedure. The questionnaire contained items regarding the patient, the operation, the postoperative course and blood transfusions.
- In patients available for follow-up, data on tape exposure, urinary and bowel symptoms, dyspareunia, and physician's assessment of the anatomical and functional results of the procedure were collected.
- Chronic pelvic pain was not a separate item on the questionnaire.
- Median number of patients per centre was 41 (range 4 to 241) and 2 centres each reported more than 150 patients.
- Some questionnaires were completed retrospectively, some prospectively.
- Compliance to the registry was voluntary and there was no mechanism for data verification.
- Subjective patient data were not acquired with standardised questionnaires and the patients seen for follow-up were not examined or interviewed by independent observers or graded with the International Continence Society (ICS) prolapse score.
- Increased intraoperative bleeding was not defined.

Study population issues:

- ICS stage of prolapse before the procedure: 38% (221/577) of patients had stage 2, 37% (215/577) stage 3 and 4, 17% (100/577) stage 1 and 8% (41/577) had missing data.
- 57% (329/577) of patients had been treated by previous gynaecologic surgery, including previous hysterectomy for 54% (310/577).
- Only 3% (17/577) of patients were treated by posterior intravaginal slingplasty as a solo procedure.

Other issues:

- During preparation of the manuscript, the IVS tunneler device was no longer available in the US.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **577**

Operating time

- PIVS only (n=17): median 45 minutes (range 30 to 111)
- Overall (n=577): median 80 minutes (range 26 to 385)

Postoperative stay: median 7 days (range 3 to 24)

Functional results assessed by physicians at median 7 weeks, range 1 to 156 (n=496)

	% (n/N) patients
Excellent	63% (314/496)
Good	20% (98/496)
Fair	8% (42/496)
Poor	5% (24/496)
Not available	3%* (17/496)

*4% written in the paper.

Anatomical results assessed by physicians at median 7 weeks, range 1-156 (n=496)

	% (n/N) patients
Excellent	59% (292/496)
Good	29% (144/496)
Fair	6% (28/496)
Poor	2% (10/496)
Not available	4% (22/496)

Safety

Intra-operative complications: *3% (16/577)**

	% (n/N) patients	Detail
Increased bleeding	1% (7/577)	Controlled with conservative measures in all patients.
Bladder injury	1% (5/577)	All the injuries occurred in patients with concomitant procedures during vaginal dissections (not with the device).
Rectum injury	1% (3/577)	All 3 injuries occurred in patients with previous hysterectomy and treated with concomitant posterior colporrhaphy. 2 of the rectal perforations occurred with the device and the tape was removed; 1 occurred during posterior colporrhaphy and the tape was placed but the patient developed an erosion in the posterior vaginal wall 9 months later and part of the tape was removed.

*As reported in the paper but the figures for the different complications make a total of 15.

Postoperative course

	% (n/N) patients
Febrile morbidity (2 temperature measurements >38ºC)	2% (13/577)
Blood transfusion	2% (9/577)
Evacuation of haematoma	1% (5/577)

- In 1 patient, ureteral obstruction was detected on day 1 after correction of stage 3 vault prolapse with PIVS and anterior colporrhaphy and additional mesh. A ureteral stent was placed for 6 weeks for treatment.
- 2 patients with haematomas (1 paravesical and 1 prerectal) had another operation on the day of surgery and received blood products. Both had been treated by PIVS with anterior and posterior colporrhaphy. 3 other patients who had been treated by PIVS with hysterectomy and anterior and posterior colporrhaphy had another operation for haematoma later than day 1.

Reoperations during follow-up (median 7 weeks, range 1–156)

	% (n/N) patients	Detail
Removal of tape[a]	4% (21/496)	Range 8-212 weeks.
Loosening of tape	<1% (1/496)	Reoperation was done at 12 weeks.
Recurrent prolapse[a]	4% (20/496)	Range for reoperation: 10 to 96 weeks.
SUI operation	2% (12/496)	Range for reoperation: 9 to 64 weeks.
Evacuation of abscess	<1% (2/496)	1 vaginal cuff abscess (irrigated and drained at day 14); 1 gluteal abscess developed 2 years after the procedure (drained and the tape removed).
Hysterectomy	<1% (1/496)	For persistent dysfunctional uterine bleeding 2 years after the procedure.
Proportion of patients needing reoperation	11% (54/496)	Intention-to-treat=9.4% (54/577)

[a]2 patients had tape exposure and recurrent prolapse.

- One patient was diagnosed with urethral stenosis 2 years after the procedure; she was treated by urethral dilatation.

Symptoms at median 7 weeks, range 1-156 (n=496)

	% (n/N) patients
Vaginal tape exposure	10%* (50/496)
De novo bowel symptoms	<1% (1/496)
De novo urinary symptoms	6% (29/496)
De novo dyspareunia (in 348 sexually active women)	7% (25/348)

*In the paper, it says 8.7%, which is based on the intention-to-treat population (n=577).

Abbreviations used: PIVS, posterior intravaginal slingplasty; SUI, stress urinary incontinence

Study 8 Capobianco G (2014)

Details

Study type	**Case series**
Country	Italy
Recruitment period	2003–04
Study population and number	**n=44** Women with symptomatic vaginal vault (n=19) or uterine prolapse (n=25).
Age	Mean 63 years
Patient selection criteria	Women with symptomatic uterine or vaginal vault prolapse that extended to or beyond the introitus (stage 2 or above).
Technique	All procedures were done with the patient under general anaesthesia. Posterior intravaginal slingplasty (infracoccygeal sacropexy) was done using the IVS tunneller, with multifilament polypropylene tape. Concomitant procedures for anterior compartment prolapse or stress urinary incontinence were selected based on clinical judgement. All patients with uterovaginal prolapse had concomitant vaginal hysterectomy.
Follow-up	**9 years**
Conflict of interest/source of funding	None

Analysis

Follow-up issues:

- No patients were lost to follow-up.

Study design issues:

- The primary outcome was the cure of genital prolapse based on a POPQ score of -5 at point C, which describes the vaginal apex and a satisfactory level I support defined objectively as stage 0 or I for points Bp, C and total vaginal length.
- Quality of life was assessed by a modified King Health Questionnaire. The patients were also given a sexuality non-validated score questionnaire and a visual analogue scale score.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **44**

Success rate at 9 year follow-up=93.2% (41/44)

Relapse of prolapse=6.8% (3/44) (2 cystocele and 1 rectocele)

International Continence Society pelvic organ prolapse score (mean±standard deviation)

	Preoperative	Postoperative 9 years	p value
Point Aa (cm)	1.21±1.81	−2.42±1.23	<0.001
Point Ba (cm)	1.36±2.12	−2.31±1.32	<0.001
Point Ap (cm)	−0.42±1.62	−2.71±0.92	<0.001
Point Bp (cm)	−0.13±1.75	−2.62±0.81	<0.001
Point C	2.24±3.34	−6.45±1.63	<0.001
Total vaginal length (cm)	7.32±2.72	7.34±1.73	0.274

Symptoms before surgery and at 9-year follow-up, % (n)

	Preoperative	Postoperative	p value
Pelvic pain	68.2% (30)	45.5% (20)	0.24
Nocturia	40.9% (18)	0	0.003
Urgency	27.3% (12)	0	0.04
Prolapse	100% (44)	6.8% (3)	0.0001
Urinary tract infection	13.6% (6)	0	0.001

Sexual questionnaire before and after surgery.

	Preoperative	Postoperative
Deep dyspareunia during intercourse	100% (44/44)	11.4% (5/44)
Leakage of urine during intercourse	37.5% (18/44)	11.4% (5/44)

86.4% of patients reported that their sexual performance improved after the procedure.

100% (44/44) responded that their quality of life had improved and they all reported that they would recommend the surgery to their friends.

Safety

Complications

- Extrusion=2.3% (1/44) (treated with antibiotics and local oestrogen therapy)

There were no cases of rectal perforation, perioperative pain or hyperpyrexia.

Study 9 Baessler K (2005)

Details

Study type	**Case series**
Country	Australia, Germany and Switzerland
Recruitment period	2001–04
Study population and number	**n=19 (8 posterior intravaginal sling, 6 anterior intravaginal sling, 5 posterior and anterior intravaginal sling)** Women with complications after intravaginal slingplasty
Age	Mean 53 years (range 35–71)
Patient selection criteria	Women who were referred to 1 of 4 centres for complications following posterior or anterior intravaginal slingplasty using multifilament tape.
Technique	Posterior or anterior intravaginal slingplasty using multifilament polypropylene tape. Five patients had an additional graft overlay (3 Pelvicol [Bard, US] and 2 Prolene [Ethicon, US]). Three patients had concomitant posterior bridge repair. One patient had a second posterior intravaginal sling inserted for recurrent prolapse.
Follow-up	**1 month (median time to start of symptoms after initial intravaginal sling procedure; range up to 12 months)**
Conflict of interest/source of funding	Not reported

Analysis

Study design issues:

- The incidence of the complications reported in this series is unclear because the denominator is unknown.

Other issues:

- The indications for treatment by intravaginal slingplasty were not reported.
- This study was mentioned in the discussion of the review by Feiner et al. (2009) but it did not meet the inclusion criteria for the analysis.

Key efficacy and safety findings

Efficacy	Safety

Number of patients analysed: 19

Anatomical findings in 19 patients with complications after intravaginal slingplasty (IVS)

	Posterior IVS (n=13)	Anterior IVS (n=11)
Pelvic organ prolapse stage 2 or more		
Anterior	3	1
Vault	3	0
Posterior	7	0

Symptoms in 19 patients with complications after intravaginal slingplasty (IVS)

	Posterior IVS (n=13)	Anterior IVS (n=11)
Predominant pain – vagina	1	6
Predominant pain – rectum/buttocks	12	0
Predominant pain – bladder	0	4
Dyspareunia (sexually active patients)	12 (12)	10 (10)
Vaginal erosion and vaginal bleeding	5	6
Purulent/offensive vaginal discharge	3	6
Retropubic abscess and cutaneous sinus	0	1
Retropubic abscess and vesico-cutaneous fistula	0	1
Intravesical mesh/permanent sutures	0	2
Voiding difficulties	4	4
Faecal urgency	2	0
Difficult and painful defaecation/buttock pain sitting	13	0

Surgery to remove the mesh was done after a median time of 24 months (range 10 weeks to 36 months).

The removed mesh and adjacent tissue was sent for histopathology in 8 women and revealed acute and chronic inflammation.

At follow-up between 6 weeks and 6 months, in all women, genital pain, chronic discharge and bleeding, voiding and defaecation difficulties had been markedly alleviated (n=5) or had ceased (n=14).

71% (12/17) of sexually active women resumed sexual intercourse without difficulties.

10 women needed further surgery for stress incontinence or pelvic organ prolapse (3 Burch colposuspension, 1 tension-free vaginal tape, 1 transobturator tape, 7 anterior or posterior repairs, 1 sacrospinous colpopexy, 2 sacrocolpopexy). One woman had a significantly shortened and narrowed vagina and was treated by a vaginoplasty.

Abbreviations used: IVS, intravaginal slingplasty

In the following summary of efficacy and safety, the term 'infracoccygeal sacropexy' has been used throughout, although some studies referred to the procedure as 'posterior intravaginal slingplasty'.

Efficacy

Prolapse repair – clinician assessed

In a systematic review of 7,054 patients, including 976 patients with vaginal vault or uterine prolapse treated by infracoccygeal sacropexy, the median clinician reported prolapse recurrence rate was 5% (range 0% to 25%; 9 studies, n=402)[1]. For vaginal vault prolapse only, clinician reported recurrent prolapse at the original site was 7% (4/60; 2 case series). In a systematic review of 2,653 patients (655 treated by infracoccygeal sacropexy), the mean objective success rate was 88% for infracoccygeal sacropexy (range 37% to 99%; 95% confidence interval [CI] 87.2 to 89.1)[2]. In a randomised controlled trial (RCT) of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, anatomical success rates were 95% (20/21) and 100% (24/24) respectively (p=0.94)[3]. In a non-randomised comparative study of 190 women treated by infracoccygeal sacropexy or abdominal sacrocolpopexy, success rates (defined as grade 0, 1 or 2 prolapse of the anterior, apex, or posterior compartments) were 91% in both groups 6 weeks after the procedure and 80% and 85% respectively at 2 year follow-up[5]. In a case series of 118 patients, recurrence of vault prolapse occurred in 3% (4/118) of all patients (4% [1/25] for patients with vaginal cuff prolapse and 3% [3/93] for patients with uterovaginal prolapse)[6]. The vault prolapse recurrences were all seen at 24 month follow-up. In a case series of 44 patients, the success rate was 93% (41/44) at 9-year follow-up[8]. In a case series of 577 patients, anatomical results at median 7-week follow-up were assessed by physicians as good or excellent in 88% (436/496) of patients; functional results were assessed by physicians as good or excellent in 83% (412/496) of patients[7].

Prolapse repair – patient reported

In the systematic review of 7,054 patients, including 976 patients with vaginal vault or uterine prolapse treated by infracoccygeal sacropexy, the median rate of patients who reported persistent symptoms was 9% (range 2% to 21%; 3 studies, n=262)[1]. For vaginal vault prolapse only, 9% (8/91; 1 case series) of patients reported persistent prolapse symptoms. In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, the mean symptom scores (measured on a visual analogue scale from 0 [no symptoms] to 10 [very severe symptoms]) were 0.7±1.5 and 1.1±1.7 respectively (p=0.57)[3]. In the case series of 118 patients, a persistent vaginal bulge occurred in 9% (11/118) of all patients (12% [3/25] for patients with vaginal cuff prolapse and 9% [8/93] for patients with uterovaginal prolapse)[6].

Reoperation rates

In the systematic review of 7,054 patients including 976 patients with uterine or vaginal vault prolapse treated by infracoccygeal sacropexy, the reoperation rate ranged from 0% to 30% (median 8%; 3 studies, n=288)[1]. In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, 1 patient out of 3 treated by infracoccygeal sacropexy without hysterectomy was re-operated 3 months later for uterine prolapse recurrence. In the sacrospinous suspension group, 1 patient treated concomitantly by anterior colporrhaphy had another operation for a cystocoele recurrence[3]. In the case series of 118 patients, 2% (2/118) of patients had another operation for recurrence of prolapse[6]. In the case series of 577 patients, 4% (20/496) of patients had another operation within 10–96 weeks of the procedure for recurrent prolapse[7].

Improvement of urinary symptoms

In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, postoperative rates of stress urinary incontinence were 0% (0/21) and 8% (2/24) respectively, compared with preoperative rates of 52% (11/21) and 29% (7/24) respectively[3]. Postoperative rates of urgency were 14% (3/21) and 25% (6/24) respectively, compared with preoperative rates of 52% (11/21) and 50% (12/24) respectively. The differences between the treatment groups were not statistically significant. In the non-randomised comparative study of 190 women treated by infracoccygeal sacropexy or abdominal sacrocolpopexy, there was a statistically significant decrease in the proportion of patients with stress urinary incontinence from 15% (14/92) and 16% (16/98) respectively at baseline to 4% (4/92) and 8% (8/98) respectively at 2 year follow-up[5]. The rate of nocturia reduced from 24% (22/92) at baseline to 14% (13/92) at 2 year follow-up in the infracoccygeal treatment group (p=0.004) and from 25% (24/98) to 21% (21/98) in the abdominal sacrocolpopexy group (p=0.250). In the case series of 118 patients, persistent stress urinary incontinence, urge incontinence and bladder overactivity symptoms were reported in 3% (3/118), 3% (4/118) and 4% (5/118) of patients respectively, after a mean follow-up of 59 months[6]. In the case series of 44 patients, none of the 18 patients who had nocturia at baseline had it at 9 year follow-up (p=0.003)[8]. Of the 12 patients with urgency at baseline, none of them reported the symptom at 9-year follow-up (p=0.04).

Improvement of disease-specific quality of life

In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, quality of life scores improved similarly in both treatment groups; the only statistically significant difference was seen for the Pelvic Organ Prolapse Distress Inventory score which improved in 75% of patients treated by infracoccygeal sacropexy and worsened in 6% compared with 65% improved and

10% worsened for sacrospinous suspension (p=0.02)[3]. In the case series of 118 patients, the Urinary Impact questionnaire scores improved from 134.6 at baseline to 115.7 after surgery (p<0.05) and the Pelvic Organ Prolapse Impact questionnaire scores improved from 164.3 at baseline to 108.4 after surgery (p<0.05), at a mean follow-up of 59 months[6]. There was no statistically significant difference in the Colorectal-Anal Impact questionnaire scores (107.5 at baseline and 114.1 after surgery).

Patient satisfaction

In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, 86% and 79% of patients respectively were satisfied or very satisfied after the procedure (p=0.85)[3]. In the case series of 44 patients, 100% (44/44) of patients responded that their quality of life had improved and they all reported that they would recommend the surgery to their friends[8].

Safety

Mesh erosion

Mesh erosion was reported in 11 studies (n=889) of infracoccygeal sacropexy, with rates ranging from 0–21% (median 7%), in a systematic review of 7,054 patients; another operation was needed for mesh erosion in up to 17% of patients (median 7%, 6 studies, n=678)[1]. For patients with vaginal vault prolapse only, mesh erosion was reported in 7% (2/30) of patients in a randomised controlled trial and 9% (22/235) of patients in 4 case series, in the systematic review[1]. Mesh erosion was reported in 8% of patients treated by infracoccygeal sacropexy (n=655) in a systematic review of 2,653 patients[2]. Mesh erosion was reported in 9% (10/118) of all patients in a case series of 118 patients with vaginal cuff or utero-vaginal prolapse; for patients with vaginal cuff prolapse, the rate of erosion was 20% (5/25)[6]. Surgery for erosion was needed in 2% (2/118) of patients. Extrusion was reported in 1 patient in a case series of 44 patients; this was treated with antibiotics and local oestrogen therapy[8]. Vaginal tape exposure was reported in 10% (50/496) of patients in a case series of 577 patients[7]. Reoperation to remove the tape was reported in 4% (21/496) of patients in the same study. Reoperation for anterior vaginal wall erosion was reported in 10% (2/21) of patients treated by infracoccygeal sacropexy and 8% (2/24) of patients treated by sacrospinous suspension, in a randomised controlled trial of 49 patients[3].

Bleeding

Intraoperative haemorrhage was reported in 1 patient treated by infracoccygeal sacropexy and 3 patients treated by sacrospinous suspension in a randomised

controlled trial (RCT) of 49 patients[3]. Intraoperative bleeding and blood transfusion were reported in 1% (7/577) and 2% (9/577) of patients respectively in the case series of 577 patients[7]. Blood transfusion was reported in 7 studies (n=383) of infracoccygeal sacropexy, with rates ranging from 0–2%, in the systematic review of 7,054 patients[1].

Haematoma

Haematoma was reported in 1% of patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients[2]. Postoperative haematoma was reported in 2 patients treated by infracoccygeal sacropexy and in no patients treated by sacrospinous suspension in the RCT of 49 patients[3]. Haematoma was reported in 3% (4/118) of all patients in the case series of 118 patients with vaginal cuff or utero-vaginal prolapse; 1 patient needed surgical evacuation and blood transfusion[6]. Haematoma was reported in 1 patient each treated by infracoccygeal sacropexy or abdominal sacrocolpopexy in a non-randomised comparative study of 190 patients[5]. Evacuation of haematoma was reported in 1% (5/577) of patients in the case series of 577 patients[7].

Organ damage

Organ damage was reported by 9 studies (n=684) on infracoccygeal sacropexy, with rates ranging from 0–3% (median 0%) in the systematic review of 7,054 patients[1]. Bladder injury was reported in 2 patients treated by infracoccygeal sacropexy and 1 patient treated by sacrospinous suspension in the RCT of 49 patients[3]. Bladder injury was reported in 1% (5/77) of patients in the case series of 577 patients; all occurred in patients with concomitant procedures, during vaginal dissections[7]. Rectal injury was reported in 1% (3/577) of patients in the same study; all occurred in patients with concomitant posterior colporrhaphy[7].

Infection, abscess or fistula formation

Infection was reported in 8 studies (n=698) of infracoccygeal sacropexy, with rates ranging from 0% to 9%, in the systematic review of 7,054 patients[1]. Pararectal abscess was reported in 1 patient treated by infracoccygeal sacropexy in the systematic review of 2,653 patients[2]. Gluteovaginal sinus formation 3 months after infracoccygeal sacropexy and rectocutaneous fistula 2 months postoperatively were each described in a case report, included in the same review[2]. Abscess or fistula was reported in 3% (3/118) of patients in the case series of 118 patients; all 3 patients were treated by surgery[6]. Evacuation of abscess was reported in less than 1% (2/496) of patients in the case series of 577 patients[7].

Dyspareunia

Dyspareunia was reported in 2% of patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients[2]. De novo dyspareunia was reported in 7% (25/348) of sexually active patients in the case series of 577 patients[7].

Pain

Prolonged pain was reported in 4 patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients[2].

Bladder symptoms

De novo urge urinary incontinence or bladder overactivity symptoms were reported in 9% (10/118) of patients and de novo stress urinary incontinence was reported in 6% (7/118) of patients in the case series of 118 patients[6]. De novo urinary symptoms were reported in 6% (29/496) of patients in the case series of 577 patients[7].

Bowel symptoms

De novo constipation after the procedure was reported in 6% (7/118) of patients in the case series of 118 patients[6]. Constipation was reported in 2% (2/92) of patients treated by infracoccygeal sacropexy and 9% (9/98) of patients treated by abdominal sacrocolpopexy in the non-randomised comparative study of 190 patients[5]. De novo bowel symptoms were reported in 1 patient in the case series of 577 patients[7].

Other

Proctotomy was reported in 1 patient treated by infracoccygeal sacropexy in the systematic review of 2,653 patients (no further details reported)[2].

Validity and generalisability of the studies

- Many studies included in the overview involved women with vaginal vault prolapse or uterine prolapse. Some of the results were not reported separately for the different indications.
- There were only 2 small randomised controlled trials, both of which were stopped early when the study centres stopped using multifilament

polypropylene tape[3,4]. An additional randomised controlled trial was included in the 2 systematic reviews but it has only been published as an abstract.

- A small proportion of patients were treated by infracoccygeal sacropexy only; most studies included concomitant procedures, including repair of other types of prolapse or procedures to treat stress urinary incontinence.
- The classification of success varied between the studies. One of the systematic reviews noted that exceptionally poor outcomes were reported from one study, which used stringent criteria of primary failure so that women with POP-Q stage 1 could have been considered as an unsuccessful outcome[2]. In most other studies, stage 1 was considered to be a success. One study included stage 2 as a successful outcome[5].

Existing assessments of this procedure

The International Federation of Gynecology and Obstetrics (FIGO) published a working group report in 2015[10]. With regard to infracoccygeal sacropexy, the recommendation stated: 'Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for uterine and vaginal vault prolapse repair is inadequate. The FIGO working group only recommends this procedure as part of a study or under the supervision of the authorities and the control of an independent monitoring board to audit benefit/success for the patients.'

In December 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published an opinion on 'The safety of surgical meshes used in urogynecological Surgery'[11]. It stated: 'The SCENIHR considers three factors as being important when assessing the risks associated with mesh application: the overall surface area of material used, the product design and the properties of the material used. In addition, the available evidence suggests a higher morbidity in treating female pelvic organ prolapse (POP) than Stress Urinary Incontinence (SUI), as the former uses a much larger amount of mesh.

The body of evidence suggests that, when assessing the health risks of synthetic meshes, there is a need to clearly separate the smaller risks associated with stress urinary incontinence sling surgery from those of pelvic organ prolapse mesh surgery.

Based on the currently marketed products, assessment of the risks reported indicates that polypropylene type 1 meshes are the most appropriate synthetic

meshes for vaginal use and polypropylene type 1 and polyester type 3 for insertion via the abdominal route. However, there is a need for further improvement in the composition and design of synthetic meshes, in particular for female pelvic organ prolapse surgery.'

SCENIHR's recommendations include:

• Material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and surgeon's experience are aspects influencing the clinical outcome following mesh implantation. Such aspects are to be considered when choosing appropriate therapy.

• For all procedures, the amount of mesh should be limited where possible.

• The implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery.

• A certification system for surgeons should be introduced based on existing international guidelines and established in cooperation with the relevant European Surgical Associations.

A mesh working group interim report was published in December 2015 by NHS England[12]. Its recommendations included: reviewing the current NICE guidance and creating new guidance, raising awareness amongst GPs of complications and how to address them, improving rates of reporting of adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA), and submissions to the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS) databases, improving Hospital Episode Statistics (HES) coding, raising awareness amongst patients of their option to use MHRA reporting procedures for adverse incidents, and developing information leaflets on mesh implant procedures for both stress urinary incontinence (SUI) and pelvic organ prolapse (POP) which provide consistent and understandable information to be used in the consenting process.

A Scottish Independent Review of the 'Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women' final report was published in March 2017 by The Scottish Government[13].

A summary of the evidence on the benefits and risks of vaginal mesh implants was published in October 2014 by the MHRA[14]. It stated: 'MHRA's current position is that, for the majority of women, the use of vaginal mesh implants is safe and effective. However, as with all surgery, there is an element of risk to the

individual patient. This conclusion is entirely dependent on compliance with NICE and other sources of guidance, which emphasise the caution that should be exercised prior to surgery being considered. Whilst some women have experienced distressing and severe effects, the current evidence shows that when these products are used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks.'

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse. NICE interventional procedure guidance 577 (2017). Available from http://www.nice.org.uk/guidance/IPG577
- Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE interventional procedure guidance 566 (2016). Available from http://www.nice.org.uk/guidance/IPG566
- Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 283 (2009). Available from http://www.nice.org.uk/guidance/IPG283
- Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair. NICE interventional procedure guidance 282 (2009). Available from http://www.nice.org.uk/guidance/IPG282
- Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE interventional procedure guidance 280 (2009). Available from http://www.nice.org.uk/guidance/IPG280
- Surgical repair of vaginal wall prolapse using mesh. NICE interventional procedure guidance 267 (2008). Available from http://www.nice.org.uk/guidance/IPG267

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two Specialist Advisor Questionnaires for infracoccygeal sacropexy using mesh for vaginal vault prolapse repair were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent 30 questionnaires to 1 NHS trust for distribution to patients who had the procedure (or their carers). NICE received 13 completed questionnaires.

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Company engagement

No structured information requests were sent to companies who manufacture a potentially relevant device for use in this procedure.

Issues for consideration by IPAC

- A device used for this procedure (IVS tunneler) has been withdrawn from the market and no other currently available devices have been identified.
- The evidence included in this overview includes a number of women with uterine prolapse, which is subject to a separate piece of guidance.

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14. MHRA report. A summary of the evidence on the benefits and risks of vaginal mesh implants. Published on 28 October 2014. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf

Appendix A: Additional papers on infracoccygeal sacropexy using mesh to repair vaginal vault prolapse

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Balsak D, Uysal A, Cavus Y et al. (2013) Treatment of Vaginal Cuff Prolapses with Posterior Intravaginal Sling and Evaluation of Efficiency with International Consultation on Incontinence Questionnaire-Vaginal Symptoms Method in the Long Term: Preliminary Results. Lower urinary tract symptoms 5: 140–4	Case series n=21 FU=25 months	The rate of surgical success was 100%, the rate of mesh erosion was 14.2% and the rate of dyspareunia was 33.3%. Vaginal symptom, sexual matter and quality of life scores were statistically significant in the postoperative period compared to the preoperative period (p=0.001, p=0.001, p=0.001, respectively).	Studies with more patients or longer follow-up are included.
Barski D, Otto T, Gerullis H. (2014) Systematic Review and Classification of Complications after Anterior, Posterior, Apical, and Total Vaginal Mesh Implantation for Prolapse Repair. Surgical Technology International XXIV.	Systematic review 1 trial on infracoccygeal sacropexy (n=118)	Long term surveillance studies and randomised controlled trials for the vaginal mesh kits are necessary.	The review only included 1 trial on infracoccygeal sacropexy, which is summarised separately in table 2 (Cosma S et al., 2011).
Beer M, Kuhn A. (2005) A.Surgical techniques for vault prolapse: A review of the literature. European Journal of Obstetrics Gynecology and Reproductive Biology 119: 144–55	Review 2 trials on infracoccygeal sacropexy	The 2 main operations for vaginal vault prolapse are abdominal sacrocolpopexy and sacrospinous fixation. New techniques, such as posterior IVS, are promising in that they use a minimally invasive approach, but prospective randomised studies with long term follow-up are lacking.	No meta-analysis. The review only identified 2 trials, both of which were included in Jia X, 2010.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Biertho I, Dallemagne B, Dewandre JM et al. (2004) Intravaginal slingplasty: Short term results. Acta Chirurgica Belgica 104: 700-704	Case series n=34 FU=median 3 months	Post-operative complication rate was 2.9%: bleeding from an internal haemorrhoid required surgical haemostasis. There was also 1 mesh erosion (2.9%). Recurrence rate was 8.8% (two cystoceles and one rectocele recurred after surgery).	Studies with more patients or longer follow-up are included.
Chen H-Y, Ho M, Chang Y-Y et al. (2011) Risk factors for surgical failure after posterior intravaginal slingplasty: a case series. European journal of obstetrics, gynecology, and reproductive biology 155: 106-9	Case series n=65 FU=30 months	The surgical failure rate following posterior intravaginal slingplasty was 13.1% (8/61). Using univariable logistic regression, C or D point stage IV before surgery was significantly associated with surgical failure of posterior intravaginal slingplasty for uterine or vaginal vault prolapse. Complications (11/61=18%) included vaginal erosion (9.8%), blood loss over 500 ml (4.9%), and perineal pain (3.3%).	Studies with more patients or longer follow-up are included.
Cosma S, Menato G, Preti M et al. (2014) Advanced utero-vaginal prolapse and vaginal vault suspension: synthetic mesh vs native tissue repair. Archives of Gynecology and Obstetrics 289: 1053–60	Non-randomised comparative study n=122 FU=56 months	Recurrent vault prolapse was observed more frequently in the uterosacral ligament suspension (ULS) group than the infracoccygeal sacropexy group with pre-intervention stage IV prolapse (0 vs 15%; p=0.04), while there was no difference in prolapse recurrence at any vaginal site. Although the subjective cure of infracoccygeal sacropexy and ULS was superimposable (92 vs 87%; p=0.25), there was a significantly higher cure rate, without adverse events, in the ULS group (90 vs 100%; p=0.01).	It appears that the patients all had uterine prolapse, which is covered by a separate piece of guidance.
Deffieux X, Desseaux K, de Tayrac R et al. (2009) Infracoccygeal sacropexy for uterovaginal prolapse. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 1: 56–9	Case series n=87 FU=27 months	Postoperative perineal pain was reported by 7 women (10%), and dyschesia and dyspareunia were observed de novo in 4 (5%) and 5 women (6%), respectively. There were 5 cases (9%) of vaginal extrusion and 9 cases (18%) of prolapse recurrence in the multifilament tape group, and in the monofilament tape group there were no cases of vaginal extrusion and 4 cases (14%) of prolapse recurrence (p=0.79 for prolapse recurrence). The recurrence-free survival curves of the 2 groups were similar.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Demirci F, Birgul K, Demirci O, et al. (2013) Perioperative complications in vaginal mesh procedures using trocar in pelvic organ prolapse repair Journal of Obstetrics & Gynaecology of India 63 (5): 328-31.	Retrospective review n=120 (17 infracoccygeal sacropexy)	3 bladder injuries (2.5%) and 1 distal rectal injury (0.8%) occurred during dissection (3 patients had previous prolapse repair). Four patients (3%) needed transfusion. Urinary retention exceeding 5 days occurred in 4 patients (3 also had TVT-O). Groin pain occurred in 2 patients, 1 of whom underwent TVT-O. Gluteal pain occurred in 1 patient. Early mesh exposure occurred in the vaginal cuff of a patient who had hysterectomy.	Only a small proportion of patients were treated by infracoccygeal sacropexy, and the results were not reported separately.
Farnsworth BN (2002) Posterior intravaginal slingplasty (Infracoccygeal Sacropexy) for severe posthysterectomy vaginal vault prolapse - A preliminary report on efficacy and safety. International Urogynecology Journal and Pelvic Floor Dysfunction 13: 4–8	Case series n=93 FU=median 12 months	The symptomatic cure rates for prolapse were 91%, urgency 79%, nocturia 82% and pelvic pain 78%. All patients were discharged home within 24 hours. There were minimal surgical complications and no transfusions were required.	Study is included in Jia X et al, 2010.
Foote AJ (2007) Infracoccygeal sacropexy. Australian and New Zealand Journal of Obstetrics and Gynaecology 47:250–251	Case series n=52 FU=20 weeks	Mesh erosion rate=21.1% This rate is higher than the rates for single-filament meshes used for suburethral slings. This study suggests that multifilament meshes should no longer be used due to the unacceptably high erosion rate.	Study is included in Jia X et al, 2010.
Ghanbari Z, Baratali BH, Mireshghi MS (2006) Posterior intravaginal slingplasty (infracoccygeal sacropexy) in the treatment of vaginal vault prolapse. International Journal of Gynecology and Obstetrics 94: 147–8	Case series n=15	Tape rejection occurred in 1 woman 6 months after the procedure. Prolapse was still present in 1 out of the 15 women after surgery.	Study is included in Jia X et al, 2010.
Grigoras D, Pirtea L, Bacila M et al. (2012) Ifracoccigeal sacropexy and sacrospinous fixation in the treatment of masive enterocele and posterior fornix syndrome. Gineco.ro 8: 86-88	Case report n=1	A bilateral sacrospinous fixation and posterior vaginal slingplasty were done. There was significant improvement: no more nocturia, urgency and frequency, and disappearance of the pelvic pain.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Grynberg M, Teyssedre J, Staerman F. (2009) Gluteo-vaginal fistula after posterior intravaginal slingplasty: a case report. International Urogynecology Journal 20: 877–9	Case report n=1	**Gluteo-vaginal fistula** The patient was treated by posterior intravaginal slingplasty (IVS) for vaginal vault prolapse and rectocele repair. The IVS tape was reinforced by interposing a monofilament polypropylene mesh. Imaging studies and surgical exploration confirmed infection of the IVS mesh and formation of a gluteo-vaginal fistula. The IVS mesh was removed and symptoms resolved within 3 months.	Fistula is already described as an adverse event in table 2.
Hefni M, Yousri N, El-Toukhy T et al. (2007) Morbidity associated with posterior intravaginal slingplasty for uterovaginal and vault prolapse. Archives of gynecology and obstetrics 5: 499–504	Case series n=127 FU=14 months	Posterior intravaginal slingplasty is a minimally invasive procedure for upper genital prolapse with an acceptable success rate. However, the operation is associated with high vaginal erosion and re-operation rates.	Study is included in Jia X et al, 2010.
Hilger WS, Cornella JL (2005) Rectovaginal fistula after posterior intravaginal slingplasty and polypropylene mesh augmented rectocele repair. International Urogynecology Journal 17: 89–92	Case report n=1	**Rectovaginal fistula** The patient developed a rectovaginal fistula 3 months after a posterior intravaginal slingplasty and mesh augmented rectocele repair for prolapse. Two attempts at repairing the fistula failed and the prolapse recurred. The patient is currently being treated by conservative management while reoperation and diverting colostomy are considered.	Fistula is already described as an adverse event in table 2.
Hinoul P, Vanspauwen R, Smajda S et al. (2010) The Posterior Intravaginal Slingplasty treatment for apical prolapse: 3 years experience in a single centre setting. Facts, views & vision in ObGyn 2: 1-8	Case series n=29 FU=3 years	No serious peroperative complications, bladder injuries or rectal perforations were encountered. Overall anatomical success rates (<Stage 2, International Continence Society criteria) declined from 86% to 58% and 50% after 1, 2 and 3 years, respectively. Erosion of the Posterior IVS tape was encountered in 14% (4/29) of patients; 2 of which presented as gluteo-vaginal fistulas. 3 years follow-up yields a high anatomical failure and substantial surgical reintervention rate.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Ilhan TT, Sivaslioglu A, Ilhan T et al. (2016) Comparison of the Efficiency of Posterior Intravaginal Sling (PIVS) Procedure in Older and Younger Groups. Journal of clinical and diagnostic research: JCDR 10: QC05-7	Case series n=40 FU=1 year	Anatomical cure rates=90% There were significantly greater improvements in POP-Q points in group I (patients younger than 60 years) than group II (patients aged 60 or above).	Studies with more patients or longer follow-up are included.
Jordaan DJ, Prollius A, Cronje HS et al. (2006) Posterior intravaginal slingplasty for vaginal prolapse. International Urogynecology Journal and Pelvic Floor Dysfunction 17: 326-329	Case series n=42 FU=median 13 months	The posterior intravaginal slingplasty (IVS) delivered satisfactory results for vault and posterior compartment prolapse, with a 75% improvement in vault prolapse. It was not possible, however, to separate the effect of posterior IVS and posterior colporrhaphy on the prevention of recurrent prolapse nor on the improvement of difficulty in defecation.	Study is included in Jia X et al, 2010.
Karp D, Apostolis C, Lefevre R et al. (2009) Atypical graft infection presenting as a remote draining sinus. Obstetrics and Gynecology 114: 443–5	Case report n=1	**Atypical infection presenting as a draining sinus tract to the lower extremity.** The patient presented with recurrent leg cellulitis 18 months after posterior intravaginal slingplasty for vaginal vault prolapse. A 35 cm fistulous tract draining from the pelvic to the lower thigh was identified. The patient was treated by surgical debridement and 12 weeks of intravenous antibiotics.	Infection is already described as an adverse event.
Kim MR, Kim JH, Cho HH. (2008) Infracoccygeal sacropexy improves the quality of life of women with uterine prolapse. Maturitas 2: 158–62	Case series n=35 FU=6 months	The preoperative grade of prolapse was 2.7+/-0.7; 6 months after the surgery, it decreased to 0.4+/-0.6. Pelvic Floor Distress Inventory-20 and its 3 respective scales demonstrated statistically significant improvements following the surgery ($p<0.05$). The 3 scales of Pelvic Floor Impact Questionnaire-7 exhibited statistically significant improvements after the surgery.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Lee Y-S, Han DH, Lee JY et al. (2010) Anatomical and functional outcomes of posterior intravaginal slingplasty for the treatment of vaginal vault or uterine prolapse: a prospective, multicenter study. Korean journal of urology 51: 187-92	Case series n=32 FU=12 months	The cure and improvement rates were 65.6% and 34.4%, respectively. All subscale scores of the Urinary Distress Inventory, the general subscale score of the Pelvic Organ Prolapse Distress Inventory, and the rectal prolapse subscale score of the Colo-Rectal-Anal Distress Inventory were significantly improved. There were no significant changes in the frequency volume chart or uroflowmetry parameters. There was 1 case of surgery-related transfusion.	Studies with more patients or longer follow-up are included.
Luck AM, Steele AC, Leong FC et al. (2008) Short-term efficacy and complications of posterior intravaginal slingplasty. International urogynecology journal and pelvic floor dysfunction 19: 795-9	Case series n=90 FU=33 weeks	There were no intraoperative bladder, bowel, or vascular injuries. Overall, 11 out of 90 patients developed recurrent or de novo prolapse; 4.4% of these had recurrent apical prolapse. There was a 17.8% incidence of mesh erosion. Only 1 of the 11 patients with recurrent prolapse had concomitant mesh erosion. The procedure demonstrated an unacceptably high erosion rate.	Studies with more patients or longer follow-up are included.
Maher C, Feiner B, Baessler K, et al. (2016) Surgery for women with apical vaginal prolapse. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD012376. DOI: 10.1002/14651858.CD012376.	Systematic review 30 RCTs (3414 women); 2 RCTs for infracoccygeal sacropexy	Sacral colpopexy is associated with lower risk of awareness of prolapse, recurrent prolapse on examination, repeat surgery for prolapse, postoperative SUI and dyspareunia than a variety of vaginal interventions. The limited evidence does not support use of transvaginal mesh compared to native tissue repair for apical vaginal prolapse. Most of the evaluated transvaginal meshes are no longer available and new lighter meshes currently lack evidence of safety.	The review only included 2 trials on infracoccygeal sacropexy, both of which were included in other systematic reviews summarised in table 2 (Jia X, 2010 and Feiner B, 2009).
Maher C, Feiner B, Baessler K et al. (2013) Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews Issue 4. Art. No.: CD004014. DOI: 10.1002/14651858.CD004014.pub5.	Systematic review 2 trials on infracoccygeal sacropexy (n=115)	The combined trials had too few data to identify differences in most of the outcomes reported, including satisfaction, objective recurrences at the upper vagina, anterior compartment prolapse, posterior compartment prolapse, the rate of post-operative stress urinary incontinence, urge incontinence, constipation, adverse events, and hospital stay. With the posterior intravaginal slingplasty operation the mean operating time was shorter (mean difference 8 min, 95% CI 4 to 11) and blood loss less (mean difference 70ml, 95% CI 56 to 84) compared with vaginal sacrospinous colpopexy.	The review only identified 2 trials, both of which were included in other systematic reviews summarised in table 2 (Jia X, 2010 and Feiner B, 2009).

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Mattox TF, Moore S, Stanford EJ et al. (2006). Posterior vaginal sling experience in elderly patients yields poor results. American Journal of Obstetrics and Gynecology 194: 1462-1466	Case series n=21	Primary or secondary failures=63% (12/19). There were 5 primary failures (26%) and 7 secondary failures (37%). The mean time to failure was 7 weeks (range 1-18). Conclusion: In our elderly population, the posterior vaginal sling has a high failure rate, occurring early in the postoperative period.	Study is included in Jia X et al, 2010.
Mikos T, Tsalikis T, Papanikolaou A et al. (2008) Gluteo-vaginal sinus formation complicating posterior intravaginal slingplasty followed by successful IVS removal. A case report and review of the literature. International Urogynecology Journal 19: 449–52	Case report n=1	**Bilateral gluteo-vaginal sinus tract formation** At 3 month follow-up, the patient had prolapse recurrence and there was defective healing at the gluteal entry points. She subsequently had a subtotal hysterectomy and sacrocervicopexy and the posterior mesh was removed. The sinus tract was managed surgically with excision of the surrounding tissues. There was no recurrence or other complications 2 months later.	Study is included in the Feiner B et al, 2009 systematic review.
Neuman M, Lavy Y (2007) Conservation of the prolapsed uterus is a valid option: Medium term results of a prospective comparative study with the posterior intravaginal slingoplasty operation. International Urogynecology Journal and Pelvic Floor Dysfunction 18: 889–93	Case series n=79 FU=30 months	The current results support the previously reported efficacy, safety, and simplicity of the PIVS procedure as well as the legitimacy of uterine preservation. Moreover, unstable bladder symptoms were found to be improved after this operation. However, long-term data are required to be able to draw solid conclusions concerning the superiority of the procedure.	Study is included in Jia X et al, 2010.
Neuman M, Lavy Y (2008) Posterior intra-vaginal slingplasty for the treatment of vaginal apex prolapse: Medium-term results of 140 operations with a novel procedure. European journal of obstetrics, gynecology, and reproductive biology 140: 230-3	Case series n=140 FU=19 months	Surgical failure=2.1% (3/14) Vaginal tape protrusion=8.6% (12/140) One patient had post-operative unilateral gluteal skin infection. She was treated by surgical removal of the infected hemi-tape. Two patients had spontaneous rejection of the tape while the vaginal apex remained well suspended. One patient suffered from post-operative fever of unknown origin, which was effectively treated with oral antibiotics.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Nyyssonen V, Talvensaari-Mattila A, Santala M (2013) Posterior Intravaginal Slingplasty versus Unilateral Sacrospinous Ligament Fixation in Treatment of Vaginal Vault Prolapse. ISRN Obstetrics and Gynecology http://dx.doi.org/10.1155/2013/958670	Non-randomised comparative study n=33 (16 versus 17) Follow-up=median 16 months (range 6 to 52)	Mesh erosion was found in 4 (25%) patients in the posterior intravaginal slingplasty (PIVS) group. Anatomical stage II prolapse or worse (any POP-Q point >-1) was detected in 8 (50%) patients in the PIVS group and 9 (53%) patients in the unilateral sacrospinous ligament fixation group. Overall satisfaction rates were 62% and 76%, respectively.	Small, non-randomised comparative study with relatively short follow-up.
Oliver R, Dasgupta C, Coker A. (2006) Posterior intravaginal slingplasty for vault and uterovaginal prolapse: An initial experience. Gynecological Surgery 3: 88-92	Case series n=14 FU=6 months	Cure of vault prolapse=100% (10/10) Cure of pelvic pain in women with vault prolapse=86% (6/7) The quality of life assessment showed improvement in all the aspects covered by the questionnaire. Larger trials and randomised trials are needed to assess the long-term efficacy and safety of the procedure.	Study is included in Jia X et al, 2010.
Oliver R, Odutola O, Coker A. (2008) Functional outcomes of posterior intravaginal slingplasty: Report on its impact on urinary, bowel and psychosexual function. Gynecological Surgery 5: 275-280	Case series n=31 FU=19 months	The results show significant improvement in all prolapse symptoms. Urinary symptoms of overactive bladder and stress incontinence improved significantly, as well as the bowel symptoms of obstructed defecation and urgency. Sexual function and psychological state also improved significantly with the procedure.	Studies with more patients or longer follow-up are included.
Papa Petros PE (2001) Vault Prolapse II: Restoration of Dynamic Vaginal Supports by Infracoccygeal Sacropexy, an Axial Day-Case Vaginal Procedure. International Urogynecology Journal and Pelvic Floor Dysfunction 12: 296–303	Case series n=75 FU=1–4.5 years	Vault prolapse recurred in 6%. The main complication was tape erosion (5.3%). Infracoccygeal sacropexy is a promising day-case alternative to conventional methods. It has built-in safety, as it avoids pudendal nerves and vessels and surface rectal veins.	Study is included in Jia X et al, 2010.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Paulson JD (2006) Rectal perforation by a posterior intervaginal slingplasty. Journal of Pelvic Medicine & Surgery 12: 169–70	Case report n=1	**Rectal perforation** The patient had a posterior intravaginal slingplasty and an anterior compartment repair. Examination of the rectum after mesh placement demonstrated mesh within the rectum. The tape was removed without rectal repair and the patient was sent home on antibiotics on postoperative day 3. At 6 months, the vault was well supported without any sequelae to the rectal perforation at the time of surgery.	Rectal perforation is already mentioned as an adverse event.
Rane A, Lim YN, Withey G et al. (2004) Magnetic resonance imaging findings following three different vaginal vault prolapse repair procedures: A randomised study. Australian and New Zealand Journal of Obstetrics and Gynaecology 44: 135 - 39	RCT n=21 (7 versus 7 versus 7) Follow-up=6 to 12 weeks	Significant improvements in the restoration of vaginal configuration were achieved in patients who underwent posterior intravaginal slingplasty or sacrocolpopexy. Sacrospinous fixation in contrast seems to increase anatomical distortion of the vaginal configuration.	Small study, which focuses on vaginal configuration on MRI after prolapse repair.
Sentilhes L, Sergent F, Resch B et al. (2008) Infracoccygeal sacropexy reinforced with posterior mesh interposition for apical and posterior compartment prolapse. European journal of obstetrics, gynecology, and reproductive biology 137: 108–13	Case series n=72 FU=26 months	Both objective and subjective success rates were 97.2%. All subjective prolapse symptoms decreased after surgery. The only intraoperative complication was one rectal injury. Vaginal erosion rate was 13.9% and mesh infection rate was 4.2%. Vaginal erosions statistically occurred less often with monofilament polypropylene (5.7%, 2/35) than with multifilament polypropylene (13.6%, 3/22) or polyester (33.3%, 5/15) ($p<0.04$).	Studies with more patients or longer follow-up are included.
Sivaslioglu AA, Gelisen O, Dolen I et al. (2005) Posterior sling (infracoccygeal sacropexy): An alternative procedure for vaginal vault prolapse. Australian and New Zealand Journal of Obstetrics and Gynaecology 45: 159–60	Case series n=30 FU=16 months	1 patient had recurrence after the procedure. There were improvements in pelvic pain, urgency, nocturia, and 'obstructed' micturition feeling. None of the patients needed blood transfusion and there were no rectal perforations.	Study is included in Jia X et al, 2010.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Vardy MD, Brodman M, Olivera CK et al. (2007) Anterior intravaginal slingplasty tunneller device for stress incontinence and posterior intravaginal slingplasty for apical vault prolapse: a 2-year prospective multicenter study. American Journal of Obstetrics and Gynecology 197:104–6	Case series n=164 posterior IVS; 122 anterior and posterior IVS	Anterior intravaginal slingplasty and posterior intravaginal slingplasty are safe and effective when performed with other procedures. For anterior intravaginal slingplasty, the rates of perforation and retention are low, but early extrusions are seen. Patients showed improvements in the Pelvic Floor Impact Questionnaire, regardless of extrusion.	Study is included in Jia X et al, 2010.
Yee YH, Lu CC, Kung FT et al. (2008) Rectocutaneous fistula: a rare complication of the posterior intravaginal sling. International Urogynaecology Journal 19: 599–601	Case report n=1	**Rectocutaneous fistula** Rectocutaneous fistula formed 2 months after placement of a posterior intravaginal sling for grade II uterine prolapse and rectocoele. Rectal perforation that occurred at the time of the procedure was undetected. The authors noted that this was 1 of the first 5 cases of this procedure to be done by the surgeon.	Study is included in the Feiner B et al, 2009 systematic review and fistula is already described as an adverse event.

Appendix B: Related NICE guidance for infracoccygeal sacropexy using mesh to repair vaginal vault prolapse

Guidance	Recommendations
Interventional procedures	**Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse. NICE interventional procedure guidance 577 (2017).** 1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to do sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse should: • Inform the clinical governance leads in their trusts. • During the consent process, ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. 1.3 Patient selection and treatment should only be done by specialists with experience in managing pelvic organ prolapse and urinary incontinence in women. All clinicians doing this procedure should have specific up-to-date training in the procedure. 1.4 Clinicians should enter details about all patients having sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical device used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency. 1.5 NICE may update the guidance on publication of further evidence.

Interventional procedures	**Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE interventional procedure guidance 566 (2016).** 1.1 The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include lasting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but, if removal is needed because of complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research. 1.2 Clinicians wishing to do single-incision short sling mesh insertion for stress urinary incontinence in women should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, and that the mesh implant is intended to be permanent so removal, if needed, may be difficult or impossible. Provide patients with clear written information. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence in women (see section 7.1). 1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence.

	1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. Removal of a short sling mesh should only be done by people with expertise in this specialised surgery. 1.5 NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.

Interventional procedures	**Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 283 (2009).** 1.1 Current evidence on the safety and efficacy of sacrocolpopexy using mesh for vaginal vault prolapse repair appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit. 1.2 During the consent process, clinicians should ensure patients understand that there is a risk of recurrence of vaginal vault prolapse after any prolapse repair procedure, and that there is also a risk of complications, including mesh erosion (for example, into the vagina), and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 Evidence on safety and efficacy outcomes is limited to 5 years. Evidence on outcomes beyond 5 years and on different types of mesh would be useful. Further research should include patientreported quality-of-life outcome measures using validated scales.

Interventional procedures	**Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair. NICE interventional procedure guidance 282 (2009).** 1.1 Current evidence on the safety and efficacy of insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair and may review the procedure on publication of further evidence on different types of mesh. Future research should include short- and long-term efficacy, safety outcomes (such as mesh erosion in the long term), patient-reported quality-of-life outcomes using validated scales and subsequent successful pregnancy.

Interventional procedures	**Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE interventional procedure guidance 280 (2009).** 1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for uterine prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake infracoccygeal sacropexy using mesh for uterine prolapse repair should take the following actions: • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for uterine prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes using validated scales.

Interventional procedures	**Surgical repair of vaginal wall prolapse using mesh. NICE interventional procedure guidance 267 (2008).** 1.1 The evidence suggests that surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional surgical repair of vaginal wall prolapse without mesh. Both efficacy and safety vary with different types of mesh, and the data on efficacy in the long term are limited in quantity. There is a risk of complications that can cause significant morbidity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake surgical repair of vaginal wall prolapse using mesh should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand that there is uncertainty about the long-term results and there is a risk of complications, including sexual dysfunction and erosion into the vagina, which would require additional procedures. They should provide them with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having surgical repair of vaginal wall prolapse using mesh (see section 3.1). 1.3 This is a technically challenging procedure that should only be carried out by gynaecologists with special expertise in the surgical management of pelvic organ prolapse. Specific training is required when trocar introducer systems are used for the insertion of mesh. 1.4 Further publication of safety and efficacy outcomes will be useful. Research should aim to address the performance of different methods of repair and different types of mesh. It should also include evidence

	about long-term outcomes and patient-reported outcomes, such as quality of life and sexual function. The Institute may review the procedure upon publication of further evidence.

Appendix C: Literature search for infracoccygeal sacropexy using mesh to repair vaginal vault prolapse

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	24/01/17	Issue 1 of 12, January 2017
HTA database (Cochrane)	24/01/17	Issue 1 of 12, January 2017
Cochrane Central Register of Controlled Trials (Cochrane)		Issue 1 of 12, January 2017
MEDLINE (Ovid)	24/01/17	1946 to December Week 1 2016
MEDLINE In-Process (Ovid)	24/01/17	January 20, 2017
EMBASE (Ovid)	24/01/17	1974 to 2017 Week 04>
PubMed	24/01/17	-
JournalTOCS	24/0117	

Trial sources searched on 22/09/2016

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on 22/09/2016

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	pelvic organ prolapse/
2	POP.ti,ab.
3	Uterine Prolapse/
4	vagina/

5	fascia/
6	((apical* or post-hysterect* or cuff* or fascia* or pelvic* or cervic* or transvagin* or vagin* or genital* or uter* or urogenit* or womb* or genito* or intravaginal*) adj2 (prolaps* or collaps* or drop*)).ti,ab.
7	rectocele/
8	cystocele/
9	(rectocele* or cystocele* or enterocele*).ti,ab.
10	or/1-9
11	(IVS tunneller or artisyn or inte-pro or intepro or uplift or prolift or perigee or apogee or elevate or capio or avaulta or i-stitch or restorelle or uphold LITE).tw.
12	(((transvagin* or intravagin*) adj4 sling*) or (infracoccygeal* adj4 sacropex*)).ti,ab.
13	((posterior or rectovagin* or recto-vagin* intravagin* or intra-vagin* or transvagin*) adj4 (sling* or colpopex* or hysteropex* or cervicopex* or sacropex* or sacrospin* or hysteropex* or sacrocolpopex* or sacral colpopex* or sacrohysteropex* or sacral hysteropex*)).ti,ab.
14	(posterior adj4 (intravagin* or intra-vagin* or transvagin*)).ti,ab.
15	(PIVS or IVS or P-IVS).ti,ab.
16	(sacrospin* adj4 (fixation or suspens*)).ti,ab.
17	or/11-16
18	10 and 17
19	animals/ not humans/
20	18 not 19