NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of infracoccygeal sacropexy using mesh to repair uterine prolapse

Uterine prolapse happens when the womb (uterus) slips down from its usual position into the vagina. 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, and then out through a cut in the other buttock. The mesh is attached to the top of the vagina. It acts like a sling, with the aim of holding the womb in place.

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 July 2016 and updated in February 2017.

Procedure name

- Infracoccygeal sacropexy using mesh to repair uterine prolapse

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

Uterine prolapse is when the uterus descends from its usual position, sometimes out through the vagina opening. It can affect quality of life by causing symptoms of pressure and discomfort, and by its effect on urinary, bowel and sexual function.

Treatments include pelvic floor muscle training, use of pessaries and surgery. Several surgical procedures can be used, including hysterectomy, mesh sacrocolpopexy, uterine suspension sling (including sacrohysteropexy) and uterine or vault suspension (without sling). Some of these procedures involve the use of mesh, with the aim of providing additional support.

What the procedure involves

Infracoccygeal sacropexy is usually 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 incision and using a tunnelling device, guided by a finger through the vaginal incision, the mesh is passed around the rectum. The mesh is then passed up the side of the vagina, across the top, 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 and acts as a tension-free sling to suspend the uterus in its natural position. The procedure is sometimes described as posterior intravaginal slingplasty.

This procedure can be combined with hysterectomy or surgery for stress urinary incontinence, such as a suburethral sling placement.

Several different types of synthetic and biological mesh are available that vary in structure and in their 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 farther 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 uterine prolapse. The following databases were searched, covering the period from their start to 26 July 2016: 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 uterine prolapse.
Intervention/test	Infracoccygeal sacropexy 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 2,286 patients treated by infracoccygeal sacropexy from 3 systematic reviews[1-3], 2 randomised controlled trials[4-5] (1 of which was also included in the systematic reviews), 1 non-randomised comparative study[6] and 4 case series[7-10].

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 uterine prolapse

Study 1 Jia X (2010) – based on the systematic review commissioned for 2008 NICE IP 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 uterine or vaginal vault 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 vaginal vault prolapse.
Technique	Infracoccygeal sacropexy using mesh.
Follow-up	**Median 13 months (range 5 to 30)**
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 IP Programme.

Analysis

Study design issues:

- The 14 studies 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): 0–25% (median 4.8%, 9 studies, n=402). • **Re-operation rate:** 0-30% (median 7.9%, n=288, 3 studies) ***Uterine prolapse only*** • **Prolapse recurrence** (clinician-reported): 1.3% (1/79, 1 non-randomised comparative study; 10% (1/10, 1 case series) ***Uterine or vaginal vault prolapse*** • **Persistent prolapse symptoms** after infracoccygeal sacropexy (patient-reported):16.4% (28/171; 2 case series) • **Prolapse recurrence** (clinician-reported): 4.8% (1/21; 1 RCT); 7.3% (17/232; 4 case series)	***Complications – all studies*** • **Mesh erosion**: 0–21% (median 6.7%, 11 studies, n=889). All studies reporting mesh erosion used non-absorbable synthetic mesh. • **Operation for mesh erosion**: 0.3–17% (median 7.2%, 6 studies, n=678). • **Blood transfusion**: 0–2% (7 studies, n=383). • **Organ damage**: 0–2.7% (median 0%, 9 studies, n=684). • **Infection**: 0–9% (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. ***Uterine prolapse only*** • **Mesh erosion**: 13% (10/79; 1 non-randomised comparative study) ***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]; 1295 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 3–120) 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, 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 (2010) and De Tayrac (2008). The 2 RCTs and 1 case series are common to both reviews (n=106). The De Tayrac (2008) RCT is included in Table 2 as well.
- 50% (5/10) of the studies included patients treated for vaginal vault prolapse only.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>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 included 107 women randomised to either infracoccygeal sacropexy or sacrospinous fixation; 1 trial reported 82% objective success rate with the infracoccygeal sacropexy compared with 88% with the sacrospinous fixation at 24-month follow up, and the other reported 95% success with infracoccygeal sacropexy 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.</td><td>Complications (weighted averages analysis)
<table><tr><th></th><th>PIVS
% (95% CI)
n=655</th><th>Apogee
% (95% CI)
n=525</th><th>Prolift
% (95% CI)
n=1295</th><th>Polypropylene
% (95% CI)
n=178</th></tr><tr><td>Total complication rate</td><td>12.1
(11.6 to 12.5)</td><td>17.6
(16.7 to 18.5)</td><td>16.5
(15.9 to 17.1)</td><td>6.9
(6.8 to 6.9)</td></tr><tr><td>Dindo grade I</td><td>3.2
(2.9 to 3.6)</td><td>4.8
(4.4 to 5.3)</td><td>6.0
(5.6 to 6.2)</td><td>1.5
(1.3 to 1.8)</td></tr><tr><td>Dindo grade II</td><td>3.2
(3.0 to 3.5)</td><td>6.5
(6.0 to 7.0)</td><td>4.1
(3.7 to 4.5)</td><td>1.5
(1.2 to 1.8)</td></tr><tr><td>Dindo grade III</td><td>5.7
(5.3 to 6.1)</td><td>6.3
(5.9 to 6.7)</td><td>6.4
(6.3 to 6.6)</td><td>3.8
(3.8 to 3.8)</td></tr><tr><td>Dindo grade IIIa</td><td>0.6
(0.5 to 0.7)</td><td>0.4
(0.3 to 0.5)</td><td>0.5
(0.4 to 0.5)</td><td>2.3
(2.1 to 2.5)</td></tr><tr><td>Dindo grade IIIb</td><td>5.5
(4.6 to 5.5)</td><td>5.9
(5.5 to 6.2)</td><td>6.0
(5.8 to 6.1)</td><td>1.5
(1.3 to 1.8)</td></tr><tr><td>Dindo grade IV</td><td>0</td><td>0</td><td>0.1</td><td>0</td></tr><tr><td>Mesh erosion</td><td>7.8
(7.2 to 8.3)</td><td>10.7
(10.1 to 11.3)</td><td>5.7
(5.5 to 6.0)</td><td>4.6
(4.2 to 5.0)</td></tr><tr><td>Dyspareunia</td><td>1.7
(1.5 to 1.9)</td><td>2.7
(2.4 to 3.0)</td><td>2.1
(2.0 to 2.2)</td><td>5.5
(4.7 to 6.3)</td></tr></table>
PIVS; 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 having 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.</td></tr>
<tr><td colspan="2">Abbreviations used: PIVS, posterior intravaginal slingplasty.</td></tr>
</table>

Study 3 Dietz V (2009)

Details

Study type	**Systematic review**
Country	Not reported for individual studies
Recruitment period	Search date: November 2007
Study population and number	**n=3,093 patients from 48 studies** (143 infracoccygeal sacropexy, 11 studies; 1,764 vaginal hysterectomy, 23 studies; 613 sacrospinous hysteropexy, 12 studies; 573 Manchester procedure, 6 studies) **Women with uterine descent**
Age	Not reported
Patient selection criteria	Type of studies: RCTs, prospective cohort studies, prospective, case-controlled studies, retrospective studies, and case reports. Infracoccygeal sacropexy: for efficacy, only studies describing the procedure undertaken with preservation of the uterus were included; for safety, studies describing the procedure in women who underwent the procedure with and without preservation of the uterus were included.
Technique	Posterior intravaginal slingplasty
Follow-up	**6 to 30 months (studies with efficacy data on infracoccygeal sacropexy)**
Conflict of interest/source of funding	None

Analysis

Study design issues:

All studies included were heterogenic with respect to follow-up time, selection of study group (for example, no stage 4 prolapse included, prior prolapse surgery, and additional surgery), definition of recurrent prolapse, and in methods of data collection. The authors noted that ‘’there may be a publication bias that could have influenced these results’’.

Other issues: There is patient overlap with Jia (2009) and Feiner (2009). All the studies included are present in the Jia (2009) systematic review and 6 are common to the Feiner (2009) study.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **143 PIVS; 1, 764 vaginal hysterectomy; 613 sacrospinous hysteropexy; 573 Manchester procedure.**

Anatomical cure rates and recurrent surgery according to surgical approach

	PIVS (n=3 studies)	**Vaginal hysterectomy (n=15 studies)**	**Sacrospinous hysteropexy (n=10 studies)**	**Manchester procedure (n=6 studies)**
Cure rate				
Apical support	90–97%	88–100%	85–100%	93–100%
Anterior support	91–97%	28–100%	62–100%	95%
Posterior support	97–100%	36–100%	97–100%	99–100%
Recurrent prolapse surgery for				
apical prolapse	3%	0–7%	0–5%	0–4%
any prolapse	3%	0–12%	0–7%	0–4%
other conditions *	0–18%	0%	0–4%	0–2%

*Such as menorrhagia and pain syndromes.

Safety

Complications during and after surgery according to surgical approach

	PIVS (n=11 studies)	**Vaginal hysterectomy (n=15 studies)**	**Sacrospinous hysteropexy (n= 10 studies)**	**Manchester procedure (n=6 studies)**
Bladder injury	0%	0–2%	0%	0–1%
Rectal injury	0–3%	0–2%	0–1%	0%
Blood transfusion	0–0.3%	0–11%	1%	0–3%
Infection with the need for antibiotics	0–0.3%	0–21%	0–2%	0–13%
Lower urinary tract symptoms	0–6%	up to 20%	Up to 37%	Up to 22%
Vault abscess or haematoma	0%	0–7%	0%	0%
Cervical stenosis	0%	Not applicable	0%	0–11%
Sensory loss skin	0%	0%	0–0.5%	0%
Buttock pain	0%	0%	3–27%	0%
Mesh erosion	0–21%	Not applicable	Not applicable	Not applicable
Mortality rate	Not available	0.4%	Not available	Not available

Abbreviations used: PIVS, posterior intravaginal slingplasty.

Study 4 de Tayrac R (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: isolated cystocoele, stage 1 prolapse, rectal prolapse, and intestinal inflammatory disease.
Technique	Infracoccygeal sacropexy was done using the IVS tunneller (Tyco Healthcare) 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 cystocoele repair, hysterectomy, suburethral tape and posterior repair.
Follow-up	**Mean 16.8 months (range 1.5–32)**
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 for achieving statistical power because patient enrolment was stopped when multifilament tape was replaced by monofilament 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).
- 23% (5/22) of patients had previously been treated by hysterectomy.

Other issues:

- This study was included in the Jia (2010) and Feiner (2009) systematic reviews as a conference abstract.

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 cystocoele >1	4.8% (1/21)	25% (6/24)	0.14
Postoperative rectocoele >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% (18/21)
- Sacrospinous suspension=79.2% (19/24)
- 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

Re-operation

- **Infracoccygeal sacropexy**:
  - 1/3 of patients treated by infracoccygeal sacropexy without hysterectomy was re-operated 3 months later for **uterine prolapse recurrence.**
  - 10% (2/21) of patients were re-operated for **anterior vaginal wall erosion**.
- **Sacrospinous suspension**:
  - 1 patient who was treated concomitantly by anterior colporrhaphy was re-operated for a **cystocoele recurrence**.
  - 8% (2/24) of patients were re-operated for **anterior vaginal wall erosion.**

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% (6/24)	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% (8/24)	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.

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 5 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 years' 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. Four patients did not complete follow-up, 3 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.
- Independent examiners were not used in follow-up examinations.

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.
- 57% (8/14) of patients in the PIVS group and 50% (4/8) in the SSLF group were previously treated by hysterectomy.
- 29% (4/14) of patients were treated concomitantly by vaginal hysterectomy in the PIVS group.

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	**PIVS n=14**		**SSLF 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

PIVS: 21% (3/14)

SSLS: 13% (1/8)

Symptoms before and 3 years after procedure (n)

Symptoms	**PIVS n=14**		**SSLF 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

	PIVS	**SSLF**
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 patient	0

Abbreviations: PIVS, posterior intravaginal slingplasty; SSLF, sacrospinous ligament fixation.

Study 6 Cosma S (2014)

Details

Study type	**Retrospective matched case-control study**
Country	Italy
Recruitment period	2004–08
Study population and number	n= **122 (61 posterior intravaginal slingplasty [PIVS] versus 61 uterosacral ligament suspension [ULS])** Women with stage 3 or 4 utero-vaginal apical prolapse
Age	Mean 65 years
Patient selection criteria	PIVS group: consecutive women with stage 3 or 4 utero-vaginal apical prolapse and clinical diagnosis according to the pelvic organ prolapse quantification system (POP-Q). ULS group: matched control group for uterine prolapse stage, age (±10 years), parity (± 1 delivery), menopause, body mass index (±2 kg/m^2) and previous prolapse surgery (yes or no).
Technique	All procedures were done with concomitant vaginal hysterectomy. All procedures were done by 3 senior staff gynaecologists with patients under regional spinal anaesthesia. For PIVS and during the first part of the study period, a multifilament polypropylene mesh was used (for 53 patients). It was withdrawn from the market by March 2006 and substituted with a monofilament polypropylene mesh that was used for the last 8 patients. For ULS, a single polysorb 1 stitch was used.
Follow-up	**Mean 56 (36 to 84) months for PIVS and 58 (36 to 84) months for ULS.**
Conflict of interest/source of funding	None

Analysis

Follow-up issues:

- All 122 patients were seen at 1–6 and 12 months; 88 patients (72%) at 48 months; 68 patients (56%) at 60 months; 40 patients (33%) at 72 months and 9 patients (7%) at 84 months.

Study design issues:

- Objective postoperative assessment was done using the POP-Q staging system. Pelvic relaxation of stage 2 or higher was considered to be a recurrence.
- Subjective data as to urinary or faecal incontinence, sexual function impairments, voiding habits and pelvic pain, were recorded prospectively.
- Quality of life was assessed using 2 validated questionnaires that were translated into Italian (Pelvic Floor Impact Questionnaire-7 [PFIQ-7] and Agachan–Wexner constipation scoring system).
- Sexual function was assessed by the short form of the pelvic organ prolapse/ urinary incontinence sexual questionnaire (pisq-12) in women reporting sexual activity with a partner within 6 months from baseline.

Study population issues:

- 79% (48/61) of pairs matched all 6 matching criteria, 8 matched 5 and 5 matched 4.
- There was a statistically significant difference between groups with regard to baseline symptoms of stress urinary incontinence: 23% (14/61) in the PIVS group compared against 48% (29/61) in the ULS group (p=0.00).

Other issues:

- There may be patient overlap between the Cosma (2014) and the Cosma (2011) studies.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **122 (61 PIVS versus 61 ULS)**

Anatomical and symptomatic results

	PIVS (n=61)	ULS (n=61)	SS
Mean follow-up (months)	56	58	NS
Anatomical results			
Vaginal vault recurrence	0	7% (4/61)	NS
Vaginal vault OAS (POP-Q stage 0)	80% (49/61)	62% (38/61)	0.04
Vaginal vault SAS	20% (12/61)	31% (19/61)	NS
Anterior vaginal wall recurrence/ de novo	18% (11/61)	25% (15/61)	NS
Posterior vaginal wall recurrence/ de novo	7% (4/61)	18% (11/61)	NS
Recurrence at any vaginal site	23% (14/61)	36% (22/61)	NS
Cure rate without adverse events	90.2%	100%	0.01
Symptomatic results			
Subjective cure (absence of vaginal bulge)	92% (56/61)	87% (53/61)	NS
De novo SUI	10% (6/61)	7% (4/61)	NS
De novo urge urinary incontinence	11% (7/61)	25% (15/61)	NS
Persistent overactive bladder symptoms	2% (1/61)	2% (1/61)	NS
De novo constipation	7% (4/61)	3% (2/61)	NS

SAS= support more apical than 1 cm proximal to the hymen.

Quality of life questionnaire scores after surgery (mean±SD)

Questionnaire	PIVS	ULS	SS
UIQ-78	12.4±17.3	9.1±14	NS
POPIQ-7*	6.7±12.7	8.2±13.3	NS
CRAIQ-7*	8.8±14.3	4.2±10.4	NS
PISQ-12**	13.9±4.0	12.2±3.5	NS
Wexner***	5.2±7.6	3.8±5.0	NS

*Range 0-100, with lower scores indicating a better QOL.

** Range 0-48, with a higher score indicating a more satisfactory sexual function.

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

Safety

There were no rectal, bladder or ureteral injuries.

Complications

	PIVS (n=61)	ULS (n=61)	SS
***Late** complications*			
Erosion	7% (4/61)	-	-
Abscess or fistula	2% (1/61)	0	NS
Reoperation rate	2% (1/61)	8% (2/25)	NS

- 2 of the 4 mesh erosions occurred within 6 months after the procedure and the other 2 were noted at the 12- and 24-month follow-up examinations.

  All the mesh erosions were treated by office multiple tape excision and antibiotics.
- Re-intervention with surgical excision of the mesh was needed in 1 patient who had a fistula.

Abbreviations used: NS, not statistically significant; OAS, optimal anatomic suspension; PIVS, posterior intravaginal slingplasty; QOL, quality of life; SAS, satisfactory anatomic suspension; SD, standard deviation; SS, statistical significance; SUI, stress urinary incontinence; ULS, uterosacral ligament suspension.

Study 7 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 or anticoagulation therapy, 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 118 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) 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.

Study population issues:

- 79% (93/118) of patients were treated concomitantly by hysterectomy, 81% (95/118) by cystocele repair, 25% (29/118) by rectocele repair and 28% (33/118) by sub-urethral sling placement.

Other issues:

- There may be patient overlap between the Cosma (2014) and the Cosma (2011) studies.

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	NS
Anatomical results				
Recurrence of vault prolapse	3.4% (4/118)	4% (1/25)	3.2% (3/93)	NS
Cystocoele recurrence	14.7% (14/95)	20% (3/15)	13.7% (11/80)	NS
de novo cystocoele formation	26% (6/23)	20% (2/10)	30.7% (4/13)	NS
Rectocoele recurrence	13.8% (4/29)	28.5% (2/7)	9% (2/22)	NS
de novo rectocoele formation	4.5% (4/89)	11.1% (2/18)	2.8% (2/71)	NS
Symptomatic results				
Persistent vaginal bulge	9.3% (11/118)	12% (3/25)	8.6% (8/93)	NS
Persistent stress urinary incontinence	2.5% (3/118)	4% (1/25)	2.1% (2/93)	NS
Persistent urge urinary incontinence	3.4% (4/118)	4% (1/25)	3.2% (3/93)	NS
Persistent bladder overactivity symptoms	4.2% (5/118)	4% (1/25)	4.3% (4/93)	NS

- The vault prolapse recurrences were all seen at 24-month follow-up.
- Overall anatomical success rate of PIVS: 97%

Quality of life questionnaire scores

Questionnaire	Baseline	After surgery	p value
UIQ-7	134.6	115.7	<0.05
POPIQ-7	164.3	108.4	<0.05
CRAIQ	107.5	114.11	NS
Agachan-Wexner*	4.6	5.5	NS

*Range 0-30, with lower scores indicating lower 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)	NS
Hyperthermia*	1.7% (2/118)	4% (1/25)	1% (1/93)	NS
Pain	2.5% (3/118)	0% (0/25)	3.2% (3/93)	NS
Urinary retention >100 ml	8.5% (10/118)	4% (1/25)	9.7% (9/93)	NS
***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)	NS
De novo urge urinary incontinence or bladder overactivity symptoms	8.5% (10/118)	8% (2/25)	8.6% (8/93)	NS
De novo stress urinary incontinence	5.9% (7/118)	4% (1/25)	6.4% (6/93)	NS
De novo constipation	5.9% (7/118)	8% (2/25)	5.4% (5/93)	NS

*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% (7/118, 2 patients with recurrence of prolapse, 2 with erosion and 3 with fistula).

Abbreviations used: CRAIQ, colorectal anal impact questionnaire; NS, not significant; PIVS, posterior intravaginal slingplasty; POPIQ, pelvic organ prolapse impact questionnaire; UIQ, Urinary impact questionnaire

Study 8 Bjelic-Radisic V (2009)

Details

Study type	**Case series – Registry data**
Country	Austria (14 centres)
Recruitment period	2001–06
Study population and number	n= **577** patients with pelvic organ prolapse treated by the posterior intravaginal slingplasty procedure
Age	Mean 64 years
Patient selection criteria	Patients with pelvic organ prolapse treated by the posterior intravaginal slingplasty procedure. All patients had clinically evident prolapse, which was staged according to the International Continence Society (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 has 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 4-241) 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 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).
- 3% (17/577) of patients only 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 30-111)
- Overall (n=577): median 80 minutes (range 26-385)

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

Functional results assessed by physicians at median 7 weeks, range 1-156 (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.

*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.
- 2 patients with haematomas (1 paravesical and 1 prerectal) were reoperated 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 were reoperated for haematoma later than day 1.

Reoperations during follow-up (median 7 weeks, range 1–156) **:** 11%[b] (54/496)

	% (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: 10-96 weeks.
SUI operation	2% (12/496)	Range for reoperation: 9-64 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.

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

[b] In the paper, it says 9.4%, which is based on the intention-to-treat population (n=577).

- One patient was diagnosed with **urethral stenosis** 2 years after the procedure; he 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 9 Capobianco G (2014)

Details

Study type	**Case series**
Country	Italy
Recruitment period	2003–04
Study population and number	**n=44** Women with symptomatic uterine prolapse (n=25) or vaginal vault (n=19).
Age	Mean 63 years
Patient selection criteria	Consecutive 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.
- The same 2 gynaecologists made preoperative and postoperative assessment but not blindly.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
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 at 18, 32 and 24 months respectively).

International Continence Society pelvic organ prolapse score (mean±standard deviation)
<table>
<tr><th></th><th>Preoperative</th><th>Postoperative 9 years</th><th>p value</th></tr>
<tr><td>Point Aa (cm)</td><td>1.21±1.81</td><td>-2.42±1.23</td><td><0.001</td></tr>
<tr><td>Point Ba (cm)</td><td>1.36±2.12</td><td>-2.31±1.32</td><td><0.001</td></tr>
<tr><td>Point Ap (cm)</td><td>-0.42±1.62</td><td>-2.71±0.92</td><td><0.001</td></tr>
<tr><td>Point Bp (cm)</td><td>-0.13±1.75</td><td>-2.62±0.81</td><td><0.001</td></tr>
<tr><td>Point C</td><td>2.24±3.34</td><td>-6.45±1.63</td><td><0.001</td></tr>
<tr><td>Total vaginal length (cm)</td><td>7.32±2.72</td><td>7.34±1.73</td><td>0.274</td></tr>
</table>
Symptoms before surgery and at 9-year follow-up, % (n)
<table>
<tr><th></th><th>Preoperative</th><th>Postoperative</th><th>p value</th></tr>
<tr><td>Pelvic pain</td><td>68.2% (30)</td><td>45.5% (20)</td><td>0.24</td></tr>
<tr><td>Nocturia</td><td>40.9% (18)</td><td>0</td><td>0.003</td></tr>
<tr><td>Urgency</td><td>27.3% (12)</td><td>0</td><td>0.04</td></tr>
<tr><td>Prolapse</td><td>100% (44)</td><td>6.8% (3)</td><td>0.0001</td></tr>
<tr><td>Urinary tract infection</td><td>13.6% (6)</td><td>0</td><td>0.001</td></tr>
</table>
Sexual questionnaire before and after surgery.
<table>
<tr><th></th><th>Preoperative</th><th>Postoperative</th></tr>
<tr><td>Deep dyspareunia during intercourse</td><td>100% (44/44)</td><td>11.4% (5/44)</td></tr>
<tr><td>Leakage of urine during intercourse</td><td>37.5% (18/44)</td><td>11.4% (5/44)</td></tr>
</table>
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 that they would recommend the surgery to their friends.
</td><td>
Complications

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

There were no cases of rectal perforation, perioperative pain or hyperpyrexia.
</td></tr>
</table>

Study 10 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. It was also mentioned in the Jia (2010) and Dietz (2009) reviews but was not included in the analysis.

Key efficacy and safety findings

Efficacy

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

Safety

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 uterine or vaginal vault prolapse treated by infracoccygeal sacropexy after a median follow-up of 13 months, the median clinician-reported prolapse recurrence rate was 5% (range 0 to 25%; 9 studies, n=402). For uterine prolapse only, clinician-reported prolapse recurrence rates were 1% (1/79; 1 non-randomised comparative study) and 10% (1/10; 1 case series). [1]

In a systematic review of 2,653 patients (655 patients with uterine or vaginal vault prolapse treated by infracoccygeal sacropexy), the mean objective success rate was 88% for infracoccygeal sacropexy (range 37–99%; 95% confidence interval [CI] 87 to 89)[2].

In a systematic review of 3,093 patients with uterine prolapse (143 patients treated by infracoccygeal sacropexy), the anatomical cure rates for apical support ranged from 90 to 97% for infracoccygeal sacropexy within 6 to 30 months after the procedure (n=3 studies). [3]

In a randomised controlled trial (RCT) of 49 patients with uterine or vaginal vault prolapse treated by infracoccygeal sacropexy or sacrospinous suspension, anatomical success rates were 95% (20/21) and 100% (24/24) respectively (p=0.94)[4].

In an RCT of 22 patients with uterovaginal or vaginal vault prolapse treated by infracoccygeal sacropexy or sacrospinous ligament fixation, anatomical recurrences of prolapse rates were 21% (3/14) and 13% (1/8) at 3-year follow-up respectively.[5]

In a matched case-control study of 122 patients treated by infracoccygeal sacropexy or uterosacral ligament suspension, anatomical prolapse recurrences at any vaginal site were reported in 23% (14/61) of patients and in 36% (22/61) of patients respectively (no statistically significant difference between groups). In the same study, there was a statistically significantly lower cure rate in the infracoccygeal sacropexy group of 90% compared against 100% in the uterosacral ligament suspension group (p=0.01). [6]

In a case series of 118 patients, recurrence of vault prolapse occurred in 3% (4/118) of all patients (3% [3/93] for patients with uterovaginal prolapse). The vault prolapse recurrences were all seen at 24 month follow-up.[7]

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.[8]

In a case series of 44 patients, the success rate was 93% (41/44) at 9-year follow-up. Relapse of prolapse occurred in 7% (3/44) of patients (2 cystocele and 1 rectocele at 18, 32 and 24 months respectively). [9]

Prolapse repair – patient reported

In the systematic review of 7,054 patients including 976 patients with uterine or vaginal vault prolapse treated by infracoccygeal sacropexy, the median rate of patient-reported persistent symptoms was 9% (range 2 to 21%; 3 studies, n=262). [1]

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).[4]

In the matched case-control study of 122 patients treated by infracoccygeal sacropexy or uterosacral ligament suspension, subjective cure rates (defined by the absence of vaginal bulge) were 92% (56/61) and 87% (53/61) respectively (no statistically significant difference between groups).[6]

In the case series of 118 patients, a persistent vaginal bulge occurred in 9% (11/118) of all patients (9% [8/93] for patients with uterovaginal prolapse).[7]

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 systematic review of 3,093 patients with uterine prolapse (143 patients treated by infracoccygeal sacropexy), the reoperation rates for prolapse recurrence for infracoccygeal sacropexy were 3% for apical prolapse and any prolapse, and 0 to 18% for other conditions such as menorrhagia and pain syndromes, within 6 to 30 months after the procedure.[3]

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 was re-operated for a cystocoele recurrence.[4]

In the matched case-control study of 122 patients treated by infracoccygeal sacropexy or uterosacral ligament suspension, the reoperation rates were 2% (1/61) and 8% (2/25) respectively (no statistically significant difference between groups). [6]

In the case series of 118 patients, 2% (2/118) of patients were re-operated for recurrence of prolapse. [7]

In the case series of 577 patients, 4% (20/496) of patients were re-operated within 10-96 weeks of the procedure for recurrent prolapse. [8]

Improvement of urinary symptoms

In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, rates of stress urinary incontinence after a mean follow-up of 17 months were 0% (0/21) and 8% (2/24) respectively, compared with preoperative rates of 52% (11/21) and 29% (7/24) respectively. Rates of urgency after a mean follow-up of 17 months 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.[4]

In the matched case-control study of 122 patients treated by infracoccygeal sacropexy or uterosacral ligament suspension, persistent overactive bladder symptoms were reported in 2% (1/61) of patients in each group (no statistical significance between groups).[6]

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.[7]

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). Of the 12 patients with urgency at baseline, none of them reported the symptom at 9-year follow-up (p=0.04).[9]

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 after a mean follow-up of 17 months; the only statistically significant difference was seen for the Pelvic Organ Prolapse Distress Inventory score which improved by 50% or more in 75% of patients treated by infracoccygeal sacropexy and worsened in 6% compared with 65% improved by 50% or more and 10% worsened for sacrospinous suspension (p=0.02).[4]

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), with a mean follow-up of 59 months. There was no statistically significant difference in the colorectal anal impact questionnaire scores (107.5 at baseline and 114.1 after surgery) and in the Agachan–Wexner scores (range 0–30, with lower scores indicating lower bowel dysfunction, 4.6 at baseline and 5.5 after surgery). [7]

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).[4]

In the case series of 44 patients, 86% of patients reported that their sexual performance improved after the procedure and 100% (44/44) responded that their quality of life had improved and that that they would recommend the surgery to their friends. [9]

Safety

Mesh erosion

Mesh erosion was reported by 11 studies (n=889) on infracoccygeal sacropexy, with rates ranging from 0 to 21% (median 7%), in a systematic review of 7,054 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse at a median follow-up of 13 months; reoperation for mesh erosion was needed in up to 17% of patients (median 7%, n=678). For patients with uterine prolapse only in the systematic review, mesh erosion was reported in 13% (10/79) of patients in a non-randomised controlled trial.[1]

Mesh erosion was reported in 8% of patients treated by infracoccygeal sacropexy (n=655) in a systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse.[2]

Mesh erosion was reported in 7% (4/61) of patients treated by infracoccygeal sacropexy in a matched case-control study of 122 patients treated by infracoccygeal sacropexy or uterosacral ligament suspension. Two of the 4 mesh erosions occurred within 6 months of the procedure and the other 2 were noted at the 12- and 24-month follow-up examinations. They were all treated by tape excision and antibiotics but 1 re-intervention with surgical excision of the mesh was needed in 1 patient who had a fistula.[6]

Mesh erosion was reported in 9% (10/118) of all patients up to 30 months after the procedure in a case series of 118 patients with vaginal cuff or utero-vaginal prolapse; for patients with utero-vaginal prolapse, the rate of erosion was 5% (5/93).[7]

Vaginal tape exposure was reported in 10% (50/496) of patients at median 7 weeks (range 1 to 156 weeks) in a case series of 577 patients with pelvic organ prolapse treated by infracoccygeal sacropexy.[8]

Extrusion was reported in 1 patient in a case series of 44 patients; this was treated with antibiotics and local oestrogen.[9]

Bleeding

Blood loss during the procedure needing transfusion was reported by 7 studies (n=383) on infracoccygeal sacropexy, with rates ranging from 0 to 2%, in the systematic review of 7,054 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse [1].

Blood transfusion was reported in 2 patient treated by infracoccygeal sacropexy in the systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse. [2]

Blood transfusion was reported in 0% to 0.3% of patients treated by infracoccygeal sacropexy (n=143), in 0% to 11% of patients treated by vaginal hysterectomy (n=1,764), in 1% of patients treated by sacrospinous hysteropexy (n=613) and in 0% to 3% of patients (n=573) treated by the Manchester procedure in a systematic review of 3,093 patients with uterine prolapse. [3]

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.[4]

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[8].

Haematoma

Haematoma was reported in 1% of patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse [2].

Haematoma or vault abscess were reported in none of the patients treated by infracoccygeal sacropexy (n=143), sacrospinous hysteropexy (n=613) by the Manchester procedure (n=573), and in 0% to 7% of patients treated by vaginal hysterectomy (n=1,764) in the systematic review of 3,093 patients with uterine prolapse. [3]

Postoperative haematoma was reported in 2 patients treated by infracoccygeal sacropexy and in none of the patients treated by sacrospinous suspension in the RCT of 49 patients.[4]

Haematoma was reported in 1 patient treated by infracoccygeal sacropexy and in none of the patients treated by sacrospinous ligament fixation in the RCT of 22 patients within 3-year follow-up. [5]

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.[7]

Evacuation of haematoma was reported in 1% (5/577) of patients in the case series of 577 patients. 2 patients with haematomas (1 paravesical and 1 prerectal) were reoperated on the day of surgery and received blood products. Both had been treated by infracoccygeal sacropexy with anterior and posterior colporrhaphy. Three other patients who had been treated by infracoccygeal sacropexy with hysterectomy and anterior and posterior colporrhaphy were reoperated for haematoma later than day 1.[8]

Organ damage

Organ damage during the procedure was reported by 9 studies (n=684) on infracoccygeal sacropexy, with rates ranging from 0 to 3% (median 0%) in the systematic review of 7,054 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse [1].

Bladder injury was reported in none of the patients treated by infracoccygeal sacropexy (n=143), in 0-2% of patients treated by vaginal hysterectomy (n=1,764), in 0% of patients treated by sacrospinous hysteropexy (n=613) and in 0-1% of patients (n=573) treated by the Manchester procedure in the systematic review of 3,093 patients with uterine prolapse. In the same study, rectal injury was reported in 0-0.3% of patients treated by infracoccygeal sacropexy (n=143), in 0-2% of patients treated by vaginal hysterectomy (n=1,764), in 0-1% of patients treated by sacrospinous hysteropexy (n=613) and in 0% of patients (n=573) treated by the Manchester procedure. [3]

Bladder injury was reported in 2 patients treated by infracoccygeal sacropexy and 1 patient treated by sacrospinous suspension in the RCT of 49 patients. [4]

Bladder injury was reported in 1% (5/577) of patients in the case series of 577 patients; all occurred in patients with concomitant procedures, during vaginal dissections[8].

Infection, abscess or fistula formation

Infection was reported by 8 studies (n=698) on infracoccygeal sacropexy, with rates ranging from 0 to 9% at a median follow-up of 13 months, in the systematic review of 7,054 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse [1].

Pararectal abscess was reported in 1 patient treated by infracoccygeal sacropexy in the systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse (timing not reported). Gluteovaginal sinus formation 3 months after infracoccygeal sacropexy and rectocutaneous fistula 2 months postoperatively were each described in a case report, included in same review[2].

Infection needing antibiotics was reported in 0% to 0.3% of patients treated by infracoccygeal sacropexy (n=143), in 0% to 21% of patients treated by vaginal hysterectomy (n=1,764), in 0-2% of patients treated by sacrospinous hysteropexy (n=613) and in 0% to 13% of patients (n=573) treated by the Manchester procedure in the systematic review of 3,093 patients with uterine prolapse.[3]

Infection at operative site was reported in 1 patient treated by infracoccygeal sacropexy and in 1 patient treated by sacrospinous ligament fixation in the RCT of 22 patients within 3-year follow-up. In the same study, urinary tract infection was reported in 43% (6/14) of patients and in 25% (2/8) respectively. [5]

Abscess or fistula was reported 1 patient treated by infracoccygeal sacropexy and in none of the patients treated by uterosacral ligament suspension in the matched case-control study of 122 patients.[6]

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.[7]

Evacuation of abscess was reported in <1% (2/496) of patients in the case series of 577 patients[8].

Dyspareunia

Dyspareunia was reported in 2% of patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse, up to a mean follow-up of 120 weeks [2].

De novo dyspareunia was reported on 1/4 sexually active patients treated by infracoccygeal sacropexy and in none of the patients treated by sacrospinous ligament fixation in the RCT of 22 patients within 3-year follow-up.[5]

De novo dyspareunia was reported in 7% (25/348) of sexually active patients in the case series of 577 patients within 1-156 weeks of follow-up[8].

Pain

Prolonged pain was reported in less than 1% of patients (4/655) treated by infracoccygeal sacropexy (n=655) up to a mean follow-up of 120 weeks in the systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse [2].

Buttock pain after the procedure was reported in 3% (3/118) of patients in the case series of 118 patients. It resolved spontaneously within a few days. [7]

Bladder symptoms

Lower urinary tract symptoms were reported in 0 to 6% of patients treated by infracoccygeal sacropexy (n=143), in up to 20% of patients treated by vaginal hysterectomy (n=1,764), in up to 37% of patients treated by sacrospinous hysteropexy (n=613) and in up to 22% of patients (n=573) treated by the Manchester procedure in the systematic review of 3,093 patients with uterine prolapse.[3]

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.[7]

De novo urinary symptoms were reported in 6% (29/496) of patients in the case series of 577 patients[8].

Bowel symptoms

De novo constipation after the procedure was reported in 6% (7/118) of patients in the case series of 118 patients.[7]

De novo bowel symptoms were reported in 1 patient in the case series of 577 patients[8].

Other

Proctotomy was reported in 1 patient treated by infracoccygeal sacropexy in the systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse (no further details reported)[2].

Reoperation for complications

In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, 10% (2/21) of patients treated by infracoccygeal sacropexy were re-operated for anterior vaginal wall erosion up to a mean of 17 months after the procedure. In the sacrospinous suspension group, 8% (2/24) of patients were re-operated for anterior vaginal wall erosion.[4]

In the case series of 118 patients, 2% (2/118) of patients were re-operated for erosion and 3% (3/118) for a fistula during a 59-month mean follow-up. [7]

In the case series of 577 patients, 4% (21/486) of patients were re-operated to remove the mesh, 1 patient to loosen the mesh, 2% (12/496) for stress urinary incontinence, less than 1% (2/496) for evacuation of an abscess and 1 patient for persistent dysfunctional uterine bleeding up to 4 years after the procedure.[8]

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 [4,5].
- 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.
- The longest follow-up was 9 years[9].
- 3 systematic reviews[1-3] have been included in table 2. Although the Dietz (2009) paper[3] does not include new studies that are not included in the other 2 systematic reviews, all the patients included in this review have uterine prolapse and the infracoccygeal sacropexy procedure is compared against 3 other procedures for uterine prolapse.

Existing assessments of this procedure

The International Federation of Gynecology and Obstetrics (FIGO) published a working group report in 2015[11]. 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’[12]. 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.[13] 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' interim report was published in October 2015 by The Scottish Government[14].

A summary of the evidence on the benefits and risks of vaginal mesh implants was published in October 2014 by the MHRA[15]. 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
- Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 281 (2009). Available from https://www.nice.org.uk/guidance/ipg281
- Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 283 (2009). Available from https://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 https://www.nice.org.uk/guidance/ipg282

- Surgical repair of vaginal wall prolapse using mesh. NICE interventional procedure guidance 267 (2008). Available from https://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 uterine prolapse repair were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

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 vaginal vault prolapse, which is subject to a separate piece of guidance.
- In the studies included in the overview, the patients treated by infracoccygeal sacropexy for uterine prolapse had either had a hysterectomy concomitantly to infracoccygeal sacropexy or no hysterectomy at all and their uterus had been preserved.

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7. Cosma S, Preti M, Mitidieri M et al. (2011) Posterior intravaginal slingplasty: efficacy and complications in a continuous series of 118 cases. International urogynecology journal 22: 611–9
8. Bjelic-Radisic V, Hartmann G, Abendstein B et al. (2009) The posterior intravaginal slingplasty operation: results of the Austrian registry. European Journal of Obstetrics & Gynecology and Reproductive Biology 144: 88–91
9. Capobianco G, Donolo E, Wenger JM et al. (2014) Efficacy and 9 years' follow-up of posterior intravaginal slingplasty for genital prolapse. The journal of obstetrics and gynaecology research 40: 219–23
10. Baessler K, Hewson AD, Tunn R et al. (2005) Severe mesh complications following intravaginal slingplasty. Obstetrics & Gynecology 106: 713–16.
11. Betschart C, Cervigni M, Contreras Ortiz O et al. (2015) Management of apical compartment prolapse (uterine and vault prolapse): a FIGO working group report. Neurourology and Urodynamics DOI 10.1002/nau.
12. SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), The safety of surgical meshes used in urogynecological surgery, 3 December 2015.

13. NHS England, Acute Care Policy and Strategy Unit. Mesh working group interim report. Published on 3 December 2015. https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf.

14. The Scottish Government. The 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 interim report. Published on 2 October 2015. http://www.gov.scot/resource/0048/00486661.pdf.

15. 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 uterine 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
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).
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. This study is included in the Dietz (2009) systematic review.
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.
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.

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.
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.
Kim MR, Kim JH, Cho HH. (2008) Infracoccygeal sacropexy improves the quality of life of women with uterine prolapse. Maturitas 59(2):158-62.	Case series n=35 FU=6 months	Infracoccygeal sacropexy was an effective method for the management of uterine/stump prolapse; further, it improved the quality of life of women with pelvic organ prolapse.	Studies with more patients or longer follow-up are included.
Kolusari A, Yildizhan R, Adali E et al. (2010) Short-term results of posterior intravaginal slingplasty in grade 4 uterine prolapse. Archives of gynecology and obstetrics 281(1):55-8.	Case series n=34 FU=12 months	97% (33/34) of patients had satisfactory level I support defined objectively as stage 0 or I for point C as described in the pelvic organ prolapse quantification system. There were no rectal, vesical, ureteric, or vascular injuries in this series. During the postoperative period no complications, including tape erosion, were seen.	Studies with more patients or longer follow-up are included.
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.

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 identified 1 RCT for the uterine prolapse indication and it is already included in Table 2 (De Tayrac 2008).
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 1 RCT for the uterine prolapse indication and it is already included in Table 2 (De Tayrac 2008).
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.
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.
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.
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.

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.
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 uterine 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. **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. **Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 281 (2009).** 1.1Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for vaginal vault 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. 1.2Clinicians wishing to undertake infracoccygeal sacropexy using mesh for vaginal vault 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. 1.3The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5NICE encourages further research into infracoccygeal sacropexy using mesh for vaginal vault 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. **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. **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. **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 uterine prolapse

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	01/02/2017	Issue 1 of 12, January 2017
Cochrane Central Database of Controlled Trials - CENTRAL	01/02/2017	Issue 1 of 12, January 2017
HTA database (Cochrane)	01/02/2017	Issue 4 of 4, October 2016
MEDLINE (Ovid)	01/02/2017	1946 to January Week 3 2017
MEDLINE In-Process (Ovid)	01/02/2017	January 31, 2017
EMBASE (Ovid)	01/02/2017	1974 to 2017 Week 05
PubMed	01/02/2017	n/a
JournalTOCS [for update searches only]	01/02/2017	n/a

Trial sources searched on 26/07/2016

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

Websites searched on 26/07/2016

- 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 Uterine Prolapse/

2 pelvic organ prolapse/

3 ((vagina* or transvaginal* or genital* or uter* or womb* or apical or (pelvic adj2 organ*) or utero-vagin*) adj4 (prolaps* or collaps* or drop* or slip* or sag* or hernia* or fall* or sink* or relax*)).tw.

4 POP.tw.

5 (pelvic adj4 floor adj4 repair).ti,ab.

6 (stress* adj4 urin* adj4 incontinen*).ti,ab.

7 urinary incontinence, stress/

8 or/1-7

9 (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.

10 (((transvagin* or intravagin*) adj4 sling*) or (infracoccygeal* adj4 sacropex*)).ti,ab.

11 ((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.

12 (posterior adj4 (intravagin* or intra-vagin* or transvagin*)).ti,ab.

13 (PIVS or IVS or P-IVS).ti,ab.

14 (sacrospin* adj4 (fixation or suspens*)).ti,ab.

15 or/9-14

16 8 and 15

17 animals/ not humans/

18 16 not 17

19 (201607* or 201608* or 201609* or 201610* or 201611* or 201612* or 2017*).ed.

20 18 and 19