NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse

Uterine prolapse happens when the womb (uterus) slips down from its usual position into the vagina. Sacrocolpopexy involves inserting a piece of mesh typically between the top and back of the vagina, to a ligament of the lower backbone, with the aim of holding the pelvic organs in place, after surgical removal of the womb (hysterectomy).

Introduction

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

Date prepared

This IP overview was prepared in September 2016.

Procedure name

- Sacrocolpopexy with hysterectomy 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 into, and sometimes through the vagina. It can affect quality of life by causing symptoms of pressure and discomfort, and by its effect on urinary, bowel and sexual function.

Current treatment options include pelvic floor muscle training, use of pessaries and surgery. Several surgical procedures can be used, including hysterectomy, infracoccygeal sacropexy, 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

Sacrocolpopexy with hysterectomy using mesh for uterine prolapse is done with the patient under general anaesthesia. An open or laparoscopic abdominal approach is used, following on from a concomitant hysterectomy procedure. Mesh is attached to the apex of the vagina and may also be attached to the anterior or posterior vaginal wall, with the aim of preventing future vaginal vault prolapse.

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

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

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse. The following databases were searched,, covering the period from their start to 07.06.2016: 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	Sacrocolpopexy with hysterectomy 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 2,277 patients (of which only 1,335 had sacrocolpopexy and concomitant hysterectomy) from 1 systematic review[1], 1 prospective case series[2] and 8 retrospective cohort studies[3-10].

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 sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse

Study 1 Jia X (2010)

Details

Study type	**Systematic review**
Country	UK
Study period	Search date: 1980-2008; searched 17 electronic databases (including Medline, Embase), conference proceedings, relevant websites, contacted manufacturers and checked bibliographies of published papers.
Study population and number	The review covered 54 studies (with 7,054 women) having surgery for uterine or vaginal vault prolapse using mesh. Of these, 32 studies (with 4,456 women) were on sacrocolpopexy, and **4 studies (with 7% [311/4,456] women) reported on sacrocolpopexy with concomitant hysterectomy for uterine prolapse.**
Age	average age 61 years
Study selection criteria	Randomised controlled trials (RCTs), RCTs published as conference abstracts from 2005 onwards, non-randomised comparative studies and case series (with sample size of 100 and a mean follow-up of 1 year); with women having uterine or vaginal vault prolapse surgery; all surgical techniques using mesh (RCTs comparing with any other techniques with or without mesh); with other concomitant procedures such as hysterectomy, anti-incontinence, anterior or posterior vaginal wall prolapse repair were included. Studies of women with cancer or with prolapse caused by congenital anomalies inherited conditions or creation of a neovagina were excluded.
Technique	**Hysterectomy followed by sacrocolpopexy in the same procedure for uterine prolapse** **(studies included in review)** 1. Braun 2007 RCT (conference abstract) 2. Costantini 2005 –non randomised comparative study 3. Griffis 2006- non randomised comparative study 4. Wu 2006- Case series Mesh type used: varied across studies.
Follow-up	**varied in systematic review; for sacrocolpopexy -median 23 months (range 8-66 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: varied follow-up across studies.

Study design issues: this systematic review included all surgical techniques using mesh for uterine or vaginal vault prolapse (including sacrocolpopexy, infracoccygeal sacropexy, sacrocolpoperinopexy, and uterine suspension sling). Data extraction and quality assessment of studies were done by 2 independent reviewers. Quality assessment checklists developed by the Review Body of Interventional Procedures (ReBIP) (an independent body that carries out systematic reviews for NICE's Interventional procedures programme) were used according to study design. Data analyses were done separately for each technique and also presented according to type of prolapse repaired: uterine, vault, and uterine and/or vault prolapse (where data not reported separately). Sub-group analyses were done for different surgical techniques, types of mesh and primary versus secondary repairs.

Other issues: studies with other surgical techniques (that use mesh) other than sacrocolpopexy with concomitant hysterectomy for uterine prolapse (sacrocolpopexy alone, infracoccygeal sacropexy, sacrocolpoperinopexy, and uterine suspension sling for vault prolapse and uterine and/or vault prolapse where data were not reported separately) have been excluded in this overview as they are outside the scope of this review.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **311**

Summary of 4 studies with hysterectomy followed by sacrocolpopexy for uterine prolapse

Study	no of patients	Intervention (route) A	Comparator (route) B	Mean follow-up months (range)
Braun 2007 (RCT, abstract)	47	hysterectomy +sacrocolpopexy (abdominal) n=23 Mesh-Vypro combined mesh	hysterectomy+ anteroposterior colporrhaphy +Mayo McCall stitch (vaginal) n=24 Mesh-no mesh	33 (20-41)
Costantini 2005 (non-randomised comparative study)	75	sacrohysteropexy (abdominal) n=36 Mesh-polypropylene, Marlex	hysterectomy +sacrocolpopexy (abdominal) n=39 Mesh-polypropylene, Marlex	51 (12-115)
Griffis 2006 (non-randomised comparative study)	88	Total hysterectomy+ sacrocolpopexy (abdominal) n=60 Mesh-polypropylene, Prolene soft, or Atrium; polyethylene tetraphalate, Mersilene	Supracervical hysterectomy+sacrocolpopexy (abdominal) n=28 Mesh-polypropylene, Prolene soft, or Atrium; polyethylene tetraphalate, Mersilene	13 (12-15)
Wu 2006 (case series)	101	hysterectomy +sacrocolpopexy (abdominal-open) Mesh- polyethylene tetraphalate, Mersilene; polypropylene; or Gore-Tex		15 (0.2-120)

Objective failure: recurrent prolapse at original site (clinician reported)

Braun 2007 RCT (abstract)

- Hysterectomy followed by sacrocolpopexy: 0% (0/23)
- vaginal hysterectomy (no mesh): 4.2% (1/24) 8 months after surgery

1 severe cystocele occurred at 3 months but not reported as recurrent or de novo prolapse.

Costantini 2005

Objective failure (defined as recurrent prolapse at less than 6cm above the hymen) was 0% at a mean follow up of 51 months in women treated by sacrohysteropexy (0/36) and in women treated by hysterectomy followed by sacrocolpopexy (0/39). None of the 75 women (0%) needed further repair for recurrent or de novo prolapse.

Safety

Adverse events across studies

Study	Intervention (route) A % (n)	Comparator (route) B % (n)
Blood loss needing transfusion		
Costantini 2005 (non-randomised comparative study)	0	5.1 (2/39)
Mesh erosion		
Braun 2007 (RCT, abstract)	4.3 (1/23)	0
Costantini2005 (Non-randomised comparative study)	0	7.6 (3/39) (needed vaginal revision)
Griffis 2006 (Non-randomised comparative study)*	10.5 (8/76)	3.5 (1/28)
Wu 2006 (case series)	6.9 (7/101) mean time to occur 8.4 months	
Wound infection		
Costantini 2005 (Non-randomised comparative study)	0	(2/39)
Incisional hernia		
Braun 2007 RCT abstract	4.3 (1/23)	0
Costantini 2005	5.5 (2/36)	2.5 (1/39)
Subaponeurotic hematoma		
Braun 2007 RCT abstract	4.3 (1/23)	0
Other events (Costantini 2005)		
Fever	2.7 (1/36)	2.5 (1/39)
Peri-vescical haematoma	5.5 (2/36)	10 (4/39)
Voiding dysfunction	11 (4/36)	2.5 (1/39)

*4 needed surgical excision, other erosions were managed conservatively.

Abbreviations used: m, months, RCT, randomised controlled trial.

Study 2 Marinkovic SP (2008)

Details

Study type	**Case series (prospective)**
Country	USA
Recruitment period	2002-5
Study population and number	n=**67 patients with International Continence Society (ICS) stage 2 or more cystocele, rectocele, and uterine prolapse.**
Age	median 55 years
Patient selection criteria	Patients with ICS stage 2 or more pelvic organ prolapse of the anterior middle and posterior pelvic compartments were included.
Technique	**Total abdominal hysterectomy with and without bilateral salpingo-oophorectomy with simultaneous sacrocolpopexy.** Mesh type used: polypropylene (Prolene) mesh extensions (2x12 inches) and 1-0 polydixanone suture used (both from Ethicon). Patients were followed up at periodic intervals.
Follow-up	**Median 27 months (range 12-48 months)**
Conflict of interest/source of funding	not reported

Analysis

Follow-up issues: 3 patients were lost to follow-up.

Study design issues: multicentre prospective study; all patients had same type of mesh closure and material. One urogyanecologist performed all sacrocolpopexies and 8 different gynaecologists performed the abdominal hysterectomies. Personal satisfaction assessment was done through interviews. All assessments were performed by a gynaecology nurse with ample experience with pelvic organ prolapse scoring and assessment.

Key efficacy and safety findings

Safety

Number of patients analysed: **64**

Patient satisfaction

	% (n)
Overall patient satisfaction	93 (60/64)
Dissatisfaction	7(4/64)
median PFDI scores (preoperative to postoperative)	improved from 50 to 10 (p=0.001)

Failure rate (recurrence): 8% (4/64)- all stage 2rectoceles

Adverse events

	% (n)
Mesh/suture erosions	0
Intraoperative cystostomy	5 (3/64)
De novo SUI (treated by tension free vaginal tape approach)	10 (5/64)
De novo urgency	12 (6/64)
Fever, abscess, DVT , ileus or bowel obstruction	0
Readmission within 30 days	0

Abbreviations used: ASC, abdominal sacrocolpopexy; DVT, deep vein thrombosis; PFDI, pelvic floor distress inventory; SUI, stress urinary incontinence.

Study 3 Eshani N (2012)

Details

Study type	**Case series (case-control study)**
Country	USA (8 centres)
Recruitment period	2006-9
Study population and number	n=**336** (**84 patients with pelvic organ prolapse; 252 matched controls)** **Abdominal sacrocolpopexy (ASC) cases 43, controls 147; Vaginal mesh procedure (VMP) cases 41, controls 105.** **Concomitant hysterectomy:** (**ASC cases 33/43, controls 83/147); (VMP cases 12/41, controls 16/105)**
Age	ASC (cases: mean 75 years, controls: mean 60 years); VMP (cases mean 61 years, controls mean 65 years)
Patient selection criteria	Women who had surgical correction for pelvic organ prolapse via ASC or VMP were included. Patients with incomplete records or insufficient follow-up data were excluded.
Technique	Pelvic organ prolapse repair with ASC or vaginal mesh procedure (VMP). Sacrocolpopexies included open, robotic, and laparoscopic routes. Vaginal mesh procedures included both free vaginal mesh and mesh kits. Procedures done by surgeons with varying levels of experience and surgical approach varied at different sites.
Follow-up	**not reported**
Conflict of interest/source of funding	3 authors are consultants for American Medical Systems and Ethicon.

Analysis

Study design issues: Multicentre retrospective study with large sample size; patients were identified using medical records with procedure coding. Surgical approach varied across sites. Cases were matched to controls by procedure type and date of surgery in an approximate 1:3 ratio. Mesh extrusion cases were defined as women who had eligible index procedure with synthetic mesh and had mesh visible through the vaginal epithelium at postoperative evaluation. Two conditional logistic regression models were constructed to assess variables associated with mesh extrusion. Mode of hysterectomy was not clearly reported.

Key efficacy and safety findings

Safety

Number of patients analysed: **336**

Multivariate model predicting extrusion after ASC (cases, n=43; controls, n=129)

Variable	AOR (95% CI)	p value
Concomitant hysterectomy (reference: previous)	3.18 (1.27-7.93)	0.01

Multivariate model predicting extrusion after VMP (cases, n=41; control, n=105)

Variable	AOR (95% CI)	p value
Concomitant hysterectomy (reference: previous)	3.72 (1.20-11.54)	0.02
Concomitant hysterectomy (reference :none)	8.63 (2.04-36.41)	0.003
Previous hysterectomy (reference: none)	2.32 (0.77-7.02)	0.14

No significant association were seen with extrusion in either group for age, smoking status, oestrogen status, type of vaginal incision or medical comorbidities.

The mean time to diagnosis of mesh extrusion in both groups was 16 weeks.

Abbreviations used: AOR, adjusted odds ratio; ASC, abdominal sacrocolpopexy; CI, confidence interval; VMP, vaginal mesh procedure.

Study 4 Costantini E (2011)

Details

Study type	**Case series (Retrospective comparative study)**
Country	Italy
Recruitment period	1998-2008
Study population and number	n=**179 patients with advanced pelvic organ prolapse** **(74 abdominal sacrocolpopexy [ASC] + hysterectomy, 54 ASC for vault prolapse, 51 ASC +uterus preservation)**
Age	mean 54.9 years
Patient selection criteria	Patients with advanced pelvic organ prolapse
Technique	74 ASC and hysterectomy, 54 ASC for vault prolapse, 51 ASC +uterus preservation. All patients followed up every 3 months in the first year, every 6 months in second year and then annually. At 1 year ultrasound and urodynamic assessment done. Mesh erosions identified were evaluated according to erosion dimension, site and signs of infection. Treatment was individualised but a general healing abnormalities protocol was adapted. Mesh type used: polypropylene, Gore-tex.
Follow-up	**Mean 57 months (range 18-120 months)**
Conflict of interest/source of funding	not reported

Analysis

Study design issues: retrospective analysis from a single centre about management of mesh erosion. Patients charts and follow-up data were entered into a database and analysis done for mesh erosion, treatment/surgery.

Key efficacy and safety findings

Safety

Number of patients analysed: **179**

Overall mesh erosion: 6.7% (12/179) 11 patients had polypropylene mesh and 1 had Gore-tex mesh.

Time to mesh erosion: mean 22.9 months (range 2-66), 4 erosions occurred within 6 months.

	ASC+ hysterectomy % (n=74)	**ASC for vault prolapse % (n=54)**	**ASC +uterus preservation % (n=51)**
Mesh erosions	6.5% (5/74) (3 at the vaginal apex 1 on posterior vaginal wall 1 in bladder)	7.4% (4/54) (2 at the vaginal apex 1 on posterior vaginal wall, 1 not reported)	5.9 (3/51) (2 on the posterior vaginal wall,1 not reported)

4 were asymptomatic and found incidentally during clinical check-up at 4, 31, 36 and 66 months.

5 patients presented with vaginal bleeding associated with dyspareunia in 2 patients. 1 had recurrent urinary tract infections, 1 with Gore-tex mesh had infection, and 1 presented with a green vaginal discharge and urinary incontinence.

Treatments were individualised and in all cases surgery was needed to remove mesh as patients did not respond to conservative management.

At a mean follow-up of 57 months after surgical treatment all patients were asymptomatic and free from erosions.

Abbreviations used: ASC, abdominal sacrocolpopexy.

Study 5 Akyol A (2014)

Details

Study type	**Case series (retrospective comparative study)**
Country	Turkey
Recruitment period	2002-12
Study population and number	n=**292 patients with stage 2-4 pelvic organ prolapse** **ASC + concomitant hysterectomy (74/292); prior hysterectomy (218/292)**
Age	mean 60.4 years
Patient selection criteria	Patients with stage 2-4 pelvic organ prolapse were included. Patients with types of mesh other than polypropylene mesh and those with no follow-up data were excluded.
Technique	ASC in conjunction with other abdominal and/or vaginal procedures doneby 2 or 3 surgeons. Mesh type used: Type 1 polypropylene mesh and polyglycolic acid sutures used. Follow-up examinations were done by surgeons.
Follow-up	**Median 42 months (range 12-68 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: long follow-up period.

Study design issues: large retrospective non-randomised comparative study from a single centre about risk factors associated with mesh erosion. Medical records and hospital charts were reviewed. All mesh exposures diagnosed during postoperative follow-up were compared with matched no mesh exposure cases.

Key efficacy and safety findings

Safety

Number of patients analysed: **292**

Overall mesh exposure: 6.5% (19/292)

Concomitant hysterectomy +ASC: 12% (9/74); Previous hysterectomy 4.5% (10/218)

Time to mesh exposure: median 16.8 months (range 3-56 months).

Rates of mesh erosion

	Mesh erosion % (n=19)	**No erosion % (n=273)**	**p value, 95% CI**
POP-Q stage >III	89.5 (17/19)	64% (175/273)	0.04
POP-Q stage <III	10.5 (2/19)	36 (98/273)	
Concomitant hysterectomy +ASC (n=74)	47.4 (9/19)	23.8 (65/273)	0.03, 95%CI (2.8-45)
Previous hysterectomy	52.6 (10/19)	76.2 (208/273)	0.03, 95% CI (2.8-45)
3 or more additional procedures	31.6 (6/19)	11.4 (31/273)	0.02, 95% CI (3.4-42.8)

Factors affecting mesh exposure (logistic regression analysis)

Variable	**p**	**OR**	**CI**
POP-Q stage>III	0.049	4.6	1.2-20.7
Concomitant hysterectomy	0.047	2.8	1.1-7.8
Concomitant procedure	0.03	3.9	1.1-13.0

Abbreviations used: ASC, abdominal sacrocolpopexy; CI, confidence interval; POP-Q, pelvic organ prolapse-quantification; OR, odds ratio.

Study 6 Crane AK (2014)

Details

Study type	**Case series (Retrospective comparative study)**
Country	USA (single centre)
Recruitment period	2009-11
Study population and number	n=**230 patients with stage 3 prolapse (112 RASC with concomitant hysterectomy versus 118 robotic sacrocolpopexy (RASC) alone)** Of those who had hysterectomy, **70.5% (79/112) had total hysterectomy (TH) and 29.5% (33/112) had supracervical hysterectomy (SCH).**
Age	RASC+ hysterectomy: mean 54.9 years; RASC alone: mean 62.3 years.
Patient selection criteria	Patients with stage 3 prolapse
Technique	Concomitant hysterectomy was done in those who did not have a previous hysterectomy. Care was taken to avoid attaching the mesh directly at the vaginal cuff. RASC alone was done in patients who had a previous hysterectomy. For sacrocolpopexy, anterior dissection was done down to the level of the bladder trigone, and posterior dissection as close to the perineal body, placing 6-8 stitches both anteriorly and posteriorly to attach the mesh to the vagina, and placing 2-3 sutures in the anterior longitudinal sacral ligament. Mesh type used: Intepro Y mesh (most commonly used) and Gynecare Gynemesh (in 4 cases). 2 types of sutures were used for sacrocolpopexy procedures.
Follow-up	**6 weeks**
Conflict of interest/source of funding	2 authors received honoraria for a symposium and Robotics fellowship grant from Intuitive Surgical.

Analysis

Follow-up issues: short term follow-up. All mesh exposures were followed up at least 6 months post-operation and/or time of mesh revision.

Study design issues: retrospective study at 1 study centre with large sample size, surgical techniques were performed as preferred by clinicians with different experience. Mesh exposures and mesh revision procedures were identified using International Classification of Diseases-9 and CPT codes, respectively in the electronic medical record/operating database, and confirmed by chart review.

Other issues: Authors state that it is unclear whether the surgeon's technique or the mesh type contributed to the difference in mesh exposure rates.

Key efficacy and safety findings

Safety

Number of patients analysed: **230**

Mesh exposure at 6 weeks after surgery: **overall 5.7% (13/230)**

3.9% (9/13) attributed to RASC, 8 occurred at the vaginal apex and 1 on the posterior mid vagina;

1.8% (4/13) were exposures of a mid-urethral sling.

RASC+ hysterectomy % (n=112)	**RASC alone % (n=118)**	p value
2.7 (3/112)*	5.1 (6/118)	0.50

*These were associated with TH and none with SCH (P = 0.55). One mesh exposure in the TH group was associated with an abscess, and there were two cuff abscesses after mesh revision. All of the mesh exposures involved the Intepro Y mesh.

5 mesh exposures were symptomatic and only 4 had mesh revision.

Abbreviations used: RASC, robotic assisted sacrocolpopexy; SCH, supracervical hysterectomy; TH, total hysterectomy.

Study 7 Osmundsen BC (2012)

Details

Study type	**Case series (Retrospective comparative study)**
Country	USA (2 sites)
Recruitment period	2007-10
Study population and number	n=**102 patients with uterovaginal prolapse** **(45 robotic sacrocolpopexy (RASC) with concomitant supracervical hysterectomy [SCH] versus 57 RASC with concomitant total hysterectomy [TH])** (36 patients were from centre 1 and 66 from centre 2; 50% in each centre had TH)
Age	mean age 58 years
Patient selection criteria	all patients with uterovaginal prolapse having robotic assisted sacrocolpopexy with SH or TH
Technique	RASC with concomitant SCH or TH (using Da Vinci S or Si robot) was done by surgeons in a similar fashion. The technique is similar to the standard open procedure. For TH bipolar/monopolar cautery is used, closure of vagina varied depending on surgeon preference. For SH, the uterus is amputated of the cervix with monopolar cautery and retrieved with morcellation. Mesh type used: type 1 monofilament prolene meshes-Intepro Y mesh, Gyne-mesh A 2-0 prolene is used to suture the mesh, a 0 Ethicon bond or Ticron is used to affix the graft with Vicryl.
Follow-up	**3 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: short term follow-up. Only 78% (80/102) patients completed the 3 months follow-up. 14 patients in SH group and 8 in TH group were lost to follow-up.

Study design issues: retrospective cohort study from a database review at 2 centres, study compared the incidence of mesh erosion in women undergoing robotic TH with those having TH during RASC for uterovaginal prolapse; surgeons in the 2 sites had same training and followed same surgical approaches. Mesh erosion was the primary outcome.

Study population issues: there were no differences in baseline characteristics between the 2 groups or by site. Population is mainly non-Hispanic white.

Other issues: Authors state that the differences in site related mesh erosion rates may be attributable to the type of mesh used (self-cut at site 1 or pre-cut polypropylene at site 2).

Key efficacy and safety findings

Safety

Number of patients analysed: **102**

Mesh erosion (defined as visible or palpable mesh material noted at any visit during the 3 month follow-up)

	RASC +SCH % (n=45)	**RASC+ TH % (n=57)**	**p value**
Total erosion	0	14 (8/57)*^	<0.01
Site 1	(0/17)	37 (7/19)	
Site 2	(0/28)	3 (1/38)	
Unexpected abnormal uterine pathology	(2/45)*		

^ All erosions occurred at the vaginal apex.

*1 patient had a grade 1 endometrial adenocarcinoma and 1 had complex hyperplasia with atypia.

Abbreviations used: RASC, robotic assisted sacrocolpopexy; SCH, supracervical hysterectomy; TH, total hysterectomy.

Study 8 Tan-Kim J (2011)

Details

Study type	**Case series (Retrospective comparative study)**
Country	USA
Recruitment period	2004-9
Study population and number	n=**188 patients with stage 3 prolapse who had minimally invasive sacrocolpopexy (MISC)** **(12% [21/188] robotic assisted sacrocolpopexy (RASC) with concomitant supracervical hysterectomy [SCH]** versus **30% (57/188) conventional LSC with concomitant total vaginal hysterectomy [TVH]** versus **58% [110/188] MISC [RASC/LSC] post hysterectomy)** (of 57 LSC + TVH, 29 had VALSC :mesh attached transvaginally; 28 had VHLSC: mesh attached laparoscopically)
Age	mean age 61+9 years
Patient selection criteria	All patients with median prolapse stage 3 who had MISC using one of 2 techniques (RASC/LSC) were included. Patients were excluded if they did not have a follow-up postoperative physical examination.
Technique	**RASC** (using Da Vinci S or Si robot): laparoscopic SCH was done in routine fashion with the uterus removed using a morcellator. Mesh type used: type 1 monofilament polypropylene mesh used with 4 monofilament permanent sutures. **LSC** was done using 3 techniques: procedure done laparoscopically for patients who were post-hysterectomy; TVH with mesh attachment transvaginally prior to vaginally assisted laparoscopic sacrocolpopexy [VALSC]; TVH followed by mesh attached laparoscopically after vaginal closure of the cuff (vaginal hysterectomy prior to laparoscopic sacrocolpopexy [VHLSC]). Mesh type used: type 1 monofilament polypropylene mesh coated with collagen (Pelvitex) or non-coated type 1 monofilament with 2-4 titanium sutures or interrupted monofilament permanent suture. Other concomitant procedures (anterior/posterior repairs, mid-urethral slings) were performed prior to or after sacrocolpopexy.
Follow-up	**RASC median 20 weeks (2-124 weeks); LSC 14 weeks (2-171 weeks).**
Conflict of interest/source of funding	2 authors were consultants for Intuitive Surgical Inc.

Analysis

Follow-up issues: follow-up intervals were not standard between all patients and in some cases it was short.

Study design issues: retrospective cohort study with small sample size at 2 centres responsible for training in the UCSD/ Kaiser Permanente San Diego female pelvic medicine and reconstructive surgery fellowship program, 6 surgeons performed different techniques with different meshes; these were based on surgeon preference. Objective outcomes were abstracted from medical/hospital records.

Key efficacy and safety findings

Safety

Number of patients analysed: **188**

Mesh erosion rate (defined as any mesh or permanent suture material seen in the vagina or other adjacent tissues)

	RASC +SCH % (n=21)	**LSC+ TVH % (n=57)**	**MISC [RASC/LSC] post hysterectomy % (n=110)**	**Total % (n=188)**
Mesh erosion	5 (1/21) (p=0.984)*	23 (13/57) (p=0.003)*	5 (5/110)	10 (19/188)^
Mean time to mesh erosion (weeks)	6 weeks	21±17 (p=0.661)	31±29	23±21 (range 3-86)
Subgroup analysis				
VALSC		14 (4/29)		
VHLSC		32 (9/28) (p=0.123)*		

*Fisher' exact test.

^ of the 19 erosions, 1 involved suture, 15 were mesh exposures at the level of the apex, 1 at the anterior wall, 1 resulted in a vesicovaginal fistula and 1 erosion was into the bladder without fistula. There were no erosions at the mid urethral sling or along the posterior wall of the vagina.

Of the 19 erosions, 15 were treated with conservative vaginal oestrogen therapy, and only 3 resolved with this treatment. 10 patients needed additional surgical procedures and 5 opted for expectant management.

Risk factors associated with mesh erosion

Multivariate regression model for posterior repair and type of hysterectomy

variable	**Exp (B) odds ratio (OR)**	**95% CI for Exp (B)**	**p value**
Constant	0.043		
Posterior repair	1.88	0.62-5.70	0.268
Reference group=post-hysterectomy			
SCH	0.99	0.119.03	0.996
TVH	5.67	1.88-17.10	0.002

Smoking, the use collagen-coated mesh, transvaginal dissection and mesh attachment transvaginally were no longer significant in the multivariate regression model.

Abbreviations used: CI, confidence interval; LSC, laparoscopic sacrocolpopexy; MISC, minimally invasive sacrcolpopexy; RASC, robotic assisted sacrocolpopexy; SCH, supracervical hysterectomy; TVH, total vaginal hysterectomy; VALSC, vaginally assisted laparoscopic sacrocolpopexy; VHLSC, vaginally hysterectomy prior to laparoscopic sacrocolpopexy (laparoscopic placement of mesh).

Study 9 Warner WB (2012)

Details

Study type	**Case series (Retrospective comparative study)**
Country	USA
Recruitment period	2006-10
Study population and number	n=**390 patients with median stage 3 prolapse who underwent laparoscopic sacrocolpopexy (LSC)** **(71% [279/390] LSC + concomitant hysterectomy[CH], 28% [108/390] prior hysterectomy, 1% (3/390) laparoscopic sacrohysteropexy)** **Of 279 LSC+CH:** (59 total vaginal hysterectomy[TVH], 126 laparoscopically assisted vaginal hysterectomy [LAVH], 92 laparoscopic supracervical hysterectomy [LSH] and 2 total laparoscopic hysterectomy[TLH])
Age	mean age 59 years
Patient selection criteria	not reported
Technique	**LSC + CH (279/390)** was done using one of the techniques: 1. Laparoscopic supracervical hysterectomy [LSH] followed by laparoscopic attachment of mesh (LSH/LSC) (92/279) Open cuff hysterectomies (59 total vaginal hysterectomy [TVH], 126 laparoscopically assisted vaginal hysterectomy [LAVH]): 2. TVH or LAVH followed by laparoscopic attachment of mesh (vaginal hysterectomy with laparoscopic sacrocolpopexy [VHLS]) in 19% (35/185) 3.TVH or LAVH followed by vaginal attachment of mesh (vaginally assisted LSC [VALS]) in 81% (150/185) Type of mesh and suture used: polypropylene mesh and permanent sutures (Ethicon primarily, Gore-tex). **Patients with prior hysterectomies (180/390):** the vaginal cuff was opened 15% (16/108) of time and remained closed 85% (92/108) of time. When the cuff was opened, mesh was attached trans-vaginally in 6 patients and laparoscopically in 10 patients. Concomitant mid-urethral slings were done when indicated.
Follow-up	**Median 26 weeks (range 2-210 weeks), mean of 47 weeks.**
Conflict of interest/source of funding	One author is on the Medtronic speakers' bureau, all others have none to disclose.

Analysis

Follow-up issues: most patients were seen for follow-up at 2, 6 and 12 weeks and screened for mesh exposure or suture extrusion. Median follow-up was short, only 6 months.

Study design issues: retrospective cohort study. Patients were identified from billing records and their medical records retrospectively reviewed. Surgeries were done by fellows and residents under guidance of trained and certified urogynaecologists and there were variations with respect to type of hysterectomy and mesh attachment based on surgeons and/or the patient preferences. The mesh exposures were staged according to the International Urogynaecological Association classification system.

Key efficacy and safety findings

Safety

Number of patients analysed: **390**

Mesh erosion

	% (n=390)
Total exposure/extrusion rate	6.4 (25/390)
Mesh exposures*	2.8 (11/390)
Suture extrusion^	3.6 (14/390)

*6 were symptomatic: the most common symptoms were bleeding and dyspareunia. 5 had reoperation and 1 was not treated.

5 were non-symptomatic: 1 resolved, 4 were observed.

^1 was symptomatic (with vaginal discharge and spotting from granulation tissue), 10 were excised and others were observed as they were too small to trim.

Mesh exposure rate

LSC +CH (n=279/390)				**Prior hysterectomy (108/390)**	
TVH (n=59)	**LAVH (n=126)**	**LSH (92/279)**	**TLH (2/279)**		
6.8% (4/59)	4% (5/126)	0% (0/92)	4.9% (9/185)		
p=0.469		p=0.032			
Mesh sutured laparoscopically (VHLS) n=35	**mesh sutured transvaginal (VALS) n=150**			**vaginal cuff opened n=16**	**vaginal cuff closed n=92**
14.3 (5/35)	2.7 (4/150)			6.3 (1/16)	1.1 (1/92)
RR=5.4, p=0.013				RR=5.7, p=0.276	

Mesh exposure was more common when the vaginal cuff was opened, either in the course of hysterectomy or during vaginal attachment of mesh in patents with a prior hysterectomy (4.9% [10/205] versus 0.5% [1/185]; relative risk RR 9.0; p=0.012.

Permanent suture exposure was significantly associated with laparoscopic versus transvaginal suturing of mesh (5.6% [13/233] versus 0.6% [1/157]; RR 8.8; p=0.010).

There were no differences between patients with mesh exposure and those without exposure with regard to age, BMI, history of diabetes, or hormone status. Only smoking history showed statistical significance (0.023).

Abbreviations used: CH, concomitant hysterectomy; LSC, laparoscopic sacrocolpopexy; RR, relative risk; SH, supracervical hysterectomy; TVH, total vaginal hysterectomy; VALSC, vaginally assisted laparoscopic sacrocolpopexy; VHLSC, vaginally hysterectomy prior to laparoscopic sacrocolpopexy (laparoscopic placement of mesh).

Study 10 Nosti PA (2016)

Details

Study type	**Case series (Retrospective comparative study)**
Country	USA
Recruitment period	2008-12
Study population and number	n=**182 patients with uterovaginal prolapse** **123 total vaginal hysterectomy with laparoscopic sacrocolpopexy (TVH-LSC) versus 59 laparoscopic supracervical hysterectomy with laparoscopic sacrocolpoexy (LSCH-LSC)**
Age	TVH +LSC: mean 55.6 years; LSCH +LSC: mean 53.5 years.
Patient selection criteria	Patients with vaginal vault prolapse, those having TVH or total laparoscopic hysterectomy with laparoscopic attachment of mesh and laparoscopic sacrohysteropexy were excluded.
Technique	TVH + LSC in 123 patients LSCH + LSC in 59 patients Placement of mesh at least 2 cm from the cuff edge. Mesh type used: Restorelle, Gynemesh or IntePro Large Pore Polyproylene Y; Sutures: Gore-tex or PDS (Ethicon) Restorelle mesh was used in majority of the cases (91% TVH+LSC versus 76% LSCH+LSC). Robotic assistance was used in some cases. Additional surgical procedures were done as necessary. Postoperative examinations were done at 2 weeks, 8 weeks and 12 months
Follow-up	**Median 9 months in both groups (range 2-17 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Short median follow-up. There was no difference in the median overall follow-up time and median examination follow-up between groups.

Study design issues: retrospective cohort study with prospective follow-up of patients by telephone interviews and repeat examination. Study was underpowered.

Patients were asked 3 questions regarding overall pelvic floor function, prolapse symptoms and sexual symptoms using a 7 point Likert scale from very much worse to very much better. Only 60% (75/123) patients of THV+LSC and 53% (31/59) patients of LSCH+LSC completed telephone interviews and few returned for examination. Patient records were identified using current procedural terminology codes and reviewed. Surgeries were done by fellows and residents under guidance of trained and certified pelvic reconstructive surgeons and were uniform and consistent.

Study population issues: patients in the TVH+LSC group had more severe (stage 3 or 4) prolapse compared with the LSCH+ LSC group (72% versus 53%, p=0.03).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **182**

Surgical success

	TVH+LSC % (n=73/123)	**LSCH+LSC % (n=31/59)**	**p value**
Anatomic success*	94.4	93.2	0.8
Subjective success^	93.3	87.1	0.3
Composite success	90.7	80.7	0.2
Operative time (minutes)	256±53	344±81	<0.01

*defined as no prolapse at or beyond the hymen and no apical prolapse beyond the mid-vagina.

^defined as the absence of bulge symptoms and PGI-I response of 'very much better' or 'much better'.

Safety

Mesh related complications

	TVH+LSC % (n=123)	**LSCH+LSC % (n=59)**	**p value**
Mesh exposure*	1.6% (2/123)^ 95% CI 0-3.86	1.7% (1/59)^^ 95% CI 0-4.99	1.0
Suture extrusion~	1%	2%	1.0
presence of granulation tissue**	10%	7%	0.6
Severe abdominal pain (due to bowel obstruction)+		n=1	

*All 3 cases occurred in the predominant mesh type (Restorelle).

^ Exposures occurred at the vaginal apex which were managed by excision at 8 and 18 months after initial surgery.

^^ exposure occurred at the posterior vaginal wall and was managed by excision 41 months after initial surgery.

~ All occurred in patients where Gore-tex was used to suture the mesh and managed in the operating room.

** 1 TVH+LSC patient with granulation at the cuff needed management in the operating room and resolved after 2 weeks.

+managed by small bowel resection and reanastomosis of the small bowel, patient recovered and no evidence of mesh exposure.

There were no differences in intraoperative and postoperative complications.

Abbreviations used: LSC, laparoscopic sacrocolpopexy; LSCH, laparoscopic supracervical hysterectomy; TVH, total vaginal hysterectomy.

Efficacy

Objective failure

In a systematic review of 311 patients, a non-randomised study that compared 36 women treated by mesh sacrohysteropexy with 39 women treated by hysterectomy followed by sacrocolpopexy reported no objective failure (defined as prolapse at less than 6 cm above the hymen) in either group (0/36 and 0/39) at a mean follow-up of 51 months[1].

Denovo/recurrent prolapse

In the systematic review of 311 patients, the non-randomised study that compared 36 women treated by mesh sacrohysteropexy with 39 women treated by hysterectomy followed by sacrocolpopexy reported that none of the 75 women needed a further operation for recurrent or de novo prolapse at a mean follow-up of 51 months[1].

A prospective case series of 67 women treated by sacrocolpopexy with concomitant total abdominal hysterectomy reported recurrent stage 2 rectocele without any cystoceles or vault prolapse in 8% (464) of patients at a median follow-up of 27 months[2].

A retrospective comparative study of 182 women with uterovaginal prolapse that compared 123 women treated by total vaginal hysterectomy followed by laparoscopic sacrocolpopexy (TVH+LSC) with 59 women treated by laparoscopic supracervical hysterectomy followed by laparoscopic sacrocolpopexy (LSCH+LSC) reported no difference in anatomical success (defined as no prolapse at or beyond the hymen and no apical prolapse beyond the mid-vagina) (TVH+LSC 94% versus LSCH+LSC 93%, p=0.8) or subjective success (defined as the absence of bulge symptoms and overall Patient Global Impression of Improvement-I response of ‘very much better’ or ‘much better’) (TVH+LSC 91% versus LSCH+LSC 81%, p=0.3) between the 2 groups[10].

Patient satisfaction

In the prospective case series of 67 women treated by sacrocolpopexy with concomitant total abdominal hysterectomy, 93% (60/64) of patients reported satisfaction with the procedure at a median follow-up of 27 months. Mean pelvic floor distress inventory scores improved from 50 to 10 (p=0.001)[2].

Safety

Mesh erosion

Abdominal sacrocolpopexy (ASC) with concomitant hysterectomy

The risk of mesh erosion varied across 4 studies on abdominal sacrocolpopexy with concomitant hysterectomy for uterine prolapse included in a systematic review[1]. Mesh erosion was reported in 4% (1/23) of women treated by hysterectomy followed by sacrocolpopexy in a randomised controlled trial of 47 women available as a conference abstract (mean follow-up 33 months). A non-randomised comparative study of 75 women reported mesh erosion in 8% (3/39) of women treated by hysterectomy followed by sacrocolpopexy group and no mesh erosions (0/36) in the sacrohysteropexy group (mean follow-up 51 months). All patients with mesh erosion needed further surgery. Another non-randomised comparative study of 88 women reported erosion rates of 11% (8/76) in women treated by total hysterectomy followed by sacrocolpopexy and 4% (1/28) in women treated by supracervical hysterectomy followed by sacrocolpopexy (median follow-up 4 months); 4 of the 8 patients in the first group with mesh erosion needed further surgery. A case series of 324 women reported that 7% (7/101) of women had mesh erosion after hysterectomy followed by sacrocolpopexy at a median follow-up of 8.4 months (range 1.4 to 13 months)[1].

No mesh erosions were reported in a prospective case series of 67 women treated by sacrocolpopexy with concomitant total abdominal hysterectomy at a median follow-up of 27 months[2].

A case control study of 336 women treated by abdominal sacrocolpopexy (ASC) (cases n=43, control n=147) or vaginal mesh procedure (VMP) (cases n=41, controls n=105) with concomitant hysterectomy in both groups reported that concomitant hysterectomy was associated with mesh extrusion among women who had ASC (odds ratio [OR], 3.18; 95% confidence interval [CI] 1.27-7.93, p=0.01) and VMP (OR 3.72, 95% CI 1.20-11.54, p=0.02)[3].

A retrospective non-randomised comparative study of 179 women reported mesh erosions in 6.5% (5/74) women in the hysterectomy and sacrocolpopexy group, 5.9% (3/51) women in the sacrohysteropexy group and 7.4% (4/54) women in the sacrocolpopexy group with prior hysterectomy at a mean follow-up 57 months[4]. The time to mesh erosion ranged from 2 to 66 months. 4 erosions were asymptomatic and 5 were presented with vaginal bleeding, associated with dyspareunia in 2, 1 with urinary tract infection, 1 with fever and infection and 1 with vaginal discharge and urinary incontinence. Treatments were individualised and in all cases surgery was needed to remove mesh as women did not respond to conservative management[4].

A retrospective non-randomised comparative study of 292 women treated by ASC (74 with concomitant hysterectomy, 218 with previous hysterectomy) reported that the rates of mesh exposure were lower in patients with previous hysterectomy (mesh erosion 53% (10/19) versus no erosion 76% (208/273), p=0.03) at a median follow-up of 42 months. Also, it found that concomitant hysterectomy (mesh erosion 47% [9/19] versus no erosion 24% [65/273], p=0.03) or 3 or more additional procedures (mesh erosion 32% (6/19) versus no erosion 11% (31/273), p=0.02) increased the risk of mesh exposure[5].

Robotic assisted sacrocolpopexy (RASC) with concomitant hysterectomy

Mesh erosion rate after robotic assisted sacrocolpopexy (RASC) with a concomitant hysterectomy (CH) or RASC alone was not significantly different (2.7% [3/112] versus 5.1% [6/118]; p=0.50) in a retrospective non-randomised comparative study of 230 patients at 6 weeks follow-up. The 2.7% (3/79) of mesh exposures in the hysterectomy group were associated with total hysterectomy and none with supracervical hysterectomy (SCH n=33), this difference was not significant (p=0.50)[6]. Another retrospective non-randomised comparative study reported a mesh exposure rate of 14% (8/57) in the combined RASC with total hysterectomy group compared to 0% (0/45) in the RASC with SCH group (p<0.01) at 3 months follow-up. All erosions occurred at the vaginal apex[7].

Laparoscopic sacrocolpopexy (LSC) with concomitant hysterectomy

Mesh erosion rates were higher in patients having conventional laparoscopic sacrocolpopexy (LSC) with concomitant total vaginal hysterectomy (TVH) compared with both robotic or conventional sacrocolpopexy after hysterectomy (23% [13/57] versus 5% [5/110]; p=0.003) and robotic LSC with SCH (23% [13/57] versus 5% [1/21]; p=0.984) in a retrospective cohort study of 188 patients (mean follow-up of 20 weeks). In multivariate regression, the odds of erosion for TVH done at the same time as sacrocolpopexy was 5.67 (95%CI 1.88 to17.10; p=0.002) compared with sacrocolpoexy done after hysterectomy[8].

Mesh exposure was more common when the vaginal cuff was opened, either in the course of hysterectomy or during vaginal attachment of mesh in patients with a previous hysterectomy (4.9% [10/205] versus 0.5% [1/185]; relative risk [RR] 9.0; p=0.012) in a retrospective non-randomised comparative study of 390 women at a median follow-up 26 weeks. In cases where concomitant hysterectomy was done, a higher mesh exposure rate was seen in open-cuff hysterectomy (TVH or laparoscopically assisted vaginal hysterectomy [LAVH]) compared to SCH (4.9% [9/185] versus 0% [0/92], p=0.032). Mesh exposure was more common when the mesh was sutured laparoscopically compared with transvaginally in patients treated by open cuff hysterectomy (14.3% [5/35] versus 2.7% [4/150]; relative risk, 5.4; p=0.013). There was no difference in exposure rates between TVH and LAVH groups (6.8% [4/59] versus 4% [5/126]; p=0.469)[9].

The rate of mesh complications was not significantly different among women who had TVH with LSC compared with women who had LSCH with LSC (1.6% [2/123] versus 1.7% [1/59]; p=1.0) in a retrospective non-randomised comparative study of 182 patients with a median prospective follow-up of 9 months[10].

Suture erosion

Extrusion of permanent suture was more common in patients treated by LSH with LSC compared with patients treated by TVH with LSC (5.6% [13/233] versus 0.6% [1/157]; relative risk, 8.8; p=0.010) in a retrospective cohort study of 390

patients. Most of these extrusions were asymptomatic and were managed non-surgically[9].

The rate of suture erosion was not significantly different among women who had TVH with LSC compared with women who had LSCH with LSC (1% versus 2%; p=1.0) in the retrospective non-randomised comparative study of 182 patients with a median prospective follow-up of 9 months[10].

Presence of granulation tissue

The rate of presence of granulation tissue was not significantly different among women who had TVH with LSC compared with women who had LSCH with LSC (10% versus 7%; p=0.6) in the retrospective non-randomised comparative study of 182 patients with a median prospective follow-up of 9 months. All patients were managed in the operating room[10].

Wound infection

Wound infection was reported in 8% (3/39) of women treated by hysterectomy and sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review[1].

Haematoma

Peri-vesical haematoma was reported in 5% (2/36) of women treated by sacrohysteropexy and 10% (4/39) of women who had hysterectomy followed by sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review. Subaponeurotic haematoma occurred in 1 patient in the abdominal sacrocolpopexy combined with hysterectomy group (n=23) in the randomised controlled trial of 47 patients included in the systematic review. The time of occurrence and further details were not reported for the above outcomes[1].

Blood loss

Blood loss needing transfusion was reported in 5% (2/39) of women who had hysterectomy followed by sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review[1].

Incisional hernia

Incisional hernia was reported in 5% (2/36) of women treated by sacrohysteropexy and 2% (1/39) of women who had hysterectomy followed by sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review. It was also reported in 1 patient in the abdominal sacrocolpopexy combined with hysterectomy group (n=23) in the randomised controlled trial of 47 patients included in the systematic review[1].

Bowel symptoms

Severe abdominal pain due to bowel obstruction was reported in 1 patient in the LSCH+LSC group (n=59) in the non-randomised comparative study of 182 patients. This was managed by small bowel resection and reanastomosis of the bowel. The patient recovered completely and there was no evidence of mesh exposure[10].

Other adverse events

Voiding dysfunction was reported in 11% (4/36) of women treated by sacrohysteropexy and 2% (1/39) of women who had hysterectomy followed by sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review. In the same study, fever was reported in 1 patient in each group[1].

Validity and generalisability of the studies

- There is limited evidence on sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair alone.
- Evidence is mainly from retrospective non-randomised comparative studies. Follow-up varied across studies and ranged from 6 weeks to 57 months.
- Studies mainly focused on the rate of mesh erosions and the risk factors associated with mesh erosion.
- Studies included compared various combinations of sacrocolpopexy with concomitant hysterectomy using mesh for uterine prolapse repair (i.e. various types of hysterectomies and approaches for mesh attachment such as open abdominal, laparoscopic and robotic sacralcolpopexy). The type of mesh used also varied. Therefore, it is difficult to make a comprehensive comparison between all techniques.
- The rate of mesh erosions and time to erosion varied across studies.
- Evidence is conflicting as some studies reported that mesh exposure is higher in the case of a concurrent hysterectomy at the time of sacrocolpopexy and others reported no mesh exposures.

Existing assessments of this procedure

In December 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published an opinion on 'The safety of surgical meshes used in urogynecological Surgery'[11]. It stated: "The SCENIHR considers 3 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. 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 British Association of Urological Surgeons (BAUS) databases, improving 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[12].

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[13].

A summary of the evidence on the benefits and risks of vaginal mesh implants was published in October 2014 by the MHRA. 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"[14].

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 for uterine prolapse repair. NICE Interventional procedure guidance IPG284 (2009). Available from https://www.nice.org.uk/guidance/IPG284
- Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG283 (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 IPG282 (2009). Available from https://www.nice.org.uk/guidance/IPG282
- Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG281 (2009). Available from https://www.nice.org.uk/guidance/IPG281
- Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG280 (2009). Available from https://www.nice.org.uk/guidance/IPG280

- Surgical repair of vaginal wall prolapse using mesh. NICE Interventional procedure guidance IPG267 (2008). Available from https://www.nice.org.uk/guidance/IPG267
- Single-incision sub-urethral short tape insertion for stress urinary incontinence in women. NICE Interventional procedure guidance IPG262 (2008). Available from https://www.nice.org.uk/guidance/IPG262 (currently updated, due to publish in November 2016)

NICE guidelines

- Urinary incontinence in women (2013) NICE guideline CG171 (2013). Available from https://www.nice.org.uk/guidance/cg171

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 sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse repair were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent 32 questionnaires to 1 NHS trust for distribution to patients who had the procedure (or their carers). When NICE receive the completed questionnaires these will be discussed by the committee.

Company engagement

A structured information request was sent to 3 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- A guideline for clinical practice from the French National College of Obstetrics and Gynecology (CNGOF) states that ‘when operated via laparotomy, a concomitant total hysterectomy significantly increases the risk of vaginal mesh exposure and does not reduce the risk of prolapse recurrence. A total hysterectomy is associated with a greater prevalence of vaginal mesh exposure, when compared to a subtotal hysterectomy. In the case of sacralcolpopexy, if hysterectomy is required, it is recommended to perform a subtotal hysterectomy (Expert opinion)’[15].

References

1. Jia X, Glazener C, Mowatt G (2010). Systematic review of the efficacy and safety of using mesh in surgery for uterine or vaginal vault prolapse. Int Urogynecol J. 2010 Nov; 21(11):1413-31.
2. Marinkovic SP (2008). Will hysterectomy at the time of sacrocolpopexy increase the rate of polypropylene mesh erosion?. Int Urogynecol J Pelvic Floor Dysfunct. 19(2):199-203.
3. Ehsani N, Ghafar MA, Antosh DD et al (2012). Risk factors for mesh extrusion after prolapse surgery: a case-control study. Female Pelvic Medicine & Reconstructive Surgery (18) 6 357-61.
4. Costantini E, Zucchi A, Lazzeri M et al (2011). Managing mesh erosion after abdominal pelvic organ prolapse repair: Ten year's experience in a single center. Urol Int 86:419-423.
5. Akyol A, Akca A, Ulker V et al (2014). Additional surgical risk factors and patient characteristics for mesh erosion after abdominal sacrocolpopexy. Journal of Obstetrics & Gynaecology Research (40) 5 1368-74.
6. Crane AK, Geller EJ, Sullivan S et al (2014). Short-term mesh exposure after robotic sacrocolpopexy with and without concomitant hysterectomy. Southern Medical Journal 2014 Oct;107(10): 603-6.
7. Osmundsen BC, Clark A, Goldsmith C et al (2012). Mesh erosion in robotic sacrocolpopexy. Female Pelvic Med Reconstr Surg. 18: 86-8
8. Tan-Kim J, Menefee SA, Luber KM et al (2011). Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy. International Urogynecology Journal (22) 2 205-12.
9. Warner WB, Vora S, Hurtado EA, Welgoss JA, Horbach NS, von Pechmann WS (2012). Effect of operative technique on mesh exposure in laparoscopic sacrocolpopexy. Female Pelvic Med Reconstr Surg. 18 (2):113-7.
10. Nosti PA, Carter CM, Sokol AI et al (2016). Transvaginal Versus Transabdominal Placement of Synthetic Mesh at Time of Sacrocolpopexy. Female Pelvic Medicine and Reconstructive Surgery (22) 3 151-155.
11. SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), The safety of surgical meshes used in urogynecological surgery, 3 December 2015.
12. 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
13. 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

14. MHRA report. A summary of the evidence on the benefits and risks of vaginal mesh implants. Published on 28 October 2014. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf
15. Deffieux X, Letouzey V et al (2012). Prevention of complications related to the use of prosthetic meshes in prolapse surgery: guidelines for clinical practice. European Journal of Obstetrics & Gynecology and Reproductive Biology. 165:170-180.

Appendix A: Additional papers on sacrocolpopexy with hysterectomy 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
Bensinger G, Lind L, Lesser M, Guess M, Winkler HA. Abdominal sacral suspensions: analysis of complications using permanent mesh. *Am J Obstet Gynecol* 2005;193:2094-8.	Retrospective non-randomised comparative study n=121 Type of prolapse: Uterine/vault 86/35 Abdominal sacral suspensions (ASC)+SCH (n=37, ASC+TAH (n=49), ASC after prior hysterectomy (n=35) Mesh used: polypropylene mesh Follow-up: mean 12.5 months	All the erosions occurred in ASC+TAH group (8.2%, 95% CI (2.3%-19.6%, *P* = .0389). The intraoperative complication rate was 2.5% and included a cystotomy (n = 2) and a small bowel laceration (n = 1). Immediate postoperative complications included partial SBO/ Ileus (3.5%), febrile morbidity (9.6%), and autologous blood transfusions (1.7%). Long-term complications included persistent vaginal discharge (4.7%), vaginal bleeding (1.6%), dysparuenia (6.3%), and recurrent prolapse (2.5%). There were no significant differences in short- or long-term complications among the 3 groups (*P* > .05).	Vaginal and/or vault prolapse repair.
Braun H, Fernandez M, Delloro A, Gonzalez F, Cuevas R, Rojas I (2007). Prospective randomised study to compare colposacropexy and Mayo McCall technique in the correction of severe genital central prolapse. Int Urogynecol J;18:S1-S24.	Randomised controlled trial (conference abstract). n=47 (23 total abdominal hysterectomy + sacrocolpopexy versus 24 vaginal hysterectomy + anteroposterior colporrhaphy + Mayo McCall stitch) patients with uterine prolapse-POP Q grade III-IV Follow-up: mean 33 months	Sarcocolpopexy with mesh with concomitant hysterectomy is more effective for central prolapse than vaginal hysterectomy plus anteroposterior colporrhaphy and Mayo McCall technique but is associated with longer surgery and hospitalisation time and to a significant complication rate (13%-1 mesh erosion, 1 subaponeurotic hematoma, 1 incisional haematoma). In the comparator group, 2 prolapses relapsed-1 with vaginal vault prolapse 8 months after surgery and 1 with severe cystocele after 3 months that needed further surgery.	Included in systematic review in table 2.

Brizzolara S, Pillai-Allen A. Risk of mesh erosion with sacral colpopexy and concurrent hysterectomy. *Obstet Gynecol* 2003;102:306-10.	Case series n=124 Type of prolapse: uterine/vault 60/64 ASC- polypropylene mesh/ allograft 60 with CH and 64 with prior hystrectomy. Follow-up: median 35.5 months	Initial operative and hospital complications were rare in both groups and included a blood transfusion of 2 U, a ureteral transection, a wound infection, heart block, and an arrhythmia. Delayed graft complications included one mesh erosion in a patient with a prior hysterectomy that was managed by office resection (0.8%).	Uterine and/or vault prolapse repair Included in systematic review in table 2.
Costantini E, Mearini L, Bini V, Zucchi A, Mearini E, Porena M (2005). Uterus preservation in surgical correction of urogenital prolapse. Eur Urol;48(4):642-9.	Non-randomised comparative study (prospective) n=72 (36 sacrohysteropexy versus 39 sacropexy with concomitant hysterectomy) patients with uterine prolapse grade III-IV Mesh-non-absorbable synthetic mesh, Marlex Follow-up: mean 51 months (range 12-115 months)	Mean operating time, length of stay, intraoperative blood loss were significantly less after sacrohysteropexy ($p<0.001$). Success rates were similar in the 2 groups (100%). Recurrent low grade cystoceles developed in 1/38 in the hysterectomy +scaropexy group and in 5/34 in the sacrohysteropexy group (p=NS). Recurrent low grade rectocele developed in 6/38 and in 3/34 patients respectively (p=NS).no patient needed surgery for recurrent prolapse. Urodynamic results show that pressure/flow parameters improved significantly ($p<0.001$) in both groups. 91% (31/34) in hysteropexy group and 87% (33/38) in the hysterectomy plus sacropexy group were satisfied and would repeat surgery again.	Included in systematic review in table 2.

Culligan PJ, Murphy M, Blackwell L, Hammons G, Graham C, Heit MH (2002). Long-term success of abdominal sacral colpopexy using synthetic mesh. Am J Obstet Gynecol. 187(6):1473-80; discussion 1481-2.	Case series (retrospective analysis) Type of prolapse: uterine/vault n=245 patients who had abdominal sacral colpopexy. Concomitant procedures done. 11 had concomitant hysterectomy. Follow-up: 6 weeks to 4 years.	Of the 11 patients who had a hysterectomy at the time of colpopexy, 3 (27%) had erosion of the graft material, but of the 234 patients who did not have a concomitant hysterectomy, 2 (1.3%) mesh erosions occurred. The difference in mesh erosion rates between the 2 groups was significant (p<0.001).	Vaginal and /or vault prolapse repair. Outcomes not reported separately for concomitant hysterectomy.
Cundiff GW, Varner E et al (2008). Risk factors for mesh/suture erosion following sacral colpopexy. Am J Obstet Gynecol. 2008 Dec;199(6):688.	Case series n=322 ASC –synthetic mesh (Mersilene, polypropylene)	6% (20/322) had mesh/suture extrusions. Concurrent hysterectomy (OR 4.9) and smoking (OR 5.2) are modifiable risks for mesh/suture erosion.	Vaginal and /or vault prolapse repair. Similar studies included in table 2.
Ginath S, Garley AD et al (2013). Mesh erosion following abdominal sacral colpopexy in the absence and presence of the cervical stump. International Urogynecology Journal (24) 1 113-8.	Retrospective cohort study n=277 195 ASC+ concomitant SCH 82 ASC alone Follow-up: mean 7-8 months	At mean postoperative follow-up of 7-8 months, there was no difference between groups in terms of de novo urinary symptoms, recurrent vaginal-wall prolapse, or dyspareunia and Pelvic Organ Prolapse Quantification (POP-Q) point C examination. Sling erosion was observed in four (4.2 %) patients in group A versus none in group B. Apical mesh erosion was diagnosed in one patient in group A (0.5 %) and two (2.4 %) patients in group B. These differences were not statistically significant. Concomitant supracervical hysterectomy with ASCP was associated with a low incidence of mesh erosion and had the same intraoperative course and postoperative outcome as ASCP with previous hysterectomy.	Similar studies (larger and with longer follow-up) included in table 2.

Griffis K, Evers MD, Terry CL, Hale DS (2006). Mesh erosion and abdominal sacrocolpopexy: A comparison of prior, total, and supracervical hysterectomy. J Pelvic Med Surg; 12:25-30.	Retrospective non-randomised comparative study n=300 (196 prior hysterectomies versus 76 total hysterectomy plus abdominal sacrocolpopexy versus 28 supracervical hysterectomy plus abdominal sacrocolpopexy) patients with uterine prolapse. Type of mesh: Prolene-soft, Prolene, or Atrium Follow-up: mean 13.1 months (range 11.7-14.5 months.	Vaginal mesh erosions were observed in 25 abdominal sacrocolopoexy cases. 16 were in the prior hysterectomy group, 8 in the total hysterectomy group and 1 in the supracervical hysterectomy group. No association was seen between erosion rates and the type of mesh used or the presence of rectocele repair.	Included in systematic review in table 2.
Henriques A, Lourenco A, Afonso, M et al ( ). Ten tips & tricks to avoid mesh exposure in pelvic organ prolapse surgery. Female Pelvic Medicine and Reconstructive Surgery (1)) S12 March-April.	Authors present 10 Tips & Tricks, exemplified in small videos, to achieve a low rate of mesh exposures.	Mesh exposure after POP surgery can be maintained at very low levels if manufacturer recommendations are always followed and additional caution is taken during critical steps of the procedure	Review
Imparato E, Aspesi G, Rovetta E, Presti M. Surgical-Management and Prevention of Vaginal Vault Prolapse. Surg Gynecol Obstet 1992;175:233-7.	ASC (Mersilene, Teflon [polytetrafluoroethylene] and Gore-Tex used n=71	The incidence of mesh erosion was higher after concomitant hysterectomy+ ASC than ASC alone.	2 different techniques (vaginal suspension to sacrospinous ligaments, ASC) assessed. Uterine and/or vault prolapse repair.
Jeffery ST (2014). Surgical options for uterine prolapse: Something old and something new. Obstetrics and Gynaecology Forum (24) 4 7-13.	General review	A broad range of surgical options are now available for women presenting with uterine prolapse.	Review on a broad range of surgical options.

Khan A, Alperin M, Wu N, Clemens JQ (2013). Comparative outcomes of open versus laparoscopic sacrocolpopexy among Medicare beneficiaries. International Urogynecology Journal (24) 11 1883-91.	Retrospective cohort study (US national data) n=970 794 abdominal sacrocolpopexy (hysterectomy 190) 176 laparoscopic SC (hysterectomy 37) Follow-up: 1 year	Laparoscopic sacrocolpopexy was associated with a significantly increased rate of re-operation for anterior vaginal wall prolapse (3.4% vs 1.0%, p = 0.018). However, more medical (primarily cardiopulmonary) complications occurred post-operatively in the open group (31.5% vs 22.7%, p = 0.023). When sacrocolpopexy was performed with concomitant hysterectomy, mesh-related complications were significantly higher in the laparoscopic group (5.4% vs 0%, p = 0.026). All complications occurred in patients who had a total hysterectomy as opposed to a supracervical hysterectomy.	Larger and similar studies reported in table 2.

Maher C, Feiner, B, Baessler K and Schmid, C (2013). Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews Issue 4. Art. No.: CD004014.	Systematic review	Abdominal sacrocolpopexy is associated with a lower rate of recurrent vault prolapse and dyspareunia than the vaginal sacrospinous colpopexy. These benefits must be balanced against a longer operating time, longer time to return to activities of daily living and increased cost of the abdominal approach. The use of mesh or graft inlays at the time of anterior vaginal wall repair may reduce the risk of recurrent cystocele. Posterior vaginal wall repair may be better than transanal repair in the management of rectoceles in terms of recurrence of prolapse. The addition of a continence procedure to a prolapse repair operation may reduce the incidence of postoperative urinary incontinence but this benefit needs to be balanced against possible differences in costs and adverse effects. Increased risk of mesh exposure with concomitant hysterectomy (8-10%) compared to post hysterectomy (1-2%) procedures.	Different surgeries for management of pelvic organ prolapse.
Sarlos D Brandner S, Kots L et al (2008) Laparoscopic sacrocolpopexy for uterine and post-hysterectomy prolapse: anatomical results, quality of life and perioperative outcome- a prospective study with 101 cases. International Urogynecology Journal (19) 10 1415-22.	Prospective cohort study n=101 women with vaginal vault prolapse 55 laparoscopic sacrocolpoexy (LSC) + supracervical hysterectomy 46 had LSC for post hysterectomy prolapse 30 patients had concomitant urethral sling for incontinence. Follow-up: median 12 months	Subjective cure rate was 93%, objective cure rate was 98%.Obective recurrence at the anterior compartment was 6%. No apical recurrences or mesh erosion occurred. Overall quality of life and sexual health showed significant improvement with less than 1% de-novo dyspareunia.	Outcomes not reported separately for the 2 groups.

Stepanian AA, Miklos JR et al (2008). Risk of mesh extrusion and other mesh-related complications after laparoscopic sacral colpopexy with or without concurrent laparoscopic-assisted vaginal hysterectomy: experience of 402 patients. J Minim Invasive Gynecol. 2008 Mar-Apr;15(2):188-96.	Historical cohort study n=402 Type of prolapse: uterine/vault CH (n=130), prior hysterectomy (n=272). LSC with polypropylene mesh in conjunction with other laparoscopic and/or vaginal procedures. Median follow-up time of 12 months	Overall vaginal mesh erosion/extrusion rate was 1.2% (95% CI 0.5%-2.7%) with an associated mesh revision rate of 1.2% (95% CI 0.5%-2.7%). Patients with concurrent hysterectomy had an erosion/extrusion rate of 2.3% (3/130) as compared with 0.7% (2/272) in patients with a history of hysterectomy, p = .18. Cuff abscess occurred in 1 patient with concurrent hysterectomy, with an overall infection rate of 0.3% (95% CI 0.01%-1.2%). One more patient developed an inflammatory reaction to the mesh. Excision of exposed mesh was performed in all 5 patients with mesh extrusion.	Uterine/vault prolapse repair. Similar studies included in table 2.
Unger CA, Paraiso MF, Jelovsek JE et al (2014). Perioperative adverse events after minimally invasive abdominal sacrocolpopexy. American Journal of Obstetrics & Gynecology (211) 5 547.e1-8.	Retrospective cohort study 249 Robotic assisted laparoscopic sacrocolpopexy (RASC) versus 121 conventional laparoscopic sacrocolpopexy (LSC) n=406 Concomitant hysterectomy in 25% (104/406) Follow-up: median 195 days	The mesh erosion for all the women was 2.7% and was not statistically different between LSC and RASC (2.4% vs 3.3%, p=0.62) and for patients who underwent concomitant hysterectomy and those who did not (2.0% [95% CI 0.8-3.4] versus 3.0% [95%CI 1.2-5.2]; p=.65). The type of hysterectomy (SCH vs TH) was not associated with mesh erosion (data not shown).	Similar studies included in table 2.

Wu JM, Wells EC, Hundley AF, Connolly A, Williams KS, Visco AG (2006). Mesh erosion in abdominal sacral colpopexy with and without concomitant hysterectomy. Am J Obstet Gynecol; 194:1418-22.	Case series (retrospective) n=313 (101 abdominal hysterectomy and sacrocolpopexy; 212 had previous hysterectomies) patients with uterine prolapse Type of mesh: polyethylene tetraphalate, Mersiline; polypropylene; or Gore-Tex. Follow-up: mean 15 months	The overall rate of mesh erosion was 5.4%. In bivariate analysis, concomitant hysterectomy was not associated with erosion (6.9% versus 4.7% previous hysterectomy, p=0.42); however oestrogen therapy was an effect modifier. In women on oestrogen, hysterectomy (OR 4.9, CI 1.2-19.7) and anterior imbrication (OR 5.6, CI 1.1-28.6) were associated with mesh erosion. No risk factors were identified in women not on oestrogen.	Included in systematic review in table 2.

Appendix B: Related NICE guidance for sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse

Guidance	Recommendations

Interventional procedures	**Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG284 (2009).** 1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Future research should address short- and long-term efficacy, erosion rates and patient-reported quality-of-life outcome measures using validated scales. **Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG283 (2009).** It replaces the previous guidance on mesh sacrocolpopexy for vaginal vault prolapse (Interventional Procedures Guidance no. 215, March 2007). 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 IPG282 (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. **Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG281 (2009).** This guidance replaces the previous guidance on posterior infracoccygeal sacropexy for vaginal vault prolapse (Interventional Procedures Guidance no. 125, May 2005). 1.1 Current 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. 1.2 Clinicians 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. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for 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. **Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG280 (2009).** 1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for uterine prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake infracoccygeal sacropexy using mesh for uterine prolapse repair should take the following actions: • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for uterine prolapse repair, and may review the procedure

	on publication of further evidence on different types of mesh. Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes using validated scales. **Surgical repair of vaginal wall prolapse using mesh. NICE Interventional procedure guidance IPG267 (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. **Single-incision sub-urethral short tape insertion for stress urinary incontinence in women. NICE Interventional procedure guidance IPG262 (2008). Available from https://www.nice.org.uk/guidance/IPG262**

NICE guidelines	**Urinary incontinence in women (2013) NICE guideline CG171 (2013).** 1.10 Surgical approaches for SUI 1.10.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence. **[new 2013]** 1.10.2 If conservative management for SUI has failed, offer: • synthetic mid-urethral tape (see recommendations 1.10.3–8), **or** • open colposuspension (see also recommendation 1.10.9), **or** • autologous rectus fascial sling (see also recommendation 1.10.10). **[new 2013]** **Synthetic tapes** 1.10.3 When offering a synthetic mid-urethral tape procedure, surgeons should: • use procedures and devices for which there is current high quality evidence of efficacy and safety[10] • only use a device that they have been trained to use (see recommendations in section 1.11) • use a device manufactured from type 1 macroporous polypropylene tape • consider using a tape coloured for high visibility, for ease of insertion and revision. **[new 2013]** 1.10.4 If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. **[new 2013]** 1.10.5 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. **[new 2013]** 1.10.6 Use 'top-down' retropubic tape approach only as part of a clinical trial. **[new 2013]** 1.10.7 Refer to single-incision sub-urethral short tape insertion for stress urinary incontinence (NICE interventional procedure guidance 262) for guidance on single-incision procedures. **[new 2013]** 1.10.8 Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery. **[new 2013]** **Colposuspension** 1.10.9 Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women. Only an experienced laparoscopic surgeon working in an MDT with expertise in the assessment and treatment of UI should perform the procedure. **[2006]** **Biological slings** 1.10.10 Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI. **[2006]**

	Intramural bulking agents 1.10.11 Consider intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that: • repeat injections may be needed to achieve efficacy • efficacy diminishes with time • efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings. **[2006, amended 2013]** 1.10.12 Do not offer autologous fat and polytetrafluoroethylene used as intramural bulking agents for the treatment of stress UI. **[2006]** **Artificial urinary sphincter** 1.10.13 In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended. **[2006]** **Considerations following unsuccessful invasive SUI procedures or recurrence of symptoms** 1.10.14 Women whose primary surgical procedure for SUI has failed (including women whose symptoms have returned) should be: • referred to tertiary care for assessment (such as repeat urodynamic testing including additional tests such as imaging and urethral function studies) and discussion of treatment options by the MDT, **or** • offered advice as described in recommendation 1.6.9 if the woman does not want continued invasive SUI procedures. **[new 2013**

Appendix C: Literature search for acrocolpopexy with hysterectomy using mesh to repair uterine prolapse

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	07/06/2016	Issue 6 of 12, June 2016
HTA database (Cochrane)	07/06/2016	Issue 2 of 4, April 2016
Cochrane Central Register of Controlled Trials (Cochrane)	07/06/2016	Issue 5 of 12, May 2016
MEDLINE (Ovid)	07/06/2016	1946 to May Week 4 2016
MEDLINE In-Process (Ovid)	07/06/2016	June 06, 2016
EMBASE (Ovid)	07/06/2016	1974 to 2016 Week 23
PubMed	07/06/2016	n/a
BLIC (British Library)	07/06/2016	n/a

Trial sources searched on 02/06/2016

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

Websites searched on 02/06/2016

- 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 Gynecologic Surgical Procedures/

2 ((gynae* or gyne*) adj4 (surgery or surgical or repair*)).tw.

3 (sacrocolpopex* or sacral colpopex*).tw.

4 (sacrohysteropex* or sacral hysteropex*).tw.

5 (sacrocervicopex* or sacral cervicopex*).tw.

6 ((colpopex* or hysteropex* or cervicopex*) adj4 (sacro* or sacral* or sacrum*)).tw.

7 Suburethral Slings/

8 (sacropex* or intravaginal* sling*).tw.

9 (sacrospin* adj4 fixat*).tw.

10 ((uter* or womb* or apical or (pelvic adj2 organ*) or utero-vagin*) adj4 (resuspen* or suspen* or preserv* or lift* or support*)).tw.

11 or/1-10

12 Surgical Mesh/

13 (mesh* or material*).tw.

14 (biologic* adj4 (graft* or plast* or sling* or tape* or suspens* or gauze*)).tw.

15 *Polypropylenes/ or *Polyglactin 910/

16 ((Polypropylene* or Polyglactin* or Novasilk* or Restonelle* or prolene* or trelex* or avaulta* or pelvitex* or prolift* or polyform* or marlex* or gynemesh* or gore* or vicryl* or tutoplast* or faslata* or fortagen* or porcine dermis* or pelvicol* or pelvisoft* or upsylon* or Elevate PC or bovine pericardium) adj2 (mesh* or graft* or plast* or sling* or tape* or suspens* or gauze*)).tw.

17 or/12-16

18 Uterine Prolapse/

19 pelvic organ prolapse/

20 ((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.

21 POP.tw.

22 or/18-21

23 Hysterectomy, Vaginal/ or Hysterectomy/

24 hysterectom*.tw.

25 ((womb* or uter*) adj4 (excis* or remov*)).tw.

26 or/23-25

27 (artisyn or inte-pro or intepro or uplift or prolife or perigee or apogee or elevate or capio or avaulta or i-stitch or restorelle or uphold LITE).tw.

28 22 and 27

29 11 and 17 and 22 and 26

30 28 or 29

31 animals/ not humans/

32 30 not 31

33 limit 32 to ed=20070701-20160531