NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of mesh sacrocolpopexy for vaginal vault prolapse

Vaginal vault prolapse occurs when organs above or around the vagina slip down from their normal position. Sacrocolpopexy is an operation that aims to provide support for the pelvic organs in their natural position. This is achieved by attaching a piece of material (mesh), usually from the top and back of the vagina, to a ligament of the lower back bone.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making 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 overview was prepared in August 2006 and updated in January 2007.

Procedure name

- Mesh sacrocolpopexy
- Mesh colopopexy

Specialty societies

- British Association of Urological Surgeons
- British Society of Urogynaecology
- Royal College of Obstetricians and Gynaecologists

Description

Summary of the condition

Vaginal vault prolapse occurs when organs of the vagina descend from their normal position towards or through the vaginal introitus. This occurs by herniation through areas of weakness or breakage in the endopelvic fascia that covers the vagina and may be a consequence of pregnancy, childbirth, aging, pelvic surgery or menopause.

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

Symptoms vary according to the type and extent of the prolapse and include pelvic heaviness, a dragging sensation in the vagina, bulge, lump or protrusion coming down from the vagina, and backache. Symptoms of bladder, bowel or sexual dysfunction may also be present.

Current treatment and alternatives

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

More severe prolapse may require surgery. A number of surgical options are available for repairing vaginal vault prolaspe using vaginal, or abdominal (open or laparoscopic) approaches. Most of the described surgical alternatives to abdominal sacrocolpoexy are vaginal procedures. These include: simple closure of an enterocoele sac; fixation of the vault using the sacrospinous ligament or iliococcygeus muscle; suspension of the vault using the uterosacral ligaments or synthetic tapes as in the posterior infracoccygeal sacropexy or so-called ‘total vaginal mesh’ reconstruction; obliteration of the vagina by colpocleisis. .

Abdominal surgery can be performed through an open incision or with laparoscopy, requiring smaller incisions. A combination of some of these procedures may be also employed in the surgical correction of prolapse.

What the procedure involves

Surgery is performed under general anaesthesia. An incision, most usually a transverse suprapubic incision, is made in the anterior abdominal wall. Usually, but not necessarily, the peritoneum over the vaginal vault and sacral

promontory are opened, and a tunnel is created between the two. A graft or piece of mesh is then attached to the longitudinal ligament of the sacrum, most often at the level of the sacral promontory, although a lower point of attachment can also be made. The other end of the mesh is then sutured to the top of the vagina and for a variable distance down the posterior vaginal wall. The peritoneum over the mesh is usually then closed.

The same procedure can also be performed via a laparoscopic approach using several small abdominal incisions rather than a single large one.

Whether undertaken with an open or laparoscopic technique, the procedure is commonly combined with further supporting procedures, for example closure of the area between the rectum and vagina to prevent a hernia of the bowel developing (levatorplasty or culdoplasty); re-attachment of the paravaginal tissues to the pelvic sidewall (paravaginal repair); hysterectomy, colposuspension or suburethral sling insertion may also be performed to support the bladder neck, as urinary stress incontinence is a commonly associated with prolapse. .

A number of meshes or grafts have been used for this procedure, including synthetic meshes (polyproplyne), allografts (cadaveric fascia lata) and xenografts (porcine dermis or small intestinal mucosa).

Efficacy

According to the Specialist Advisors, important efficacy outcomes for this procedure include correction of symptoms, prolapse recurrence rate, improvement in quality of life and sexual function.

The evidence on this procedure is based on eight studies, including a systematic review (meta-analysis) of three randomised controlled trials (n=333). Out of the remaining five studies, two report specifically on laparoscopic sacrocolpopexy and two on the use of different types of mesh (biological or synthetic).

Objective and subjective success rates

In a randomised controlled trial comparing abdominal sacrocolpopexy (n=47) with vaginal sacrospinous colpopexy (n=48), both objective (based on anatomical findings) and subjective (presence of symptoms) success rates were similar between the two techniques at a median of two years. The objective success rate was 76% (35/46) in the abdominal-surgery group and 69% (29/42) in the vaginal-surgery group ($p = 0.46$); the subjective success rate was 93% (43/46) in the abdominal-surgery group and 91% (39/43) in the vaginal-surgery group ($p = 0.19$).

Higher success rates were reported in the case-series studies, with one study reporting a 98% (211/217) objective success rate at 3 years following abdominal sacrocolpopexy and another study reporting objective and subjective success rates of 96% (312/325) at 14.6 months following laparoscopic sacrocolpopexy.

Prolapse recurrence

In a systematic review, the rate of recurrent vault prolapse was lower in women treated with abdominal sacrocolopexy (2/46) than in those treated with vaginal sacrospinous colpopexy (8/43). Combining the data from two randomised controlled trials (meta analysis), 4% (3/84) of women in the abdominal-surgery group had recurrent prolapse compared with 15% (13/85) in the vaginal-surgery group (relative risk 0.23; 95% confidence intervals [CI] 0.07 to 0.77).

Patient-focused outcomes

Few studies reported on patient-focused outcomes. In a randomised controlled trial, abdominal sacrocolopexy (n=47) and vaginal sacrospinous colpopexy (n=48) led to similar significant reductions in scores obtained on disease-specific scales.

Type of material used

Two studies reported on efficacy outcomes using different types of mesh. In a randomised controlled trial comparing fascia and synthetic mesh, objective (anatomical) failures were reported in 32% (14/44) of women at 12 months in the fascia group compared with 9% (4/45) in the synthetic-mesh group ($p = 0.007$). In a second study comparing xenograft with synthetic mesh, after a follow-up of approximately 7 months, 29% (8/27) of women presented with stage II prolapse, compared with 24% (6/25) in the synthetic mesh group ($p = 0.4$).

The Specialist Advisors expressed few concerns about the efficacy of this procedure, but noted that there were still some uncertainties around the laparoscopic technique and the optimum material to be used as the reinforcing mesh.

Safety

The evidence on safety is based on nine studies.

Intraoperative complications following sacrocolpopexy included bladder perforation [1] [2] (2/103; 1/217) and rectal injury [2] (1/217).

Data from two case series reported postoperative complication rates of 15% (50/325) [3] and 23% (50/217) [2]. Complications included urinary retention (2/325), (20/217), urge incontinence (19/325), urinary tract infections (8/217), wound infections (7/217), haematomas (7/217), ileus (5/217), pelvic infection (1/217) and chronic pelvic pain (1/217).

De novo symptoms

De novo dyspareunia and stress urinary incontinence were measured in a number of studies but not always reported well. In a randomised controlled trial comparing abdominal sacrocolpopexy with vaginal sacrospinous colpopexy de novo dyspareunia and urinary incontinence was 11% (2/19) and

9% (2/22) in the abdominal group and 18% (3/17) and 33% (8/24) p=NR, p=0.09 respectively.

Erosion rates

Erosion rates varied among the studies. In one study the incidence of mesh erosion was 0.9% (3/325) [3] whereas in two other studies rates of 8% (7/91 and 9% (9/103) [4 1] were reported. In this later study the authors noted that women who had mesh inserted vaginally were more likely to develop erosion.

The Specialist Advisors listed potential adverse events as mesh erosion, mesh infection, bowel obstruction, bowel and bladder perforation, and bleeding.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to mesh sacrocolpopexy for pelvic organ prolapse Searches were conducted via the following databases, covering the period from their commencement to December 2006: 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.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. If these 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 if no clinical outcomes were reported, or if the paper was a review, editorial, or laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patients	Women with pelvic organ prolapse
Intervention/test	Mesh sacrocolpopexy (abdominal or laparoscopic)
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 overview

This overview is based on ten studies including one systematic review which reports on three randomised controlled trials comparing abdominal sacrocolpopexy with vaginal colpopexy. The remaining seven studies compromise two randomised controlled trials, one non-randomised controlled trial and four case series studies.

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.

Existing reviews on this procedure

Cochrane review

A Cochrane systematic review on the surgical management of pelvic organ prolapse in women has been published [5]. The review has been included in the main data extraction table (Table 2).

Related NICE guidance

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

Interventional procedures:

- Posterior infracoccygeal sacropexy for vaginal vault prolapse. *NICE interventional procedure guidance* no. 125 (2005), available from www.nice.org.uk/IPG125.

Technology appraisals

None relevant

Clinical guidelines

None relevant

Public health

None relevant

Table 2 Summary of key efficacy and safety findings on mesh sacrocolpopexy for pelvic organ prolapse

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
Maher (2004) [6] Systematic review/meta-analysis (Cochrane) 3 randomised controlled trials **Benson, 1996** **n = 101** Population: Women with uterine or vault prolapse Indications: Cervix to or beyond hymen, vaginal vault inversion >50% length and anterior wall to or beyond introitus Technique: • Sacrocolpopexy (abdominal group: mesh was not specified) • Vaginal group: bilateral sacrospinous colpopexy • Women also had paravaginal repair and procedures for SUI. Follow-up: 2.5 years **Lo, 1998** **n = 138** Population: Women with prolapse at least grade III (ICS classification) Indications: Women with urinary incontinence were excluded. Technique: 52 women had	**Outcomes measured** The authors noted that abdominal sacral colpopexy was better than vaginal colpopexy in terms of: ▪ a lower rate of recurrent vault prolapse (3/84 (4%) vs 13/85 (15%); RR 0.23; CI 0.07 to 0.77) based on two studies (Benson) ({Maher) ▪ the number of women whose symptoms failed to improve to stage 2 or better (3/52 (6%) vs 13/66 (20%); RR 0.29; CI 0.09 to 0.97) based on one study (Lo) ▪ less postoperative dyspareunia (7/45 (16%) vs 22/61 (36%); RR 0.39; CI 0.18 to 0.86) based on three studies (Benson) (Lo) (Maher) ▪ less postoperative SUI (14/74 (19%) vs 28/81 (35%), RR 0.55; CI 0.32 to 0.95) based on two studies (Benson) (Maher).. The authors noted that caution should be exercised when interpreting these results, given the different methodologies used in the included studies. ▪ The lower re-operation rate for prolapse after abdominal surgery did not reach statistical significance (6/84 (7%) vs 14/85 (16%); RR 1.46; CI 0.19 to 1.11) based on two studies (Benson) (Maher) In one trial, women treated abdominally took significantly longer to present with recurrent prolapse than those who underwent vaginal procedures. Patient satisfaction was similar between the groups (limited evidence).	**Complications** The authors noted that although data were available for bowel outcomes and adverse events, they were too few to provide sufficiently precise estimates to identify or rule out clinically important differences between the groups.	Although the study results were pooled, comparisons between the studies are difficult because different combinations of surgeries were used. [7]. A test of heterogeneity was performed (p=0.97). The authors noted that the finding of lesser frequency postoperative SUI following abdominal sacrocolpopexy should be viewed with some caution because different continence procedure were performed within the trials.

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
abdominal sacrocolpopexy with Mersiline mesh; 66 women had vaginal scarospinious colopexy. Other procedures included posterior repair and hysterectomy. Median follow-up: 2.1 years (range 1–5.2 years) **Maher, 2004** **n = 95** Population: Women with symptomatic posthysterectomy vaginal vault prolapse to introitus Indications: Women with previous sacrocolpopexy were excluded. Technique: • Abdominal group: sacral colopopexy with prolene mesh, paravagainal repair. • Vaginal group: right-sided sacrospinous colpopexy, enterocele and anterior and post repair. • Both groups had colposuspension for occult or potential SUI. Follow-up: 24 months Conflict of interest: Lead reviewer, Christopher Maher, is an author of one of the included trials.			

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
Maher (2004) [7] **Randomised controlled trial** Australia September 1997–December 2000 **n = 95** • 47 in the abdominal group (46 evaluable) • 48 in the vaginal group (43 evaluable) Population: • abdominal group – mean age 63.4 years (range 39–84 years) • vaginal group – mean age 62.9 years (range 35–88 years) There were no significant differences between the groups. Indications: Women with symptomatic posthysterectomy vaginal vault prolapse to introitus. Women with prior sacrocolpopexy were excluded. Technique: • Abdominal group: sacral colopopexy prolene mesh, paravagainal repair • Vaginal group: right-sided sacrospinous colpopexy, enterocele and anterior and post repair • Both groups had colposuspension for occult or potential SUI. **Mean follow-up: abdominal group, 24 months (range 6–60 months); vaginal group, 22 months (range 6–58 months)**	**Subjective success rate (not prolapse symptoms) (p = 0.19)** Abdominal group 93% (43/46) Vaginal group 91% (39/43) **Objective cure rate (site-specific stage II or greater) (p = 0.46)** Abdominal group 76% (35/46) Vaginal group 69%(29/42) **Satisfied with surgery (p = 0.78)** Abdominal group 85% (39/46) Vaginal group 81% (35/43) **Number of women sexually active** Abdominal group 45% (19/42) Vaginal group 46% (17/37) **De novo dyspareunia** Abdominal group 2/19 (11%) Vaginal group 3/17 (18%) **De novo SUI (p = 0.09)** Abdominal group 9% (2/22) Vaginal group 33% (8/24) **De novo overactive bladder (denominator not reported) p=0.44** Abdominal group 34% Vaginal group 22% **Postoperative anterior vaginal wall prolapse p=NR** Abdominal group 9% (4/46) Vaginal group 19% (8/43) **Postoperative vault prolapse p=NR** Abdominal group 4% (2/46) Vaginal group 9% (8/43)	**Complications** **Abdominal group** • 1 woman required blood transfusion. • 1 woman required cystotomy. • 1 woman had a wound infection. • 1 woman developed mesh infection, requiring removal. • 2 women developed incisional hernias. **Vaginal group** • 1 woman required blood transfusion. • 1 woman required cystotomy. • 1 woman developed a rectovaginal haematoma. • 1 woman had vaginal pain of undetermined origin (no further details given)	**This study was included in the above systematic review [6]** The randomisation list was computer generated. Six women did not complete the follow-up: 1 in the abdominal group and 5 in the vaginal group. The authors undertook an intent-to-treat analysis. Validated symptom and quality-of-life questionnaires were used. The authors noted that the differences in de novo SUIO rates between the groups may be explained by paravaginal repairs performed in 19/47 women in the abdominal group. The authors noted that a limitation of the study is the fact that 7% of the women did not complete meaningful follow-up and approximately 10% did not complete full review. Authors suggested that the results indicate that the abdominal approach may be preferable in women with predominately anterior and vault prolapse. **It should be noted that some of the percentages in the text of the published study do not correspond with the figures given. Also the reported**

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
Conflict of interest: supported by a scholarship from the Royal Australian and New Zealand College of Obstetrics and Gynaecology.	**Postoperative posterior wall prolapse p=NR** Abdominal group 33% (15/46) Vaginal group 19% (8/43) Constipation remained unchanged postoperatively in both the abdominal group and the vaginal group. **Obstructed defecation p=0.26** Abdominal group 4% (2/46) Vaginal group 12% (5/43) **Quality of life** The authors noted that in both groups there was a significant and similar reduction in scores on both the Short Urinary Distress Inventory and Short Incontinence Impact Questionnaire post procedurally and compared to baseline. There was a significant improvement compared with baseline in the physical role parameter of the SF-36 Health Survey in the abdominal-surgery group and in the physical function compared with baseline and bodily pain parameters in the vaginal-surgery group.		**denominator varies between the outcomes.**
Brubaker (2006) [9] Randomised controlled trial USA March 2002 – February 2005 322 women - 165 mesh sacrocolpopexy - 157 mesh sacrocolpopexy + Burch colpopsuspension Population: • Mesh group – mean age 60.3 years	Burch group n=157 / Mesh group n=165 Stress incontinence outcome (total) P<0.001: 35/147 (23.8%) / 67/152 (44.1%) - according to symptoms p<0.001: 29/153 (19.0%) / 60/15` (39.7%) - according to stress testing p=0.14: 7/148 (4.7%) / 14/162 (8.6%) - according to treatment p=0.05: 8/157 (5.1%) / 19/165 (11.5%) Other measures of stress incontinence bothersome stress: 9/147 (6.1%) / 37/151	**Complications (3 months)** Burch group n=157 / Mesh group n=165 All events P=0.79: 14.6% (23) / 14.5% (24) Urological and gynaecological events p=0.70: 3.2% (5) / 3.0% (5) Plausibily related events p=0.24: 4.5% (7) / 3.0% (5)	**Included following post consultation literature search.** The randomisation list was computer generated and groups were stratified according to surgeon and intention to perform paravaginal repair (done at the surgeon's discretion and disclosed before randomisation). The women, research staff, and telephone interviewers were unaware of the treatment assignments for a minimum of

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Study details	Key efficacy findings		Key safety findings	Comments
(range not stated) • Mesh+burch group – mean age 62.4 years (range not stated) There were no significant differences between the groups. Indications: Women planning mesh sacrocolopexy for stage II, III, IV prolapse were invited to participate if they did not have symptoms of stress incontinence. Technique: • mesh group: abdominal sacral colopopexy prolene mesh, • mesh + burch group abdominal sacral colopopexy prolene mesh plus colposuspension (suturing periuretheral vaginal tissue to the iliopectineal ligaments on each side to support the urethra). **Follow-up: 3 months** Conflict of interest: supported grants from the National Institute of Child Health and Human Development. Some of the researchers received research funding from pharmaceutical companies.	incontinence P<0.001 -MESA score for stress incontinence P<0.001 Urge outcome – total p=0.48 Urge incontinence p=018 Enuresis p=0.50 Frequency p=0.74 Urgency p=0.52 Nocturia p=0.53 Treatment for urge outcome p=0.27 Other measures of urge symptoms - urge symptoms, regardless of bother p=0.94 - urge incontinence, regardless of bother P=0.30 MESA score p=0.007	(24.5%) 13.3 50/153 (32.7%) 10/147 (6.8%) 0/153 (0%) 17/153 (11.1%) 9/153 (5.9%) 24/153 (15.7%) 2/153 (1.3%) 122/153 (79.9%) 26/153 (17.0%) 11.8	23.3 58/151 (38.4%) 18/151 (11.0%) 1/152 (0.7%) 16/152 (10.5%) 14/152 (9.2%) 21/152 (13.8%) 5/152 (3.3%) 123/152 (80.9%) 35/151 (23.2%) 16.8	three months and blinding was intended to be maintained for two years after surgery. The primary outcomes were stress incontinence and urge symptoms three months after surgery. Prolapse was staged using the POP-Q system. 163/165 mesh group completed 3 month visit 147/157 mesh + burch group completed 3 month visit.

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
Cosson (2000) [2] **Case series** France November 1986–November 1997 **n = 217** Population: Mean age 49.9 years (range 27–79 years). 81 women (37%) had history of surgery for vaginal prolapse or SUI. SUI was present in 59% (128) of women, anterior wall prolapse in 71% (155) , uterine prolapse in 63% (137) and posterior wall prolapse in 58% (126). Indications: Women previously treated with colposacropexy (sacrocolpopexy)for grade 2 or grade 3 prolapse. Technique: mesh was attached anteriorly and posteriorly in 182 women (84%). Mersilene mesh was used in 196 women (90%). Other procedures such as Burch and hysterectomy were also undertaken. **Mean follow-up: 5.5 years (range 1–136 months)** Conflict of interest: not reported	**Outcomes measured** **Anatomical and functional results** The authors noted a treatment success rate of 97.7%; this result was stable up to 3 years after the procedure. **Prolapse recurrence** Five women required further surgery for recurrent prolapse, with no further recurrence after the second operation. **SUI** • 58% of women were totally continent in the long term (no postoperative SUI). • 82% were classified as having been successfully treated (no postoperative SUI, or improved SUI). • 13 women (14.5% of those without SUI) developed de novo SUI following the procedure. • 8 women required surgery for recurrent SUI; 7 were successfully treated after a second operation. The authors noted that SUI was more likely to occur in women in whom anterior mesh was used alone; de novo SUI was more likely to occur in women who had not undergone a Burch procedure.	**Complications** **Intraoperative complications** ▪ 1 woman had a bladder injury. ▪ 1 woman had a rectal injury. ▪ 2 women had a haemorrhage (one left primitive iliac venous wound and one hemorrhagic dissection of the prevesical cavity). **Postoperative complications** Complications occurred in 50 women (23%): ▪ 20 women had urinary retention (range 3–8 days) ▪ 8 women had urinary infections ▪ 7 women had wound infections ▪ 7 women had haematomas (wound, prevescial cavity or perineum) ▪ 5 women had ileus ▪ 1 woman had a pelvic infection ▪ 1 woman had dyspareunia ▪ 1 woman had chronic pelvic pain. **Graft rejection** 5 grafts were rejected – 3/18 (17%) Gore-Tex mesh and 2/196 (1%) Mersilene mesh	Retrospective review of consecutive patients (n = 271). All women had immediate follow-up at 1 month; however, 217 had longer-term follow-up. It is this group that forms the basis of this study. The authors noted that there were no differences between the group with longer follow-up (217) and the group with only immediate follow-up (54). The Baden and Walker system was used for classification of prolapse and SUI. Failure was defined as recurrent prolapse requiring further surgery (grade 2 or grade 3). Treatment of women without SUI was considered a failure if there was de novo SUI. The authors commented that alternative mesh materials were tested for a short time but this was abandoned because of results obtained. Three surgeons performed 94.5% of the procedures, with 65.9% of these performed by one surgeon.
Rozet (2005) [3] **Case series**	**Outcomes measured** The authors noted that the cure rate at the last follow-up physical examination was 96% (312 of the women were anatomically were cured at 14.6 months) and	**Complications** Complications occurred in 50 women (15%) • 19 (6%) women had urge	**This study was included because it reported on the laparoscopic approach.**

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
France June 1996–March 2003 **n = 325** Population: Mean age 63 years (35–78 years); 117 women had associated SUI Indications: Women with a clinical diagnosis of symptomatic genitourinary prolapse, with or without SUI (grade II–IV) Technique: Laparoscopic approach. Silicone mesh was placed both anteriorly and posteriorly. Women with SUI (177)had a transvaginal procedure. **Mean follow-up: 14.6 months (range 6–60 months); 67% were followed up for 5 years.** Conflict of interest: not reported	there was a 96% a satisfaction rate. Only 13 women had persisting prolapse; 7 prolapses were considered as early failure because they occurred within 6 months of the surgery.	incontinence. • 8 (2%) women required conversion to open surgery. • 3 (0.9%) women had vaginal (prosthesis) erosion. • 2 (0.6%) women had mesh infection. • 2 (0.6%) women had urinary retention. • 1 (0.3%) woman had spondylitis. • 1 (0.3%) woman had port hernia. • 1 (0.3%) had intestinal obstruction. • 13 (4%) had prolapse relapse. De novo SUI occurred in 19 women for whom the procedure failed. These women underwent surgery early in the study, without an associated procedure for SUI. (Authors note that 13 have been successfully treated with reduction and 6 had a TVT) Persistent constipation during the first 6 months after surgery occurred in 6% of women but resolved within the follow-up period.	Retrospective analysis. Prolapse was defined according to the Baden and Walker grading system. A total of 363 women had the procedure but only 325 women had complete medical charts and completed the questionnaire. The authors have not performed an analysis to check whether there were any differences between the complete and incomplete responder groups (325 vs 38). The 8 women required conversion to an open procedure and were not included in the final analysis. Follow-up was performed by means of a postal questionnaire and physical examination at 6 months and then 1, 3 and 5 years. Satisfaction was measured by questionnaire. The authors noted that the questionnaire was non validated.
Higgs (2005) [1] **Case series** UK 1993–1999 **n = 140 (103 evaluable)**	**Outcomes measured** **Post-procedure prolapse grade (POP-Q findings) n = 66** POP-Q: n Stage 0: 28 (42%) Stage I: 13 (20%) Stage II: 21 (32%)	**Complications** **Intraoperative** • 2 women had a bladder perforation, 1 requiring a conversion to laparotomy. • 2 women had bowel perforations that occurred during colposuspension.	**This study was included because it reported on the laparoscopic approach.** Retrospective review of 140 consecutive cases. The authors noted that the surgical technique evolved

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<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Population: Mean age at the time of surgery 58 years (range not stated); 77 women had at least one previous procedure.

Indications: Women previously treated with colposacropexies.

Technique: Laparoscopic approach. Mesh was placed anteriorly and posteriorly; 20 women had mesh inserted vaginally; 83 had mesh inserted laparoscopically; 55/103 (55) women had other procedures performed at the same time (colposuspension and paravaginal repair)

Median follow-up: 66 months (range 3–124 months)

Conflict of interest: Not stated</td>
<td>
<table>
<tr><td>Stage III</td><td>4 (6%)</td></tr>
<tr><td>Stage IV</td><td>0 (0%)</td></tr>
</table>

Changes in symptoms following surgery n = 103
<table>
<tr><td>Symptom</td><td></td><td>n</td></tr>
<tr><td>Change in symptoms</td><td>Cured</td><td>39 (38%)</td></tr>
<tr><td></td><td>Improved</td><td>42 (41%)</td></tr>
<tr><td></td><td>No change</td><td>10 (10%)</td></tr>
<tr><td></td><td>Worse</td><td>11 (11%)</td></tr>
<tr><td></td><td>No response</td><td>1</td></tr>
<tr><td>Presence of a lump</td><td>Yes</td><td>39 (38%)</td></tr>
<tr><td></td><td>No</td><td>64 (62%)</td></tr>
<tr><td>Change in urinary symptoms n = 89</td><td>Improved</td><td>25 (28%)</td></tr>
<tr><td></td><td>No change</td><td>44 (49%)</td></tr>
<tr><td></td><td>Worse</td><td>12 (14%)</td></tr>
<tr><td></td><td>No response</td><td>8 (9%)</td></tr>
<tr><td>Change in bowel symptoms n = 63</td><td>Improved</td><td>11 (17%)</td></tr>
<tr><td></td><td>No change</td><td>30 (48%)</td></tr>
<tr><td></td><td>Worse</td><td>5 (8%)</td></tr>
<tr><td></td><td>No response</td><td>17 (27%)</td></tr>
</table>

11/103 (11%) had further prolapse surgery

5/103 (5%) were awaiting further prolapse surgery at the time of the study, giving an overall re-operation need rate of 16%

Non-vault recurrence rate of 35% (23/66)

Successful vault support was reported in 92% of women

Patient satisfaction (denominator unclear)
71 patients (71%) were very satisfied
14 patients (14%) outcomes was acceptable
16 patients (16%) not satisfied or very unsatisfied</td>
<td>Postoperative
• 5 women developed wound haematoma.
• 2 women required overnight intensive care (one for hypercarboxaemia; another for hyponatraemia).
• 2 women developed urinary tract infections.
• 3 women developed voiding dysfunction.
• 3 women developed sciatica.
• 9 women developed mesh erosion (all had polyproplene mesh and the complication occurred 6 months – 3 years after surgery).

Authors note that women who had mesh inserted vaginally were more likely to develop an erosion.

1 woman required complete excision of the mesh; 4 women had vaginal excisions of the mesh.</td>
<td>during the study period – primarily in relation to the insertion and attachment of the mesh.

Follow-up: women were contacted by telephone or letter and seen in a gynaecology clinic. Women who did not attend a clinic were sent a questionnaire.
• 66 women attended clinic and answered a questionnaire.
• 37 women answered a questionnaire.

Relatively low response rate.

30 women could not be contacted, 2 women had died and 5 women declined follow-up (no further details provided).

The authors have not done an analysis to check whether there were any differences between the groups (103 vs 37).

The authors noted that the questionnaire was not validated.

Prolapse staging was based on the POP-Q score.

The authors noted that preoperative data were missing for some outcomes (e.g. sexual function).</td>
</tr>
</table>

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
Begley (2005) [4] **Case series** USA November 1997–October 2003 **n = 91 (92 procedures)** Population: • Fascia group (n = 14) mean age 63 years (range 25–83 years) • Gore-Tex group (n = 33) mean age 66 years (range 37–84 years) • Silicone group (n = 21) mean age 66 years (range 40–85 years) • Polypropylene group (n = 24) mean age 68.5 years (range 49–86 years) (n = 24) Seven women had been previously treated with repeated prolapse procedures that had failed. Indications: Women previously treated with sacrocolpopexy (abdominal or laparoscopic) Technique: The abdominal approach was used in the majority of women; 8 women underwent laparoscopic sacrocolopexy. Twenty women also underwent concurrent hysterectomy.	**Outcomes measured** Durable support of the vaginal apex was achieved in 88 women, giving a 97% success rate.	**Complications** Erosion occurred in: • 0/14 (0%) women in the fascia group (1 with autologous graft and 13 with cadaveric fascia) • 3/33 (9%) women in the Gore-Tex group • 4/21 (19%) women in the silicone-coated mesh group • 0/24 (0%) in the polypropylene group Total: 7/91 (8%)	**This study was included because it reported on safety.** The primary aim of the study was to report on the incidence and management of mesh erosions. Retrospective review. All 7 patients with graft-erosion complications were managed surgically, with either transvaginal partial graft excision or laparotomy and graft removal. The authors noted that 20 women underwent concurrent hysterectomy, which may influence the rates of erosion.

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
Mean follow-up: **Fascia group, 18.6 months** **Gore-Tex group, 29.3 months** **Silicone group, 15.5 months** **Polypropylene group, 9.8 months** Conflict of interest: none reported			
Culligan (2005) **Randomised controlled trial** USA July 2001–June 2003 **n = 100 (89 followed up)** • **Fascia, n = 46** • **Polypropylene mesh n = 54** Population: • Fascia group, mean age 57.5 years (range not stated). Preoperative prolapse stage 2.4; 41% had prior continence or prolapse surgery • Mesh group, mean age 60.4 years (range not stated). Preoperative prolapse stage 2.5, 44% had prior continence or prolapse surgery The authors reported there were no significant differences between the groups. Indications: Women with posthysterectomy vaginal vault prolapse	**Outcomes measured** Objective anatomical failures (defined by Weber using the POP-Q system): • Fascia group: 14/44 (32%) • Mesh group: 4/45 (9%) (p = 0.007) The authors noted significant differences between the groups with respect to the 1-year postoperative comparisons of points Aa and C, and POP-Q stage, the mesh group having a lower POP-Q stage. There were no differences between the groups with respect to total vaginal length, genital hiatus, perineal body or points along the posterior vaginal wall.	**Complications** **Postoperative fever p=1.0** Fascia 2/46 patients Mesh 2/54 patients **Ileus p=0.5** Fascia 0/46 patients Mesh 2/54 patients **Wound breakdown p=0.8** Fascia 5/46 patients Mesh 8/54 patients **Graft erosion p=0.5** Fascia 0/46 patients Mesh 2/54 patients **Intraoperative bladder injury p=1.0** Fascia 0/46 patients Mesh 1/54 patient **Blood transfusion p=1.0** Fascia 0/46 patients Mesh 1/54 patients **Postoperative pulmonary embolism p=1.0**	**This study was included because it compared synthetic and biological meshes**. 201 women were eligible for the study but 101 declined enrolment. The authors noted that there were no differences between the women who declined inclusion into the study and those who took part. Randomisation was undertaken using a computer-generated block design. All preoperative and postoperative measures were obtained by a single-blinded examiner. A total of 89 women, 44 in the fascia group and 45 in the mesh group, were follow up at 1 year. Although data on secondary endpoints such as quality of life, urinary incontinence, pain and

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
scheduled for sacrocolpopexy Technique: 3–5 rows of sutures were used to fix a piece of graft material to the anterior vaginal wall. A separate piece of graft material was then attached to the posterior vaginal wall. Concomitant prolapse and/or continence procedures were performed if required. **Follow-up: 12 months** Conflict of interest: none stated		Fascia 0/46 patients Mesh 1/54 patients **Total number of patients with graft complications** Fascia 7/46 (15%) patients Mesh 14/54 (26%) patients • .	constipation were collected, these were not reported in the study. Non conventional reporting of p-values.
Altman (2006) [8] **Non-randomised controlled trial** Sweden 1998–2002 **n = 52** • **27 had porcine dermal collagen graft (xenograft)** • **25 had synthetic mesh** Population: • xenograft group – mean age at surgery, 68.6 years (range 55–84 years). Five had previously undergone vaginal hysterectomy, 19 abdominal hysterectomy, 7 combined anterior and posterior wall repair, 1 anterior wall repair, 2 posterior wall repair and 1 previous sacrocolpopexy. • mesh group – mean age at surgery, 65.9 years (range 54–83 years). Nine had previously undergone vaginal hysterectomy,	**Outcomes** **Post procedural prolapse grade (short-term follow-up)** Stage II prolapse was present in 8/27 (30%) of women in the xenograft group and 6/25 (24%) of women in the mesh group (p = 0.4) **Re-do procedures (long-term follow-up)** None of the women in either cohort had undergone a secondary sacrocolpopexy. **Survey of pelvic floor symptoms (long-term follow-up)** n = 45/52 (23/27 in xenograft group; 22/25 in mesh group) The authors noted that no significant differences between the groups were found in lower urinary tract symptoms, other than a significantly greater daytime micturition frequency (p < 0.05) and increased frequency of urge episodes (p < 0.05) in the mesh cohort compared with the xenograft group. No significant differences were found in anorectal symptoms or quality of life between the groups. Mild-to-moderate complaints were common in both	**Complications** **Fever > 3 days after surgery (p < 0.001**). Xenograft 8/27 patients Mesh 1/22 patients **Fever 4 days-1 week after surgery p =0.08** Xenograft 4/27 patients Mesh 0/22 patients **Cystitis p=0.2** Xenograft 5/27 patients Mesh 2/22 patients **Wound infection p=0.4** Xenograft 3/27 patients Mesh 1/22 patient **Vaginal vault haematoma (p = 0.8)** .Xenograft 1/27 patients Mesh 1/22 patient **Wound haematoma p=0.7** Xenograft 0/27 patients Mesh 1/22 patient	Retrospective review with consecutive patients. At follow-up, stage II or worse vaginal vault prolapse was considered unsuccessful. The authors did not use the POP-Q staging system. Long-term follow-up was performed by administering a self-reported pelvic floor questionnaire by mail and by chart review.

Abbreviations used: CI, confidence intervals; ICS, International Continence Society; POP-Q, pelvic organ prolapse quantification; RR, relative risk; SF-36, short-form; SUI, stress urinary incontinence; MESA – Medical, Epidemiological, and Social Aspects of Aging (MESA)

Study details	Key efficacy findings	Key safety findings	Comments
16 abdominal hysterectomy, 7 combined anterior and posterior wall repair, 4 anterior wall repair, 1 posterior wall repair and 1 previous sacrocolpopexy Indications: women with vaginal vault prolapse who underwent abdominal sacrocolpopexy. All women presented with stage II–III vaginal vault prolapse. Technique: All women underwent a standardised procedure regardless of mesh used. **Follow-up:** • **Xenograft group – mean short-term follow-up 7.1 months; mean long-term follow-up 2.5 years** • **Synthetic mesh group – mean short-term follow-up 7.4 months; mean long-term follow-up 4.3 years** Conflict of interest: study was financially supported by hospital-administered research funds	cohorts.	**Implant complication (p = 0.9).** Xenograft 0/27 patients Mesh 0/22 patients **Total number of patients with complications** Xenograft 22/27 patients Mesh 4/22 patients No further complications were reported during short- or long-term follow-up.	

Validity and generalisability of the studies

- The studies showed great variation in the way the procedure was performed: for example, the type of mesh used, whether mesh was attached anteriorly and/or posteriorly, and whether the procedure was performed open or laparoscopically.
- In most studies, a significant proportion of women underwent different concomitant operations for conditions such as stress urinary incontinence. It has been suggested that this may explain some of the differences in efficacy and safety outcomes between the studies. [6]
- Patient characteristics also varied between the studies, as did the definition of prolapse.
- In terms of efficacy outcomes, studies reported either anatomical outcomes using measures such as the Baden–Walker scale or the POP-Q system, or outcomes using a variety of symptom scales (often not unvalidated).
- Three studies were included that evaluated safety outcomes with the use of different mesh materials; however, it was difficult to draw conclusions about whether the use of a particular type of mesh had an influence on complication rates.
- Very few studies reported on good-quality patient outcomes.
- A now discontinued type of mesh (Gore-Tex) was used in several studies.
- Long-term follow up is important in order to determine the procedural erosion rate, as the available evidence indicates that most such events may occur after a considerable amount of time post-procedurally.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr Alfred Cutner, Mr Andrew Thorpe, Mr Vik Khullar, Mr Mark Slack, Dr David Richmond

- All the specialist advisors commented that this was established practice and no longer new.
- There is a high incidence of mesh infection requiring removal when used as support for posterior wall repair.
- Few published studies compare the various types of material used for this procedure.
- Approximately 10–12% of prolapse operations need to be redone.
- Long-term follow-up (more than 5 years) is needed to determine failure rates.
- The status of the procedure in terms of its use for recurrent vaginal vault prolapse is secure. Its role as a primary procedure has still to be established.

- Less evidence has been published on the laparoscopic approach than on open surgery.
- There is debate about the most appropriate route for mesh insertion when performed laparoscopically (retroperitoneal or transperitoneal).
- There is uncertainty in the short term about whether synthetic or biosynthetic materials are optimum for the reinforcing mesh; however, biological mesh materials are less effective than synthetic ones in the long term.
- There is some controversy as to whether routine continence procedures should be carried out at the same time.

Issues for consideration by IPAC

- There is a very large body of published evidence on this procedure. The main data extraction table presents only a selected group of studies.
- This procedure was originally notified as insertion of biological and synthetic mesh for pelvic organ prolapse. This question was then divided into three questions (mesh sacrocolpopexy, vaginal mesh repair and mesh repair with other procedures). This overview represents the first of the three questions.
- A number of randomised trials evaluating different meshes for the treatment of pelvic organ prolapse were presented at the 2005 International Continence Society meeting.

References

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2 Cosson M, Occelli B, Narducci F et al. (2000) Causes of failure of abdominal colposacropexy for the treatment of genital and vaginal vault prolapse. Journal of Gynecologic Surgery Vol. 16: 148.

3 Rozet F, Mandron E, Arroyo C et al. (2005) Laparoscopic sacral colpopexy approach for genito-urinary prolapse: experience with 363 cases. European Urology 47: 230-236.

4 Begley JS, Kupferman SP, Kuznetsov DD et al. (2005) Incidence and management of abdominal sacrocolpopexy mesh erosions. American Journal of Obstetrics & Gynecology 192: 1956-1962.

5 Stanosz S, Wilanowski K, Zebrowski W et al. (1995) [Certain biochemical markers in women with abnormal states of the reproductive system]. [Polish]. Ginekologia Polska 66: 518-522.

6 Maher C, Baessler K, Glazener CMA et al. (2004) Surgical management of pelvic organ prolapse in women. Maher.C, Baessler.K, Glazener.CMA., Adams.EJ, Hagen.S.Surgical management of pelvic organ prolapse in women.The Cochrane Database of Systematic Reviews: Reviews 2004 Issue 4 John Wiley & Sons, Ltd Chichester, UK DOI.: 10.1002/14651858.CD004014.pub2.

7 Maher CF et al. (2004) Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. American Journal of Obstetrics and Gynecology 190: 20-26.

8 Altman D, Anzen B, Brismar S et al. (2006) Long-term outcome of abdominal sacrocolpopexy using xenograft compared with synthetic mesh. Urology 67: 719-724.

9 Brubaker L, Cundiff GW, Fine P et al. (13-4-2006) Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence. New England Journal of Medicine 354: 1557-1566.

Appendix A: Additional papers on mesh sacrocolpopexy for pelvic organ prolapse not included in summary table 2

The following table outlines the studies that are considered potentially relevant to the 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
Altman D, Lopez A, Gustafsson C et al. (2005) Anatomical outcome and quality of life following posterior vaginal wall prolapse repair using collagen xenograft. *International Urogynecology Journal* 16: 303.	32 women Mean follow-up: 12 months	Posterior vaginal wall prolapse repair using a collagen xenograft was associated with an unsatisfying anatomical outcome at 1 year.	A similar study was included in the main data extraction table looking at different grafts types.
Antiphon P, Elard S, Benyoussef A et al. (2004) Laparoscopic promontory sacral colpopexy: is the posterior, recto-vaginal, mesh mandatory? *European Urology* 45: 655–661.	108 women Comparison between single anterior mesh and double anterior and posterior mesh	The posterior mesh appeared to increase the risk of postoperative complications and side effects.	Other studies that include laparoscopic procedures are included in the main data extraction table. The study also examined a separate question about placement of mesh, which is beyond the scope of the overview.
Baker KR, Beresford JM and Campbell C. (1990) Colposacropexy with Prolene mesh. *Surgery, Gynecology & Obstetrics* 171: 51–54.	59 women (51 evaluable) Mean follow-up: 6 months	No infections; no patient needed a repeat procedure.	Limited data reported on outcomes; short-term follow-up.
Baessler K and Schuessler B. (2001) Abdominal sacrocolpopexy and anatomy and function of the posterior compartment. *Obstetrics & Gynecology* 97: 678–684.	33 women Mean follow-up: 26 months	The procedure was effective for vaginal vault prolapse, enterocele and anterior rectal wall procidentia.	A similar study was included in the main data extraction table. Study also evaluated the obliteration of the pouch of Douglas.
Barranger E, Fritel X and Pigne A. (2003) Abdominal sacrohysteropexy in young women with uterovaginal prolapse: long-term follow-up. *American Journal of Obstetrics & Gynecology* 189: 1245–1250.	30 women Mean follow-up: 44.5 months	At last follow-up, two women had recurrent uterovaginal prolapse.	Long-term follow-up. Similar studies have been included in the main data extraction table.
Blanchard KA, Vanlangendonck R and Winters JC. (2006) Recurrent pelvic floor defects after abdominal sacral colpopexy. *Journal of Urology* 175: 1010–1013.	40 women Mean follow-up: 25.5 months	18 women had significant recurrent prolapse – surgery was considered a failure for 8.	A similar study was included in the main data extraction table.
Brieger GM, MacGibbon AL and Atkinson KH. (1995) Sacrospinous colpopexy. *Australian & New Zealand Journal of Obstetrics &*	104 women Mean follow-up:	The authors noted that this is a quick procedure, which avoids intra-abdominal	Limited information.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Gynaecology 35: 86–87.	5.9 months	trauma, has a high success rate and a low complication rate.	
Clavero PA, Guerrero JA, and Salamanca A. (1-5-2006) Gore-Tex mesh pelvic occlusion and secondary colpopexy: A new surgical technique for posthysterectomy vaginal vault prolapse. European Journal of Obstetrics, Gynecology, & Reproductive Biology 126: 113-115.	16 patients Mean follow-up 16-46 months	Gore-text mesh can treat prolapse	Other studies included in the main data extraction table.
Collopy BT and Barham KA. (2002) Abdominal colporectopexy with pelvic cul-de-sac closure.[see comment]. *Diseases of the Colon & Rectum* 45: 522–526.	89 women Mean follow-up: 5 years	The authors noted that this operation provided considerable relief of symptoms, with no evidence of recurrence.	Other studies included in the main data extraction table. The study focused on women with rectal prolapse.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Cosson M, Boukerrou M, Narducci F et al. (2003) Long-term results of the Burch procedure combined with abdominal sacrocolpopexy for treatment of vault prolapse. *International Urogynecology Journal* 14: 104–107.	82 women (all with SUI) Mean follow-up: 86 months	34% of women were dry and another 46% were improved compared with preoperative SUI status.	Primary aim was to evaluate SUI.
Cosson M, Rajabally R, Bogaert E et al. (2002) Laparoscopic sacrocolpopexy, hysterectomy, and Burch colposuspension: feasibility and short-term complications of 77 procedures. *Journal of the Society of Laparoendoscopic Surgeons* 6: 115–119.	77 women Mean follow-up: 343 days	8 women had complications – including one case of erosion 6 months after the operation; 3 women required re-operation.	Similar studies with larger patient numbers were included in the main data extraction table.
Costantini E, Lombi R, Micheli C et al. (1998) Colposacropexy with Gore-Tex mesh in marked vaginal and uterovaginal prolapse. *European Urology* 34: 111–117.	21 women Follow-up: 12– 68 months	19 women considered the operation to be successful and were satisfied.	Larger studies were included in the main data extraction table.
Elliott DS, Krambeck AE, and Chow GK. (2006) Long-term results of robotic assisted laparoscopic sacrocolpopexy for the treatment of high grade vaginal vault prolapse. Journal of Urology 176: 655-659.	30 patients Folllow-up: 1 year	Simailar results to open operation	Robot assisted Similar studies were included in the main data extraction table.
Elneil S, Cutner AS, Remy M et al. (2005) Abdominal sacrocolpopexy for vault prolapse without burial of mesh: a case series. *Journal of Obstetrics & Gynaecology* 112: 486–489.	128 women Median follow-up: 19 months	3 women had mesh erosion. 90% of women had good resolution of symptoms but 10% required further surgery.	Similar studies with longer follow-up were included in the main data extraction table.
Flynn MK, Webster GD and Amundsen CL. (2005) Abdominal sacral colpopexy with allograft fascia lata: one-year outcomes. *American Journal of Obstetrics & Gynecology* 192: 1496–1500.	24 women Mean follow-up: 3 months	No significant intraoperative or postoperative complications or graft erosions.	Similar studies with longer follow-up were included in the main data extraction table.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Fox SD and Stanton SL. (2000) Vault prolapse and rectocele: assessment of repair using sacrocolpopexy with mesh interposition. *British Journal of Obstetrics & Gynaecology* 107: 1371–1375.	29 women Mean follow-up: 14 months	All stage II and stage III prolapses were corrected. I postoperative mesh infection	Small study – larger studies were included in the main data extraction table.
Geomini PM, Brolmann HA, van Binsbergen NJ et al. (2001) Vaginal vault suspension by abdominal sacral colpopexy for prolapse: a follow up study of 40 women. *European Journal of Obstetrics, Gynecology, & Reproductive Biology* 94: 234–238.	45 women Median follow-up: 38 months	3 women had recurrent prolapse within the follow-up period. 2 women had infection of the mesh.	Similar studies were included in the main data extraction table.
Govier FE, Kobashi KC, Kozlowski PM et al. (2005) High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. *Urology* Vol. 65: 1103.	45 women Mean follow-up: 9.5 months	The authors noted that they have abandoned the use of silicone mesh because of the unacceptably high extrusion rate and now use polypropylene mesh.	Similar studies were included in the main data extraction table.
Gregory WT, Otto LN, Bergstrom JO et al. (2005) Surgical outcome of abdominal sacrocolpopexy with synthetic mesh versus abdominal sacrocolpopexy with cadaveric fascia lata. *International Urogynecology Journal* 16: 369–374.	18 women	Authors considered that cadaveric fascia lata may not be a good choice for the procedure.	Similar studies with longer follow-up were included in the main data extraction table.
Guner H, Noyan V, Tiras MB et al. (2001) Transvaginal sacrospinous colpopexy for marked uterovaginal and vault prolapse. *International Journal of Gynaecology & Obstetrics* 74: 165-170.	26 women Mean follow-up 2.6 years	3 women had recurrent prolapse of some vaginal compartments.	Similar studies were included in the main data extraction table.
Hewson AD. (1998) Transvaginal sacrospinous colpopexy for posthysterectomy vault prolapse. *Australian & New Zealand British Journal of Obstetrics & Gynaecology* 38: 318–324.	114 women Follow-up: 8 months to 5 years	The authors noted that subsequent prolapse is more likely to be in the anterior vaginal wall; the risk of this occurring is approximately 5%.	Similar studies with longer follow-up were included in the main data extraction table.
Higgs P, Goh J, Krause H et al. (2005) Abdominal sacral colpopexy: an independent prospective long-term follow-up study. *Australian & New Zealand British Journal of Obstetrics & Gynaecology* 45: 430–434.	93 women (64 had clinical follow-up) Mean follow-up: 45 months	Recurrent vault prolapse occurred in 3%; recurrent prolapse in other organs occurred in 40.6%.	Retrospective. A similar study was included in the main data extraction table.
Hilger WS, Poulson M and Norton PA. (2003) Long-term results of abdominal sacrocolpopexy. *American Journal of Obstetrics & Gynecology* 189: 1606–1610.	38 women Mean follow-up: 13.7 years	10 women reported failures.	Long-term results but small number of patients.
Hoffman MS, Harris MS and Bouis PJ. (1996) Sacrospinous colpopexy in the management of uterovaginal prolapse. *Journal of Reproductive Medicine* 41: 299–303.	45 women Mean follow-up: 29 months	The authors noted that the procedure is safe and effective for re-establishing support.	A similar study was included in the main data extraction table.
Iosif CS. (1993) Abdominal sacral	40 women	No intraoperative	A similar study was

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
colpopexy with use of synthetic mesh. *Acta Obstetricia et Gynecologica Scandinavica* 72: 214–217.	Follow-up: 1-10 years	complications. One woman developed a recurrent wall prolapse.	included in the main data extraction table.
Kammerer-Doak DN, Rogers RG and Bellar B. (2002) Vaginal erosion of cadaveric fascia lata following abdominal sacrocolpopexy and suburethral sling urethropexy. *International Urogynecology Journal* 13: 106–109.	32 women Mean follow-up: 13.1 months	Vaginal erosion was noted in 3 women. The authors noted that none of the women experienced recurrence of prolapse.	A similar study was included in the main data extraction table.
Kerkhof MH, Geomini PJAG and Brolmann HAM. (2005) Organic grafts in sacral colpopexy; are they introduced prematurely? Long term results for 29 women. *Gynecological Surgery* 2: 282.	29 women Mean follow-up: 32.2 months	Failure based on the anatomical result occurred in 11 women; 14 women considered the operation successful.	A similar study was included in the main data extraction table.
Kohli N, Walsh PM, Roat TW et al. (1998) Mesh erosion after abdominal sacrocolpopexy. *Obstetrics & Gynecology* 92: 999–1004.	57 women Mean follow-up: 19.9 months	7 women (12%) had erosions (2 suture, 5 mesh). Mean time to erosion was 14 months.	A similar study was included in the main data extraction table..
Leonardo C, Gentili G and Leonardo F. (2002) Abdominal sacral colpopexy with Mersilene mesh. *Urologia Internationalis* 68: 6–9.	25 women Mean follow-up: 4 years	No intraoperative or postoperative complications were encountered.	A similar study was included in the main data extraction table.
Leron E and Stanton SL. (2001) Sacrohysteropexy with synthetic mesh for the management of uterovaginal prolapse. *British Journal of Obstetrics & Gynaecology* 108: 629–633.	13 women Mean follow-up: 16 months	At follow-up only 1 woman had a first-degree uterine prolapse.	Limited information.
Limb J, Wood K, Weinberger M et al. (2005) Sacral colpopexy using mersilene mesh in the treatment of vaginal vault prolapse. *World Journal of Urology* 23: 55–60.	61 women (58 were evaluable) Median follow-up: 26 months	Total complication rate was 15%. Complete correction of vaginal prolapse was found in 91% of women.	Studies with more evaluable patients were included in the main data extraction table.
Mahendran D, Prashar S, Smith ARB et al. (1996) Laparosopic sacrocolpopexy in the management of vaginal vault prolapse. *Gynaecological Endoscopy* 5: 222.	29 women Mean follow-up: 6 months	3 women had intraoperative complications. 8 women had rectocoele at 6 months and 1 had recurrent vault prolapse.	Studies with more evaluable patients were included in the main data extraction table.
Mattox TF, Stanford EJ, and Varner E. (2004) Infected abdominal sacrocolpopexies: diagnosis and treatment. *International Urogynecology Journal* 15: 319–323.	20 women Mean follow-up: 8.8 months	All women had mesh infection (15 Gore-Tex, 5 polytetrapylene)	Study specifically reports on safety – similar studies have been included in the main data extraction table.
Rae D and Hawthorn R. (2002) Sacrocolpopexy for vaginal vault prolapse: A combined vaginal and laparoscopic approach. *Gynaecological Endoscopy* 11: 3.	22 women Mean follow-up: 12.5 months	Erosion of mesh occurred in 2 women. The vaginal vault remained well	A similar study was included in the main data extraction table.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
		supported in all 22 women.	
Roovers JP et al. (2005) A randomized comparison of post-operative pain, quality of life, and physical performance during the first 6 weeks after abdominal or vaginal surgical correction of descensus uteri. *Neurourology and Urodynamics* 24: 334-340.	82 women Mean follow-up: 6 weeks	The vaginal operation to correct a descensus uteri is associated with less pain, morbidity and greater quality of life.	This study was analysed separately in the Cochrane review as the vaginal group did not undergo a sacrospinous colpopexy and the abdominal group included uterine preservation.
Roovers JP, van der Vaart CH, van der Bom JG et al. (2004) A randomised controlled trial comparing abdominal and vaginal prolapse surgery: effects on urogenital function. *British Journal of Obstetrics & Gynaecology* 111: 50–56.	82 women Follow-up reported at 12 months	Vaginal hysterectomy is preferable to abdominal sacrocolopexy with preservation of the uterus.	This study was analysed separately in the Cochrane review as the vaginal group did not undergo a sacrospinous colpopexy and the abdominal group included uterine preservation.
Ross JW and Preston M. (2005) Laparoscopic sacrocolpopexy for severe vaginal vault prolapse: Five-year outcome. *Journal of Minimally Invasive Gynecology* 12: 226.	51 women Mean follow-up: 5 years	Of the 51 women, 43 women were seen at 5-year follow-up. 3 had recurrent vaginal prolapse (objective cure rate 93%); 4 women had mesh erosion at the vaginal apex.	A similar study was included in the main data extraction table.
Sze EH, Kohli N, Miklos JR et al. (1999) A retrospective comparison of abdominal sacrocolpopexy with Burch colposuspension versus sacrospinous fixation with transvaginal needle suspension for the management of vaginal vault prolapse and coexisting stress incontinence. *International Urogynecology Journal* 10: 390–393.	117 women 61 had sacrospinous fixation with transvaginal needle suspension. 56 women underwent colpopexy Mean follow-up: 23 months	The authors noted that the results seem to indicate that the combined abdominal approach has a lower incidence of recurrent prolapse and fewer urinary tract symptoms.	Historical study. Similar studies (Cochrane review) were included in the main data extraction table.
Thompson PK, Pugmire JE, and Sangi-Haghpeykar H. (2004) Abdominal sacrocolpopexy utilizing Gore-Tex in genital prolapse: Unresolved issues. *Journal of Pelvic Medicine & Surgery* 10: 317.	168 women Mean follow-up 43 months (for 80% of women)	The authors noted that the complication rate in this study (11%) was higher than that for other meshes. The erosion rate was 2.4%.	This study evaluated a now-discontinued Gore-Tex tape.
Virtanen H, Hirvonen T, Makinen J et al. (1994) Outcome of thirty women who underwent repair of posthysterectomy prolapse of the vaginal vault with abdominal sacral colpopexy. *Journal of*	30 women Mean follow-up: 3 years	Good vaginal support was observed in 85% of women.	A similar study was included in the main data extraction table.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
the American College of Surgeons 178: 283–287.			
Wille S, Braun M, Heidenreich A et al (2006) Sacral colpopexy with concurrent Burch colposuspension in patients with vaginal vault prolapse. *Urologia Internationalis* 76: 339-344..	47 patients Case series	Both procedures provide good satisfaction, durable pelvic support and restores vaginal function.	Larger studies were included in Table 2
Wu JM, Wells EC, Hundley AF et al. (2006) Mesh erosion in abdominal sacral colpopexy with and without concomitant hysterectomy. *American Journal of Obstetrics & Gynecology* 194: 1418-1422.	313 women	In women on oestrogen therapy, hysterectomy was associated with mesh erosion.	Contains information about mesh erosion however evaluating the role of hysterectomy.

Appendix B: Related published NICE guidance for mesh sacrocolpopexy for pelvic organ prolapse

Guidance programme	Recommendation
Interventional procedures	**Posterior infracoccygeal sacropexy for vaginal vault prolapse. *NICE interventional procedure guidance* no.125 (2005).** 1.1 Current evidence on the safety and efficacy of posterior infracoccygeal sacropexy for vaginal vault prolapse does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake posterior infracoccygeal sacropexy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and are fully informed of the alternative treatment options. Patients should be provided with clear written information and use of the Institute's *Information for the public* is recommended. • Audit and review clinical outcomes of all patients having posterior infracoccygeal sacropexy for vaginal vault prolapse. 1.3 Further research will be useful and clinicians are encouraged to collect long-term data on clinical and quality-of-life outcomes. The Institute may review the procedure upon publication of further evidence.
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for mesh sacrocolpopexy for pelvic organ prolapse

Databases	Version searched (if applicable)	Date searched
The Cochrane Library	2005 Issue 1	14.5.2006
CRD Databases	March 2005	14.5.2006
Embase	1980 to 2005 week 15	14.5.2006
Medline	1966 to March week 5 200	13.5.2006
Premedline	April 13, 2005	14.5.2006
CINAHL	1982 to April week 2 2005	14.5.2006
British Library Inside Conferences (limited to current year only)	2004–2005	14.5.2006
National Research Register	2005 Issue 1	14.5.2006
Controlled Trials Registry	N/A	14.5.2006

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

1 (pelvic adj3 prolapse).tw.
2 (uter$ adj3 prolapse).tw.
3 (urogenital adj3 prolapse).tw.
4 (urethra$ adj3 prolapse).tw.
5 urethrocele.tw.
6 (genital$ adj3 prolapse).tw.
7 (vagin$ adj3 prolapse).tw.
8 (bladder adj3 prolapse).tw.
9 cystocele.tw.
10 cystourethrocele.tw.
11 enterocele.tw.
12 rectocele.tw.
13 exp Uterine Prolapse/su [Surgery]
14 or/1-13
15 mesh.tw.
16 exp Surgical Mesh/
17 exp transplantation/
18 biologic$ graft$.tw.
19 donor graft$.tw.
20 sacrohysteropexy.tw.
21 sacral hysteropexy.tw.
22 sacrocolpopexy.tw.
23 sacral colpopexy.tw.
24 or/15-23
25 14 and 24
26 Animals/
27 Humans/
28 26 not (26 and 27)
29 25 not 28
30 limit 29 to english language
31 limit 30 to yr="1990 - 2005"