NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of surgical repair of vaginal wall prolapse using mesh

Vaginal wall prolapse occurs when the normal support structures for the pelvic organs are weakened, for example by previous pregnancy and childbirth or hysterectomy. As a result, one or more of the organs can drop down (prolapse) into the vagina. Surgical repair with mesh involves removing some of the stretched tissue, tightening the underlying tissue (colporrhaphy). The mesh aims to support the repair.

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 January 2017.

Procedure name

- Surgical repair of vaginal wall prolapse using mesh.

Specialist societies

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

Description

Indications and current treatment

Vaginal wall prolapse is a protrusion of one or more pelvic organs (such as the bladder or the rectum) through the vaginal fascia. The vaginal wall then moves from its normal position (prolapses), into or outside the vagina. Vaginal wall prolapse can affect a woman's quality of life because of its local physical effects (pressure, bulging, heaviness or discomfort). It can also affect urinary, bowel or sexual function. There are different types of vaginal wall prolapse depending on the organs and sites involved. These include anterior vaginal wall prolapse (including urethrocele and cystocele) and posterior vaginal wall prolapse (including rectocele and enterocele). A woman can present with prolapse of one or both of these sites.

Current treatment options for vaginal wall prolapse include pelvic floor muscle training, use of mechanical devices (ring or shelf pessaries) and surgery, including anterior or posterior colporrhaphy, and site-specific defect repair such as paravaginal repair.

The aims of using mesh in the repair of vaginal wall prolapse are to add additional support and to reduce the risk of recurrence, particularly for women with recurrent prolapse or with congenital connective tissue disorders (such as Ehlers–Danlos syndrome or Marfan’s syndrome).

What the procedure involves

Surgical repair with mesh involves removing some of the stretched tissue if needed, and tightening the underlying tissue (colporrhaphy). Mesh is then used to support the repair.

The procedure is usually done with the patient under general anaesthesia. Anterior colporrhaphy involves dissection of the vaginal mucosa through a midline incision in the anterior vaginal wall to expose the bladder and pubocervical fascia. The fascia is then plicated (folded), some excess tissue may be removed and the incision is closed. Posterior colporrhaphy involves a vaginal incision and plication of the levator ani. Other site-specific procedures, such as paravaginal repair, may also be done using methods similar to colporrhaphy.

The technique for inserting mesh varies. Mesh placement is usually done using an open technique, although trocar introducers can also be used without direct visualisation. The mesh may be positioned and sutured over the fascial defect as an 'inlay', or the whole vagina may be surrounded by mesh ('total mesh' technique). Mesh repair is theoretically suitable for any degree of symptomatic anterior or posterior vaginal wall prolapse.

A number of different synthetic and biological mesh materials are available, which vary in structure and in their physical properties such as absorbability. Newer lightweight meshes have been developed.

Outcome measures and disease classification

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

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

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

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

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to surgical repair of vaginal wall prolapse using mesh. The following databases were searched, covering the period from their start to 18 January 2017: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant

published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

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

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with vaginal wall prolapse.
Intervention/test	Surgical repair of vaginal wall prolapse 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 more than 90,000 patients from 2 randomised controlled trials (reported in a single publication), 4 systematic reviews, and 4 case series[1–9]. Although the duplicate reports have been removed from the total number of patients where possible, there is still some patient overlap between the 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.

Table 2 Summary of key efficacy and safety findings on surgical repair of vaginal wall prolapse using mesh

Study 1 Glazener C (2016)

Details

Study type	**2 RCTs (PROSPECT)**
Country	UK (35 centres)
Recruitment period	2010– 2013
Study population and number	**n=1348** **Mesh trial: n=865 (435 mesh augmentation, 430 standard repair alone)** **Graft trial: n=735 (368 graft augmentation, 367 standard repair alone)** Women with anterior or posterior vaginal wall prolapse.
Age	Mesh trial: mean 60 years (both groups) Graft trial: mean 59 years (graft augmentation); 60 years (standard repair)
Patient selection criteria	All women under the care of a collaborating surgeon were potentially eligible for inclusion if a decision had been made to have primary pelvic organ prolapse surgery for anterior or posterior vaginal wall prolapse. Women who were having a repeat repair (in the same compartment) were not included.
Technique	The participating surgeons used their usual techniques for transvaginal mesh, graft and standard repairs. All surgeons doing mesh surgery used non-absorbable type 1 monofilament macroporous polypropylene mesh for inlays (mesh weight ranged from 19 to 44 g/m^2). The biological graft materials were porcine acellular collagen matrix, porcine small intestinal submucosa, or bovine dermal grafts. The mesh or graft was inserted below the fascial layer if possible and secured with peripheral sutures. The planned surgery could include concomitant uterine, vault or continence surgery.
Follow-up	**2 years**
Conflict of interest/source of funding	The project was funded by the National Institute for Health Research Health Technology Assessment Programme.

Analysis

Follow-up issues: Primary outcome data at 1 year were available for 91% (784/865) of women in the mesh trial and 92% (679/735) of women in the graft trial. Data at 2 years were available for 80% (691/865) and 82% (599/735) of women respectively.

Study design issues: Randomisation was done by a remote web-based randomisation system. Patients, ward staff and outcome assessors were blinded to treatment allocation where possible. Some women who were assigned to standard repair were included in both trials. The study was adequately powered to detect a clinically meaningful difference in prolapse symptoms. The primary outcome was the woman's report of prolapse symptoms, measured using the Pelvic Organ Prolapse Symptom Score (POP-SS). This consists of 7 items related to frequency of prolapse symptoms in the previous 4 weeks (score ranges from 0 to 28, with lower scores indicating fewer symptoms). The minimally clinically important difference of the POP-SS is 2. Subjective failure was defined as POP-SS greater than 0 and any report of something coming down. A second primary outcome was condition-specific quality of life measured using a visual analogue scale. Objective measurement of prolapse stage was done using the Pelvic Organ Prolapse Quantification system (POP-Q). Objective failure was defined as the leading edge of the prolapse beyond the hymen (>0 cm). The proportion of women who had surgery and received their allocated treatment was 95% for the standard arms in both trials (mesh trial 403/425, graft trial 342/359) versus 80% for mesh (341/425) and 81% for graft (294/363). Data from all women who had surgery and provided outcome data were analysed by modified intention-to-treat, remaining in the group to which they were randomised.

Study population issues: Baseline demographic and clinical characteristics were similar between groups.

Other issues: Eligible surgeons had to be proficient in transvaginal anterior and posterior prolapse repair (subspecialist urogynaecologists and special interest general gynaecologists).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **mesh=865 (435 vs 430); graft=735 (368 vs 367)**

Mesh trial

Clinical symptoms and quality-of-life outcomes

Outcome	Synthetic mesh	Standard repair	Estimate of treatment effect size	p value
1-year follow-up (n=389 versus 395)				
POP-SS	5.5 (5.1); 389	5.4 (5.5); 395	0.00 (−0.70 to 0.71)	0.99
Prolapse-related QoL score	2.2 (2.7); 380	2.0 (2.7); 389	0.13 (−0.25 to 0.51)	0.50
Symptomatic prolapse	85% (329/389)	83% (328/395)	1.01 (0.95 to 1.08)	0.64
Women reporting SCD	35% (138/389)	36% (143/395)	0.98 (0.82 to 1.18)	0.85
Severe urinary incontinence	8% (29/354)	6% (21/361)	1.34 (0.79 to 2.26)	0.27
Faecal incontinence	25% (91/358)	28% (102/365)	0.92 (0.74 to 1.13)	0.41
ICI vaginal symptoms score	7.5 (8.1); 327	7.2 (7.2); 338	0.52 (−0.64 to 1.68)	0.38
Severe dyspareunia	5% (9/173)	4% (8/186)	1.73 (0.52 to 5.78)	0.37
EQ-5D-3L score	0.83 (0.22); 384	0.83 (0.25); 385	0.01 (−0.02 to 0.04)	0.65
2-year follow-up (n=343 versus 438)				
POP-SS	5.3 (5.1); 342	4.9 (5.1); 347	0.32 (−0.39 to 1.03)	0.37
Prolapse-related QoL score	2.2 (2.6); 329	1.9 (2.5); 335	0.15 (−0.23 to 0.54)	0.44
Symptomatic prolapse	85% (291/342)	82% (283/347)	1.04 (0.97 to 1.11)	0.30
Women reporting SCD	34% (116/342)	31% (106/347)	1.06 (0.85 to 1.32)	0.59
Severe urinary incontinence	6% (21/334)	6% (19/343)	1.01 (0.51 to 1.99)	0.97
Faecal incontinence	27% (92/338)	26% (89/343)	1.13 (0.92 to 1.41)	0.25
ICI vaginal symptoms score	7.3 (7.8); 311	7.0 (7.3); 313	−0.18 (−1.34 to 0.98)	0.76
Severe dyspareunia	3% (4/145)	5% (9/166)	0.49 (0.15 to 1.55)	0.22
EQ-5D-3L score	0.83 (0.22); 334	0.81 (0.28); 340	0.02 (−0.02 to 0.06)	0.26

Data are mean (standard deviation), n or % (n/N). Estimates of treatment effect size are mean difference (95% CI).

Safety

Mesh trial

Serious adverse effects related to prolapse surgery, readmissions and treatment

Outcome	Synthetic mesh	Standard repair	Estimate of treatment effect size	p value
6-month follow-up				
Readmissions*	3% (12/381)	3% (11/398)	1.15 (0.51 to 2.57)	0.74
1-year follow-up				
Readmissions* (6–12 months)	1% (5/389)	1% (4/395)	1.32 (0.36 to 4.81)	0.68
New prolapse operation	3% (12/389)	2% (6/395)	1.99 (0.76 to 5.24)	0.16
Same compartment	2% (8/389)	<1% (3/395)	2.55 (0.68 to 9.53)	0.16
Different compartment	1% (4/389)	<1% (3/395)	1.35 (0.31 to 5.96)	0.69
New continence operation	<1% (2/389)	1% (5/395)	0.40 (0.08 to 2.04)	0.27
Any serious adverse effects#	8% (34/435)	7% (31/430)	1.08 (0.68 to 1.72)	0.73
Mesh complications	7% (32/435)	<1% (2/430)	–	–
Surgical removals	5% (23/435)	<1% (2/430)	–	–
2-year follow-up				
Readmissions* (12–24 months)	0% (0/343)	<1% (3/348)	–	–
New prolapse operation	4% (15/343)	5% (16/348)	0.94 (0.47 to 1.88)	0.87
Same compartment	2% (7/343)	3% (9/348)	0.79 (0.30 to 2.11)	0.64
Different compartment	2% (8/343)	2% (7/348)	1.14 (0.42 to 3.10)	0.80
New continence operation	1% (5/343)	1% (4/348)	1.28 (0.35 to 4.73)	0.71
Any serious adverse effects#	<1% (4/435)	1% (6/430)	0.66 (0.19 to 2.30)	0.51
Mesh complications	6% (25/435)	<1% (1/430)	–	–
Surgical removals	4% (17/435)	0% (0/430)	–	–

Data are mean (standard deviation), n or % (n/N). Estimates of treatment effect size are risk ratio (95% CI).

* readmissions related to prolapse surgery

excluding mesh complications. Serious adverse effects included infection, urinary retention, dyspareunia and other pain.

Women in the standard repair group could have a mesh complication if the surgeon chose to use mesh for the repair or for a concomitant procedure.

One woman had total mesh removal within 2 weeks of surgery because of severe infection.

The cumulative number of women with a mesh complication over 2 years in women exposed to synthetic mesh was 12% (51/434), of whom 37 (9%) needed surgical removal.

Abbreviations used: CI, confidence interval; EQ-5D-3L, European Quality of Life-5 Dimensions 3-level; ICI, International Consultation on Incontinence; POP-SS, Pelvic Organ Prolapse Symptom Score; QoL, quality of life; SCD, something coming down.

Graft trial

Clinical symptoms and quality-of-life outcomes

Outcome	Biological graft	Standard repair	Estimate of treatment effect size	p value
1-year follow-up (n=337 versus 342)				
POP-SS	5.6 (5.6); 337	5.5 (5.6); 342	−0.15 (−0.93 to 0.63)	0.71
Prolapse-related QoL score	2.4 (2.9); 330	2.2 (2.8); 335	0.13 (−0.30 to 0.56)	0.54
Symptomatic prolapse	82% (276/337)	83% (283/342)	0.99 (0.93 to 1.06)	0.85
Women reporting SCD	42% (140/337)	34% (117/342)	1.18 (0.97 to 1.43)	0.10
Severe urinary incontinence	5% (17/313)	8% (26/315)	0.61 (0.33 to 1.12)	0.11
Faecal incontinence	25% (77/314)	27% (84/316)	0.92 (0.72 to 1.17)	0.50
ICI vaginal symptoms score	9.0 (9.1); 294	7.1 (6.9); 294	1.31 (0.04 to 2.59)	0.04
Severe dyspareunia	5% (8/165)	6% (9/149)	1.17 (0.43 to 3.23)	0.76
EQ-5D-3L score	0.82 (0.25); 333	0.81 (0.27); 335	0.02 (−0.01 to 0.06)	0.21
2-year follow-up (n=300 versus 299)				
POP-SS	5.5 (5.7); 299	4.9 (5.1); 298	0.32 (−0.48 to 1.12)	0.43
Prolapse-related QoL score	2.2 (2.8); 291	2.0 (2.5); 290	0.10 (−0.33 to 0.52)	0.66
Symptomatic prolapse	82% (245/299)	81% (242/298)	0.99 (0.92 to 1.07)	0.85
Women reporting SCD	40% (120/299)	31% (91/298)	1.26 (1.01 to 1.58)	0.04
Severe urinary incontinence	7% (20/297)	7% (21/294)	0.80 (0.44 to 1.46)	0.47
Faecal incontinence	26% (77/298)	27% (81/295)	0.95 (0.75 to 1.21)	0.69
ICI vaginal symptoms score	8.1 (8.8); 278	6.8 (6.8); 271	0.36 (−0.95 to 1.67)	0.59
Severe dyspareunia	4% (6/154)	4% (5/125)	0.93 (0.29 to 2.99)	0.90
EQ-5D-3L score	0.82 (0.27); 294	0.81 (0.28); 291	0.03 (−0.01 to 0.07)	0.17

Data are mean (standard deviation), n or % (n/N). Estimates of treatment effect size are mean difference (95% CI).

Graft trial

Serious adverse effects related to prolapse surgery, readmissions and treatment

Outcome	Biological graft	Standard repair	Estimate of treatment effect size	p value
6-month follow-up				
Readmissions*	4% (14/335)	3% (9/338)	1.54 (0.68 to 3.51)	0.30
1-year follow-up				
Readmissions* (6–12 months)	2% (6/337)	1% (4/342)	1.67 (0.48 to 5.79)	0.42
New prolapse operation	3% (10/337)	2% (7/342)	1.44 (0.56 to 3.73)	0.45
Same compartment	1% (5/337)	1% (5/342)	0.98 (0.29 to 3.34)	0.98
Different compartment	1% (5/337)	<1% (2/342)	2.50 (0.49 to 12.7)	0.27
New continence operation	2% (7/337)	<1% (2/342)	3.49 (0.73 to 16.7)	0.12
Any serious adverse effects#	10% (36/368)	6% (23/367)	1.57 (0.95 to 2.59)	0.08
Mesh complications	<1% (2/368)	<1% (2/367)	–	–
Surgical removals	<1% (1/368)	<1% (2/367)	–	–
2-year follow-up				
Readmissions* (12–24 months)	1% (4/300)	<1% (2/299)	1.95 (0.36 to 10.6)	0.44
New prolapse operation	5% (15/300)	5% (15/299)	0.99 (0.49 to 1.98)	0.98
Same compartment	3% (8/300)	2% (7/299)	1.13 (0.41 to 3.06)	0.82
Different compartment	2% (7/300)	3% (8/299)	0.86 (0.32 to 2.33)	0.76
New continence operation	1% (5/300)	2% (7/299)	0.56 (0.17 to 1.90)	0.35
Any serious adverse effects#	1% (5/368)	1% (4/367)	1.25 (0.34 to 4.60)	0.74
Mesh complications	<1% (1/368)	<1% (1/367)	–	–
Surgical removals	0% (0/368)	0% (0/367)	–	–

Data are mean (standard deviation), n or % (n/N). Estimates of treatment effect size are risk ratio (95% CI).

* readmissions related to prolapse surgery

excluding mesh complications. Serious adverse effects included infection, urinary retention, dyspareunia and other pain.

Women in the standard repair group could have a mesh complication if the surgeon chose to use mesh for the repair or for a concomitant procedure.

All 4 women with mesh complications in the first year had concomitant synthetic mesh.

Abbreviations used: CI, confidence interval; EQ-5D-3L, European Quality of Life-5 Dimensions 3-level; ICI, International Consultation on Incontinence; POP-SS, Pelvic Organ Prolapse Symptom Score; QoL, quality of life; SCD, something coming down.

Objective measures of prolapse at 1-year follow-up
Mesh trial

	Synthetic mesh n=374	Standard repair n=381	Estimate of treatment effect size	p value
POP-Q (cm from hymen)				
Ba (anterior edge)	-1.3 (1.6); 327	-1.3 (1.6); 323	0.06 (-0.17 to 0.29)	0.62
C (cervix/ vault)	-6.0 (2.3); 321	-6.0 (2.1); 318	-0.03 (-0.36 to 0.31)	0.88
Bp (posterior edge)	-2.1 (1.1); 326	-2.0 (1.2); 322	-0.03 (-0.21 to 0.15)	0.74
Total vaginal length	8.2 (1.3); 318	8.1 (1.2); 320	0.12 (-0.07 to 0.30)	0.21
Overall POP-Q stage				
0	14% (48/339)	16% (56/341)	1.11 (0.83 to 1.47)	0.49
1	33% (113/339)	32% (108/341)	-	-
2	47% (158/339)	45% (153/341)	-	-
3	6% (19/339)	6% (22/341)	-	-
4	<1% (1/339)	<1% (2/341)	-	-
2b, 3 or 4*	16% (54/336)	14% (47/338)	1.12 (0.79 to 1.60)	0.52

Graft trial

	Biological graft n=319	Standard repair n=319	Estimate of treatment effect size	p value
POP-Q (cm from hymen)				
Ba (anterior edge)	-1.2 (1.7); 293	-1.3 (1.7); 299	0.12 (-0.1 to 0.4)	0.34
C (cervix/ vault)	-5.7 (2.1); 292	-5.8 (1.9); 292	0.15 (-0.2 to 0.5)	0.37
Bp (posterior edge)	-2.0 (1.2); 290	-2.1 (1.2); 299	0.13 (-0.1 to 0.3)	0.20
Total vaginal length	7.8 (1.2); 286	7.8 (1.2); 291	0.07 (-0.1 to 0.3)	0.50
Overall POP-Q stage				
0	14% (42/299)	17% (51/305)	1.26 (0.93 to 1.71)	0.13
1	28% (85/299)	31% (96/305)	-	-
2	48% (144/299)	44% (135/305)	-	-
3	8% (25/299)	7% (21/305)	-	-
4	1% (3/299)	<1% (2/305)	-	-
2b, 3 or 4*	18% (54/298)	16% (47/303)	1.14 (0.80 to 1.62)	0.47

Data are mean (standard deviation); n or % (n/N). Estimates of treatment effect are mean difference (95% CI).
* defined as leading edge beyond the hymen (>0 cm) when POP-Q data available.

Abbreviations used: CI, confidence interval; POP-Q, Pelvic Organ Prolapse Quantification system.

Study 2 Maher C (2016)

Details

Study type	**Systematic review (Cochrane review)**
Country	Studies were conducted in Australia, Belgium, Canada, Chile, Czech Republic, Denmark, Finland, France, India, Italy, Sweden, the Netherlands, Turkey, UK, and US.
Recruitment period	Search date: July 2015
Study population and number	**n=4,023 (1,986 transvaginal graft repair versus 2,037 traditional native tissue repair [colporrhaphy]); 37 RCTs** Adult women seeking treatment for symptomatic pelvic organ prolapse (anterior vaginal wall prolapse, upper vaginal prolapse, or posterior vaginal wall prolapse)
Age	Not reported
Patient selection criteria	Study selection criteria: randomised controlled trials (RCTs) comparing different types of vaginal repair (mesh, biological graft, or native tissue). Studies had to include at least 20 participants in each arm.
Technique	Transvaginal graft repair for vaginal wall prolapse included the following procedures (as described in the review): self-styled armless soft polypropylene (Gynemesh) mesh without anterior colporrhaphy, anterior colporrhaphy with tension-free polypropylene (Gynemesh PS) overlay, fascial repair plus polyglactin mesh overlay, Gynecare transvaginal anterior mesh (Prolift), anterior and posterior repair with Gynemesh PS augmentation, polypropylene macroporous monofilament Prolift mesh, porcine dermal implant (Pelvicol, Bard Sweden) as inlay with no fascial plication, anterior polypropylene macroporous mesh (Ugtex, Sofradim, Covidien) 4-armed transobturator mesh, non-cross-linked xenograft porcine small intestine submucosa, “ultra-lateral” midline plication of anterior endopelvic connective tissue, plus additional cadaveric fascia lata patch (Tutoplast) anchored at the lateral limits of the colporrhaphy, anterior colporrhaphy with bovine pericardium collagen matrix graft reinforcement, self-styled 4-arms monofilament polypropylene mesh (Vypro mesh, J&J), polypropylene transobturator mesh (Perigee AMS), non-absorbable monofilament polypropylene (Parietene light, Sofradim, France), porcine small intestine submucosa graft inlay (Fortagen), small intestine mesh-augmented procedure, biosynthetic system monofilament polypropylene mesh with central portion coated in absorbable hydrophylic porcine collagen film (Bard Avaulta Plus anterior), Vicryl mesh, Nazca TC kit (Promedon, Córdoba, Argentina) monofilament macroporous 4 arms, trocar-guided transobturator synthetic mesh (Avaulta), anterior repair plus mesh: standard plication midline polyglactin (Vicryl) mesh overlay.
Follow-up	**3 months–3 years**
Conflict of interest/source of funding	6 of the included studies were judged to be at high risk of bias because of funding sources or conflicts of interest.

Analysis

Follow-up issues: Loss to follow-up varied, ranging from 0% to 53%. 22 RCTs were rated as being at low risk of attrition bias, 5 as at unclear risk, and 10 as at high risk of bias in this domain.

Study design issues: The primary outcomes were awareness of prolapse, repeat surgery, and recurrent prolapse on examination. The quality of the evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency, and imprecision.

Study population issues: All trials reported baseline descriptive characteristics, and there was no evidence of a difference between the groups, except in 3 trials. All trials reported preoperative prolapse status, but 2 trials did not specifically report equal distribution and severity of prolapse between groups. One trial included 7% of women with stage 1 anterior vaginal wall prolapse preoperatively (at time of inclusion), which would also have been classified as a postoperative success.

Other issues: The review notes that in 2011, many transvaginal permanent meshes were voluntarily withdrawn from the market, and the newer, lightweight transvaginal permanent meshes still available have not been evaluated within a RCT. 11 of the included studies were also included in Jia X et al., 2008 (n=1,410) and 10 studies were also included in Barski et al, 2013 (n=1,490).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **4,023 (1,986 versus 2,037)**

Any transvaginal permanent mesh versus native tissue repair for vaginal prolapse

	Illustrative comparative risks* (95% CI)				
	Assumed risk	**corresponding risk**			
Outcomes (review 1–3 years)	**Native tissue repair**	**Any transvaginal permanent mesh**	**Relative risk (CI)**	**n**	**Quality of evidence (GRADE)**
Awareness of prolapse	188 per 1,000	124 per 1,000 (101 to 152)	0.66 (0.54 to 0.81)	1,614 (12 RCTs)	moderate
Repeat surgery - prolapse	32 per 1,000	17 per 1,000 (10 to 28)	0.53 (0.31 to 0.88)	1675 (12 RCTs)	moderate
Repeat surgery - continence surgery	26 per 1,000	28 per 1,000 (16 to 48)	1.07 (0.62 to 1.83)	1284 (9 RCTs)	low
Repeat surgery - surgery for prolapse, SUI, or mesh exposure	48 per 1,000	114 per 1,000 (72 to 181)	2.40 (1.51 to 3.81)	867 (7 studies)	moderate
Recurrent prolapse**	381 per 1,000	152 per 1,000 (114 to 202)	0.40 (0.30 to 0.53)	2,494 (21 studies)	low

* The basis for the assumed risk is the median control group risk across studies. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
**I^2=73%

Objective failure (1–3 year review)
Anterior compartment
Women who had a transvaginal mesh repair were less likely to have a stage 2 or greater anterior compartment prolapse on examination than those undergoing a native tissue repair (RR 0.45, 95% CI 0.36 to 0.55, 13 RCTs, n=1,406, I^2=35%).

When the analysis was limited to studies of anterior compartment repair, the benefit in the mesh group was more pronounced (RR 0.36, 95% CI 0.28 to 0.47, 9 RCTs, n=1004, I^2=0%). When the analysis was limited to studies of multi-compartment repair, there was no conclusive evidence of a difference between the groups (RR 0.73, 95% CI 0.51 to 1.06, 4 RCTs, n=402, I^2=0%).

Posterior vaginal compartment
There was no evidence of a difference between the groups in rates of grade 2 or greater posterior compartment prolapse (RR 0.64, 95% CI 0.29 to 1.42, 3 RCTs, n=226, I^2=0%).

Safety

Adverse events – any transvaginal permanent mesh

Mesh exposure=12% (134/2,097) (transvaginal permanent mesh groups in 19 RCTs, 1–3 year review)

Anterior repair only: mesh exposure=10% (76/753)
Multi-compartment repair: mesh exposure=17% (58/344)
Surgery for mesh exposure=8% (100/1,227)

Injuries to the bladder or bowel
Women undergoing a transvaginal permanent mesh repair were more likely to have a bladder injury than those undergoing a native tissue repair (RR 3.92, 95% CI 1.62 to 9.50, 11 RCTs, n=1,514, I^2=0%, moderate-quality evidence).

Only 1 trial reported bowel injury as an outcome; there was no evidence of a difference between the 2 groups (RR 3.26, 95% CI 0.13 to 78.81, 1 RCT, n=169).

De novo stress urinary incontinence (SUI)
Women undergoing a transvaginal permanent mesh repair were more likely to develop de novo SUI than those undergoing native tissue repair (RR 1.39, 95% CI 1.06 to 1.82, 12 RCTs, n=1512, I^2=0%, low-quality evidence).

De novo bladder voiding difficulties or urgency
There was no evidence of a difference between the groups in the rate of de novo voiding disorder, urgency, detrusor overactivity, or overactive bladder (RR 0.75, 95% CI 0.35 to 1.63, 3 RCTs, n=236, I^2=0%)

De novo dyspareunia
There was no evidence of a difference between the groups in the rate of de novo dyspareunia (RR 0.92, 95% CI 0.58 to 1.47, 11 RCTs, n=764; I^2=21%)

Pelvic Organ Prolapse Quantification (POP-Q) scores

Point Ba (mid-anterior vaginal wall)

Evidence suggested that Point Ba on the mid-anterior vaginal wall had better support after transvaginal permanent mesh repair than after native tissue repair (random-effects model; MD −0.93, 95% CI −1.27 to −0.59, 10 RCTs, n=1,125, I^2=86%).

Point Bp (mid-posterior vaginal wall)

There was no evidence of a difference between the groups at Point Bp (random-effects model; MD 0.05, 95% CI −0.34 to 0.44, 7 RCTs, n=832, I^2=86%).

Total vaginal length (cm)

There was no evidence of a difference between the groups in total vaginal length (random-effects model; MD 0.07, 95% CI -0.25 to 0.40; 5 RCTs, n=611; I^2=43%, directions of effect were not consistent).

Absorbable mesh versus native tissue repair for vaginal prolapse

	Illustrative comparative risks* (95% CI)				
	Assumed risk	**corresponding risk**			
Outcomes	**Native tissue repair**	**Absorbable mesh**	**Relative risk (CI)**	**n**	**Quality of evidence (GRADE)**
Awareness of prolapse at 2 years	724 per 1,000	760 per 1,000 (558 to 1,000)	1.05 (0.77 to 1.44)	54 (1 study)	very low
Repeat surgery – prolapse stage 2 or more at 2 years	125 per 1,000	59 per 1,000 (11 to 300)	0.47 (0.09 to 2.40)	66 (1 study)	very low
Recurrent prolapse at 3 months to 2 years	429 per 1,000	304 per 1,000 (223 to 411)	0.71 (0.52 to 0.96)	292 (3 studies)	low
Stress urinary incontinence at 2 years	593 per 1,000	818 per 1,000 (563 to 1,000)	1.38 (0.95 to 2)	49 (1 study)	very low

Biological graft versus native tissue repair for vaginal prolapse

	Illustrative comparative risks* (95% CI)				
	Assumed risk	**corresponding risk**			
Outcomes	**Native tissue repair**	**Biological graft**	**Relative risk (CI)**	**n**	**Quality of evidence (GRADE)**
Awareness of prolapse at 1 to 3 years	105 per 1,000	102 per 1000 (68 to 151)	0.97 (0.65 to 1.43)	777 (7 studies)	low
Repeat prolapse surgery 1 to 2 years	43 per 1,000	52 per 1000 (26 to 105)	1.22 (0.61 to 2.44)	306 (5 studies)	low
Recurrent prolapse at 1 year	295 per 1,000	277 per 1000 (177 to 434)	0.94 (0.60 to 1.47)	587 (7 studies)	very low

Abbreviations used: CI, confidence interval; RR, relative risk; SUI, stress urinary incontinence

Adverse events – biological graft

Injury to the bladder or bowel

There was no evidence of a difference between the groups for this outcome, and only one event occurred in each comparison (bladder injury: RR 0.35, 95% CI 0.01 to 8.40, 1 RCT, n = 137; bowel injury: RR 3.13, 95% CI 0.13 to 75.57, 1 RCT, n = 137, very low-quality evidence).

Blood transfusion

Only 1 study reported this outcome in a format suitable for analysis. There was no evidence of a difference between the groups (RR 2.13, 95% CI 0.14 to 32.90, 1 RCT, n=100).

De novo stress urinary incontinence

1 study (n=93) reported de novo stress urinary incontinence,but there were no events.

De novo urinary dysfunction (bladder overactivity and voiding dysfunction)

There was no evidence of a difference between the groups (RR 0.81, 95% CI 0.29 to 2.26, 2 RCTs, n=93, I^2=0%).

De novo faecal incontinence or obstructed defecation

None of the included studies reported this outcome in a form suitable for analysis.

De novo dyspareunia (one-year review)

There was no evidence of a difference between the groups, but only 6 events were reported (RR 0.85, 95% CI 0.20 to 3.67, 1 RCT, n=37, very low-quality evidence).

Study 3 Barski D (2013)

Details

Study type	**Systematic review**
Country	Not reported
Recruitment period	Search date: January 2008–July 2013
Study population and number	**n=2,289** (20 articles; 11 RCTs, 9 prospective studies) Women treated by anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair.
Age	Not reported
Patient selection criteria	The search was restricted to RCTs and prospective studies with 100 or more patients and at least 6 months follow-up. Case reports and retrospective studies were excluded.
Technique	The vaginal mesh kits included Apogee and Perigee (American Medical Systems Inc., US), Gynecare Prolift System and Total Gynecare Prolift System (Ethicon Women's Health and Urology, US), Nazca TC (Promedon, Argentina) and other miscellaneous transvaginal approaches.
Follow-up	**Median 12 months (range 7–60)**
Conflict of interest/source of funding	None for the authors of the systematic review. No details were reported for the individual studies.

Analysis

Follow-up issues: The review does not report the losses to follow-up in the individual studies.

Study design issues: The review focuses on complications associated with the procedure. It states that 5 quality multicentre RCTs were included in the analysis. The authors note that the recommendations derived from the review were limited by heterogenous patient populations, outcome measures, and various surgical procedures (with or without concomitant procedures) and materials, making it difficult to extract and compare the complications associated with mesh implantation.

Study population issues: Some studies only included women having a primary procedure for pelvic organ prolapse and others also included secondary treatment after relapse. Prolapse of different compartments and of varying severity were included.

Other issues: The review includes 1 study on apical mesh implantation with 118 women treated by posterior intravaginal slingplasty, which would be covered by a separate piece of interventional procedure guidance. The results for this study have not been presented in the table below. There is some patient overlap with the systematic review by Maher et al., 2016 (n=1,490).

Key efficacy and safety findings

Safety

Number of patients analysed: **2171 (excluding the study of 118 women treated by posterior intravaginal slingplasty)**

Complications after transvaginal implantation of alloplastic materials for vaginal wall prolapse repair (mean and range or median and range), classified according to the Clavien-Dindo grading system

Approach	anterior	posterior	combined	p value
Number of trials	14	4	8	
Number of patients	1395	228	548	
Median follow-up (range), months	12 (7–38)	12 (6–24)	12 (7–60)	
Mean complication rate (range), %	27 (3.4–50)	20.3 (0–50)	40 (16.6–93)	Not significant
Grade 1	13.4 (1.8–48)	13.2 (0–35.5)	23.3 (1.4–77.3)	Not significant
Prolonged pain/neurological	7.3 (0.6–28)	2.7 (0–7.1)	5.5 (1.6–10.4)	Not significant
Haematoma	1.4 (0–4.4)	4.5 (0–14.3)	4.6 (1.2–14)	Not significant
Urge *de novo*	1.7 (0–3.5)	3.9 (0.7–7.1)	7.8 (4.9–10.8)	Not significant
SUI *de novo*	7.8 (0–19)	0.3 (0–0.7)	16 (5.5–35)	Not significant
Bladder emptying difficulty	7 (0–13.3)	1.5 (0–4.4)	3.5 (0–7.9)	Not significant
Mesh erosion	3.9 (0–8.3)	2.9 (0–7.1)	5.5 (1.4–10)	Not significant
Grade II	9.1 (0–26.3)	3.6 (0–7.1)	6.5 (0–22.3)	Not significant
Transfusion (median, range)	0.5 (0–5)	0	0.7 (0–1.8)	Not significant
Urinary tract infection	13 (3.3–2.1)	1.4 (0–2.9)	6 (4.8–8.6)	Not significant
Fever of unclear origin	3.5 (0.5–5.3)	1.8 (0–7.1)	7.1 (3.1–11)	Not significant
Cardiac complication	1.1 (0–5)	1 (0–2.9)	2.8 (2.5–3.2)	Not significant
Grade IIIA	2 (0–6.3)	0.3 (0–1.4)	5.7 (4.9–6.2)	<0.05
Mesh erosion	2.9 (0–6.3)	0	3.9 (3.1–4.7)	Not significant
Infection/abscess	0.6 (0–3.1)	0.3 (0–1.4)	3.1 (1.3–4.9)	Not significant
Grade IIIB	7.1 (0–15.7)	3.2 (0–7.1)	10.5 (4.7–16)	0.05
Mesh erosion	5 (0–13.2)	3 (0–7.1)	7.4 (1.9–16)	Not significant
Bleeding	0.2 (0–1)	0	0	Not significant
Visceral injury	2.7 (0–6.3)	0.2 (0–0.7)	2.5 (0–4.8)	Not significant
Fistula	0	0	0	Not significant
Grade IVA,B	0.04 (0–0.5)	0	0	Not significant
Cardiac complication	0.04 (0–0.5)	0	0	Not significant
Pulmonary complication	0	0	0	Not significant
Grade V (death) median, range	0.04 (0–0.5)	0	0	Not significant
Dyspareunia *de novo*	11.3 (2.5–26)	16.7 (12–21.4)	16.4 (9.1–28)	Not significant
Re-operation rate for prolapse	3.1 (0–11)	2.4 (0–7.1)	2.9 (0–5.5)	Not significant
Re-operation rate for SUI	1.3 (0–2.5)		6.3 (5–7.7)	<0.05

The outcomes of de novo incontinence and dyspareunia only include women who were free of these symptoms at baseline.

Mesh erosion was defined as exposed or extruded mesh material in the vagina or surrounding pelvic organs. If treatment was not specified, it was assumed that 50% of patients were treated medically (Dindo II) and the other 50% by operative revision (Dindo III).

Dyspareunia was reported by a small number of trials with different definition criteria and was therefore analysed separately from other complications.

Grade I and II complications occurred early after the procedure (within the first 3 months) and were transient. The majority of complications that were graded III or higher needed surgical intervention under general anaesthesia.

Most mesh erosions were reported in the first 2 years after the procedure.

Abbreviations used: SUI, stress urinary incontinence

Study 4 Abed H (2011)

Details

Study type	**Systematic review**
Country	Countries of individual studies not reported
Recruitment period	Search date: 1950–2010
Study population and number	**126 studies; total number of patients was not reported (n=11,785 for 110 studies reporting graft erosion)** Women treated by transvaginal pelvic organ prolapse repair with any type of graft material
Age	Not reported
Patient selection criteria	Studies were selected if they reported information on graft erosion, wound granulation, and dyspareunia in all comparative studies or case series with at least 30 patients in the graft arm, with no language restrictions. Graft erosion was defined as exposed graft material in the vagina or surrounding pelvic organs. Granulation tissue was defined as the formation of granulation tissue at the site of graft placement. All reported cases of de novo dyspareunia were included as well as persistent dyspareunia after surgery. Reports on abdominal or laparoscopic graft use were excluded.
Technique	Meta-analyses were restricted to the 2 most commonly used graft materials: non-absorbable synthetic and biological graft.
Follow-up	**Not reported**
Conflict of interest/source of funding	None (for the authors of the systematic review)

Analysis

Study design issues: Medline was the only source used to search for articles. The authors noted that most published studies were underpowered to detect a difference in functional outcomes between graft and no-graft treatment arms. Also, the indirect comparisons across studies done for this review cannot fully account for differences in populations, settings and surgery unrelated to the choice of graft material. There is no discussion about the risk of bias in the included studies. Statistical heterogeneity between the studies was noted for all 3 outcomes (graft erosion, wound granulation and dyspareunia).

Study population issues: The patient populations are not described with regard to baseline characteristics, severity and type of prolapse and type of surgery. There is some patient overlap between this review and the other systematic reviews described in table 2.

Key efficacy and safety findings

Safety

Number of patients analysed: **total not reported**

Comparison of rates of adverse events between non-absorbable synthetic and biological graft

Adverse event Graft type	Number of studies	Total number of events/total number of patients	Summary adverse event rate (%), calculated by meta-analysis (95% CI)	Reported range of event rates	p value for difference between subgroups
*Graft erosion**					
All grafts	110	982/11,785	10.3 (9.7 to 10.9)	0–29.7%	Not statistically significant
Non-absorbable synthetic	91	897/10,440	10.3 (9.7 to 11.0)		
Biological	19	85/1,345	10.1 (8.3 to 12.3)		
*Wound granulation tissue formation**					
All grafts	16	92/1,762	7.8 (6.4 to 9.5)	0–19.1%	Not statistically significant
Non-absorbable synthetic	9	49/1,113	6.8 (5.2 to 8.9)		
Biological	7	43/649	9.1 (6.8 to 12.1)		
*Dyspareunia**					
All grafts	70	350/5,638	9.1 (8.2 to 10.0)	0–66.7%	Not statistically significant
Non-absorbable synthetic	54	284/4,566	8.9 (8.0 to 10.0)		
Biological	16	66/1,072	9.6 (7.6 to 12.1)		

* the studies were statistically heterogenous

Graft erosion symptoms included vaginal discharge, odour, vaginal pain, dyspareunia, or pain experienced by the sexual partner.

Management of graft erosion in non-absorbable synthetic graft was reported in 76 studies (n=795): 165 (21%) were successfully treated with oestrogen or antiseptic agents, 87 (11%) were successfully treated by excision in the surgeon's office and 448 (56%) were treated by surgical excision in the operating theatre. Some women needed 2 to 3 additional operations to resolve symptoms.

Management of erosion in biological graft was reported in 12 studies (n=35): 50% of patients responded to local treatment with topical agents.

The authors noted that most vaginal erosions appear to be captured within the first year after surgery.

Abbreviations used: CI, confidence interval

Study 5 Jia X (2008) – commissioned for 2008 NICE guidance

Details

Study type	**Systematic review**
Country	Studies were conducted in Australia, Belgium, Canada, Denmark, Egypt, Finland, France, Italy, South Africa, Spain, Sweden, UK, and US.
Recruitment period	Search date: July 2007
Study population and number	n=4,569 women (49 studies; 6 full text RCTs, 11 RCTs available as conference abstracts, 7 non-randomised comparative studies, 1 prospective registry, and 24 case series with a minimum sample size of 50 women) Women treated by anterior and/or posterior vaginal wall prolapse surgery, using mesh/graft.
Age	In studies providing this information, the mean age was 64 years (range 24–96 years).
Patient selection criteria	Study selection: Randomised controlled trials (RCTs), non-randomised comparative studies, registries, case series involving at least 50 women, and RCTs published as conference abstracts from 2005 onwards. Studies of women with prolapse caused by pelvic trauma, congenital disease, or prolapse after creation of a neovagina were excluded. Women undergoing other concomitant operations, such as hysterectomy or a continence procedure, were considered providing the main indication for surgery was anterior or posterior prolapse. The interventions considered were anterior and/or posterior vaginal wall prolapse repair with mesh/graft. There were no restrictions on type of mesh/graft or technique used. For RCTs and non-randomised comparative studies, the comparators were another operation technique using mesh/graft or a type of surgery that did not involve mesh/graft.
Technique	The surgical techniques for implanting mesh/graft varied considerably across studies. 56% (1404/2497) of women had a concomitant procedure for urinary incontinence and 37% (953/2583) had a hysterectomy. Overall, 51% (2320/4569) of women were treated by non-absorbable synthetic mesh, but for anterior repair alone and for posterior repair alone, biological graft was the most common alternative (46% [1124/2472] and 29% [121/417], respectively). The mesh/grafts used in the studies included absorbable synthetic mesh (Vicryl mesh, Ethicon US), absorbable biological graft (SIS/SurgiSIS, Cook Biotechnology Inc.; Duraderm, CR Bard Inc.; Repliform, Boston Scientific Corp.; PelviSoft BioMesh, CR Bard Inc.; AlloDerm, LifeCell Corp.; Pelvicol® Acellular Collagen Matrix, CR Bard Inc.; Fortagen, Oganogenesis Inc.; Axis Tutoplast® Processed Dermis Coloplast Group, Mentor Corporation; Intaxen, American Medical Systems, Inc.; Tutoplast, Mentor Corporation; Faslata® Allograft Tissue, CR Bard Inc.), combined mesh/graft with non-absorbable part (Avaulta Anterior Biosynthetic Support System, CR Bard Inc.; Avaulta Posterior Biosynthetic Support System, CR Bard Inc.; Avaulta Plus Biosynthetic Support System, CR Bard Inc.; Pelvitex polypropylene mesh, CR Bard Inc.; Ugytex (Pelvitex) Ugytex, softradim, France, distributed by Bard as Pelvitex; VYPRO II, Ethicon; Vypro, Johnson & Johnson), non-absorbable synthetic mesh (Apogee Vault Suspension System, American Medical Systems; Perigee System with IntePro, American Medical Systems; Perigee System for biologic InteGraft, American Medical Systems; Straight-In sacral colpopexy system with IntePro large pore polypropylene Y-sling, American Medical Systems; BioArc device, American Medical Systems; Atrium, Atrium Medical Corporation; Polyform Synthetic Mesh, Boston Scientific; Marlex, CR Bard; Novasilk Polypropylene Mesh Coloplast Group, Mentor Corporation; Gynecare Prolift Total/Anterior/Posterior Pelvic Floor Repair System, Ethicon Inc.; Gynemesh, Gynecare (Prolene mesh), Ethicon; Gynemesh-Soft, Gynecare (Prolene soft mesh), Ethicon; MINIMESH®, Mpathy Medical Devices Ltd.; Parietene light Sofradim, Trevoux; Polyatex A4, Cousin Biotech; Mersilene, Ethicon; Gore-Tex, Teflon, Bard; Tissue Fixation System (TFS).
Follow-up	**Median 13 months (range 1–51 months)**
Conflict of interest/source of funding	Of the 17 RCTs, 1 was funded by Johnson and Johnson, Ethicon, 1 was funded by American Medical Systems; 2 were supported by unrestricted educational grant (from Mentor Corp and Organogenesis Inc. respectively), and 1 was funded by The American College of Obstetricians and Gynecologists/Ethicon Research Award for Innovations in Gynecologic Surgery, and by the Department of Gynecology and Obstetrics at the Cleveland Clinic Foundation. In the non-randomised studies, 4 studies reported that at least 1 author had financial interest and/or other relationship with companies including Mentor, Boston Scientific, AMS, Bioform, Genyx, Ortho McNeil, Surx, Lilly and Watson. The registry study was funded by University-administered research funds but pretrial scientific meetings were sponsored by Gynecare, Sweden AB. The transvaginal mesh manufacture company had no influence over study aim, design, execution, or analysis and interpretation of data. One author has an educational advisory position for Gynecare Sweden AB and another is a member of the Johnson & Johnson advisory board. One case series reported that the first author had a financial interest in the device under investigation.

Analysis

Follow-up issues: The drop-out rates in the included studies ranged from 0 to 30%.

Study design issues: The methodological quality was assessed for only the full text studies. For the 6 RCTs, adequate approaches to sequence generation for randomisation were reported in all studies except 1; concealment of treatment allocation was adequate in all RCTs except 2; all follow-up periods were 1 year or more; all studies used intention-to-treat analysis in that women were analysed in the groups to which they were randomised. For the 7 included non-randomised comparative studies, mean follow-up was less than 1 year in 2 studies. For the registry and case series, mean follow-up was 1 year or more in 17 studies. Primary outcomes for efficacy included persistent prolapse symptoms (subjective failure) and recurrent prolapse at original site (objective failure). For objective failure, outcomes measured by different systems, such as pelvic organ prolapse quantification system and Baden–Walker system, were combined. The review noted that there were too few data reported for most outcomes to draw reliable conclusions.

Study population issues: 72% of repairs were primary procedures. The most common use of mesh or graft was for anterior repair (54%, 2472/4569).

Other issues: there is some patient overlap with Maher C et al., 2016.

Key efficacy and safety findings

Efficacy

Number of patients analysed: anterior repair (n=2472; 30 studies, median follow-up=14 months [range 1–38]); posterior repair (n=417; 9 studies, median follow-up=12 months [range 1–17]); anterior and/or posterior repair (n=1680; 14 studies, median follow-up=13 months [range 1–51]).

Efficacy of anterior repair, summary of crude event rates (95% CI, any study design) by type of mesh/graft

Outcome	No mesh, n/N (%, 95% CI)	Absorbable synthetic mesh, n/N (%, 95% CI)	Biological graft, n/N (%, 95% CI)	Non-absorbable synthetic mesh, n/N (%, 95% CI)
Subjective failure	19/179 (10.6, 6.9 to 16.0)	5/112 (4.5, 1.9 to 10.0)	36/486 (7.4, 5.4 to 10.1)	1/55 (1.8, 0 to 6.5)
Objective failure	184/640 (28.8, 25.4 to 32.4)	63/273 (23.1, 18.5 to 28.4)	186/1041 (17.9, 15.7 to 20.3)	48/548 (8.8, 6.7 to 11.4)
De novo prolapse	-	-	8/58 (13.8, 7.2 to 24.9)	8/45 (17.8, 9.3 to 31.3)
Further operation needed*	2/85 (2.4, 0.6 to 8.2)	16/174 (9.2, 5.7 to 14.4)	9/280 (3.2, 1.7 to 6.0)	3/234 (1.3, 0.4 to 3.7)
Persistent urinary symptoms	9/10 (90.0, 59.6 to 98.2)	5/49 (10.2, 4.4 to 21.8)	13/14 (92.9, 68.5 to 98.7)	17/44 (38.6, 25.8 to 53.4)

* Surgery for prolapse (recurrent or de novo).

In 10 RCTs involving 1148 women, mesh/graft (any type) was better than no mesh for preventing objectively determined recurrence of anterior prolapse (14% [77/557] versus 30% [179/591]; relative risk 0.48, 95% CI 0.32 to 0.72.

Efficacy of posterior repair, summary of crude event rates (95% CI, any study design) by type of mesh/graft

Outcome	No mesh, n/N (%, 95% CI)	Absorbable synthetic mesh, n/N (%, 95% CI)	Biological graft, n/N (%, 95% CI)	Combined mesh/graft, n/N (%, 95% CI)	Non-absorbable synthetic mesh, n/N (%, 95% CI)
Subjective failure	9/60 (15.0, 8.1 to 26.1)	-	9/78 (11.5, 6.2 to 20.5)	-	-
Objective failure	18/142 (12.7, 8.2 to 19.1)	6/70 (8.6, 4.0 to 17.5)	19/93 (20.4, 13.5 to 29.7)	-	2/31 (6.5, 1.8 to 20.7)
Further operation needed*	3/70 (4.3, 1.5 to 11.9)	-	2/29 (6.9, 1.9 to 6.9)	-	-
Persistent bowel symptoms	19/58 (32.8, 22.1 to 45.6)	-	14/82 (17.1, 10.5 to 26.6)	5/43 (11.6, 5.2 to 24.6)	-
Persistent dyspareunia	-	-	5/14 (35.7, 16.3 to 61.2)	-	-

* Surgery for prolapse (recurrent or de novo).

Efficacy of anterior and/or posterior repair, summary of crude event rates (95% CI, any study design) by type of mesh/graft

Outcome	No mesh, n/N (%, 95% CI)	Absorbable synthetic mesh, n/N (%, 95% CI)	Combined mesh/graft, n/N (%, 95% CI)	Non-absorbable synthetic mesh, n/N (%, 95% CI)
Subjective failure	14/34 (41.2, 26.4 to 57.8)	14/32 (43.8, 28.2 to 60.7)	-	0/148 (0, 0 to 2.5)
Objective failure	27/109 (24.8, 17.6 to 33.6)	2/26 (7.7, 2.1 to 24.1)	11/143 (7.7, 4.3 to 13.2)	41/645 (6.4, 4.7 to 8.5)
Further operation needed*	-	-	-	7/161 (4.3, 2.1 to 8.7)
Persistent urinary symptoms	-	-	-	46/203 (22.7, 17.4 to 28.9)
Persistent bowel symptoms	-	-	-	1/21 (4.8, 0.8 to 22.7)
Persistent dyspareunia	-	-	1/10 (10.0, 1.8 to 40.4)	-

* Surgery for prolapse (recurrent or de novo).

Safety

Safety of anterior repair, summary of crude event rates (95% CI, any study design) by type of mesh/graft

Outcome	No mesh, n/N (%, 95% CI)	Absorbable synthetic mesh, n/N (%, 95% CI)	Biological graft, n/N (%, 95% CI)	Non-absorbable synthetic mesh, n/N (%, 95% CI)
Blood transfusion	1/88 (1.1, 0.2 to 6.2)	0/147 (0, 0 to 2.5)	3/198 (1.5, 0.5 to 4.4)	4/161 (2.5, 1.0 to 6.2)
Damage to surrounding organs	0/19 (0, 0 to 16.8)	0/112 (0, 0 to 3.3)	0/94 (0, 0 to 3.9)	6/251 (2.4, 1.1 to 5.1)
Mesh/graft erosion	N/A	1/147 (0.7, 0.1 to 3.8)	35/581 (6.0, 4.4 to 8.3)	68/666 (10.2, 8.1 to 12.7)
Operation for mesh/graft erosion	N/A	1/35 (2.9, 0 to 3.3)	4/154 (2.6, 1.0 to 6.5)	23/347 (6.6, 4.5 to 9.7)
De novo urinary symptoms	-	0/63 (0, 0 to 5.7)	3/42 (7.1, 2.5 to 19.0)	3/44 (6.8, 2.3 to 18.2)
De novo dyspareunia	-	-	-	4/11 (36.4, 15.2 to 64.6)
Infection	4/142 (2.8, 1.1 to 7.0)	0/112 (0, 0 to 3.3)	5/477 (1.0, 0.4 to 2.4)	11/558 (2.0, 1.1 to 3.5)
Other serious adverse effects	1/93 (1.1, 0.2 to 5.8)	0/35 (0, 0 to 9.9)	2/212 (0.9, 0.3 to 3.4)	4/248 (1.6, 0.6 to 4.1)

Safety of posterior repair, summary of crude event rates (95% CI, any study design) by type of mesh/graft

Outcome	No mesh, n/N (%, 95% CI)	Absorbable synthetic mesh, n/N (%, 95% CI)	Biological graft, n/N (%, 95% CI)	Combined mesh/graft, n/N (%, 95% CI)	Non-absorbable synthetic mesh, n/N (%, 95% CI)
Blood transfusion	3/79 (3.8, 1.3 to 10.6)	0/5 (0, 0 to 43.4)	1/31 (3.2, 0.6 to 16.2)	0/90 (0, 0 to 4.1)	1/71 (1.4, 0.2 to 7.6)
Damage to surrounding organs	2/79 (2.5, 0.7 to 8.8)	0/5 (0, 0 to 43.4)	1/31 (3.2, 0.6 to 16.2)	0/90 (0, 0 to 4.1)	3/71 (4.2, 1.4 to 11.7)
Mesh/graft erosion	N/A	-	0/28 (0, 0 to 12.1)	16/115 (13.9, 8.7 to 12.1)	2/31 (6.5, 1.8 to 20.7)
Operation for mesh/graft erosion	N/A	-	-	11/90 (12.2, 7.0 to 20.6)	-
De novo bowel symptoms	-	-	-	2/45 (4.4, 1.2 to 14.8)	1/29 (3.4, 0.6 to 17.2)
De novo dyspareunia	-	4/25 (16.0, 6.4 to 34.7)	-	2/36 (5.6, 1.5 to 18.1)	-
Infection	13/94 (13.8, 8.3 to 22.2)	0/5 (0, 0 to 43.4)	7/48 (14.6, 7.2 to 27.2)		4/106 (3.8, 1.5 to 9.3)

Safety of anterior and/or posterior repair, summary of crude event rates (95% CI, any study design) by type of mesh/graft

Outcome	No mesh, n/N (%, 95% CI)	Combined mesh/graft, n/N (%, 95% CI)	Non-absorbable synthetic mesh, n/N (%, 95% CI)
Blood transfusion	1/35 (2.9, 0.5 to 14.5)	-	11/810 (1.4, 0.8 to 2.4)
Damage to surrounding organs	-	4/143 (2.8, 1.1 to 7.0)	12/541 (2.2, 1.3 to 3.8)
Mesh/graft erosion	N/A	9/143 (6.3, 3.3 to 11.5)	62/1119 (5.5, 4.3 to 7.0)
Operation for mesh/graft erosion	N/A	6/143 (4.2, 1.9 to 8.9)	45/1098 (4.1, 3.1 to 5.4)
De novo urinary symptoms	-	-	34/355 (9.5, 6.9 to 13.1)
De novo bowel symptoms	-	-	1/47 (2.1, 0.4 to 11.1)
De novo dyspareunia	-	10/78 (12.8, 7.1 to 22.0)	3/42 (7.1, 2.5 to 19.0)
Infection	-	-	33/661 (5.0, 3.6 to 6.9)
Other serious adverse effects	-	-	3/278 (1.1, 0.4 to 3.1)

Abbreviations used: CI, confidence interval; N/A; not applicable

Study 6 Chughtai B (2015)

Details

Study type	**All inclusive, population-based cohort study**
Country	US
Recruitment period	2008–11
Study population and number	**n=27,991 (7,338 mesh versus 20,653 without mesh)** Women who had a prolapse repair procedure in New York state
Age	<45 years=14%, 45–64=48%, 65–74=24%, ≥75=14%
Patient selection criteria	Patients with a diagnosis of pelvic organ prolapse (ICD-9-CM 618.0–618.9) and a record of a first prolapse repair procedure in the New York State Department of Health Statewide Planning and Research Cooperative System within the study period. Patients who had any type of prolapse repair surgery before the index date were excluded from the analyses. Mesh was defined as any augmenting material, including synthetic and biological materials, and was determined by specific ICD-9 procedure codes and CPT-4 codes.
Technique	A proportion of patients had concurrent hysterectomy (38.5% of patients treated by mesh repair and 51.3% of patients treated by prolapse repair without mesh); 20.0% of patients in the mesh group and 14% of patients treated without mesh had concomitant sling procedures.
Follow-up	**1 year**
Conflict of interest/source of funding	The study was funded in part through a grant from the US National Institutes of Health and the FDA. There were no financial relationships with any organisation that might have an interest in the submitted work in the previous 3 years.

Analysis

Follow-up issues: A unique personal identifier was assigned to every patient in the database, allowing longitudinal analyses.

Study design issues: The data source was a cohort created using information from the New York State Department of Health Statewide Planning and Research Cooperative System. This database collects patient and treatment information for every hospital discharge, outpatient service, and emergency department admission in New York state. Outcomes included 90 day safety, including medical complications, surgical complications and readmissions within 90 days, and 1-year follow-up for reintervention after the initial procedure. Reintervention was determined on the basis of repeated prolapse repair procedures and mesh revision procedures. Patients who had death recorded during the 1-year follow-up were censored. Propensity score matching was used to adjust for differences in baseline characteristics between mesh and no mesh groups. Patients who had missing values for variables regarding hospital characteristics were excluded from the propensity score matching.

Study population issues: More patients were aged 65 years or older in the mesh group than in the non-mesh group (44% versus 35%). A higher proportion of patients treated without mesh also had a hysterectomy at the same time (51% versus 39%). Comorbidity profiles in the 2 groups were similar, except that prevalence of hypertension was higher in the mesh group than non-mesh group (40% versus 34%).Patients in the mesh group were more likely than patients in the non-mesh group to have been treated in an inpatient setting (77% versus 72%) and in teaching facilities (53% versus 43%). There were no data on the severity of prolapse.

Other issues: The data may include some women treated by abdominal mesh procedures, although patients with CPT-4 codes specific to abdominal procedures were removed.

Key efficacy and safety findings

Number of patients analysed: **27,991 (7,338 versus 20,653)**

90 day safety, no. (%) of events

	Before propensity score matching			After propensity score matching		
	Mesh n=7,338	**No mesh n=20,653**	**RR (95% CI)**	**Mesh n=7,295**	**No mesh n=7,295**	**RR (95% CI)**
Medical complications	186 (2.5)	451 (2.2)	1.16 (0.98 to 1.37)	185 (2.5)	173 (2.4)	1.07 (0.87 to 1.31)
Bleeding	110 (1.5)	316 (1.5)	0.98 (0.79 to 1.22)	110 (1.5)	97 (1.3)	1.13 (0.87 to 1.49)
Urinary tract infection	249 (3.4)	662 (3.2)	1.06 (0.92 to 1.22)	247 (3.4)	229 (3.1)	1.08 (0.90 to 1.29)
Urinary retention	551 (7.5)	1,106 (5.4)	1.40 (1.27 to 1.55)*	554 (7.5)	408 (5.6)	1.33 (1.18 to 1.51)*
Bladder injury	59 (0.8)	93 (0.5)	1.79 (1.29 to 2.47)*	59 (0.8)	42 (0.6)	1.40 (0.95 to 2.09)
Other surgical complications	172 (2.3)	436 (2.1)	1.10 (0.93 to 1.31)	170 (2.3)	147 (2.0)	1.16 (0.93 to 1.44)
Inpatient readmission	392 (5.3)	1,042 (5.0)	1.06 (0.95 to 1.19)	390 (5.3)	365 (5.0)	1.07 (0.93 to 1.23)
Emergency room readmission	633 (8.6)	1,997 (9.7)	0.89 (0.82 to 0.97)	631 (8.6)	601 (8.6)	1.05 (0.94 to 1.17)

*p<0.05

1-year follow-up, no. (%) of events – reinterventions determined on the basis of repeated prolapse repair procedures and mesh revision procedures

	Before propensity score matching			After propensity score matching		
	Mesh n=7,338	**No mesh n=20,653**	**Hazard ratio (95% CI)**	**Mesh n=7,295**	**No mesh n=7,295**	**Hazard ratio (95% CI)**
Reintervention	241 (3.3)	419 (2.0)	1.66 (1.41 to 1.94)*	240 (3.3)	164 (2.2)	1.47 (1.21 to 1.79)*
Reintervention with mesh	53 (0.7)	104 (0.5)	-	53 (0.7)	42 (0.6)	-

*p<0.05

Abbreviations used: CI, confidence interval; RR, risk ratio

Study 7 Funk MJ (2013)

Details

Study type	**Population-based cohort study**
Country	US
Recruitment period	2005–10
Study population and number	**n=27,809 (6,871 mesh versus 20,938 without mesh)** Women who had an anterior colporrhaphy procedure, with or without vaginal mesh
Age	Median 59 years (mesh) versus 55 years (native tissue), p<0.0001
Patient selection criteria	Women aged 18 years or older who had anterior colporrhaphy with mesh augmentation or native tissue anterior colporrhaphy. Women without 6 months of continuous enrolment before the index procedure were excluded. Women who had mesh placed during the baseline period and those with a previous abdominal or laparoscopic sacrocolpopexy were excluded. If a procedure to remove or revise mesh was done before the index period, those women were also excluded. Women with other concomitant prolapse procedures, including posterior coloporrhaphy were excluded.
Technique	Anterior colporrhaphy procedure, with or without vaginal mesh (no further details given).
Follow-up	**Median 1.4 years (mesh) versus 1.3 years (native tissue), p=0.44**
Conflict of interest/source of funding	None.

Analysis

Study design issues: Data were obtained from 2 healthcare claims databases, including claims for approximately 28.3 million individuals in 2005, increasing to 48.4 million in 2010. Contributing individuals included those with commercial, employment-based insurance, such as employees, their spouses, dependants, as well as retirees.
Study population issues: 71% of women in the mesh repair group had recent or concurrent sling surgery versus 62% of women in the native tissue group (p<0.0001). 18% of women in the mesh group had concurrent hysterectomy compared with 38% of women in the native tissue group (p<0.0001). There was an increase in the proportion of procedures involing vaginal mesh from 2005 to 2010 (p<0.0001). Fewer women with native tissue repairs had a concomitant or recent sling (62% versus 71%, p<0.0001) but a higher proportion had a concurrent hysterectomy (38% versus 18%, p<0.0001).
Other issues: A mesh complication could occur in the native tissue cohort if the patient had mesh placed before the baseline period (more than 6 months before the index procedure) or if a midurethral sling resulted in a sling revision/removal because of a mesh complication that was not coded using the typical code for sling revision/removal.

Key efficacy and safety findings

Number of patients analysed: **27,809 (6,871 versus 20,938)**

Years of follow-up	Number at risk		Surgery for recurrent prolapse				Surgery for mesh complications			
	Mesh (n=6,871)	Native tissue (n=20,938)	Mesh (%)	95% CI	Native tissue (%)	95% CI	Mesh (%)	95% CI	Native tissue (%)	95% CI
1	3,935	11,805	5.0	4.5 to 5.6	5.1	4.8 to 5.4	3.0	2.5 to 3.4	0.4	0.3 to 0.5
2	2,358	7,180	6.8	6.1 to 7.5	6.5	6.1 to 6.9	4.3	3.7 to 4.9	0.5	0.4 to 0.6
3	1,261	4,235	8.1	7.2 to 9.0	7.5	7.1 to 8.0	4.9	4.2 to 5.6	0.6	0.4 to 0.7
4	571	2,291	9.4	8.3 to 10.5	8.5	7.9 to 9.0	5.9	5.0 to 6.9	0.6	0.5 to 0.8
5	152	903	10.4	8.8 to 12.1	9.3	8.6 to 10.0	5.9	5.0 to 6.9	0.7	0.5 to 0.9

5-year cumulative risk of any repeat surgery after the index surgery for anterior prolapse:

- Mesh=15.2%
- Native tissue=9.8%, p<0.0001

Abbreviations used: CI, confidence interval

Study 8 Morling JR (2016)

Details

Study type	**Population-based cohort study**
Country	Scotland
Recruitment period	1997 to 2016
Study population and number	n=18,986 (1,279 mesh repair) **Patients treated by a first, single prolapse procedure.**
Age	Mean 62 years (anterior repair); 59 years (posterior repair)
Patient selection criteria	Women aged 20 years or older who were treated by a first, single prolapse procedure. Combination procedures were excluded as well as any patient who been treated by an incontinence or prolapse procedure in the preceding 5 years. Women with previous hysterectomy were included for vaginal vault prolapse procedures.
Technique	Anterior colporrhaphy with or without mesh for anterior compartment repair; posterior colporrhaphy with or without mesh for posterior compartment repair; sacrospinous fixation of the vagina (non-mesh), vaginal mesh vault repair (mesh), and open sacrocolpopexy (abdominal mesh) for repair of vaginal vault prolapse; vaginal hysterectomy (non-mesh) for repair of uterine prolapse.
Follow-up	**Up to 5 years**
Conflict of interest/source of funding	One author reports personal fees and non-financial support from Bard and SEP Pharma, and non-financial support from Boston Scientific and Neomedic, outside the submitted work. One author reports departmental educational support for staff from Astellas, grants and funding to attend courses from Gynecare, and grants from AMS, outside the submitted work. The remaining authors declare no competing interests.

Analysis

Study design issues: Data were extracted from the Scottish hospital discharge dataset held by the Information Services Division of NHS National Services Scotland. This is a national healthcare use database with complete population coverage. Some additional validation of the coding of index mesh prolapse procedures and their complications was done. Procedures were identified using OPCS4 codes and data relating to the type of mesh used was not available. The primary outcomes focused on diagnoses and procedures severe enough to need hospital admission or readmission. It was not possible to capture data on complications managed in outpatient or primary care settings. It was also not possible to ensure that outcomes were a direct consequence of the index procedure of interest and not related to an alternative event. Some patients may have been treated more than 5 years previously, so the data may include some repeat procedures. Mesh procedures were generally carried out in the more recent years of the study period.

Key efficacy and safety findings

Adverse events following first, single prolapse procedures

	Anterior colpo-rrhaphy (non-mesh) n=7643	Anterior colporrhaphy with mesh n=278	Posterior colporrhaphy (non-mesh) n=6061	Posterior colporrhaphy with mesh n=209	Sacrospinous fixation of the vagina (non-mesh) n=2058	Vaginal mesh vault repair n=112	Open sacro-colpopexy (abdominal mesh) n=680	Vaginal hysterectomy (non-mesh) n=1945
Immediate postoperative complications								
No. of patients with complication	343 (4%)	20 (4%)	199 (3%)	3 (1%)	91 (4%)	5 (4%)	43 (6%)	105 (5%)
Unadjusted RR (95% CI)	1 (ref)	0.80 (0.43 to 1.49)	0.73 (0.62 to 0.87)	0.32 (0.10 to 0.99)	0.98 (0.78 to 1.24)	0.99 (0.41 to 2.39)	1.40 (1.02 to 1.92)	1.20 (0.96 to 1.49)
Adjusted RR (95% CI)	1 (ref)	0.78 (0.41 to 1.46)	0.74 (0.62 to 0.89)	0.31 (0.10 to 0.98)	0.94 (0.74 to 1.19)	0.95 (0.39 to 2.31)	1.32 (0.96 to 1.82)	1.24 (0.99 to 1.54)
Late postoperative complications								
Patients with 1 or more admission	504 (7%)	49 (18%)	477 (8%)	42 (20%)	184 (9%)	17 (15%)	78 (11%)	150 (8%)
Total number of admissions within 5 years	730	87	673	72	259	27	121	217
Crude incidence rate per 1000 person-years	22.0	70.4	25.9	77.1	39.5	52.1	38.7	24.9
Unadjusted IRR (95% CI)	1 (ref)	3.19 (2.55 to 3.98)	1.18 (1.06 to 1.31)	3.49 (2.74 to 4.44)	1.78 (1.55 to 2.05)	2.36 (1.61 to 3.46)	1.75 (1.44 to 2.12)	1.13 (0.97 to 1.31)
Adjusted IRR (95% CI)	1 (ref)	3.18 (2.54 to 3.99)	1.15 (1.03 to 1.27)	3.23 (2.52 to 4.13)	1.79 (1.55 to 2.07)	2.22 (1.51 to 3.27)	1.86 (1.53 to 2.26)	1.09 (0.93 to 1.27)

Most immediate and later complications were infection or directly procedure related.

In patients who had mesh index prolapse surgery, up to 50% of all late complication admissions contained a code indicating a subsequent mesh removal procedure.

Abbreviations used: CI, confidence interval; IRR, incidence rate ratio; RR, rate ratio

Direct comparison of adverse events (missing data excluded from the regression models), for anterior and posterior compartment prolapse

	Anterior colporrhaphy (non-mesh)	Anterior colporrhaphy with mesh	Posterior colporrhaphy (non-mesh)	Posterior colporrhaphy with mesh
Immediate postoperative complications				
Unadjusted RR (95% CI)	1 (ref)	0.94 (0.50 to 1.78)	1 (ref)	0.50 (0.16 to 1.57)
Adjusted RR (95% CI)	1 (ref)	0.93 (0.49 to 1.79)	1 (ref)	0.49 (0.15 to 1.58)
Late postoperative complication admissions				
Unadjusted IRR (95% CI)	1 (ref)	2.95 (2.33 to 3.73)	1 (ref)	2.84 (2.20 to 3.67)
Adjusted IRR (95% CI)	1 (ref)	3.15 (2.46 to 4.04)	1 (ref)	2.76 (2.11 to 3.61)
Further incontinence surgery admissions				
Unadjusted IRR (95% CI)	1 (ref)	3.49 (2.29 to 5.32)	1 (ref)	1.51 (0.76 to 3.02)
Adjusted IRR (95% CI)	1 (ref)	3.20 (2.06 to 4.96)	1 (ref)	1.40 (0.68 to 2.86)
Further prolapse surgery admissions				
Unadjusted IRR (95% CI)	1 (ref)	1.78 (1.37 to 2.30)	1 (ref)	1.77 (1.26 to 2.49)
Adjusted IRR (95% CI)	1 (ref)	1.69 (1.29 to 2.20)	1 (ref)	1.70 (1.20 to 2.42)

Abbreviations used: CI, confidence interval; IRR, incidence rate ratio; RR, rate ratio

Study 9 Kasyan G (2014)

Details

Study type	**Case series**
Country	Russia
Recruitment period	2006 to 2010
Study population and number	n=677 **Patients treated for pelvic organ prolapse with vaginal mesh (303 anterior repair, 51 posterior repair, 232 vaginal vault repair, 91 combined anterior and posterior repair).**
Age	Mean 60 years
Patient selection criteria	Patients treated surgically for pelvic organ prolapse (anterior, posterior or apical) with vaginal mesh.
Technique	Trocar-guided transvaginal mesh kit (Prolift, Gynecare, US).
Follow-up	**1 to 3 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Only 86.5% (586/677) were available for phone interview, the others were lost to follow-up mainly because of failure to contact the patients.

Study design issues: Retrospective analysis of patient files for intraoperative and postoperative complications. A phone interview was also done to evaluate the patient's self-perception. Any patient who considered herself to be symptomatic was invited for a check-up that included vaginal examination, uroflowmetry and post-void residual measurement followed by cystoscopy when appropriate.

Key efficacy and safety findings

Number of patients analysed: 677

Total complication rate (including intraoperative and early postoperative complications and mesh-related injuries)=22.5% (152/677)

Intraoperative and early postoperative complications

Complication	**% (n)**
Vaginal or pelvic haematoma	5.5% (37)
Perineal haematoma	2.5% (17)
Bleeding more than 500 ml	2.2% (15)
Bladder injury	1.6% (11)
Rectal damage	0.7% (5)
Urethral trauma	0.3% (2)
Ureteral trauma	0.2% (1)

Mesh-related complications

Complication	**% (n)**
Mesh erosions	4.8% (32)
Pain and dyspareunia	2.4% (16)
Mesh shrinkage	1% (7)
Pelvic abscess	0.6% (4)
Symptomatic vaginal synechiae	0.3% (2)
Protrusion into the bladder	0.2% (1)
Fistulas with mesh	0.3% (2)

3 women had serious vascular injuries: inferior gluteal vessels, obturator vessels, paraurethral venous plexus. In all these patients, blood transfusion was done because of massive blood loss.

10 major vaginal haematomas led to urinary retention or transformed into an abscess. Several of them needed a transcutaneous drainage.

In 2 patients, urinary tract injury was not recognised at the time of surgery and led to stone formation. One patient needed a laparotomy and removal of the mesh with resection of the bladder wall.

The patient with a ureteral injury was treated by ureterneocystotomy.

In all 5 patients with rectal injury, the mesh was not inserted and traditional posterior colporrhaphy was done; none of the patients needed a colostomy.

Two women had large mesh extrusions with signs of local infection and abscess. They were treated by total surgical removal of the mesh, under general anaesthesia. One patient, with a history of intrauterine device inserted 30 years ago, had necrotising fasciitis. The patient developed signs of systemic toxicity 6 days after the prolapse repair. She was treated by fasciotomy and debridement but died after 18 days.

Risk factors

	Operative complications		Mesh-related complications	
	OR	95% CI	OR	95% CI
Age <55 years	3.3	2.2 to 5.0*	8.2	2.5 to 14.9
Body mass index >35	1.2	0.8 to 1.7	0.3	0.2 to 1.8
Endocrine diseases	0.6	0.5 to 1.2	1.2	0.5 to 2.4
Genitourinary disease	0.7	0.5 to 1.0	1.3	0.7 to 2.4
Less than III POP-Q	2	0.9 to 4.5	4.0	1.7 to 8.9*
POP-Q IV	2	1.0 to 4.0	3.0	1.5 to 6.0*
Operating time >120 minutes	10	5.4 to 18.2	6.0	1.2 to 10.9
Vaginal hysterectomy	2.8	1.7 to 4.6*	2.4	1.3 to 4.4*
Postoperative haematoma	-	-	2.5	1.4 to 5.1*

* statistically significant

Abbreviations used: CI, confidence interval; OR, odds ratio

Efficacy

Symptoms

In a randomised controlled trial (RCT) of 865 women with anterior or posterior vaginal wall prolapse treated by synthetic mesh-augmented repair or standard repair alone, there were no statistically significant differences in prolapse symptom scores (5.3 versus 4.9, p=0.37), symptomatic prolapse (85% [291/342] versus 82% [283/347], p=0.30) or the proportion of women reporting 'something coming down' (34% [116/342] versus 31% [106/347], p=0.59) at 2-year follow-up[1]. The quality-of-life scores were also similar. In an RCT of 735 women with anterior or posterior vaginal wall prolapse treated by biological graft augmented repair or standard repair alone, there were no statistically significant differences in prolapse symptom scores (5.5 versus 4.9, p=0.43) or symptomatic prolapse (82% [245/299] versus 81% [242/298], p=0.85). The proportion of women reporting 'something coming down' was statistically significantly higher in the graft augmented repair group (40% [120/299] versus 31% [91/298], p=0.04) at 2-year follow-up[1]. The quality-of-life scores were similar between the 2 groups.

In a systematic review of 4,023 patients, there was a statistically significantly lower risk of awareness of prolapse in women treated by transvaginal permanent mesh compared with native tissue repair (relative risk [RR] 0.66, 95% confidence interval [CI] 0.54 to 0.81; n=1,614, 12 RCTs) at 1- to 3-year follow-up[2].

Objective assessment of prolapse

In the RCT of 865 women with anterior or posterior vaginal wall prolapse treated by synthetic mesh-augmented repair or standard repair alone, there were no statistically significant differences in the proportion of women with an overall POP-Q score of 2b, 3 or 4 (16% [54/336] versus 14% [47/338], p=0.52) at 1-year follow-up[1]. In the RCT of 735 women with anterior or posterior vaginal wall prolapse treated by biological graft augmented repair or standard repair alone, the proportion of women with an overall POP-Q score of 2b, 3 or 4 was 18% (54/298) and 16% (47/303) respectively at 1-year follow-up (p=0.47)[1]. In the systematic review of 4,023 patients, those who had a transvaginal mesh repair were less likely to have a stage 2 or greater anterior compartment prolapse on examination than those undergoing a native tissue repair (RR 0.45, 95% CI 0.36 to 0.55, 13 RCTs, n=1,406, I^2=35%) at 1- to 3-year follow-up[2]. The risk of recurrent prolapse was lower in the transvaginal permanent mesh group compared with native tissue repair (RR 0.40, 95% CI 0.30 to 0.53, 21 studies, n=2,494, I^2=73%)[2].

Further operation needed for prolapse

In the systematic review of 4,023 patients, those who had a transvaginal mesh repair were less likely to have repeat surgery for prolapse (RR 0.53, 95% CI 0.31

to 0.88, 12 RCTs, n=1,675) at 1 to 3-year follow-up[2]. In a population-based cohort study of 27,809 patients who had mesh or native tissue repair, surgery for recurrent prolapse was reported in a similar proportion of patients: 5% of patients in both groups at 1-year follow-up and 10% (95% CI 9 to 12%) in the mesh group at 5-year follow-up compared with 9% (95% CI 9 to 10%) in the native tissue group[7]. In the RCT of 865 patients who had synthetic mesh or standard repair, further prolapse surgery was needed in a similar proportion of patients (4% [15/343] versus 5% [16/348]) at 2-year follow-up[1]. In the RCT of 735 patients who had biological graft or standard repair, further prolapse surgery was needed in 5% of patients in both groups (15/300 and 15/299) at 2-year follow-up[1]. In a cohort study of 27,991 patients who had prolapse repair with or without mesh, the reintervention rate (repeated prolapse repair and mesh revision procedures) within 1 year, after propensity score matching, was 3% in patients who had mesh repair and 2% in patients who had repair without mesh (hazard ratio 1.47, 95% CI 1.21 to 1.79). Further prolapse surgery admissions were more common after anterior repair with mesh than after anterior repair without mesh (adjusted incidence rate ratio 1.69, 95% CI 1.29 to 2.20) in a cohort study of 18,986 patients[8].

Safety

Non-mesh-related serious adverse effects

Serious adverse effects of any kind (but excluding mesh complications) were reported in 8% (34/435) of patients who had a synthetic mesh repair and 7% (31/430) of patients who had a standard repair (p=0.73) at 1-year follow-up in an RCT of 865 patients. Serious adverse effects if any kind (but excluding mesh complications) were reported in 10% (36/368) of patients who had a biological graft repair and 6% (23/367) of patients who had a standard repair (p=0.08) at 1-year follow-up in an RCT of 735 patients. Immediate postoperative complications were reported in 4% (20/278) of patients who had anterior prolapse repair with mesh and 4% (343/7643) of patients who had repair without mesh in a cohort study of 18,986 patients[8]. Late postoperative complications were more common in patients who had mesh repair compared with a non-mesh repair (adjusted incidence rate ratio 3.15, 95% 2.46 to 4.04) in the same study.

Mesh-related complications

Mesh complications were reported in 12% (51/434) of patients who were exposed to synthetic mesh at 2-year follow-up in the RCT of 865 patients. Surgical removal of the mesh was needed in 9% (37/434) of patients in the same study[1]. Mesh complications were reported in less than 1% (2/368) of patients who had a biological graft repair and less than 1% (2/367) of patients who had a standard repair in the RCT of 735 patients; all 4 patients had concomitant synthetic mesh. Surgical removal was needed in 3 of the 4 patients[1]. Surgery for mesh complications was reported in 6% of patients who had a mesh repair in a cohort study of 27,809 patients at 5-year follow-up [7].

Mesh exposure

Mesh exposure was reported in 12% (134/2,097) of patients who had a transvaginal permanent mesh repair in a systematic review of 4,023 patients at 1 to 3 year review. Surgery for mesh exposure was reported in 8% (100/1,227) of patients[2]. The overall rate of graft erosion (by meta-analysis of 110 studies) was 10% (95% CI 10 to 11%) of procedures in a systematic review of 126 studies[4]. There was no statistically significant difference between non-absorbable synthetic grafts and biological grafts. Mesh erosion was reported in 5% (32/677) of patients in a case series of 677 patients[9].

Injury to bladder or bowel

Bladder injury was more common in women who had a transvaginal permanent mesh repair than those who had a native tissue repair (RR 3.92, 95% CI 1.62 to 9.50, 11 RCTs, n=1,514, I^2=0%, moderate-quality evidence) in the systematic review of 4,023 patients[2]. Bowel injury was reported in 1 study in the same systematic review, and there was no evidence of a difference between the 2 groups (RR 3.26, 95% CI 0.13 to 78.81, 1 RCT, n=169). Bladder injury and rectal damage were reported in 2% (11/677) and 1% (5/677) of patients respectively in a case series of 677 patients[9]. In 2 patients, urinary tract injury was not recognised at the time of surgery and led to stone formation. One patient needed a laparotomy and removal of the mesh with resection of the bladder wall. Ureteral trauma was reported in 1 patient in the same study; this was treated by ureterneocystotomy[9].

Fistula

Fistula was reported in less than 1% of patients (2/677) in the case series of 677 patients[9].

Wound complications

The overall rate of wound granulation (by meta-analysis of 16 studies) was 8% (95% CI 6 to 10%) of procedures in a systematic review of 126 studies[4]. There was no statistically significant difference between non-absorbable synthetic grafts and biological grafts.

Bleeding

Bleeding more than 500 ml was reported in 2% (15/677) of patients in the case series of 677 patients[9].

Haematoma

Vaginal or pelvic haematoma was reported in 6% (37/677) of patients in a case series of 677 patients[9]. In 10 patients, major vaginal haematomas led to urinary retention or transformed into an abscess. Several of them needed to be drained

transcutaneously. Perineal haematoma was reported in 3% (17/677) of patients in the same study.

Infection

Pelvic abscess was reported in 1% (4/677) of patients in the case series of 677 patients[9]. One patient, with a history of intrauterine device inserted 30 years ago, had necrotising fasciitis. The patient developed signs of systemic toxicity 6 days after the prolapse repair. She was treated by fasciotomy and debridement but died after 18 days.

Stress urinary incontinence

De novo stress urinary incontinence was more common in patients who had a transvaginal permanent mesh repair than those who had a native tissue repair (RR 1.39, 95% CI 1.06 to 1.82, 12 RCTs, n=1,512, I^2=0%, low-quality evidence) in the systematic review of 4,023 patients[2]. Incontinence surgery admissions were more common after anterior repair with mesh than after anterior repair without mesh (adjusted incidence rate ratio 3.20, 95% CI 2.06 to 4.96) in a cohort study of 18,986 patients[8].

Urinary retention

Urinary retention within 90 days was more common in patients who had a mesh repair than those who had a repair without mesh (8% versus 6%, risk ratio 1.33, 95% CI 1.18 to 1.51) in a cohort study of 27,991 patients[6].

Dyspareunia

The overall rate of dyspareunia (by meta-analysis of 70 studies) was 9% (95% CI 8 to 10%) of procedures in a systematic review of 126 studies[4]. There was no statistically significant difference between non-absorbable synthetic grafts and biological grafts. Pain and dyspareunia was reported in 2% (16/677) of patients in the case series of 677 patients[9].

Validity and generalisability of the studies

- The majority of studies do not present data beyond about 5 years of follow-up, often much less than this.
- There are data from the UK, including a recent, large randomised controlled trial[1].
- A large proportion of patients who have surgical repair of the vaginal wall prolapse using mesh have other procedures done at the same time.

- Some studies included patients with apical prolapse as well as those with anterior or posterior vaginal wall prolapse.
- There are a variety of techniques and different types of mesh used for this procedure, and their safety and efficacy may vary.
- Some of the meshes that were used in the earlier studies have been withdrawn. Newer, ultra-lightweight meshes have been introduced more recently.
- The evidence base for this procedure has increased substantially since the original guidance was produced in 2008.

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'[10]. It stated: "*The SCENIHR considers three factors as being important when assessing the risks associated with mesh application: the overall surface area of material used, the product design and the properties of the material used. In addition, the available evidence suggests a higher morbidity in treating female pelvic organ prolapse (POP) than Stress Urinary Incontinence (SUI), as the former uses a much larger amount of mesh.*

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

Based on the currently marketed products, assessment of the risks reported indicates that polypropylene type 1 meshes are the most appropriate synthetic meshes for vaginal use and polypropylene type 1 and polyester type 3 for insertion via the abdominal route. However, there is a need for further improvement in the composition and design of synthetic meshes, in particular for female pelvic organ prolapse surgery."

SCENIHR's recommendations include:

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

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

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

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

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

A Scottish Independent Review of the 'Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women' interim report was published in October 2015 by The Scottish Government[11].

A summary of the evidence on the benefits and risks of vaginal mesh implants was published in October 2014 by the MHRA[12]. It stated: "*MHRA's current position is that, for the majority of women, the use of vaginal mesh implants is safe and effective. However, as with all surgery, there is an element of risk to the individual patient. This conclusion is entirely dependent on compliance with NICE and other sources of guidance, which emphasise the caution that should be exercised prior to surgery being considered. Whilst some women have experienced distressing and severe effects, the current evidence shows that when these products are used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks.*"

Related NICE guidance

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

Interventional procedures

- Surgical repair of vaginal wall prolapse using mesh. NICE interventional procedure guidance 267 (2008). This guidance is currently under review and is

expected to be updated in 2017. For more information, see http://www.nice.org.uk/guidance/IPG267

- Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse. NICE interventional procedure guidance 577 (2017). Available from http://www.nice.org.uk/guidance/IPG577
- Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE interventional procedure guidance 566 (2016). Available from http://www.nice.org.uk/guidance/IPG566
- Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 283 (2009). Available from http://www.nice.org.uk/guidance/IPG283
- Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair. NICE interventional procedure guidance 282 (2009). Available from http://www.nice.org.uk/guidance/IPG282
- Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 281 (2009). Available from http://www.nice.org.uk/guidance/IPG281
- Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE interventional procedure guidance 280 (2009). Available from http://www.nice.org.uk/guidance/IPG280
- Insertion of biological slings for stress urinary incontinence in women. NICE interventional procedure guidance 154 (2006). Available from http://www.nice.org.uk/guidance/IPG154

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 Adviser Questionnaires for surgical repair of vaginal wall prolapse using mesh were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 10 companies who manufacture a potentially relevant device for use in this procedure. NICE received completed submissions from 4 companies. These were considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Ongoing trials:
  - Restorelle® Transvaginal Mesh Versus Native Tissue Repair for Treatment of Pelvic Organ Prolapse, Restorelle 522 Study (NCT02162615); cohort study; US, Australia, Canada and the Netherlands; estimated enrolment=892; start date August 2014; estimated completion date April 2019.
  - Prospective Randomized Trial of Anterior Colporrhaphy Versus Cystocele Repair Using Polypropylene Mesh or Porcine Dermis (NCT01393171); RCT; US; estimated enrolment=100; start date October 2005; estimated study completion date December 2017.
  - Comparisons of Clinical Outcomes Between Novel Tailored Transvaginal Mesh Surgery and Vaginal Native Tissue Repair Surgery for Pelvic Organ Prolapse (NCT02465710); observational case only study; Taiwan; estimated enrolment=350; start date April 2015; estimated study completion date April 2016.
  - Evaluation of the Use of Transvaginal Resorbable Biologic Mesh as Compared to Traditional Non-Mesh Surgical Repair for Treating Pelvic Floor

Disorders (NCT02021279); non-randomised study; US; estimated enrolment=162; start date June 2014; estimated completion date January 2020.

- Randomized Controlled Trial Comparing Laparoscopic Sacropexy and Vaginal Mesh Surgery for Women Cystocele Repair: Functional and Anatomical Results at Four Years Follow-up (NCT02272361); RCT; France; estimated enrolment 262; start date October 2014; estimated study completion date December 2019.

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11. 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

12. SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), The safety of surgical meshes used in urogynecological surgery, 3 December 2015

Appendix A: Additional papers on surgical repair of vaginal wall prolapse using mesh

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.

Case series with fewer than 100 patients were excluded unless follow-up was longer than 4 years. Studies that were published before the search date of the systematic review (July 2007) that was commissioned for the 2008 NICE guidance are not included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Abbott S, Unger CA, Evans JM et al. (2014) Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. American journal of obstetrics and gynecology 210: 163.e1-8	Case series n=347	Patients with transvaginal mesh or sacrocolpopexy were more likely to have mesh erosion and vaginal symptoms compared with sling only. The median number of treatments for mesh complications was 2 (range, 1-9); 60% of the women required ≥2 interventions. Initial treatment intervention was surgical for 49% of patients. Of those that initially were managed nonsurgically, 59% went on to surgical intervention.	The study includes complications after a number of different prolapse repair procedures.
Abdel-Fattah M, Ramsay I, West of Scotland Study, and Group (2008) Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse. BJOG : an international journal of obstetrics and gynaecology 115: 22-30	Non-randomised comparative study n=329 FU=3 months	Operative complications included: bladder injury (2%), rectal injury (1%) and 2 women with serious vascular injuries. Postoperative complications included: buttock pain (5%), vaginal erosion (10%), 1 woman with bladder erosion and 2 women (1%) with serious infection, leading to necrotising fasciitis in 1 woman. Short-term cure rates in different groups varied from 94 to 100%, depending on vaginal compartment and device used. In total 15 women (5%) had persistent prolapse at 3-month follow-up.	Studies with more patients or longer follow-up are included.
Allahdin S, Glazener C, Bain C. (2008) A randomised controlled trial evaluating the use of polyglactin mesh, polydioxanone and polyglactin sutures for pelvic organ prolapse surgery. Journal of Obstetrics and Gynaecology 28:427–31	RCT n=73 FU=6 months	There were no significant differences in the mean difference in prolapse symptoms and quality-of-life scores according to the randomised groups. The majority (86%) of women were satisfied with their surgery.	Study is included in the systematic review by Maher C et al. (2016).

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Alperin M, Sutkin G, Ellison R et al. (2008) Perioperative outcomes of the Prolift pelvic floor repair systems following introduction to a urogynecology teaching service. International urogynecology journal and pelvic floor dysfunction 19: 1617-22	Case series n=100	Complications included bladder perforation (2%), blood transfusion (2%), mesh exposure (4%), and urinary tract infections (28%). 11% of women reported postoperative pain, and 34% needed catheterisation at discharge for incomplete bladder emptying.	Studies with more patients or longer follow-up are included.
Altman D, Falconer C (2007) Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair. Obstetrics and Gynecology 109: 303-308	Case series n=248	Serious complications occurred in 4% of patients (n=11) and were dominated by visceral injury (10 of 11 cases). One case of bleeding in excess of 1,000 ml occurred. Minor complications occurred in 15% of patients (n=36), and the majority were urinary tract infections, urinary retention, and postoperative fever.	Studies with more patients or longer follow-up are included.
Altman D, Vayrynen T, Engh ME et al. (2008) Short-term outcome after transvaginal mesh repair of pelvic organ prolapse. International urogynecology journal and pelvic floor dysfunction 19: 787-93	Case series n=123 FU=2 months	There were 2 cases of mesh exposure, an increase of mild-moderate granuloma formation in the operated areas ($p<0.003$) but no cases of serious adverse tissue reactions related to the polypropylene mesh. Postoperative anatomical cure (defined as POP-Q stage 0-1) was 87% after anterior repair, 91% after posterior repair and 88% after total repair. All quality-of-life aspects measured by the IIQ-7 improved 2 months after surgery. Pelvic heaviness, vaginal bulging, and vaginal protrusion all decreased considerably ($p<0.001$). There was also a significant improvement in several lower urinary tract symptoms and a decreased need for manually assisted defaecation.	Studies with more patients or longer follow-up are included.
Altman D, Elmer C, Kiilholma P et al. (2009) Sexual dysfunction after trocar-guided transvaginal mesh repair of pelvic organ prolapse. Obstetrics and gynecology 113: 127-33	Case series n=105 FU=12 months	Overall sexual function scores worsened from 15.5 (SD 8.0) at baseline to 11.7 (SD 6.9) 1 year after surgery ($p<0.001$).	Studies with more patients or longer follow-up are included.
Altman D, Vayrynen T, Engh ME et al. (2011) Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. The New England journal of medicine 364: 1826-36	RCT n=389 FU=12 months	As compared with anterior colporrhaphy, use of a standardised, trocar-guided mesh kit for cystocele repair resulted in higher short-term rates of successful treatment but also in higher rates of surgical complications and postoperative adverse events.	Study is included in the systematic review by Maher C et al., 2016.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Andy UU, Harvie HS, Ackenbom MF et al. (2014) Single versus multi-dose antibiotic prophylaxis for pelvic organ prolapse surgery with graft/mesh. European Journal of Obstetrics, Gynecology, and Reproductive Biology 181: 37-40	Case series n=460	A single-dose antibiotic regimen is sufficient for prophylaxis against postoperative infections in women undergoing prolapse surgery with graft/mesh.	Study focuses on antibiotic prophylaxis regimen.
Anger JT, Khan AA, Eilber KS et al. (2014) Short-term outcomes of vaginal mesh placement among female Medicare beneficiaries. Urology 83: 768-73	Non-randomised comparative study n=18,713 (1,804 with mesh versus 16,909 without mesh) FU=1 year	Prolapse re-operation within 1 year of surgery was higher in non-mesh versus mesh cohorts (6 to 7% versus 4%, p<0.02). Mesh removal rates were higher in mesh versus non-mesh group (4% versus 0 to 1%, p<0.001). Mesh use was associated with more dyspareunia, mesh-related complications, and urinary retention, even when controlling for concomitant sling.	Study includes different types of prolapse and different techniques for prolapse repair.
Araco F, Gravante G, Sorge R et al. (2009) The influence of BMI, smoking, and age on vaginal erosions after synthetic mesh repair of pelvic organ prolapses. A multicenter study. Acta obstetricia et gynecologica Scandinavica 88: 772-80	Case series n=460	Postoperative erosions were present in 7% of patients. Body mass index greater than 30 conferred a 10.1-fold increase in the risk of developing erosions, smoking a 3.7-fold increase, and age greater than 60 years a 2.2-fold increase.	Study focuses on the effect of body mass index, age and smoking on the risk of erosions.
Araco F, Gravante G, and Piccione E (2009) Bladder erosion after 2 years from cystocele repair with type I polypropylene mesh. International Urogynecology Journal and Pelvic Floor Dysfunction 20: 731-733	Case report n=1	**Bladder erosion** Bladder erosion manifested 2 years after initial cystocele repair surgery with type 1 polypropylene mesh.	Case report of adverse event that is already reported in table 2.
Ashok K, Wang A (2013) Customised mesh. Current Women's Health Reviews 9: 131-138	Review n=89 papers	In the anterior compartment, anatomical failure rate for custom mesh is around 17%, and that of subjective failure rate is around 4%. The risk of vaginal exposure for custom mesh ranges from 5 to 17%. New onset of dyspareunia was noted in 5% to 17% of patients. In terms of efficacy, custom mesh gives equally good success comparable to that of pre-designed mesh kits. Complication rates are similar between custom meshes and pre-designed mesh kits, with the exception of reduced blood loss in custom meshes.	Review focuses on the use of customised mesh versus pre-designed mesh kits.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Bai SW, Jung HJ, Jeon MJ et al. (2007) Surgical repair of anterior wall vaginal defects. International Journal of Gynaecology & Obstetrics 98: 147-50	Non-randomised comparative study n=138 FU=1 year	Transvaginal surgical repair seems to be more efficacious than internal surgical repair for central types of anterior vaginal wall defects.	Non-randomised study with relatively short-term follow-up.
Balchandra P, Marsh F, Landon C (2015) Perioperative outcomes and prospective patient-reported outcome measures for transvaginal mesh surgery. Archives of gynecology and obstetrics 292: 875-82	Case series n=159	98% (156/159) of patients did not have any intraoperative complications. 1 patient had a bladder injury. Mesh exposure was noted in 4% (6/135) at follow-up with overall re-operation rate of 9% (13/135). Statistically significant improvement in most arms of the ICIQ-VS questionnaire was noted in a cohort of 51 patients at follow-up.	Studies with more patients or longer follow-up are included.
Bartley JM, Sirls LT, Killinger KA et al. (2015) Secondary surgery after vaginal prolapse repair with mesh is more common for stress incontinence and voiding dysfunction than for mesh problems or prolapse recurrence. International urology and nephrology 47: 609-15	Case series n=335	77/335 women (23%) had 100 additional procedures. Median (range) time to re-operation was 51 (5-1168) days: 4 (1%) had primary prolapse surgery at a different site, 3 (1%) repeat prolapse repair from the same site, 23 (7%) surgery for complications and 50 (15%) had stress urinary incontinence (SUI)/sling-related procedures.	Studies with more patients or longer follow-up are included.
Bartuzi A, Futyma K, Kulik-Rechberger B et al. (2013) Self-perceived quality of life after pelvic organ prolapse reconstructive mesh surgery: prospective study. European Journal of Obstetrics, Gynecology, and Reproductive biology 169: 108-12	Case series n=113 FU=16 to 18 months	Reconstructive mesh surgery improved significantly various self-perceived quality-of-life dimensions. Therefore, women should expect significant improvement in their general quality of life after this type of operation.	Studies with more patients or longer follow-up are included.
Benbouzid S, Cornu JN, Benchikh A et al. (2012) Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow-up. International Journal of Urology 19: 1010-6	Case series n=75 FU=mean 54 months	At last follow-up, 64 (85%) patients were cured, with no prolapse recurrence. Mesh exposure occurred in 4 (5%) patients. The Pelvic Floor Distress Inventory-20 symptom score was low at last follow-up (median 8, range 3 to 18), in accordance with objective cure data.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Bjelic-Radisic V, Aigmueller T, Preyer O et al. (2014) Vaginal prolapse surgery with transvaginal mesh: Results of the Austrian registry. International Urogynecology Journal and Pelvic Floor Dysfunction 25: 1047-1052	Registry data n=726 FU=12 months	Intra- and perioperative complications were reported in 7% of patients. The most common complication was increased intraoperative bleeding (2%). Bladder and bowel perforation occurred in 6 (0.8%) and 2 (0.3%) cases. Mesh exposure was seen in 11% at 3 and in 12% at 12 months. 24 (10%) previously asymptomatic patients developed bowel symptoms by 1 year. De novo bladder symptoms were reported in 39 (10%) at 3 and in 26 (11%) at 12 months. Dyspareunia was reported by 7% and 10% of 265 and 181 sexually active patients at 3 and 12 months postoperatively respectively.	Drop-out rates were 45% at 3 months and 68% at 1-year follow-up.
Bontje HF, van de Pol G, van der Zaag-Loonen HJ et al. (2014) Follow-up of mesh complications using the IUGA/ICS category-time-site coding classification. International Urogynecology Journal 25: 817-22	Case series n=107 FU=median 36 months	Perioperative complications (6%) included haemorrhage and bladder perforation. Six patients had surgery for symptomatic mesh exposure or local pain. At secondary follow-up exposure was diagnosed in another 4 patients (12%). In 36% mesh wrinkling or shrinkage was discovered, although without complaints in most. Eight women had daily complaints or dyspareunia. 82% of patients indicated strong improvement after surgery.	Studies with more patients or longer follow-up are included.
Buca DIP, Leombroni M, Falo E et al. (2016) A 2-Year Evaluation of Quality-of-Life Outcomes of Patients with Pelvic Organ Prolapse Treated with an Elevate Prolapse Repair System. Female Pelvic Medicine and Reconstructive Surgery 2: 410-414	Case series n=116 FU=2 years	Patient's quality of life improved substantially following prosthetic vaginal surgery. In particular, a clear improvement in the "general state of patients health" ($p<0.05$), and a reduction in the daily physical, social, and psychological quality of life ($p<0.05$) connected to the prolapse of pelvic organ were observed. Furthermore, a significant reduction in the percentage of patients with urinal disturbances (86% preoperative vs 21% postoperative; $p<0.05$), and an improvement in patient's relations with their partners with 12 patients resuming sexual activity were found.	Studies with more patients or longer follow-up are included.
Cao Q, Chen YS, Ding JX et al. (2013) Long-term treatment outcomes of transvaginal mesh surgery versus anterior-posterior colporrhaphy for pelvic organ prolapse. Australian and New Zealand Journal of Obstetrics and Gynaecology 53: 79-85	Non-randomised comparative study n=158 FU=median 55 months	Anatomical success rate for mesh surgery (MPFR) and anterior-posterior colporrhaphy (APC) was 88% versus 65% ($p=0.001$). Both operations significantly improved quality of life, and a greater improvement was seen in MPFR group than in APC group ($p=0.013$). Complication rates did not differ significantly between the 2 groups. The mesh erosion rate was 4%.	Retrospective non-randomised cohort study.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Caquant F, Collinet P, Debodinance P et al. (2008) Safety of Trans Vaginal Mesh procedure: Retrospective study of 684 patients. Journal of Obstetrics and Gynaecology Research 34: 449-456	Case series n=684 FU=mean 3.6 months	Peri-surgical complications: 5 bladder wounds (0.7%), 1 rectal wound (0.2%) and 7 haemorrhages greater that 200 ml (1%). Early post-surgical complications (during the first month after surgery): 2 pelvic abscesses (0.3%), 13 pelvic hematomas (2%), 1 pelvic cellulitis (0.2%), 2 vesicovaginal fistulas and 1 rectovaginal fistula (0.2%). Late post-surgical complications: 77 granulomas or prosthetic expositions (11% [7% in the vaginal anterior wall, 2% in the vaginal posterior wall and 5% in the fornix]), 80 prosthetic retractions (12%), 36 relapse of prolapse (7%) and 37 de novo stress urinary incontinence (5%).	Retrospective case series with short-term follow-up. More recent studies are included.
Carey M, Higgs P, Goh J et al. (2009) Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. BJOG : an international journal of obstetrics and gynaecology 116: 1380-6	RCT n=139 FU=12 months	Success in the mesh group was 81% (51/63) compared with 66% (40/61) in the no mesh group (p=0.07). A high level of satisfaction with surgery and improvements in symptoms and quality-of-life data were observed at 12 months compared to baseline in both groups, but there was no significant difference in these outcomes between the 2 groups. Vaginal mesh exposure occurred in 4 women in the mesh group (6%). De novo dyspareunia was reported by 5 of 30 (17%) sexually active women in the mesh group and 5 of 33 (15%) in the no mesh group at 12 months.	Study is included in the systematic review by Maher C et al., 2016.
Chang TC, Hsiao SM, Chen CH et al. (2015) Clinical Outcomes and Urodynamic Effects of Tailored Transvaginal Mesh Surgery for Pelvic Organ Prolapse. BioMed Research International Article ID 191258	Case series n=104 FU=median 26 months	The anatomic cure rate was 98% (102/104). Mesh extrusion (n=4), vaginal hematoma (n=3), and voiding difficulty (n=2) were noted postoperatively. Quality of life was substantially improved. Anterior transvaginal mesh surgery additionally provided an anti-incontinence effect.	Studies with more patients or longer follow-up are included.
Chen YS, Cao Q, Ding JX, et al. (2012) Midterm prospective comparison of vaginal repair with mesh vs Prolift system devices for prolapse. European Journal of Obstetrics Gynecology and Reproductive Biology 164: 221-6	Non-randomised comparative study n=223 FU=median 36 months	Anatomic success for modified pelvic floor reconstructive surgery with mesh (MPFR) and Prolift was 87% and 93%, respectively (p=0.1339). Both operations significantly improved quality of life, and PFDI-20 scores were lower in the Prolift group than the MPFR group (p=0.03). Complication rates did not differ significantly between the 2 groups and the prevalence of urinary symptoms decreased postoperatively in both groups.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Chmielewski L, Walters MD, Weber AM et al. (2011) Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success. American journal of obstetrics and gynecology 205: 69.e1-8	RCT n=114 FU=median 26 months	88% of patients met the definition of success at 1 year. One patient had re-operation for recurrence 29 months after surgery. No differences among the 3 groups were noted for any outcomes. Reanalysis of a trial of 3 methods of anterior colporrhaphy revealed considerably better success with the use of clinically relevant outcome criteria compared with strict anatomic criteria.	Secondary analysis of a study that is included in the systematic review by Maher C et al. (2016).
Choi J, Nguyen V, Snyder M et al. (2012) Complex rectovaginal fistulas after posterior compartment repair with synthetic mesh: Identification and management of this devastating complication. Neurourology and Urodynamics 31: 268	Case series n=7 FU=median 13 months	**Complex rectovaginal fistulas** Time to presentation was 9 to 960 days after prolapse repair. Presenting symptoms included: drainage of stool in the vagina (4), rectal bleeding (2), dyspareunia (2), vaginal bleeding (1), rectal pain (1), dyschezia (1), and mesh protruding from anus (1). Mesh was palpated in the rectum in 5 patients. Patients needed a median 3 (range 1-5) procedures for definitive repair. Diverting ileostomy was necessary in 4 of 7 patients; 1 patient refused. Two patients have persistent fistulas on follow-up; 1 is still diverted and long-term colostomy is planned.	Fistula is already described as an adverse event.
Chughtai B, Barber MD, Mao J et al. (2016) Association Between the Amount of Vaginal Mesh Used With Mesh Erosions and Repeated Surgery After Repairing Pelvic Organ Prolapse and Stress Urinary Incontinence. JAMA Surg	Non-randomised comparative study n=41,604 FU=1 year	The highest risk of erosions was found in the vaginal mesh plus sling group (2.7%; 95% CI, 2.3% to 3.2%) and the lowest in the SUI sling group (1.6%; 95% CI 1.4% to 1.7%). The risk of repeated surgery with concomitant erosion diagnosis was also the highest in the vaginal mesh plus sling group (2.1%; 95% CI 1.8% to 2.6%) and the lowest in the SUI sling group (1.2%; 95% CI 1.0% to 1.3%).	This study includes women treated for stress urinary incontinence only as well as those treated for prolapse. A more relevant study by the same authors is included in table 2.
Chughtai B, Sedrakyan A, Mao J et al. (2016) Is Vaginal Mesh a stimulus of autoimmune disease?. Am J Obstet Gynecol	Non-randomised comparative study n=2,102 patients with mesh-based POP surgery FU=up to 6 years	In the control cohorts, 37,298 patients underwent colonoscopy and 7,338 underwent vaginal hysterectomy. When patients were matched based on demographics, comorbidities and procedure time, mesh-based surgery was not associated with an increased risk of developing autoimmune disease at any of the evaluated time periods.	Study focuses on the risk of developing autoimmune disease after mesh-based surgery.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Cooper JC, Bondili A, Deguara C et al. (2013) Vaginal repair with polypropylene mesh compared to traditional colporrhaphy for pelvic organ prolapse: Medium-term follow-up. Journal of Gynecologic Surgery 29: 1-6	Non-randomised comparative study n=85 FU=up to 3 years	There were significant improvements with mesh compared with traditionally treated patients only with regard to vaginal soreness and dragging pain. In the mesh group, the exposure rate was 10% (n=4). Both groups had statistically significant improvements in all their postoperative symptoms except for the symptoms of vaginal dryness and vaginal sensation in the traditional group.	Small, non-randomised comparative study.
Culligan PJ, Littman PM, Salamon CG et al. (2010) Evaluation of a transvaginal mesh delivery system for the correction of pelvic organ prolapse: subjective and objective findings at least 1 year after surgery. American journal of obstetrics and gynecology 203: 506.e1-6	Case series n=120 FU=mean 14 months	Surgical cure rate was 81%. Mesh erosion and de novo pain occurred in 12% and 3%, respectively. Pelvic Floor Distress Inventory, Short Form 20/Pelvic Floor Impact Questionnaire, Short Form 7 scores improved ($p<0.01$).	Studies with more patients or longer follow-up are included.
Dahlgren E, Kjolhede P, and Group Rpop-Pelvicol Study (2011) Long-term outcome of porcine skin graft in surgical treatment of recurrent pelvic organ prolapse. An open randomized controlled multicenter study. Acta obstetricia et gynecologica Scandinavica 90: 1393-401	RCT n=132 FU=3 years	With the surgical technique used in this study, Pelvicol did not provide advantages over conventional colporrhaphy in recurrent pelvic organ prolapse concerning anatomical and subjective outcomes.	Study is included in the systematic review by Maher C et al., 2016.
Damiani GR, Riva D, Pellegrino A et al. (2016) Conventional fascial technique versus mesh repair for advanced pelvic organ prolapse: Analysis of recurrences in treated and untreated compartments. Journal of Obstetrics and Gynaecology 36: 410-415	RCT n=117 FU=2 years	Anatomic failure=19% (11/58) of patients in the mesh group and in 27% (16/59) of patients ($p=0.3$) in the conventional group. 9 of 11 failures in the mesh group (16%) were observed in the untreated compartment (de novo recurrences), 14% in Pelvisoft and 17% in Avaulta arm, while only 1 recurrence in the untreated compartment (2%) was observed in the conventional group (odds ratio 10.6, $p=0.03$).	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Dass AK, Lo TS, Khanuengkitkong S et al. (2013) A delayed type of ureteric injury developed after transobturator mesh procedure for massive prolapse. Female Pelvic Medicine and Reconstructive Surgery 19: 179-180	Case report n=1	**Hydroureteronephrosis and ureterovaginal fistula** The patient had continuous leakage of urine per vagina 28 days after vaginal hysterectomy, mesh-augmented anterior repair and sacrospinous ligament fixation for stage IV pelvic organ prolapse. CT scan revealed an intact bladder, right hydroureteronephrosis, and right ureterovaginal fistula. Immediate laparotomy revealed that the right lower mesh arm was entangled with the distal end of the right ureter. Right ureteric reimplantation was done.	Ureter damage and fistula are already described as adverse events.
Davila GW, Guerette NL, Peterson TV et al. (2009) Anterior repair with or without collagen matrix reinforcement. Obstetrics and gynecology 114: 59-65	RCT n=94 FU=2 years	The use of bovine pericardium graft for anterior vaginal prolapse does not have higher complication rates or healing difficulties. At 1- and 2-year follow-up, anterior colporrhaphy with bovine pericardium reinforcement did not show a statistically significant improvement over colporrhaphy alone.	Study is included in the systematic review by Maher C et al., 2016.
de Boer TA, Kluivers KB, Withagen MIJ et al. (2010) Predictive factors for overactive bladder symptoms after pelvic organ prolapse surgery. International urogynecology journal 21: 1143-9	Case series n=505 FU=median 13 months	Bothersome overactive bladder (OAB) symptoms decreased after POP surgery. De novo bothersome OAB symptoms appeared in 5 to 6% of the women. Frequency and urgency were more likely to improve as compared with urge incontinence and nocturia. The best predictor for the absence of postoperative symptoms was the absence of preoperative bothersome OAB symptoms.	Study focuses on overactive bladder symptoms.
De Landsheere L, Ismail S, Lucot JP et al. (2012) Surgical intervention after transvaginal Prolift mesh repair: Retrospective single-center study including 524 patients with 3 years' median follow-up. American Journal of Obstetrics and Gynecology 206: 83.e1–7	Case series n=524 FU=median 3 years	Global re-operation rate was 12%. Indications of intervention were surgery for urinary incontinence (7%), mesh-related complications (4%), or prolapse recurrence (3%).	Retrospective single-centre study, which includes patients with any type of prolapse (stage II or more).
De Tayrac R, Sentilhes L (2013) Complications of pelvic organ prolapse surgery and methods of prevention. International Urogynecology Journal and Pelvic Floor Dysfunction 24: 1859-1872	Review	Transvaginal mesh has a higher re-operation rate than native tissue vaginal repairs. If a synthetic mesh is placed via the vaginal route, it is recommended that a macroporous polypropylene monofilament mesh should be used.	A more recent systematic review is included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
de Tayrac R, Cornille A, Eglin G et al. (2013) Comparison between transobturator transvaginal mesh and traditional anterior colporrhaphy in the treatment of anterior vaginal wall prolapse: results of a French RCT. International urogynecology journal 24: 1651-61	RCT n=147 FU=12 months	The anatomical success rate was significantly higher in the mesh group (89%) than in the colporrhaphy group (64%) (p=0.0006). Anatomical and functional recurrence was less frequent in the mesh group (31% vs 52%, p=0.007). 2 patients were re-operated on in the colporrhaphy group for anterior vaginal wall prolapse recurrence. No significant difference was noted regarding minor complications. Erosion rate=9.5%. De novo dyspareunia occurred in 1 patient in the colporrhaphy group and in 3 patients in the mesh group. There was an overall improvement in quality of life in both groups, with no statistical difference between them. Satisfaction rates were high in both groups (92% in the colporrhaphy group and 96% in the mesh group).	Study is included in the systematic review by Maher C et al., 2016.
de Tayrac R, Brouziyne M, Priou G et al. (2015) Transvaginal repair of stage III-IV cystocele using a lightweight mesh: safety and 36-month outcome. International Urogynecology Journal and Pelvic Floor Dysfunction 8: 1147-1154	Case series n=111 FU=36 months	2 intraoperative complications occurred (1 bladder and 1 rectal injury, 2%). Medium-term analysis of 79 patients (84%) showed a satisfaction rate of 99% (78/79), a mesh contraction rate of 5% (4/78), 1 vaginal mesh exposure (1%), no cases of chronic pelvic pain, and a postoperative dyspareunia rate of 3% (1/36). The anatomic success rate of cystocele repair was 75/79 (95%) and a highly significant improvement was noted for symptoms and on quality of life questionnaires. Overall, 7/79 patients (9%) had repeat surgery; 1 for haemorrhage, 1 for vaginal mesh exposure, 3 for stress urinary incontinence, and 2 for cystocele recurrence (3%).	Studies with more patients or longer follow-up are included.
Deffieux X, Thubert T, de Tayrac R et al. (2012) Long-term follow-up of persistent vaginal polypropylene mesh exposure for transvaginally placed mesh procedures. International urogynecology journal 23: 1387-90	Case series n=9 FU=median 121 months	**Persistent mesh exposure** The median surface area of vaginal mesh exposure (1 cm^2) did not change significantly during the follow-up. No pelvic or perineal abscess occurred during the follow-up. Only 1 patient was sexually active; she complained of dyspareunia at the last follow-up, but refused renewed surgery since she had sexual intercourse on only a small number of occasions per year.	Small case series of patients with persistent vaginal mesh exposure.

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Delroy CA, Castro R de A, Dias MM et al. (2013) The use of transvaginal synthetic mesh for anterior vaginal wall prolapse repair: a randomized controlled trial. International urogynecology journal 24: 1899-907	RCT n=79 FU=1 year	Anatomical success rates for colporrhaphy and repair with mesh placement groups were 56% vs 83%, respectively (p=0.018). Similar total complication rates were observed in both groups, with tape exposure observed in 5% of the patients. There was a significant improvement in all P-QOL domains as a result of both procedures (p<0.001).	Study is included in the systematic review by Maher C et al., 2016.
Demirci F, Birgul K, Demirci O et al. (2013) Perioperative complications in vaginal mesh procedures using trocar in pelvic organ prolapse repair. Journal of obstetrics and gynaecology of India 63: 328-31	Case series n=120	Three bladder injuries (2.5%) and 1 distal rectal injury (0.8%) occurred during dissection. Three of 4 organ injuries (75%) had previous prolapse repair. Overall 4 patients (3%) needed transfusion. Urinary retention exceeding 5 days occurred in 4 patients. Three of them (60%) also underwent TVT-O. Groin pain occurred in 2 patients, 1 of whom underwent TVT-O. Gluteal pain occurred in 1 patient. Early mesh exposure occurred in the vaginal cuff of a patient who had a hysterectomy.	Studies with more patients or longer follow-up are included.
Dietz V, Maher C (2013) Pelvic organ prolapse and sexual function. International urogynecology journal 24: 1853-7	Review	With regard to the anterior compartment, the use of mesh is associated with neither a worsening in sexual function nor an increase in de novo dyspareunia compared with traditional anterior colporrhaphy. There is insufficient information to provide evidence-based recommendations on sexual function after vaginal mesh in the posterior compartment or after new lightweight or absorbable meshes.	A more recent systematic review is included.
dos Reis Brandao da Silveira S, Haddad J, Jarmy-Di Bella Zik et al. (2014) Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. International urogynecology journal and pelvic floor dysfunction 26: 335-42	RCT n=184 FU=1 year	Both techniques were effective. Anatomical efficacy was superior in the mesh group regarding the anterior compartment; quality-of-life changes were also greater in the mesh group. Complications were significantly higher in the mesh group.	Study is included in the systematic review by Maher C et al., 2016.
Eboue C, Marcus-Braun N, von Theobald P (2010) Cystocele repair by transobturator four arms mesh: monocentric experience of first 123 patients. International urogynecology journal 21: 85-93	Case series n=123 FU=1 year	Perioperative complications occurred in 6 patients. After 1 year, erosion rate was 6.5%, and 3 cystoceles recurred. After treatment of SUI with the same mesh, 88% restored continence. Overall patient satisfaction rate was 94%.	Studies with more patients or longer follow-up are included.

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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: 357-61	Non-randomised comparative study n=336	Concomitant hysterectomy was positively associated with mesh extrusion among women who had abdominal sacral colpopexy (adjusted odds ratio, 3.2; 95% confidence interval, 1.3 to 7.9; p=0.01) and vaginal mesh procedure (adjusted odds ratio, 3.7; 95% confidence interval, 1.2 to 11.5; p=0.02). Age, race, type of vaginal incision, menopausal status, medical comorbidities, and smoking were not significantly associated with extrusion in either group.	Studies with more patients or longer follow-up are included.
Ek M, Altman D, Falconer C et al. (2010) Effects of anterior trocar-guided transvaginal mesh surgery on lower urinary tract symptoms. Neurourology and urodynamics 29: 1419-23	Case series n=121 FU=1 year	Trocar-guided transvaginal mesh surgery for anterior vaginal wall prolapse was associated with an overall resolution of most symptoms associated with overactive bladder syndrome and bladder outlet obstruction. These beneficial effects should be weighed against an increased risk for stress urinary incontinence related to the procedure.	Studies with more patients or longer follow-up are included.
Ek M, Tegerstedt G, Falconer C et al. (2010) Urodynamic assessment of anterior vaginal wall surgery: a randomized comparison between colporraphy and transvaginal mesh. Neurourology and urodynamics 29: 527-31	RCT n=50 FU=2 months	De novo stress urinary incontinence was significantly more common after trocar-guided transvaginal mesh surgery compared to colporraphy. In comparison to baseline urodynamics, transvaginal mesh surgery resulted in a significant decrease in maximal urethral closing pressures whereas conventional anterior colporraphy had no significant effect on urodynamic parameters.	Studies with more patients or longer follow-up are included.
Ek M, Altman D, Gunnarsson J et al. (2013) Clinical efficacy of a trocar-guided mesh kit for repairing lateral defects. International Urogynecology Journal and Pelvic Floor Dysfunction 24: 249-254	RCT n=99 FU=1 year	Use of a transvaginal mesh kit increases the odds for anatomical correction of lateral defects compared with anterior colporrhaphy but does not necessarily improve lower urinary tract symptoms.	Studies with more patients or longer follow-up are included.
El-Khawand D, Wehbe SA, O'Hare PG et al. (2014) Risk factors for vaginal mesh exposure after mesh-augmented anterior repair: a retrospective cohort study. Female pelvic medicine & reconstructive surgery 20: 305-9	Case series n=201 FU=mean 14 months	Concomitant total hysterectomy is an independent risk factor for mesh exposure after mesh-augmented anterior repair, whereas BMI may negatively correlate with exposure rates.	Studies with more patients or longer follow-up are included.

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Ellington DR, Richter HE (2013) The role of vaginal mesh procedures in pelvic organ prolapse surgery in view of complication risk. Obstetrics and gynecology international 2013, 356960	Review	A wide spectrum of potential complications exist with the use of transvaginal mesh in POP surgery. Rare, but severe complications, including death, fistula formation, and mesh erosion into adjacent organs, have been reported in the MAUDE database. Three of 7 deaths were related directly to mesh placement procedures and included 2 bowel perforations and 1 haemorrhage. Vesicovaginal fistula formation after the use of synthetic transvaginal mesh in the anterior compartment as well as retrovesical hematoma formation and mesh erosions into the bladder have also been reported.	Non-systematic review. More recent studies are included.
Elmer C, Altman D, Engh ME et al. (2009) Trocar-guided transvaginal mesh repair of pelvic organ prolapse. Obstetrics and gynecology 113: 117-26	Case series n=261 FU=1 year	Anatomic cure=79% (96/121) after anterior repair with mesh (p<0.001), and 82% (56/68) after posterior repair with mesh (p<0.001). For combined anterior and posterior mesh repair, cure was 81% (51/63) and 86% (54/63) for the anterior and posterior compartment, respectively (p<0.001 for both). Bladder and rectal perforations occurred in 3% (9/252) of patients. Vaginal erosions, the majority mild to moderate, occurred in 11% (26/232) of patients. Surgical intervention because of mesh exposure occurred in 7 patients (3%). There were significant quality-of-life improvements in all domains of the IIQ-7.	Study is included in Barski et al. (2013) systematic review.
Elmer C, Falconer C, Hallin A et al. (2012) Risk factors for mesh complications after trocar-guided transvaginal mesh kit repair of anterior vaginal wall prolapse. Neurourology and urodynamics 31: 1165-9	Case series n=353 FU=1 year	Mesh exposures, of which the majority were mild-moderate, occurred in a total of 30/349 patients (9%). Multivariate logistic regression showed increased odds for mesh exposures for women who smoked before surgery (OR 3.48, 95% CI 1.18 to 10.28), who had given birth to more than 2 children (OR 2.64, 95% CI 1.07 to 6.51) and those with somatic inflammatory disease (OR 5.11, 95% CI 1.17 to 22.23). Age, body mass index, and menopausal status showed no significant association with clinical mesh exposures.	Studies with more patients or longer follow-up are included.
El-Nazer MA, Gomaa IA, Ismail M et al. (2012) Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study. Archives of gynecology and obstetrics 286: 965-72	RCT n=44 FU=24 months	Repair with mesh is superior to anterior colporrhaphy with more satisfactory outcome to the patients.	Studies with more patients or longer follow-up are included.

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Falagas ME, Velakoulis S, Iavazzo C et al. (2007) Mesh-related infections after pelvic organ prolapse repair surgery. European journal of obstetrics, gynecology, and and reproductive biology 134: 147-56	Review	The incidence of mesh-related infections and erosion ranged from 0 to 8%, and 0 to 33%, respectively, in the published studies. Non-specific pelvic pain, persistent vaginal discharge or bleeding, dyspareunia, and urinary or faecal incontinence are the most common manifestation of vaginal mesh-related infection. Various pathogens have been implicated, including Gram-positive and Gram-negative aerobic and anaerobic bacteria.	More recent studies are included.
Farthmann J, Watermann D, Niesel A et al. (2013) Lower exposure rates of partially absorbable mesh compared to non-absorbable mesh for cystocele treatment: 3-year follow-up of a prospective randomized trial. International urogynecology journal 24: 749-58	RCT n=200 FU=3 years	Mesh exposure rate was smaller in the group of the partially absorbable mesh. Over the course of time, mesh exposure was observed in 27 patients, with surgical intervention necessary in 11 patients. The rate of recurrent POP was higher ($p>0.05$) in patients with the partially absorbable mesh. The majority of patients were fully satisfied with the operation (53%) and had no pelvic floor pain (68%).	Study compares 2 different types of mesh.
Farthmann J, Mengel M, Henne B et al. (2016) Improvement of pelvic floor-related quality of life and sexual function after vaginal mesh implantation for cystocele: primary endpoint of a prospective multicentre trial. Archives of Gynecology & Obstetrics 294: 115-21	Case series n=289 FU=12 months	All domains of QoL improved significantly compared after surgery: mean prolapse score dropped from 73.7 to 19.4 after 6 and 16.2 after 12 months ($p<0.001$). Sexual function also improved significantly. The rate of dyspareunia was lower at follow-up.	Studies with more patients or longer follow-up are included.
Feiner B, O'Rourke P, Maher C (2012) A prospective comparison of two commercial mesh kits in the management of anterior vaginal prolapse. International Urogynecology Journal 23: 279-83	Non-randomised comparative study (2 mesh kits) n=106 FU=median 11months	At follow-up, objective success rates (Prolift, 89%; Perigee, 80%; $p=0.23$), subjective success rates (Prolift, 94%; Perigee, 96%; $p=0.62$), mean +/- SD patient satisfaction (Prolift, 8.2 +/- 2.0; Perigee, 8.2 +/- 1.8; $p=0.91$), and complication rates did not differ significantly between the 2 groups.	Small study comparing 2 different mesh kits.

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Feiner B, Maher C (2010) Vaginal mesh contraction: definition, clinical presentation, and management. Obstetrics and gynecology 115: 325-30	Case series n=17	**Vaginal mesh contraction** Clinical presentation included severe vaginal pain, dyspareunia and focal tenderness. Mesh erosion, vaginal tightness and shortening were frequently present. Surgical intervention consisted of mobilisation of the mesh from the underlying tissue, division of fixation arms from the central graft, and excision of contracted mesh. After surgery, 88% (15/17) of women had substantial reduction in vaginal pain and 64% (9/14) had substantial reduction in dyspareunia. Three women required subsequent excision of the entire accessible mesh because of persisting symptoms.	Small case series of women with vaginal mesh contraction.
Feldner Jr PC, Castro RA, Cipolotti LA et al. (2010) Anterior vaginal wall prolapse: A randomized controlled trial of SIS graft versus traditional colporrhaphy. International Urogynecology Journal and Pelvic Floor Dysfunction 21: 1057-1063	RCT n=56 FU=12 months	SIS group had 86% anatomic cure compared to 59% for traditional colporrhaphy (p=0.03). SIS improved point Ba measurement significantly (-1.93 cm versus-1.37 cm, p=0.02). Both operations significantly improved quality of life, although there were no differences between the groups. There were more complications in the SIS group, with no infections or erosion.	Study is included in the systematic review by Maher C et al., 2016.
Feldner PC Jr, Delroy CA, Martins SB et al. (2012) Sexual function after anterior vaginal wall prolapse surgery. Clinics (Sao Paulo, and Brazil) 67: 871-5	RCT n=56 FU=12 months	Small intestine submucosa repair and traditional colporrhaphy both improved sexual function postoperatively. However, no differences were observed between the 2 techniques.	Study is included in the systematic review by Maher C et al., 2016.
Finamore PS, Echols KT, Hunter K et al. (2010) Risk factors for mesh erosion 3 months following vaginal reconstructive surgery using commercial kits vs. fashioned mesh-augmented vaginal repairs. International urogynecology journal 21: 285-91	Case series n=124 FU=3 months	The overall erosion rate was 11%. There was a significantly lower erosion rate when using "commercial kits" vs. our traditional repairs (1% [1/69] vs. 24% [13/55]; p<0.001).	Studies with more patients or longer follow-up are included.

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Foon R, Toozs-Hobson P, Latthe P M (2008) Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. International urogynecology journal and pelvic floor dysfunction 19: 1697-706	Systematic review n=1,087 (10 RCTs)	Meta-analysis showed a lower risk of objective recurrence after 1 year in the patients having an anterior repair with a biological adjuvant material (odds ratio 0.56; 95% confidence interval 0.34 to 0.92) and absorbable synthetic adjuvant material (odds ratio 0.44; 95% confidence interval 0.21 to 0.89).	A more recent systematic review is included.
Frankman EA, Alperin M, Sutkin G et al. (2013) Mesh exposure and associated risk factors in women undergoing transvaginal prolapse repair with mesh. Obstetrics and gynecology international 926313	Case series n=201	Mesh exposure occurred in 12% (24/201) of patients. Median time to mesh exposure was 62 days (range: 10-372). When mesh was placed in the anterior compartment, the frequency of mesh exposure was higher than that when mesh was placed in the posterior compartment (9% versus 3%, p=0.04). Independent risk factors for mesh exposure were diabetes and surgeon.	Studies with more patients or longer follow-up are included.
Futyma K, Miotla P, Bartuzi A et al. (2014) Does a midurethral sling inserted at the time of pelvic organ prolapse mesh surgery increase the rate of de novo OAB? A prospective longitudinal study. Ginekologia polska 85: 652-7	Case series n=234 FU=12 months	Midurethral sling insertion at the time of pelvic organ prolapse surgery significantly decreases the rate of postoperative de novo overactive bladder symptoms. The lack of anatomical success of the mesh-based reconstructive surgery is a risk factor for the development of de novo overactive bladder symptoms.	Studies with more patients or longer follow-up are included.
Gandhi S, Goldberg RP, Kwon C et al. (2005) A prospective randomized trial using solvent dehydrated fascia lata for the prevention of recurrent anterior vaginal wall prolapse. American Journal of Obstetrics and Gynecology 192: 1649-54	RCT n=162	Sixteen women (21%) in the patch group and 23 (29%) in the control group experienced recurrent anterior vaginal wall prolapse (p=0.229). Only 26% of all recurrences were symptomatic.	Study is included in the systematic review by Maher C et al., 2016.

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Ganj FA, Chesson RR, Ibeanu OA et al. (2008) Complications associated with the use of transvaginal mesh in pelvic organ prolapse repair. Journal of Pelvic Medicine and Surgery 14: 277-278	Case series n=127 FU=mean 19 months	Mesh erosion rate=10%; significant correlation was observed between mesh erosion and concurrent vaginal hysterectomy (p=0.008, OR=6). There was also correlation between intraoperative bladder perforation and mesh erosion (p=0.028, OR=21). Parity and anterior vaginal mesh were risk factors for postoperative de novo urinary incontinence (p<0.05). Posterior vaginal mesh and parity were risk factors for the development of prolapse in the hitherto uninvolved pelvic compartment (p<0.05). Combined anterior and posterior vaginal mesh surgery increased the risk of intraoperative bleeding and need for blood transfusion (p<0.05).	Studies with more patients or longer follow-up are included.
Gauruder-Burmester A, Koutouzidou P, Rohne J et al. (2007) Follow-up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse. International urogynecology journal and pelvic floor dysfunction 18(9), 1059-64	Case series n=120 FU=1 year	Postoperatively, 112 (93%) women were free of vaginal prolapse, whereas 8 (7%) had level 2 defects.	Studies with more patients or longer follow-up are included.
Gold KP, Ward RM, Zimmerman CW et al. (2012) Factors associated with exposure of transvaginally placed polypropylene mesh for pelvic organ prolapse. International urogynecology journal 23: 1461-6	Non-randomised comparative study n=96	Bleeding complications at the time of mesh implantation were identified as a risk factor for mesh exposure requiring re-operation.	Studies with more patients or longer follow-up are included.
Gomelsky A, Haverkorn RM, Simoneaux WJ et al. (2007) Incidence and management of vaginal extrusion of acellular porcine dermis after incontinence and prolapse surgery. International urogynecology journal and pelvic floor dysfunction 18: 1337-41	Case series n=270	19 women (7%) had partial or complete vaginal graft extrusion. Two women underwent additional surgery to address extensive extrusion, and both prolapses recurred.	Studies with more patients or longer follow-up are included.

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Grgic O, Oreskovic S, Grsic H et al. (2012) Outcome and efficacy of a transobturator polypropylene mesh kit in the treatment of anterior pelvic organ prolapse. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 116: 72-5	Case series n=198 FU=12 months	The cure rate was 93% overall and 91% among women who had previously undergone a hysterectomy or a traditional anterior colporrhaphy. Vaginal or bladder erosions were observed in 3 patients. Other short- and long-term complications were infrequent and not statistically significant.	Studies with more patients or longer follow-up are included.
Guerette NL, Peterson TV, Aguirre OA et al. (2009) Anterior repair with or without collagen matrix reinforcement: a randomized controlled trial. Obstetrics and Gynecology 114: 59-65	RCT n=94 FU=2 years	One year after surgery, successful anterior vaginal wall support was obtained in 86% of the bovine pericardium graft group and 78% of anterior colporrhaphy-alone group (p=0.544). At 2 years, the success rate was 77% for the bovine pericardium graft group and 63% for anterior colporrhaphy-alone group (p=0.509). Postoperative Urogenital Distress Inventory-6 and Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire-12 scores were uniformly improved over baseline in both groups.	Study is included in the systematic review by Maher C et al., 2016.
Gupta B, Vaid NB, Suneja A et al. (2014) Anterior vaginal prolapse repair: A randomised trial of traditional anterior colporrhaphy and self-tailored mesh repair. South African Journal of Obstetrics and Gynaecology 20: 47-50	RCT n=106 FU=1 year	Postoperative outcome was significantly better than preoperative staging, but no significant difference was seen in the 2 groups. On follow-up, the primary endpoints did not differ significantly between the 2 groups. There were more complications in the mesh group. Satisfaction and acceptability were similar in the 2 groups.	Study is included in the systematic review by Maher C et al., 2016.
Gutman RE, Nosti P, Sokol A et al. (2013) Three-year outcomes of vaginal mesh for prolapse: a randomized controlled trial. Obstetrics and Gynecology 122: 770-7	RCT (mesh versus no mesh) n=65 FU=3 years	The study was prematurely halted as a result of a 16% mesh exposure rate. No differences were observed between groups at 3 years for prolapse stage or individual prolapse points. Stage improved for each group (90% and 86%) from baseline to 3 years (p<0.01). Symptomatic improvement was observed with no differences in scores between groups. Cure rates did not differ between groups using a variety of definitions, and anatomic cure was lowest for the anterior compartment.	Study is included in the systematic review by Maher C et al., 2016.

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Handel LN, Frenkl TL, Kim YH (2007) Results of Cystocele Repair: A Comparison of Traditional Anterior Colporrhaphy, Polypropylene Mesh and Porcine Dermis. Journal of Urology 178: 153-156	Non-randomised comparative study n=119 FU=mean 14 months	Based on the type of repair 36% of patients (20/56) with porcine dermal grafts had recurrence compared to 4% (1 /25) and 6% (1/18) using polypropylene and traditional repair, respectively. Mean time to cystocele recurrence was 5 months (range 0.5 to 20). A total of 12 patients (21%) had extrusion of porcine grafts through the anterior vaginal wall incision compared to 1 (4%) with polypropylene mesh.	Studies with more patients or longer follow-up are included.
Hefni M, Barry JA, Koukoura O et al. (2013) Long-term quality of life and patient satisfaction following anterior vaginal mesh repair for cystocele. Archives of gynecology and obstetrics 287: 441-6	Case series n=127 FU=1 to 3 years	Patients reported good current quality of life and high patient satisfaction. There were high quality-of-life scores at an average 2 years after anterior compartment mesh repair.	Studies with more patients or longer follow-up are included.
Heinonen P, Ala-Nissila S, Aaltonen R et al. (2011) Trocar-guided polypropylene mesh for pelvic organ prolapse surgery-perioperative morbidity and short-term outcome of the first 100 patients. Gynecological Surgery 8: 165-170	Case series n=100 FU=1 year	2 patients had perioperative bleeding of more than 1,000 ml, antibiotic treatment was needed in 28 patients and 2 hematomas were evacuated. 16 patients had surgery for de novo stress urinary incontinence. 4 patients needed cystocele repair after a posterior mesh and 8 patients posterior repair after an anterior mesh. Mesh exposure was diagnosed in 14 patients. No serious complications occurred. 53 (60%) patients reported all preoperative symptoms cured, 27 (30%) reported persistent symptoms and 5 patients were hesitant. Of the respondents, 63 (71%) were satisfied with the operation.	Studies with more patients or longer follow-up are included.
Hiltunen R, Nieminen K, Takala T et al. (2007) Low-weight polypropylene mesh for anterior vaginal wall prolapse: A randomized controlled trial. Obstetrics and Gynecology 110: 455-462	RCT n=202 FU=12 months	Anterior colporrhaphy, reinforced with, tailored mesh significantly reduced the rate of recurrence of anterior vaginal wall prolapse compared with the traditional operation, but was associated more often with stress urinary incontinence.	Study is included in the systematic review by Maher C et al., 2016.
Hollander MH, Pauwels EMAM, Buytaert GMJL et al. (2010) Anterior and posterior repair with polypropylene mesh (Prolift) for pelvic organ prolapse: Retrospective review of the first 323 patients. Journal of Gynecologic Surgery 26: 1-5	Case series n=323	At follow-up: 20% incontinence, 12% erosions, and 3% recurrence.	Studies with more patients or longer follow-up are included.

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Hong MK, Liao CY, Chu TY et al. (2011) Internal pudendal artery injury during prolapse surgery using nonanchored mesh. Journal of minimally invasive gynecology 18: 678-81	Case report n=1	**Artery injury and haematoma** Transcatheter arterial embolisation was done immediately, and the bleeding stopped. The patient subsequently experienced difficulty micturating and defaecating because of presacral hematoma compression. This resolved by 1 week after surgery. The hematoma resolved completely by 71 days postoperatively.	Adverse event is already described.
Huang WC, Yang JM (2013) Voiding dysfunction related to a vaginal hematoma after a Perigee™ procedure. Ultrasound in obstetrics & gynecology: the official journal of the International Society of Ultrasound in Obstetrics and Gynecology 41: 230-1	Case report n=1	**Voiding dysfunction related to a vaginal hematoma**	Adverse event is already described.
Huffaker RK, Shull BL, Thomas JS (2009) A serious complication following placement of posterior Prolift. International urogynecology journal and pelvic floor dysfunction 20: 1383-5	Case report n=1	**Rectovaginal fistula** A 32-year-old female with Crohn's disease experienced a rectovaginal fistula and abscess with rectal expulsion of posterior Prolift. She underwent diagnostic laparoscopy, transanal incision and drainage of abscess, transanal excision of mesh, and laparotomy with loop ileostomy. Weeks later, she underwent colectomy, near-total proctectomy, end ileostomy, and fistula repair.	Adverse event is already described.
Hurtado EA, Bailey HR, Reeves KO (2007) Rectal erosion of synthetic mesh used in posterior colporrhaphy requiring surgical removal. International urogynecology journal and pelvic floor dysfunction 18: 1499-501	Case report n=1	**Rectal erosion of mesh** A 47-year-old woman had a laparoscopic supracervical hysterectomy and a posterior repair with polypropylene mesh resulting in a rectal erosion. Despite removal of all of the mesh that could be excised rectally resulting in a healed rectal mucosa, the patient had persistent dyspareunia and pain requiring complete removal of the mesh using a vaginal approach. After surgery, the patient had resolution of all her symptoms.	Adverse event is already described.

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Hurtado EA, Appell RA (2008) A tertiary referral center's experience with complications arising from transvaginal mesh kit procedures. Journal of Pelvic Medicine and Surgery 14: 272-273	Case series n=12	**Surgical removal of mesh** In surgery, 8 of 12 patients had mesh that had bunched together creating a fibrotic band. Six patients had complete resolution of pain. The other 6 patients had improvement of their pain though 3 patients described it as still bothersome. Of the 9 patients with mesh exposure, all required significant resection of the vaginal wall because of mesh present within 1 mm of the epithelial layer. One patient required resection of a 5 X 5 cm area. After resection, no further mesh exposure occurred. Of 8 pieces of mesh sent for microscopic analysis, 2 had chronic inflammatory changes, 2 had giant cells present, and 3 had both giant cells with chronic inflammation.	Small case series of patients needing surgery to removed mesh.
Hviid U, Hviid T, Vauvert F et al. (2010) Porcine skin collagen implants for anterior vaginal wall prolapse: a randomised prospective controlled study. International urogynecology journal 21: 529-34	RCT n=61 FU=12 months	Four patients among controls (15%) and 2 in the graft group (7%) had objective recurrence.	Study is included in the systematic review by Maher C et al., 2016.
Iglesia CB, Sokol AI, Sokol ER et al. (2010) Vaginal mesh for prolapse: a randomized controlled trial. Obstetrics and gynecology 116: 293-303	RCT n=65 FU=median 10 months	At 3 months, there was a high vaginal mesh erosion rate (16%) with no difference in overall objective and subjective cure rates.	Study is included in the systematic review by Maher C et al., 2016.
Iyer S, Botros SM (2016) Transvaginal mesh: a historical review and update of the current state of affairs in the United States. International Urogynaecology Journal DOI: 10.1007/s00192-016-3092-7	Review 22 articles	There continues to be heated debate about balancing the efficacy of mesh use to decrease recurrent prolapse and complications. Research into safety and efficacy, along with tighter FDA regulations, is ongoing.	A recent systematic review is included (Maher C et al., 2016).

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Jacquetin B, Hinoul P, Gauld J et al. (2013) Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. International urogynecology journal 24: 1679-86	Case series n=90 FU=5 years	Success=90%, 88% and 84% at the 1-, 3-, and 5-year endpoints respectively. Quality-of-life improvement was sustained over the 5 years. 4 patients (5%) needed reintervention for prolapse; 14 patients (16%) experienced mesh exposure for which 8 resections were needed. Seven exposures were still ongoing at the 5-year endpoint, all asymptomatic. 33 out of 61 (54%) sexually active patients at baseline remained so at 5 years. De novo dyspareunia was reported by 10%, but no new cases at the 5-year endpoint. One patient reported de novo unprovoked mild pelvic pain at 5 years, 5 reported pains during pelvic examination only.	Study is included in Barski et al. (2013) systematic review.
Jambusaria LH, Murphy M, Lucente VR (2015) One-year functional and anatomic outcomes of robotic sacrocolpopexy versus vaginal extraperitoneal colpopexy with mesh. Female pelvic medicine & reconstructive surgery 21: 87-92	Non-randomised comparative study n=76 FU=1 year	Transabdominal and transvaginal techniques of colpopexy using synthetic mesh implants both improve quality of life and anatomic measures with similar outcomes.	Studies with more patients or longer follow-up are included.
Jeffery S, Nieuwoudt A (2012) Beyond the complications: medium-term anatomical, sexual and functional outcomes following removal of trocar-guided transvaginal mesh. A retrospective cohort study. International urogynecology journal 23(10), 1391-6	Case series n=21	In the cohort of 21 women, 18 needed surgery for pain or dyspareunia. At 6 weeks, 2 women still had pain and required a second intervention. Fifteen women had reached a 6-month follow-up, 1 of whom had persistent pain needing repeat surgery. Of the 15 women, 7 were sexually active and in 6 cases the dyspareunia had resolved completely. Six women had been seen at 12 months and all 4 of the sexually active women had no dyspareunia. There were no symptoms relating to prolapse in any of the women at 6 weeks, 6, 12 or 24 months.	Small case series of patients with complications after prolapse repair with mesh.
Juliato CRT, do Santos Junior LC, Haddad JM et al. (2016) Mesh surgery for anterior vaginal wall prolapse: a meta-analysis. Revista Brasileira de Ginecologia e Obstetricia 38: 356–64	Systematic review n=1,540 (12 RCTs)	Objective cure was greater in the mesh surgery group (odds ratio [OR]=1.28 [1.07 to 1.53]), which also had greater blood loss (mean deviation [MD]=45.98 [9.72 to 82.25]), longer surgery time (MD=15.08 [0.48 to 29.67]), but less prolapse recurrence (OR=0.22 [0.13 to 0.38]). Dyspareunia, symptom resolution and re-operation rates were not statistically different between groups. Quality-of-life (QOL) assessment through the pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ-12), the pelvic floor distress inventory (PFDI-20), the pelvic floor impact questionnaire (PFIQ-7), and the perceived quality-of-life scale (PQOL) was not significantly different.	All of the studies included in the meta-analysis are also included in the systematic review by Maher C et al. (2016).

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Juma S, Raheem O A (2016) Solvent-dehydrated dermal allograft (AXIS) augmented cystocele repair: longitudinal results. Int Urogynecol J	Case series n=184 FU=12 months	19 patients (10%) had repeat cystocele repair. 38 patients (22%) had postoperative recurrence. Dermal allograft related adverse events included 1 allograft vaginal exposure, 1 dyspareunia and 1 transient hydronephrosis. There were no vascular, vesical, visceral or neurological injuries.	Studies with more patients or longer follow-up are included.
Kanasaki H, Oride A, Mitsuo T et al. (2014) Occurrence of pre- and postoperative stress urinary incontinence in 105 patients who underwent tension-free vaginal mesh surgery for pelvic organ prolapse: A retrospective study. ISRN Obstetrics and Gynecology 2014 (1), no pagination	Case series n=105 FU=6 months	Of the 50 patients with preoperative stress urinary incontinence (SUI), SUI was resolved in 14 (28%). Of the 55 patients without preoperative SUI, de novo postoperative SUI appeared in 26 (47%), of whom approximately half experienced resolution or improvement of SUI within 6 months postoperatively.	Studies with more patients or longer follow-up are included.
Karmakar D, Hayward L, Smalldridge J et al. (2015) Vaginal mesh for prolapse: a long-term prospective study of 218 mesh kits from a single centre. International urogynecology journal 26: 1161-70	Case series n=158 FU=median 138 and 105 weeks (for different mesh kits)	Cure rates for prolapse using mesh kits in patients with a history of native tissue POP repair in the same compartment were 91% for the anterior compartment (60/66) and 96% for the posterior compartment (45/47). The cumulative mesh extrusion/exposure rate was 16% of patients. The rate of extrusion/exposure was significantly lower with IntePro Lite than with IntePro (p=0.04 for Perigee and p=0.0001 for Apogee). 8% of extrusions/exposures needed revision of the mesh.	Studies with more patients or longer follow-up are included.
Kato K, Suzuki S, Yamamoto S et al. (2009) Clinical pathway for tension-free vaginal mesh procedure: evaluation in 300 patients with pelvic organ prolapse. International journal of urology : official journal of the Japanese Urological Association 16: 314-7	Case series n=300	Perioperative complications were: bladder injury (4%), vaginal wall hematoma (0.7%), rectal injury (0.3%) and temporary hydronephrosis (0.3%). Two patients were re-hospitalised within 1 month because of vaginal bleeding or gluteal pain.	Study is included in Barski et al. (2013) systematic review.
Kaufman Y, Singh SS, Alturki H et al. (2011) Age and sexual activity are risk factors for mesh exposure following transvaginal mesh repair. International urogynecology journal 22: 307-13	Case series n=114 FU=mean 7 months	Procedure failure=5% (6/114); mesh exposure=12% (14/114), more commonly on the anterior vaginal wall. Age was inversely related to the risk of having late mesh exposure (p=0.02) with an odds ratio of 1.99 (95% confidence interval 1.10 to 3.59) for each decrease of 10 years in age. Late mesh exposure was significantly more common in sexually active patients (p=0.016)	Study is included in Barski et al. (2013) systematic review.

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Kelly EC, Winick-Ng J, Welk B (2016) Surgeon Experience and Complications of Transvaginal Prolapse Mesh. Obstetrics & Gynecology 128: 65-72	Case series n=5,488 FU=median 5 years.	Approximately 5% of women who had mesh-based prolapse surgery needed re-operation for a mesh complication within 10 years. The risk of re-operation was lowest for surgeons performing 14 or more procedures per year.	Study focuses on surgeon experience.
Khan ZA, Thomas L, Emery SJ (2014) Outcomes and complications of transvaginal mesh repair using the Prolift™ kit for pelvic organ prolapse at 4 years median follow-up in a tertiary referral centre. Archives of gynecology and obstetrics 290: 1151-7	Case series n=106 FU=median 4 years	Perioperative bladder injury=2% 6% of patients had mesh exposure postoperatively. Re-operation rates for recurrent prolapse in the operated compartment were 3%. At follow-up, prolapse recurrence in the operated compartment was noted in another 7% of patients. De novo prolapse in the non-operated compartment occurred=20%.	Studies with more patients or longer follow-up are included.
Khandwala S, Jayachandran C (2011) Transvaginal mesh surgery for pelvic organ prolapse-Prolift+M: A prospective clinical trial. International urogynecology journal and pelvic floor dysfunction 22(11), 1405-11	Case series n=167	Composite success score=73% (treatment failures per POP-Q stage 1%, perception of bulge 4%, erosions 4%, pain/dyspareunia 4%, incontinence 1%, de novo urge urinary incontinence 9%, voiding dysfunction 1%, recurrent urinary tract infection 2%, and anal incontinence 2%).	Studies with more patients or longer follow-up are included.
Khandwala S (2013) Transvaginal mesh surgery for pelvic organ prolapse: one-year outcome analysis. Female pelvic medicine & reconstructive surgery 19(2), 84-9	Case series n=157	Composite success score=88%. Pure anatomic success based on Pelvic Organ Prolapse Quantification lower than stage II was 94%. There were 3 cases (2%) of mesh exposure in the vagina. There were no visceral injuries. The incidence of de novo dyspareunia was 6%.	Studies with more patients or longer follow-up are included.
Khandwala S, Williams C, Rumschlag E et al. 2014) Review of 250 consecutive cases of vaginal mesh surgery for genital organ prolapse. Journal of Gynecologic Surgery 30(3), 134-140	Case series n=250 FU=mean 13 months	Composite success score was 89%. Pure anatomic success based upon POP-Q<stage II was 94%. There were 12 (5%) cases of mesh exposure in the vagina. There were no visceral injuries or mesh erosions. The incidence of de novo dyspareunia was 16%.	Studies with more patients or longer follow-up are included.
Kowalik CR, Lakeman MME, Oryszczyn JE et al. (2016) Reviewing Patients Following Mesh Repair; The Benefits. Gynecologic and Obstetric Investigation, no pagination	Case series n=188 FU=median 40 months	11 women (6%) had a symptomatic exposure of whom 8 women underwent surgery. Nine women (5%) had de novo pain following mesh surgery and in 3 women, (2%) this symptom was persistent despite treatment. 86% of the responders were satisfied about their treatment.	Studies with more patients or longer follow-up are included.

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Kozal S, Ripert T, Bayoud Y et al. (2014) Morbidity and functional midterm outcomes using Prolift pelvic floor repair systems. Canadian Urological Association journal = Journal de l'Association des urologues du Canada 8(9-10), E605-9	Case series n=112 FU=median 9.5 months	Failure rate=8% (9/112) occurring after a median follow-up of 9.5 months (range: 1 to 45). Among the 64 patients who had preoperative sexual activity (57%), de novo dyspareunia occurred in 9 patients (16%).	Studies with more patients or longer follow-up are included.
Lamblin G, Van-Nieuwenhuyse A, Chabert P et al. (2014) A randomized controlled trial comparing anatomical and functional outcome between vaginal colposuspension and transvaginal mesh. International Urogynecology Journal and Pelvic Floor Dysfunction 25(7), 961-970	RCT n=68 FU=2 years	The anatomical result was significantly better at 2 years in the mesh group than in the colposuspension group (p=0.02). Concerning POP-Q stages, the anatomical success rate at 2 years was 84% for colposuspension and 100% for mesh (p=0.05). There were 5 anatomic recurrences (16%) in the colposuspension group. The erosion rate was 6% (n=2). No significant difference was noted regarding minor complications. Analysis of QoL questionnaires showed overall improvement in both groups, with no significant difference between them.	Study is included in the systematic review by Maher C et al., 2016.
Lamblin G, Gouttenoire C, Panel L et al. (2016) A retrospective comparison of two vaginal mesh kits in the management of anterior and apical vaginal prolapse: long-term results for apical fixation and quality of life. International Urogynecology Journal 27(12), 1847-1855	Non-randomised comparative study n=126 FU=2 years	Function improved in both groups, with significantly better PFIQ-7 (p=0.03) and PFDI-20 (p=0.02) scores in the Elevate Ant group at 2 years. Vaginal exposure was not seen in the Elevate Ant group but occurred in 2 patients in the Perigee group (p=0.33). Factors associated with success were age >65 years (OR 7.16, 95 % CI 1.83 to 27.97) and treatment with Elevate Ant mesh (OR 10.16, 95 % CI 2.78 to 37.14). Postoperative stress urinary incontinence rate was greater with the Elevate Ant group (30% and 17%; p=0.11).	Studies with more patients or longer follow-up are included.
Lang P, Oliphant S, Mizell J et al. (2015) Rectal perforation at the time of vaginal mesh placement and subsequent abdominal mesh removal. International Urogynecology Journal 26(10), 1545-6	Case report n=1	**Rectal perforation** In the immediate postoperative period, the patient had severe pain radiating down her right leg, pelvic pain, dyspareunia, dyschezia, diarrhoea, and new onset faecal incontinence. The patient underwent exploratory laparotomy, removal of the mesh, primary repair of 2 perforating rectal defects and diverting loop ileostomy. Postoperatively she experienced immediate improvement in pain and later underwent successful take-down of her ileostomy.	Adverse event is already described.

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Larouche M, Merovitz L, Correa JA et al. (2015) Outcomes of trocar-guided Gynemesh PS™ versus single-incision trocarless Polyform™ transvaginal mesh procedures. International urogynecology journal 26(1), 71-7	Non-randomised comparative study n=103 FU=median 340 days	Objective success rates were 55% (26/47) in the trocar group and 61% (34/56) in the trocarless group (p=0.9), whereas subjective success was 83% (39/47) and 95% (53/56), respectively (p=0.1). The adjusted odds of developing mesh exposure were significantly less after trocarless transvaginal mesh procedures compared to trocar-guided ones [odds ratio (OR) 0.16, 95 % confidence interval (CI) 0.03 to 0.97]. Surgical reinterventions, aimed mostly at treating recurrent prolapse, mesh exposure, and latent stress urinary incontinence, were also significantly less frequent after trocarless procedures [5 patients (9%) requiring reintervention versus 15 (32%), respectively, adjusted OR 0.15, 95 % CI 0.04 to 0.60]	Studies with more patients or longer follow-up are included.
Lau HY, Twu NF, Chen YJ et al. (2011) Comparing effectiveness of combined transobturator tension-free vaginal mesh (Perigee) and transobturator tension-free vaginal tape (TVT-O) versus anterior colporrhaphy and TVT-O for associated cystocele and urodynamic stress incontinence. European journal of obstetrics, gynecology, and and reproductive biology 156(2), 228-32	Non-randomised comparative study n=115 FU=1 year	The objective cure rates for cystocele at one year were significantly higher in Group I (mesh) than in Group II (99% and 87%, p=0.018), respectively. The cure rates for stress urinary incontinence in the 2 groups were 91% vs. 91% (p=1.000). Symptomatic improvement of frequency was better in Group I than Group II (88% vs. 70%, p=0.03). There were no significant differences with regard to intraoperative and postoperative complications between the 2 groups.	Studies with more patients or longer follow-up are included.
Lee U, Wolff EM, Kobashi KC (2012) Native tissue repairs in anterior vaginal prolapse surgery: examining definitions of surgical success in the mesh era. Current opinion in urology 22(4), 265-70	Review 12 RCTs	Although mesh repair had superior anatomic success (38 to 93 vs. 27 to 71%), both mesh and native tissue repair had excellent rates of symptomatic success (75 to 96 and 62 to 100%, respectively). Taken together, the overall re-operation rate for native tissue repair was 5% compared with 9% for mesh-augmented repair	A more recent systematic review is included (Maher C, 2016).
Lee D, Dillon B, Lemack G et al. (2013) Transvaginal mesh kits--how "serious" are the complications and are they reversible? Urology 81(1), 43-8	Case series n=58	Most women presented with multiple complaints, with mesh extrusion the most frequently reported (n=43 [74%]). Of the 58 women, 17 (29%) needed re-excision of residual mesh, 13 once and 4 twice. Five women developed recurrent symptomatic pelvic organ prolapse (7%). The residual rate of dyspareunia and pelvic pain was 14% and 22%, respectively. Fourteen women (24%) were treated successfully, with complete resolution of all presenting symptoms.	Small case series of patients with complications after prolapse repair with mesh.

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Lensen EJM, Withagen MIJ, Kluivers KB et al. (2013) Comparison of two trocar-guided transvaginal mesh systems for repair of pelvic organ prolapse: a retrospective cohort study. International urogynecology journal 24(10), 1723-31	Non-randomised comparative study n=569 FU=1 year	Failure rates were similar in the 2 groups; the re-operation rate in the untreated compartments was higher in the non-absorbable mesh group compared with the partially absorbable mesh group (5% vs 1%). Mesh exposure rate in the non-absorbable mesh group was 12% and in the partially absorbable mesh group it was 5%. Other complication and patient satisfaction rates were similar.	Study focuses on comparison of 2 types of mesh.
Letouzey V, Deffieux X, Gervaise A et al. (2010) Transvaginal cystocele repair using a tension-free polypropylene mesh: more than 5 years of follow-up. European journal of obstetrics, gynecology, and and reproductive biology 151(1), 101-5	Case series n=63 FU=79 months	45 women were anatomically cured (76%). Four (7%) were lost to follow-up and 14 (24%) presented with stage 2 or 3 cystocele recurrences. None of them needed surgery for cystocele recurrence. Vaginal extrusion was reported in 10 (16%) patients (in 4 cases after 4 years of follow-up) and all required partial surgical removal of the mesh (n=10, 16%).	Studies with more patients or longer follow-up are included.
Letouzey V, Ulrich D, Balenbois E, Cornille A et al. (2015) Utero-vaginal suspension using bilateral vaginal anterior sacrospinous fixation with mesh: intermediate results of a cohort study. International Urogynecology Journal and Pelvic Floor Dysfunction 26(12), 1803-1807	Case series n=118	Anatomical success at a mean follow-up of 23 months was 93%, with a patient satisfaction rate of 95%. Four patients (8%) experienced de novo dyspareunia related to the mesh. The re-operation rate for mesh-related complications was 3%; no patients were re-operated for recurrence.	Studies with more patients or longer follow-up are included.
Liang CC, Lin YH, Chang YL et al. (2011) Urodynamic and clinical effects of transvaginal mesh repair for severe cystocele with and without urinary incontinence. International Journal of Gynecology and Obstetrics 112: 182-186	Case series n=100 FU=mean 35 months	Transvaginal mesh repair is effective and safe in patients with severe cystocele, but may have an impact on voiding and sexual activity.	Studies with more patients or longer follow-up are included.
Lin LL, Haessler AL, Ho MH et al. (2007) Dyspareunia and chronic pelvic pain after polypropylene mesh augmentation for transvaginal repair of anterior vaginal wall prolapse. International Urogynecology Journal and Pelvic Floor Dysfunction 18: 675-678	Case report n=1	**Severe dyspareunia and pelvic pain** Postoperatively, the patient developed severe dyspareunia and debilitating chronic pelvic pain. The patient failed conservative medical therapy and now requests complete removal of the synthetic mesh.	Case report of adverse event that is already described.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Liu CK, Tsai CP, Chou MM et al. (2014) A comparative study of laparoscopic sacrocolpopexy and total vaginal mesh procedure using lightweight polypropylene meshes for prolapse repair. Taiwanese journal of obstetrics & gynecology 53(4), 552-8	Non-randomised comparative study n=69 FU=1 year	Pelvic organ prolapse repair by laparoscopic sacrocolpopexy or total vaginal mesh using the new lightweight polypropylene meshes seems to be safe and has comparable outcomes, but limitations may vary.	Studies with more patients or longer follow-up are included.
Lo TS, Tan YL, Khanuengkitkong S et al. (2013) Surgical outcomes of anterior transobturator mesh and vaginal sacrospinous ligament fixation for severe pelvic organ prolapse in overweight and obese Asian women. International Urogynecology Journal and Pelvic Floor Dysfunction 24(5), 809-816	Case series n=200 FU=mean 36 months	Objective cure for the normal weight, overweight, and obese were 93%, 93% and 91% respectively. The subjective cure was no different. All categories improved significantly with regard to anatomical outcome, UDI-6, IIQ-7, POPDI-6, PISQ-12 after primary surgery ($p<0.05$) and none had recurrence requiring further surgery. However, obese patients have significantly less improvement in POPDI-6 ($p<0.037$) and PISQ-12 ($p<0.005$) compared with normal weight. There were no differences with regard to perioperative complications and the vaginal mesh exposure rate was 4%.	Study is included in Barski et al. (2013) systematic review.
Lo TS, Pue LB, Tan YL er al. 2014) Delayed intravesical mesh erosion in a midurethral sling following further mesh-augmented pelvic prolapse surgery. The journal of obstetrics and gynaecology research 40(3), 862-4	Case report n=1	**Delayed intravesical mesh erosion** Intravesical mesh erosion from a sling suspension developed 4 years after primary prolapse surgery with mesh reinforcement. The mesh was excised via a vaginal approach and both bladder mucosa and vaginal wall were repaired.	Case report of erosion.
Lo TS, Pue LB, Tan Y et al. (2014) Long-term outcomes of synthetic transobturator non-absorbable anterior mesh versus anterior colporrhaphy in symptomatic, advanced pelvic organ prolapse surgery. International urogynecology journal 25(2), 257-64	Non-randomised comparative study n=198	Transobturator synthetic non-absorbable anterior mesh combined with sacrospinous ligament fixation yielded a favourable and sustainable result over 5 years as compared to traditional anterior colporrhaphy, both in anatomical and subjective success rate. Mesh-related morbidities were low and acceptable.	Studies with more patients or longer follow-up are included.

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Lo TS, Bt K, Nazura C et al. (2015) Comparison between Elevate anterior/apical system and Perigee system in pelvic organ prolapse surgery: clinical and sonographic outcomes. International urogynecology journal 26(3), 391-400	Non-randomised comparative study n=118 FU=minimum 1 year	Elevate offered a lower incidence of mesh erosion and comparable results on anatomical correction; however, incidence of de novo stress urinary incontinence was high.	Studies with more patients or longer follow-up are included.
Lo TS, Nawawi EAB, Wu PY et al. (2015) Objective and subjective outcome 3 years after synthetic transobturator non-absorbable anterior mesh use in symptomatic advanced pelvic organ prolapse surgery. Gynecology and Minimally Invasive Therapy 4(2), 37-40	Case series n=114 FU=median 60 months	The objective cure rate was 100% for anterior and apical compartments and 90% for posterior compartment. Mesh exposure=4% There were no cases of mesh erosion into the bladder or other organs, and no patient needed mesh removal because of chronic pain or infection. There was no recurrence in the anterior and apical compartment. Eleven patients (10%) had recurrence of the posterior compartment. There was a significant improvements in all questionnaires with $p<0.001$ for POP Distress Inventory 6, Urogenital Distress Inventory, and Incontinence Impact Questionnaire, and $p=0.001$ for Prolapse/Urinary Incontinence Sexual Function Questionnaire.	Studies with more patients or longer follow-up are included.
Lo TS, Cortes EF, Wu PY et al. (2016) Assessment of collagen versus non collagen coated anterior vaginal mesh in pelvic reconstructive surgery: prospective study. European journal of obstetrics, gynecology, and and reproductive biology 198: 138-44	Non-randomised comparative study n=110	The collagen coated mesh group was comparable to the non-collagen coated group in terms of erosion rate, ultrasound and clinical assessment. Collagen coating may induce delayed inflammatory response, however it may also delay tissue integration.	Study compares 2 types of mesh.
Lo TS, Shailaja N, Hsieh WC et al. (2016) Predictors of voiding dysfunction following extensive vaginal pelvic reconstructive surgery. Int Urogynecol J	Case series n=1,425	Of 380 women (28%) with preoperative voiding dysfunction, 37 (10%) continued to have voiding dysfunction postoperatively. Of the remaining 991 women (72%) with normal preoperative voiding function, 11 (1%) developed de novo voiding dysfunction postoperatively. The overall incidence of postoperative voiding dysfunction was 4%.	Study focuses on voiding dysfunction.

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Long CY, Hsu CS, Jang MY et al. (2011) Comparison of clinical outcome and urodynamic findings using "Perigee and/or Apogee" versus "Prolift anterior and/or posterior" system devices for the treatment of pelvic organ prolapse. International urogynecology journal 22(2), 233-9	Non-randomised comparative study n=108	Perigee/Apogee and Prolift devices for POP repair have comparable success rates, mesh-related morbidities, and similar impacts on functional outcome.	Small non-randomised study comparing 2 different mesh systems.
Long CY, Hsu CS, Wu MP et al. (2011) Comparison of the changes in sexual function of premenopausal and postmenopausal women following transvaginal mesh surgery. Journal of Sexual Medicine 8(7), 2009-2016	Case series n=152	Transvaginal mesh procedure is effective for the anatomical restoration of pelvic organ prolapse. However, dyspareunia may worsen in the premenopausal women. Additionally, over one third of premenopausal women could have a worsening sexuality domain postoperatively.	Studies with more patients or longer follow-up are included.
Long CY, Lo TS, Wang CL et al. (2012) Risk factors of surgical failure following transvaginal mesh repair for the treatment of pelvic organ prolapse. European Journal of Obstetrics Gynecology and Reproductive Biology 161(2), 224-227	Case series n=113	Advanced uterine prolapse and lack of surgical experience were 2 significant predictors of failure following transvaginal mesh. Prolapse recurrence after mesh repair appears to be unlikely beyond the learning curve.	Studies with more patients or longer follow-up are included.
Long CY, Hsu CS, Wu CH et al. (2012) Three-year outcome of transvaginal mesh repair for the treatment of pelvic organ prolapse. European Journal of Obstetrics Gynecology and Reproductive Biology 161(1), 105-108	Case series n=124	Overall success rate=94% (116/124). Various urinary symptoms improved significantly following transvaginal mesh ($p<0.01$). In addition, residual urine, functional urethral length, and the rate of detrusor overactivity, improved significantly after surgery ($p<0.05$). Apart from vaginal erosion (14/124; 11%), the rates of other surgical complications were acceptably low.	Studies with more patients or longer follow-up are included.
Lukban JC, Mooret R (2008) Incidence of extrusion in patients treated with type I polypropylene mesh "KITS" in pelvic Organ prolapse repair. Journal of Pelvic Medicine and Surgery 14(4), 256-257	Case series n=368	One must consider the risks and benefits of using type I polypropylene mesh in the anterior and posterior compartments Extrusions in our study required revision in the operating room in less than 5% and 8% of cases following Perigee and Apogee, respectively. Patients exhibiting vaginal exposure of mesh maintained a high rate of anatomic "cure."	Studies with more patients or longer follow-up are included.

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Lukban JC, Roovers JP, Van Drie DM et al. (2012) Single-incision apical and posterior mesh repair: 1-year prospective outcomes. International Urogynecology Journal and Pelvic Floor Dysfunction 23(10), 1413-1419	Case series n=129 FU=12 months	Objective posterior wall and apical cure rates were 93% and 89%, respectively, with an extrusion rate of 7%.	Study is included in Barski et al. (2013) systematic review.
Lunardelli JL, Auge AP, Lemos NL et al. (2009) Polypropylene mesh vs. site-specific repair in the treatment of anterior vaginal wall prolapse: preliminary results of a randomized clinical trial. Revista do Colégio Brasileiro de Cirurgiões 36(3), 210-6	RCT n=32 FU=mean 9 months	The results demonstrate the superiority of the anatomical outcomes with the use of polypropylene mesh over site-specific repair. Regarding surgical morbidity, shorter operative time was observed for the mesh group.	Studies with more patients or longer follow-up are included.
MacDonald S, Terlecki R, Costantini E et al. (2016) Complications of Transvaginal Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence: Tips for Prevention, Recognition, and Management. European Urology Focus 2(3), 260-267	Review	Vaginal extrusion, persistent pain, and urethral and/or bladder erosion are the 3 most common product-specific complications following mesh-based repair for SUI or POP. Conservative therapies may be attempted, but most patients ultimately require partial or complete mesh excision.	Another systematic review is included (Maher C, 2016).
Madhuvrata P, Glazener C, Boachie C et al. (2011) A randomised controlled trial evaluating the use of polyglactin (Vicryl) mesh, polydioxanone (PDS) or polyglactin (Vicryl) sutures for pelvic organ prolapse surgery: outcomes at 2 years. Journal of obstetrics and gynaecology : the journal of the Institute of Obstetrics and Gynaecology 31(5), 429-35	RCT n=66 FU=2 years	The response rate at 2 years was 82%. There were no differences in the prolapse symptom scores between the randomised groups. Prolapse-related QoL score (mean difference: 2.05, 95% CI 0.19 to 3.91) and urinary incontinence score (mean difference: 2.56, 95% CI 0.02 to 5.11) were significantly lower (better) in women who had Vicryl compared with PDS sutures.	Studies with more patients or longer follow-up are included.

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Maher C, Feiner B, Baessler K et al. (2016) Surgery for women with anterior compartment prolapse. Cochrane Database of Systematic Reviews 11, CD004014	Systematic review n=33 trials (3332 women)	Biological graft repair or absorbable mesh provides minimal advantage compared with native tissue repair. Native tissue repair was associated with increased awareness of prolapse and increased risk of repeat surgery for prolapse and recurrence of anterior compartment prolapse compared with polypropylene mesh repair. However, native tissue repair was associated with reduced risk of de novo SUI, reduced bladder injury, and reduced rates of repeat surgery for prolapse, stress urinary incontinence and mesh exposure (composite outcome).Current evidence does not support the use of mesh repair compared with native tissue repair for anterior compartment prolapse owing to increased morbidity. Many transvaginal polypropylene meshes have been voluntarily removed from the market, and newer lightweight transvaginal meshes that are available have not been assessed by RCTs. Clinicans and women should be cautious when utilising these products, as their safety and efficacy have not been established.	Another systematic review, which also includes posterior repair, by the same author is included.
Margulies RU, Lewicky-Gaupp C, Fenner DE et al. (2008) Complications requiring re-operation following vaginal mesh kit procedures for prolapse. American journal of obstetrics and gynecology 199(6), 678.e1-4	Case series n=13	Thirteen referred women underwent surgery for vaginal mesh-related complications. All meshes were Apogee and/or Perigee. Ten had symptomatic mesh exposures, 1 had an exposure with pelvic abscess, and 2 had pain syndromes without mesh exposure. Patients also had rectovaginal fistula, vesicovaginal fistula, recurrent POP, and persistent discharge. Five women had prior surgery for this problem. All patients underwent transvaginal mesh excision and other indicated procedures at our institution, and 6 women required a second surgery at our institution, with a median of 2 surgeries per patient.	Small case series of patients with complications after mesh repair.
Masata J, Dundr P, Martan A (2014) Actinomyces infection appearing five years after trocar-guided transvaginal mesh prolapse repair. International urogynecology journal 25(7), 993-6	Case report n=1	**Infection** Bacterial colonization and chronic infection following mesh-augmented pelvic floor reconstructive surgery may be 1 reason for abnormal healing and the occurrence of complications such as a mesh erosion, pain, and shrinkage. This case presents a patient with Actinomyces infection that appeared 5 years after trocar-guided transvaginal mesh repair of pelvic organ prolapse (POP).	Case report of adverse event that is already described.

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McDermott CD, Terry CL, Woodman PJ et al. (2011) Surgical outcomes following total Prolift: colpopexy versus hysteropexy. The Australian & New Zealand journal of obstetrics & gynaecology 51(1), 61-6	Non-randomised comparative study n=89 FU=6 to 12 months	This study showed that total Prolift: colpopexy and total Prolift hysteropexy have similar surgical outcomes, except for vaginal vault measurements reflected by POP-Q point	Studies with more patients or longer follow-up are included.
McDermott CD, Park J, Terry CL et al. (2013) Sacral colpopexy versus transvaginal mesh colpopexy in obese patients. Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC 35(5), 461-7	Non-randomised comparative study n=91 FU=6 to 12 months	In these 91 obese patients with pelvic organ prolapse, sacral colpopexy resulted in better anatomical outcomes than transvaginal mesh colpopexy. However, the 2 procedures had similar outcomes with regard to recurrent symptoms and surgical satisfaction.	Studies with more patients or longer follow-up are included.
McLennan GP, Sirls LT, Killinger KA et al. (2013) Perioperative experience of pelvic organ prolapse repair with the Prolift and Elevate vaginal mesh procedures. International urogynecology journal 24(2), 287-94	Non-randomised comparative study n=220	Operative and postoperative experiences were similar between groups. There were no bowel or major vascular injuries, and the Prolift trocar bladder injuries did not alter the surgical procedure.	Studies with more patients or longer follow-up are included.
Menefee SA, Dyer KY, Lukacz ES et al. (2011) Colporrhaphy compared with mesh or graft-reinforced vaginal paravaginal repair for anterior vaginal wall prolapse: a randomized controlled trial. Obstetrics and gynecology 118(6), 1337-44	RCT n=99 FU=minimum 2 years	Patients treated by mesh had a significantly lower anatomic failure rate (18%) than both the porcine (46%, p=0.015) and colporrhaphy groups (58%, p=0.002). All groups had statistically similar reductions in their prolapse and urinary symptom subscale scores. Composite failure was not statistically different between groups: 13% colporrhaphy, 12% porcine, and 4% mesh. Two reoperations for anterior prolapse occurred in the porcine group. Mesh erosion rates were 14% for the mesh group.	Study is included in the systematic review by Maher C et al., 2016.
Mettu JR, Colaco M, Badlani GH (2014) Evidence-based outcomes for mesh-based surgery for pelvic organ prolapse. Current opinion in urology 24(4), 370-4	Review 18 studies	Synthetic mesh provides superior anatomical and subjective cure rates compared with native tissue repair. Success rates varied greatly depending on the nature of prolapse and surgical approach. Furthermore, recurrence rates for mesh-based surgery are significantly lower than that for native tissue repair. The main unique complication of mesh is exposure and was reported in a mean of 11% of patients, with 7% of patients requiring surgical partial excision of mesh.	A more recent systematic review is included (Maher C, 2016).

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Miklos JR, Chinthakanan O, Moore RD et al. (2016) The IUGA/ICS classification of synthetic mesh complications in female pelvic floor reconstructive surgery: a multicenter study. International urogynecology journal 27(6), 933-8	Case series n=445	4% of patients had viscus organ penetration or vaginal exposure as their presenting chief complaint. The most common category was spontaneous pain (33%) followed by dyspareunia (15%). The sling group was 20% more likely to have pain compared with the pelvic organ prolapse (POP) mesh group (OR 1.2, 95 % CI 0.8 to 1.6). The most commonly affected site was away from the suture line (49%). Compared with the sling group, the POP group had a higher rate of mesh exposure, which mostly occurred at the suture line area. The majority of patients presented with mesh-related complications more than 1 year post-insertion (average 3.7+/-2.5 years).	Studies with more patients or longer follow-up are included.
Milani AL, Hinoul P, Gauld JM et al. (2011) Trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh: 1 year outcomes. American journal of obstetrics and gynecology 204(1), 74.e1-8	Case series n=127 FU=1 year	Anatomic success=77% (95% confidence interval, 69 to 84%). Significant improvements in bother, quality of life, and sexual function were detected at 3 months and 1 year compared with baseline. At 1-year after surgery, 86% of patients indicated their prolapse situation to be "much better." Mesh exposure rate was 10% and rate of de novo dyspareunia 2% at 1 year.	Studies with more patients or longer follow-up are included.
Milani AL, Withagen MI, The HS et al. (2011) Sexual function following trocar-guided mesh or vaginal native tissue repair in recurrent prolapse: a randomized controlled trial. The journal of sexual medicine 8(10), 2944-53	RCT n=60 FU=12 months	At 12 months, PISQ-12 scores were not different in either treatment arm, but were affected differently by trocar-guided mesh insertion or by native tissue repair. Mesh exposure was independently associated with deterioration in sexual function.	Studies with more patients or longer follow-up are included.
Milani AL, Withagen MIJ, Vierhout ME (2012) Outcomes and predictors of failure of trocar-guided vaginal mesh surgery for pelvic organ prolapse. American journal of obstetrics and gynecology 206(5), 440.e1-8	Case series n=433 FU=1 year	Treated compartment failure=15% (95% confidence interval [CI], 12 to 19%). Overall prolapse failure=41% (95% CI, 36 to 45%). Composite failure=9% (95% CI, 7 to 13%). Predictor of failure in all outcomes was the combined anterior/posterior mesh with the uterus in situ.	Studies with more patients or longer follow-up are included.

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Min H, Li H, Bingshu L et al. (2013) Meta-analysis of the efficacy and safety of the application of adjuvant material in the repair of anterior vaginal wall prolapse. Archives of Gynecology and Obstetrics 287: 919–36	Systematic review n=2,313 (20 RCTs)	Adjuvant material is worthy of clinical popularisation, especially the biological graft type because of its lower anatomy failure rate and no difference in safety compared with the control group. However, exposure to adjuvant materials and erosion rates are high, which are the most important aspects to be improved.	A more recent systematic review is included (Maher C, 2016), which has 18 of the 20 RCTs analysed in this review and reports similar outcomes. The 2 RCTs that weren't included were reported as conference abstracts.
Minassian V, Parekh M, Poplawsky D et al. (2014) Randomized controlled trial comparing two procedures for anterior vaginal wall prolapse. Neurourology and urodynamics 33(1), 72-7	RCT n=70 FU=2 years	At 2 years follow-up, anterior colporrhaphy with polyglactin 910 mesh and abdominal paravaginal defect repair have similar success rates, with most objective failures being asymptomatic	Studies with more patients or longer follow-up are included.
Moore RD, Beyer RD, Jacoby K et al. (2010) Prospective multicenter trial assessing type I, polypropylene mesh placed via transobturator route for the treatment of anterior vaginal prolapse with 2-year follow-up. International urogynecology journal 21(5), 545-52	Case series n=114 FU=2 years	Efficacy=89% (77/87). Pelvic floor distress inventory, pelvic floor impact questionnaire-7, and pelvic organ prolapse/urinary incontinence sexual questionnaire were all significantly improved from baseline ($p<0.001$). Complication rates reported were vaginal mesh extrusion 11% (12/114) and groin, pelvic, or vaginal pain 4% (5/114). Six patients reported de novo dyspareunia. Out of the 49 patients reporting dyspareunia at baseline, 15 were resolved postoperatively.	Study is included in Barski et al. (2013) systematic review.
Moore RD, Lukban JC (2012) Comparison of vaginal mesh extrusion rates between a lightweight type I polypropylene mesh versus heavier mesh in the treatment of pelvic organ prolapse. International urogynecology journal 23(10), 1379-86	Non-randomised comparative study n=349 FU=mean 2 years	No statistically significant difference in extrusion rates were seen following use of IntePro versus IntePro Lite; however, the 46% reduction in rate of mesh exposure observed in those receiving the lighter weight mesh may represent clinical importance.	Studies with more patients or longer follow-up are included.
Mourtialon P, Letouzey V, Eglin G, et al (2013) Transischioanal trans-sacrospinous ligament rectocele repair with polypropylene mesh: A prospective study with assessment of rectoanal function. International Urogynecology Journal and Pelvic Floor Dysfunction 24(1), 81-89	Case series n=116 FU=mean 36 months	The objective success rate was 95% and subjective (by patient satisfaction) was 93%. Colorectal-Anal Impact (CRAI) and Colorectal-Anal Distress Inventory (CRADI) scores were both significantly decreased at midterm follow-up in comparison with baseline (42.7 at baseline vs 11.4 at 24- or 36-month follow-up, $p=0.001$ for CRAI, and 81.1 vs 34.4, $p<0.001$ for CRADI) highlighting the benefits of rectocele repair on colorectal-anal function.	Studies with more patients or longer follow-up are included.

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Nauth M, Henne B, Wagner A et al. (2010) Anterior transobturator Vaginal Mesh results of a prospective multicenter observational trial. Geburtshilfe und Frauenheilkunde 70(1), 52-56	Case series n=116 FU=6 months	Recurrence of stage II or more cystoceles= 4% of patients (1 needed treatment). Urinary stress incontinence was cured in 52% and urge incontinence was cured in 38%. De novo urinary stress or urge incontinence occurred in less than 5%, respectively. Mesh erosion occurred in 14%. Among sexually active women, the rate of dyspareunia was 40% preoperatively and 20% after surgery. Quality of life improved in 90% of patients and 98% would have the procedure again.	Studies with more patients or longer follow-up are included.
Nguyen JN, Burchette Raoul J (2008) Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstetrics and gynecology 111(4), 891-8	RCT n=75 FU=1 year	Optimal and satisfactory anterior vaginal support were obtained in 55% (21/38) of the colporrhaphy group and 87% (33/38) of the mesh group (p=0.005). Patients in both groups reported less bother after surgery in both prolapse and urinary symptoms. The rates of de novo dyspareunia 16% (4/26) and 9% (2/23) in the colporrhaphy and mesh groups, respectively. Two (5%) patients had vaginal mesh extrusion.	Study is included in the systematic review by Maher C et al., 2016.
Nguyen JN, Jakus-Waldman SM, Walter AJ et al. (2012) Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. Obstetrics and gynecology 119(3), 539-46	Case series n=1,508 prolapse repair procedures using implanted prostheses. FU=12 months	Reoperations after prolapse procedures were performed more often for vaginal mesh erosion (29/858 [3%]) than for biologic graft infection (2/650 [0.3%]; p=0.01) and were performed more commonly after anterior (19/307 [6%]) compared with apical (9/487 [2%]) or posterior vaginal mesh repairs (1/64 [2%]; p=0.018).	More recent studies are included.
Nicolson A, Adeyemo D (2009) Colovaginal fistula: a rare long-term complication of polypropylene mesh sacrocolpopexy. Journal of obstetrics and gynaecology : the journal of the Institute of Obstetrics and Gynaecology 29(5), 444-5	Case report n=1	**Colovaginal fistula** Colovaginal fistula was diagnosed 2 years after mesh sacrocolpopexy. The patient's medical history included left colon diverticulitis, hysterectomy and mesh sacrocolpopexy for recurrent urogenital prolapse 7 years after a previous suture sacrospinous fixation. The mesh was disconnected from the sacrum and excised along with the diseased sigmoid colon.	Fistula is already described as an adverse event.
Nieminen K, Hiltunen R, Takala T et al. (2010) Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. American journal of obstetrics and gynecology 203(3), 235.e1-8	RCT n=202 FU=36 months	Recurrences of anterior vaginal prolapse were noted in 40 of the 97 (41%) in the colporrhaphy group and 14 of 105 (13%) in the mesh group (p<0.0001). The number needed to treat was thus 4. The proportion of symptomatic patients, including those with dyspareunia, did not differ between the groups. The mesh erosion rate was 19%.	Study is included in the systematic review by Maher C et al., 2016.

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Murphy M, Holzberg A, van Raalte H et al. (2012) Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safet Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. International Urogynecology Journal 23: 5–9	Review	Transvaginal mesh is an important tool in the surgical armamentarium that may be the best option in some cases. There may be instances when a surgeon suspects that a native tissue repair will have a high risk of failure and that the potential benefits of a mesh repair outweigh the risks.	A more recent systematic review is included.
Nussler EK, Greisen S, Kesmodel US et al. (2013) Operation for recurrent cystocele with anterior colporrhaphy or non-absorbable mesh: patient-reported outcomes. International urogynecology journal 24(11), 1925-31	Non-randomised comparative study n=286 FU=12 months	The odds ratio (OR) of patient-reported cure was 2.90 (1.34 to 6.31) after mesh implants compared with anterior colporrhaphy. Both patient- and doctor-reported complications were found more often in the mesh group. However, no differences in serious complications were found. Thus, an organ lesion was found in 2% after mesh implant compared with 3% after anterior colporrhaphy (p=0.58). Two patients in the mesh group (1%) were re-operated compared with 1 patient (1%) in the anterior colporrhaphy group (p=0.58). The infection rate was higher after mesh (9%) than after anterior colporrhaphy (3%; OR 3.19 ; 1.07 to 14.25).	Studies with more patients or longer follow-up are included.
Nussler E, Kesmodel US, Lofgren M et al. (2014) Operation for primary cystocele with anterior colporrhaphy or non-absorbable mesh: patient-reported outcomes. International Urogynecology Journal and Pelvic Floor Dysfunction 26(3), 359-366	Non-randomised comparative study n=6,247 FU=12 months	Mesh reinforcement, in primary anterior vaginal wall prolapse patients, enhanced the likelihood of anatomical success at 1 year after surgery. However, mesh implant was associated with a significantly higher incidence of bladder injury, reoperations, both patient- and surgeon-reported complications, more patient-reported pain and a longer hospital stay.	Studies with longer follow-up are included.
Nyyssonen V, Santala M, Ala-Nissila S et al. (2016) Posterior Transvaginal Mesh without Concurrent Surgery: How Does It have an Effect on the Untreated Vaginal Compartment. Gynecol Obstet Invest	Case series n=111 FU=3 months	De novo anterior prolapse emerged in 3 to 15% of the women, depending on the definition. Posterior POP-Q stage </=I was obtained in 92 (84%) women and leading edge at or above the hymen in 107 (98%) women. Bulge symptoms disappeared in 86% of the cases. One mesh exposure was detected. Re-operation rate was 3%, and 4% of patients experienced postoperative pain. PFDI-20 and PISQ-12 scores improved significantly.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Ow LL, Lim YN, Dwyer PL et al. (2016) Native tissue repair or transvaginal mesh for recurrent vaginal prolapse: what are the long-term outcomes?. International Urogynecology Journal 27(9), 1313-20	Non-randomised comparative study n=237 FU=12 months	Compared with the transvaginal mesh (TVM) group, women having repeat native tissue repair were more likely to have anatomical recurrence (anterior 41% vs 25%, p=0.02, posterior 25% vs 8%, p=0.01), report vaginal bulge (anterior 34% vs 12%, p<0.01, posterior 24% vs 8%, p=0.02) and had a higher prolapse re-operation rate (anterior 24% vs 7%, p<0.01, posterior 20% vs 8%, p=0.08). Using composite outcomes, the success rate was higher with TVM repair in both compartments (anterior 34% vs 14%, p<0.01, posterior 57% vs 23%, p<0.01). Reoperations for mesh exposure were 9% anteriorly and 15% posteriorly. Although the number of women requiring a prolapse re-operation is lower in the TVM group, the overall re-operation rate was not significantly different when procedures to correct mesh complications were included.	Studies with more patients or longer follow-up are included.
Pushkar DY, Vasilchenko MI, Kasyan GR (2013) Necrotising fasciitis after hysterectomy and concomitant transvaginal mesh repair in a patient with pelvic organ prolapse. International urogynecology journal 24(10), 1765-7	Case report n=1	**Necrotising fasciitis** The patient was treated by a transvaginal hysterectomy and anterior vaginal wall repair augmented with trocar-guided mesh. Examination of the removed uterus confirmed the presence of an intrauterine device and additionally found endometrial cancer (T1N0M0), which was not revealed during the preoperative ultrasound. Within 6 days of the surgery, the patient developed anaerobic bilateral necrotising fasciitis on both thighs. After 18 days of intensive care, the patient died of fatal coagulopathy.	Adverse event is already described in table 2.
Quemener J, Joutel N, Lucot JP et al. (2014) Rate of reinterventions after transvaginal pelvic organ prolapse repair using partially absorbable mesh: 20 months median follow-up outcomes. European journal of obstetrics, gynecology, and and reproductive biology 175, 194-8	Case series n=250 FU=median 20 months	The global rate of reinterventions was 8%. The main indications were mesh exposure (2%), prolapse recurrence (1%), and urinary complications such as de novo stress urinary incontinence (5%).	Studies with more patients or longer follow-up are included.

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Ramanah R, Mairot J, Clement MC et al. (2010) Evaluating the porcine dermis graft InteXen in three-compartment transvaginal pelvic organ prolapse repair. International urogynecology journal 21(9), 1151-6	Non-randomised comparative study n=126 FU=36 months	No case of mesh erosion or infection was noted. The objective (17% vs 8%, p=0.12) and subjective recurrence rates (13% vs 5%, p=0.12) between the 2 groups were not statistically different.	Studies with more patients or longer follow-up are included.
Rane A, Iyer J, Kannan K et al. (2012) Prospective study of the PerigeeTM system for treatment of cystocele - our five-year experience. The Australian & New Zealand journal of obstetrics & gynaecology 52(1), 28-33	Case series n=376 FU=5 years	The anatomical success rate for the device was 94%, and there were no life-threatening complications with the procedure. 39 (11%) of women had small mesh extrusion through the vagina, and 20 (6%) had recurrence of stage II cystocoele. Of the subset of women analysed, 45% reported no sexual dysfunction, 41% reported improvement in sexual function, while 4% reported worsening of dyspareunia.	Studies with more patients or longer follow-up are included.
Richter LA, Sokol AI (2016) Pelvic Organ Prolapse---Vaginal and Laparoscopic Mesh: The Evidence. Obstetrics and gynecology clinics of North America 43(1), 83-92	Review	Transvaginal mesh repair of the anterior compartment is associated with anatomic support compared with native tissue repair, but without significant improvement in quality-of-life parameters.	Another systematic review is included (Maher C, 2016).
Robert M, Girard I, Brennand E et al. (2014) Absorbable mesh augmentation compared with no mesh for anterior prolapse: a randomized controlled trial. Obstetrics and gynecology 123(2 Pt 1), 288-94	RCT n=57 FU=12 months	At the 12-month follow-up, 56% (15/27) in the mesh group and 61% (17/28) in the no-mesh group were considered cured (relative risk 0.90, 95% confidence interval 0.52 to 1.54). There were no significant differences between groups in recurrent or persistent prolapse (7% in each group) nor in patient-reported outcomes.	Studies with more patients or longer follow-up are included.
Rogowski A, Bienkowski P, Tosiak A et al. (2013) Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair. International Urogynecology Journal and Pelvic Floor Dysfunction 24(12), 2087-2092	Case series n=103 FU=6 months	Mesh retraction assessed on ultrasound examination after anterior vaginal mesh repair may correlate with de novo overactive bladder symptoms and vaginal pain.	Studies with more patients or longer follow-up are included.

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Rudnicki M, Laurikainen E, Pogosean R et al. (2016) A 3-year follow-up after anterior colporrhaphy compared with collagen-coated transvaginal mesh for anterior vaginal wall prolapse: A randomised controlled trial. BJOG 123(1), 136-42	RCT n=160 FU=3 years	POP-Q revealed an objective anatomic cure for 88 and 91%, respectively, in the mesh group at the 1- and 3-year follow-ups, compared with 40 and 41% in the colporrhaphy group. No difference between the groups was observed regarding PFIQ-7, PFDI-20, and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) scores. The number of mesh exposures did not change during the study period and all exposures were minor.	Study is included in the systematic review by Maher C et al., 2016.
Sartore A, Zennaro F, Banco R (2014) An unusual long-term complication of transobturator polypropylene mesh. Archives of gynecology and obstetrics 290(6), 1273-4	Case report n=1	**Thigh pain** A 48-year-old woman underwent the Perigee procedure because of a stage 3 anterior wall prolapse. Eleven months after surgery, the patient became suddenly unable to walk because of a strong pain to the left thigh root after running. The MRI revealed an external obturator left muscle hyperintensity consistent with muscular oedema; the patient was treated with oral corticosteroids with a complete resolution of the pain.	Case report of adverse event that resolved after conservative treatment.
Sayer T, Lim J, Gauld J M et al. (2012) Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device. International Urogynecology Journal and Pelvic Floor Dysfunction 23(4), 487-493	Case series n=110 FU=median 29 months	The primary anatomic success, defined as POP-Q 0-I, was 69%; however, in 85% of the cases, the leading vaginal edge was above the hymen. Pelvic symptoms and sexual function improved significantly from baseline ($p<0.01$). Mesh exposure rate was 9%. 5% reported stress urinary incontinence and 3% required further prolapse surgery.	Studies with more patients or longer follow-up are included.
Schimpf MO, Abed H, Sanses T et al. (2016) Graft and mesh use in transvaginal prolapse repair. Obstetrics and Gynecology 128(1), 81-91	Systematic review 66 comparative studies (38 RCTs)	Synthetic mesh augmentation of anterior wall prolapse repair improves anatomic outcomes and bulge symptoms compared with native tissue repair. Biologic grafts do not improve prolapse repair outcomes in any compartment. Mesh erosion occurred in up to 36% of patients, but re-operation rates were low.	A systematic review with a later search date is included (Maher C, 2016).
Sergent F, Sentilhes L, Resch B et al. (2010) Treatment of concomitant prolapse and stress urinary incontinence via a transobturator subvesical mesh without independent suburethral tape. Acta obstetricia et gynecologica Scandinavica 89(2), 223-9	Case series n=105 FU=median 45 months	A total of 102 women (97%) were cured of their prolapse, of whom 72 (69%) were cured of their SUI and 13 (12%) showed improvement. Pad test, visual analogic scale and quality-of-life questionnaires were all improved ($p<0.05$). Complications consisted of 1 rectal injury, 1 transitory urinary retention, and 2 hematomas. Of the erosions 6% was observed for monofilament polypropylene prostheses.	Studies with more patients or longer follow-up are included.

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Shah HN, Badlani G H (2012) Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review. Indian Journal of Urology 28(2), 129-153	Systematic review n=170 articles	While the incidence of extrusion and erosion with midurethral sling is low, the extrusion rate in prolapse repair is somewhat higher and the use in posterior compartment remains controversial. When used through the abdominal approach the extrusion and erosion rates are lower.	Includes treatment for stress urinary incontinence as well as prolapse. A more recent review is included.
Shveiky D, Iglesia CB, Sokol AI et al. (2009) Robotic sacrocolpopexy versus vaginal mesh colpopexy for treatment of anterior and apical prolapse - A retrospective cohort study. Journal of Pelvic Medicine and Surgery 15(2), 57	Non-randomised comparative study n=54 FU=5 months	In this study, robotic sacrocolpopexy and vaginal mesh colpopexy result in similar short-term cure rates for prolapse with similar complication rates.	Studies with more patients or longer follow-up are included.
Simon M, Debodinance P (2011) Vaginal prolapse repair using the ProliftTM; kit: A registry of 100 successive cases. European Journal of Obstetrics Gynecology and Reproductive Biology 158(1), 104-109	Case series n=100 FU=12 months	Recurrence=4% at 6 months and 10% at 12 months. Significant ($p<0.05$) improvements were seen in median scores for the various POP-Q items. With respect to functional problems, stress urinary incontinence was cured in 92% of the patients but 8% reported new-onset urinary incontinence after 1 year. One case of vaginal exposure after 1 year was observed and major or symptomatic mesh retraction was observed in 8%. New-onset dyspareunia was reported by 11% of the patients.	Studies with more patients or longer follow-up are included.
Sirls LT, McLennan GP, Killinger KA et al. (2013) Exploring predictors of mesh exposure after vaginal prolapse repair. Female pelvic medicine & reconstructive surgery 19(4), 206-9	Case series n=335	Vaginal mesh exposure=8% (27/335) Median time to exposure was 96 days (15-1129 days). Exposure rates decreased over time (17% in 2005 to 12% in 2006, then 5%-8% in 2006-2011) but were not statistically significant (p=0.49).	Studies with more patients or longer follow-up are included.
Sokol AI, Iglesia CB, Kudish BI et al. (2012) One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. American journal of obstetrics and gynecology 206(1), 86.e1-9	RCT n=65 FU=12 months	The quality of life improved and did not differ between groups: 96% mesh vs 91% no-mesh subjects reported a cure of bulge symptoms; 16% had mesh exposures, and re-operation rates were higher with mesh.	Studies with more patients or longer follow-up are included.

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Song W, Kim TH, Chung JW et al. (2016) Anatomical and Functional Outcomes of Prolift Transvaginal Mesh for Treatment of Pelvic Organ Prolapse. Luts 8(3), 159-64	Case series n=163 FU=mean 40 months	Optimal or satisfactory anatomic outcomes for anterior, apical, and posterior prolapse occurred in 77, 85, and 83% of cases, respectively. Mean values for points in the POP-Q, urinary distress inventory (UDI), and pelvic organ prolapsed distress inventory (POPDI) in the Pelvic Floor Distress Inventory (PFDI) were all significantly improved after the operation. The overall satisfaction rate for the operation was 85%. Five patients (3%) had vaginal erosion and were treated by partial excision of the mesh without evidence of infection.	Studies with more patients or longer follow-up are included.
Stanford EJ, Mattox TF, Pugh CJ (2011) Outcomes and complications of transvaginal and abdominal custom-shaped lightweight polypropylene mesh used in repair of pelvic organ prolapse. Journal of minimally invasive gynecology 18(1), 64-7	Non-randomised comparative study n=154 FU=minimum 24 months	Overall success=97%. There were 4 failures (3%), defined as stage II prolapse or greater. Comparison of POP-Q points Aa, Ba, C, Ap, and Bp preoperatively and postoperatively revealed statistically significant improvement at each point ($p<001$). Complications were observed in 17 patients (11%), with mesh extrusion in 1 (0.7%).	Studies with more patients or longer follow-up are included.
Stanford EJ, Cassidenti A, Moen MD (2012) Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: providing an accurate interpretation of current literature. International urogynecology journal 23(1), 19-28	Review	Anterior native tissue success is as low as 30% in some studies, but generally is 88-97% when prolapse is the primary outcome particularly if apical support is included. This compares to the 87-96% success reported for anterior mesh repair. Posterior native tissue success is 54-81%, which is lower than the 92-97% reported for posterior mesh repair when prolapse is the outcome measure. There are some differences in the complications reported. The rate of complications is approximately 8% for native tissue and is reported at 0-19% for mesh.	A more recent systematic review is included (Maher C, 2016).
Stanford EJ, Moore RD, Roovers JP et al. (2013) Elevate anterior/apical: 12-month data showing safety and efficacy in surgical treatment of pelvic organ prolapse. Female pelvic medicine & reconstructive surgery 19(2), 79-83	Case series n=142 FU=12 months	Anatomic success rate=88% (95% confidence interval, 80% to 93%) for the anterior compartment and 96% (95% confidence interval, 89% to 99%) for the apical compartment. POP-Q measurements (Aa, Ba, and C) improved significantly ($p<0.001$). Related adverse events reported at greater than 2% were mesh exposure (8; 6%), urinary tract infection (7; 6%), transient buttock pain (5; 4%), de novo stress incontinence (5; 4%), retention (5; 4%), dyspareunia (3; 3%), and hematoma (3; 2%). All quality-of-life scores significantly improved from baseline ($p<0.001$).	Studies with more patients or longer follow-up are included.

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Stanford EJ, Moore RD, Roovers JP et al. (2015) Elevate and Uterine Preservation: Two-Year Results. Female pelvic medicine & reconstructive surgery 21(4), 205-10	Case series n=142 FU=24 months	Anatomic success and complications for the Elevate Anterior and Apical do not appear to be significantly impacted when the uterus is removed before or during surgery or preserved. There may be a trend towards increased mesh extrusion when a hysterectomy is performed.	Studies with more patients or longer follow-up are included.
Steinberg BJ, Finamore PS, Sastry DN et al. (2010) Postoperative urinary retention following vaginal mesh procedures for the treatment of pelvic organ prolapse. International urogynecology journal 21(12), 1491-8	Case series n=142	48 patients (34%) developed urinary retention after surgery. Of those, 30 patients (63%) had a combined anterior and posterior repair (p=0.033). There was a greater association of urinary retention among patients with concomitant retropubic slings compared with transobturator slings (OR=3.6, 95% confidence interval=1.3 to 9.8).	Studies with more patients or longer follow-up are included.
Su TH, Lau HH, Huang WC et al. (2014) Single-incision mesh repair versus traditional native tissue repair for pelvic organ prolapse: results of a cohort study. International urogynecology journal 25(7), 901-8	Non-randomised comparative study n=201 FU=1 year	The anatomical success rate of the anterior compartment was significantly higher in the ElevateTM repair group than in the traditional repair group (98% vs 87%, p=0.006), but not for the posterior (100% vs 97%, p=0.367) compartments. Both groups showed significant improvements in the quality of life after surgery with no statistical difference. Mesh-related complications included extrusion (3%) and the need for revision of the vaginal wound (1 %).	Studies with more patients or longer follow-up are included.
Sun Y, Tang C, Luo D et al. (2016) The treatment of anterior vaginal wall prolapsed by repair with mesh versus colporrhaphy. International Urology & Nephrology 48(2), 155-67	Review n=11 articles (1,455 patients)	There were no significant differences for the following complications: urinary retention, urinary incontinence, voiding difficulty, dyspareunia, urinary tract infection and vaginal bulge. There were instances of more serious complications in the mesh group. However, cure rate was significantly higher in the mesh group (RR 1.44, 95% CI 1.34 to 1.55, p< 0.00001). The cure rate was not significantly dependent on patient satisfaction or postoperative sexual function.	A systematic review is included (Maher et al., 2016)
Sun Z, Zhu L, Xu T et al. (2016) Effects of preoperative vaginal estrogen therapy for the incidence of mesh complication after pelvic organ prolapse surgery in postmenopausal women: Is it helpful or a myth? A 1-year randomized controlled trial. Menopause (New York, and N.Y.) 23(7), 740-8	RCT n=186 FU=1 year	In postmenopausal women with severe pelvic organ prolapse who underwent transvaginal pelvic reconstructive surgery with mesh, non-vaginal oestrogen therapy before surgery was noninferior to vaginal oestrogen therapy regarding mesh exposure rate within 1 year of follow-up.	Study assesses the effects of preoperative vaginal oestrogen therapy.

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Sung VW, Rogers RG, Schaffer JI et al. (2008) Graft use in transvaginal pelvic organ prolapse repair: a systematic review. Obstetrics and gynecology 112(5), 1131-42	Systematic review n=74 articles	Overall, the existing evidence is limited to guide decisions regarding whether to use graft materials in transvaginal prolapse surgery. Adequately powered randomised trials evaluating anatomic and symptomatic efficacy as well as adverse events are needed.	A more recent systematic review is included (Maher et al., 2016).
Takahashi S, Obinata D, Sakuma T et al. (2010) Tension-free vaginal mesh procedure for pelvic organ prolapse: A single-center experience of 310 cases with 1-year follow-up. International Journal of Urology 17(4), 353-358	Case series n=310 FU=12 months	Perioperative complications: 5 bladder injuries (2%), 3 haemorrhages greater than 400 ml (1%). The anatomical cure rate (% stage 0 cases) at 12 months after surgery was 92%. Short Form-36 and prolapse-QOL parameters were significantly improved, and maintained during the follow-up period. Postoperative complications: 5 pelvic haematomas (2%), 1 wound infection (0.3%), 10 vaginal mesh extrusions (3%), and 3 cases of pelvic pain (1%). Complications concerning lower urinary tract function were: 8 cases of postoperative stress urinary incontinence (3%), 3 cases of transient urinary retention (1%), and 2 cases of de novo overactive bladder (0.6%).	Studies with more patients or longer follow-up are included.
Tamanini JT, de Oliveira SC, Renata C et al. (2015) A prospective, randomized, controlled trial of the treatment of anterior vaginal wall prolapse: medium-term follow-up. The Journal of urology 193(4), 1298-304	RCT n=100 FU=24 months	No difference was found between the groups when considering 2 cure criteria on prolapse stage and subjective parameters. Asymptomatic mesh exposure developed on the anterior vaginal wall prolapse in 7 patients (16%) in the mesh group. Minor mesh-related complications consisted of mesh exposure, prepubic ecchymosis and groin pain, of which most were treated conservatively. Urinary retention was treated surgically.	Trial was included in Maher et al, 2016 systematic review.
Tan YL, Lo TS, Khanuengkitkong S et al. (2014) Comparison of outcomes after vaginal reconstruction surgery between elderly and younger women. Taiwanese journal of obstetrics & gynecology 53(3), 348-54	Non-randomised comparative study n=225 FU=mean 34 months	This study showed that adequately optimised older patients undergoing pelvic organ prolapse surgery experienced the same anatomical outcomes, comparable improved quality of life, morbidity, and mortality as their counterparts of younger age.	Study focuses on outcomes according to patient age group.
Taylor GB, Moore RD, Miklos JR et al. (2008) Posterior repair with perforated porcine dermal graft. International braz j urol : official journal of the Brazilian Society of Urology 34(1), 84-90	Non-randomised comparative study n=127	Perforated porcine dermal grafts retain their tensile properties and are associated with fewer vaginal incision dehiscences than non-perforated grafts.	Study compares perforated porcine with non-perforated grafts.

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Tomoe H (2015) Improvement of overactive bladder symptoms after tension-free vaginal mesh operation in women with pelvic organ prolapse: Correlation with preoperative urodynamic findings. International Journal of Urology 22(6), 577-580	Case series n=100 FU=3 months	Pelvic organ prolapse-associated overactive bladder or detrusor overactivity conditions can be reversed in most cases within a short period of time after surgical correction of pelvic organ prolapse.	Studies with more patients or longer follow-up are included.
Turgal M, Sivaslioglu A, Yildiz A et al. (2013) Anatomical and functional assessment of anterior colporrhaphy versus polypropylene mesh surgery in cystocele treatment. European journal of obstetrics, gynecology, and and reproductive biology 170(2), 555-8	Non-randomised comparative study n=40 FU=12 months	Anatomical cure rates were 75% (15/20) in the anterior colporrhaphy group and 95% (19/20) in the mesh repair group ($p<0.05$). De novo stress urinary incontinence developed in 1 patient treated by colporrhaphy. Mesh erosion developed postoperatively in 3 patients (15%).,	Studies with more patients or longer follow-up are included.
Vaiyapuri GR, Han HC, Lee LC et al. (2011) Use of the Gynecare Prolift system in surgery for pelvic organ prolapse: 1-year outcome. International urogynecology journal 22(7), 869-77	Case series n=254 FU=1 year	The subjective and objective cure rates at 1 year after this mesh implant surgery in 2006, 2007 and 2008 were 92% and 92%; 97% and 92% and 100% and 97%, respectively. The mesh erosion rate was lower in 2008 as compared to 2007 and 2006 ($p<0.001$).	Studies with more patients or longer follow-up are included.
Vollebregt A, Gietelink D, Fischer K et al. (2010) One year results of colporraphy anterior versus a trocar-guided transobturator synthetic mesh in primary cystocele repair: A randomized controlled trial. Neurourology and Urodynamics 29(6), 880-882	RCT n=125 FU=12 months	A statistically significant better anatomical outcome was found in the mesh group. Functional outcome (UDI and IIQ scores) improved significantly at 12 months, with no significant differences between groups. Erosions occurred in 2 (4%) cases in the Avaulta group, both treated with local excision. De novo dyspareunia was reported in 3/20 (15%) women in the Avaulta group versus 2/21 (9%) in the colporraphy group ($p<0.05$).	Study is included in Maher et al, 2016 systematic review.

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Vollebregt A, Fischer K, Gietelink D et al. (2011) Primary surgical repair of anterior vaginal prolapse: a randomised trial comparing anatomical and functional outcome between anterior colporrhaphy and trocar-guided transobturator anterior mesh. BJOG : an international journal of obstetrics and gynaecology 118(12), 1518-27	RCT n=125 FU=12 months	Compared with the anterior colporrhaphy group, the mesh reduced the risk of anatomical failure from 59 to 9% (risk reduction 50%, 95% CI 35.5 to 65.1). Three (5%) reoperations for anatomical failure in the anterior colporrhaphy group were done versus 0% in the mesh group. Functional outcome improved significantly on almost all domains, with similar results between groups. Mesh exposure occurred in 2 (4%) women. Baseline dyspareunia disappeared significantly more often after an anterior colporrhaphy (80%) than in the mesh group (20%). There was a trend towards more de novo dyspareunia in the mesh group (15% versus 9%).	Study is included in Maher et al, 2016 systematic review.
Vollebregt A, Fischer K, Gietelink D et al. (2012) Effects of vaginal prolapse surgery on sexuality in women and men; results from a RCT on repair with and without mesh. The journal of sexual medicine 9(4), 1200-11	RCT n=125 FU=6 months	Women after an anterior colporrhaphy report a significant and clinically relevant improvement of their sexual functioning, whereas women after a mesh procedure did not.	Study focuses on the effect of the procedure on sexuality in men and women.
Walter JE, Urogynaecology Committee, Lovatsis D et al. (2011) Transvaginal mesh procedures for pelvic organ prolapse. Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC 33(2), 168-74	Review	Patients should be counselled that transvaginal mesh procedures are considered novel techniques for pelvic floor repair that demonstrate high rates of anatomical cure in uncontrolled short-term case series. Patients should be informed of the range of success rates until stronger evidence of superiority is published. Training specific to transvaginal mesh procedures should be undertaken before procedures are performed. Patients should undergo thorough preoperative counselling regarding (a) the potential serious adverse sequelae of transvaginal mesh repairs, including mesh exposure, pain, and dyspareunia; and (b) the limited data available comparing transvaginal mesh systems with traditional vaginal prolapse repairs or with traditional use of graft material in the form of augmented colporrhaphy and sacral colpopexy. Until appropriate supportive data are available, new trocarless kits should be considered investigative.	A more recent systematic review is included (Maher et al., 2016).

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Weintraub AY, Neuman M, Reuven Y et al. (2016) Efficacy and safety of skeletonized mesh implants for advanced pelvic organ prolapse: 12-month follow-up. World Journal of Urology	Case series n=103 FU=12 months	The present study showed excellent anatomical and quality-of-life results in patients with advanced POP treated with a skeletonised and reduced mesh system. No mesh exposure was recorded within the first year after surgery.	Studies with more patients or longer follow-up are included.
Withagen MIJ, Vierhout ME, Milani AL (2010) Does trocar-guided tension-free vaginal mesh (Prolift) repair provoke prolapse of the unaffected compartments? International urogynecology journal 21(3), 271-8	Case series n=150 FU=12 months	23% of all patients developed a de novo POP stage II or greater in the untreated compartment. This occurred in 46% and 25% of patients after an isolated anterior and isolated posterior Prolift, respectively.	Studies with more patients or longer follow-up are included.
Withagen MI, Milani AL, den Boon J et al. (2011) Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstetrics and gynecology 117(2 Pt 1), 242-50	RCT n=190 FU=12 months	Anatomic failure in the treated compartment was observed in 45% (38/84) of patients in the conventional group and in 10% (8/83) of patients in the mesh group ($p<0.001$; odds ratio, 7.7; 95% confidence interval, 3.3 to 18). Patients in either group reported less bulge and overactive bladder symptoms. Subjective improvement was reported by 80% (64/80) of patients in the conventional group compared with 81% (63/78) of patients in the mesh group. Mesh exposure was detected in 17% (4/83) of patients.	Study is included in Maher et al, 2016 systematic review.
Withagen MI, Vierhout ME, Hendriks JC et al. (2011) Risk factors for exposure, pain, and dyspareunia after tension-free vaginal mesh procedure. Obstetrics and gynecology 118(3), 629-36	Case series n=294 FU=12 months	Smoking, total tension-free vaginal mesh, and experience were predictive factors for mesh exposure.	Studies with more patients or longer follow-up are included.

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Withagen MI, Milani AL, de Leeuw JW et al. (2012) Development of de novo prolapse in untreated vaginal compartments after prolapse repair with and without mesh: a secondary analysis of a randomised controlled trial. BJOG : an international journal of obstetrics and gynaecology 119(3), 354-60	RCT n=121 FU=12 months	17% (10/59) of women in the conventional group versus 47% (29/62) of women in the mesh group were diagnosed with a de novo pelvic organ prolapse stage II or higher in the untreated compartment (p<0.001, odds ratio 4.3, 95% confidence interval 1.9 to 10). Additional apical support to a mesh-augmented anterior repair significantly reduced the de novo prolapse rate. Women with a de novo prolapse in the mesh-treated group demonstrated significantly higher mean bother scores on the domain genital prolapse of the Urogenital Distress Inventory score (13.1 +/- 24.2) compared with those without de novo prolapse (2.9 +/- 13.9) (p=0.03).	Secondary analysis of trial included in Maher et al, 2016 systematic review.
Wong KS, Nguyen JN, White T et al. (2013) Adverse events associated with pelvic organ prolapse surgeries that use implants. Obstetrics and gynecology 122(6), 1239-45	Case series n=1,282 FU=mean 358 days	Vaginal exposures occurred more often with permanent mesh (53/847 [6%]) than biologic grafts (10/637 [2%]) (p<0.001). Resolution of vaginal exposure after the first treatment occurred in 24 of 63 (38%), whereas 39 of 63 (62%) required multiple treatments. Surgical excision was performed in 20 of 63 (32%) exposures. Permanent mesh exposures were more likely to require surgical excision (20/53 [38%]) than biologic graft exposures (0/10) (p=0.02).	Studies with more patients or longer follow-up are included.
Wong V, Shek K, Rane A et al. (2013) Is levator avulsion a predictor of cystocele recurrence following anterior vaginal mesh placement? Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology 42(2), 230-4	Case series n=209 FU=2 years	Levator avulsion doubles the risk of cystocele recurrence after anterior colporrhaphy with transobturator mesh.	Studies with more patients or longer follow-up are included.
Wong V, Shek KL, Goh J et al. (2014) Cystocele recurrence after anterior colporrhaphy with and without mesh use. European journal of obstetrics, gynecology, and and reproductive biology 172, 131-5	Non-randomised comparative study n=183 FU=mean 4 years	At a mean of 4 years' follow-up, mesh augmentation was associated with reduced cystocele recurrence, but this effect was limited to patients with levator avulsion.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Wong V, Shek KL, Rane A et al. (2014) A comparison of two different mesh kit systems for anterior compartment prolapse repair. The Australian & New Zealand journal of obstetrics & gynaecology 54(3), 212-7	Non-randomised comparative study n=229 FU=mean 1 year	24% (n=55) of patients had symptoms of prolapse recurrence, 46% (n=106) had a clinical recurrence, and 41% (n=95) a recurrent cystocele sonographically. All objective results favoured the Perigee group. The superiority of the Perigee kit remained highly significant ($p<0.0001$ for all clinical and ultrasound measures of prolapse recurrence) on multivariate analysis.	Study compares 2 different mesh kits.
Yang X, Li H (2012) A modified anterior compartment reconstruction and Prolift-a for the treatment of anterior pelvic organ prolapse: a non-inferiority study. Archives of gynecology and obstetrics 285(6), 1593-7	Non-randomised comparative study n=105	The cure rates were 94% (64/68) in the modified group and 97% (36/37) in the Prolift-a group, respectively. No significant difference was found between these 2 groups in the cure rate by non-inferiority test. The blood loss and hospitalisation costs were significantly lower in the modified group than the Prolift-a group ($p<0.05$), while other clinical parameters showed no significant difference between the 2 groups.	Studies with more patients or longer follow-up are included.
Yasmin H, Mokrzycki ML (2008) Levator-ani necrosis-a rare complication following pelvic floor repair of apical and posterior vaginal prolapse. Journal of Pelvic Medicine and Surgery 14(4), 342	Case report n=1	**Levator-ani necrosis** The patient was treated by sacrospinous ligament fixation, a posterior colporrhaphy augmented by a Gynemesh graft and pubovaginal sling. She presented later with a 5 month history of a hard mass in her right buttock. On pelvic exam, the posterior vaginal wall revealed a defect in the right levator-ani muscle area. The mass was confirmed to be impacted stool in an area of the rectum that had prolapsed into the right levator-ani muscle area. The defect in levator-ani complex could have possibly resulted from haemorrhagic necrosis after either of the above 2 procedures or secondary to nerve damage during surgery leading to weakness of the Levator-ani complex. This could have possibly resulted in a weakness defect of Levator ani causing prolapse of bowel into this defect.	Case report of levator-ani necrosis. The patient had more than 1 procedure and it is not clear if the adverse event was related to the mesh repair.
Yonguc T, Gunlusoy B, Arslan B et al. (2014) Does concomitant vaginal prolapse repair affect the outcomes of the transobturator tape procedure in the long term? International urogynecology journal 25(10), 1419-23	Non-randomised comparative study n=232 FU=mean 66 months	Concomitant vaginal prolapse repair with TOT does not have any negative effects on continence outcomes; on the contrary, it increases patient satisfaction.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Yonguc T, Bozkurt IH, Arslan B et al. (2015) Outcomes of two different incision techniques for surgical treatment of stress urinary incontinence with concomitant anterior vaginal wall prolapse. World journal of urology 33(7), 1045-9	Non-randomised comparative study n=233 FU=mean 44 months	Both incision techniques have satisfactory outcomes in the surgical treatment of SUI with cystocele; nevertheless, the postoperative complications favour the double incision.	Study compares single incision with double-incision technique for stress urinary incontinence and anterior vaginal wall prolapse.
Zambon JP, Badlani GH (2016) Vaginal Mesh Exposure Presentation, Evaluation, and Management. Current Urology Reports 17(9), 65	Review	The exponential increase in the number of mesh-related complications is related mainly to a lack of surgeon's experience and proper training in reconstructive pelvic surgeries as well as availability of easy-to-handle kits. Despite improvements in short- and long-term outcomes since the introduction of mesh in pelvic surgeries, the incidence of postoperative complications remains elevated.	The main focus of the review is to report an algorithm developed to facilitate prompt recognition and treatment of vaginal mesh exposure.
Zargham M, Alizadeh F, Tadayyon F et al. (2013) Concomitant surgical correction of severe stress urinary incontinence and anterior vaginal wall prolapse by anterior vaginal wall wrap: 18 months outcomes. Journal of research in medical sciences : the official journal of Isfahan University of Medical Sciences 18(7), 588-93	RCT n=56 FU=18 months	Vaginal sling surgery using an anterior vaginal wall strip can improve stress urinary incontinence and in comparison with propylene mesh is associated with lower complication rates.	Larger studies are included.
Zhang L, Zhu L, Liang S et al. (2015) Short-term effects on voiding function after mesh-related surgical repair of advanced pelvic organ prolapse. Menopause 22(9), 993-999	Case series n=171 FU=3 months	Women with a higher Pelvic Organ Prolapse Quantification stage in the anterior compartment and a lower preoperative average urine flow rate are prone to postoperative voiding dysfunction.	Studies with more patients or longer follow-up are included.
Zhang L, Zhu L, Xu T et al. (2015) Postoperative voiding difficulty and mesh-related complications after Total Prolift System surgical repair for pelvic organ prolapse and predisposing factors. Menopause 22(8), 885-892	Case series n=206 FU=4 years	Low average urine flow rate and preoperative urinary retention can be used to predict postoperative voiding difficulty. Vaginal complications (mesh exposure/contraction) are the primary mesh-related complications and are predicted by greater blood loss and past pelvic surgical operation.	Studies with more patients or longer follow-up are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Zyczynski HM, Carey MP, Smith ARB et al. (2010) One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. American journal of obstetrics and gynecology 203(6), 587.e1-8	Case series n=136 FU=1 year	At follow-up, 7% were stage 0/I; however, in 87% of patients, the leading vaginal edge was above the hymen. Pelvic symptoms, quality of life, and sexual function improved significantly from baseline ($p<0.05$). Median visual analogue scale scores for vaginal support device awareness and discomfort were 2.6 and 1.2, respectively (0=none; 10=worst possible).	Studies with more patients or longer follow-up are included.

Appendix B: Related NICE guidance for surgical repair of vaginal wall prolapse using mesh

Guidance	Recommendations
Interventional procedures	**Surgical repair of vaginal wall prolapse using mesh. NICE interventional procedure guidance 267 (2008)** (current guidance) 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.

Interventional Procedures	**Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE interventional procedure guidance 566 (2016)** 1.1 The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include lasting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but, if removal is needed because of complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research. 1.2 Clinicians wishing to do single-incision short sling mesh insertion for stress urinary incontinence in women should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, and that the mesh implant is intended to be permanent so removal, if needed, may be difficult or impossible. Provide patients with clear written information. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence in women (see section 7.1). 1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence. 1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. Removal of a short sling mesh should only be done by people with expertise in this specialised surgery. 1.5 NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.

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

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

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

Interventional Procedures	**Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE interventional procedure guidance 281 (2009)** 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.

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

Interventional Procedures	**Insertion of biological slings for stress urinary incontinence in women. NICE interventional procedure guidance 154 (2006)** 1.1 Current evidence on the safety and short-term efficacy of the insertion of biological slings for stress urinary incontinence in women is adequate to support the use of this procedure provided that normal arrangements are in place for consent and clinical governance. 1.2 Data on the long-term efficacy of the insertion of biological slings for stress urinary incontinence in women are limited to autologous slings. Clinicians should therefore audit patients in the longer term. Publication of further audit data and research will be helpful in determining the usefulness of different types of sling for this procedure. 1.3 Clinicians should ensure that patients understand that slings made of cadaveric or animal tissue may be implanted, and that the use of such slings is acceptable to the patient.

Appendix C: Literature search for surgical repair of vaginal wall prolapse using mesh

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	18/01/2017	Issue 1 of 12, January 2017
Cochrane Central Database of Controlled Trials - CENTRAL	18/01/2017	Issue 11 of 12, November 2016
HTA database (Cochrane)	18/01/2017	Issue 4 of 4, October 2016
MEDLINE (Ovid)	18/01/2017	1946 to December Week 1 2016
MEDLINE In-Process (Ovid)	18/01/2017	January 17, 2017
EMBASE (Ovid)	18/01/2017	1974 to 2017 Week 03
PubMed	18/01/2017	n/a
JournalTOCS [for update searches only]	18/01/2017	n/a

Trial sources searched on 01/06/2016

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

Websites searched on 25/05/2016 and 01/06/2016

- 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 pelvic organ prolapse/
2 Uterine Prolapse/
3 vagina/
4 fascia/
5 ((fascia* or pelvic* or cervic* or transvagin* or vagin* or genital* or uter* or urogenit* or womb* or genito* or intravaginal*) adj2 (prolaps* or collaps* or drop*)).ti,ab.

6	rectocele/
7	cystocele/
8	(rectocele* or cystocele* or enterocele*).ti,ab.
9	or/1-8
10	surgical mesh/
11	suburethral slings/
12	((cervic* or transvagin* or vagin* or genital* or pelvic* or uter* or urogenit* or womb* or genito* or intravaginal* or fascia* or small intestine submucosa or SIS) adj2 (mesh* or graft* or plast* or sling* or tape* or suspens* or gauze*)).ti,ab.
13	*Polypropylenes/ or *Polyglactin 910/
14	((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*)).ti,ab.
15	or/10-14
16	9 and 15
17	*gynecologic surgical procedures/
18	((anterior* or posterior* or apical* or prolaps* or drop* or collaps*) adj2 (repair* or reconstruct* or surg*)).ti,ab.
19	(AWP or PWP).ti,ab.
20	(Colporrhaph* or colpoperineorraph* or cystopex* or sacrohysteropex* or sacrocolpopex* or sacropex*).ti,ab.
21	or/17-20
22	16 and 21
23	animals/ not humans/
24	22 not 23
25	limit 24 to ed=20071101-20160531