A report for
Universitätsklinikum Schleswig-Holstein/Campus Kiel
on shared decision making
for treatment of women with pelvic organ prolapse

Kleijnen Systematic Reviews Ltd

May 2020

Kleijnen Systematic Reviews Ltd
Unit 6, Escrick Business Park
Riccall Road
Escrick
York
YO19 6FD
United Kingdom
Telephone: +44 (0)1904 727980
Fax: +44 (0)1904 720429
Email: robert@systematic-reviews.com
Website: www.systematic-reviews.com

Steve Ryder
Stephanie Swift
Lisa Stirk
Jos Kleijnen
Robert Wolff

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LIST OF ABBREVIATIONS

ADL	Activities of daily living
ASC	Abdominal sacrocolpopexy
CDSR	Cochrane Database of Systematic Reviews
CESA	Cervicosacropexy
CI	Confidence interval
CRD	Centre for Reviews and Dissemination
DARE	Database of Abstracts of Reviews of Effects
DDI	Defecatory Distress Inventory
EQ-5D	EuroQoL – 5 dimensions
FAQ	Frequently asked questions
G	Guideline
G-I-N	Guidelines International Network
HSP	Hysterosacropexy/sacrohysteropexy
HTA	Health technology assessment
IIQ	Incontinence impact questionnaire
KSR	Kleijnen Systematic Reviews
LC	Laparoscopic colpopexy
LP	Laparoscopic pectopexy
LSC	Laparoscopic sacrocolpopexy
MD	Mean difference
ml	Millilitre
NA	Not applicable
ND	No difference
NE	Not estimable
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NR	Not reported
OR	Odds ratio
PFDI	Pelvic Floor Distress Inventory
PFIQ	Pelvic Floor Impact Questionnaire
PFSI	Pelvic Floor Sexual Impact-7
PGI-I	Patient Global Impression of Improvement
PICOS	Population, intervention, comparator, outcome and study design
PISQ	Prolapse and Incontinence Sexual Questionnaire
POP	Pelvic organ prolapse
P-QOL	Prolapse quality of life
QoL	Quality of life
RALSC	Robot-assisted laparoscopic sacrocolpopexy
RCOG	Royal College of Obstetrics and Gynaecology
RCT	Randomised controlled trial
RD	Risk difference
RR	Risk ratio
SD	Standard deviation
SDM	Shared decision making
SF-36	Short-Form 36

SR	Systematic review
SSLF	Sacrospinal ligament fixation
SUDI	Short Urinary Distress Inventory
StUI	Stress urinary incontinence
SUI	Serious unintended injury
TSSLF	Transvaginal sacrospinal ligament fixation
UDI	Urinary Distress Inventory
UISQ	Urinary Incontinence Sexual Questionnaire-12
UTI	Urinary tract infection
UUI	Urge urinary incontinence
VAS	Visual analogue scale
VASA	Vaginosacropexy
VSC	Vaginal sacrospinous colpopexy

1. OBJECTIVES

A key aim of the research project “Making SDM a reality” is to create interactive websites to inform patients as part of shared decision making (SDM).

To support this, Kleijnen Systematic Reviews (KSR) Ltd. has prepared an evidence report with a synthesis of the literature underpinning the supporting evidence table of the relevant treatment options.

The topic of this evidence report is treatment for pelvic organ prolapse (POP).

2. METHODS

2.1 INCLUSION CRITERIA

The research question underpinning the literature searches for this topic was developed in conjunction with clinical departments at Universitätsklinikum Schleswig-Holstein/Campus Kiel.

The review focuses on two separate populations. The main population is all women with vaginal or mixed pelvic prolapse who are symptomatic while an additional population was defined by those who had undergone a prior hysterectomy. The research question for the main group (Table 1) and subgroup (Table 2) was framed in terms of population, intervention, comparators, outcomes and study design (PICOS).

As detailed in section 1.3, literature searches were carried out using a stepwise approach to identify relevant studies according to study design. In the first step, searches aimed to identify relevant systematic reviews and guidelines.

Table 1: Treatment of women with pelvic organ prolapse – main population

PICOS	Included	Excluded
Population	• Women with vaginal prolapse who are symptomatic (such as vaginal pressure, pelvic pain, overactive bladder or sexual problems). • Mixed pelvic prolapse (that reports vaginal prolapse as a subgroup) is included.	• Women with anterior or posterior pelvic organ prolapse • Women intending to get pregnant • Rectal prolapse • Bladder prolapse
Intervention	• **Mesh-based treatments**, such as: ○ **Sacropexy/ sacrocolpopexy** - Abdominal sacrocolpopexy (ASC) - Laparoscopic sacrocolpopexy (mesh fixed medially at the longitudinal ligament of the os sacrum) (LSC) - Robot-assisted sacrocolpopexy (RALSC) - Cervicosacropexy (CESA) - Vaginosacropexy (VASA) - Hysterosacropexy/ Sacrohysteropexy (with attachment to the sacral bone) (HSP) ○ **Pectopexy** - Laparoscopic pectopexy	Anterior vaginal repair techniques, including: • Colporrhaphy • McCaul culdoplasty • Paravaginal repair Posterior vaginal repair techniques, including: • Perineoplasty • Rectocele therapies Other repair techniques: • Transvaginal mesh Hysteropexy without attachment to the sacral bone or not using mesh Paravaginal repair Rectopexy (all types) Colporectopexy

PICOS	Included	Excluded
	(mesh fixed at the iliopectinal ligament) (LP) - Laparoscopic colpopectopexy (mesh fixed laterally at the pectineal ligament) (LC) • **Non-mesh-based treatments**, such as: ○ **Sacrospinal ligament fixation** (SSLF) including transvaginal fixation e.g. Amreich-Richter - not mesh Any of these treatments undertaken in combination with any other procedure are to be included.	Sacrospinous hysteropexy Manchester Procedure Vaginal Hysterectomy Infracoccygeal sacropexy Non-surgical interventions, including: • Pessaries • Pelvic floor muscle training • Watchful waiting Comparisons of different types of mesh
Comparator	Any of the above interventions compared directly against the other.	As above.
Outcomes	• Length of operation • Length of hospital stay • Improvement of symptoms, including: ○ vaginal pressure ○ pelvic pain ○ bladder function ○ bowel function ○ incontinence ○ sexual function, such as: ▪ Prolapse and Incontinence Sexual Questionnaire (PISQ-12) ○ painful intercourse • Recurrence of prolapse • Quality of life, such as: ○ Prolapse Quality of Life (P-QOL) ○ PFDI-7 ○ PFDI-20 ○ VAS • Time to return to usual activity • Time off work or return to work • Time to return to sexual activity • Major bleeding	

PICOS	Included	Excluded

	• Infection rate
	• Fever
	• Issues with wound healing
	• Blood loss during surgery
	• Surgical injuries
	  ○ Urinary tract injuries
	  ○ Rectal injuries
	  ○ Pelvic floor complications
	  ○ Abdominal complications
	  ○ Mesh-related problems (e.g. exposure)
	• Mortality
	• Impact on dependents/family
	• Patient satisfaction.	

Study design	Systematic reviews	Literature reviews; expert opinions; primary research; letters

ASC = abdominal sacrocolpopexy; CESA = cervicosacropexy; HSP = hysterosacropexy/ sacrohysteropexy; LC = laparoscopic colpopexy; LP = laparoscopic pectopexy; LSC = laparoscopic sacrocolpopexy, PFDI = Pelvic Floor Distress Index; PISQ-12 = Prolapse and Incontinence Sexual Questionnaire-12; P-QOL = Prolapse Quality of Life; RALSC = robot-assisted laparoscopic sacrocolpopexy; SSLF = sacrospinal ligament fixation; VAS = visual analogue scale; VASA = vaginosacropexy

Table 2: PICOS: Treatment of women with pelvic organ prolapse who had previously undergone hysterectomy.

	Included	Excluded
Population	• Women with vaginal prolapse who are symptomatic (such as vaginal pressure, pelvic pain, overactive bladder or sexual problems) with prior hysterectomy*. • Mixed pelvic prolapse (that reports vaginal prolapse as a subgroup) is included.	• Women with anterior or posterior pelvic organ prolapse • Women intending to get pregnant • Rectal prolapse • Bladder prolapse • Women without prior hysterectomy

Intervention	• **Mesh-based treatments**, such as:
	  - Abdominal sacrocolpopexy (ASC)
	  - Laparoscopic sacrocolpopexy (mesh fixed medially at the longitudinal ligament of the os sacrum)(LSC)
	  - Robotic sacrocolpopexy (RALSC)
	  - Laparoscopic
		Anterior vaginal repair techniques, including:
		• Colporrhaphy
		• McCaul culdoplasty
		• Paravaginal repair
		
		Posterior vaginal repair techniques, including:
		• Perineoplasty
		• Rectocele therapies
		
		Other repair techniques:

	Included	Excluded
	colpopectopexy (mesh fixed laterally at the pectineal ligament)(LC) - Laparoscopic pectopexy (mesh fixed at the iliopectinal ligament) (LP) • **Non-mesh-based treatments**, such as: - Transvaginal sacrospinal ligament fixation (Amreich-Richter) (sacrospinal ligament pelvic floor reconstruction) (TSSLF) - Sacrospinal ligament fixation (SSLF)	• Transvaginal mesh Non-surgical interventions, including: • Pessaries • Pelvic floor muscle training • Watchful waiting Combination treatments
Comparator	Any of the above interventions compared against the other	As above.
Outcomes	• Length of operation • Length of hospital stay • Improvement of symptoms, including: ○ vaginal pressure ○ pelvic pain ○ bladder function ○ bowel function ○ incontinence ○ sexual function, such as: ▪ Prolapse and Incontinence Sexual Questionnaire (PISQ-12) ○ painful intercourse • Recurrence of prolapse • Quality of life, such as: ○ Prolapse Quality of Life (P-QOL) ○ PFDI-7 ○ PFDI-20 ○ VAS • Time to return to usual activity • Time off work or return to work • Time to return to sexual activity • Major bleeding	

	Included	Excluded

	• Infection rate
	• Fever
	• Issues with wound healing
	• Blood loss during surgery
	• Surgical injuries
	  ○ Urinary tract injuries
	  ○ Rectal injuries
	  ○ Pelvic floor complications
	  ○ Abdominal complications
	  ○ Mesh-related problems (e.g. exposure)
	• Mortality
	• Impact on dependents/family
	• Patient satisfaction.	

Study design	Systematic reviews	Literature reviews; expert opinions; primary research; letters
Effect modification / Subgroups	With or without stress urinary incontinence	

* Mixed populations were included if 80% or more of women had undergone a prior hysterectomy.
ASC = abdominal sacrocolpopexy; CESA = cervicosacropexy; HSP = hysterosacropexy/ sacrohysteropexy; LC = laparoscopic colpopexy; LP = laparoscopic pectopexy; LSC = laparoscopic sacrocolpopexy, PFDI = Pelvic Floor Distress Index; PISQ-12 = Prolapse and Incontinence Sexual Questionnaire-12; P-QOL = Prolapse Quality of Life; RALSC = robot-assisted laparoscopic sacrocolpopexy; SSLF = sacrospinal ligament fixation; VAS = visual analogue scale; VASA = vaginosacropexy

2.2 Frequently Asked Questions

The following research questions were identified as frequently asked questions (FAQs) for both the main group and subgroup (post hysterectomy):

1. **What does treatment of POP involve?**
   a. Rationale
   b. Length of procedure
   c. Length of stay
   d. Other issues
2. **Will symptoms get better?**
   a. Recurrence of POP
   b. Incontinence
   c. Bladder/urinary function
   d. Sexual function
   e. Bowel function
3. **Will quality of life get better?**
   a. Quality of life
   b. Satisfaction levels

4. **When will the patient recover?**
    a. Time to return to usual activity
    b. Time to return to work
    c. Time to return to sexual function
    d. Other (e.g. sports function)
5. **What are the long-term risks and implications?**
    a. Bleeding volumes / blood loss
    b. Pelvic pain
    c. Wound infections
    d. Urinary tract infections (UTI)
    e. Rectal injury
    f. Other Serious Unintended Injury (SUI)
    g. Other pelvic floor/ abdominal complications
    h. Mesh-related problems
    i. Other long-term risks
    j. Re-operation

2.3 LITERATURE SEARCHES

Literature searches were carried out to identify relevant systematic reviews and evidence-based guidelines on pelvic organ prolapse. To inform FAQs, a second targeted database search on shared decision making was also undertaken.

The search strategies were developed specifically for each database and the keywords adapted according to the configuration of each database. Searches were limited by date range for systematic reviews and guidelines to 2012-2019. Targeted searches on SDM and pelvic organ prolapse were limited to the last six years as current and up-to-date evidence in this area was considered to be most relevant. Searches were not limited by language or publication status.

Literature searches were conducted on 17 September 2019 to identify evidence to inform questions (FAQs) and to answer these FAQs based on systematic reviews, meta-analyses and evidence-based guidelines.

For this evidence report, searches for systematic reviews and guidelines were supplemented by targeted web searches to find information for the more narrative aspects of FAQs. The bibliographies of included studies and review articles were also checked for additional relevant articles.

2.3.1 Systematic reviews and guidelines

The following systematic review specific databases were searched from 2012 to present:

- Cochrane Database of Systematic Reviews (CDSR) (Wiley): 2012-2019/Iss9
- Database of Abstracts of Reviews of Effects (DARE) (www.crd.york.ac.uk): 2012-2015/03/31

- Health Technology Assessment (HTA) database (www.crd.york.ac.uk): 2012-2018/03/31
- KSR Evidence (KSR): up to 2019/09/17
- Epistemonikos (www.epistemonikos.org): 2012-2019/09/17

The following guidelines resources were searched from 2012 to present:

- Guidelines International Network (G-I-N) (www.g-i-n.net): up to 2019/09/17
- NHS Evidence (www.evidence.nhs.uk): 2012/01/01-2019/09/17
- ECRI Guidelines Trust (https://guidelines.ecri.org/): up to 2019/09/17
- NICE (www.nice.org.uk): up to 2019/09/17

2.3.2 Targeted searches

An additional set of searches was conducted on 28 January 2020 to identify primary studies specifically relating to the topic of pectopexy. The following databases were searched:

- Embase (Ovid): 1912-27.1.20
- MEDLINE, Medline In Process, Daily Update and Epub Ahead of Print (Ovid): 1912-27.1.20
- Northern Light Life Sciences Conference Abstracts (Ovid): 2012-2020 Week 3
- Cochrane Central Register of Controlled Trials (Wiley): 2012-Issue 1 of 12, January 2020

Full details of all search strategies are presented in Appendix 1.

2.3.3 Handling of citations

Identified references from the bibliographic database searches were downloaded into EndNote bibliographic management software for further assessment and handling.

2.3.4 Supplementary searches

Internet searches were performed to add more qualitative patient-related information to inform the more narrative FAQs.

2.4 STUDY SELECTION

Two reviewers independently screened the title and abstract of each record identified by the search and determined the potential relevance of each record. For potentially relevant records, the full paper was obtained, independently checked, and inclusion criteria applied. Any disagreements were resolved through discussion.

An evidence hierarchy was used to select the most appropriate study(ies) to populate the evidence tables. Where more than one study could provide evidence, the most relevant studies were selected using the following criteria: recency (most recent preferred), quality (highest quality preferred), representativeness (populations which are representative of the target population or sub population preferred). Where there were gaps in the evidence (no systematic review or guideline available), as described before, relevant randomised controlled trials (RCTs) were searched for and extracted, and where no RCTs were identified, observational studies were assessed.

2.5 DATA EXTRACTION

For each study, data were extracted by one reviewer and checked by another. Any disagreements were resolved by consensus. Primary studies reported in systematic reviews were checked to determine if they reported any additional evidence for outcomes that were not reported in secondary sources (i.e. evidence gaps). In some instances, effect sizes were not reported in the source paper but were instead calculated separately based on analysis in Review Manager 5.3 using random effects and the Mantel-Haenszel test.

Where effect sizes indicated a small difference (effect estimate 0.9 to 1.1) and the 95% confidence interval (CI) crossed the line of no effect, a judgement of no difference (ND) was applied.

3. RESULTS - OVERVIEW

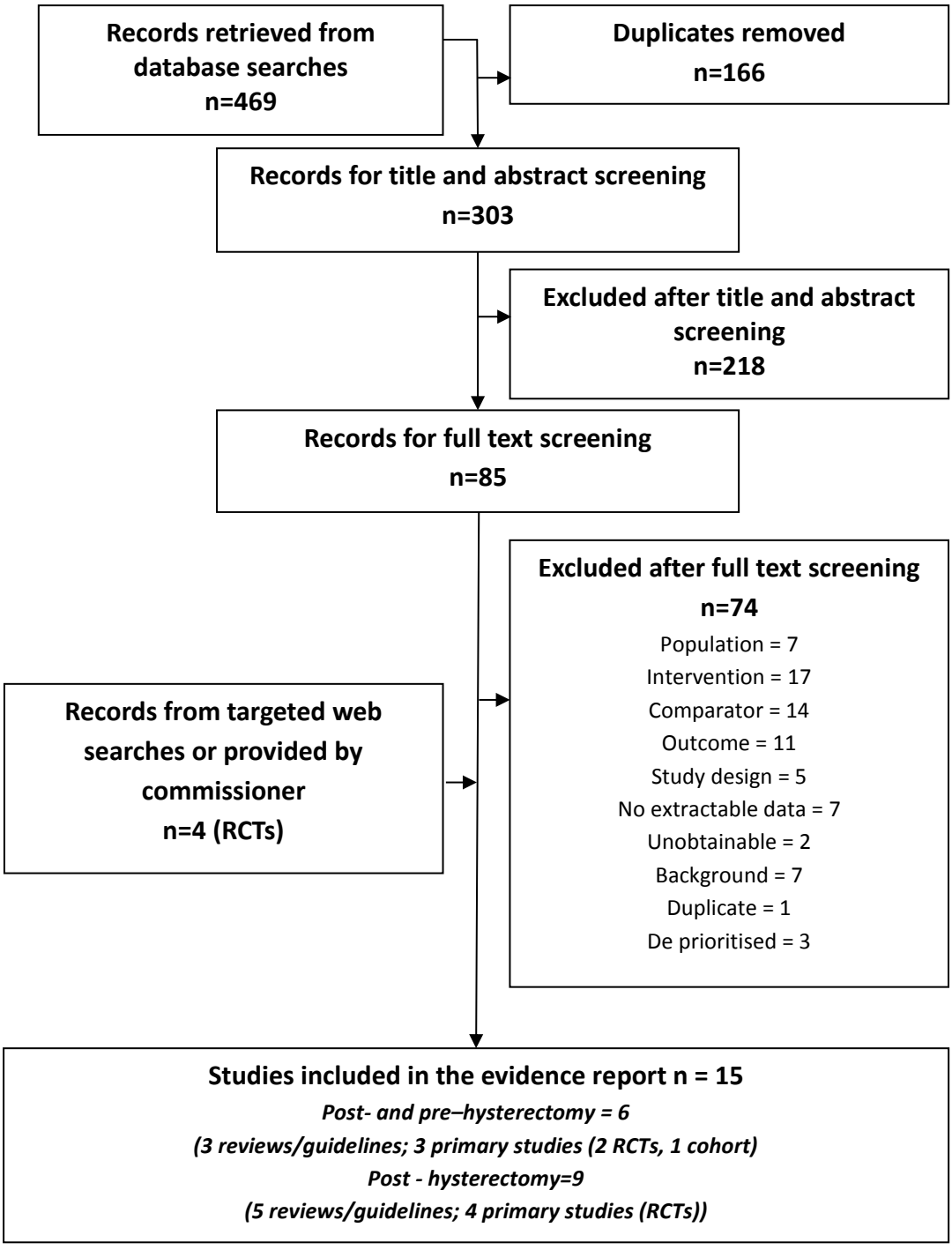
3.1 LITERATURE SEARCH RESULTS AND INCLUSION ASSESSMENT

A total of 469 records were retrieved from literature searches. After de-duplication, 303 titles and abstracts were screened by two reviewers. Eighty-five full papers were identified as potentially relevant. After further review, 74 records were excluded. A total of 15 studies were included. Six were deemed of relevance in the overall population (three reviews/guidelines and three primary studies) with a further nine of relevance in the subpopulation for post–hysterectomy (five reviews/guidelines and four primary studies) selected for this report (Table 2).

A summary of the study selection process according to a modified PRISMA flow chart is reported in Figure 1.

Risk of bias assessment of the primary RCTs is set out in Appendix 2.

Figure 1: PRISMA flow diagram women with pelvic organ prolapse



3.2 OVERVIEW OF THE EVIDENCE

Table 3 summarises the studies used to answer the FAQs.

Table 3: Evidence sources

Study	FAQ 1.What does treatment of POP involve?	FAQ 2.Will symptoms get better?	FAQ 3.Will quality of life get better?	FAQ 4.When will the patient recover?	FAQ 5.What are the long-term risks and implications?
All women with pelvic organ prolapse					
Systematic reviews /Guidelines					
National Institute for Health and Care Excellence 2019[1]	Background*				
National Institute for Health and Care Excellence 2018[2]	Background*				
National Institute for Health and Care Excellence, 2017[3]	Background*	✓			✓
De Gouveia De Sa 2016[4]	✓	✓	✓		✓
De Gouveia De Sa 2016[5]	✓		✓		✓
Maher 2016[6]	✓		✓		✓
Primary studies – RCTs (unless stated)					
Biler 2018[7] (non-RCT)	✓	✓	✓		✓
Noe 2015[8**]	✓	✓	✓		✓
Noe2013[9]	✓	✓	✓		✓
Post-hysterectomy – subgroup					
Systematic reviews /Guidelines					
British Society of Urogynaecology 2017[10]	Background*				
German Society of Gynaecology and Obstetrics 2016[11]	Background*				
National Institute for Health and Care Excellence 2019[12]	Background*				
Barber 2013[13]	✓	✓		✓	✓
British Society of Urogynaecology 2017[14]	✓				
Coolen 2017[15]	✓	✓	✓		✓
Maher 2013[16]		✓			✓

Study	FAQ 1.What does treatment of POP involve?	FAQ 2.Will symptoms get better?	FAQ 3.Will quality of life get better?	FAQ 4.When will the patient recover?	FAQ 5.What are the long-term risks and implications?
Royal College of Obstetricians and Gynaecologists 2015[17]	✓	✓	✓	✓	
Primary studies – RCTs					
Coolen 2017[18]		✓	✓		✓
Freeman 2013[19]		✓	✓		✓
Maher 2004[20]	✓	✓	✓	✓	✓
Paraiso 2011[21]	✓	✓	✓	✓	✓

* Background papers included where they were useful for FAQ1 (only); ** Papers are a follow up of Noe 2013[9]. Hereafter, this study will be referred to as Noe 2015[8, 9]
FAQ = frequently asked question; RCT = randomised controlled trial

3.3 FAQ1: WHAT DOES IT INVOLVE?

A description of the procedures and disease can be found in section 3.3.1 while additional details on procedures and disease related to the subgroup are presented in section 5.1.1.

Further details regarding the timings of surgery and hospitalisation for the main population and the subgroup are presented in sections 4.1 and 5.1, respectively.

3.3.1 Description of the Procedures and Disease

This report specifically addresses apical prolapse of the vaginal vault (i.e. the top of the vagina/front passage). A vaginal vault prolapse occurs when the upper part of the vagina descends from its usual position, which leads to one of more of the pelvic organs bulging downwards into or out of the vagina.[14] It is often caused by a weakness in the supporting tissues and muscles of the vagina. This can impact quality of life by causing pressure and discomfort, and by affecting urinary, bowel, and sexual function.[22]

There is also room for shared decision making in the choice of surgical treatment, and this is what this report aims to provide evidence for.

For women with post-hysterectomy vaginal vault prolapse, the Royal College of Obstetricians and Gynaecologists 2015 guideline suggests that the type of operation should be tailored to each individual patient depending on their circumstances, including concomitant prolapse in other compartments, sexual activity, previous abdominal surgery, previous prolapse surgery, total vaginal length and associated comorbidities.[17]

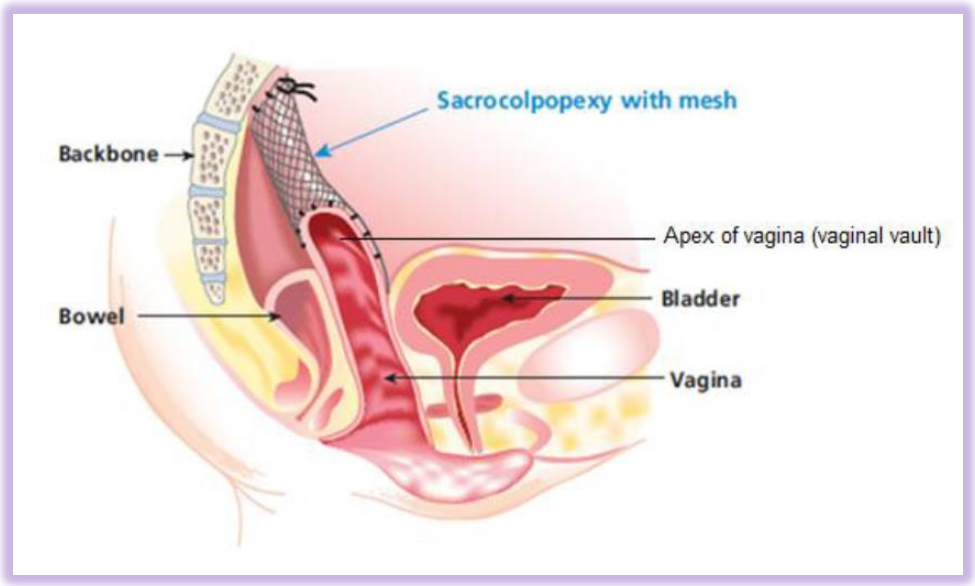
3.3.1.1 Sacrocolpopexy

Sacrocolpopexy is a surgical operation that uses mesh (a structure like a fine net which is usually made of polypropylene) to repair a prolapse of the vaginal vault, in women who have had a hysterectomy. The mesh is used to lift the top of the vagina and hold it in place.[14] The operation is performed with the patient under a general anaesthetic (i.e. you will be asleep for the entire procedure).

The procedure aims to use mesh to support and restore the pelvic organs to their natural position. This is achieved by attaching one end of a piece of mesh to the vagina, and the other end is attached using stitches or staples to a prominent bone at the bottom of the spine. Once attached, the mesh remains permanently in the body. A urinary catheter is often left in place overnight (Figure 2).

The mesh can either be attached to the cervix (called a cervicosacropexy (CESA)) or to the vaginal vault (called a vaginosacropexy (VASA)) to support the pelvic organs.[1]

Figure 2: Sacrocolpopexy



Reproduced from British Society of Urogynaecology 2017[14]

Sacrocolpopexy can be performed by one of three different approaches:

Abdominal sacrocolpopexy (ASC)

ASC is primarily an operation to treat prolapse of the vaginal vault. The operation is performed as an open procedure under general anaesthetic. Open entry involves a horizontal or bikini incision in the lower abdomen.[14]

Laparoscopic sacrocolpopexy (LSC)

LSC is primarily an operation to treat prolapse of the vaginal vault. The operation is performed as a laparoscopic keyhole procedure, where a surgeon makes three or four small cuts in the abdomen under general anaesthetic.[14]

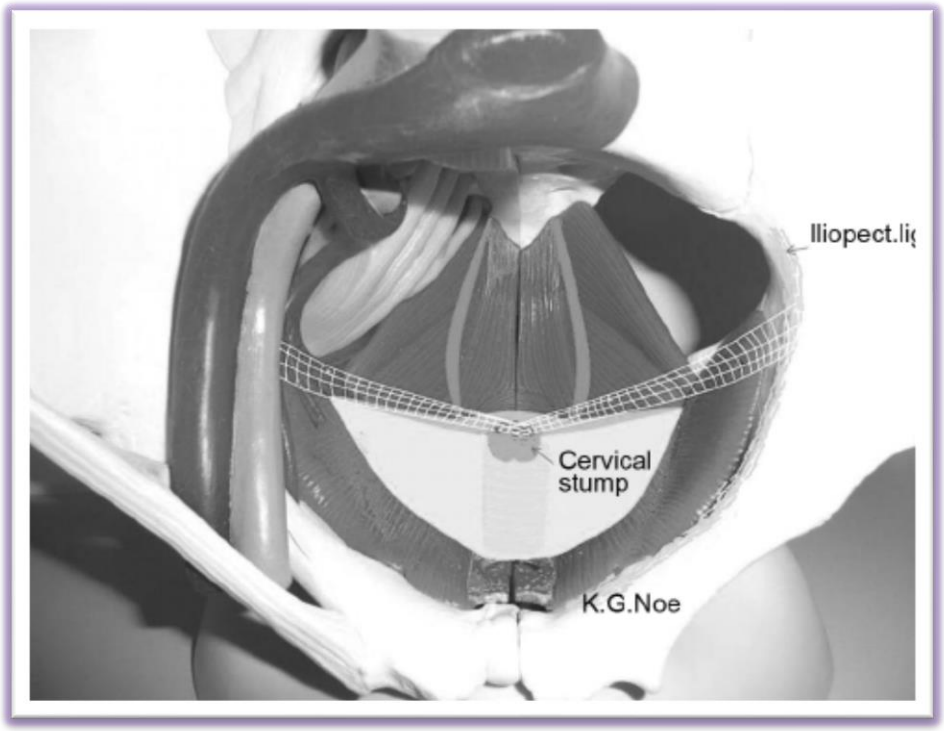
Robot-assisted laparoscopic sacrocolpopexy (RALSC)

RALSC is primarily an operation to treat prolapse of the vaginal vault. The operation is performed as a laparoscopic keyhole procedure, and a surgeon uses a robotic platform to make three or four small cuts in the abdomen under general anaesthetic.[14]

3.3.1.2 Pectopexy

Pectopexy is a surgical operation where mesh is inserted into the abdominal cavity. Each end of the mesh is fixed to the iliopectineal ligament on each side of the pelvis. The mesh follows the natural biological structures of the body without crossing sensitive spots such as the ureter or bowel (Figure 3). The cervical stump or the vaginal apex is lifted into an optimal position, and then fixed to the central part of the mesh. The mesh is then covered in peritoneum (part of the tissue of the internal body wall) so that it is hidden and protected in the abdominal cavity.[2]

Figure 3: Pectopexy



Reproduced from Alkatout *et al.* 2014[23]

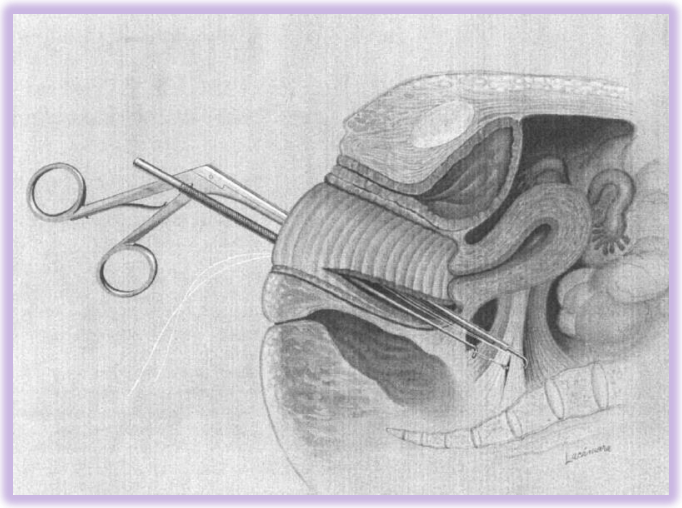
3.3.1.3 Sacrospinal fixation

Sacrospinal fixation involves lifting and supporting the vagina by stitching it into place. Access for the surgical repairs is usually through cuts in the wall of the vagina (transvaginal).

Sacrospinal ligament fixation (SSLF; also known as vaginal sacrospinous colpopexy, VSC) involves placing one or two stitches in the top of the vagina and attaching these to the sacrospinous ligament at the base of the spine to anchor and support the vaginal vault. This can be done using either absorbable or non-absorbable stitches.[17] No cuts are made in the abdomen, but a cut is made on the inside of the vagina. SSLF can be performed under either a local spinal anaesthetic (you are awake but numb from the waist down) or a general anaesthetic (you are asleep) (Figure 4).[10, 12]

Of note, the Royal College of Obstetricians and Gynaecologists (RCOG) noted that SSLF may not be appropriate in women with a short vaginal length or women with pre-existing dyspareunia.[17]

Figure 4: Sacrospinal ligament fixation



Reproduced from British Society of Urogynaecology 2017[10]

4. RESULTS – MAIN POPULATION

4.1 FAQ1: WHAT DOES IT INVOLVE – MAIN POPULATION

4.1.1 How long might the surgery take?

4.1.1.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

Two studies provided information on operating times for pectopexy versus different forms of sacrocolpopexy. Noe 2015[8, 9] suggested that operating time was significantly quicker for LP when compared to LSC. This finding was supported by separate evidence from Biler 2018[7]. Both studies were however at high risk of bias (Table 4).

4.1.1.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Maher 2014[6] reported that operating time was significantly shorter for ASC compared to LSC (based on results from two separate studies and that LSC, in turn, had shorter operating time than RALSC, based on two different studies (Table 4).

4.1.2 How long might I be in surgery and in hospital?

4.1.2.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

Two studies provided information on length of hospital stay for pectopexy versus different forms of sacrocolpopexy. Noe 2015[8, 9] suggested that length of stay was longer for LP when compared to LSC, however this difference was not significant. This finding was supported by separate evidence from Biler 2018[7] although, in this instance the difference was significant. Both studies were however at high risk of bias (Table 4).

4.1.2.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

De Gouveia reported that length of stay was significantly shorter for LSC compared to ASC (based on results from four separate studies).[5] This result was supported by analysis from a single study as reported in Maher 2016.[6] A separate review by De Gouveia De Sa reported no significant difference in length of stay following either RALSC or LSC.[4]

Table 4: Length of operating time or hospital stay

Comparison	Treatment Arm	Study [Type]	# Studies	Total # Patients	Mean	SD	N	P-value	Mean difference	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Length of operating time in theatre (minutes)													
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	43.1	27 to 63[a]	43	0.0002	NA	NA	NA	LP*	High (one low quality RCT)
	LSC				52.1	40 to 95[a]	40						
ASC vs. LSC vs. LP	**ASC**	Biler 2018[7] [Non-RCT]	1	110	117.3	41.6	68	<0.01	NA	NA	NA	LP*	High (one non-RCT)
	LSC				178.5	50.5	14						
	LP				74.9	34.05	28						
LSC vs. ASC	**LSC**	Maher 2014[6] [Systematic Review]	2	120	192.95[ø]	40.85[ø]	60	0.026	19.93	2.42	37.45	ASC*	Moderate (two moderate quality RCTs)
	ASC				168.80[ø]	52.89[ø]	60						
RALSC vs. LSC	**LSC**	Maher 2014[6] [Systematic Review]	2	145	187.60[ø]	48.22[ø]	70	0.027	-45.27	-85.45	-5.09	LSC*	Low (two high quality RCTs)
	RALSC				231.93[ø]	47.90[ø]	75						
Length of hospital stay (days)													
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	5.1	3 to 11[a]	43	0.2267	NA	NA	NA	ND	High (one low quality RCT)
	LSC				4.9	4 to 7[a]	40						
ASC vs. LSC vs. LP	**ASC**	Biler 2018[7] [Non-RCT]	1	110	2.3	0.92	68	0.048	NA	NA	NA	LSC*, LP*	High (one non-RCT)
	LSC				2.0	0.5	14						
	LP				2.0	0.01	28						
LSC vs. ASC	**LSC**	Costantini 2013[24] [RCT] from Maher 2015[6]	1	73	4.6	0.9	37	<0.00001	-1.70	-2.21	-1.19	LSC*	High (one moderate quality RCTs)
	ASC				6.3	1.3	36						
LSC vs. ASC	**LSC**	De Gouveia De Sa 2016[5] [Systematic Review]	4	1472	NR	NR	690	<0.00001	-1.57	-1.91	-1.23	LSC*	1 moderate quality RCT; 3 low quality non-RCTs favouring LSC (see Appendix 2)
	ASC						782						
RALSC vs. LSC	**RALSC**	De Gouveia De Sa 2016[4] [Systematic Review]	3	141	NR	NR	71	0.8	0.17	-1.16	1.50	ND	1 high quality RCT with ND; 1 non-RCT favouring LSC & 1 non-RCT favouring RALSC
	LSC						100						

Comparison	Treatment Arm	Study [Type]	# Studies	Total # Patients	Mean	SD	N	P-value	Mean difference	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
													(see Appendix 2)

[ø] Calculated manually (not reported in the source paper); [a] Range; [*] Statistically significant change; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; IQR = interquartile range; LSC = laparoscopic sacrocolpopexy; RALSC = robot-assisted laparoscopic sacrocolpopexy; SSLF= Sacrospinal ligament fixation; NA= Not applicable; ND = No difference; NR= Not reported; SD = standard deviation

FAQ 1: EVIDENCE SUMMARY

What does it involve?

Rationale

Several treatment options are available for women with vaginal prolapse who are symptomatic (such as vaginal pressure, pelvic pain, overactive bladder or sexual problems). This summary describes those techniques and the evidence which support their relevance

Different interventions are available:

1. Sacropexy: Sacrocolpopexy is a surgical operation that uses mesh to repair a prolapse of the vaginal vault. Variants include:
   a. Abdominal sacrocolpopexy (ASC)
   b. Laparoscopic sacrocolpopexy (LSC)
   c. Robot-assisted laparoscopic sacrocolpopexy (RALSC)

Alternative techniques of sacrocolpopexy include:
Cervicosacropexy (CESA)
Vaginosacropexy (VASA)
Hysterosacropexy/Sacrohysteropexy (HSP)

2. Pectopexy
Laparoscopic pectopexy (LP)

3. Sacrospinal ligament fixation (SSLF) including transvaginal fixation

Operating time

LP is associated with shorter operating times than different forms of sacrocolpopexy. These results were found in a single RCT and an observational study. Comparisons of different forms of sacrocolpopexy suggest that ASC has shorter operating times than LSC which, in turn, had shorter operating times than RALSC.

Length of stay

LP is associated with slightly longer hospital stays than LSC. These results were found in a single RCT. Comparisons of different forms of sacrocolpopexy suggest that LSC is associated with shorter hospital stays than ASC. No significant difference was observed between LSC and RALSC (see Tables above for details).

Evidence is lacking for CESA, VASA, HSP, and SSLF.

4.2 FAQ2: WILL MY SYMPTOMS GET BETTER?

4.2.1 Prolapse recurrence

4.2.1.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

Two studies provided evidence for prolapse recurrence. The study by Noe was a single RCT which suggested a numerical advantage for LP over LSC in terms of relapse of apical decensus. The observational study reported by Biler 2018[7] found no recurrent prolapse for any of the three intervention arms (Table 5). Additionally, "….no significant differences were found in the apical prolapse recurrence rate at one year"[25-27] from De Gouveia De Sa 2016[4] [RALSC vs. LSC]. Another study by Nosti[25] also found no significant difference in the apical prolapse recurrence rate at one year after controlling for confounding factors" (from De Gouveia De Sa 2016[5] [ASC vs. LSC]).

4.2.2 Bladder incontinence

4.2.2.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

De novo stress urinary incontinence was assessed in two studies both judged to be at high risk of bias. There were proportionately more cases of de novo stress urinary incontinence following LSC compared to ASC or LP (Table 6).[7, 9]

4.2.2.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Two studies examined RALSC versus LSC. De Gouveia De Sa 2016[4] provided analysis based on eight RCTs and of the four which reported urinary incontinence, all favoured LSC. Combined analysis was, however, not statistically significant. De Gouveia De Sa 2016[5] also compared ASC with LSC based on analysis of six RCTs. Results were inconclusive but favoured LSC (numerically only) (Table 6).

4.2.3 Any incontinence

4.2.3.1 Laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One study examined this outcome but found no cases in either arm (Table 7).[9]

4.2.4 Other bladder or urinary function

4.2.4.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

Two studies (one RCT and one observational study) provided evidence for either voiding difficulties or de novo urgency. The RCT reported a numerical advantage in relation to voiding difficulties for LP compared to LSC but the reverse in terms of de novo urgency.[9] The observational study reported a numerical advantage for LSC or LP compared to ASC (Table 8).[7]

4.2.5 Sexual function - Dyspareunia (difficult or painful sexual intercourse)

4.2.5.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One observational study reported on dyspareunia but found only one instance in the ASC arm (none for LSC or LP) (Table 9).[7]

4.2.5.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

An observational study reported in De Gouveia De Sa 2016 found 3/47 instances of dyspareunia for LSC and 0/20 for RALSC.[4] However, this difference was not statistically significant (Table 9).

4.2.5.3 Abdominal sacrocolpopexy vs. robot-assisted sacrocolpopexy

There were no comparisons between ASC and RALSC.

4.2.6 Bowel function

4.2.6.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One RCT reported no defecation problems for either LP or LSC but did find an advantage for ASC and LP over LSC in terms of *de novo* constipation due to a single case observed from 1/14 cases with LSC.[9] An observational study found no clear differences between ASC, LSC and LP for de novo persistent constipation (Table 10).[7]

4.2.6.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

One study examined RALSC versus LSC. De Gouveia De Sa 2016[4] provided analysis based on eight RCTs but no significant differences were found in relation to Ileus/Small Bowel Obstruction/Constipation. Using the same outcome measure, De Gouveia De Sa 2016[5] also compared ASC with LSC based on analysis of six RCTs. Results were inconclusive but favoured LSC (numerically only, Table 10).

Table 5: Prolapse recurrence

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Relapse of apical decensus														
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	21.8 (range 12 to 35)	1	42	2.3	0.361	RR 0.24ø	0.03ø	2.09ø	LP	High (one low quality RCT)
	LSC				19.5 (range: 12 to 37)	4	41	9.8						
Recurrent prolapse (any site on examination)														
LSC vs. ASC vs. LP	**ASC**	Biler 2018[7] [Non-RCT]	1	110	6	0	68	0	NR	NE	NE	NE	ND	High (one non-RCT)
	LSC					0	14	0						
	LP					0	28	0						

ø Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NE = not estimable; NR = not reported; RALSC = robot-assisted laparoscopic; RCT = randomised controlled trial; RD = risk difference; RR = risk ratio; SSLF = sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 6: Bladder incontinence

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
***De novo* stress urinary incontinence**														
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	21.8 (range 12 to 35)	2	42	4.8	1.000	RR 0.98ø	0.14ø	6.61ø	ND	High (one low quality RCT)
	LSC				19.5 (range: 12	2	41	4.9						

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
					to 37)									
ASC vs. LSC vs. LP	**ASC**	Biler 2018[7] [Non-RCT]	1	110	6	2	68	2.9	0.361	NE	NE	NE	ASC, LP	High (one non-RCT)
	LSC					1	14	7.1						
	LP					1	28	3.5						
Urinary incontinence														
RALSC vs. LSC	**RALSC**	De Gouveia De Sa 2016[4] [Systematic Review]	8	612	NR	18	302	6.0	0.24	OR 0.65	0.31	1.34	LSC	Moderate (one moderate quality RCT & 3 non-RCTs, all favouring LSC)[#]
	LSC					18	310	5.8						
ASC vs. LSC	**ASC**	De Gouveia De Sa 2016[5] [Systematic Review]	6	2303	Postoperative	7	935	0.75	0.36	OR 0.55	0.15	1.97	LSC	Moderate (one RCT and 1 non-RCT both favouring LSC; 4 non-RCTs NE)
	LSC					4	1368	0.29						
Stress urinary incontinence (*de novo* and persistent)														
LSC vs. RALSC	**LSC**	Anger 2014[28] [RCT] from Maher 2014[6]	1	73	NR	3	35	8.6	NR	RR 1.63	0.29	9.18	RALSC	Moderate (one moderate quality RCT)
	RALSC					2	38	5.3						

[ø] Calculated manually (not reported in the source paper); * indicates a statistically significant change; [‡] not further defined; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2; [#] Figure S11 of the paper reported odds ratio in favour of RALSC.[4] Based on number of events, this was corrected for this report.

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NE = not estimable; NR = not reported; RALSC = robot-assisted laparoscopic; RCT = randomised controlled trial; RD = risk difference; RR = risk ratio; SSLF = sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 7: Any incontinence

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
***De novo* incontinence**													
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	In-hospital	0	43	0.0	NE	NE	NE	ND	High (one low quality RCT)
	LSC					0	40	0.0					

ø Calculated manually (not reported in the source paper)´; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NE = not estimable; NR = not reported; RCT = randomised controlled trial; RD = risk difference; RR = risk ratio; SSLF = sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 8: Other bladder or urinary function

Surgical Comparison	Treatment Arm	Study	# Studies	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Voiding difficulties													
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	In-hospital	3	43	7.0	NR	RR 2.79ø	0.30ø	25.74ø	LSC	High (one low quality RCT)
	LSC				1	40	2.5						
***De novo* urgency**													
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT[	1	21.8 (range 12 to 35)	3	42	7.1	0.194	RR 0.42ø	0.12ø	1.51ø	LP	High (one low quality RCT)
	LSC			19.5 (range: 12 to 37)	7	41	17.0						
ASC vs. LSC vs. LP	**ASC**	Biler 2018[7] [Non-RCT]	1	6	4	68	5.8	0.456	NE	NE	NE	LSC/LP	High (one non-RCT)
	LSC				1	14	7.1						
	LP				2	28	7.1						

ø Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NE = not estimable; NR = not reported; RR = risk ratio; SSLF = sacrospinal

Surgical Comparison	Treatment Arm	Study	# Studies	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ligament fixation													

Table 9: Dyspareunia (difficult or painful sexual intercourse)

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. LSC vs. LP	ASC	Biler 2018[7] [Non-RCT]	1	110	6	1	68	1.4	0.292	NE	NE	NE	LSC or LP	High (one non-RCT)
	LSC					0	14	0.0						
	LP					0	28	0.0						
RALSC vs. LSC	RALSC	Seror 2012[27] [non-RCT] from De Gouveia De Sa 2016[4]	1	67	15	0	20	0.0	0.45	OR 0.31	0.02	6.29	RALSC	High (one low quality non-RCT)
	LSC					3	47	6.4						

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias – see Appendix 2 ;[ø] Calculated manually (not reported in the source paper)
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NE = not estimable; NR = not reported; OR = odds ratio; RALSC = robot-assisted laparoscopic; RR = risk ratio

Table 10: Bowel function

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Defecation problems														
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	In-hospital	0	43	0.0	NR	NE	NE	NE	ND	High (one low quality RCT)
	LSC					0	40	0.0						
***De novo* constipation**														
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	21.8 (range 12 to 35)	0	42	0.0	0.002	RR 0.06[ø]	0.00[ø]	0.96[ø]	LP[*]	High (one low quality RCT)
	LSC				19.5 (range: 12 to 37)	8	41	19.5						
***De novo* persistent constipation**														
ASC vs. LSC vs. LP	ASC	Biler 2018[7] [Non-RCT]	1	110	6	0	68	0.0	0.194	NE	NE	NE	ASC, LP	High (one non-RCT)
	LSC					1	14	7.1						
	LP					0	28	0.0						
Ileus/Small Bowel Obstruction/Constipation														
RALSC vs. LSC	**RALSC**	De Gouveia De Sa 2016[4] [Systematic Review]	8	612	NR	3	302	0.99	0.51	OR 1.69	0.35	8.26	ND	Moderate (one high quality RCT, 1 moderate quality RCT, 1 low quality non-RCT (reported results))
	LSC					2	310	0.65						
ASC vs. LSC	**ASC**	De Gouveia De Sa 2016[5] [Systematic Review]	6	2303	Postoperative	15	935	1.6	0.61	OR 0.81	0.36	1.81	LSC	Moderate (4 non-RCTs with 2 favouring LSC, 1 favouring ASC and 1 ND)
	LSC					11	1368	0.8						

[ø] Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias – see Appendix 2; [*] Study reported that the difference was statistically significant

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; RALSC = robot-assisted laparoscopic; ND = no difference; NE = not estimable; NR = not reported; RR = risk ratio

FAQ 2: EVIDENCE SUMMARY

Will my symptoms get better?

Evidence for comparisons involving laparoscopic pectopexy (LP) is relatively weak and is based on findings from one individual RCT (see Appendix A2.5) and one observational study which are both judged to be at high risk of bias. Evidence for comparisons of different forms of sacrocolpopexy tends to be of moderate quality as it is based on systematic reviews of RCTs.

Recurrent vault prolapse/other prolapse

One primary study reported a numerically lower risk of relapse of apical decensus for LP compared to LSC. No other evidence was found supporting a difference in recurrent prolapse

Incontinence

For bladder incontinence, one RCT reported no differences between LP and LSC while another RCT found more cases of de novo stress urinary incontinence following LSC compared to ASC or LP. Two systematic reviews were inconclusive regarding the effect of LSC compared with RALSC (one favouring LSC, one favouring RALSC) and that LSC was associated with less urinary incontinence that ASC. In both instances, differences were not significant (see Tables above for details). One further RCT reported a slightly lower (non-significant) rate of de novo and persistent stress urinary incontinence when RALSC was compared to LSC

During hospital stay, one RCT reported that LSC was associated with fewer voiding difficulties when compared to LP but the same study also reported that LP was associated with less de novo urgency. Neither of these results were statistically significant (see Tables above for details). One observational study also reported that ASC was associated with higher levels of de novo urgency that either LP or LSC.

Sexual issues

Very little information was available for dyspareunia (the only sexual issue where evidence was found). One observational study reported a solitary instance of dyspareunia with ASC but this might have been simply a reflection of the higher numbers treated this way (compared to LSC or LP). One other observational study did find greater numbers of patients with dyspareunia when treated with LSC as opposed to RALSC. However, this difference was not statistically significant (see Tables above for details).

Bowel function

One RCT reported no defecation problems for either LP or LSC but did find a statistically significant advantage for LP over LSC in terms of the risk of *de novo* constipation. An observational study found no clear differences between ASC, LSC and LP for *de novo* persistent constipation. One study examined RALSC versus LSC based on 8 RCTs but no significant differences were found in relation to Ileus / Small Bowel Obstruction / Constipation. ASC was compared to LSC using the same outcome measure based on analysis of 6 RCTs. Results were inconclusive but favoured LSC (numerically only).

Evidence is lacking for CESA, VASA, HSP, SSLF.

4.3 FAQ3: WILL THE PATIENT'S QUALITY OF LIFE GET BETTER?

4.3.1 Quality of life

4.3.1.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

There were no quality of life studies involving comparisons with laparoscopic pectopexy.

4.3.1.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

One systematic review, de Gouveia de Sa 2016, was identified.[5] It included three studies evaluating post-operative quality of life (QoL) (Table 11).[19, 29, 30]

One of these studies showed no significant difference between groups applying the Short Form-36 (SF-36) Health Survey when comparing LSC vs. ASC.[19] Similarly, applying the Prolapse QoL (P-QoL) Questionnaire, the study showed no significant differences between the approaches (p=0.95) (Table 11).[19]

One systematic review, de Gouveia de Sa 2016, was identified.[5] of relevance to ASC vs. RALSC. It included three studies evaluating post-operative quality of life (QoL) (Table 11).[19, 29, 30]

One of these studies showed no significant difference between groups applying the SF-36 Health Survey when comparing RALSC vs. ASC.[29] Similarly, no significant differences were found for the subscales of the Pelvic Floor Disability Index (PFDI)-20 and the Pelvic Floor Impact Questionnaire (PFIQ-7) (p=0.68) or the Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire (PISQ-12) questionnaire (p=0.32) when comparing RALSC vs. ASC (Table 11).[30]

One systematic review, De Gouveia de Sa 2016, was identified[4] of relevance to LSC vs. RALSC. It included four studies evaluating post-operative quality of life (QoL) (Table 11).[21, 26-28]

Two of these studies found no significant differences between RALSC and LSC in any of the subscales of the PFDI-20 or PFSI (Pelvic Floor Sexual Impact)-7 at three, six or 12 months after operation.[21, 28] Similar results were found by Seror et al. 2012 when assessing PFDI-20 (no further details reported).[27] Moreover, no significant differences were found when the EQ-5D (EuroQol-5 dimensions) health questionnaire was applied.[21, 28] Finally, Chan et al. 2011 found no differences in the subjective postoperative QoL, i.e. level of women's satisfaction (Table 11).[26]

4.3.2 Patient satisfaction

4.3.2.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One RCT, including 83 women, found no relevant difference between LP and LSC.[8, 9]

A retrospective cohort study which included 110 women undergoing ASC (n=68), LP (n=28) and LSC (n=14) did not find significant difference regarding patient satisfaction after a follow-up of 6 months (Table 12).[7]

4.3.2.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

One systematic review, de Gouveia de Sa 2016, was identified comparing ASC with LSC.[5] It included one RCT (n=53) evaluating patient satisfaction.[19] That study found no significant difference in the satisfaction rate between LSC and ASC (Table 12).

One systematic review, de Gouveia de Sa 2016, was identified comparing RALSC with LSC.[4] It included one RCT (n=36) evaluating patient satisfaction.[26] That study found no differences in the subjective postoperative QoL, i.e. level of women's satisfaction (Table 12).

No evidence comparing abdominal sacrocolpopexy and robotic laparoscopic sacrocolpopexy regarding patient satisfaction was identified.

Table 11: Quality of life

Surgical Comparison	Arm	Study	# Studies	Total # Patients	Follow-Up Time (months)	N	Mean (SD)	P value	Mean diff	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias[†]
EQ-5D													
LSC vs. RALSC	LSC	Anger 2014[28] and Paraiso 2011[21] from de Gouveia de Sa 2016[4]	2	156	3, 6, 12	76	NR	NR	NR	NR	NR	ND	Moderate (one low-quality RCT, one high-quality RCT)
	RALSC					80	NR						
PFDI-20													
ASC vs. RALSC	ASC	Geller 2012[30] from de Gouveia de Sa 2016[5]	1	84	44	53	NR	NR	NR	NR	NR	ND	High (one low quality retrospective cohort study)
	RASLC					31	NR						
LSC vs. RALSC	LSC	Anger 2014,[28] Paraiso 2011,[21] and Seror 2012[27] from de Gouveia de Sa 2016[4]	3	223	3, 6, 12; 18 (Seror 2012[27])	123	NR	NR	NR	NR	NR	ND	Moderate (one low-quality RCT, one high-quality RCT, one low-quality prospective cohort study)
	RALSC					100	NR						
PFSI-7													
LSC vs. RALSC	LSC	Anger 2014[28] and Paraiso 2011[21] from de Gouveia de Sa 2016[4]	2	156	3, 6, 12	76	NR	NR	NR	NR	NR	ND	Moderate (one low-quality RCT, one high-quality RCT)
	RALSC					80	NR						

Surgical Comparison	Arm	Study	# Studies	Total # Patients	Follow-Up Time (months)	N	Mean (SD)	P value	Mean diff	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
PFIQ-7													
ASC vs. RALSC	ASC	Geller 2012[30] from de Gouveia de Sa 2016[5]	1	84	44	53	NR	0.68	NR	NR	NR	ND	High (one low quality retrospective cohort study)
	RASLC					31	NR						
PISQ-12													
ASC vs. RALSC	ASC	Geller 2012[30] from de Gouveia de Sa 2016[5]	1	84	44	53	NR	0.32	NR	NR	NR	ND	High (one low quality retrospective cohort study)
	RASLC					31	NR						
P-QoL													
ASC vs. LSC	ASC	Freeman 2013[19] from de Gouveia de Sa 2016[5]	1	137	3, 12	27	NR	0.95	NR	NR	NR	ND	High (one low quality RCT)
	LSC					26	NR						
SF-36													
ASC vs. LSC	ASC	Freeman 2013[19] from de Gouveia de Sa 2016[5]	1	137	3 and 12	27	NR	NR	NR	NR	NR	ND	High (one low quality RCT)
	LSC					26	NR						
ASC vs. RALSC	ASC	Collins 2012[29] from de Gouveia de Sa 2016[5]	1	52	10 days	22	NR	NR	NR	NR	NR	ND	High (one low quality prospective cohort study)
	RALSC					30	NR						
	RASLC					20	NR						

† Risk of bias assessed in systematic review (Cochrane ROB tool for RCTs, Newcastle-Ottawa-Scale for cohort studies)

ASC = abdominal sacrocolpopexy; CI = confidence interval; EQ-5D = EuroQol-5 dimension; LSC = laparoscopic sacrocolpopexy; ND = no difference; NR = not reported; PFDI-

Surgical Comparison	Arm	Study	# Studies	Total # Patients	Follow-Up Time (months)	N	Mean (SD)	P value	Mean diff	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias[†]
20 = pelvic floor distress inventory-20; PFIQ 7 = pelvic floor impact questionnaire; PFSI-7 = Pelvic Floor Sexual Impact-7; PISC-12 = Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire; QoL = quality of life; RALSC = robot-assisted laparoscopic sacrocolpopexy; RCT = randomised controlled trial; SD = standard deviation; SF-36 = short-form 36													

Table 12: Patient satisfaction

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias[†]
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	21.8 (range 12 to 35)	41	42	97.6	0.54[ø]	RR 1.03[ø]	0.94[ø]	1.12[ø]	ND	High (one low quality RCT)
	LSC				19.5 (range: 12 to 37)	39	41	95.1						
ASC vs. LSC	**ASC**	Freeman 2013[19] from de Gouveia de Sa 2016[5]	1	137	3, 12	NR	27	NR	NR	NR	NR	NR	ND	High (one low quality RCT)
	LSC					NR	26	NR						
ASC vs. LSC vs. LP	**ASC**	Biler 2018[7] [Non-RCT]	1	110	6	67	68	98.5	0.162	NE	NE	NE	ND	High (one non-RCT)
	LSC					14	14	100.0						
	LP					27	28	96.4						
Subjective postoperative QoL (level of women's satisfaction)														
LSC vs. RASLC	**LSC**	Chan 2011[26] from de Gouveia de Sa 2016[4]	1	36	16 (RALSC), 39 (LSC)	NR	16	NR	NR	NR	NR	NR	ND	High (one low-quality retrospective cohort study)
	RASLC					NR	20	NR						

[†] Risk of bias assessed in systematic review (Cochrane ROB tool for RCTs, Newcastle-Ottawa-Scale for cohort studies); [ø] Calculated manually (not reported in the source paper)

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NE = not estimable; NR = not reported; RALSC = robot-assisted laparoscopic sacrocolpopexy; RCT = randomised controlled trial; RR = risk ratio

FAQ 3: EVIDENCE SUMMARY

Will my quality of life get better?

Quality of life

No relevant differences were observed when comparing:

- ASC vs. LSC (P-QoL, SF-36)
- ASC vs. RASLC (PFDI-20, PFIQ-7, PISQ-12, SF-36)
- LSC vs. RALSC (EQ-5D, PFDI-20, PFSI-7)

Patient Satisfaction

No relevant differences were observed when comparing:

- ASC vs. LSC
- ASC vs.LSC vs.LP
- LP vs. LSC
- LSC vs. RASLC

Evidence is lacking for CESA, VASA, HSP, SSLF.

4.4 FAQ4: WHEN WILL THE PATIENT RECOVER?

No studies evaluating time to return to usual activity, return to work, time to return to sexual function, time to return to other activities (such as sports), or impact on dependents/family were identified.

4.4.1 Time to return to usual activity

No evidence was identified for the time to return to usual activity.

4.4.2 Time to return to work

No evidence was identified for the time to return to work outcome.

4.4.3 Time to return to sexual function

No evidence was identified for the time to return to sexual function outcome.

4.4.4 Time to return to other activities, such as sports

No evidence was identified for the time to return to other activities outcome.

4.4.5 Impact on dependents/family

No evidence was identified for the impact on dependents/family outcome.

FAQ 4: EVIDENCE SUMMARY

When will the patient recover?

Evidence is lacking for time to return to work, time to return to sexual function, time to return to other activities (such as sports), and impact on dependents/family.

4.5 FAQ5: What are the risks and long-term implications?

4.5.1 Operative blood loss

4.5.1.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One primary study at high risk of bias (Noe 2015[8, 9]) reported a decrease in the mean blood volume lost during surgery for LP compared to LSC (mean 4.6 ml vs. 15.3 ml, respectively; 1 RCT, n=83 women) (Table 13).

One primary observational study at high risk of bias (Biler 2018[7]) did not report on blood loss volumes but did report on the number of patients experiencing haemorrhage. This was reported to be lower for patients undergoing LSC or LP compared to ASC (1 of 68 (1.4%) for ASC; 1 of 14 (7.1%) for LSC; and 1 of 28 (1.7%) for LP; 1 study (non-RCT), n=110 women). No formal statistical comparisons between groups were provided (Table 13).

4.5.1.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Pooled analysis reported a mean decrease in blood volume lost during LSC compared to ASC (mean difference [MD] -113.27 ml, 95% confidence interval [CI] -163.67 to -62.87; 5 studies (1 RCT), n=1,520 women= (Table 13).[5]

Pooled analysis reported a numerical decrease in blood volume lost during RALSC compared to LSC, however this was not a statistically significant difference (MD -56.20 ml, 95% CI -158.17 to 45.77; 5 studies (1 RCT), n=375 women) (Table 13).[4]

4.5.2 Pelvic pain

No evidence was identified for pelvic pain in the general population of women with middle compartment prolapse.

4.5.3 Wound infection

4.5.3.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One primary observational study at high risk of bias (Biler 2018[7]) reported a higher rate of wound infection for women undergoing ASC compared to LSC or LP (3 of 68 (4.4%) for ASC; 0 of 14 (0%) for LSC; and 0 of 28 (0%) for LP; 1 study (non-RCT), n=110 women). No formal statistical comparisons between groups were provided (Table 14).

4.5.3.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

No evidence was identified.

4.5.4 Urinary tract injury

4.5.4.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

No evidence was identified.

4.5.4.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Pooled analysis reported a numerical reduction in the odds of bladder injury for ASC compared to LSC; however this was not a statistically significant difference (odds ratio [OR] 2.12, 95% CI 0.81 to 5.57; 5 studies (1 RCT), n=1,786 women) (Table 15).[5]

Pooled analysis reported a numerical reduction in the odds of bladder injury for RALSC compared to LSC; however this was not a statistically significant difference (OR 0.62, 95% CI 0.29 to 1.33; 8 studies (2 RCTs), n=612 women) (Table 15).[4]

4.5.5 Rectal injury

4.5.5.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One primary study at high risk of bias (Noe 2015[8, 9]) reported no cases of bowel injury or obstruction in women undergoing either LP or LSC (1 RCT, n=83 women) (Table 16).

4.5.5.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Pooled analysis at unclear risk of bias reported a numerical reduction in the proportion of women experiencing bowel injury for LSC compared to ASC (0.07% for LSC; 0.42% for ASC; study designs not reported and an unclear number of women included in the analysis). No formal statistical comparisons between groups were provided (Table 16).[5]

4.5.5.3 Laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

No evidence was identified for rectal injury for LSC vs. RALSC.

4.5.6 Other serious unintended injuries

No evidence was identified for other serious unintended injuries.

4.5.7 Other pelvic floor or abdominal complications

4.5.7.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One primary study at high risk of bias (Noe 2015[8, 9]) reported no intraoperative complications (defined as intraoperative injuries) in women undergoing either LSC or LP (1 RCT, n=83 women) (Table 17).

Noe 2015[8, 9] also reported a numerical increase in the risk of experiencing new or worsening central defect cystocele following LP compared to LSC; however, this was not a statistically significant difference and was associated with a large amount of uncertainty (RR 1.46, 95% CI 0.26 to 8.31; 1 RCT, n=83 women) (Table 17).

Noe 2015[8, 9] also reported a numerical decrease in the risk of experiencing new lateral defect cystocele following LP compared to LSC; however, this was not a statistically significant difference (RR 0.09, 95% CI 0.01 to 1.56; 1 RCT, n=83 women) (Table 17).

Noe 2015[8, 9] also reported no difference in the risk of experiencing new or worsening rectocele following LP compared to LSC (RR 0.98, 95% CI 0.26 to 3.64; 1 RCT, n=83 women) (Table 17).

One primary observational study at high risk of bias (Biler 2018[7]) reported no major intraoperative complications (defined as injuries to bowel, urinary bladder and ureter) in women undergoing ASC, LSC or LP (1 study (non-RCT), n=110 women) (Table 17).

The same study (Biler 2018[7]) reported a numerical reduction in the proportion of women experiencing any intraoperative complications (defined as any complication that happened during surgery or within 6 to 10 weeks postoperatively, including injury to the bladder, bowel, vagina, ureters, or vessels; wound complications; haematoma; abscess; urinary tract infection; bowel obstruction; ileus; blood transfusion; and mesh infection) for LP compared to LSC compared to ASC (9 of 68 (13.2%) for ASC; 1 of 14 (7.1%) for LSC; and 1 of 28 (3.6%) for LP; 1 study (non-RCT), n=110 women). No formal statistical comparisons between groups were provided (Table 17).

Biler 2018[7] also reported no cases of anterior or lateral defect cystocele; and no cases of rectocele for women undergoing ASC, LSC or LP (1 study (non-RCT), n=110 women) (Table 17).

4.5.7.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Pooled analysis reported a numerical reduction in the odds of experiencing intraoperative complications for LSC compared to ASC; however, this was not a statistically significant difference (OR 0.83, 95% CI 0.51 to 1.34; 6 studies (1 RCT), n=2,303 women) (Table 17).[5]

Pooled analysis reported a numerical reduction in the odds of intraoperative complications for RALSC compared to LSC; however this was not a statistically significant difference (OR 0.78, 95% CI 0.42 to 1.43; 8 studies (2 RCTs), n=612 women)[4] (Table 17).

4.5.8 Urinary tract infection

4.5.8.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One primary study at high risk of bias (Noe 2015[8, 9]) reported a numerical reduction in the risk of urinary tract infection (UTI) in women undergoing LSC compared to LP; however, this was not a statistically significant difference (RR 1.86, 95% CI 0.18 to 19.73; 1 RCT, n=83 women) (Table 18).

One primary observational study at high risk of bias (Biler 2018[7]) reported a lower proportion of women experiencing UTI following LSC or LP compared to ASC (2 of 68 (2.9%) for ASC; 0 of 14 (0%) for LSC; and 0 of 28 (0%) for LP; 1 study (non-RCT), n=110 women). No formal statistical comparisons between groups were provided (Table 18).

4.5.8.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Pooled analysis reported a numerical reduction in the odds of UTI for LSC compared to ASC; however, this was not a statistically significant difference (OR 0.86, 95% CI 0.53 to 1.40; 6 studies (non-RCTs), n=2303 women) (Table 18).[5]

Pooled analysis reported a numerical reduction in the odds of UTI for LSC compared to RALSC; however, this was not a statistically significant difference (OR 0.77, 95% CI 0.33 to 1.80; 8 studies (2 RCTs), n=612 women) (Table 18).[4]

4.5.9 Mesh-related problems

4.5.9.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One primary study at high risk of bias (Noe 2015[8, 9]) reported no cases of mesh infection in women undergoing LSC or LP (1 RCT, n=83 women) (Table 19).

4.5.9.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

Pooled analysis reported a numerical reduction in the odds of mesh erosion for ASC compared to LSC; however, this was not a statistically significant difference (OR 1.41, 95% CI 0.37 to 5.44; 6 studies (1 RCT), n=2176 women) (Table 19).[5]

Pooled analysis reported no difference in the odds of mesh erosion for LSC compared to RALSC (OR 0.98, 95% CI 0.35 to 2.78; 8 studies (2 RCTs), n=607 women) (Table 19).[4]

4.5.10 Mesh Exposure

4.5.10.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

One primary observational study at high risk of bias (Biler 2018[7]) reported no cases of mesh exposure or erosion for ASC, LSC or LP (1 study (non-RCT), n=110 women) (Table 19).

4.5.10.2 Laparoscopic sacrocolpopexy vs. laparoscopic pectopexy

No evidence was identified for mesh exposure for LP vs. LSC.

4.5.10.3 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

No evidence was identified for mesh exposure.

4.5.11 Long-term risks

No evidence was identified for long-term risks (apart from the named risks already presented) in the general population of women with middle compartment prolapse.

4.5.12 Reoperation for POP

No evidence was identified for reoperation for POP in the general population of women with middle compartment prolapse.

4.5.13 Mortality

No evidence was identified for mortality in the general population of women with middle compartment prolapse.

Table 13: Blood loss

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Mean (ml)	SD	N	P-value	Mean diff (ml)	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
LP vs. LSC	**LP**	Noe 2015[8, 9] [RCT]	1	83	4.6	0 to 40[a]	43	<0.001	NE	NE	NE	LP*	High (one low quality RCT)
	LSC				15.3	0 to 80[a]	40						
LSC vs. ASC	**LSC**	De Gouveia De Sa 2016[5] [Systematic Review]	5	1520	119.97[b]	138.20 [b]	720	<0.0001	-113.27	-163.67	-62.87	LSC*	1 RCT at moderate risk; 4 non-RCTs at moderate to high risk of bias
	ASC				201.95 [b]	148.31 [b]	800						
RALSC vs. LSC	**RALSC**	De Gouveia De Sa 2016[4] [Systematic Review]	5	375	85.60 [b]	59.07 [b]	161	0.28	-56.20	-158.17	45.77	RALSC	1 RCT at moderate risk of bias; 4 moderate quality non-RCTs
	LSC				139.51 [b]	107.51 [b]	214						

a Range; b Calculated manually (i.e. not reported in the original publication); * Study reported that the difference was statistically significant; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ml = millilitre; NA = Not applicable; NE = not estimable; RCT = randomised controlled trial; SD = standard deviation; SSLF = Sacrospinal ligament fixation

Table 14: Wound infection

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. LSC vs. LP	**ASC**	Biler 2018[7] [Non-RCT]	1	110	3	68	4.4	NE	NE	NE	No instances reported for LSC and LP	High (one non-RCT)
	LSC				0	14	0.0					
	LP				0	28	0.0					

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NE = not estimable; RCT = randomised controlled trial

Table 15: Urinary tract injury

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Follow-Up time point (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
LSC vs. ASC	**LSC**	De Gouveia De Sa 2016[5] [Systematic Review]	5	1786	Intraoperative	12	1368	0.9	0.13	OR 2.12	0.81	5.57	ASC	1 moderate quality RCT and 3 non-RCTs favouring ASC & 1 non-RCT favouring LSC
	ASC					6	935	0.6						
RALSC vs. LSC	**RALSC**	De Gouveia De Sa 2016[4] [Systematic Review]	8	612	Intraoperative	11	302	3.6	0.22	OR 0.62	0.29	1.33	RALSC	2 mixed quality RCTs & 6 non-RCTs, all favouring RALSC
	LSC					20	310	6.5						

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NA = Not applicable; ND = no difference; NE = not estimable; OR = odds ratio; UTI = urinary tract infection

Table 16: Rectal injury

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Follow-Up time point (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Bowel injury or obstruction														
LP vs. LSC	LP	Noe 2015[8, 9] [RCT]	1	83	In-hospital	0	43	0.0	NR	NE	NE	NE	ND	High (one low quality RCT)
	LSC					0	40	0.0						
Bowel injury														
LSC vs. ASC	LSC	De Gouveia De Sa 2016[5] [Systematic Review]	7	NR	NR	NR	NR	0.07	NR	NE	NE	NE	NE	Unclear (included studies not reported)
	ASC					NR	NR	0.42						

ø Calculated manually (not reported in the source paper); * Study reported that the difference was statistically significant; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NA = Not applicable; ND = no difference; NE = not estimable; OR = odds ratio; UTI = urinary tract infection

Table 17: Other pelvic floor or abdominal complications

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Follow-Up time point (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
New or worsening central defect cystocele														
LP vs.	LP	Noe 2015[8, 9]	1	83	21.8 (range 12	3	42	7.1	0.67	RR	0.26ø	8.31ø	LSC	High

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Follow-Up time point (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
LSC		[RCT]			to 35)					1.46[ø]				(one low quality RCT)
	LSC				19.5 (range: 12 to 37)	2	41	4.9						
New lateral defect cystocele														
LP vs. LSC	LP	Noe 2015[8, 9] [RCT]	1	83	21.8 (range 12 to 35)	0	42	0.0	0.10	RR 0.09[ø]	0.01[ø]	1.56[ø]	LP	High (one low quality RCT)
	LSC				19.5 (range: 12 to 37)	5	41	12.2						
Anterior or lateral defect cystocele														
ASC vs. LSC vs. LP	ASC	Biler 2018[7] [Non-RCT]	1	110	6	0	68	0	NR	NE	NE	NE	ND	High (one non-RCT)
	LSC				0	0	14	0						
	LP				0	0	28	0						
New or worsening rectocele														
LP vs. LSC	LP	Noe 2015[8, 9] [RCT]	1	83	21.8 (range 12 to 35)	4	42	9.5	0.97	RR 0.98[ø]	0.26[ø]	3.64[ø]	ND	High (one low quality RCT)
	LSC				19.5 (range: 12 to 37)	4	41	9.8						
Rectocele														
ASC vs. LSC vs. LP	ASC	Biler 2018[7] [Non-RCT]	1	110	6	0	68	0	NR	NE	NE	NE	ND	High (one non-RCT)
	LSC				0	0	14	0						
	LP				0	0	28	0						
Intraoperative complications														
LP vs. LSC	LP	Noe 2015[8, 9] [RCT]	1	83	21.8 (range 12 to 35)	0	43	0.0	NR	NE	NE	NE	ND	High (one low quality RCT)
	LSC				19.5 (range: 12 to 37)	0	40	0.0						

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Follow-Up time point (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. LSC vs. LP	ASC	Biler 2018[7] [Non-RCT]	1	110	Intraoperative	0[a]	68	0.0	NA	NR	NR	NR	ND	High (one non-RCT)
	LSC					0[a]	14	0.0						
	LP					0[a]	28	0.0						
ASC vs. LSC vs. LP	ASC	Biler 2018[7] [Non-RCT]	1	110	2.5	9[b]	68	13.2	0.332	NR	NR	NR	LP	High (one non-RCT)
	LSC					1[b]	14	7.1						
	LP					1[b]	28	3.6						
LSC vs. ASC	LSC	De Gouveia De Sa 2016[5] [Systematic Review]	6	2303	NR	35	1368	2.6	0.44	OR 0.83	0.51	1.34	LSC	1 low quality RCT, 3 studies favoured ASC whilst 2 studies (including one large study) favoured LSC
	ASC					36	935	3.9						
RALSC vs. LSC	RALSC	De Gouveia De Sa 2016[4] [Systematic Review]	8	612	NR	20	302	6.6	0.42	OR 0.78	0.42	1.43	RALSC	2 low to moderate quality RCTs (reported events)
	LSC					28	310	9.0						

[ø] Calculated manually (not reported in the source paper); [*] Study reported that the difference was statistically significant; [a] major complications defined as injuries to bowel, urinary bladder, and ureter; [b] Perioperative complications defined as any complication that happened during surgery or within 6 to 10 weeks postoperatively, including injury to the bladder, bowel, vagina, ureters, or vessels; wound complications; hematoma; abscess; urinary tract infection; bowel obstruction; ileus; blood transfusion; and mesh infection; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NA = Not applicable; ND = no difference; NE = not estimable; OR = odds ratio; UTI = urinary tract infection

Table 18: Urinary tract infection

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Follow-Up time point (months)	n	N	%	P-value	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
LP vs. LSC	LP	Noe 2015[8, 9] [RCT]	1	83	Unclear	2	43	4.7	NR	RR 1.86ø	0.18ø	19.73ø	LSC	High (one low quality RCT)
	LSC					1	40	2.5						
RALSC vs. LSC	RALSC	De Gouveia De Sa 2016[4] [Systematic Review]	8	612	Post-operative	15	302	5.0	0.54	OR 0.77	0.33	1.80	LSC	2 mixed quality RCTs; 1 lower quality non-RCT (reported events)
	LSC					12	310	3.9						
ASC vs. LSC	ASC	De Gouveia De Sa 2016[5] [Systematic Review]	6	2303	Post-operative	28	935	3.0	0.54	OR 0.86	0.53	1.40	LSC	2 non-RCTs both favouring LSC; 4 studies NE
	LSC					41	1368	3.0						
ASC vs. LSC vs. LP	ASC	Biler 2018[7]	1	110	2.5	2[a]	68	2.9	NR	NE	NE	NE	LSC or LP	High (one non-RCT)
	LSC					0[a]	14	0.0						
	LP					0[a]	28	0.0						

ø Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NA = Not applicable; ND = no difference; NE = not estimable; OR = odds ratio; UTI = urinary tract infection

Table 19: Mesh-related problems or mesh exposure

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Mesh infection												
LP vs. LSC	LP	Noe 2015[8, 9] [RCT]	1	83	0	43	0.0	NE	NE	NE	ND	High (one low quality RCT)
	LSC				0	40	0.0					
Mesh erosion												
LSC vs. ASC	LSC	De Gouveia De Sa 2016[5] [Systematic Review]	6	2176	5	1318	0.4	OR 1.41	0.37	5.44	ASC	1 RCT (reported events) & 5 non-RCTs
	ASC				4	858	0.5					
RALSC vs. LSC	RALSC	De Gouveia De Sa 2016[4] [Systematic Review]	8	607	6	300	2.0	OR 0.98	0.35	2.78	ND	2 mixed quality RCTs (reported events); 3 non-RCTs
	LSC				6	307	2.0					
Mesh exposure												
LSC vs. RALSC	LSC	Anger 2014[28] [RCT]	1	78	0	38	0.0	NR	NE	NE	ND	Moderate (One moderate quality RCT)
	RALSC				0	40	0.0					
Mesh erosion or exposure												
ASC vs. LSC vs. LP	ASC	Biler 2018[7] [Non-RCT]	1	110	0	68	0	NR	NE	NE	ND	High (one non-RCT)
	LSC				0	14	0					
	LP				0	28	0					

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NE = not estimable; NR = not reported; OR = odds ratio; RALSC = robot-assisted laparoscopic sacrocolpopexy; SSLF = sacrospinal ligament fixation

FAQ 5: EVIDENCE SUMMARY

What are the risks and long term implications?

Blood loss

One primary RCT reported lower blood volume loss for LP compared to LSC; another primary study reported a lower proportion of women with haemorrhage following LP (or ASC) compared to LSC. Pooled analysis reported lower blood volume loss for LSC compared to ASC. Pooled analysis reported reduced blood volume loss during RALSC compared to LSC; however, not statistically significant (see Tables above for details). It appears LP was associated with the most favourable outcome.

Wound infection

One primary observational study reported no cases of wound infection for LSC or LP, although 4.4% of women receiving ASC experienced wound infection. It appears that LP and LSC had the most favourable outcomes.

Urinary tract injury

Pooled analysis reported a lower odds of bladder injury for ASC compared to LSC; however, this was not a statistically significant difference (see Tables above for details). Pooled analysis also reported a lower odds of bladder injury for RALSC compared to LSC; however, this was not a statistically significant difference (see Tables above for details). It appears that ASC had the most favourable outcome.

Rectal injury

One primary RCT reported no cases of bowel injury or obstruction in women undergoing either LP or LSC. Pooled analysis reported a lower proportion of women experiencing bowel injury for LSC compared to ASC. It is reasonable to conclude that LP and LSC were associated with the most favourable outcomes.

Other Pelvic Floor or Abdominal Complications

One primary RCT reported no intraoperative injuries in women undergoing either LSC or LP. One primary observational study reported no major intraoperative injuries to bowel, urinary bladder and ureter in women undergoing ASC, LSC or LP. The same study reported a lower proportion of women experiencing any type of intraoperative complication for LP compared to LSC compared to ASC (9 of 68 (13.2%) for ASC; 1 of 14 (7.1%) for LSC; and 1 of 28 (3.6%) for LP). Pooled analysis reported lower odds of experiencing intraoperative complications for LSC compared to ASC; however, this was not a statistically significant difference (see Tables above for details). Pooled analysis reported lower odds of intraoperative complications for RALSC compared to LSC; however, this was not a statistically significant difference (see Tables above for details). Overall, it is reasonable to conclude that LP and LSC were associated with the most

Urinary Tract Infection (UTI)

One primary RCT reported a lower risk of UTI in women undergoing LSC compared to LP; however, this was not a statistically significant difference (see Tables above for details). One primary observational study reported a lower proportion of women experiencing UTI following LSC or LP compared to ASC (2 of 68 (2.9%) for ASC; 0 of 14 (0%) for LSC; and 0 of 28 (0%) for LP). Pooled analysis reported lower odds of UTI for LSC compared to ASC; however, this was not a statistically significant difference (see Tables above for details). Pooled analysis also reported lower odds of UTI for LSC compared to RALSC; however, this was not a statistically significant difference. It is reasonable to conclude that LP and LSC were associated with the most favourable outcomes.

Mesh-related problems

One primary RCT reported no cases of mesh infection in women undergoing LSC or LP. Pooled analysis reported a lower odds of mesh erosion for ASC compared to LSC; however, this was not a statistically significant difference (see Tables above for details). Pooled analysis reported no difference in the odds of mesh erosion for LSC compared to RALSC. It is reasonable to conclude that all routes and surgeries were associated with similar levels of mesh erosion.

Mesh exposure

One primary observational study reported no cases of mesh exposure or erosion for ASC, LSC or LP. Similarly, one primary RCT reported no cases of mesh exposure for LSC or RALSC.

Most studies exhibited actual or potential risk of bias in some domains.

Evidence lacking for:

- Major bleeding, fever, issues with wound healing; other serious unintended injuries; pelvic pain; mesh-related problems (other than mesh exposure); long-term risks; mortality; and re-operation for POP.
- Limited evidence was identified for wound infection.

4.6 Assessment of the clinical review evidence – main population

Evidence sources and associated outcomes are set out in Table 20 below.

Table 20: Overview of the clinical evidence and included guidelines

Study ID	Number of Participants	Interventions	Outcomes	Study Design	Follow-up (longest months)
De Gouveia De Sa 2016[4]	612	RALSC, LSC	Length of stay, Bladder incontinence, Dyspareunia, Bowel function, Quality of Life, Patient satisfaction, Blood loss, Urinary Tract Injury, Other pelvic floor or abdominal complications, Urinary tract infection	SR	NA
De Gouveia De Sa 2016[5]	2203	ASC, LSC	Length of stay, Bladder incontinence, Bowel function, Quality of Life, Patient satisfaction, Blood loss, Urinary Tract Injury, Rectal injury, Other pelvic floor or abdominal complications, Urinary tract infection, Mesh-related problems or mesh exposure	SR	NA
Maher 2016[6]	NA	ASC, LSC	Operative time, Length of stay, Bladder incontinence	SR	NA
Noe 2015[8, 9]	83	LP, LSC	Operative time, Length of stay, Prolapse recurrence, Bladder incontinence, Any incontinence, Other bladder or urinary function, Bowel function, Patient satisfaction, Blood loss, Rectal injury, Other pelvic floor or abdominal complications, Urinary tract infection, Mesh-related problems or mesh exposure	Primary - RCT	37
Biler 2018[7] (non-RCT)	110	ASC, LSC, LP	Operative time, Length of stay, Prolapse recurrence, Bladder incontinence, Other bladder or urinary function, Dyspareunia, Bowel function, Patient satisfaction, Wound infection, Other pelvic floor or abdominal complications, Urinary tract infection	Primary - observational	6

ASC = abdominal sacrocolpopexy; G = guideline; LP = laparoscopic pectopexy; LSC = laparoscopic sacrocolpopexy; NA= Not appropriate; NR = not reported; RALSC = robot-assisted laparoscopic sacrocolpopexy; SR = systematic review

A summary of evidence is set out in Table 21. No evidence was found for CESA, VASA, HSP, or SSLF. Accordingly, these procedures have not been included in the summary of evidence.

Table 21: Summary of evidence

Evidence	Sacrocolpopexy			Pectopexy	Notes
	ASC	LSC	RALSC	LP	
FAQ 1. What does treatment involve?					
Operating time	✓ vs. LSC × vs. LP	× vs. LP ✓ vs. RALSC	× vs. LSC	✓ vs. ASC, LSC	Laparoscopic pectopexy (LP) is associated with shorter operating times than different forms of sacrocolpopexy. These results were found in a single RCT and an observational study. Comparisons of different forms of sacrocolpopexy suggest that ASC has shorter operating times than LSC which, in turn, had shorter operating times than RALSC.
Length of stay	× vs. LSC -	✓ vs. ASC ✓ vs. LP -	-	× vs. LSC ✓ vs. ASC	LP is associated with slightly longer hospital stays than LSC. These results were found in a single RCT with a further observational study suggesting no real difference. Comparisons of different forms of sacrocolpopexy suggest that LSC is associated with shorter hospital stays than ASC. No significant difference was observed between LSC and RALSC.
FAQ 2. Will symptoms get better?					
Prolapse recurrence	-	× vs. LP	-	✓ vs. LSC	Based on one low quality RCT.
Bladder incontinence – de novo stress urinary incontinence	✓ vs. LSC	× vs. ASC, LP	-	✓ vs. LSC	Based on a single observational study.
Bladder incontinence – urinary incontinence	× vs. LSC	✓ vs. ASC, RALSC	× vs. LSC		Moderate quality evidence based on SR of RCTs.
Bladder incontinence – stress urinary incontinence		× vs. RALSC	✓ vs. LSC		Based on one moderate quality RCT.
Any incontinence	-	-	-	-	No relevant differences were observed

Evidence	Sacrocolpopexy			Pectopexy	Notes
	ASC	LSC	RALSC	LP	
Other bladder or urinary function	× vs. LP, LSC	-		-	One RCT reported a numerical advantage in relation to voiding difficulties for LP compared to LSC but the reverse in terms of de novo urgency. An observational study reported a numerical advantage for LSC or LP compared to ASC.
		× vs. LP		✓ vs. LSC	
		✓ vs. LP		× vs. LSC	
Sexual function - Dyspareunia (difficult or painful sexual intercourse)	-	-	-	-	No relevant differences were observed
Bowel function	-	-	-	-	One RCT reported no defecation problems for either LP or LSC but did find a statistically significant advantage for LP over LSC in terms of de novo constipation. When ASC was compared to LSC for Ileus / Small Bowel Obstruction / Constipation results were inconclusive but favoured LSC (numerically only).
		× vs. LP			
	× vs. LSC	✓ vs. ASC		✓ vs. LSC	
FAQ 3: Will quality of life get better?					
Quality of life	-	-	-		No relevant differences were observed
Patient satisfaction	-	-	-	-	No relevant differences were observed
FAQ 4. When will the patient recover?					
No information was found in regard of time to return to normal activity or changes in normal activity					
FAQ 5. What are the long-term risks and implications?					
Blood loss	× vs. LSC	× vs. LP	✓ vs. LSC	✓ vs. LSC	One primary study, at high risk of bias, reported a decrease in the mean blood volume lost during surgery for LP compared to LSC. Pooled analysis of five studies reported a mean decrease in blood volume lost during LSC compared to ASC
		✓ vs. ASC			
		× vs.			

Evidence	Sacrocolpopexy			Pectopexy	Notes
	ASC	LSC	RALSC	LP	
		RALSC			
Wound infection	× vs. LSC, LP	✓ vs. ASC		✓ vs. ASC	No relevant differences were observed
Urinary tract injury	✓ vs. LSC	× vs. ASC, RALSC	✓ vs. LSC		
Rectal injury	× vs. LSC	-		-	No relevant differences were observed
		✓ vs. ASC			
Other pelvic floor or abdominal complications	-	-	✓ vs. LSC	-	No relevant differences were observed
	× vs. LSC, LP	✓ vs. LP, ASC		✓ vs. LSC, ASC	
		× vs. LP		× vs. LSC	
Urinary tract Infection	× vs. LSC, LP	✓ vs. LP,LSC, ASC	× vs. LSC	× vs. LSC	No relevant differences were observed
				✓ vs. ASC	
Mesh-related problems	✓ vs. LSC	-	-	-	No relevant differences were observed
		× vs. ASC			

Key	
O	Not evaluated
-	No numerical difference
✓	Numerically better but not statistically significant. Any advantage may not be sustained in the long term
	Statistically significantly better than comparators or clearly identified as guideline recommendation

Evidence	Sacrocolpopexy			Pectopexy	Notes
	ASC	LSC	RALSC	LP	
×	Numerically inferior but not statistically significant. Any disadvantage may not be sustained in the long term				
	Statistically significantly inferior or not recommended in guidelines				
ASC = abdominal sacrocolpopexy; FAQ = frequently asked question; LSC = laparoscopic sacrocolpopexy; RALSC = robot-assisted laparoscopic sacrocolpopexy; RCT = randomised controlled trial; SR = systematic review; SSLF= Sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence					

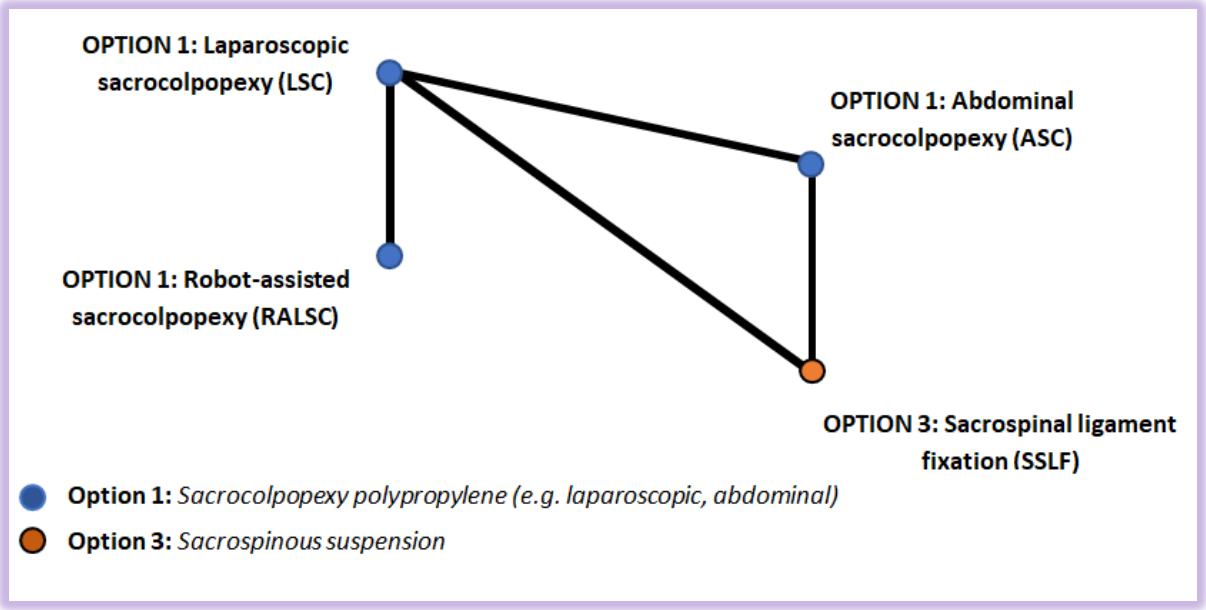
5. RESULTS – POST-HYSTERECTOMY (SUBGROUP)

5.1 FAQ1: WHAT DOES IT INVOLVE?

5.1.1 Description of the Procedures and Disease

A network of different surgical approaches to treatment of POP was identified by Coolen 2017.[15] We have modified this network for the purposes of our review and have considered outcomes in relation to these different treatments. Modification involved grouping ASC, LSC and RALSC to option 1 and assigning SSLF to option 3 to match the protocol of this review. Figure 2 sets out the network with separate identification of mesh (option 1) and non-mesh (option 3) treatments. We did not identify any evidence for option 2 (pectopexy) in the population of interest (women who were post-hysterectomy); consequently, this has not been included in the network.

Figure 5: Network of treatment options



5.1.2 How long might I be in surgery and in hospital?

5.1.2.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

In terms of **operating time**, in a post-hysterectomy population with vaginal vault prolapse, pooled analysis reported a shorter operating time for ASC compared with LSC (MD 12.29 minutes, 95% confidence interval [CI] 1.64 to 22.94; 2 RCTs, n=127 women) (Table 22).[15]

In terms of **hospital stay**, in a post-hysterectomy population with vaginal vault prolapse, pooled analysis reported a shorter hospital stay for LSC compared with ASC (MD -1.35 days, 95% CI -2.23 to -0.47; 2 RCTs, n=127 women) (Table 22).[15]

5.1.2.2 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

In terms of **operating time**, in a post-hysterectomy population with vaginal vault prolapse, pooled analysis reported a longer operating time for ASC compared with SSLF (MD 21.04 minutes, 95% CI 12.15 to 29.94; 3 RCTs, n=293 women) (Table 22).[16]

In terms of **hospital stay**, in a post-hysterectomy population with vaginal vault prolapse, one primary study (Maher 2004[20]) reported a numerically longer hospital stay for ASC compared to SSLF; however, this was not a statistically significant difference (1 RCT, n=95 women) (Table 22).

5.1.2.3 Laparoscopic sacrocolpopexy vs. robot-assisted sacrocolpopexy

In terms of **operating time**, in a post-hysterectomy population with vaginal vault prolapse, one primary study (Paraiso 2011[21]) reported a shorter operating time for LSC compared with ASC (MD 66 minutes, 95% CI 43 to 90; 1 RCT, n=68 women) (Table 22).

In terms of **hospital stay**, in a post-hysterectomy population with stage 2-4 vaginal prolapse, one primary study (Paraiso 2011[21]) from Barber 2013[13] reported a numerically shorter hospital stay for LSC compared to RALSC; however, this was not a statistically significant difference (MD 0.38 days, 95% CI -0.17 to 0.96; 1 RCT, n=68 women) (Table 22).

Table 22: Length of operating time or hospital stay

Treatment Arm	Study [Type]	# Studies	Total # Patients	Mean	SD	N	Mean difference	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Length of operating time in theatre (minutes)											
ASC	Maher 2004[20] [RCT] from Maher 2013[16] [Systematic Review]	1	95	106	37	47	30.0	14.09	45.91	SSLF*	High (selection, performance, detection, attrition)
SSLF				76	42	48					
ASC	Coolen 2017[15] [Systematic Review]	2	127	120.6	33.9	64	12.29	1.64	22.94	ASC*	NA
LSC				132.8	29.8	63					
LSC	Paraiso 2011[21] [RCT]	1	68	199	46	33	66	43	90	LSC*	Unclear (attrition, other)
RALSC				265	50	35					
Length of hospital stay (days)											
ASC	Maher 2004[20] [RCT] from RCOG 2015[17] and Barber 2013[13]	1	95	5.4	2.2	47	NR	NR	NR	SSLF	High (selection, performance, detection, attrition)
SSLF				4.8	1.4	48					
ASC	Coolen 2017[15] [Systematic Review]	2	127	4.16	1.91	64	-1.35	-2.23	-0.47	LSC*	NA
LSC				2.73	0.93	63					
LSC	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	68	1.4	0.46	33	0.38	-0.17	0.96	LSC	Unclear (attrition, other)
RALSC				1.8	1.54	35					

* Statistically significant change

† Risk of bias was assessed for RCTs using the Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; IQR = interquartile range; LSC = laparoscopic sacrocolpopexy; RALSC = robot-assisted laparoscopic sacrocolpopexy; SSLF= Sacrospinal ligament fixation; NA= Not applicable; NR= Not reported; SD = standard deviation

FAQ 1: EVIDENCE SUMMARY

What does it involve?

Rationale

Several treatment options are available for women with vaginal prolapse who are symptomatic (such as vaginal pressure, pelvic pain, overactive bladder or sexual problems) with prior hysterectomy. This summary describes those techniques and the evidence which support their relevance. Unless otherwise stated, evidence can be judged as relatively weak compared to that found in other conditions and for other procedures in that it is based on findings from individual RCTs which are judged to be at high or unclear risk of bias.

Eligibility

Women with vaginal prolapse who are symptomatic and have had a prior hysterectomy. Exclusions are women with anterior or posterior pelvic organ prolapse; pregnancy intentions; rectal prolapse or bladder prolapse.

Surgical techniques

Different interventions are available:

- Sacrocolpopexy is a surgical operation that uses mesh to repair a prolapse of the vaginal vault. Variants include:
  a. Abdominal sacrocolpopexy (ASC) involves a longer stay than when it is performed laparoscopically.
  b. Laparoscopic sacrocolpopexy (LSC) involves a shorter stay than when it is performed either abdominally or robot-assisted (evidence being less clear for robot assisted).
  c. Robot-assisted laparoscopic sacrocolpopexy (RALSC) involves a longer stay than when it is performed laparoscopically (but the evidence suggests a degree of uncertainty with this finding)
- Pectopexy is a surgical operation which uses the iliopectineal ligament (a portion of the pelvic fascia attached to the iliopectineal line and to the capsular ligament of the hip joint) on both sides for mesh fixation so that there is no restriction caused by the mesh with the mesh following natural structures without crossing sensitive spots such as the ureter or bowel. No evidence was identified for this surgery in the population of interest.
- Sacrospinal ligament fixation (SSLF) is a type of surgery that involves lifting and supporting the vagina by stitching it into place. This procedure may involve a shorter stay than abdominal sacrocolpopexy, although not significantly so.

Operating time in theatre

- ASC is associated with significantly longer operating times than SSLF and significantly shorter operating times than LSC (based on meta analysis of two RCTs) and LSC is associated with significantly shorter operating times than RALSC (see Tables above for details).

Length of stay in hospital

- SSLF is associated with slightly shorter stays than ASC. LSC is associated with significantly shorter stays than ASC (based on meta analysis of two RCTs) and slightly shorter stays than RALSC (see Tables above for details).

Evidence lacking for pectopexy (see discussion section).

5.2 FAQ2: WILL MY SYMPTOMS GET BETTER?

5.2.1 Prolapse recurrence

5.2.1.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) reported a lower risk of recurrent vault prolapse for ASC compared to SSLF (risk ratio [RR] 0.23, 95% CI 0.05 to 1.04; 1 RCT, n=89 women) (Table 23).[17] This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data – see Appendix 2. Two further studies reported in Maher 2016[6] suggested little (RR 0.75, 95% CI 0.14 to 4.12, LSC vs. RALSC) or no difference (RR 1.04, 95% CI 0.16 to 6.80, LSC vs. ASC) between different forms of sacrocolpopexy.

5.2.2 Any prolapse (objective failure)

5.2.2.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) from Barber 2013[13], Maher 2013[16] and RCOG 2015[17] and reported a numerically lower risk of any prolapse (objective failure) for ASC compared to SSLF; however, this was not a statistically significant difference (RR 0.77, 95% CI 0.39 to 1.53; 1 RCT, n=88 women) (Table 24). This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data– see Appendix 2.

5.2.2.2 Laparoscopic sacrocolpopexy vs. robot-assisted laparoscopic sacrocolpopexy

One primary study (Paraiso 2011[21]) from Barber 2013[13] reported a numerically lower risk of any prolapse (objective failure; defined as stage ≥2) for LSC compared to RALSC (39.1% vs. 46.2%, respectively; 1 RCT, n=49 women) (Table 24). This study was associated with an unclear risk of bias in terms of incomplete outcome data and other sources of bias– see Appendix 2.

5.2.3 Bladder incontinence

5.2.3.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) from RCOG 2015[17] and Maher 2013[16] reported a numerical reduction in the risk of post-operative SUI for ASC compared to SSLF (RR 0.54, 95% CI 0.20 to 1.43; 1 RCT, n=75 women); however, this was not a statistically significant difference (Table 25).[17]

5.2.3.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

One primary study (Coolen 2017[18]) from Coolen 2017[15] reported on rates of new urge urinary incontinence (UUI) and rates of new stress urinary incontinence (SUI) (i.e. in women that did not have these issues prior to surgery). At 12 months, the rate of new UUI was reported to be higher for ASC compared to LSC (8% vs. 5%, respectively; 1 RCT, n=74 women) (Table 25). This study was associated with a high risk of bias in terms of blinding of participants/personnel and blinding of outcome assessors.

A second primary study (Freeman 2013[19]) reported that rates of new or continued UUI were numerically higher for ASC compared to LSC; however, this was not a statistically significant difference (Table 6). At 12 months, the rate of new SUI was reported to be lower for ASC compared to LSC (11% vs. 14%, respectively; 1 RCT, n=74 women) (Table 25). This study was associated with a high risk of bias in terms of incomplete outcome data, and an unclear risk of bias in terms of blinding of participants and personnel.

5.2.4 Bowel incontinence

5.2.4.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) from Maher 2013[16] reported no difference in the risk of faecal incontinence for ASC compared to SSLF (RR 0.93, 95% CI 0.06 to 14.48; 1 RCT, n=89 women) (Table 26). This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data.

5.2.5 Any incontinence

5.2.5.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

One primary study (Freeman 2013[19]) from Coolen 2017[15] reported on rates of any new incontinence. At 12 months, the rate of any new incontinence was reported to be higher for ASC compared to LSC (15% vs. 8%; 1 RCT, n=53 women) (Table 27). This study was associated with a high risk of bias in terms of incomplete outcome data, and an unclear risk of bias in terms of blinding of participants and personnel.

5.2.6 Other bladder or urinary function

5.2.6.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) reported a decrease in the proportion of women experiencing resolution of preoperative overactive bladder for ASC compared to SSLF (27% vs. 37%, respectively; 1 RCT, n=22 women) (Table 28). This study was associated with a high

risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data.

One primary study (Maher 2004[20]) reported no difference in the proportion of women experiencing resolution of preoperative voiding dysfunction for ASC compared to SSLF (78% vs. 80%, respectively; 1 RCT, n=14 women) (Table 28). This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data.

5.2.7 Sexual function - dyspareunia (difficult or painful sexual intercourse)

5.2.7.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) reported a numerically lower risk of post-operative dyspareunia for ASC compared to SSLF (RR 0.77, 95% CI 0.32 to 1.83; 1 RCT, n=36 women) (Table 10).[17] This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data.

In, the same primary study (Maher 2004[20]) from Maher 2013[16], a numerical reduction was reported in the risk of new dyspareunia (i.e. in women that did not have dyspareunia prior to surgery) for ASC compared to SSLF; however, this was not a statistically significant difference (RR 0.60, 95% CI 0.11 to 3.15; 1 RCT, n=36 women) (Table 29). This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data.

5.2.7.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

One primary study (Freeman 2013[19]) reported no difference in dyspareunia at 12 months following ASC compared to LSC; however, no further details (or values) were provided (1 RCT, n=47 women) (Table 29). This study was associated with a high risk of bias in terms of incomplete outcome data, and an unclear risk of bias in terms of blinding of participants and personnel.

A second primary study (Coolen 2017[18]) reported a numerical reduction in the proportion of women reporting 'quite a bit' or 'some' dyspareunia for ASC compared to LSC at 12 months; however, this was not a statistically significant difference (1 RCT, n=60 women) (Table 29). This study was associated with a high risk of bias in terms of blinding of participants/personnel and blinding of outcome assessors.

5.2.8 Sexual function - frequency of sexual activity

5.2.8.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

One primary study (Coolen 2017[18]) reported an increase in the frequency of sexual activity in women undergoing either ASC or LSC; with no differences noted between surgeries (1 RCT, n=60 women) (Table 30). This study was associated with a high risk of bias in terms of blinding of participants/personnel and blinding of outcome assessors.

5.2.9 Bowel function

5.2.9.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) from Maher 2013[16] reported a numerical increase in the risk of constipation for ASC compared to SSLF; however, this was not a statistically significant difference (RR 1.40, 95% CI 0.64 to 3.10; 1 RCT, n=89 women) (Table 31).

The same primary study (Maher 2004[20]) reported a numerical decrease in the risk of obstructed defecation for ASC compared to SSLF (RR 0.37, 95% CI 0.08 to 1.83; 1 RCT, n=89 women) (Table 31). This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data.

5.2.9.2 Laparoscopic sacrocolpopexy vs. robot-assisted laparoscopic sacrocolpopexy

One primary study (Paraiso 2011[21]) reported a numerical decrease in the proportion of women experiencing small bowel obstruction for LSC compared to RALSC; however, this was not a statistically significant difference (6% vs. 0%, respectively; 1 RCT, n=68 women) (Table 31). This study was associated with an unclear risk of bias in terms of incomplete outcome data and other sources of bias.

5.2.10 Prolapse symptoms or subjective failure

5.2.10.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) reported a numerically lower risk of subjective failure for ASC compared to SSLF; however, this was not a statistically significant difference (RR 0.70, 95% CI 0.17 to 2.95; 1 RCT, n=89 women) (Table 32). The definition of 'subjective failure' was not clearly reported; however, it is likely that this referred to the presence of prolapse symptoms. This study was associated with a high risk of bias in terms of allocation concealment, blinding of participants/personnel, blinding of outcome assessors, and incomplete outcome data.

Table 23: Recurrent vault prolapse

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from RCOG 2015[17] & Maher 2013[16]	1	89	NR	2	46	4.3	0.23 (RR)	0.05	1.04	ASC	High (selection, performance, detection, attrition)
	SSLF					8	43	18.6					
LSC vs. ASC	**LSC**	Freeman 2013[19] [RCT] from Maher 2014[6]	1	46	NR	2	23	8.7	1.04 (RR)	0.16	6.80	ND	Moderate (one moderate quality RCT)
	ASC					2	24						
LSC vs. RALSC	**LSC**	Paraiso 2011[21] [RCT] from Maher 2014[6]	1	49	NR	2	23	11.5	0.75 (RR)	0.14	4.12	LSC	Low (one high quality RCT)
	RALSC					3	26						

* indicates a statistically significant difference; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NR = not reported; RCOG = Royal College of Obstetrics and Gynaecology; RCT = randomised controlled trial; RD = risk difference; RR = risk ratio; SSLF = sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 24: Any prolapse (objective failure)

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Barber 2013[13], Maher 2013[16] and RCOG 2015[17]	1	88	NR	11	46	23.9	0.77 (RR)	0.39	1.53	ASC	High (selection, performance, detection, attrition)
	SSLF					13	42	31.0					
LSC vs. RALSC	**LSC**	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	49	12	9	23	39.1	0.85[ø] (RR)	0.44[ø]	1.64[ø]	LSC	Unclear (attrition, other)
	RALSC					12	26	46.2					

[ø] Calculated manually (not reported in the source paper); [†] Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NR = not reported; RALSC = robot-assisted laparoscopic sacrocolpopexy; RCT = randomised controlled trial; RD = risk difference; RR = risk ratio; SSLF = sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 25: Bladder incontinence

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
StUI													
ASC vs. SSLF	**ASC**	Maher 2004[20] from RCOG 2015[17] and Maher 2013[16]	1	75	Post-operative‡	5	36	14	0.54 (RR)	0.20	1.43	ASC	High (selection, performance, detection, attrition)
	SSLF					10	39	26					
Resolution of preoperative overactive bladder													
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from RCOG 2015[17] and Barber 2013[13]	1	22	NR	3	11	27	0.75ø (RR)	0.22ø	2.60ø	SSLF	High (selection, performance, detection, attrition)
	SSLF					4	11	37					
New UUI													
ASC vs. LSC	**ASC**	Coolen 2017[18] [RCT] from Coolen 2017[15]	1	74	12	3	37	8	1.50ø (RR)	0.27ø	8.46ø	LSC	High (performance, detection)
	LSC					2	37	5					
	ASC	Freeman 2013[19]	1	53	NR	4	27	14.8	1.93ø (RR)	0.39ø	9.63ø	LSC	High (attrition), Unclear

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
	LSC	[RCT]				2	26	7.7					(performance)
New StUI													
ASC vs. LSC	**ASC**	Coolen 2017[18] [RCT] from Coolen 2017[15]	1	74	12	4	37	11	0.80ø (RR)	0.23ø	2.75ø	ASC	High (performance, detection)
	LSC					5	37	14					

* indicates a statistically significant change; ǂ not further defined; ø Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NR = not reported; RR = risk ratio; SSLF = sacrospinal ligament fixation; StUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 26: Bowel incontinence

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Faecal incontinence													
ASC vs. SSLF	ASC	Maher 2004[20] [RCT] from Maher 2013 [16]	1	89	NR	1	46	2.2	0.93 (RR)	0.06	14.48	ND	High (selection, performance, detection, attrition)
	SSLF					1	43	2.3					

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = No difference ; NR = not reported; RR = risk ratio; SSLF = sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 27: Any new incontinence

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. LSC	ASC	Freeman 2013[19] [RCT] from Coolen 2017 [15]	1	53	12	4	27	15	1.93ø (RR)	0.39ø	9.63ø	LSC	Unclear (attrition), Unclear (performance)
	LSC					2	26	8					

ø Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NR = not reported; RR = risk ratio; SSLF = sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence

Table 28: Other bladder or urinary function

Surgical Comparison	Treatment Arm	Study	# Studies	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Newly manifesting outcomes - New overactive bladder												
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Maher 2013[16] and Barber 2013[13]	1	NR	NR	NR	34	NR	NR	NR	SSLF	High (selection, performance, detection, attrition)
	SSLF				NR	NR	22					
Newly manifesting outcomes - New voiding dysfunction												
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Maher 2013[16] and Barber 2013[13]	1	NR	1	NR	NR	NR	NR	NR	NR	High (selection, performance, detection, attrition)
	SSLF				1	NR	NR					
Resolution of outcomes -preoperative overactive bladder												
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Maher 2013[16]	1	NR	3	11	27	0.75ø (RR)	0.22ø	2.60ø	SSLF	High (selection, performance, detection, attrition)
	SSLF				4	11	37					
Resolution of outcomes - preoperative voiding dysfunction												
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Maher 2013[16]	1	NR	7	9	78	0.97ø (RR)	0.56ø	1.70ø	ND	High (selection, performance, detection, attrition)
	SSLF				4	5	80					

ø Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NR = not reported; ND = No difference; RR = risk ratio; SSLF = sacrospinal ligament fixation

Table 29: Dyspareunia (difficult or painful sexual intercourse)

Comparison	Treatment Arm	Study	# Studies	Timepoint (months)	n	N	%	Baseline	Follow-Up	Effect	Risk of Bias†

						n	N	%	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	
Quite a bit or some dyspareunia																
ASC vs. LSC	**ASC**	Coolen 2017[18] [RCT]	1	60	12	5	13	38.5	0	13	0	1.09ø (RR)	0.42ø	2.79ø	ND	High (performance, detection)
	LSC					6	17	35.3	1	18	5.5					
Dyspareunia																
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from RCOG 2015[17] & Maher 2013[16]	1	36	Post-operative ǂ	NR	NR	NR	6	19	31.6	0.77 (RR)	0.32	1.83	ASC	High (selection, performance, detection, attrition)
	SSLF					NR	NR	NR	7	17	41.1					
New dyspareunia																
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Maher 2013[16]	1	36	NR	NR	NR	NR	2	19	10.5	0.60 (RR)	0.11	3.15	ASC	High (selection, performance, detection, attrition)
	SSLF					NR	NR	NR	3	17	17.7					

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2; ǂ not further defined; ø Calculated manually (not reported in the source paper)
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no difference; NR = not reported; RR = risk ratio; SSLF = sacrospinal ligament fixation

Table 30: Frequency of sexual activity

Outcome definition	Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	Baseline			Follow-Up			Change (%)ø	Risk of Bias†
							n	N	%	n	N	%		

Outcome definition	Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	Baseline			Follow-Up			Change (%)[ø]	Risk of Bias†
							n	N	%	n	N	%		
Coitus frequency - never	**ASC vs. LSC**	**ASC**	Coolen 2017[18] [RCT]	1	60	12	18	31	52.9	15	29	51.7	-1.2	High (performance, detection)
		LSC					17	34	50.0	11	31	35.5	-14.5	
Coitus frequency – less than once a month		**ASC**		1	60	12	5	31	16.1	4	29	13.8	-2.3	
		LSC					4	34	11.8	3	31	9.7	-2.1	
Coitus frequency – once or twice a month		**ASC**		1	60	12	3	31	9.7	6	29	20.7	+11	
		LSC					4	34	11.8	9	31	29.0	+17.2	
Coitus frequency – once a week		**ASC**		1	60	12	3	31	9.7	1	29	3.5	-6.2	
		LSC					6	34	17.7	4	31	12.9	-14.8	
Coitus frequency – more than once a week		**ASC**		1	60	12	2	31	6.5	2	29	6.9	+0.4	
		LSC					1	34	2.9	1	31	3.2	+0.3	

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; LSC = laparoscopic sacrocolpopexy

Table 31: Bowel function

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Constipation													
ASC vs. SSLF	ASC	Maher 2004[20] [RCT] from Maher 2013[16]	1	89	NR	12	46	26.1	1.40 (RR)	0.64	3.10	SSLF	High (selection, performance, detection, attrition)
	SSLF					8	43	18.6					
Obstructed defecation													
	ASC	Maher 2004[20] [RCT] from Maher 2013[16]	1	89	NR	2	46	4.4	0.37 (RR)	0.08	1.83	ASC	High (selection, performance, detection, attrition)
	SSLF					5	43	11.6					
Small bowel obstruction													
LSC vs. RALSC	LSC	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	68	NR	0	33	0	0.21ø (RR)	0.01ø	4.25ø	LSC	Unclear (attrition, other)
	RALSC					2	35	6					

ø Calculated manually (not reported in the source paper)† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NR = not reported; RR = risk ratio; SSLF = sacrospinal ligament fixation

Table 32: Prolapse symptoms – subjective failure

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. SSLF	**ASC**	Maher 2004[20][RCT] from RCOG 2015[17] & Maher 2013[16]	1	89	NR	3	46	6.5	0.70 (RR)	0.17	2.95	ASC	High (selection, performance, detection, attrition)
	SSLF					4	43	9.3					

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NR = not reported; RCOG = Royal College of Obstetrics and Gynaecology; RR = risk ratio; SSLF = sacrospinal ligament fixation

FAQ 2: EVIDENCE SUMMARY

Will my symptoms get better?

Evidence is relatively weak compared to that found in other conditions and for other procedures in that it is based on findings from individual RCTs which are judged to be at high or unclear risk of bias.

Recurrent vault prolapse /other prolapse

One primary study reported a numerically lower risk of recurrent vault prolapse for ASC compared to SSLF. Additionally, one primary study reported a lower risk of any prolapse (objective failure) for ASC compared to SSLF; however, this was also not a statistically significant difference (see Tables above for details). A separate primary study reported a lower risk of any prolapse for LSC compared to RALSC.

Incontinence

For any type of incontinence, almost twice as many patients experienced new incontinence after surgery for ASC compared to LSC (15% versus 8%). However, this was not a significant difference, and the evidence was from a relatively small study (see Tables above for details).

For bladder incontinence, one primary study reported a numerical reduction in the risk of post-operative SUI for ASC compared to SSLF however, this was not a statistically significant difference (see Tables above for details). One small primary study reported a decrease in the proportion of women experiencing resolution of preoperative overactive bladder for ASC compared to SSLF. One small primary study reported no difference in the proportion of women experiencing resolution of preoperative voiding dysfunction.

For faecal incontinence, no difference in the risk of faecal incontinence was reported for ASC compared to SSLF, with approximately 2% of women affected with either technique.

Two primary studies reported that rates of new urinary urge incontinence (UUI) at 12 months were higher, though not significantly so, for ASC compared to LSC (see Tables above for details). One primary study reported that rates of new stress urinary incontinence (SUI) at 12 months were higher, though not significantly, for LSC compared to ASC

Sexual issues

One primary study reported that ASC was associated with a lower, but not significantly so, risk of new difficult or painful sexual activity compared to SSLF. One primary study suggested that the risk of difficult or painful sexual activity was numerically lower for ASC compared to SSLF. One primary study also suggested that ASC outperformed LSC in terms of the proportion of women who experienced ‘quite a bit’ or ‘some’ difficult or painful sexual activity at 12 months after surgery. The frequency of sexual activity was reported to be similar for women undergoing ASC compared to LSC in one primary study.

Bowel function

One primary study reported a numerical increase in the risk of constipation for ASC compared to SSLF; however, the same study reported a numerical decrease in the risk of obstructed defecation for ASC compared to SSLF. Neither of these findings were statistically significant (see Tables above for details). One primary study reported a numerical decrease in the proportion of women experiencing small bowel obstruction for LSC compared to RALSC; however, this was not a statistically significant difference (6% vs. 0%, respectively) (see Tables above for details).

Prolapse symptoms

One primary study reported a numerically lower risk of subjective failure for ASC compared to SSLF; however, this was not a statistically significant difference. The definition of 'subjective failure' was not clearly reported; however, it is likely that this referred to the presence of prolapse symptoms.

All studies exhibited actual or potential risk of bias in some domains.

Evidence is lacking for vaginal pressure.

5.3 FAQ3: Will the patient's quality of life get better?

For most quality of life scales (except SF-36), higher scores suggest a lower quality of life. For SF-36, lower scores suggest a lower quality of life.

5.3.1 Quality of life

5.3.1.1 Abdominal sacrocolpopexy vs. sacrospinous ligament fixation

In a post-hysterectomy population with vaginal vault prolapse, a single study (Maher 2004[20]) reported on two different quality-of-life questionnaires: the Short Urinary Distress Inventory (SUDI) and the short form-36 (SF-36) health survey form (which was split into physical role, physical function and bodily pain domains). For SUDI, there was an improvement reported in both groups, but the authors indicated that this change was similar for both treatment groups. For SF-36, improvements were reported in the physical role domain for ASC; and improvements were reported in the physical function and bodily pain domain for SSLF. However, no statistically significant differences were reported between ASC compared to SSLF for any of the SF-36 domains (Table 33).

5.3.1.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

In a post-hysterectomy population with vaginal vault prolapse, a single primary study (Freeman 2013[19]) reported on prolapse quality of life. This study reported no difference in prolapse QOL score for ASC compared to LSC (1 RCT, n=54 women) (Table 33).

A second primary study (Coolen 2017[18]) reported on three different quality-of-life questionnaires: the Urinary Distress Inventory (UDI), the defecatory distress inventory (DDI) and the incontinence impact questionnaire (IIQ). No differences between treatment groups

were reported; however, both groups were reported to show significant improvements in UDI domain scores at 12 months following surgery compared to baseline (Table 33).

5.3.1.3 Laparoscopic sacrocolpopexy vs. robot-assisted laparoscopic sacrocolpopexy

In a post-hysterectomy population with vaginal vault prolapse, a single study (Paraiso 2011[21]) reported on three different quality-of-life questionnaires: the pelvic floor distress inventory-20, the pelvic floor impact questionnaire and the pelvic organ prolapse/urinary incontinence sexual questionnaire-12. For all three questionnaires, no difference was reported for LSC compared to RALSC (Table 33).

5.3.2 Patient satisfaction

5.3.2.1 Abdominal sacrocolpopexy vs. sacrospinous ligament fixation

In a post-hysterectomy population with vaginal vault prolapse, a single study (Maher 2004[20]) reported a numerical decrease in the risk of women being unsatisfied with surgery following ASC compared to SSLF; however, this was not a statistically significant difference (RR 0.82, 95% CI 0.32 to 2.06; 1 RCT, n=89 women) (Table 34). This was based on a VAS-100 questionnaire performed at an unspecified time point.

5.3.2.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

In a post-hysterectomy population with vaginal vault prolapse, pooled analysis reported a numerical increase in the odds of scoring “much better” or “better” in the Patient Global Impression of Improvement (PGI-I) questionnaire at 12 months following ASC compared to LSC; however, this was not a statistically significant change (odds ratio [OR] 0.75, 95% CI 0.33 to 1.71; 2 RCTs, n=105 women) (Table 34).[15]

Table 33: Quality of Life

Treatment Arm	Assessment Tool	Study	# Studies	Total # Patients (Baseline/Follow-up)	Baseline (Mean (SD))	Follow-Up (Mean (SD))	Follow-Up Time (months)	N (Baseline/ Follow-up)	Intervention favoured	Risk of Bias†
ASC vs. LSC										
ASC	P-QOL	Freeman 2013[19] [RCT]	1	53/47	80.7 (25.2)	29.3 (38.9)	12	27/24	NA	High (attrition), Unclear (performance)
LSC					74.7 (24.1)	28.6 (29.7)		26/23		
ASC	UDI – overactive bladder	Coolen 2017[18] [RCT]	1	65/60	44.4[ø] (22 to 50)	5.6[ø] (0 to 19)	12	31/29	NA	High (performance, detection)
LSC					33.3[ø] (11 to 56)	0.0[ø] (0 to 11)		34/31		
ASC	UDI – incontinence				16.7[ø] (0 to 42)	16.7[ø] (0 to 33)		31/29	NA	
LSC					16.7[ø] (0 to 50)	16.7[ø] (0 to 33)		34/31		
ASC	UDI – pain/discomfort				33.3[ø] (17 to 33)	8.3[ø] (0 to 33)		31/29	NA	
LSC					16.7[ø] (0 to 50)	0.0[ø] (0 to 29)		34/31		
ASC	UDI – genital prolapse				66.7[ø] (33 to 67)	0.0[ø] (0 to 0)		31/29	NA	
LSC					66.7[ø] (58 to 92)	0.0[ø] (0 to 29)		34/31		
ASC	UDI – obstructive micturition				16.7[ø] (58 to 92	0.0[ø] (0 to 0)		31/29	NA	
LSC					0.0[ø] (0 to 33)	0.0[ø] (0 to 13)		34/31		
ASC	DDI - constipation				0.0[ø] (0 to 33.3)	0.0[ø] (0 to 17)		31/29	NA	
LSC					0.0[ø] (0 to 17)	0.0[ø] (0 to 17)		34/31		
ASC	DDI – obstructive defecation				8.3[ø] (0 to 25)	0.0[ø] (0 to 8)		31/29	NA	
LSC					4.2[ø] (0 to 17)	0.0[ø] (0 to 17)		34/31		
ASC	DDI – pain/				0.0[ø] (0 to 0)	0.0[ø] (0 to 17)		31/29	NA	

Treatment Arm	Assessment Tool	Study	# Studies	Total # Patients (Baseline/Follow-up)	Baseline (Mean (SD))	Follow-Up (Mean (SD))	Follow-Up Time (months)	N (Baseline/ Follow-up)	Intervention favoured	Risk of Bias†
LSC	discomfort				0.0[ø] (0 to 0)	0.0[ø] (0 to 0)		34/31		
ASC	DDI - incontinence				0.0[ø] (0 to 17)	0.0[ø] (0 to 0)		31/29	NA	
LSC					8.3[ø] (0 to 25)	0.0[ø] (0 to 8)		34/31		
ASC	DDI – incontinence flatus				33.3[ø] (0 to 67)	0.0[ø] (0 to 17)		31/29	NA	
LSC					33.3[ø] (0 to 67)	0.0[ø] (0 to 33)		34/31		
ASC	IIQ - physical				0.0[ø] (0 to 33)	0.0[ø] (0 to 17)		31/29	NA	
LSC					25.0[ø] (0 to 50)	0.0[ø] (0 to 25)		34/31		
ASC	IIQ - mobility				33.3[ø] (11 to 44)	11.1[ø] (0 to 25)		31/29	NA	
LSC					11.1[ø] (0 to 33)	0.0[ø] (0 to 28)		34/31		
ASC	IIQ - social				11.1[ø] (0 to 33)	0.0[ø] (0 to 11)		31/29	NA	
LSC					11.1[ø] (0 to 22)	0.0[ø] (0 to 6)		34/31		
ASC	IIQ - shame				16.7[ø] (0 to 17)	0.0[ø] (0 to 17)		31/29	NA	
LSC					0.0[ø] (0 to 17)	0.0[ø] (0 to 8)		34/31		
ASC	IIQ - emotional				22.2[ø] (0 to 17)	0.0[ø] (0 to 25)		31/29	NA	
LSC					11.1[ø] (0 to 33)	0.0[ø] (0 to 22)		34/31		
ASC vs. SSLF										
ASC	SUDI (Short Urinary Distress Inventory)	Maher 2004[20] [RCT] from Maher 2013[16]	1	95/89	38 (27)	18 (23)	NR	47/46	ND	High (selection, performance, detection, attrition)
SSLF					32 (27)	17 (22)		48/43		
ASC	SF-36 – Physical role			95/89	39 (41)	63 (41)	NR	47/46	ND	
SSLF					57 (45)	72 (40)		48/43		
ASC	SF-36 – Physical			95/89	52 (27)	59 (29)	NR	47/46	ND	

Treatment Arm	Assessment Tool	Study	# Studies	Total # Patients (Baseline/Follow-up)	Baseline (Mean (SD))	Follow-Up (Mean (SD))	Follow-Up Time (months)	N (Baseline/ Follow-up)	Intervention favoured	Risk of Bias†
SSLF	function				60 (28)	73 (28)		48/43		
ASC	SF-36 – Bodily pain			95/89	59 (24)	67 (35)	NR	47/46	ND	
SSLF					61 (29)	75 (28)		48/43		
LSC vs. RALSC										
LSC	Pelvic Floor Distress Inventory (PFDI)-20	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	78/61	117^{ø} (17 to 248)	38^{ø} (0 to 226)	12	38/29	ND	Unclear (attrition, other)
RALSC					128^{ø} (0 to 267)	44^{ø} (0 to 161)		40/32		
LSC	Pelvic Floor Impact Questionnaire (PFIQ)				40^{ø} (0 to 262)	0^{ø} (0 to 167)		38/29	ND	
RALSC					63^{ø} (0 to 271)	0^{ø} (0 to 124)		40/32		
LSC	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-(POP/UISQ-12)				19^{ø} (4 to 38)	11^{ø} (3 to 22)		38/29	ND	
RALSC					20^{ø} (3 to 36)	16^{ø} (3 to 27)		40/32		

* indicates a statistically significant difference; ø indicates median and range values; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ADL = activities of daily living; ASC = abdominal sacrocolpopexy; CI = confidence interval; DDI = defecatory distress inventory; IIQ = incontinence impact questionnaire; LSC = laparoscopic sacrocolpopexy; NA = not assessed; ND = no difference; NR = not reported; PFDI-20 = pelvic floor distress inventory-20; PFIQ = pelvic floor impact questionnaire; POP/UISQ-12 = pelvic organ prolapse/urinary incontinence sexual questionnaire-12; P-QOL = prolapse quality of life; SD = standard deviation; SF-36 = short-form 36; SUDI = Short Urinary Distress inventory; UDI = Urinary distress inventory

Table 34: Patient Satisfaction

Surgical Comparison	Treatment Arm	Study	Timepoint (months)	# Studies	Total # Patients	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
PGI-I													
ASC vs. LSC	ASC	Coolen 2017[15] [Systematic Review]	12	2	105	36	51	70.6	OR 0.75 RR 1.09[ø]	0.33 0.84[ø]	1.71 1.41[ø]	ASC	High (performance, detection)
	LSC					35	54	64.8					
VAS-100													
ASC vs. SSLF	ASC	Maher 2004[20] [RCT] from Maher 2013[16]	NR	1	89	39	46	85	RR 1.04[ø]	0.86[ø]	1.26[ø]	ND	High (selection, performance, detection, attrition)
	SSLF					35	43	81					

[ø] Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = No difference; NR = not reported; OR = odds ratio; PGI-I = patient global impression of improvement; RR = risk ratio; VAS = visual analogue scale

FAQ 3: EVIDENCE SUMMARY

Will my quality of life get better?

Unless otherwise stated, evidence can be judged as relatively weak compared to that found in other conditions and for other procedures in that it is based on findings from individual RCTs which are judged to be at high or unclear risk of bias.

Quality of life

Four separate RCTs reported on different aspects of quality of life, mainly at 12 months following surgery. Two studies evaluated ASC versus LSC and one each assessed ASC versus SSLF and LSC versus RALSC. None of the comparisons yielded conclusive results. All studies exhibited actual or potential risk of bias in some domains.

Patient Satisfaction

One RCT reported slightly higher satisfaction levels following ASC compared to SSLF. This was based on VAS-100 administered at unspecified timepoints. Pooled analysis from two RCTs reported on patient satisfaction using a tool measuring patient global impression of improvement (PGI-I) at 12 months following surgery. Satisfaction levels were reported to be higher for ASC than for LSC but the study was small and so there is considerable uncertainty as to whether this is a real effect.

5.4 FAQ4: WHEN WILL THE PATIENT RECOVER?

5.4.1 Time to return to usual activity

5.4.1.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) from RCOG 2015[17] reported an increase in the time to return to normal activity for ASC compared to SSLF (MD 8.30 days, 95% CI 3.91 to 12.69; 1 RCT, n=95 women) (Table 35).

5.4.1.2 Laparoscopic sacrocolpopexy vs. robot-assisted laparoscopic sacrocolpopexy

One primary study (Paraiso 2011[21])) reported no difference in the return to normal activity for LSC compared to RALSC (1 RCT, n=68 women) (Table 36).

5.4.2 Time to return to work

No evidence was identified for the time to return to work outcome.

5.4.3 Time to return to sexual function

No evidence was identified for the time to return to sexual function outcome.

5.4.4 Time to return to other activities, such as sports

No evidence was identified for the time to return to other activities outcome.

5.4.5 Impact on dependents/family

No evidence was identified for the impact on dependents/family outcome.

Table 35: Time to return to normal activity

Surgical Comparison	Treatment Arm	Assessment Tool	Study	# Studies	Total # Patients	Mean (days)	SD	N	Mean difference (days)	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. SSLF	**ASC**	ADL	Maher 2004[20] [RCT] from RCOG 2015[17]	1	95	34.0	12.1	47	8.30	3.91	12.69	SSLF*	High (selection, performance, detection, attrition)
	SSLF					25.7	9.7	48					

* indicates a statistically significant difference; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ADL = activities of daily living (described as simple household duties, driving) ; ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; RCOG = Royal College of Obstetrics and Gynaecology; SD = standard deviation

Table 36: Change in normal activity

Surgical Comparison	Treatment Arm	Assessment Tool	Study	# Studies	Total # Patients	Baseline (Median, range)	Follow-Up	Follow-Up Time	N	P-value	Intervention favoured	Risk of Bias†
LSC vs. RALSC	**LSC**	VAS-100	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	68	22 (0 to 80)	88 (2 to 100)	Week 1 to Week 6	33	0.43	ND	Unclear (attrition, other)
	RALSC					21 (0 to 86)	85 (13 to 100)	Week 1 to Week 6	35			

† Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ADL = activities of daily living; ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ND = no significant difference; SD = standard deviation; VAS = visual analogue scale

FAQ 4: EVIDENCE SUMMARY

When will the patient recover?

Evidence is relatively weak compared to that found in other conditions and for other procedures in that it is based on findings from individual RCTs which are judged to be at high or unclear risk of bias.

Time to return to normal activity

One RCT from 2004 in 95 women reported that return to normal activities was quicker following SSLF than with ASC (on average about four weeks compared to five weeks). One RCT reported no difference in the return to normal activity for LSC compared to RALSC. All studies exhibited actual or potential risk of bias in some domains.

Evidence is lacking for time to return to work; time to return to sexual function; time to return to other activities (such as sports); and impact on dependents/family.

5.5 FAQ5: WHAT ARE THE RISKS AND LONG-TERM IMPLICATIONS?

5.5.1 Operative blood loss

5.5.1.1 Abdominal sacrocolpopexy vs. sacrospinous ligament fixation

One primary study (Maher 2004[20]) reported a numerically lower volume of blood loss for SSLF compared to ASC; however, this was not a statistically significant difference (MD 56.00 ml, 95% CI -32.89 to 144.89; 1 RCT, n=95 women) (Table 37).

5.5.1.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

Pooled analysis reported that ASC was associated with a higher volume of operative blood loss compared to LSC (mean difference [MD] -146.21 ml, 95% CI -211.24 to -81.17; 2 RCTs, n=127 women) (Table 37).[15]

5.5.2 Pelvic pain

5.5.2.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

Very limited evidence was identified for pelvic pain. One primary study (Freeman 2013[19]) narratively reported that there was no difference in pelvic pain for ASC compared to LSC (1 RCT, n=54 women); however, no further numerical data was provided.

One primary study (Coolen 2017[18]) reported that worsened pelvic pain was self-reported by three patients in the ASC group and one patient in the LSC group as a complaint (1 RCT, n=60 women). Based on questionnaires, the same study reported that pelvic pain was present in a numerically increased number of patients receiving ASC compared to LSC after 12 months; however, this was not a statistically significant difference (Table 38).

5.5.3 Wound infection

5.5.3.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) reported a numerical increase in the proportion of women experiencing wound infection for ASC compared to SSLF (6% vs. 0%, respectively; 1 RCT, n=95 women) (Table 39).

5.5.3.2 Laparoscopic sacrocolpopexy vs. robot-assisted laparoscopic sacrocolpopexy

One primary study (Paraiso 2011[21]) reported a numerical decrease in the proportion of women experiencing wound infection for LSC compared to RALSC; however, this was not a statistically significant difference (6% vs. 0%, respectively; 1 RCT, n=68 women) (Table 39).

5.5.4 Urinary tract injury

No evidence was identified for urinary tract injury.

5.5.5 Rectal Injury

No evidence was identified for rectal injury.

5.5.6 Other serious unintended injuries

No evidence was identified for other serious unintended injuries.

5.5.7 Other pelvic floor or abdominal complications

5.5.7.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

Pooled analysis demonstrated a numerical increase in the odds of complications for ASC compared to LSC; however, this was not a statistically significant difference (OR 0.53, 95% CI 0.16 to 1.72; 2 RCTs, n=127 women) (Table 40).[15]

5.5.7.2 Laparoscopic sacrocolpopexy vs. robot-assisted laparoscopic sacrocolpopexy

One primary study (Paraiso 2011[21]) from Barber 2013[13] reported a decrease (reported as statistically significant) in the proportion of women experiencing complications for LSC compared to RALSC (18% vs. 71%, respectively; 1 RCT, n=78 women) (Table 40).

5.5.8 Mesh-related problems

No evidence was identified for mesh related problems other than mesh exposure (see below).

5.5.9 Mesh exposure

5.5.9.1 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

Two primary studies (Freeman 2013[19], Coolen 2017[18]) from Coolen 2017[15] reported that no women experienced mesh exposure at 12 months following ASC or LSC (1 RCT, n=53; 1 RCT, n=74) (Table 41).

5.5.9.2 Laparoscopic sacrocolpopexy vs. robot-assisted laparoscopic sacrocolpopexy

One primary study (Paraiso 2011[21]) from Barber 2013[13] reported a numerical decrease in the proportion of women experiencing mesh erosion at 12 months for LSC compared to RALSC; however, this was not a statistically significant difference (0% vs. 6%, respectively; 1 RCT, n=78 women) (Table 41).

5.5.10 Long-term risks

No evidence was identified for long term risks other than reoperation (see below).

5.5.11 Reoperation for POP

5.5.11.1 Abdominal sacrocolpopexy vs. sacrospinal ligament fixation

One primary study (Maher 2004[20]) reported a numerical decrease in the risk of reoperation for POP for sacrocolpopexy (ASC) compared to SSLF (RR 0.31, 95% CI 0.03 to 12.88; 1 RCT, n=89 patients); however, this was not a statistically significant difference (Table 42).

5.5.11.2 Abdominal sacrocolpopexy vs. laparoscopic sacrocolpopexy

A pooled analysis reported a numerical decrease in the odds of reoperation for POP at 12 months for ASC compared to LSC (OR 3.96, 95% CI 0.63 to 25.06; 2 RCTs, n=127 women); however this was not a statistically significant difference and was associated with a large amount of uncertainty (Table 42).[15] Although the definition of reoperation for POP was largely unclear, it was likely reoperation for prolapse, incontinence and/or complications.

Table 37: Blood loss

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Mean (ml)	SD	N	Mean difference (ml)	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. LSC	**ASC**	Coolen 2017[15] [Systematic Review]	2	127	218.84	183.01	64	-146.21	-211.24	-81.17	LSC*	NA
	LSC				73.54	153.00	63					
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Maher 2013[16]	1	95	362	239	47	56.00	-32.89	144.89	SSLF	High (selection, performance, detection, attrition)
	SSLF				306	201	48					

* Study reported that the difference was statistically significant; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ml = millilitre; NA = Not applicable; SD = standard deviation; SSLF = Sacrospinal ligament fixation

Table 38: Pelvic Pain

Surgical Comparison	Treatment Arm	Study	# Studies	n	N	%	Follow-Up time point (months)	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
Pain self-reported as a 'complaint'												
ASC vs. LSC	**ASC**	Coolen 2017[18] [RCT]	1	3	29	10.3	12	3.21ø (RR)	0.35ø	29.11ø	LSC	High (performance, detection)
	LSC			1	31	3.2						
Pain by questionnaire												
ASC vs. LSC	**ASC**	Coolen 2017[18] [RCT]	1	13	29	44.8	12	RR 1.74ø	0.84ø	3.57ø	LSC	High (performance, detection)
	LSC			8	31	25.8						

ø Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; ml = millilitre; SD = standard deviation

Table 39: Wound Infection

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from Maher 2013[16]	1	95	1	47	2	RR 3.06[ø]	0.13[ø]	73.33[ø]	SSLF	High (selection, performance, detection, attrition)
	SSLF				0	48	0					
LSC vs. RALSC	**LSC**	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	68	0	33	0	RR 0.21[ø]	0.01[ø]	4.25[ø]	LSC	Unclear (attrition, other)
	RALSC				2	35	6					

[ø] Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; OR = odds ratio

Table 40: Other pelvic floor or abdominal complications

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. LSC	**ASC**	Coolen 2017[15] [Systematic Review]	2	127	9	64	14.1	OR 0.53 RR 1.77[ø]	0.16 0.62[ø]	1.72 5.08[ø]	LSC	NA
	LSC				5	63	7.9					
LSC vs. RALSC	**LSC**	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	78	7	38	18	RR 0.26[ø]	0.13[ø]	0.53[ø]	LSC*	Unclear (attrition, other)
	RALSC				28	40	71					

[ø] Calculated manually (not reported in the source paper); [*] Study reported that the difference was statistically significant; † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NA = Not applicable; OR = odds ratio

Table 41: Mesh Exposure

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. LSC	**ASC**	Freeman 2013[19] [RCT] from Coolen 2017 [15]	1	53	12	0	26	0	NE	NE	NE	ND	High (attrition), Unclear (performance)
	LSC					0	27	0					
	ASC	Coolen 2017[18] [RCT] from Coolen 2017 [15]	1	74		0	37	0	NE	NE	NE	ND	High (performance, detection)
	LSC					0	37	0					
LSC vs. RALSC	**LSC**	Paraiso 2011[21] [RCT] from Barber 2013[13]	1	78	12	0	33	0	RR 0.21[ø]	0.01[ø]	4.25[ø]	LSC	Unclear (attrition, other)
	RALSC					2	35	6					

[ø] Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2

ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NE = not estimable; NR = not reported; OR = odds ratio; RALSC = robot-assisted laparoscopic sacrocolpopexy; SSLF = sacrospinal ligament fixation

Table 42: Reoperation for Prolapse

Surgical Comparison	Treatment Arm	Study	# Studies	Total # Patients	Timepoint (months)	n	N	%	Effect Estimate	Lower 95% CI	Upper 95% CI	Intervention favoured	Risk of Bias†
ASC vs. SSLF	**ASC**	Maher 2004[20] [RCT] from RCOG 2015[17] & Maher 2013[16]	1	89	NR	1	46	2.2	RR 0.31	0.03	2.88	ASC	High (selection, performance, detection, attrition)
	SSLF					3	43	7.0					
ASC vs. LSC	**ASC**	Coolen 2017[15] [Systematic Review]	2	127	12	1	64	1.6	OR 3.96 RR 0.27[ø]	0.63 0.05[ø]	25.06 1.59[ø]	ASC	NA
	LSC					5	63	7.9					

[ø] Calculated manually (not reported in the source paper); † Risk of bias was assessed for RCTs using Cochrane Risk of Bias Tool – see Appendix 2
ASC = abdominal sacrocolpopexy; CI = confidence interval; LSC = laparoscopic sacrocolpopexy; NA = Not applicable; NR = not reported; OR = odds ratio; SSLF = sacrospinal ligament fixation

FAQ 5: EVIDENCE SUMMARY

What are the risks and long-term implications?

Unless otherwise stated, evidence can be judged as relatively weak compared to that found in other conditions and for other procedures in that it is based on findings from individual RCTs which are judged to be at high or unclear risk of bias.

Blood loss

One primary study reported a lower volume of blood loss for SSLF compared to ASC; however, this was not statistically significant (see Tables above for details). Pooled analysis reported that ASC was associated with a significantly higher volume of operative blood loss compared to LSC. It is reasonable to conclude that LSC and SSLF are associated with the most favourable outcomes.

Pelvic pain

Very limited evidence was identified for pelvic pain. One primary study reported no difference in pelvic pain for ASC compared to LSC. One primary study reported that pelvic pain was worsened (either through self-reports or based on questionnaires) after ASC compared to LSC after 12 months; however, this was not a statistically significant difference (see Tables above for details).

Wound infection

One primary study reported more women experienced wound infection after ASC compared to SSLF; however, this was not a statistically significant difference. A further primary study reported less women experiencing wound infection for LSC compared to RALSC; however, this was not a statistically significant difference (see Tables above for details). It is reasonable to conclude that both ASC and RALSC have worse outcomes than alternative treatments, albeit with a degree of uncertainty given effects were observed in single small studies.

Other Pelvic Floor or Abdominal Complications

Pooled analysis demonstrated an increase in the odds of complications for ASC compared to LSC; however, this was not a statistically significant difference (see Tables above for details). One primary study reported a significant decrease in the proportion of women with complications for LSC compared to RALSC. It seems reasonable to conclude that LSC is associated with improved outcomes when compared to either RALSC or ASC.

Mesh exposure

Two primary studies reported that no women experienced mesh exposure at 12 months following ASC or LSC. One primary study reported a numerical decrease in the proportion of women experiencing mesh erosion at 12 months for LSC compared to RALSC; however, this was not a statistically significant difference (see Tables above for

Reoperation for prolapse

One primary study reported a decrease in the risk of reoperation for POP for ASC compared to SSLF; however, this was not a statistically significant difference (see Tables above for details). Pooled analysis of two studies reported a decrease in the odds of reoperation for POP at 12 months for ASC compared to LSC; however, this was not a statistically significant difference.

Evidence lacking for:

- Major bleeding, fever, issues with wound healing, urinary tract injury (UTI) ; rectal injury ; other serious unintended injuries; mesh-related problems (other than mesh exposure); long-term risks; mortality
- Very limited evidence was identified for pelvic pain.

5.6 Assessment of the clinical review evidence

Evidence sources and associated outcomes are set out in Table 43 below.

Table 43: Overview of the clinical evidence and included guidelines

Study ID	Number of Participants	Interventions	Outcomes	Study Design	Longest follow-up (months)
Barber 2013[13]	185	ASC, LSC, RALSC, SSLF	Length of stay, any prolapse, resolution of preoperative overactive bladder, other bladder or urinary function, small bowel obstruction, pelvic Floor Distress Inventory (PFDI)-20, change in normal activity, other pelvic floor or abdominal complications, mesh exposure, wound infection	SR	NR
Coolen 2017[15]	437	ASC, LSC, RALSC, SSLF	Length of stay, bladder incontinence, any incontinence, patient satisfaction, operative blood loss, other pelvic floor or abdominal complications, mesh exposure, reoperation for POP	SR	12
Maher 2013[16]	NR	ASC, SSLF	Bowel incontinence, sexual function – dyspareunia; bowel function; prolapse recurrence; any prolapse, other bladder or urinary function, prolapse symptoms, quality of life, blood loss, wound infection, reoperation for prolapse,	SR	NR
Coolen 2017[18]	74	ASC, LSC	Sexual function – dyspareunia, sexual function - Frequency of sexual activity, bladder incontinence, quality of life	RCT	12
Freeman 2013[19]	53	ASC, LSC	Sexual function – dyspareunia, bladder incontinence, any incontinence, quality of life, pelvic pain, mesh exposure	RCT	12
Maher 2004[20]	95	ASC, SSLF	Length of stay, any prolapse, bladder incontinence, bowel incontinence, other bladder/urinary function, sexual function – dyspareunia, bowel function, resolution of preoperative overactive bladder, quality of life, patient satisfaction, time to return to normal activity, wound	RCT	NR

Study ID	Number of Participants	Interventions	Outcomes	Study Design	Longest follow-up (months)
			infection		
Paraiso 2011[21]	68	LSC, RALSC	Length of stay, any prolapse, bowel function, quality of life, time to return to normal activity, wound infection, other pelvic floor or abdominal complications, mesh exposure.	RCT	12
Royal College of Obstetricians and Gynaecologists 2015[17]	547	ASC, SSLF	Description of treatment, length of hospital stay, prolapse recurrence, bladder incontinence, sexual function – dyspareunia, prolapse symptoms, time to return to normal activity, reoperation of prolapse	G	NA
British Society of Urogynaecology 2017[14]	NA	ASC, LSC, RALSC	Description of treatment	G	NA
British Society of Urogynaecology 2017[10]	NA	SSLF	Description of treatment	G	NA
German Society of Gynaecology and Obstetrics 2016[11]	NA	NA	Description of treatment	G	NA
National Institute for Health and Care Excellence 2019[12]	NA	ASC, LSC, RALSC, SSLF	Description of treatment	G	NA

ASC = abdominal sacrocolpopexy; G = guideline; LSC = laparoscopic sacrocolpopexy; NA= Not appropriate; NR = not reported; RALSC = robot-assisted laparoscopic sacrocolpopexy; SR = systematic review; SSLF = sacrospinous ligament fixation

Unless otherwise stated, evidence can be judged as relatively weak compared to that found in other conditions and for other procedures in that it is based on findings from individual RCTs which are judged to be at high or unclear risk of bias. No evidence was found for LP, CESA, VASA or HSP. Accordingly, these procedures have not been included in the summary of evidence. (see Table 44)

Table 44: Summary of evidence

Evidence	Sacrocolpopexy			Sacrospinous suspension	Notes
	ASC	LSC	RALSC	SSLF	
FAQ 1. What does treatment involve?					
Length of operating time	✓ (v LSC) × (v SSLF)	× (v ASC) ✓ (v RALSC)	×	✓	ASC is associated with significantly shorter stays than LSC and significantly longer stays than SSLF. LSC is associated with significantly shorter stays than RALSC.
Length of hospital stay	× (v LSC) × (v SSLF)	✓	-	✓	LSC is associated with significantly shorter stays than ASC and slightly shorter stays than RALSC. SSLF is associated with slightly shorter stays than ASC.
FAQ 2. Will symptoms get better?					
Recurrent vault prolapse	✓			×	One primary study reported a numerically lower risk of recurrent vault prolapse for ASC compared to SSLF.
Objective failure (any prolapse)	✓	✓	×	×	One primary study reported a numerically lower risk of any prolapse (objective failure) for ASC compared to SSLF; however, this was not a statistically significant difference. A separate primary study reported a numerically lower risk of any prolapse (objective failure; defined as stage ≥2 prolapse) for LSC compared to RALSC; however, this was not a statistically significant difference.
Bladder incontinence – new UUI	×	✓			Two primary studies reported on rates of new UUI at 12 months or an unspecified time point. The rate was reported to be higher, though not significantly so, for ASC compared to LSC (8% vs. 5%, or 14.8% vs. 7.7% respectively).

Evidence	Sacrocolpopexy			Sacrospinous suspension	Notes
	ASC	LSC	RALSC	SSLF	
Bladder incontinence – new SUI	✓	×			One primary study reported on rates of new SUI at 12 months. The rate was reported to be higher, though not significantly so, for LSC compared to ASC (14% vs. 11%, respectively).
SUI	✓			×	One primary study reported a lower risk, though not significantly so, for post-operative SUI for ASC compared to SSLF (14% vs. 26%, respectively).
Faecal incontinence	-			-	No difference was observed in the risk of faecal incontinence for ASC compared to SSLF, with approximately 2% of cases affected with either technique.
Any new incontinence	×	✓			One primary study reported that rates of any type of new incontinence were higher for ASC compared to LSC (15% versus 8%); however, this was not a statistically significant difference, and was from a relatively small study.
Other bladder or urinary function (resolution of preoperative voiding dysfunction)	-			-	One small primary study reported no difference in the proportion of women experiencing resolution of preoperative voiding dysfunction for ASC compared to SSLF (78% vs. 80%, respectively), although this finding was based on results from only 14 women.
Other bladder or urinary function (resolution of preoperative overactive bladder)	×			✓	One small primary study reported a decrease in the proportion of women experiencing resolution of preoperative overactive bladder for ASC compared to SSLF (27% vs. 37%, respectively); however, this was not statistically significant.
Dyspareunia (difficult or painful sexual intercourse)	× (v LSC) ✓ (v SSLF)	✓		×	One primary study reported that ASC was associated with a numerical increase in the proportion of women reporting 'quite a bit' or 'some' dyspareunia at a 12 month follow up compared to LSC; however, this was not a statistically significant difference. One primary study reported that the risk of post-operative dyspareunia or new dyspareunia was numerically lower following ASC compared to SSLF; however, these were not statistically significant differences.
Frequency of	-	-			Frequency of sexual activity was assessed in a single study comparing ASC and LSC.

Evidence	Sacrocolpopexy			Sacrospinous suspension	Notes
	ASC	LSC	RALSC	SSLF	
sexual activity					There were no significant differences between the groups.
Bowel function - constipation	×			✓	One primary study reported a numerical increase in the risk of constipation for ASC compared to SSLF; however, this was not a statistically significant difference.
Bowel function – obstructed defecation	✓			×	One primary study reported a numerical decrease in the risk of obstructed defecation for ASC compared to SSLF; however, this was not a statistically significant difference.
Bowel function – small bowel obstruction		✓	×		One primary study reported a numerical decrease in the proportion of women experiencing small bowel obstruction for LSC compared to RALSC; however, this was not a statistically significant difference (6% vs. 0%, respectively).
Prolapse symptoms (subjective failure)	✓			×	One primary study reported a numerically lower risk of subjective failure for ASC compared to SSLF; however, this was not a statistically significant difference. The definition of 'subjective failure' was not clearly reported; however, it is likely that this referred to the presence of prolapse symptoms.
FAQ 3. Will quality of life get better?					
Quality of life (various measures)	-	-	-	-	Four studies reported on different aspects of quality of life, mainly at 12 months after surgery. Two studies evaluated ASC versus LSC and one each assessed ASC versus SSLF or LSC versus RALSC. None of the comparisons between interventions provided conclusive results.
Patient satisfaction	✓	×		×	Pooled analysis assessed patient satisfaction using a tool measuring patient global impression of improvement (PGI-I) at 12 months following surgery. Satisfaction levels were higher for ASC than for LSC; however, this was not a statistically significant difference and the study was small. One primary study used a slightly different measure of patient satisfaction and reported higher satisfaction levels following ASC compared to SSLF; however, this was not a statistically significant difference.
FAQ 4. When will the patient recover?					
Time to return to normal activity	×			✓	One study of 95 patients found that the return to normal activities was quicker following SSLF compared to ASC (on average about 4 weeks compared to 5 weeks)
Change in normal		-	-		One primary study reported no difference in the return to normal activity for LSC

Evidence	Sacrocolpopexy			Sacrospinous suspension	Notes
	ASC	LSC	RALSC	SSLF	
activity					compared to RALSC.
FAQ 5. What are the long-term risks and implications?					
Blood loss	✗ (v LSC) ✗ (v SSLF)	✓		✓	Pooled analysis reported that ASC was associated with a significantly higher volume of operative blood loss compared to LSC. One primary study reported a numerically higher volume of blood loss for ASC compared to SSLF; however, this was not a statistically significant difference. On this basis, it is reasonable to conclude that ASC is associated with the most favourable outcomes.
Pelvic pain	✗ (v LSC) - (v LSC)	✓ -			Very limited evidence was identified for pelvic pain. One primary study reported that there was no difference in pelvic pain for ASC compared to LSC (1 study, n=54 women); however, no further numerical data was provided. A separate primary study reported that more women reported worsened pelvic pain (by either self-reporting or through a questionnaire) after ASC compared to the LSC at 12 months following surgery; however, this was not a statistically significant difference.

Evidence	Sacrocolpopexy			Sacrospinous suspension	Notes
	ASC	LSC	RALSC	SSLF	
Wound infection	×	✓	×	✓	One primary study reported a numerical increase in the proportion of women experiencing wound infection for ASC compared to SSLF (2% vs. 0%, respectively). However, this was not a statistically significant difference. A separate primary study reported a numerical decrease in the proportion of women experiencing wound infection for LSC compared to RALSC; however, this was not a statistically significant difference. On this basis, it is reasonable to conclude that both ASC and RALSC have worse outcomes than alternative treatments, albeit with a degree of uncertainty given effects were observed in single small studies.
Other Pelvic Floor or Abdominal Complications	× (v LSC)	✓ (v RALSC) ✓ (v ASC)	× (v LSC)		Pooled analysis reported a numerical increase in the odds of complications for ASC compared to LSC; however, this was not a statistically significant difference. One primary study reported a significant decrease in the proportion of women experiencing complications for LSC compared to RALSC. On this basis, it seems reasonable to conclude that LSC is associated with improved outcomes when compared to either RALSC or ASC.
Mesh exposure	-	- (v ASC) ✓ (v RALSC)	×		Two primary studies reported that no women experienced mesh exposure at 12 months following ASC or LSC. However, one primary study reported a numerical decrease in the proportion of women experiencing mesh erosion at 12 months for LSC compared to RALSC; however, this was not a statistically significant difference.
Reoperation for prolapse	✓ (v LSC or SSLF)	× (v ASC)		× (v ASC)	Pooled analysis of two studies reported a numerical decrease in the risk of reoperation for POP at 12 months for ASC compared to LSC; however, this was not a statistically significant difference and was associated with a large amount of uncertainty. Although the definition of reoperation for POP was largely unclear, it was likely reoperation for prolapse, incontinence and/or complications.

Evidence	Sacrocolpopexy			Sacrospinous suspension	Notes
	ASC	LSC	RALSC	SSLF	
					One primary study reported a numerical decrease in the risk of reoperation for POP for ASC compared to SSLF; however, this was not a statistically significant difference.
Key					
	Not evaluated				
-	No numerical difference				
✓	Numerically better but not statistically significant. Any advantage may not be sustained in the long term				
✓	Statistically significantly better than comparators or clearly identified as guideline recommendation				
✗	Numerically inferior but not statistically significant. Any disadvantage may not be sustained in the long term				
✗	Statistically significantly inferior or not recommended in guidelines				
ASC = abdominal sacrocolpopexy; FAQ = frequently asked question; LSC = laparoscopic sacrocolpopexy; RALSC = robot-assisted laparoscopic sacrocolpopexy; SSLF= Sacrospinal ligament fixation; SUI = stress urinary incontinence; UUI = urinary urge incontinence					

6. DISCUSSION

Three surgical options were deemed of relevance to women with vaginal prolapse who were symptomatic (such as vaginal pressure, pelvic pain, overactive bladder or sexual problems) with or without prior hysterectomy: sacrocolpopexy, pectopexy and sacrospinous ligament fixation. Evidence was identified in relation to two of these options in each of the populations studied: sacrocolpopexy and pectopexy in the main population and sacrocolpopexy and sacrospinal ligament fixation in the post hysterectomy population.

One German guideline on female genital prolapse was identified that was published in 2016.[11] Chapter 7 of the guideline included ten recommendation regarding therapeutic options for pelvic prolapse related to the middle compartment. The first recommendation (7.E1) stated that a decision for a specific treatment should be made based on all symptoms, comorbidities, risk factors as well as preference by the patient ("Welches Verfahren gewählt wird, muss mit der Patientin unter Beachtung aller Befunde und Symptome, Comorbiditäten, Risikofaktoren, gleichzeitig geplanter totaler Hysterektomie, Wünsche der Patientin und Expertise der Abteilung abgewogen werden"), i.e. this report is in line with that recommendation. The guideline had no specific guidance or recommendations regarding women who had undergone a prior hysterectomy.

Maher 2013[16] identified two primary studies (Benson 1996[31], Lo 1998[32]) that compared ASC vs. SSLF in the main population of women with prolapse of pelvis (excluding post hysterectomy which we have reported separately). Benson 1996[31] reported a lower rate of recurrent vault prolapse (1 out of 38 versus 5 out of 42; RR 0.22, 95% CI 0.03 to 1.81); less post-operative SUI (9 out of 38 versus 18 out of 42, RR 0.55, 95% CI 0.28 to 1.08) and fewer cases of post-operative dyspareunia (0 out of 15 versus 4 out of 26, RR 0.19, 95% CI 0.01 to 3.26). Lo 1998[32] also reported fewer cases of post-operative dyspareunia (1 out of 11 versus 11 out of 18, RR 0.15, 95% CI 0.02 to 1.00) although this was a small study. None of these results was statistically significant. Due to the early dates of study enrolment (Benson performed surgeries between 1989 and 1992; Lo enrolled women between 1991 and 1996), these primary studies were excluded to prevent the introduction of surgical technique invalidity and clinical heterogeneity into the dataset. More than 20% of women in the Benson 1996 study also underwent McCall's culdoplasty, which is an excluded technique of sacrospinal fixation rather than the one focused on in this report (Amreich-Ritter, see Table 1) Accordingly, exclusion is in line with IQWiG criteria: "Studies are also included in which at least 80% of patients fulfil the inclusion criterion regarding the test intervention (intervention group of the study).[33] Maher 2013[16] also identified Maher 2004[20] which was included in the post-hysterectomy population (see section 5 of the report).

6.1 STRENGTHS, LIMITATIONS AND UNCERTAINTIES

A key strength of this report is the incorporation of evidence from systematic reviews and clinical practice guidelines. This evidence was supplemented with data from primary studies where limited evidence was identified from systematic reviews (e.g. quality of life, pelvic

pain etc.) or where the primary study reported in more detail than found within systematic reviews. These primary studies were identified from within the included systematic review publications. Other strengths of this report include a thorough literature search and the inclusion of the most recently published evidence. The report also covered a wide range of outcomes of interest.

One limitation was the uncertainty associated with linking results from one comparison to another. For example, some evidence was found for length of hospital stay. However, length of stay variability can often be related to factors beyond procedure type, for example between different studies performed at different centres and in different countries. In this scenario, although operating times may appear significantly shorter for one procedure over another, different operating theatre protocols or staffing expertise at different study sites this should further be taken into account. This suggests that a degree of caution should be used when interpreting results. Van de Vijsel and colleagues draw attention to this: "*These (length of stay) variations [can be] found even after controlling for various patient characteristics (case-mix). Several studies explained part of the variation in case-mix adjusted LOS by the accessibility of hospitals, organisational factors or the availability of formal and informal aftercare".*[34]

It is clear from the evidence provided in this review that there are a number of pros and cons associated with each of the procedures for which evidence is available. That being said, virtually no evidence was found which supported use of RALSC over any alternative treatment in either the main population or sub population.

For the main population, with the exception of operating times, ASC offered no advantages when compared to either LSC or LP. LP offered advantages in terms of bowel function and blood loss when compared to LSC although slightly longer hospital stays were reported.

For the subgroup of women who had undergone a previous hysterectomy, SSLF had very few advantages when compared to alternative techniques although it did appear to have a reasonable length of hospital stay profile (when compared to ASC) and was also associated with a decrease in the proportion of women experiencing resolution of preoperative overactive bladder, a decrease in constipation, a decrease in wound infection and a shorter time to return to work (compared to ASC). Generally, ASC and LSC offered advantages in comparison to other techniques across a range of outcomes. However, when compared head to head, ASC and LSC were perhaps more balanced in terms of advantages/disadvantages.

Results for both populations are summarised in Tables 21 and 44.

7. REFERENCES

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APPENDIX 1: SEARCH STRATEGIES

Systematic review and guideline searches

Database	Dates	Results
CDSR	2012 - Issue 9 of 12, September 2019	13
DARE	2012 to 31 March 2015	20
HTA	2012 to 31 March 2018	6
KSR Evidence	2012-2019	144
Epistemonikos	2012-2019	250
NHS Evidence	2012-2019	22
NICE Guidance	2012-2019	10
GIN	2012-2019	1
ECRI	2012-2019	3
Total		**469**
Total after de-duplication		**303**

Cochrane Database of Systematic Reviews (CDSR) (Wiley): Issue 9 of 12, September 2019
Searched: 17.9.19

#1 MeSH descriptor: [Pelvic Organ Prolapse] explode all trees 470
#2 ((vagin* or Uterine or uterus or pelvic or pelvis or urogenital or "uro-genital" or vault or uterovagin* or "utero-vagin*" or genital* or apex or apical or "central compartment" or "middle compartment" or urethral or "genital-urinary" or "genito-urinary" or genitourinary) NEAR/3 (prolaps* or descent or procidentia)):ti,ab,kw 1698
#3 (colpoptosis or cystocele or colpocele or enterocele or rectocele or Urethrocele or Cystourethrocele or "cysto-urethrocele" or "urethro-cystocele" or urethrocystocele or Sigmoidocele):ti,ab,kw 341
#4 (douglas NEAR/3 (hernia* or hernii)):ti,ab,kw 0
#5 ((posterior or anterior) NEAR/3 (compartment or wall) NEAR/3 (descent or prolaps* or procidentia)):ti,ab,kw 168
#6 ((central or middle) NEAR/3 compartment NEAR/3 (descent or prolaps* or procidentia)):ti,ab,kw 3
#7 (AVWP or PVWP):ti,ab,kw 6
#8 (bladder NEAR/3 (prolaps* or protrusion or protrud* or procidentia)):ti,ab,kw 41
#9 ("bladder ptosis" or "cystic hernia*" or cystoptosis):ti,ab,kw 0
#10 ((bladder or urinary) NEAR/3 hernia*):ti,ab,kw 15
#11 (("complete external" or overt) NEAR/3 prolaps*):ti,ab,kw 0
#12 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 with Cochrane Library publication date Between Jan 2012 and Sep 2019, in Cochrane Reviews 13

Database of Abstracts of Reviews of Effects (DARE) (CRD): 2012 to 31 March 2015
https://www.crd.york.ac.uk/CRDWeb/
Searched: 17.9.19

1 ((vagin* or Uterine or uterus or pelvic or pelvis or urogenital or "uro-genital" or vault or uterovagin* or "utero-vagin*" or genital* or apex or apical or "central compartment" or "middle compartment" or urethral or "genital-urinary" or "genito-urinary" or genitourinary) and (prolaps* or descent or procidentia)) 97

2 ((colpoptosis or cystocele or colpocele or enterocele or rectocele or Urethrocele or Cystourethrocele or "cysto-urethrocele" or "urethro-cystocele" or urethrocystocele or Sigmoidocele)) 4
3 ((douglas and (hernia* or hernii))) 0
4 (((posterior or anterior) and (compartment or wall) and (descent or prolaps* or procidentia))) 13
5 (((central or middle) and compartment and (descent or prolaps* or procidentia))) 5
6 ((AVWP or PVWP)) 0
7 ((bladder and (prolaps* or protrusion or protrud* or procidentia))) 14
Delete8 (("bladder ptosis" or "cystic hernia*" or cystoptosis)) 0
9 (((bladder or urinary) and hernia*)) 30
10 ((("complete external" or overt) and prolaps*)) 1
11 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 130
12 (#11) IN DARE FROM 2012 TO 2019 20

Health Technology Assessment Database (HTA) (CRD): 2012 to 31 March 2018
https://www.crd.york.ac.uk/CRDWeb/
Searched: 17.9.19
1 ((vagin* or Uterine or uterus or pelvic or pelvis or urogenital or "uro-genital" or vault or uterovagin* or "utero-vagin*" or genital* or apex or apical or "central compartment" or "middle compartment" or urethral or "genital-urinary" or "genito-urinary" or genitourinary) and (prolaps* or descent or procidentia)) 97
2 ((colpoptosis or cystocele or colpocele or enterocele or rectocele or Urethrocele or Cystourethrocele or "cysto-urethrocele" or "urethro-cystocele" or urethrocystocele or Sigmoidocele)) 4
3 ((douglas and (hernia* or hernii))) 0
4 (((posterior or anterior) and (compartment or wall) and (descent or prolaps* or procidentia))) 13
5 (((central or middle) and compartment and (descent or prolaps* or procidentia))) 5
6 ((AVWP or PVWP)) 0
7 ((bladder and (prolaps* or protrusion or protrud* or procidentia))) 14
8 (("bladder ptosis" or "cystic hernia*" or cystoptosis)) 0
9 (((bladder or urinary) and hernia*)) 30
10 ((("complete external" or overt) and prolaps*)) 1
11 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 130
12 (#11) IN HTA FROM 2012 TO 2019 6

KSR Evidence (Internet): 2012 to 17 September 2019
www.ksrevidence.com
Searched: 17.9.19
1 (vagin* or Uterine or uterus or pelvic or pelvis or urogenital or "uro-genital" or vault or uterovagin* or "utero-vagin*" or genital* or apex or apical or "central compartment" or "middle compartment" or urethral or "genital-urinary" or "genito-urinary" or genitourinary) and (prolaps* or descent or procidentia) in All text 106

2 colpoptosis or cystocele or colpocele or enterocele or rectocele or Urethrocele or Cystourethrocele or "cysto-urethrocele" or "urethro-cystocele" or urethrocystocele or Sigmoidocele in All text 13
3 douglas and (hernia* or hernii) in All text -
4 (posterior or anterior) and (compartment or wall) and (descent or prolaps* or procidentia) in All text 10
5 (central or middle) and compartment and (descent or prolaps* or procidentia) in All text 4
6 AVWP or PVWP in All text -
7 bladder and (prolaps* or protrusion or protrud* or procidentia) in All text 24
8 "bladder ptosis" or "cystic hernia*" or cystoptosis in All text -
9 (bladder or urinary) and hernia* in All text 29
10 ("complete external" or overt) and prolaps* in All text 2
11 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 144

Epistemonikos (Internet): up to 17 September 2019
https://www.epistemonikos.org/en/
Searched: 17.9.19
(title:((title:((vagin* OR Uterine OR uterus OR pelvic OR pelvis OR urogenital OR "uro-genital" OR vault OR uterovagin* OR "utero-vagin*" OR genital* OR apex OR apical OR "central compartment" OR "middle compartment" OR urethral OR "genital-urinary" OR "genito-urinary" OR genitourinary) AND (prolaps* OR descent OR procidentia)) OR abstract:((vagin* OR Uterine OR uterus OR pelvic OR pelvis OR urogenital OR "uro-genital" OR vault OR uterovagin* OR "utero-vagin*" OR genital* OR apex OR apical OR "central compartment" OR "middle compartment" OR urethral OR "genital-urinary" OR "genito-urinary" OR genitourinary) AND (prolaps* OR descent OR procidentia))) OR (title:(colpoptosis OR cystocele OR colpocele OR enterocele OR rectocele OR Urethrocele OR Cystourethrocele OR "cysto-urethrocele" OR "urethro-cystocele" OR urethrocystocele OR Sigmoidocele) OR abstract:(colpoptosis OR cystocele OR colpocele OR enterocele OR rectocele OR Urethrocele OR Cystourethrocele OR "cysto-urethrocele" OR "urethro-cystocele" OR urethrocystocele OR Sigmoidocele)) OR (title:(douglas AND (hernia* OR hernii)) OR abstract:(douglas AND (hernia* OR hernii))) OR (title:((posterior OR anterior) AND (compartment OR wall) AND (descent OR prolaps* OR procidentia)) OR abstract:((posterior OR anterior) AND (compartment OR wall) AND (descent OR prolaps* OR procidentia))) OR (title:((central OR middle) AND compartment AND (descent OR prolaps* OR procidentia)) OR abstract:((central OR middle) AND compartment AND (descent OR prolaps* OR procidentia))) OR (title:(AVWP OR PVWP) OR abstract:(AVWP OR PVWP)) OR (title:(bladder AND (prolaps* OR protrusion OR protrud* OR procidentia)) OR abstract:(bladder AND (prolaps* OR protrusion OR protrud* OR procidentia))) OR (title:("bladder ptosis" OR "cystic hernia*" OR cystoptosis) OR abstract:("bladder ptosis" OR "cystic hernia*" OR cystoptosis)) OR (title:((bladder OR urinary) AND hernia*) OR abstract:((bladder OR urinary) AND hernia*)) OR (title:(("complete external" OR overt) AND prolaps*) OR abstract:(("complete external" OR overt) AND prolaps*))) OR abstract:((title:((vagin* OR Uterine OR uterus OR pelvic OR pelvis OR urogenital OR "uro-genital" OR vault OR uterovagin* OR "utero-vagin*" OR genital* OR apex OR apical OR "central compartment" OR "middle compartment" OR urethral OR "genital-urinary" OR "genito-urinary" OR genitourinary) AND (prolaps* OR descent OR procidentia)) OR

abstract:((vagin* OR Uterine OR uterus OR pelvic OR pelvis OR urogenital OR "uro-genital" OR vault OR uterovagin* OR "utero-vagin*" OR genital* OR apex OR apical OR "central compartment" OR "middle compartment" OR urethral OR "genital-urinary" OR "genito-urinary" OR genitourinary) AND (prolaps* OR descent OR procidentia))) OR (title:(colpoptosis OR cystocele OR colpocele OR enterocele OR rectocele OR Urethrocele OR Cystourethrocele OR "cysto-urethrocele" OR "urethro-cystocele" OR urethrocystocele OR Sigmoidocele) OR abstract:(colpoptosis OR cystocele OR colpocele OR enterocele OR rectocele OR Urethrocele OR Cystourethrocele OR "cysto-urethrocele" OR "urethro-cystocele" OR urethrocystocele OR Sigmoidocele)) OR (title:(douglas AND (hernia* OR hernii)) OR abstract:(douglas AND (hernia* OR hernii))) OR (title:((posterior OR anterior) AND (compartment OR wall) AND (descent OR prolaps* OR procidentia)) OR abstract:((posterior OR anterior) AND (compartment OR wall) AND (descent OR prolaps* OR procidentia))) OR (title:((central OR middle) AND compartment AND (descent OR prolaps* OR procidentia)) OR abstract:((central OR middle) AND compartment AND (descent OR prolaps* OR procidentia))) OR (title:(AVWP OR PVWP) OR abstract:(AVWP OR PVWP)) OR (title:(bladder AND (prolaps* OR protrusion OR protrud* OR procidentia)) OR abstract:(bladder AND (prolaps* OR protrusion OR protrud* OR procidentia))) OR (title:("bladder ptosis" OR "cystic hernia*" OR cystoptosis) OR abstract:("bladder ptosis" OR "cystic hernia*" OR cystoptosis)) OR (title:((bladder OR urinary) AND hernia*) OR abstract:((bladder OR urinary) AND hernia*)) OR (title:(("complete external" OR overt) AND prolaps*) OR abstract:(("complete external" OR overt) AND prolaps*))))

NICE Evidence Search: limited to guidance and SRs only (Internet): up to 17 September 2019

https://www.evidence.nhs.uk/

Searched 17.9.19

Search terms	**Results (Guidance): 01/01/2012-17/9/2019**
vagina* prolaps*	66
pelvi* prolaps*	79
genital prolaps*	32
urethral prolaps*	36
bladder prolaps*	62
apical prolaps*	20
bladder hernia*	70
urinary hernia*	92
sacrocolpopexy	16
sacropexy	5
pectopexy	3
vaginal sacrospin* fixation	3
Total retrieved	**484**
Total (without duplicates)	**186**
Sifted for relevance	**22**

National Institute for Health and Care Excellence (NICE): Guidelines. Up to 17 September 2019

https://www.nice.org.uk/
Searched 17.9.19

Search terms	Results (limited to 'Guidance')
(vaginal or pelvic or pelvis or genital* or urethral or bladder or apical) and (prolaps* or descent or procidentia)	10/45
(bladder or urinary) and hernia*	2/19
Sacrocolpopexy or sacropexy or pectopexy	7/13
Vaginal sacrospin* fixation	2/2
Total (excl. duplicates)	**10**

Guidelines International Network (GIN) Library (Internet): up to 17 September 2019
http://www.g-i-n.net
Searched 17.9.19

Search terms	Results (limited to 'Guidance')
prolaps*	1/6
(bladder or urinary) and hernia*	0/41
Sacrocolpopexy or sacropexy or pectopexy	0
Vaginal sacrospin* fixation	0
Total (excl. duplicates)	**1**

ECRI Institute Guidelines Trust (Internet): up to 17 September 2019
https://guidelines.ecri.org/
Searched: 17.9.19

Search terms	Results (limited to 'Guidance')
prolaps*	2/6
(bladder or urinary) and hernia*	1/19
Sacrocolpopexy or sacropexy or pectopexy	0
Vaginal sacrospin* fixation	0/40
Total (excl. duplicates)	**3**

Targeted searches for pectopexy

Northern Light Life Sciences Conference Abstracts (Ovid): 2010 - 2020 Week 03
Embase (Ovid): 1974 to 2020 January 27
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily Update (Ovid): 1946 to January 27, 2020
Date searched: 28.1.20
Records found:

Embase 29
MEDLINE, Epub Ahead of Print, In-Process, Daily Update 0
Northern Light 2

1 (pectopexy or pectopexies or pecto pexy or pecto pexies).ti,ot,ab,kw. (50)

2 remove duplicates from 1 (33)
3 limit 2 to yr="2012 -Current" (31)

Cochrane Central Register of Controlled Trials
Issue 1 of 12, January 2020
Date searched: 28.1.20
Records found: 5
#1 pectopexy or pectopexies or pecto pexy or pecto pexies with Publication Year from 2012 to 2020, in Trials 5

APPENDIX 2: RISK OF BIAS SUMMARY OF PRIMARY RCTS

A2.1 De Gouveia De Sa 2016a

Risk of bias of the nine included primary studies was assessed in De Gouveia De Sa 2016[4] by using the Cochrane risk of bias assessment tool.

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Anger, 2014[28]	-	-	+	+	+	+	+
Antosh, 2012[35]	-	-	-	-	+	?	?
Awad, 2012[36]	-	-	-	-	+	?	?
Chan, 2011[26]	-	-	-	-	+	?	?
Nosti, 2014[25]	-	-	-	-	?	-	+
Paraiso, 2011[21]	+	+	+	+	+	+	+
Pulliam, 2012[37]	-	-	-	-	+	?	+
Seror,2012[27]	-	-	-	-	+	?	?
Tan-Kim, 2011[38]	-	-	-	-	?	?	?

A2.2 De Gouveia De Sa 2016b

Risk of bias of the 12 included primary studies was assessed in De Gouveia De Sa 2016[5] by using the Cochrane risk of bias assessment tool.

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Collins, 2012[29]	-	-	-	+	+	+	?
Coolen, 2013[39]	-	-	-	-	?	-	?
Elliot, 2012[40]	-	-	-	-	+	+	?
Freeman, 2013[19]	+	-	+	+	?	+	-
Geller, 2008[41]	-	-	-	-	+	+	-
Geller,2012[30]	-	-	-	+	+	-	-
Hoyte, 2012[42]	-	-	-	+	+	+	-
Khan, 2013[43]	-	-	-	-	?	?	-
Klauschie, 2009[44]	-	-	-	-	?	+	?
Nosti, 2014[25]	-	-	-	-	?	-	+
Paraiso, 2005[45]	-	-	-	-	?	-	?
Tyson, 2013[46]	-	-	-	-	+	?	?

A2.3 MAHER 2016

Risk of bias of the four included primary studies was assessed in Maher 2016[6] by using the Cochrane risk of bias assessment tool.

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Anger, 2014[28]	+	+	?	-	+	+	+
Constantini, 2013[24]	+	?	?	?	?	?	?
Freeman, 2013[19]	+	?	-	-	+	+	?
Paraiso, 2011[21]	+	+	+	+	+	+	+

A2.4 COOLEN 2017

Risk of bias of the four included primary studies was assessed in Coolen 2017[15] by using the Cochrane risk of bias assessment tool.

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Coolen 2017[18]	+	+	-	-	+	+	+
Freeman 2013[19]	+	+	?	+	-	+	+
Maher 2004[20]	+	-	-	-	-	+	+
Paraiso 2011[21]	+	+	+	+	?	+	?

A2.5 NOE 2015

Risk of bias for Noe 2015[8] by using the Cochrane risk of bias assessment tool (performed by two reviewers (consensus) at Kleijnen Systematic Reviews).

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Noe 2015[8]	+	+	-	-	-	-	-

Notes:

- Performance bias (Clinical suitability for procedures could have been addressed independently of participating surgeons)
- Outcome assessment not independent
- Incomplete data (2 lost to follow up not reported)
- Selective reporting – nothing in regard protocol outcomes and nothing about sexual function or lower back pain