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ESCP GUIDELINES

European Society of Coloproctology guidance on the use of mesh in the pelvis in colorectal surgery

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Abstract

This is a comprehensive and rigorous review of currently available data on the use of mesh in the pelvis in colorectal surgery. This guideline outlines the limitations of available data and the challenges of interpretation, followed by best possible recommendations.

KEYWORDS
colorectal surgery, guidance, mesh, perineal reconstruction, prolapse

The shorter version pdf will be available in supporting information section.

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This guidance was formulated based on current published evidence. It is intended to provide information that may assist colorectal surgeons and other healthcare professionals, and recommendations are targeted at clinicians only.

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EXECUTIVE SUMMARY

Meshes are increasingly used in colorectal surgery. Broadly speaking, there are synthetic and biological meshes. Use of mesh may strengthen and prolong the durability of a repair or reconstruction.

The outcome of the use of mesh has been reported in numerous studies. However, many of these are case series of small numbers of patients compounded by heterogeneity of indications and cross-sectional analysis, which makes it challenging for meaningful extrapolation of data. Literature reviews from these studies have been hampered by lack of clarity on evidence grading and robust data synthesis. As use of mesh has become more common, concerns have been raised, particularly in relation to the emergence of chronic and debilitating symptoms following transvaginal implantation of mesh. In general, use of mesh in the pelvis in colorectal surgery is relatively recent, unlike its use in urogynaecology, and therefore the benefits and risks have not been assessed thoroughly in relation to colorectal procedures.

The ESCP Guideline Committee aimed to conduct a thorough literature review, assess currently available evidence and collate expert opinion on the safety of mesh when used in the pelvis as part of a colorectal procedure and to determine how best to handle mesh complications should they arise.

Evidence was graded using GRADE (Grading of Recommendations Assessment, Development and Evaluation). The recommendations are based on the rigour and robust methodology derived from GRADE and follows their style:

- **Strong recommendation** is one for which the guidance panel is confident that the desirable effects of an intervention outweigh its undesirable effects.
- **Conditional recommendation** is one for which the desirable effects probably outweigh the undesirable effects but implies that not all individuals will be best served by the recommended course of action.

In addition, standard terminology was used based on the level of evidence whenever possible, namely:

- must be used (high level of evidence)
- should be used (moderate level of evidence)
- could be used (low level of evidence)

Some recommendations were made if and when the group agreed, using appropriate wording for very low levels of evidence ('can be considered').

There is a need to consider more carefully than usual the individual patient's circumstances, preferences and values. When there are *conditional* recommendations caregivers need to allocate more time to shared decision making, making sure that they explain clearly and

comprehensively the potential benefits and harms to the patient. The rationale for each recommendation is detailed with data synthesis in relevant sections.

Mesh rectopexy

By the Mesh in Pelvis Group strongly believe that rectopexy should be undertaken only by colorectal surgeons with a specialist interest in pelvic floor disorders in centres with regular multidisciplinary team meetings. Procedure-specific enhanced governance including monitoring of adverse events and reporting of long-term functional outcomes are essential in order to establish safe practice.

Extensive patient information including reiteration of non-invasive treatment options and the possibility of long-term mesh complications such as postoperative pain and onset of new symptoms should be used to inform patient–clinician shared decision making.

The indications for surgery to address anatomical abnormalities such as internal rectal prolapse, intussusception, rectocoele and/or enterocoele are still debated. Symptoms reported are variable and include faecal incontinence, obstructed defaecation and/or pelvic heaviness/pain. The group emphasizes that surgical correction of anatomical abnormalities does not automatically lead to (complete) resolution of symptoms.

Treatment of any pelvic floor condition should always start with conservative measures such as advice on diet and toileting behaviour and may be combined with physiotherapy, medication, irrigation and psychological support. Detailed evaluation of this, however, is outside the remit of this guidance.

Use of mesh for external full-thickness rectal prolapse

Recommendations

- In patients with full-thickness rectal prolapse, mesh could be used for abdominal rectopexy as it may reduce the chance of recurrence. [*Conditional recommendation*]
- Any of the currently available meshes can be considered for rectopexy to reduce the incidence of prolapse recurrence. [*Conditional recommendation*]

Use of mesh rectopexy for posterior pelvic floor disorders other than full-thickness external prolapse, including internal rectal prolapse, rectocoele, enterocoele and solitary rectal ulcer syndrome

Recommendations

- Mesh rectopexy can be considered for posterior pelvic floor disorders including internal rectal prolapse, rectocoele, enterocoele and solitary rectal ulcer syndrome. [*Conditional recommendation*]
- It is recommended that patients are considered for this surgery only when their symptoms have a strong negative impact on their daily quality of life and they have exhausted maximal conservative management. [*Conditional recommendations*]
- Patients should be informed and adequately counselled regarding potential harm. [*Conditional recommendation*]
- Patients should be informed that rectopexy with or without the use of mesh has a limited but real risk of de novo constipation or worsening of existing constipation. [*Conditional recommendation*]
- Either biological or synthetic mesh can be considered. [*Conditional recommendation*]
- Surgeons can use any approach or surgical technique based on their familiarity, experience and skills. [*Conditional recommendation*]

Mesh for pelvic reconstruction

There have been two randomized controlled trials that report conflicting results concerning pelvic floor reconstruction using mesh. One showed no benefit of using mesh compared to primary closure following abdominoperineal resection, whilst the second study did show benefit. The former study reported no difference in complication rate whilst the latter study indicated that postoperative pain was greater with the use of biological mesh. Neither study made clear the selection criteria for use of mesh. The choice of closure method also was dictated by local availability of plastic surgical expertise and availability of mesh. There has been no study to compare whether mesh is superior to primary closure with any of the new vacuum-assisted devices or dressings. This is something that could be considered in future.

Recommendations

- Use of biological mesh can be considered for perineal reconstruction. [*Conditional recommendation*]
- The choice for reconstruction should be based on the size of the defect, patient characteristics and surgical expertise. [*Conditional recommendation*]
- Overall morbidities and perineal septic complications occur in about a quarter to a third of patients, and perineal pain occurs significantly more often in patients who had mesh reconstruction. Patients need to be informed appropriately about these adverse effects prior to surgery along with the morbidity of the primary repair or the use of flaps. [*Conditional recommendation*]

Mesh for other indications

The number of studies on the use of mesh for other indications in the pelvis was limited and of low quality. If the use of mesh is considered for any new indication in the future, it should be introduced with the rigour of adequate training and supervision,

prospective audit and monitoring of long-term outcomes and complications.

Recommendations

- Use of mesh for anal sphincter repair is currently not recommended due to the very low quality of available evidence. [*Conditional recommendation*]
- Use of mesh for repairing ano/rectovaginal fistula is currently not recommended due to the very low quality of available evidence. [*Conditional recommendation*]
- Use of mesh for recreating the anorectal angle for faecal incontinence could not be recommended due to the very low quality of available evidence. [*Conditional recommendation*]
- Placing a mesh transperineally for rectocoele repair cannot be recommended due to the very low quality of available evidence and concerns for safety. [*Conditional recommendation*]

Mesh complications

The literature was quite limited about complications, as mesh-related complications in colorectal surgery were not explicitly reported, or some symptoms were attributed to other conditions or stated as 'unrelated' without a clear explanation despite occurring within a short period after surgery.

Reported low morbidities with mesh may be due to the fact that in mesh rectopexy the approach is abdominal, not transvaginal. However, most likely it is because most of the studies report on short-term outcome (<12 months) only. On the other hand, due to lack of comparative studies, it was difficult to identify complication rates when mesh was not used.

Recommendations

- Reoperation to reattach mesh to the sacral promontory can be considered in patients with recurrence of full-thickness rectal prolapse. [*Conditional recommendation*]
- Treatment of mesh erosion depends on the site. Surgical removal of mesh could be considered if technically feasible. This may require a defunctioning stoma. [*Conditional recommendation*]
- Re-intervention presents a significant technical challenge and should be performed only at experienced centres with a robust system of auditing outcome. [*Conditional recommendation*]

Quality of data and future perspectives

The majority of available studies were case series or cross-sectional studies with variable follow-up periods with significant heterogeneity of included patients and lack of definition of reported complications. In most studies, short- and long-term outcomes were reported without consideration for length of time bias. Some studies did not report on complications and, when reported, details were not always explicit. There were significant challenges to extrapolate data on complications not only because of timing issues but also because definitions of complications were variable. Data concerning mortality were not well documented particularly in relation to whether outcomes were directly related to the surgery or not.

There were few randomized controlled trials. There are many challenges to running a well-designed randomized controlled trial with adequate power and randomization is not necessarily the best design to address certain topics. In order truly to look into the long-term outcomes, cohort studies with explicit reporting on missing data may be more helpful.

BACKGROUND

Meshes are increasingly used in colorectal surgery. Broadly speaking, there are synthetic and biological meshes and use of mesh may strengthen and prolong the durability of a repair or reconstruction.

The ideal properties of a mesh are minimal foreign body reaction (biologically inert), minimal shrinkage and formation of adhesions, yet with sufficient tensile strength, good memory, resembling the elasticity of the surrounding tissues (compliance) and cost-effectiveness.

There are different types of synthetic meshes with various materials, absorbability, tensile strength and pore size available. Synthetic meshes are woven or knitted and composed of polypropylene, polyester or expanded polytetrafluoroethylene. Biological meshes are derived from human (allograft), bovine or porcine tissue (xenograft) and subdivided into crosslinked or non-crosslinked meshes. Harvested tissue is decellularized and the extracellular matrix acts as a scaffold for tissue ingrowth. The consequent inflammatory response allows incorporation of the mesh. The choice for one type of mesh over another can be influenced by patient or surgeon preference, cost, degree of contamination and risk of adverse events.

There have been many studies reporting on the use of mesh in colorectal surgery. However, interpretation of outcome has been challenging for multiple reasons: there have been few randomized controlled trials (RCTs), case series have been largely of a small number of heterogeneous patients with short-term follow-up, and literature reviews have not robustly synthesized data with explicit evidence grading.

In urogynaecology, adverse events such as mesh erosion, infection and chronic pain have been associated with use of non-absorbable synthetic mesh. As use of mesh became more common, the reports on problems associated with its use, particularly those of chronic and debilitating symptoms, alerted clinicians and triggered increased awareness amongst patients and the general public on the risk of mesh-related complications. This has led to some high-profile

campaigning and class action to ban mesh use. Unlike use in urogynaecology, mesh has not been widely used in colorectal surgery and the benefits and risks of such use have not been thoroughly assessed.

The ESCP Guideline Committee was established to improve the quality of care by providing a guidance that sets out the current best practice in Europe based on available evidence in order to improve outcomes for patients. The Committee set up a group to conduct a thorough literature review, assess currently available evidence and collate expert opinion on the use of mesh in the pelvis in colorectal surgery. The intention was to develop robust guidance based on the rigour of GRADE and AGREE II (Appraisal of Guideline for Research and Evaluation II) for transparency and clarity.

METHODS

Formation of guidance working group

A steering group was formed of experts who had a common interest in improving the clinical practice of using mesh in the pelvis in colorectal surgery.

A call for other experts and stakeholders to take part was announced by ESCP e-newsletters and invitations by email. The selection of experts was conducted by the steering group by assessing candidates' CVs and applications according to the set criteria: (1) appropriate and relevant clinical experience, (2) proven track record of scientific knowledge and research skills, (3) international experience and/or recognition or willingness to collaborate with diverse professionals and patients, (4) geographical distribution.

Process of guidance construction

The guidance was written based on a robust literature search with transparency. Construction was based on established guideline methods such as the AGREE II tool [1] and in line with the guidance by the European Commission (Scientific Committee on Emerging and Newly Identified Health Risks, 'Opinion on the safety of surgical meshes used in urogynecological surgery', accessible from https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_27_en).

Involvement of stakeholders

Invitations to stakeholders such as

- healthcare providers and commissioners (e.g., NHS England and equivalent organizations in EU countries)
- statutory organizations (e.g., Medicines and Healthcare Products Regulatory Agency, UK, and equivalent organizations in EU countries)
- organizations representing patients (e.g., Meshies United, Scottish MESH Survivors, The Voices Today on Messed up Mesh [TVT MUM], meshedup.eu and similar organizations in other EU countries)
- healthcare professional organizations (e.g., International Urogynecological Association, International Continence Society, Association of Coloproctology of Great Britain and Ireland [ACPGBI], Royal College of Surgeons and similar organizations in EU countries)
- biomaterial specialists
- surgical mesh manufacturers and industry representatives

were sent by email for their input. A website for public consultation was established on the ESCP website.

Scope of guidance

The guidance defines a mesh as a sheet of synthetic or biological material, manufactured to be implanted in humans. As such, it does not cover other types of implants such as neurostimulators, artificial sphincter devices or injectable implants. The guidance aims to focus on the pelvis; therefore it does not cover meshes implanted in the abdominal wall or groin. The guidance is limited to the field of colorectal surgery—hence it does not include the use of mesh in the field of urogynaecology.

The guidance aims to address the following PICO (Patient/Population/Problem, Intervention, Comparison, Outcome) questions.

- Use of mesh for repair of full-thickness rectal prolapse
  1. Is using mesh better than no mesh in preventing the recurrence of rectal prolapse?
  2. Is one mesh better than others in maintaining rectal prolapse repair?
- Use of mesh for obstructive defaecation symptoms (ODS) other than full-thickness rectal prolapse (e.g., internal prolapse/intussusception, anterior/posterior rectocoele, enterocoele, solitary rectal ulcer syndrome [SRUS])
  1. Is mesh rectopexy effective for ODS/faecal incontinence (FI) symptoms with internal prolapse/intussusception, anterior/posterior rectocoele, enterocoele or SRUS?
- Use of mesh for full-thickness prolapse and ODS
  1. Does the use of mesh increase the risk of adverse events?
  2. Do specific types of mesh increase the risk of adverse events?
  3. Do certain surgical techniques (open/laparoscopic/robotic, fixation methods, concomitant resection, concomitant repair of other pelvic organ prolapse) reduce the recurrence of prolapse or carry more risks of complications with the use of mesh?
  4. Are there certain groups of patients who have higher risks of developing adverse events with the use of mesh?
- Perineal reconstruction and other uses of mesh in colorectal surgery

1. Is using a mesh in perineal reconstruction better than classical reconstruction (primary closure with mesh versus no mesh, transpositioned/interpositioned flap with/without mesh)?
2. Is one mesh better than others when used for perineal reconstruction?
3. Does the use of mesh increase the risk of adverse events?
4. Do specific types of mesh increase the risk of adverse events?
5. Do certain surgical techniques (fixation methods, concomitant resection, soft tissue cover with a flap, use of wound management system) prevent hernia after perineal reconstruction or carry more risks?

- Other indications of mesh in colorectal surgery
  1. Should a mesh be used in repairing the anal sphincter?
  2. Should a mesh be used in repairing ano/rectovaginal fistula?
  3. Should a mesh be used to recreate the anorectal angle for FI?
- Management of complications of mesh used in the pelvis by colorectal surgeons

  1. Do any approaches (transabdominal/transvaginal) to implant mesh carry more risks?
  2. What are the techniques to deal with mesh complications (conservative treatment, mesh removal, diversion)?

Definition of complications

Complications were defined as any untoward symptom/event that occurred after an operation with the use of mesh in the pelvis when the causative relationship to mesh is likely. Some of these include but are not limited to

- acute and/or chronic pain/discomfort in pelvis, groin, back, thigh, leg, abdomen
- bleeding, haemorrhage, formation of haematoma
- infection, wound breakdown, formation of abscess
- mesh-related events such as erosion, extrusion, exposure, fistula formation in the vagina, rectum, colon, small bowel, blood vessels, bladder, lower urinary tract
- difficulties with voiding and/or defaecation
- pain during intercourse or sexual dysfunction
- recurrence or exacerbation of prolapse/incontinence/ODS/constipation
- formation of adhesions/scarring/contractures
- over-correction or under-correction resulting in one of the above symptoms

The list was drawn by referring to a comprehensive list of complications compiled by the Australian Government Department of Health Therapeutic Goods Administration (https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications). Other complications were added arising from the outcome of the literature search.

Definition and glossary

Please see Appendix S3.

Literature search strategy

MEDLINE, Embase, Central and Web of Science were searched using the keywords for articles published between January 1950 and March 2018 that were related to (a) mesh in the pelvis and (b) outcome and complications relevant to the practice of colorectal surgery in adults. A manual and recursive search for relevant articles and references that may have been missed by the search was also performed.

Selected references were pooled in an Endnote library so that the working group could share the same library. Professional librarians' assistance was solicited for refining the search strategy and extracting relevant publications (see Acknowledgements).

Study eligibility assessment and selection

The group identified all studies, both those fully published and those in abstract form. Controlled and observational (prospective and retrospective) studies reporting indications, outcome and complications associated with the use of mesh in the pelvis in colorectal surgery were included.

The eligibility of the studies was assessed independently by two/three reviewers in each group, using a standardized hierarchical list of inclusion/exclusion criteria. Discrepancies were resolved through discussion and reaching of consensus. Review articles and reports of implants that did not conform to the definition of mesh were excluded.

Study quality evaluation

Individual study quality was assessed using the GRADE score. Additionally, the quality of the evidence for each question was evaluated with the use of the GRADE system, which assigns one of four levels of evidence: very low (⊕◯◯◯), low (⊕⊕◯◯), moderate (⊕⊕⊕◯) or high (⊕⊕⊕⊕). Within the GRADE system, RCTs were generally rated as high quality, but may have been downgraded based on specific design flaws. Observational studies were generally assigned a low quality but may have been upgraded based on the strength of the association demonstrated and the absence of bias. The outcomes of study assessment are presented using GradePro Guideline Development Tool (https://gdt.gradepro.org/app/). Likewise, the strength of recommendations was categorized into 'strong' and 'conditional' according to the GRADE Handbook (https://gdt.gradepro.org/app/handbook/handbook.html#h.w29yp7vuyzwo):

- A **strong recommendation** is one for which the guidance group is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention).
- A **conditional recommendation** is one for which the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists.

A conditional recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences and values. When there are conditional recommendations, caregivers need to allocate more time to shared decision making, being sure that they explain clearly and comprehensively the potential benefits and harms to a patient.

Working process

The experts were divided into four groups to collate evidence from the literature and draft statements. The details of group members and process are presented in Appendix S2.

Methods used to make recommendations

Standard terminology was used based on the level of evidence whenever possible, namely:

- **must be used** (high level of evidence)
- **should be used** (moderate level of evidence)
- **could be used** (low level of evidence)

Some recommendations were made if and when the group agreed, using appropriate wording for very low levels of evidence (‘**can be considered**’).

Consensus process

The consensus process was conducted by a modified Delphi method: two face-to-face meetings and several virtual meetings. All working group members were asked to comment on draft guidance statements.

The final draft of the guidance was opened for public consultation, inviting representatives from stakeholder groups and other experts. Participants were asked to comment on the statements via the ESCP website, specifically designed for this purpose. Any participant during the public consultation could maintain anonymity but if agreed and with consent all comments were published openly on the ESCP website. Patients' views and experiences of mesh in the pelvis in colorectal surgery were explored by a separate web-based survey.

Consideration of privacy

During public consultation, only the minimal information required was collected. This included name, email address, country of residence and category of submission (healthcare professional, patient, manufacturer, lay person etc.) and was published only with consent to specific disclosure of personal data.

RESULTS

Use of mesh for external full-thickness rectal prolapse

Q1. Is using mesh better than no mesh in preventing the recurrence of rectal prolapse?

Recommendation

- In patients with full-thickness rectal prolapse, mesh could be used for abdominal rectopexy as it may reduce the chance of recurrence [*Conditional recommendation*]. This recommendation is based on a combination of moderate and very low quality evidence.

Rationale for recommendation. The group considers it is good clinical practice to discuss alternative options with the patient given that there was no statistically significant evidence to support the use of mesh and to explain possible benefits and risks/harm associated with both the use and non-use of a mesh. The group encourages all surgeons who perform abdominal mesh rectopexy to be vigilant about the latest information available regarding mesh.

Background

Many surgical procedures have been described to achieve anatomical correction of full-thickness rectal prolapse, varying from abdominal to transperineal and transanal approaches recorded in both the colorectal and gynaecological literature. Suspension, resection (of bowel, uterus or both) and reinforcement procedures (with/without autologous/prosthetic [absorbable/non-absorbable] component) have all been reported.

Since D’Hoore described the ventral mesh rectopexy (VMR) procedure in 2004 [2], it has rapidly become the most frequently performed intervention in Europe and Australia due to the attractive combination of hitching the rectum back into its ‘normal’ anatomical position without the need for resection and the reinforcement of the rectovaginal septum with a mesh (of any sort). VMR can be performed as a minimally invasive procedure and is theoretically ‘nerve

sparing' by mainly using the anterior approach. Both aspects have contributed to its widespread adoption.

Methods

The PubMed and Embase search identified 2779 records. Titles and abstracts were screened permissively to include all possibly relevant studies. One hundred and ten full articles were screened and 49 articles were included.

Outcome

1.1 Recurrence: mesh versus no mesh, randomized controlled trial. There were three RCTs assessing the efficacy of abdominal mesh rectopexy against a controlled intervention [3-5]. The studies by Emile et al. [3] and Lundby et al. [4] used laparoscopic ventral rectopexy with polypropylene mesh as per the technique advocated by D'Hoore. The control group for the study by Emile et al. was Delorme's procedure and that of Lundby et al.'s study was laparoscopic suture rectopexy. The study by Luukkonen et al. [5] compared posterior mesh rectopexy using polyglycolic mesh against a control group intervention of posterior suture rectopexy with sigmoidectomy.

All studies showed a trend of benefit of using mesh with risk of recurrence reduced by 67% (recurrence with mesh 2.6% vs. no mesh 7.8%). However, this was not statistically significant (P = 0.18). Other limitations were noted: the studies were inadequately powered and the intervention for the control group was variable including both perineal and abdominal approaches.

Risk of bias: The risk of bias is deemed not serious. All three studies used sealed envelope methods. Methods of blinding were not clear in two studies (Emile et al. [3] and Luukkonen et al. [5]) but the overall risk of bias is low.

Inconsistency: There was no inconsistency among the included studies.

Indirectness: Downgraded by 1. Intervention in two studies was ventral/anterior mesh rectopexy whilst that of the third study was posterior mesh rectopexy. The control intervention was different in all three studies.

Imprecision: Downgraded by 1 as all the studies were underpowered. With a relative risk reduction (RRR) of 67% from the current analysis, with alpha 0.05 and beta 0.2 and a power of 0.8, n = 285 for each arm is needed for an adequately powered study.

Other considerations: Upgraded by 1. A large effect was noted as risk ratio (RR) = 0.38.

Overall, the quality of evidence was moderate combining the above assessment.

1.2 Recurrence: mesh versus no mesh, comparative studies. There were seven studies that had a control group. However, four studies [6-9] had no recurrence in either the mesh rectopexy group or the control group; hence the effect was not estimable. The pooled data are from the remaining three studies [10-12].

Risk of bias: Downgraded by 1. The risk of bias is serious as all studies were case controlled studies with no blinding and have potential selection bias.

Inconsistency: Downgraded by 2. There is a wide variation in effect (OR 0.17–1.06) with an I^2 statistic of 64% representing substantial heterogeneity.

Indirectness: Downgraded by 1. Three included studies had different interventions as control: one study [10] was a cross-sectional study (mesh technique not specified), the second study was a mesh Orr–Loygue repair against suture rectopexy with sigmoid resection [11], and the third study was an Orr–Loygue repair compared with Delorme's procedure [12].

Imprecision: Downgraded by 1 because the power of all studies was inadequate. With an RRR of 41% from the current analysis (mesh group recurrence 18/360 = 5% vs. no mesh group recurrence 46/547 = 8.4%), with alpha 0.05, beta 0.2 and a power of 0.8, n = 848 for each arm is needed for an adequately powered study. 95% CI (0.13–1.96) overlaps no effect (included an RR of 1).

Other considerations: A large effect was not noted as RR = 0.51.

Overall, the quality of evidence was very low combining the above assessments.

1.3 Recurrence: mesh versus mesh, observational studies. There were 38 studies reporting the outcome of the use of mesh with rectopexy [13-51] and one study reporting the outcome of resection suture rectopexy [45]. It was not possible to estimate the effect from pooled data in GRADE evidence due to lack of a comparator in all studies and one non-mesh study with 0% recurrence.

Risk of bias: Downgraded by 2. The risk of bias is very serious as only one of the studies had a control arm with no blinding.

Inconsistency: Downgraded by 1. The number of participants was variable (8–242) with a recurrence rate of 6% (range 0%–17%), suggesting substantial heterogeneity.

Indirectness: Downgraded by 2. Techniques (D'Hoore, Orr–Loygue, posterior, Ripstein, Wells) and types of mesh used (Adhesix®, HiTEC, Marlex, Mersilene, Nylon, Parietex™, Permacol™, polyester, polypropylene, Prolene, Surgisis®) were variable.

Imprecision: Downgraded by 1 as all of the studies were underpowered.

Overall, the quality of evidence was very low combining the above assessments (Table 1).

Q2. Is one mesh better than others in maintaining rectal prolapse repair?

Recommendation

- Any of the currently available meshes can be considered for rectopexy to prevent recurrence [*Conditional recommendation*]. This is based on limited and low to very low quality of evidence.

TABLE 1 *Recurrence of full-thickness external rectal prolapse: mesh versus no mesh*

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	No mesh	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: mesh versus no mesh, randomized controlled trials												
3	Randomized controlled trials	Not serious	Not serious	Serious[a]	Serious[b]	Strong association	2/78 (2.6%)	6/77 (7.8%)	RR 0.37 (0.09 to 1.52)	49 fewer per 1000 (from 71 fewer to 41 more)	⨁⨁⨁◯ MODERATE	IMPORTANT
Recurrence: mesh versus no mesh, comparative studies												
7	Comparative studies	Serious[c]	Very serious[d]	Serious[e]	serious[f]	All plausible residual confounding would reduce the demonstrated effect	18/360 (5.0%)	46/547 (8.4%)	RR 0.49 (0.11 to 1.91)	43 fewer per 1000 (from 75 fewer to 77 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Recurrence: mesh versus no mesh, observational studies												
38	Observational studies	Very serious[g]	Serious[h]	Very serious[i]	Serious[j]	All plausible residual confounding would reduce the demonstrated effect	146/2438 (6.0%)	0/34 (0.0%)	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	IMPORTANT

Abbreviations: RR, risk ratio; RRR, relative risk reduction.

[a]Downgraded by 1. Control intervention was different in three studies: Delorme's [3], abdominal suture rectopexy [4] and abdominal rectopexy with sigmoid resection [5].

[b]Downgraded by 1 due to the power of all studies being inadequate and the CI included an RR of 1. With RRR of 67% from the current analysis, with alpha 0.05, beta 0.2 and a power of 0.8, $n = 285$ for each arm is needed for an adequately powered study. The CI overlaps no effect (included an RR of 1).

[c]Downgraded by 1. The risk of bias is serious as all studies were case controlled studies with no blinding and have potential selection bias.

[d]Downgraded by 2. There is a wide variation in effect (OR 0.17–1.06) of the three included studies with an I^2 statistic of 64% representing substantial heterogeneity.

[e]Downgraded by 1. The three included studies had either no direct comparator or had different intervention as control: one study [10] was a cross-sectional study (mesh technique not specified), a second study was mesh Orr–Loygue against suture rectopexy with sigmoid resection [11] and a third study was Orr–Loygue compared against Delorme's procedure [12].

[f]Downgraded by 1 due to the power of all studies being inadequate. With relative risk reduction RRR of 41% from the current analysis (mesh group recurrence 18/360 = 5% vs. no mesh group recurrence 46/547 = 8.4%), with alpha 0.05, beta 0.2 and a power of 0.8, $n = 848$ for each arm is needed for an adequately powered study. The 95% CI (0.13–1.96) overlaps no effect (included an RR of 1).

[g]Downgraded by 2. None of the studies had a control arm.

[h]Downgraded by 2. The number of participants was variable (8–242) with recurrence rate 6% (range 0%–17%), suggesting substantial heterogeneity.

[i]Downgraded by 2. Three included studies had no direct comparator. Techniques (D'Hoore, Orr–Loygue, posterior, Ripstein, Wells) and types of mesh used (Adhesix®, HiTEC, Marlex, Mersilene, Nylon, Parietex™, Permacol™, polyester, polypropylene, Prolene, Surgisis®) were also variable.

[j]Downgraded by 1 due to the power of all studies being inadequate.

Rationale for the recommendation. There was one study that compared absorbable and non-absorbable mesh and one study comparing biological and synthetic mesh. Neither study was randomized. Thirty other studies identified were case series. There was no statistically significant difference between the different meshes and due to poor quality it was not possible to pool the data.

Methods

The PubMed and Embase search identified 2779 records. Titles and abstracts were screened permissively to include all possibly relevant studies. One hundred and ten full articles were screened and 32 were included.

Outcome

2.1 Recurrence: absorbable versus non-absorbable mesh, comparative studies. One study directly compared absorbable (polyglycolic acid) and non-absorbable (polypropylene) mesh [52]. In both groups, mesh was fixed posteriorly to the rectum. There was one recurrence among 20 patients in the absorbable mesh group while none of the 17 patients in the non-absorbable mesh group had recurrence. The difference was statistically not significant ($P = 0.59$).

Risk of bias: Downgraded by 1 as the risk of bias is serious. Although patients were randomly allocated to either mesh, neither the method of randomization nor the method of blinding was clear.

Inconsistency: This is not estimable as there was only one study.

Indirectness: There was no concern.

Imprecision: Downgraded by 1 due to significant underpower of the study.

Overall, the quality of evidence was low combining the above assessments.

2.2 Recurrence: biological versus synthetic mesh, comparative studies. There was only one case-matched study that compared non-crosslinked biological mesh (Biodesign®, Cook Medical, Bloomington, Indiana, USA) and non-absorbable (polypropylene) mesh [37]. In both groups, the mesh was fixed posteriorly to the rectum. There was one recurrence among 14 patients (7%) in the biological mesh group while four of the 19 patients (21%) in the non-absorbable mesh group had recurrence. The difference was not statistically significant ($P = 0.29$).

Risk of bias: Downgraded by 1. The risk of bias is serious as the study was case controlled without blinding and had potential selection bias.

Inconsistency: Not applicable.

Indirectness: No concern.

Imprecision: Downgraded by 1 because the power of the study was inadequate. With an RRR of 66% from the current analysis (biological mesh group recurrence 1/14 = 7% vs. non-absorbable mesh group recurrence 4/19 = 21%), with alpha 0.05, beta 0.2 and a power of 0.8, $n = 85$ for each arm is needed for an adequately powered study.

Overall, the quality of evidence was very low combining the above assessment.

2.3 Recurrence: biological versus synthetic mesh, observational studies. There were 30 studies that reported the outcome of the use of mesh with rectopexy [6,7,8,11,12,13,14,15,16,17,18,19,20,22,25,26,27,30,32,33,34,35,36,38,41,43,48,49,50,51]. The pooled recurrence rate in the biological mesh group was 4.5% while that in the synthetic mesh group was 4.6%. However, it was not possible to estimate the effect from pooled data in GRADE evidence due to lack of a comparator in all studies.

Risk of bias: Downgraded by 2. The risk of bias is very serious as none of the studies had a control arm with blinding leading to potential selection bias.

Inconsistency: Downgraded by 1. The number of participants was variable (9–242) with a range of recurrence rates 0%–21%, suggesting substantial heterogeneity.

Indirectness: Downgraded by 2. Techniques (D'Hoore, Orr–Loygue, posterior, Ripstein, Wells) of rectopexy and types of mesh used for both biological (Biodesign® and Permacol™) and synthetic mesh (Adhesix®, HiTEC, Marlex, Mersilene, Nylon, Parietex™, Permacol™, polyester, polypropylene, Prolene, Surgisis®) were variable.

Imprecision: Downgraded by 1 as the studies were underpowered.

Overall, the quality of evidence was very low combining the above assessments (Table 2).

Research gaps

Compared to the number of published observational studies, it is clear that there is a distinct shortage of well-designed RCTs to assess the efficacy of using mesh for rectopexy. There has been no RCT to evaluate whether a specific type of mesh is better than other meshes.

Where to apply mesh (anterior or posterior or both) and the amount of rectal mobilization has changed over time, as has the type of mesh, with the evolution of technologies. Some studies included patients with pathologies other than full-thickness rectal prolapse (e.g., internal intussusception, rectocoele, enterocoele) and it was not always possible to separate the outcome for specific patient groups. Outcome measures used were not consistent, some defined recurrence as full-thickness rectal prolapse, some included mucosal prolapse requiring further surgical intervention and no study separated outcomes for patients operated for recurrence of prolapse after previous surgery. Most observational studies were cross-sectional, which made it difficult to interpret the true recurrence rate in both the short and long term.

The group encourages all surgeons to report outcome according to the IDEAL recommendations [53]. The group feels that this intervention is in the 'assessment stage' rather than exploration stage and would benefit from case matching studies or larger RCTs. None of the observational or randomized trials had patient input. The group feels this is crucial in future trials given recent adverse publicity regarding urogynaecological use of mesh.

TABLE 2 *Recurrence of full-thickness external rectal prolapse: one mesh compared to another mesh*

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	One mesh	Another mesh	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: absorbable versus non-absorbable												
1	Observational study	Serious[a]	Not serious	Not serious	Serious[b]	None	1/20 (5.0%)	–	–	–	⨁◯◯◯ VERY LOW	CRITICAL
Recurrence: biological versus synthetic mesh, comparative studies												
1	Observational study	Serious[c]	Not serious	Not serious	Serious[d]	None	Biological 1/14 (7%)	non-absorbable 4/19(21%)	OR 0.29 (0.03 to 2.92)	– 0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	CRITICAL
Recurrence: biological versus synthetic mesh, observational studies												
30	Observational studies	Very serious[e]	Serious[f]	Very serious[g]	Serious[h]	None	6/133 (4.5%)	69/1506 (4.6%)	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	CRITICAL

Abbreviations: RR, risk ratio; RRR, relativve risk reduction.

[a]Downgraded by 1. Although patients were randomly allocated to either mesh, the methods of randomization and blinding were not clear.

[b]Downgraded by 1 due to significant underpower of the study and CI overlaps no effect (included an RR of 1).

[c]Downgraded by 1. The study was case controlled with no blinding and has potential selection bias.

[d]Downgraded by 1 due to the power of the study being inadequate. With an RRR of 66% from the current analysis (biological mesh group recurrence 1/14 = 7% vs. non-absorbable mesh group recurrence 4/19 = 21%), with alpha 0.05, beta 0.2 and a power of 0.8, $n = 85$ for each arm is needed for an adequately powered study. The 95% CI (0.03–2.92) overlaps no effect (included an OR of 1).

[e]Downgraded by 2. The risk of bias is very serious as none of the studies had a control arm with no blinding and the studies have potential selection bias.

[f]Downgraded by 1. The number of participants was variable (9–242) with recurrence rate range 0%–21%, suggesting substantial heterogeneity.

[g]Downgraded by 2. Techniques (D'Hoore, Orr–Loygue, posterior, Ripstein, Wells) of rectopexy and types of mesh used for both biological (Biodesign® and Permacol™) and synthetic mesh (Adhesix®, HiTEC, Marlex, Mersilene, Nylon, Parietex™, Permacol™, polyester, polypropylene, Prolene, Surgisis®) were also variable.

[h]Downgraded by 1 due to the power of all studies being inadequate.

Use of mesh rectopexy for posterior pelvic floor disorders other than full-thickness external prolapse, including internal rectal prolapse, rectocoele, enterocoele and SRUS

Q3. Is mesh rectopexy effective for ODS/FI symptoms with internal prolapse/intussusception, anterior/posterior rectocoele, enterocoele or SRUS?

Recommendations

- Mesh rectopexy can be considered for posterior pelvic floor disorders including internal rectal prolapse, rectocoele, enterocoele and SRUS [*Conditional recommendation*]. This recommendation is based on very low quality of evidence.
- It is recommended that patients are considered for this surgery only when their symptoms have a strong negative impact on their daily quality of life and they have exhausted maximal conservative management. [*Conditional recommendation*]

Rationale for the recommendation. The use of different evaluation tools, differences in definition of improvement and variable timing of outcome measurement made it impossible to estimate the effect by pooling data (very low quality evidence). No long-term cohort outcomes are currently available.

The group recognizes that the most important safety concern is long-term complications, such as major component mesh infection/erosion and pelvic pain. The panel emphasizes that currently available outcome data are at best those of mid-term results, reported in observational studies without control groups or active follow-up strategies; thus the long-term cumulative rate of complications may be higher.

Background

This section focuses on the use of rectopexy for all the conditions other than external full-thickness prolapse, such as high grade full-thickness internal intussusception (Oxford Grade III/IV), (complex) rectocoele, enterocoele, SRUS or a combination of these.

Indications for surgery of these anatomical conditions are less well defined as reported symptomatic indications are variable including FI, ODS and/or pelvic heaviness/pain. The group emphasizes that surgical correction of anatomical abnormalities does not automatically lead to resolution or amelioration of symptoms.

The indicative symptoms may be classified as 'benign' or 'functional'; therefore the group is aware that all interventions should be based on the principle of 'do no harm'. However, the group also acknowledges that symptoms can be extremely socially debilitating, often with significant impact on daily life, and can lead to substantive personal societal and financial loss.

The treatment of any pelvic floor condition should start with conservative measures such as advice on diet and toileting behaviour and may be combined with physiotherapy, medication, irrigation and psychological support. A detailed evaluation of this, however, is outside the remit of this guidance.

Methods

A systematic literature search of PubMed and Embase identified 2779 records. Studies were included in this part of the analysis when they reported specifically on the results of laparoscopic VMR (LVMR) and/or robotic VMR (RVMR) for conditions other than external full-thickness rectal prolapse (ERP). Publications containing mixed study populations (ERP and 'non-ERP' indications) were used only if results were reported with clear distinction between these entities. Conditions studied consisted of internal full-thickness intussusception (Oxford Grade III and IV), (complex) rectocoele, enterocoele and posterior compartment prolapse. Due to the close anatomical overlap between these entities, the lack of uniform diagnostic criteria and definitions, and the lack of specification in the individual studies, results for these three subgroups are compiled under the term non-ERP (non-external rectal prolapse).

Outcome

There were no RCTs and very limited comparative data reporting specifically on the functional outcome of LVMR for non-ERP.

3.1 Improvement of symptoms

3.1.1 Improvement of ODS and constipation, observational studies

Seventeen studies reported on change in constipation and/or ODS with laparoscopic rectopexy for non-external rectal prolapse [13,16,34,54,55,56,57,58,59,60,61,62,63,64,65,66,67].

There are limitations in interpreting the data. The paper by Consten et al. [16] did not use any validated score and reported the number with new onset constipation and the change of proportion of patients with presence of outlet obstruction as an outcome which may or may not coexist with constipation. The paper bundled ERP and non-ERP patients—hence outcome specifically for non-ERP patients could not be extrapolated. Reporting the results of a mixture of ERP and non-ERP patients was also seen in the papers by Albayati et al. [13], Formijne Jonkers et al. [55], Mantoo et al. [62], McLean et al. [34] and Owais et al. [59]. Assessing from the inclusion period of the cases, there is a concern that the paper by Formijne Jonkers et al. [55] is likely to be completely overlapping with data presented in the paper by Consten et al. [16]. Another two papers by the same author (Gosselink et al. [57,58]) are likely also to be overlapping, as one paper's inclusion period is August 2009 to July 2011 [57] whilst the other paper's inclusion period is June 2010 to October 2012 for the same indication (LVMR for FI) [58]. The inclusion period and indication of rectopexy also overlapped in two papers by the same group of authors (Franceschilli et al. [56] and Sileri et al. [64]); hence only the latest paper [56] was included. A paper by Wahed et al. [65] was excluded as the dataset was completely overlapping with the latest publication by the same group of authors [34]. Wong published two papers on an overlapping group of patients: one paper [66] compared the outcome of RVMR versus LVMR for complex rectocoele (63 patients) between March 2008 and December 2009, and the second paper was on the outcome of laparoscopic mesh rectopexy for complex rectocoele (84 patients) between January 2004 and December 2008 [67]. As the former paper focused on operative

and technical aspects with no functional outcome, only the latter was included.

As a result, only eight out of 17 studies that reported on constipation and ODS specifically for non-ERP patients [54,56,57,58,60,61,63,67] were included, bearing in mind that four of these papers may contain overlapping data.

Five papers used the Wexner or Cleveland Clinic Constipation score as an assessment tool while Borie et al. [61], Portier et al. [63] and Wong et al. [67] used other scores or simply symptom descriptions.

The paper by Collinson et al. [54] included 75 patients with internal rectal prolapse, whose median score improved from 12 preoperative to 4 postoperative at 3 months which was maintained at 5 at 12 months. Franceschilli et al. [56] included 100 patients with internal rectal prolapse whose Wexner constipation score was 5 or above in their series. Their definition of improvement was at least 25% reduction in score and cure was defined as a score lower than 5. The score improved from 18.4 ± 11.6 SD to 5.4 ± 4.1 SD at the end of follow-up which was at a median of 20 months (range 6–54 months). Two studies by the same group of authors [57,58] have overlapping inclusion periods of LVMR for FI: the paper published in 2013 [57] reported a reduction of Wexner constipation score from a median of 13 to 8 at 1 year, whilst the paper published in 2015 [58] included 43 patients with high grade internal prolapse and their median preoperative score was 10.3 (0–23) which improved to 7.2 (0–21).

Tsunoda et al. [60] reported the proportion of patients with >50% reduction in their score (nine patients, 41%) and overall score change reported in median and range.

Borie et al. [61] reported on functional outcome of LVMR for rectoanal intussusception and rectocoele, compared with a stapled transanal rectal resection (STARR) using Altomare's ODS score. The selection of STARR or rectopexy was not randomized and was based on whether the external sphincter was intact (for STARR) or not (rectopexy). Mean ODS score improved in both groups (16–7.6 in the LVMR group and 15–6 in the STARR group).

The paper by Portier et al. [63] was a selective report about 40 of 139 patients who underwent rectopexy who had faecal incontinence and intra-anal rectal prolapse.. The authors did not specify the assessment score used for constipation other than 'symptoms of constipation' and reported two patients with new onset constipation, but 13 of 20 patients with preoperative constipation were cured.

Wong et al. [67] reported improvement of ODS (preoperative 83%, postoperative 46%) and vaginal discomfort (86%, postoperative 20%). They reported the proportion of patients with subjective symptoms but no objective scores were used.

Due to these differences in the definition of improvement, and mostly reported in median and range, the scores could not be pooled.

Risk of bias: Downgraded by 1. The risk of bias is serious as all studies were cross-sectional studies with no blinding and have potential selection bias.

Inconsistency: Downgraded by 1. There was no inconsistency in terms of outcome as all studies showed reduction of score or improvement of ODS and/or constipation symptoms. However, follow-up assessments were done at various different timings.

Indirectness: Downgraded by 1 as there was no control treatment.

Imprecision: Downgraded by 1. All studies were small case series with mesh rectopexy only.

Overall, the quality of evidence was very low when combining the above assessments.

3.1.2 Improvement in FI, observational studies

Twenty studies reported information regarding FI [13,16,33,34,54,55,56,57,58,59,60,61,62,63,64,65,67,68,69,70].

In total, 12 studies were excluded. As stated in outcome 3.1.1, some studies did not report outcome separately for non-ERP patients [13,16,34,55,59,62,69]. A paper by Wahed et al. [65] was excluded as the dataset completely overlapped with the latest publication by the same group [34] which was excluded as above. The inclusion period and indication of rectopexy was also overlapping in two papers by the same group of authors (Franceschilli et al. [56] and Sileri et al. [64]); hence only the latest paper [56] was included.

The study by Borie et al. [61] reported on the incidence only of FI postoperatively. In contrast, a study by Powar et al. [70] reported the number of patients with FI preoperatively but did not report FI as one of the outcomes of their study. An RCT by a Finnish group mentioned preoperative FI in two patients randomized to RVMR and one patient in LVMR [33].

There were six studies that used the Fecal Incontinence Severity Index (FISI) as an outcome assessment [54,56,57,58,60,68]. Collinson et al. [54] studied 75 patients with internal rectal prolapse of whom 59 (79%) complained of FI preoperatively: 49 with mixed FI/ODS and 10 pure FI. Fifty patients had either cure or improvement of FI, and the FISI mirrored this with a median preoperative score of 28 improved to 8 at 3 months. This was maintained at 12 months.

A study by Evans et al. 68 looked into a cohort of patients with SRUS and reported improvement of FI as a secondary outcome. However, patients also had concurrent internal rectal prolapse (n = 20), external rectal prolapse (n = 14) or anismus (n = 2). The interventions also were variable: 29 patients had VMR and one a STARR procedure. Of 30 patients who underwent an operation, an improvement of FISI was reported from a median of 24 (0–53) to 2 (0–53).

Franceschilli et al. [56] included 100 patients with internal rectal prolapse. Their definition of improvement was an at least 25% reduction in score and cure was defined as a score lower than 10. The score improved from 8.4 ± 4 SD to 3.3 ± 2.3 SD at the end of follow-up which was at a median of 20 months (range 6–54 months). It is worth noting that, according to their definition, fewer than 50% of patients (n = 43) suffered from FI with an FISI ≥10 preoperatively.

Two studies by the same group of authors (Gosselink et al. [57,58]) have overlapping inclusion periods of LVMR for FI. The paper published in 2013 [57] reported on 74 patients who underwent LVMR for FI: 40 patients had ≥50% reduction of FISI score whilst 32 patients had no reduction of FISI score ≥50%. The median FISI score reduced from 31 to 15 1 year after VMR and 21 (29%) patients were reported to be completely continent 1 year after surgery. The

paper published in 2015 [58] included 43 patients with high grade internal prolapse diagnosed by proctogram and seven patients diagnosed by examination under anaesthesia. Their median preoperative FISI score was 42 (30–61), which improved to 25 (0–56) at 1 year ($P < 0.01$) with 11 (22%) patients being completely continent.

Of 26 patients in the study by Tsunoda et al. [60], 21 had FI before surgery and an improvement score of at least 50% was seen in 14 patients at 6 months after surgery.

One study used the Cleveland Clinic (or Wexner) Incontinence Score. Portier et al. [63] reported the outcome of 139 consecutive patients with VMR between 2002 and 2008. 53 (38%) were for intra-anal rectal prolapse and, of these, 40 (29%) had FI. The mean Cleveland Clinic Incontinence Score was 13.3 (SE 4.25) preoperatively, which improved to 3 (SE 3.44) postoperatively ($P = 0.001$) at a mean follow-up of 22 months (SE 21). Twenty-seven patients complained of urgency preoperatively which improved to eight postoperatively. Twenty-six patients felt their FI was cured.

A study by Wong et al. [67] performed VMR for rectocoele. They did not use a validated score but used questionnaires and a visual analogue scale. Twenty patients had symptoms of FI preoperatively and 16 patients suffered from persistent FI postoperatively ($P > 0.05$).

Due to these differences in definition of improvement, and mostly reported as median and range, the group felt the reported scores could not be pooled.

Risk of bias: Downgraded by 1. The risk of bias is serious, as all studies were case series with a small number of patients.

Inconsistency: Downgraded by 1. Studies have a mixture of patients with high intrarectal, intra-anal prolapse and SRUS and it was not clear how these variable mechanical abnormalities contributed to symptoms of FI. In some studies, it was not clear whether FI score was only assessed for those with preoperative symptoms of FI or assessed for all (which is a possibility given that the range included 0).

Indirectness: Downgraded by 1. Although six studies used FISI, the scores were evaluated at various different follow-up points and could not be separately extrapolated and combined for either short-term or long-term outcomes.

Imprecision: Downgraded by 1 due to a relatively small number of patients and variations in definition of improvement.

Overall, the quality of evidence was very low combining the above assessments (Table 3).

3.2 New onset or worsening symptoms of constipation/ODS, FI or dyspareunia

Overall, published data were not sufficiently explicit to identify new onset symptoms of constipation/ODS and FI nor to distinguish patients with these symptoms from patients with persistent and recurrent symptoms. There were few data on dyspareunia/sexual dysfunction.

As in the previous section, several studies did not report outcomes separately for non-ERP patients and such studies were excluded [13,16,34,55,59,62,69]. The paper by Wahed et al. [65] was excluded as the dataset overlapped with the latest publication by the same group [34] which had been excluded as above. The inclusion period and indication for rectopexy also overlapped in two papers by the same group of authors (Franceschilli et al. [56] and Sileri et al. [64]); hence only the latest paper [56] was included.

3.2.1 New onset or worsening of constipation and ODS

There were three studies reporting worsening of constipation and ODS. Tsunoda et al. [60] assessed patients with evacuation proctography post LVMR for rectoanal intussusception. Of 26 patients included in the study, two experienced worsening of ODS and one developed de novo constipation [60]. Other studies have reported similar occurrence of worsening symptoms of ODS [33] or new onset of constipation [63].

Four studies reported no new onset of constipation [54,56,58,67].

3.2.2 New onset or worsening of FI

Two studies reported on persistent FI but details were not available as to whether symptoms had deteriorated. One study reported that 12 (24%) patients with high rectal internal prolapse had persistent FI at 1-year follow-up. The second study reported four out of 21 with persistent FI [58,60].

Four studies reported no new onset of FI [54,56,67,68].

3.2.3 New onset or worsening symptoms of dyspareunia/sexual dysfunction

One paper specifically stated that there was no patient either male or female with sexual dysfunction following LVMR [54]. However, most studies did not report on this outcome as either a primary or a secondary end-point.

3.3 Recurrence

Recurrence is one of the outcomes considered an important end-point in treatment for rectal prolapse. However, there appears to be significant under-reporting of this end-point when it comes to the literature on rectopexy for non-ERP. This may be primarily because the definition of recurrence is unclear. Often no clear distinction is made between anatomical or radiological recurrence compared to recurrence of symptoms.

Recurrence of symptoms seems not uncommon after VMR for non-ERP. There are few data that relate persistence or early anatomical/radiological recurrence with non-resolution of symptoms. It seems unlikely that radiological follow-up offers any benefit in asymptomatic patients but could provide valuable information in patients with recurrent or persistent symptoms.

A study by Collinson et al. [54] reported four (5%) patients who had recurrence of internal rectal prolapse on proctography, two of whom benefitted from reattachment of mesh. Another study reported recurrence on postoperative proctography: Gosselink et al. reported that three of 43 patients with high grade internal rectal prolapse had persistent internal rectal prolapse on postoperative proctography and experienced recurrent or persistent symptoms [58].

Two studies each reported a single recurrence without further details [33,63]. No long-term follow-up data were available.

Risk of bias: Downgraded by 1. The risk of bias is serious, the studies having a small number of included patients.

TABLE 3 Is mesh rectopexy effective for obstructive defaecation/faecal incontinence symptoms with internal prolapse/intussusception, anterior/posterior rectocoele, enterocoele or solitary rectal ulcer syndrome? Improvement of symptoms

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Rectopexy	(Comparison)	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Improvement in symptoms of obstructive defaecation and constipation												
8	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[d]	None			Not estimable		⨁◯◯◯ VERY LOW	IMPORTANT
Improvement of symptoms of faecal incontinence												
8	Observational studies	Serious[e]	Serious[f]	Serious[g]	Serious[h]	None	The use of different evaluation tools, differences in definition of improvement and variable timing of outcome measurement made it inappropriate to pool data				⨁◯◯◯ VERY LOW	IMPORTANT

[a]Cross-sectional studies, no blinding, overlapping inclusion periods of some of the studies by the same group of authors, selective reporting in at least one study.

[b]Definition of effectiveness and timing of assessment were variable.

[c]No comparator to mesh rectopexy (e.g., no mesh or suture rectopexy).

[d]All studies were small case series with mesh rectopexy only.

[e]Cross-sectional observational studies only. The number of included patients was small.

[f]Patients with mixed pathologies (intrarectal/intra-anal prolapse and solitary rectal ulcer) and relationship between these pathologies and symptom severity was unclear from presented data. Symptom score may have included those without symptoms.

[g]Objective scores were evaluated at various different follow-up points and could not be separately extrapolated and combined for either short-term or long-term outcome.

[h]Relatively small number of patients in each study and variations in definition of improvement.

Inconsistency: Downgraded by 1. Due to variability of the definition of recurrence and follow-up, the risk of bias is serious.

Indirectness: Downgraded by 1. Outcome measure was unclear (anatomical/radiological/symptoms).

Imprecision: Downgraded by 1 due to the relatively small number of patients and variation in the definition of improvement.

Overall, the quality of evidence was very low combining the above assessments.

3.4 Is mesh rectopexy effective for solitary rectal ulcer syndrome (SRUS)?

Six studies reported the healing rate of SRUS [68,69,71,72,73,74]. Two of these papers [69,71] were from the same centre with overlapping inclusion periods; hence only the most recent paper [71] was included.

Badrek-Al Amoudi et al. [71] reported the outcome of 48 patients with SRUS and is the largest published series of LVMR for SRUS. Although all rectal ulcers were reported to have healed within 3 months, interpretation of the data is difficult, as the study includes patients with follow-up varying between 1 month and 186 months, with different outcome measures included such as quality of life and ODS. The relationship of these symptoms to ulcer healing is unclear.

Evans et al. [68] reported on 30 patients with SRUS who underwent LVMR. Of these, 21 healed and nine had non-resolution and required further interventions (six posterior STARR).

Kargar et al. [72] used posterior mesh rectopexy in 39 patients with SRUS who had not responded to conservative treatment. Symptoms were 'controlled' but no information was given regarding the timing of follow-up and the definition of 'controlled' symptoms.

Marchal et al. [73] reported outcomes of various interventions (excision, stoma, Delorme's) for SRUS. Of 13 patients, three had an Orr–Loygue rectopexy, two had no recurrence at 42 and 112 months while one had recurrence at 6 months and underwent a Delorme's procedure.

Tweedie et al. [74] reported a case series of patients who underwent LVMR for SRUS. The rectal ulcer healed in all 11 patients, and in seven patients followed up at a median of 89 months none had recurrence.

Due to the small number of samples, uncertainties of outcome measure and variable timing of follow-up, the results could not be pooled.

Risk of bias: Downgraded by 1. The risk of bias is serious, as studies having small numbers were included, retrospective in nature, and there were no controls.

Inconsistency: Downgraded by 1. There was high heterogeneity among the included studies. Three of the five studies used VMR (D'Hoore technique), one used ventral mesh (Orr–Loygue technique) and one study a posterior mesh. The timings of follow-up were variable with no consistent outcome measures.

Indirectness: Downgraded by 1. One study had three interventions (stoma, Delorme's and Orr–Loygue) and the selection to each intervention was unclear. One study used surrogate outcome measures.

Imprecision: Downgraded by 1. The sample sizes in all studies were small and the total number of participants in the five studies was less than that required for a single adequately powered trial.

Overall, the quality of evidence was very low combining the above assessments (Table 4).

Research gaps

The pelvic floor community has not established uniform definitions of outcome. There are no exact measurements and/or consensus of normal (variants of) anatomy, nor clear and unambiguous terminology to describe abnormalities. Complex rectocoele, anterior rectal intussusception and posterior compartment syndrome are terms that are frequently used and possibly interchangeable but might mean different things in different centres and countries. This section was hindered by the lack of a clear distinction in several large studies between internal and external prolapse. The diagnostic criteria, clinical, patient reported or radiological findings (ultrasound/dynamic proctogram/magnetic resonance imaging) were poorly defined.

Whether there is a direct link between anatomical abnormalities and symptoms is complex as there are many other factors that influence and modify symptoms such as diet, stool consistency, physical activity, patients' coping mechanisms and personal perspectives. Severity of symptoms and impact on quality of life is highly subjective and influenced by many factors including psychological wellbeing, individual resilience and personal expectations and outlook on life and health.

A few questionnaires have been developed in an attempt to try and capture this delicate interplay between actual physical symptoms and (bowel-specific) quality of life (PAC-QOL, FiQol, ICIQ-B). Unfortunately, these questionnaires are prone to bias, have a high variability, are often cumbersome, and more importantly are not universally accepted for use in routine practice. There is a need for a patient centred, internationally accepted uniform symptom severity and impact on quality of life questionnaire.

VMR can sometimes be a technically challenging procedure, especially in obese patients or in the case of previous pelvic/abdominal surgery. Although the general technique for VMR has been outlined by Andre D'Hoore in his landmark paper, variations do exist, such as the extent and depth of dissection in the rectovaginal septum, the number and position of sutures used to secure the mesh and the tension generated by the mesh. (Note that the influence of (types of) mesh will be discussed in other sections.) The group recognizes that the majority of publications are coming from expert and high-volume pelvic floor centres. The learning curve for this procedure is estimated to be 25–54 cases [75,76].

Such variations in techniques and technical proficiency may lead to differences in functional outcome and/or recurrence. The group therefore recommends that VMR should only be undertaken by adequately trained colorectal surgeons with a specialist interest in pelvic floor disorders in a department with regular multidisciplinary team meetings. It is also strongly recommended

TABLE 4 Is mesh rectopexy effective for obstructive defaecation symptoms other than full-thickness rectal prolapse (e.g., 'internal prolapse/intussusception', anterior/posterior rectocoele, enterocoele, solitary rectal ulcer syndrome)? Improvement of solitary rectal ulcer syndrome

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Rectopexy	(Comparison)	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Healing of SRUS												
5	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[d]	None		Not pooled	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	IMPORTANT

[a]The included studies were not randomized and did not have control groups.

[b]Three of the five studies used ventral mesh and the D'Hoore technique, one study used ventral mesh and the Orr–Loygue technique and one study used posterior mesh. Timings of follow-up were variable with no consistent outcome measure.

[c]One study had three interventions (stoma, Delorme's and Orr–Loygue) and the selection to each intervention was unclear. One study used a surrogate outcome measure.

[d]The sample size of all studies was small and the total number of participants in the five studies is less than the number of participants required for a single adequately powered trial.

that individual surgeons participate in continuous audit of adverse events and functional outcomes. Extensive patient information including reiteration of all non-invasive treatment options and the possibility of long-term mesh complications, pain and onset of new symptoms should be used to enhance patient–clinician shared decision making.

The panel acknowledges that this guidance is based almost exclusively on retrospective or observational cohort studies, without control groups and with relatively short follow-up, thereby providing GRADE evidence of very low quality. There is an absolute need for RCTs, although the panel also recognizes that a randomized controlled comparison of VMR versus conservative management will have many problems of its own.

Use of mesh for external full-thickness rectal prolapse and ODS: complications and risks

Q4. Does the use of mesh increase the risk of adverse events?

Recommendations

- Patients should be informed and adequately counselled regarding potential harm. [*Conditional recommendation*]
- Patients should be informed that the use of mesh for rectopexy could cause de novo constipation or worsen existing constipation. [*Conditional recommendation*]

These recommendations are based on moderate to very low quality of evidence.

Rationale for the recommendation

- Three RCTs that compared mesh rectopexy against controlled intervention reported the complication rate to be 11.5%. It was also noted that, despite more than 40 case series reporting on the outcome of mesh rectopexy, only seven comparative studies were available for analysing complications. Nearly 70% of the included evidence comes from posterior mesh rectopexy techniques, which are not the most commonly reported technique in recent years, and this makes it difficult to translate it to the complication rate of anterior/VMR.
- There was only one randomized study which showed the occurrence of de novo constipation or exacerbation of constipation with mesh rectopexy in a third of patients compared with the control group (resection rectopexy); this approached statistical significance ($P = 0.07$). Due to lack of a comparator and poor quality of data, it was not possible to perform a robust effect analysis using pooled data from observational studies.
- Although the use of mesh does not appear to increase the risk of complications, the rate of complications is higher than previously reported from case series (just over 1 in 10).

Methods

The PubMed and Embase search identified 2779 records. Titles and abstracts were screened permissively to include all possibly relevant studies. One hundred and ten full-text articles were screened and 58 were included.

Outcome

4.1 Overall complications: mesh versus no mesh, randomized controlled studies

Three RCTs reported the incidence of all complications that occurred [3,5,77]. The incidence of complications was similar in both mesh rectopexy and the control intervention: 11.5% (9/78) in the mesh rectopexy group versus 13.0% (10/77) in the control group.

Risk of bias: The risk of bias is deemed not serious. All three studies used sealed envelope methods. Methods of blinding were not clear in two studies [3,5] but the overall risk of bias is probably low.

Inconsistency: There was no inconsistency among the included studies.

Indirectness: Downgraded by 1. The control intervention was different in all three studies.

Imprecision: Downgraded by 2 because the power of all studies was inadequate.

Overall, the quality of evidence was low combining the above assessments.

4.2 Overall complications: mesh versus no mesh, comparative studies

There were seven studies that reported complications with the use of mesh rectopexy against rectopexy without mesh [6,7,8,9,11,12,78]. Five studies compared mesh rectopexy against suture rectopexy (two with additional sigmoid resection), and two studies compared mesh rectopexy against Delorme's procedure. Only one study [7] used an anterior mesh rectopexy, giving 31.1% weight in the total effect analysis. The rest were posterior in two, Orr–Loygue (two), Ripstein technique (one) and in one study the technique was not clear [78].

This makes the interpretation of evidence difficult as different approaches and place of mesh application have potential impact on surgical complications.

Risk of bias: Downgraded by 1. The risk of bias is serious as all studies were case controlled studies with no blinding and have potential selection bias.

Inconsistency: Downgraded by 2. There is a wide variation in effect (OR 0.16–2.60) with an I^2 statistic of 61% representing substantial heterogeneity.

Indirectness: Downgraded by 1 due to different mesh techniques and comparators.

Imprecision: Downgraded by 2 because the power of all studies was inadequate. The 95% CI (0.76–1.94) overlaps no effect (included an OR of 1).

Overall, the quality of evidence was very low combining the above assessments.

4.3 Major and minor complications: mesh versus no mesh, randomized controlled studies

There was only one RCT that specifically reported on major and minor complications separately [3]. The incidence of major complications in both mesh rectopexy and the control group was 0%; thus the effect was not estimable.

Minor complications occurred in five (20%) of 25 patients in the mesh rectopexy group while three (12%) of 25 patients had minor complications in the control group.

Risk of bias: The risk of bias is deemed not serious. The study used the sealed envelope method, and although the method of blinding was not clear the risk of bias is probably low.

Inconsistency: Not applicable as there was only one study.

Indirectness: Downgraded by 1. The control intervention was a perineal approach. Patient selection for abdominal and perineal approaches may be different; these two approaches have different types of complications, so this study may not provide a direct answer to the clinical question.

Imprecision: Downgraded by 2 due to the study being underpowered. CI overlaps no effect (included an OR of 1).

Overall, the quality of evidence was low combining the above assessments.

4.4 Major and minor complications: mesh versus no mesh, comparative studies

There was only one comparative study that reported on major and minor complications separately, with the use of mesh rectopexy against controls [7]. Major complications occurred in two (5%) of 40 patients in the mesh group (both myocardial ischaemia, Clavien–Dindo Grade IV) while one (3.6%) of 28 patients in the control group had an intra-abdominal collection that required interventional radiological drainage (Clavien–Dindo Grade IIIa).

There was a significant difference between ventral rectopexy and resection rectopexy: minor complications were reported in two (5%) of 40 patients in the ventral rectopexy group versus eight (28.6%) of 28 in the resection rectopexy group.

Risk of bias: Downgraded by 1. The risk of bias is serious as the data were amalgamated from two centres, each of which exclusively performed one procedure.

Inconsistency: Not applicable as there was only one study.

Indirectness: Downgraded by 1 due to different techniques being used.

Imprecision: Downgraded by 1 due to the power of the study being inadequate. For minor complications, downgraded by 1 due to inadequate power of the study only.

Overall, the quality of evidence was very low combining the above assessments.

4.5 Mortality: mesh versus no mesh, randomized controlled studies

Three RCTs reported on the incidence of mortality [4,5,79]. Mortality was 0% in the mesh rectopexy group (LVMR and mesh resection rectopexy) while there was one death in the control group (Delorme's, suture rectopexy or resection rectopexy) (1.3%).

Risk of bias: The risk of bias is deemed not serious. All three studies used sealed envelope methods. Methods of blinding were not clear in two studies [5,79] but the overall risk of bias was probably low.

Inconsistency: Heterogeneity was not calculable.

Indirectness: Downgraded by 1. The control intervention was different in all three studies.

Imprecision: Downgraded by 1 as all the studies were underpowered.

Overall, the quality of evidence was low combining the above assessments.

4.6 Mortality: mesh versus no mesh, comparative studies

There were three studies that included data on mortality explicitly with the use of mesh rectopexy (posterior mesh rectopexy, Orr–Loygue) compared with controls without mesh (resection/suture rectopexy, Delorme's) [6,8,12].

Risk of bias: Downgraded by 1. The risk of bias is serious as all studies were case controlled studies with no blinding and have potential selection bias.

Inconsistency: It was not possible to assess the extent of heterogeneity.

Indirectness: Downgraded by 1 due to different mesh techniques and comparator.

Imprecision: Downgraded by 1 as all the studies were underpowered.

Overall, the quality of evidence was very low combining the above assessments.

4.7 De novo or worsening constipation, randomized controlled trial

There was only one study [5] that compared abdominal rectopexy with sigmoid resection (group 1) with abdominal rectopexy using polyglycolic acid mesh without sigmoid resection (group 2). In group 1, no patient developed new onset or an exacerbation of constipation while five of 15 patients in group 2 developed new onset constipation. The difference was not statistically significant ($P = 0.07$).

Risk of bias: The risk of bias is not serious. The study used sealed envelope methods. Although the method of blinding was not clear, the overall risk of bias is probably low.

Inconsistency: This is not estimable as there was only one study.

Indirectness: There was no concern.

Imprecision: Downgraded by 1 as the study was significantly underpowered.

Overall, the quality of evidence was moderate combining the above assessments.

4.8 De novo or worsening constipation, observational studies

There were 16 observational studies that reported de novo or worsening constipation [6,7,8,11,12,18,19,22,25,32,34,38,41,42,49,51].

The pooled occurrence rate of de novo or worsening constipation in the mesh rectopexy group was 14.7% (96 of 653) while that of rectopexy without mesh was 7.1% (7 of 99). However, only four studies [6,7,11,12] had a comparative group to estimate the true effect.

The limitations of interpreting this outcome for non-full-thickness external prolapse are discussed in Q3.

Risk of bias: Downgraded by 2. The risk of bias is very serious as no study was randomized and without blinding there is potential selection bias.

Inconsistency: Downgraded by 2. Odd ratios ranged from 0.69 to 4.8 with no significant overlap of CI, suggesting substantial heterogeneity.

Indirectness: Downgraded by 2. Techniques (D'Hoore, Orr–Loygue, posterior, Wells) in the investigation arm for rectopexy and in the control group (suture rectopexy, posterior, suture rectopexy with resection, Delorme's) were variable, which makes it difficult to generalize the findings.

Imprecision: Downgraded by 1 as all the studies were inadequately powered.

Overall, the quality of evidence was very low combining the above assessments (Tables 5 and 6).

Q5. Do specific types of mesh increase the risk of adverse events?

Recommendation

- Either biological or synthetic mesh could be considered [*Conditional recommendation*]. This is based on low or very low quality evidence.

Rationale for recommendation

- There are limited data to suggest that biological mesh may be superior in preventing mesh-related complications.
- More overall complications were seen with the use of biological mesh (28%) compared with synthetic mesh (14%). Mesh-specific complications occurred less frequently with the use of biological mesh (5/615, 0.08%) compared with synthetic mesh (47/1913, 2.46%). However, the difference was not statistically significant.
- The follow-up periods were generally short. Surgeons need to be aware of emerging evidence relating to long-term outcomes following mesh implantation. The group feels that it is good practice for surgeons to audit their own outcomes to understand the true long-term complication rate.

TABLE 5 Does the use of mesh increase the risk of adverse events?

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	No mesh	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Overall complications: randomized controlled studies												
3	Randomized trials	Not serious	Not serious	Serious[a]	Very serious[b]	None	9/78 (11.5%)	10/77 (13.0%)	OR 0.88 (0.33–2.31)	14 fewer per 1000 (from 83 fewer to 127 more)	⨁⨁◯◯ LOW	IMPORTANT
Overall complications: comparative studies												
7	Observational studies	Serious[c]	Very serious[d]	Serious[e]	Very serious[f]	None	42/231 (18.2%)	0.0%	OR 1.21 (0.76–1.94)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	IMPORTANT
Major complications: observational studies												
1	Observational studies	Serious[g]	Not serious	Serious[h]	Serious[i]	None	2/40 (5.0%)	1/28 (3.6%)	OR 1.42 (0.12–16.48)	14 more per 1000 (from 31 fewer to 343 more)	⨁◯◯◯ VERY LOW	IMPORTANT
								0.0%		0 fewer per 1000 (from 0 fewer to 0 fewer)		
Minor complications: randomized controlled study												
1	Randomized trials	Not serious	Not serious	Serious[j]	Very serious[k]	None	5/25 (20.0%)	3/25 (12.0%)	OR 1.83 (0.39–8.67)	80 more per 1000 (from 70 fewer to 422 more)	⨁⨁◯◯ LOW	IMPORTANT
Minor complications: observational studies												
1	Observational studies	Serious[g]	Not serious	Serious[h]	Serious[l]	None	2/40 (5.0%)	8/28 (28.6%)	OR 0.13 (0.03–0.68)	236 fewer per 1000 (from 72 fewer to 274 fewer)	⨁◯◯◯ VERY LOW	IMPORTANT
Mortality: randomized controlled studies												
3	Randomized trials	Not serious	Not serious	Serious[a]	Serious[b]	None	0/78 (0.0%)	1/77 (1.3%)	OR 0.31 (0.01–8.28)	9 fewer per 1000 (from 13 fewer to 85 more)	⨁⨁◯◯ LOW	IMPORTANT

(Continues)

TABLE 5 (Continued)

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	No mesh	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Mortality: observational studies												
3	Observational studies	Serious[c]	Not serious	Serious[e]	Serious[i]	None	0/80 (0.0%)	0.0%	OR 0.17 (0.01–3.29)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	IMPORTANT

[a]Downgraded by 1. The control intervention was different in all three studies, including both perineal and abdominal intervention.

[b]Downgraded by 1 due to the power of all studies being inadequate. The CI overlaps no effect (included an OR of 1).

[c]Downgraded by 1. The risk of bias is serious as all studies were case controlled studies with no blinding and have potential selection bias.

[d]Downgraded by 1. There is a wide variation in effect (OR 0.16–2.60) with an I^2 statistic of 61% representing substantial heterogeneity.

[e]Downgraded by 1 due to different mesh techniques and comparator.

[f]Downgraded by 1 due to the power of all studies being inadequate. The 95% CI (0.76–1.94) overlaps no effect (included an OR of 1).

[g]Downgraded by 1. The risk of bias is serious as the study did not randomize patients and there was data amalgamation of two centres with each centre exclusively performing one procedure. As such, there was no blinding and potential selection bias.

[h]Downgraded by 1 due to different techniques being used.

[i]Downgraded by 1 due to the power of the study being inadequate and the CI overlapping no effect (included an OR of 1).

[j]Downgraded by 1. The control intervention was the perineal approach; thus patient selection and the nature of complications are different. This study may not provide a direct answer to the clinical question.

[k]Downgraded by 1 due to the power of the study being inadequate. The CI overlaps no effect (included an OR of 1).

[l]Downgraded by 1 due to the power of the study being inadequate.

TABLE 6 Does rectopexy increase de novo constipation?

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	No mesh	Relative (95% CI)	Absolute (95% CI)		
De novo or worsening constipation, randomized controlled trials												
1	Randomized trials	Not serious	Not serious	Not serious	Serious[a]	None	5/15 (33.3%)	0/15 (0.0%)	OR 16.24 (0.81–325.88)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
De novo or worsening constipation, observational studies												
16	Observational studies	Very serious[b]	Very serious[c]	Very serious[d]	Serious[e]	None	96/653 (14.7%)	–	–	–	⨁◯◯◯ VERY LOW	CRITICAL

[a]Downgraded by 1 due to significant underpower of the study and the CI overlapping no effect (included a risk ratio of 1).

[b]Downgraded by 2. The risk of bias is serious as none of the studies was randomized and they had no blinding and potential selection bias.

[c]Downgraded by 2. Although the I^2 statistic was 0%, the ORs ranged from 0.69 to 4.8 with no significant overlap of CI and the CI included 1, suggesting substantial heterogeneity.

[d]Downgraded by 2. The techniques (D'Hoore, Orr–Loygue, posterior, Wells) of the investigated arm rectopexy and control groups (suture rectopexy, posterior, suture rectopexy with resection, Delorme's) were variable and different, which makes it difficult to generalize the findings.

[e]Downgraded by 1 due to the power of all studies being inadequate.

Methods

The PubMed and Embase search identified 2779 records. Titles and abstracts were screened permissively to include all possibly relevant studies. One hundred and ten full-text articles were screened and five articles were included.

Outcome

5.1 Overall complications: biological versus synthetic mesh, comparative studies

There was no randomized study. There were two studies that reported complications following mesh rectopexy for both biological and synthetic mesh [37,46]. The study by Ogilvie et al. [37] used non-crosslinked biological mesh (Biodesign®) and polypropylene mesh, while Swain et al. [46] used Prolene and Permacol™ mesh. In both studies, the technique was ventral rectopexy.

The study by Swain et al. [46] reported no complications in either group (possibly due to short follow-up); hence the effect was not estimable. Ogilvie et al. [37] reported 28% (8/29) complications in the biological mesh group while that in the synthetic mesh group was 14% (4/29). The difference was not statistically significant.

Risk of bias: Downgraded by 1. The risk of bias is serious as the studies were cross-sectional without blinding and have potential selection bias.

Inconsistency: Not applicable, as there was only one study with complications.

Indirectness: No concern.

Imprecision: Downgraded by 1 due to the power of the study being inadequate.

Overall, the quality of evidence was very low combining the above assessments.

5.2 Complications: absorbable versus non-absorbable mesh, randomized controlled trial

There was one study [52] that directly compared absorbable (polyglycolic acid) and non-absorbable (polypropylene) mesh. In both groups, the mesh was fixed posteriorly to the rectum. The complication rate was 25% (5/20) in the absorbable mesh group while that in the non-absorbable mesh group was 23.5% (4/17). The difference was not statistically significant ($P = 0.92$).

Risk of bias: Downgraded by 1 as the risk of bias is serious. Although patients were randomly allocated to either mesh, neither the method of randomization nor the method of blinding was clear.

Inconsistency: This is not estimable as there was only one study.

Indirectness: There was no concern.

Imprecision: Downgraded by 1 due to significant underpower of the study.

Overall, the quality of evidence was low combining the above assessments.

5.3 Mesh-specific complications: biological versus synthetic mesh, comparative studies

There were two studies reporting the outcome of the use of mesh with rectopexy [80,81].

Borie et al. [80] performed a retrospective study that reviewed all patients who had rectopexy with a synthetic mesh (either polyester or polypropylene). The rate of mesh-related complications (infections and erosions) was 3.3% with polyester and 1.1% with polypropylene. There was no significant statistical difference.

Evans et al. [81] pooled data of ventral rectopexies done in five centres (three in the UK, one in Australia, one in Italy) with detailed reports on mesh erosion. The overall rate of mesh erosion was 2.0%: mesh erosions after the use of synthetic mesh (mostly polyester or polypropylene) was 2.4%, while that of biological mesh was 0.7%.

Risk of bias: Downgraded by 1. The risk of bias is serious as none of the studies was randomized controlled and they were retrospective in nature.

Inconsistency: Downgraded by 1. One study compared the outcome between two different synthetic meshes, while the second study compared biological and synthetic meshes. The selection criteria for use of a specific type of mesh were unclear in both studies.

Indirectness: Downgraded by 1. The timing of follow-up was different in one study, making it difficult to interpret whether the difference in complication rates was due to the type of mesh or to the difference in the follow-up period.

Imprecision: No concern.

Overall, the quality of evidence was very low combining the above assessments (Table 7).

Q6. Do certain surgical techniques (open/laparoscopic/robotic, fixation methods, concomitant resection, concomitant repair of other pelvic organ prolapse) prevent recurrence of prolapse or carry more risks of complications?

Recommendations

- Surgeons could use any approach or certain surgical techniques based on their familiarity, experience and skills [*Conditional recommendation*]. This is based on low and very low quality of evidence.

Rationale for recommendation

There are no data to suggest any specific approach (laparoscopic/open/robotic) is superior in preventing recurrence.

One RCT showed laparoscopic mesh rectopexy was superior to the open approach in prevention of complications. However, the quality of evidence was low and, given the paradigm shift to the laparoscopic approach, combined with other benefits such as reduced pain and length of stay, it is difficult to extrapolate this evidence into modern practice.

Available data were generally of low or very low quality. There was no study that directly compared the technical details of rectopexy. There were no specific technical details (concomitant sigmoid resection, repair of pelvic organ prolapse, lateral ligament preservation/division, peritoneal closure, mesh fixation) that had an impact on recurrence or complications.

Outcome

6.1 Laparoscopy versus open

6.1.1 Laparoscopy versus open: recurrence

There was one RCT [82] and two observational comparative studies [15,44,82].

The RCT was focused on technical feasibility, recovery from surgery and non-inferiority of laparoscopy. The study by Boccasanta et al. [15] used Wells rectopexy with polypropylene mesh while the study by Solomon et al. [82] used posterior mesh rectopexy. The type of mesh used was not specified. Both studies were small and reported no recurrence in either group; hence the effect was not estimable.

Risk of bias: Downgraded by 1 for the RCT. The only RCT was single-blinded (assessors) and the method of randomization was not made explicit in the paper. Downgraded by 1 for the two comparative studies as there was no randomization and selection criteria for allocating treatment were not clear.

Inconsistency: As there was only one RCT, and the two comparative studies had no recurrence in both experimental and control groups, it was not possible to assess inconsistency.

Indirectness: No concern for the RCT. Downgraded by 1 for the observational studies as the techniques used were different and the type of mesh used was not clear.

Imprecision: Downgraded by 1. All studies were inadequately powered.

Overall, the quality of evidence was low combining the above assessments (Table 8).

6.1.2 Laparoscopy versus open: overall and major complications

The data were available from the same set of papers as for the above section on recurrence [15,44,82].

In the RCT, overall morbidity was significantly lower in the laparoscopic group compared with the open rectopexy group (laparoscopy 6/20, open 14/19, $P < 0.01$). Major morbidity occurred only in the open surgery group. Nonetheless, the outcome of the study was limited by its small sample size ($n = 39$) and unknown randomization method, resulting in low quality of evidence. A pooled analysis of both comparative observational studies, including posterior mesh rectopexy [44] and Wells rectopexy with polypropylene mesh [15], showed reduced morbidity in the laparoscopy group that did not reach statistical significance and was limited by small sample size and wide confidence interval (OR 0.71; 95% CI 0.17–2.94; $P = 0.63$).

6.1.3 Laparoscopy versus open: mortality

The data available were from the two aforementioned observational studies with one death after open surgery in all 66 patients in both studies [15,44]. No conclusion could be drawn.

TABLE 7 Do specific types of mesh increase the risk of adverse events?

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	One mesh	Another mesh	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Complications: biological versus synthetic mesh												
2	Observational studies	Serious[a]	Not serious	Not serious	Serious[b]	None	8/32 (25.0%)	4/34 (11.8%)	OR 2.38 (0.63–9.03)	123 more per 1000 (from 40 fewer to 429 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Complications: absorbable versus non-absorbable												
1	Randomized trial	Serious[c]	Not serious	Not serious	Serious[b]	None	5/20 (25.0%)	4/17 (23.5%)	OR 1.08 (0.24–4.90)	14 more per 1000 (from 167 fewer to 366 more)	⨁⨁◯◯ LOW	IMPORTANT
Mesh specific complications: biological versus synthetic												
2	Observational studies	Serious[d]	Serious[e]	Serious[f]	Not serious	None	5/615 (0.8%)	47/1913 (2.5%)	Not estimable		⨁◯◯◯ VERY LOW	IMPORTANT

[a]The studies were cross-sectional with no blinding and have potential selection bias.

[b]Underpowered.

[c]The method of randomization and the method of blinding were unclear.

[d]None of the studies was a randomized controlled study and they were retrospective in nature.

[e]One study compared the outcome between two different synthetic meshes, whilst the other study looked into both biological and synthetic meshes. The selection criteria for the use of a specific type of mesh were not clear in the two studies.

[f]Not only was there no direct comparison but the timing of follow-up was different in one study, making it difficult to interpret whether the difference in complication rates was due to the type of mesh or to the difference in the follow-up period.

TABLE 8 Laparoscopy compared to open for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopy	Open	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: laparoscopy versus open, randomized controlled study												
1	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	0/20 (0.0%)	1/19 (5.3%)	OR 0.30 (0.01–7.85)	36 fewer per 1000 (from 52 fewer to 251 more)	⨁⨁◯◯ LOW	IMPORTANT
Recurrence: laparoscopy versus open, comparative studies												
2	Observational studies	Serious[c]	Not serious	Serious[d]	Serious[e]	None	0/29 (0.0%)	Not pooled	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	IMPORTANT

[a]Downgraded by 1. Single-blinded and randomization method unclear.

[b]Downgraded by 1 as the power of the study was not adequate.

[c]Downgraded by 1 as there was no randomization and selection criteria for each group were not clear.

[d]Downgraded by 1 as techniques and mesh used were variable.

[e]Downgraded by 1 as the studies were inadequately powered and effect was not estimable because of null values in both groups.

TABLE 9 Open compared to laparoscopy in complications

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Open	Laparoscopy	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Overall complications: randomized controlled studies												
1	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	14/19 (73.7%)	6/20 (30.0%)	OR 0.20 (0.04–0.90)	221 fewer per 1000 (from 283 fewer to 22 fewer)	⨁⨁◯◯ LOW	IMPORTANT
Overall complications: observational study												
2	Observational studies	Very serious[c]	Not serious	Serious[d]	Serious[b]	None	4/29 (13.8%)	0.0%	OR 0.71 (0.17–2.94)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	
Major complications: open versus laparoscopic, randomized controlled trials												
1	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	4/19 (21.1%)	0/20 (0.0%)	OR 0.07 (0.00–1.34)	0 fewer per 1000 (from 0 fewer)	⨁⨁◯◯ LOW	

(Continues)

TABLE 9 (Continued)

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Open	Laparoscopy	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Mortality: open versus laparoscopic												
2	Observational studies	Very serious[c]	Not serious	Serious[d]	Serious[b]	None	0/29 (0.0%)	1/37 (2.7%)	OR 0.36 (0.01–9.43)	17 fewer per 1000 (from 27 fewer to 181 more)	⨁◯◯◯ VERY LOW	

[a]Single-blinded, randomization method unclear.
[b]The power of the study was inadequate.
[c]The studies were essentially case series with no randomization and no clear selection criteria.
[d]The technique and type of mesh used were different across the studies.

Risk of bias: Downgraded by 2, as there was no randomization and selection criteria for allocating treatment were not clear.

Inconsistency: Two observational studies showed no complications in the laparoscopy group.

Indirectness: Downgraded by 1 as the techniques were different and the type of mesh used was not clear.

Imprecision: Downgraded by 1. All studies were inadequately powered.

Overall, the quality of evidence was very low combining the above assessments (Table 9).

6.2 Laparoscopy versus robotic

6.2.1 Laparoscopy versus robotic: recurrence

There were three comparative studies comparing a robotic to a laparoscopic approach [33,35,83].

Recurrence following robotic rectopexy was lower (0%) compared with laparoscopic rectopexy (3.3%). The pooled analysis showed an odds ratio of recurrence with robotic rectopexy compared to laparoscopic rectopexy of 0.53 (95% CI 0.05–5.55). This was not statistically significant. The follow-up of all three studies was within 12 months; thus the risk of recurrence was probably low regardless of technique. All three studies were underpowered.

There were four other case series reporting on the outcome of robotic rectopexy [24,27,46,48]. However, they were not included due to the lack of a control arm.

Risk of bias: Downgraded by 1. Two studies were cross-sectional studies. The study by Mehmood et al. [35] stated that the treatment was allocated randomly in a 2:1 ratio, but the method of randomization was not stated.

Inconsistency: There was no inconsistency as only zero or one recurrence in each arm.

Indirectness: Downgraded by 1. All studies used the VMR technique; however, Brunner et al. [83] used biological mesh while Makela-Kaikkonen et al. [33] included rectopexy for rectal intussusception. This makes it difficult to generalize interpretation of the results.

Imprecision: Downgraded by 2. All studies were underpowered and reported outcomes were short term.

Overall, the quality of evidence was low combining the above assessments (Table 10).

6.2.2 Laparoscopy versus robotic: complications

One RCT [84] and four observational studies [33,35,62,83] analysed complications of patients following RVMR and LVMR, including patients with either external or internal rectal prolapse [33,35,62,83,84].

While both studies by Makela-Kaikkonen et al. [33,84] showed a non-significant but higher risk for complications after a robotic procedure, the study by Mantoo et al. [62] resulted in a higher risk of complications in the laparoscopic group. All studies were characterized by groups of small numbers and short-term follow-up.

Risk of bias: The RCT did not have any risk as the randomization method was clearly explained.

TABLE 10 Robotic compared to laparoscopic for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Robot	Laparoscopy	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: robotic versus laparoscopic, comparative studies												
3	Observational studies	Serious[a]	Not serious	Serious[b]	Very serious[c]	None	0/34 (0.0%)	2/61 (3.3%)	OR 0.53 (0.05–5.55)	15 fewer per 1000 (from 31 fewer to 126 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 1. Two studies were cross-sectional studies with no randomization. One study stated laparoscopic or robotic approach was randomly allocated 2:1 but the method of randomization or concealment was not mentioned.

[b]Downgraded by 1. All studies used ventral rectopexy but one study included rectopexy for intussusception and another study used biological mesh, making the findings difficult to compare directly.

[c]Downgraded by 2. All studies were underpowered with short-term results only.

Inconsistency: For the RCT it was not possible to ascertain as there was only one study. For the observational studies, it was downgraded by 1 due to conflicting results.

Indirectness: No concern for the RCT. Downgraded by 1 for the observational studies, as there were variations in indication and techniques used.

Imprecision: Downgraded by 1. All studies were underpowered and reported outcomes were short term.

Overall, the quality of evidence was low and very low combining the above assessments.

6.2.3 Laparoscopy versus robotic: mortality

Not all studies mentioned mortality as an outcome. Two observational studies that mentioned mortality reported no mortality; hence an effect of robotic versus laparoscopic approach was not estimable [33,62].

Overall, the quality of evidence was very low combining the above assessments (Table 11).

6.3 With or without sigmoid resection

6.3.1 With or without sigmoid resection: recurrence

One study compared mesh rectopexy without sigmoid resection and suture rectopexy with resection; thus there was not a direct comparison of the use of mesh with or without resection [11]. The authors selected patients with delayed colonic transit time for the resection arm. The effect was not estimable.

Another study compared perineal proctectomy (Altemeier) alone versus perineal proctectomy with biological mesh (Bio-Thiersch) [85]. Use of biological mesh appears to have reduced recurrence (with mesh 8% vs. without mesh 29%); however, the difference was not statistically significant.

Risk of bias: Downgraded by 2, as studies were retrospective reviews of consecutive patients without randomization.

Inconsistency: Downgraded by 1. Only one study was included, thus not estimable.

Indirectness: Downgrade by 1. The study by Lechaux et al. [11] compared mesh without resection and suture rectopexy with resection; thus interpretation of the effect of mesh is not possible. As two studies used different surgical techniques, the effect of mesh is difficult to assess.

Imprecision: Downgraded by 2. Both studies were significantly underpowered and reported only short-term outcome.

Overall, the quality of evidence was very low combining the above assessments (Table 12).

6.3.2 With or without sigmoid resection: complications

Two relevant papers were also included in the previous section. Eftaiha et al. [85] found no differences in complication between the two groups (resection alone 3/62, resection with mesh 1/25), but this was not a comparison with or without resection, while Lechaux et al. [11] did not separate the two groups (with or without resection) when reporting complications; hence analysis was not possible.

One observational study compared patients who underwent rectosigmoid resection with or without rectopexy [78]. The methods of rectopexy were variable, as some patients had suture only while

TABLE 11 Laparoscopic compared to robotic for complications

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopy	Robot	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Complications: a randomized controlled study												
1	Randomized trials	Not serious	Not serious	Not serious	Serious[a]	None	3/16 (18.8%)	1/14 (7.1%)	OR 3.00 (0.27–32.75)	116 more per 1000 (from 51 fewer to 644 more)	⨁⨁◯◯ LOW	IMPORTANT
Complications: observational studies												
4	Observational studies	Serious[b]	Serious[c]	Serious[d]	Serious[a]	None	9/v104 (8.7%)	37/228 (16.2%)	OR 0.50 (0.23–1.09)	74 fewer per 1000 (from 120 fewer to 12 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Mortality: observational studies												
2	Observational studies	Serious[b]	Not serious	Serious[d,e]	Serious[a]	None	0/64 (0.0%)	0/94 (0.0%)	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	IMPORTANT

[a]The power of the study was inadequate.

[b]These were not randomized studies.

[c]The outcomes were conflicting between the studies.

[d]There were variations in indications and used techniques.

[e]They reported on short-term outcome only.

TABLE 12 With sigmoid resection compared to without sigmoid resection for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	With sigmoid resection	Without sigmoid resection	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: mesh rectopexy with or without sigmoid resection												
1	Observational studies	Very serious[a]	Serious[b]	Serious[c]	Very Serious[d]	None	0/13 (0.0%)	0/35 (0.0%)	Not estimable		⨁◯◯◯ VERY LOW	NOT IMPORTANT
Recurrence: perineal proctectomy with or without biological mesh												
1	Observational studies	Very serious[e]	Serious[b]	Serious	Very serious[d]	None	2/25 (8.0%)	18/62 (29.0%)	OR 0.21 (0.05–1.00)	211 fewer per 1000 (from 270 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 2. No randomization. The study was a retrospective review of patients. Also, suture rectopexy with resection was chosen for patients with slow transit (selection bias).

[b]Cannot be assessed as there was only one study.

[c]Downgraded by 1. The comparison was not direct: mesh without resection versus suture rectopexy with resection.

[d]Downgraded by 2. The study was significantly underpowered.

[e]Downgraded by 2. No randomization. The study was a retrospective review of patients.

other patients had mesh implantation (mostly Wells procedure, *n* = 37). Of these patients, some received additional procedures (e.g., Thiersch, Sudeck, sphincter reefing), limiting interpretation of the results. Complication rates did not differ between groups (OR 0.89; 95% CI 0.2–3.87; *P* = 0.88).

Risk of bias: Downgraded by 2, as the study was an observational study and selection criteria for each intervention were not clear.

Inconsistency: Downgraded by 1 as only one study was included, and within the study there were uncertainties about the number and type of concomitant procedures.

Indirectness: Downgraded by 2. The intervention and type of mesh application were variable.

Imprecision: Downgraded by 1. The study was significantly underpowered.

Overall, the quality of evidence was very low (Table 13).

6.4 With or without concomitant repair of other pelvic organ prolapse

One study reported outcomes without a control arm [28] thus no data were available to address this question.

6.5 With or without lateral ligament division

6.5.1 With or without lateral ligament division: recurrence

One study compared outcome with or without division of the lateral ligament [6]. There was no recurrence in either group.

There were 17 case series studies that reported on recurrence with techniques that divided the lateral ligaments (three studies: [32,36,51] or preserved the lateral ligaments (14 studies: [8,11,12,14,15,17,19,20,22,27,30,48,49,50]. The pooled results from the three studies showed recurrence to be 2% after division while those of the 17 studies with ligament preservation showed a recurrence of 3.4%. Odds ratio and relative risks were not estimable.

Other studies that may have preserved ligaments but were not explicit regarding the treatment of the lateral ligaments were excluded.

Risk of bias: Downgraded by 2. All studies were cross-sectional studies without randomization.

Inconsistency: There was only one comparative study. Inconsistency could not be assessed for 17 studies.

Indirectness: Downgraded by 2. The comparative study used posterior mesh or suture rectopexy with resection or suture rectopexy without resection; thus the effect of ligament division/preservation as an individual element is difficult due to complexity. The other 17 studies had no control group.

Imprecision: Downgraded by 2. All studies were underpowered.

Overall, the quality of evidence was very low combining the above assessments (Table 14).

6.5.2 With or without lateral ligament division: complications

One observational study compared posterior mesh rectopexy (polypropylene mesh) and dividing lateral ligaments (*n* = 14), with resection suture rectopexy also dividing lateral ligaments (*n* = 18) and suture rectopexy with preserving lateral ligaments (*n* = 16) [6]. As there was only one mesh group with divided lateral ligaments,

TABLE 13 With resection compared to without resection in complications

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	With resection	Without resection	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Complications: with resection versus without resection												
1	Observational studies	Very serious[a]	Serious[b]	Very serious[c]	Serious[d]	None	4/16 (25.0%)	6/22 (27.3%)	OR 0.89 (0.20–3.87)	22 fewer per 1000 (from 203 fewer to 319 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]A prospective case series and selection of intervention was pragmatic.

[b]Only one study available and interpretation was limited due to uncertainties about the number and type of concomitant procedure.

[c]Downgraded by 2. The intervention and type of mesh application were variable.

[d]The study was underpowered.

TABLE 14 Lateral ligament divided compared to preserved for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Lateral ligament divided	Preserved	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: comparative study												
1	Observational studies	Very serious[a]	Not serious	Very serious[b]	Very serious[c]	None	0/14 (0.0%)	0/34 (0.0%)	Not estimable		⨁◯◯◯ VERY LOW	NOT IMPORTANT
Recurrence: observational studies without control arm												
17	Observational studies	Very serious[a]	Not serious	Very serious[d]	Very serious[c]	None	1/51 (2.0%)	23/685 (3.4%)	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 2. All studies were cross-sectional studies with no randomization.

[b]Downgraded by 2. The study used posterior mesh or suture rectopexy with resection or suture rectopexy without resection; thus the effect of ligament division/preservation as an element is difficult due to complexity.

[c]Downgraded by 2. Studies were underpowered.

[d]Downgraded by 2. All studies were reports of either ligament division or preservation; hence there was no comparator.

the effect of lateral ligament preservation versus division in mesh rectopexy is not estimable.

Risk of bias: Downgraded by 2. The study was cross-sectional with no randomization.

Inconsistency: There was only one comparative study and the inconsistency could not be assessed.

Indirectness: Downgraded by 2. Reporting outcomes at short term only.

Imprecision: Downgraded by 2. The study was underpowered.

Overall, the quality of evidence was very low (Table 15).

6.6 With or without peritoneal closure: recurrence and complications

Twenty-four studies reported whether the peritoneum was closed after rectopexy: two studies showed outcomes of not closing and closing the peritoneum [19,30]. Other studies reported outcomes following closure of the peritoneum [7,9,11,13,14,20,22,27,32,33,34,35,36,37,38,40,43,46,48,49,50,79].

The pooled results showed recurrence of 5.1% with peritoneal closure versus 7.8% without peritoneal closure. The complication rate was 8.3% with peritoneal closure versus 19.8% without peritoneal closure. Odds ratios and relative risks were not estimable.

Other studies that may have closed the peritoneum but were not explicit regarding this were excluded.

Risk of bias: Downgraded by 2. All studies were cross-sectional studies with no randomization.

Inconsistency: Inconsistency could not be assessed for the included studies.

Indirectness: Downgraded by 2. No study had a control group or exclusively reported on the specific element of the procedure.

Imprecision: Downgraded by 2. All studies were underpowered.

Overall, the quality of evidence was very low combining the above assessments (Tables 16 and 17).

6.7 Type of mesh fixation

6.7.1 Type of mesh fixation: recurrence

Twenty-four studies reported mesh fixation methods: 10 studies used sutures [8,9,15,17,30,36,41,50,51,86] and the remaining studies (14) used ProTack™, spiked chromium or staplers [6,7,13,14,19,20,33,35,40,44,46,48,49,79].

One observational study compared the use of glue and suture for mesh fixation [43].

The pooled results showed 4.9% recurrence with the use of ProTack™/staples compared with 3.9% following suture fixation of mesh. The odds ratio and relative risks were not estimable. The comparison of glue and suture showed recurrence of 20% with glue and 16.2% with suture.

Risk of bias: Downgraded by 2. All studies were cross-sectional studies with no randomization.

Inconsistency: Inconsistency could not be assessed for the included studies.

Indirectness: Downgraded by 2 for 24 cross-sectional studies. No study had a control group or reported specifically on mesh fixation.

TABLE 15 Complications: comparing with or without lateral ligament division for pelvis for rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Q6 Complications: with	Without lateral ligament division	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Q6 Complications: with versus without lateral ligament division												
1	Observational studies	Very serious[a]	Not serious	Very serious[b]	Very serious[c]	None	2/14 (14.3%)	5/34 (14.7%)	OR 0.97 (0.16–5.69)	4 fewer per 1000 (from 120 fewer to 348 more)	⨁◯◯◯ VERY LOW	CRITICAL

[a]No randomization.

[b]Reporting outcomes at short term.

[c]Underpowered study and 95% CI overlapped 1.

TABLE 16 Without peritoneal closure compared to with peritoneal closure for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Without peritoneal closure	With peritoneal closure	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: observational studies												
24	Observational studies	Very serious[a]	Not serious	Very serious[b]	Very serious[c]	None	9/116 (7.8%)	48/949 (5.1%)	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 2. All studies were cross-sectional studies with no randomization.

[b]There were no comparative studies. There was no study that addressed this element of the procedure exclusively.

[c]Downgraded by 2. All studies were underpowered.

TABLE 17 With peritoneal closure compared to no peritoneal closure

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	With peritoneal closure	No peritoneal closure	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Complications: cohort, non-comparative studies												
17	Observational studies	Very serious[a]	Very serious[b]	Very serious[c]	Very serious[d]	None	104/1248 (8.3%)	16/81 (19.8%)	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]No randomization; no comparison.
[b]Estimates widely vary across studies.
[c]High heterogeneity of the included patients.
[d]Large 95% CIs.

Imprecision: Downgraded by 2. All studies were underpowered.

Overall, the quality of evidence was very low combining the above assessments.

6.7.2 Type of mesh fixation: complications

The same 25 studies used in the previous section 6.7.1 were analysed [6,7,8,9,13,14,15,17,19,20,30,33,35,36,40,41,43,44,46,48,49,51,52,79,85]. The pooled results showed that the overall complication rate was 21.7% with use of ProTack™/staples compared with 8.5% with suture fixation of mesh. Odds ratios and relative risks were not estimable.

One observational trial compared anterior rectal wall fixation of a polyester mesh with glue (cyanoacrylate) with non-absorbable suture fixation [43]. The patient cohort was heterogeneous including patients with internal as well as those with external rectal prolapse, and included open and laparoscopic approaches. More patients who underwent open surgery had suture fixation compared with glue fixation (33.6% vs. 10.6% respectively). The only mesh dislocation occurred in a patient with glue fixation. Complication risks did not differ between glue and suture fixation (OR 0.92; 95% CI 0.29–2.87; $P = 0.89$).

Risk of bias: Downgraded by 2, as the studies were not randomized.

Inconsistency: Downgraded by 2. This is not estimable as there was only one study for suture versus glue and no comparative studies for suture versus the ProTack™/stapler.

Indirectness: Downgraded by 1. The study comparing glue with suture fixation by Silveira et al. [43] had technical variability due to approach (open vs. laparoscopy). Other studies did not directly compare fixation methods.

Imprecision: Downgraded by 1. All studies were significantly underpowered.

Overall quality of evidence was considered very low combining the above assessments (Tables 18–20).

6.8 One mesh technique versus another mesh technique

6.8.1 Mesh technique: recurrence

There was no comparative study available for VMR (D'Hoore) versus Orr–Loygue, or VMR versus Ripstein or VMR versus posterior mesh. One study compared the outcome of VMR and Wells rectopexy [31].

Risk of bias: Downgraded by 2. The study was a retrospective review, hence no randomization. The treatment allocation was based on surgeon's preference.

Inconsistency: Not applicable.

Indirectness: No major concern for indirectness. The groups were matching in demographics.

Imprecision: Downgraded by 2. The study was underpowered.

Overall quality of evidence was considered very low.

6.8.2 Mesh technique: complications

One observational study analysed VMR in comparison to posterior sling rectopexy (Wells procedure) [31]. The risk of complications was not different between the groups (OR 1.45; 95% CI 0.47–4.52; $P = 0.52$). The type of mesh implanted was not stated. The limitations of the study were the retrospective design and small sample size.

Risk of bias: Downgraded by 2, as the study had no randomization.

Inconsistency: Not applicable as only one study was included.

TABLE 18 One mesh fixation method compared to another mesh fixation method for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	One mesh fixation method	Another mesh fixation method	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: mesh fixation using ProTack™/stapler versus suture												
24	Observational studies	Very serious[a]	Not serious	Very serious[b]	Very serious[c]	None	30/611 (4.9%)	16/412 (3.9%)	Not pooled	See comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT
Recurrence: mesh fixation using glue versus suture												
1	Observational studies	Very serious[d]	Very serious	Serious	Serious[e]	None	3/15 (20.0%)	6/37 (16.2%)	OR 1.29 (0.28–6.01)	38 more per 1000 (from 111 fewer to 376 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 2. All studies were cross-sectional studies with no randomization.

[b]Downgraded by 2. All studies had no control group and rectopexy methods were variable.

[c]Downgraded by 2. All studies were underpowered.

[d]The study was an observational cohort study with no randomization. Method of selection to use glue or suture was not clear.

[e]Downgraded by 2. The study was underpowered.

TABLE 19 Complications: suture compared to ProTack™/stapler

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Suture	ProTac/stapler	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Complications: suture versus. tacs—cohort, non-comparative studies												
24	Observational studies	Very serious[a]	Very serious[b]	Very serious[c]	Very serious[d]	None	80/941 (8.5%)	164/757 (21.7%)	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]No randomization; no comparison.

[b]Estimates widely vary across studies.

[c]Very heterogeneous patients.

[d]No comparison; no power calculation.

TABLE 20 Complications: suture compared to glue (anterior only, non-absorbable suture was used for fixation to sacral promontory) for pelvis for rectal prolapse

Certainty assessment							No. of patients	Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Q6 Complications: suture	Glue (anterior only, non-absorbable suture was used for fixation to sacral promontory)	Relative (95% CI)	Absolute (95% CI)		
Q6 Complications: suture versus glue (anterior only, non-absorbable suture was used for fixation to sacral promontory)												
1	Observational studies	Serious[a]	Not serious	Serious[b]	Serious[c]	None	5/66 (7.6%)	9/110 (8.2%)	OR 0.92 (0.29–2.87)	6 fewer per 1000 (from 57 fewer to 122 more)	⨁◯◯◯ VERY LOW	CRITICAL

[a]No randomization.
[b]The reported outcomes were short term only.
[c]Significantly underpowered study.

Indirectness: Not considered serious. Outcomes were reported at various time points.

Imprecision: Downgraded by 2. The study was significantly underpowered.

Overall quality of evidence was considered very low (Tables 21 and 22).

Q7. Are there certain groups of patients who have higher risks of developing adverse events?

There were no extractable data to answer this question.

Research gaps

Some major limitations were found during the literature review concerning postoperative complications. Definitions varied, some included complications only during the perioperative period, and others reported all complications during follow-up. There were various categories of complications (e.g., major and minor, medical and surgical, intra-operative or not); the majority of studies were cross-sectional with variable lengths of follow-up and some reported in percentages only, which precluded data analysis.

Future study protocols should include clear definitions and not report complications selectively. In order to appraise any surgical technique, it is essential that the data are transparent not only for the primary outcome but also for all secondary outcomes. A consensus process on reporting complications and treatment may be helpful for future reporting.

The current analysis suggests that there may be a tendency towards de novo constipation or worsening existing constipation following VMR. It is recommended that, in future studies, the number of patients with constipation and defaecatory disorders is clearly documented preoperatively and postoperatively and assessment of symptoms is performed using validated scores.

Perineal reconstruction and other uses of mesh in colorectal surgery

Q8. Is using a mesh in perineal reconstruction better than classical reconstruction (primary closure, flap)?

Q9. Is one mesh better than the others?

Q10. Does the use of mesh increase the risk of adverse events?

Q11. Do specific types of mesh increase the risk of adverse events?

Q12. Do certain surgical techniques (fixation methods, use of wound management system etc.) prevent hernia after perineal reconstruction?

Recommendations

- Use of biological mesh could be considered for perineal reconstruction. [*Conditional recommendation*]

TABLE 21 D'Hoore compared to Wells for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	D'Hoore	Wells	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence: D'Hoore versus Wells												
1	Observational studies	Very serious[a]	Not serious	Not serious	Very serious[b]	None	1/41 (2.4%)	1/33 (3.0%)	OR 0.80 (0.05–13.29)	6 fewer per 1000 (from 29 fewer to 263 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 2. The study was a retrospective review of case series.

[b]Downgraded by 2. The study was underpowered.

TABLE 22 Complications: ventral compared to posterior sling (Wells) for pelvis for rectal prolapse

No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Q6 Complications: ventral	Posterior sling (Wells)	Relative (95% CI)	Absolute (95% CI)		
Q6 Complications: ventral versus posterior sling (Wells)												
1	Observational studies	Very serious[a]	Not serious	Not serious	Very serious[b]	None	10/41 (24.4%)	6/33 (18.2%)	OR 1.45 (0.47–4.52)	62 more per 1000 (from 87 fewer to 319 more)	⨁◯◯◯ VERY LOW	CRITICAL

[a]Retrospective study.

[b]Underpowered study and 95% CI overlapped 1.

- The choice for reconstruction should be based on the size of the defect, patient characteristics and surgical expertise. [*Conditional recommendation*]

These recommendations are based on moderate to very low quality of evidence.

Rationale for the recommendation

- Two RCTs showed fewer perineal hernias with the use of biological mesh compared with primary closure (14.1% vs. 21.8%). One study reported that mesh was more cost effective than using vertical rectus abdominus myocutaneous (VRAM) flaps. Length of stay has been reported to be comparable to or shorter in patients following mesh reconstruction compared with flap and primary reconstruction. However, small numbers of patients and events might have led to coincidental differences in length of stay.
- There was no difference between biological mesh and primary reconstruction in the rate of perineal septic complication in two RCTs [high quality evidence]. Overall morbidities and perineal septic complications occur in 25%–33% of patients. Use of mesh did not improve the wound healing rate in an RCT.
- Flap reconstruction results in optimal obliteration of dead space, but can result in donor site morbidities.
- The interpretation of data regarding the comparison between mesh reconstruction and musculocutaneous flap is difficult as two closure methods were performed in two different time periods, and the difference in the rate of perineal hernia may be due to the considerable difference in follow-up periods.
- There was no study that directly compared biological mesh with synthetic mesh, or one biological mesh against another. As there were no comparative data, it was not possible to analyse whether any specific type of mesh was associated with an increased risk of adverse events.
- Perineal pain appears to have occurred more frequently in patients who had mesh reconstruction. Some of the studies reported no obvious cause found despite extensive investigations. Given that this is a well-known complication associated with use of mesh in the pelvis for other indications, the group recommends that patients need to be informed and counselled appropriately.
- The current evidence was limited as there was no study that compared directly different surgical techniques of mesh placement. Placing of a mesh after laparoscopic abdominoperineal resection is more frequently performed by a perineal approach.

Background

Perineal reconstruction after rectal surgery, especially after extralevator abdominoperineal excision (ELAPE), can be technically demanding and is associated with significant postoperative morbidity [87]. There are a number of approaches for reconstruction such as direct repair, use of flaps or prosthetic materials including meshes which have been used as a simple and cost-effective method for perineal reconstruction.

Primary closure may not be possible following ELAPE or pelvic exenteration. Postoperatively, fluid collections may develop in the residual dead space that may become infected. Flaps can provide optimal bulk to obliterate dead space and close the perineal defect. In addition, flaps may be used for vaginal reconstruction. Flaps are more demanding in terms of operation time and expose patients to additional donor site morbidity.

Methods

A total of 2180 articles and abstracts were identified: 1228 titles for Q8, 213 for Q9, 221 for Q10, 122 for Q11. After screening titles, abstracts and papers, 18 full articles and four abstracts were deemed relevant to address the themes in this section. Only papers reporting on perineal reconstruction with mesh or flap were included.

Two RCTs compared primary closure with closure using biological mesh [88,89]. Thirteen observational studies primarily reported on the use of biological mesh. These described closure with BioA (absorbable synthetic, a copolymer that combines 67% polyglycolic acid and 33% trimethylene carbonate, Gore Medical) [90], human acellular dermal matrix (HADM) mesh (Qingyuanweiye Bio-Tissue Engineering) [91-93], Permacol™ (a porcine dermal crosslinked collagen, Covidien) [94-98], Surgisis®/Biodesign® (a porcine decellularized small intestine submucosa, Cook Medical) [99-101], Strattice (a porcine-derived acellular dermal matrix, Allergan) [102] and Tutomesh® (an avital, acellular, xenogenic collagen membrane made from bovine pericardium, RTI Surgical) [103]. Four studies provided data for comparison of some of the outcomes [92,93,96,104].

There were no randomized studies that compared musculocutaneous flap and mesh or primary closure. The only comparative studies available were a retrospective study by Christensen et al. that compared fasciocutaneous gluteal flap and Permacol™ [105], a retrospective study by Peacock et al. that compared vertical rectus muscle flap and Surgisis®/Biodesign® [106], and an abstract by Tharakan et al. that compared inferior gluteal artery perforator (iGAP) flap or VRAM flap against primary closure or biological mesh (product name or type not specified) [104].

Jones et al. [107] reported from a registry and a large series but outcomes for primary closure versus mesh versus flap could not be extrapolated separately. The same issue was noted with the paper by Sayers et al. [108].

The two papers by the same author group [88,92] may be overlapping as the former included patients operated between January 2008 and February 2009, whilst the latter is a multicentre study with some overlap in the study period and may have included some of the patients in the former study. There were two papers and one abstract from the same centre that may also be overlapping [99,101,106].

Four studies [104,107,108,109] reported the use of biological mesh, but the mesh type was not specified.

A paper by Wille-Jorgensen et al. [110] was excluded as the cohort of patients included appears to overlap with that of later work published by the same group [97].

Six publications mentioned the use of muscle flap and/or mesh but wound healing and complications were not reported or separately reported for different methods of reconstruction [108,109,111,112,113,114].

Outcome

8.1 Wound healing: primary closure versus mesh

8.1.1 Wound healing: primary closure versus mesh, randomized controlled trials

There were two RCTs. Han et al. [88] compared cylindrical abdominoperineal excision of the rectum (APER) with HADM closure against conventional APER with primary closure; thus both the approaches to excise the rectum and to close were different in the two arms. Musters et al. [89] randomized patients who underwent ELAPE to primary closure or closure using a biological mesh (Strattice™). This was the only study to have uncomplicated perineal wound healing as an outcome.

Risk of bias: The risk of bias is deemed not serious. The study used a central automated randomization website preoperatively.

Inconsistency: Not applicable as only one study was included.

Indirectness: No concern as the study compared directly the current standard approach (primary closure) against mesh closure.

Imprecision: Downgraded by 1 due to inadequate power. With an RRR of 3.5% (mesh group healing 30/48 = 63% vs. primary closure healing 33/50 = 66%), with alpha 0.05 and beta 0.2 and power of 0.8), n = 3993 for each arm would be needed for an adequately powered study. The current study power was 4.9%. However, on balance, the difference of 3.5% is clinically not relevant in this patient group. The confidence interval of RR was 0.7854–1.4197 which overlaps no effect (included an RR of 1).

Overall, the quality of evidence was moderate combining the above assessments.

8.1.2 Wound healing: primary closure versus mesh, comparative studies

There were three studies [92,93,104] that compared primary closure and closure with mesh. However, the study by Han et al. reported healing of the whole cohort and results for each group could not be extrapolated separately [92]. The two remaining studies reported the numbers of wound dehiscence [93,104].

Among the case series studies, Harries et al. reported healing as an outcome [96], with 44 out of 48 patients healing following mesh closure.

Risk of bias: Downgraded by 1 as the risk of bias is serious. The method of allocation to each treatment was not clear.

Inconsistency: There was no concern.

Indirectness: Downgraded by 1 as the meshes used were different in the two studies (HADM/not specified/Permacol™).

Imprecision: Downgraded by 1 due to inadequate powering of the study. With mesh group healing of 53/59 = 89% versus primary closure group healing of 19/25 = 76%, with alpha 0.05 and beta 0.2 and a power of 0.8, n = 133 for each arm is needed for an adequately powered study.

Overall, the quality of evidence was very low combining the above assessments.

8.2 Wound healing: flap versus mesh, comparative studies

There were no RCTs that compared closure with fasciocutaneous or musculocutaneous flap and mesh.

There were three observational studies that compared flap and mesh after APER. A study by Christensen et al. compared gluteal flap with closure with Permacol™ [105], a study by Peacock et al. compared VRAM flap and closure with Surgisis®/Biodesign® [106], and a study by Tharakan et al. compared a series of patients closed by iGAP and VRAM against those closed with a biological mesh (type not specified) [104].

There was no difference in wound healing rates (mesh 92.9% vs. flap 83.6%, RR 1.08, 95% CI 0.93–1.24).

Risk of bias: Downgraded by 1 as the risk of bias is serious. The time periods of when flap and mesh were used were different, which made the follow-up period different (longer with flap closure).

Inconsistency: There was no inconsistency among the included studies.

Indirectness: Downgraded by 1. Both control intervention (gluteal/VRAM/ combination of iGAP and VRAM) and type of mesh (Permacol™/Surgisis®/unspecified) were different in all three studies.

Imprecision: Downgraded by 1 because the power of the study was inadequate. With mesh group healing of 39/42 = 92.9% versus flap group healing of 46/55 = 83.6%, with alpha 0.05 and beta 0.2 and power of 0.8, n = 187 for each arm is needed for an adequately powered randomized study.

Overall, the quality of evidence was very low combining the above assessments.

9 Is one mesh better than the other?

There was no study that compared different types of mesh for perineal reconstruction.

10 Risk of adverse events with mesh

10.1 General morbidity

There were two RCTs [88,89], one comparative observational study [92] and five case series using mesh [90,91,93,100,101] that reported on overall morbidity. One observational study that compared the use of flaps and meshes [106] reported on non-specific overall morbidities. The overall morbidity rate was 25.3% in the mesh group and 24.7% in the primary closure group combining the two

randomized studies. Data from cohort studies and case series were not pooled due to the poor quality of the data.

10.1.1 General morbidity: primary closure versus mesh, randomized controlled trials

Risk of bias: The risk of bias is deemed not serious. One study used sealed envelopes on the day before surgery and another study used a central automated randomization website preoperatively.

Inconsistency: Both studies reported identical general morbidity rates for the mesh and primary closure groups; hence there was no obvious heterogeneity. The complication rates were similar: both Han et al. [88] and Musters et al. [89] reported postoperative complications (surgical and non-surgical) in about half of the patients.

Indirectness: No concern for the study by Musters et al. [89] as it directly compared the current standard approach (primary closure) against mesh closure. The study by Han et al. [88] used different surgical techniques for rectum excision (cylindrical, extralevator vs. conventional). However, the risk of influence on indirectness is negligible.

Imprecision: Downgraded by 1 due to inadequate powering of both studies. Confidence interval overlaps no effect (included an OR of 1).

Overall, the quality of evidence was moderate combining the above assessments.

10.1.2 General morbidity: primary closure versus mesh, comparative studies

Risk of bias: Downgraded by 1 as the risk of bias is serious. The method of allocation to mesh reconstruction or primary closure was unclear.

Inconsistency: There was no concern as there was only one study.

Indirectness: No major concern.

Imprecision: Downgraded by 1. It was noted that selection criteria between mesh reconstruction and primary closure were not explicit; thus the effect of the use of mesh was not estimable.

Overall, the quality of evidence was moderate to very low combining the above assessments.

10.1.3 General morbidity: primary closure versus mesh, case series

Risk of bias: Downgraded by 1. The risk of bias is serious as the included studies only had series of mesh reconstructions.

Inconsistency: Downgraded by 1. The rate of morbidities varied between 0% and 42%.

Indirectness: Downgraded by 1 as there was no control treatment.

Imprecision: Downgraded by 1. All studies were small case series with mesh reconstruction only.

Overall, the quality of evidence was very low combining the above assessments.

10.1.4 General morbidity: flap versus mesh, comparative study

Risk of bias: Downgraded by 1. The risk of bias is serious as the study is a series of flap reconstructions in the first period followed by mesh reconstruction in the second period (no selection criteria, no control arm and different follow-up length for each intervention).

Inconsistency: No concern as there was only one study.

Indirectness: Downgraded by 1 as two reconstruction methods were performed in two different time periods.

Imprecision: Downgraded by 1 as the study size was small.

Overall, the quality of evidence was very low combining the above assessments.

10.2 Perineal septic complications

There were two RCTs [88,89] and three observational studies [92,93,104] comparing primary closure with mesh implantation, and 12 case series [90,91,94,95,96,97,98,99,100,101,102,103]. There were three observational studies that compared the use of flap and mesh [104-106].

The two RCTs found no difference in the rates of perineal septic complication between mesh and primary closure (31.8% vs. 37.2%, OR 0.81, 95% CI 0.42–1.59). The comparative observational studies showed that the rate of septic complications was reduced by more than 70% using mesh (7.4% vs. 36.4%, OR 0.29, 95% CI 0.10–0.87).

10.2.1 Perineal septic complications: primary closure versus mesh, randomized controlled trials

Risk of bias: The risk of bias is deemed not serious. One study used sealed envelopes on the day before surgery and the other study used a central automated randomization website preoperatively.

Inconsistency: Han et al. [88] reported a septic complication rate of 11% for the mesh group and 19% for the primary closure group while Musters et al. [89] reported complicated perineal wound healing in 46% for mesh and 48% for primary closure. Pooled analysis showed no differences between the two groups and it was consistent from this perspective, yet it was noted that the definitions were different in the two studies.

Indirectness: There is no concern for the study by Musters et al. [89] as it directly compared the current standard approach (primary closure) against mesh closure. The study by Han et al. [88] used different surgical techniques for rectum excision (cylindrical, extralevator vs. conventional). However, the risk of influence on indirectness is negligible.

Imprecision: The odds ratio did overlap 1 but with a confidence interval of 0.42–1.59 the size of the studies was deemed adequate.

Overall, the quality of evidence was moderate combining the above assessments.

10.2.2 Perineal septic complications: primary closure versus mesh, comparative studies

Risk of bias: Downgraded by 1 as the risk of bias is serious. The method of allocation to mesh reconstruction or primary closure was unclear.

Inconsistency: All three studies favoured the use of mesh. The septic complication rates of the mesh group were 0%–25%, while those of the primary closure group were 16%–67%.

Indirectness: Downgraded by 1. The type of patients who had mesh reconstruction and primary closure may have been different. Two studies did not make the selection criteria between mesh and primary closure explicit [92,104] while one study chose mesh only when the defect was too large for primary closure [93].

Imprecision: Downgraded by 1 due to the power of the study being inadequate. With a mesh group complication rate of 7/94 = 7% versus a primary closure group septic complication rate of 16/44 = 36%, with alpha 0.05 and beta 0.2 and a power of 0.8, n = 30 for each arm is needed for an adequately powered randomized study.

Overall, the quality of evidence was very low combining the above assessments.

10.2.3 Perineal septic complications: primary closure versus mesh, case series

Risk of bias: Downgraded by 1. The risk of bias is serious as the included studies were a series of mesh reconstructions only.

Inconsistency: Downgraded by 1. The rate of morbidities varied between 0% and 43%.

Indirectness: Downgraded by 1 as there was no control treatment.

Imprecision: Downgraded by 1. All studies were small case series with mesh reconstruction only.

Overall, the quality of evidence was very low combining the above assessments.

10.2.4 Perineal septic complications: flap versus mesh, case series

Risk of bias: Downgraded by 1. The risk of bias is serious as the use of flap and mesh were in two different periods in two studies [105,106]. One study did not reveal the method of choice between mesh and flap.

Inconsistency: Downgraded by 1. The rate of morbidities varied in both flap (6%, 20% and 25%) and mesh (17%, 20%, 76%) groups.

Indirectness: Downgraded by 1 as two reconstruction methods were performed in two different time periods; hence they were not compared directly. In all studies, the selection criteria for the closure method were unclear.

Imprecision: Downgraded by 1 as the size of the studies was small.

Overall, the quality of evidence was very low combining the above assessments.

10.3 Perineal hernia

There were two RCTs [88,89] and two observational studies comparing primary closure and mesh implantation [92,93]. There were nine case series using mesh [90,91,95,96,97,98,99,100,101]; eight of these studies reported that there was no perineal hernia. There were two observational studies that compared the use of flap and mesh [105,106]. Two studies [108,109] were not included as the reported perineal hernia complications were a combination of the flap and mesh patients.

The two RCTs showed there was no difference in the rate of perineal hernia between the mesh and primary closure patients (14.1% vs. 21.8%, OR 0.60, 95% CI 0.27–1.32)[moderate quality evidence]. Other analyses yielded very low quality evidence only.

10.3.1 Perineal hernia: primary closure versus mesh, randomized controlled trials

Risk of bias: The risk of bias is deemed not serious. One study used sealed envelopes on the day before surgery and another study used a central automated randomization website preoperatively.

Inconsistency: Downgraded by 1. Han et al. [88] reported perineal hernia rates of 14% for the mesh group and 12% for primary closure while Musters et al. [89] reported 13% for mesh and 27% for primary closure. Thus one study showed a tendency in favour of mesh while the other study showed no significant difference. However, the heterogeneity I^2 index was 29% indicating only small heterogeneity. The study by Musters et al. [89] assessed perineal complication up to 12 months post-surgery.

Indirectness: No concern for the study by Musters et al. [89] as it directly compared the current standard approach (primary closure) against mesh closure. The study by Han et al. [88] used different surgical techniques for rectum excision (cylindrical, extralevator vs. conventional). However, the risk of influence on indirectness is deemed negligible.

Imprecision: The odds ratio did overlap 1 and the size of the studies was probably inadequate.

Overall, the quality of evidence was low combining the above assessments.

10.3.2 Perineal hernia: primary closure versus mesh, comparative studies

Risk of bias: Downgraded by 1 as the risk of bias is serious. The method of allocation to mesh reconstruction or primary closure was not randomized.

Inconsistency: Effectively, there was only one study for analysis as the study by Chi et al. [93] had no perineal hernia in either group. In the study by Han et al. [92] perineal hernia was seen in four out of 83 patients (5%) in the mesh group and two out of 19 patients after primary closure (11%). As there was only one study for analysis, there was no concern for inconsistency.

Indirectness: Downgraded by 1. The type of patients who had mesh reconstruction and primary closure was different. Han et al. [92] did not make the selection criteria between mesh and primary closure explicit while the other study chose mesh when the defect was too large for primary closure [93].

Imprecision: Downgraded by 1 as the power of the studies was inadequate.

Overall, the quality of evidence was very low combining the above assessments.

10.3.3 Perineal hernia: primary closure versus mesh, case series

Risk of bias: Downgraded by 1. The risk of bias is serious as the included studies were series of mesh reconstructions only.

Inconsistency: Eight out of nine studies reported there was no perineal hernia at variable periods of follow-up.

Indirectness: Downgraded by 1 as there was no control treatment.

Imprecision: Downgraded by 1. All studies were small case series with mesh reconstruction only.

Overall, the quality of evidence was very low combining the above assessments.

10.3.4 Perineal hernia: flap versus mesh, comparative studies

Risk of bias: Downgraded by 1. The risk of bias is serious as the uses of flap and mesh were in two different periods in both studies (not randomized).

Inconsistency: Effectively, there was only one study for analysis as the study by Peacock et al. [106] had no perineal hernias in either group. As there was only one study available, there was no concern about inconsistency.

Indirectness: Downgraded by 1 as two reconstruction methods were performed in two different time periods; hence they were not compared directly. In the study by Christensen et al. [105] perineal hernia was seen in none of the 24 patients (0%) in the mesh group and in seven out of 22 patients after primary closure (32%). However, it was noted that the follow-up timing was considerably different (median 1.7 years for meshes, 3.2 years for flaps) which is likely to have had an impact on the outcome assessment.

Imprecision: Downgraded by 1 as the size of the studies was small.

Overall, the quality of evidence was very low combining the above assessments.

10.4 Perineal pain

There was only one randomized study that reported specifically on perineal pain [88] in which more than half the patients who had mesh reconstruction had issues with perineal pain (51.4% vs. 6.3% with primary closure, OR 15.88, 95% CI 3.28–76.91). Another randomized study [89] reported on postoperative pain but did not elaborate further as to whether this was perineal pain or inclusive of all wound pain and pelvic pain associated with the reconstruction.

There was only one comparative study comparing mesh and primary closure [92]. There were six case series that reported on the incidence of perineal pain [90,91,96,97,100,101]. The follow-up or assessment timing was around 12 months. Some studies reported that pain was transient [97] or minor [100], while others reported chronic pain [90,91,101].

There was only one study that compared flap and mesh closure [106], which was a retrospective case series with longer follow-up for the musculocutaneous flap group.

10.4.1 Perineal pain: primary closure versus mesh, randomized controlled trial

Risk of bias: The risk of bias is deemed not serious. The study used sealed envelopes on the day before surgery.

Inconsistency: As there was only one study available, there was no concern about heterogeneity.

Indirectness: Downgraded by 1. The study used different surgical techniques for rectal excision (cylindrical extralevator vs. conventional).

Imprecision: No concern.

Overall, the quality of evidence was moderate combining the above assessments.

10.4.2 Perineal pain: primary closure versus mesh, comparative studies

Risk of bias: Downgraded by 1 as the risk of bias is serious. The method of allocation to mesh reconstruction or primary closure was not randomized.

Inconsistency: As there was only one study for analysis, there was no concern about inconsistency.

Indirectness: Downgraded by 1. The study did not make the selection criteria between mesh and primary closure explicit and there is a significant difference in the number of patients who underwent mesh (83) versus primary (19) closure.

Imprecision: Downgraded by 1 as the power of the studies was inadequate.

Overall, the quality of evidence was very low combining the above assessments.

10.4.3 Perineal pain: primary closure versus mesh, case series

Risk of bias: Downgraded by 1 as the risk of bias is serious. The included studies were a series of mesh reconstructions only.

Inconsistency: Downgraded by 1. The occurrence of perineal pain varied between 2% and 33%. One of the studies, which reported 2% perineal pain, had 42% of patients from the original cohort missing from follow-up [97]. Two studies had a considerable range in the timing of follow-up (Harries et al. [96], between 1 and 85 months; Peacock et al. [101]: between 1 and 54 months). There was also a study with no clear follow-up timing [100].

Indirectness: Downgraded by 1 as there were no control treatments.

Imprecision: Downgraded by 1. All studies were small case series with mesh reconstruction only.

Overall, the quality of evidence was very low combining the above assessments.

10.4.4 Perineal pain: flap versus mesh, case series

Risk of bias: Downgraded by 1. The risk of bias is serious as the uses of flap and mesh were in two different periods for both studies (not randomized).

Inconsistency: As there was only one study available, there was no concern for inconsistency.

Indirectness: Downgraded by 1 as two reconstruction methods were performed in two different time periods; hence they were not compared directly.

Imprecision: Downgraded by 1 as the size of the studies was small.

Overall, the quality of evidence was very low combining the above assessments.

Q11: Do specific types of mesh increase the risk of adverse events?

There was no study that compared different types of mesh for perineal reconstruction.

Q12: Do certain surgical techniques (fixation methods, use of wound management system etc.) prevent hernia after perineal reconstruction?

There was no study that compared different surgical techniques with perineal hernia as an outcome.

Research gaps

The vast majority of the literature dealing with mesh pelvic floor reconstruction after rectal resection relates to patients who underwent ELAPE. This is understandable, as the perineal defect is much larger after ELAPE compared with that following conventional APER. There was no report of the use of mesh for ischioanal APER and data were very limited on more extensive excisions such as pelvic exenteration. Whether there is any role for using mesh, at least as an adjunct, remains to be determined.

Although it is widely accepted that neoadjuvant chemoradiotherapy negatively affects tissue healing (especially anastomoses), reports on its influence on perineal wound healing after pelvic floor mesh reconstruction are scarce. Most reports focus on the portion of patients who received neoadjuvant therapy without clarifying its effect on perineal wound healing. In one paper [107] the authors reported a significantly higher incidence of wound breakdown after neoadjuvant radiotherapy (38% vs. 16%) regardless of the extent of pelvic floor resection. However, the outcome was not reported separately according to the type of reconstruction. Musters et al. [89] reported a similar incidence of postoperative perineal wound complications (about a third) after ELAPE in both primary closure and biological mesh closure. Since the incidence of neoadjuvant therapy in both groups was also similar, they concluded that biological mesh closure does not improve healing of ELAPE after preoperative radiotherapy.

There are other factors that may influence wound healing. Data on the incidence of obesity in the relevant papers dealing with pelvic floor reconstruction after APER for rectal cancer and its impact on perineal wound healing and perineal hernia formation are practically non-existent. If at all, the authors only report on the average body mass index of their patients. The role of smoking on perineal wound healing and perineal hernia formation after APER for rectal cancer cannot be assessed since only two publications reported on the smoking status of the patients without analysing its influence any further. Similarly, the incidence of diabetes in patients who underwent APER for rectal cancer was rarely reported. In one publication [108] six out of 54 analysed patients after ELAPE had diabetes; the incidence of diabetes in those who had perineal wound complications was three out of 24.

In the randomized study by Musters et al. [89] occurrence of perineal hernia after 1 year was significantly lower in the biological mesh closure cohort. However, as the authors pointed out, the results were only at 1 year and the data do not reflect the long-term occurrence of perineal hernia [115].

Data interpretation and limitations

Most studies were case series with a correspondingly low level of evidence (low or very low). Two RCTs were included, one of which was rated as high quality and the other as moderate [88,89].

Outcomes were poorly defined in most studies. In addition, wound healing was not clearly reported and instead there was a tendency towards reporting only wound complications. There were variable definitions of infection, such as superficial versus deep, or requiring surgery or other interventions. The site of infection (perineal, abdominal or donor site in the case of musculocutaneous flap) was often not specified and it was difficult to understand the true severity of complications. Methods of diagnosing sepsis and wound healing, and the timing of follow-up, were not well described in most case series. Despite short-term wound complications, some wounds heal eventually and it is imperative that the true wound healing rate is reported at a defined follow-up time.

For the majority of studies, length of follow-up varied with a minimum follow-up of 1–3 months. Case–control series reported different lengths of follow-up for flap and mesh reconstruction groups, due to the different reconstruction methods used at different time periods [101,105,106]. The most common reasons for downgrading were imprecision (low number of patients and/or events).

The level of mesh placement will influence the volume of dead space and subsequent fluid accumulation in the pelvis. Mesh fixation, such as with slowly resorbable or non-resorbable sutures, may lead to long lasting pain at fixation points, as has been observed with mesh fixation to the abdominal wall in incisional hernia surgery. In future, any report should make explicit the techniques used for reconstruction, the fixation method and whether there was any adjunct intervention deployed (e.g., omental interposition, negative wound pressure).

Wound management systems with or without topical negative pressure may help to reduce oedema and promote uncomplicated wound healing. Most surgeons hesitate to apply topical negative pressure wound therapy on open perineal wounds due to concerns about enterocutaneous fistula formation. Whether this can be prevented by placement of omentum or mesh under a negative pressure system remains to be investigated.

Future research should compare flaps and meshes, with a standard type of resection and type of mesh. It is inevitable that the size of the defect will determine the closure techniques needed and it is important that the extent of resection is described so that indications for different reconstructions become clearer.

Ideally two different types of mesh should be included with prospective evaluation by CT or MRI to have an objective measure of postoperative hernia occurrence. Cost-effectiveness should also be evaluated, including costs of the operation, hospitalization, reoperation (if needed) and postoperative recovery. Subgroup analysis should be included for risk factors such as smoking, diabetes, obesity, preoperative stage and treatment (radiotherapy or chemotherapy). Scores to measure wound complications should also be included. The primary objective should be perineal wound healing, but secondary objectives such as hernia formation would also be of major interest.

New meshes, including slowly resorbable synthetic meshes, may or may not prove to be of value for perineal reconstruction. Any study of new meshes should report rigorously on the properties of the mesh (material, pore size, mechanical property and, if biological, crosslinked or not) together with the surgical techniques, and whether mesh was used as the primary reconstruction technique or as an adjunct to other types of reconstruction.

There are currently, at the point of writing, three trials registered in the public domain to evaluate perineal reconstruction using mesh: a French multicentre study entitled 'Cost-utility evaluation of two strategies of perineal reconstruction after abdominoperineal resection for anorectal carcinoma: perineal filling with biological meshes versus primary perineal wound closure' (NCT02841293) comparing primary closure and mesh closure (type of biological mesh unspecified); a study entitled '"Cross" closure for reconstructing the perineal wound of abdominoperineal resection (CCRPWAR)' comparing two different methods of primary closure in China (NCT03731754); and 'Collagen implant (biological mesh) versus GM flap for reconstruction of pelvic floor after ELAPE in rectal cancer (NEAPE)' (NCT01347697) (Tables 23–25).

Other indications for mesh in colorectal surgery

Q13. What are the effects and adverse effects of adding mesh to sphincter repair (sphincteroplasty) compared with conventional sphincter repair in treating anal sphincter injury?

Q14. What are the effects and adverse effects of adding mesh to repair of ano/rectovaginal fistulas compared with conventional repair in treating ano/rectovaginal fistulas?

Q15. What are the effects and adverse effects of using a mesh to recreate the anorectal angle compared with conventional postanal repair for FI?

Q16. What are the effects and adverse effects of placing mesh through a transperineal approach compared with conventional repair in treating rectocoele?

Recommendation

- Use of mesh for anal sphincter repair (sphincteroplasty) is currently not recommended due to the very low quality of available evidence. [*Conditional recommendation*]
- Use of mesh for repairing ano/rectovaginal fistula is currently not recommended due to the very low quality of available evidence. [*Conditional recommendation*]
- Use of mesh for recreating the anorectal angle for FI could not be recommended due to the very low quality of available evidence. [*Conditional recommendation*]
- Placing a mesh transperineally for rectocoele repair could not be recommended due to the very low quality of available evidence and concern for safety. [*Conditional recommendation*]

Rationale for recommendation

- There are only four studies regarding use of mesh for anal sphincter repair and all were case series. One study, published more than 30 years ago, using mesh, reported a high incidence of complications (>50%). Other papers reported very few or no complications. Due to this heterogeneity coupled with the limited number of cases included in all studies, the group feels this procedure cannot be recommended. The group suggests that any new study using mesh for anal sphincter repair should be at least a comparative study against standard sphincter repair and possible complications should be monitored and documented rigorously before the use of mesh can be recommended for this indication.
- Regarding use of mesh for repairing ano/rectovaginal fistula, not only was the available evidence limited but also the quality was very low, with most studies not reporting complications. Recurrence data were mostly for patients with Crohn's disease and there are hardly any safety data relating to the use of mesh in this group. For this reason, the group cannot recommend use of mesh for this indication and would recommend that published studies report long-term outcome and complications. Any new study should have clear outcome measures and reporting of adverse events.
- The available studies on the use of mesh for recreating the anorectal angle for FI reported mostly short-term outcomes and the results were not comparable due to the use of different types of meshes. In the absence of robust safety data, any new study exploring this concept should be performed under the rigour of clinical trials with reporting of outcome measures and adverse events in the medium to long term.
- The duration of follow-up in the available studies on the use of mesh for transperineal repair of rectocoele was mostly up to 12 months, which is well short of other studies that reported adverse events such as mesh erosion. In recent years, there has been an increasing adverse publicity concerning meshes inserted transvaginally with reported symptoms of dyspareunia and chronic pain. Given that the mesh is placed anatomically in the same position, this aspect needs to be looked into in the longer term and also with the placement of transperineal mesh. Rectocoele is an anatomical finding but is not necessarily related to functional abnormality. Further trials are needed with a comparative arm without the use of mesh to truly assess the outcome of rectocoele repair.

Background

Surgical mesh is used to reinforce the repair of damaged tissue and to increase the durability of surgical results. For challenging surgical procedures such as reconstruction of the external anal sphincter, closure of anovaginal fistula and rectocoele repair, use of a mesh may improve surgical outcomes in terms of healing and long-term effect. For patients with FI a mesh can be inserted as a sling behind the rectum to create an anorectal angle between the axis of the rectum and the anal canal, thereby facilitating the normal closing mechanism to keep stool in the rectum.

TABLE 23 Wound healing: mesh compared to primary closure/flap for perineal reconstruction

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	Primary closure/ flap	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Primary closure versus mesh, randomized controlled trial												
1	Randomized trial	Not serious	Not serious	Not serious	Serious[a]	None	30/48 (62.5%)	33/50 (66.0%)	OR 0.86 (0.38–1.96)	**35 fewer per 1000** (from 235 fewer to 132 more)	⨁⨁⨁◯ MODERATE	IMPORTANT
Primary closure versus mesh, comparative studies												
3	Observational studies	Serious[b]	Not serious	Serious[c]	Serious[d]	None	0 cases 0 controls –	0.0%	Not estimable	–	⨁◯◯◯ VERY LOW	IMPORTANT
Flap versus mesh, comparative studies												
3	Observational studies	Serious[e]	Not serious	Serious[f]	Serious[d]	None	39/42 (92.9%)	46/55 (83.6%)	RR 1.08 (0.93–1.24)	67 more per 1000 (from 59 fewer to 201 more)	⨁◯◯◯ VERY LOW	IMPORTANT

Abbreviation: RR, risk ratio.

[a]Downgraded by 1, as the study was underpowered.

[b]Downgraded by 1, as the method to allocate mesh or primary closure was not clear.

[c]Downgraded by 1, as the mesh used was different in the three studies.

[d]Downgraded by 1, as the studies were underpowered.

[e]Downgraded by 1, as the time period when mesh and flap were used was different.

[f]Downgraded by 1, as the types of both flap and mesh used were different in all three studies.

TABLE 24 Perineal septic complication mesh compared to primary closure/flap for perineal reconstruction

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	Primary closure/flap	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Primary closure versus mesh, randomized controlled trials												
2	Randomized trials	Not serious	Not serious	Not serious	Not serious	None	27/85 (31.8%)	32/86 (37.2%)	OR 0.81 (0.42–1.59)	48 fewer per 1000 (from 173 fewer to 113 more)	⨁⨁⨁⨁ HIGH	CRITICAL
Primary closure versus mesh, comparative studies												
3	Observational studies	Serious[a]	Not serious	Serious[b]	Serious[c]	None	7/94 (7.4%)	16/44 (36.4%)	OR 0.29 (0.10–0.87)	**221 fewer per 1000** (from 310 fewer to 32 fewer)	⨁◯◯◯ VERY LOW	CRITICAL
Primary closure versus mesh, case series												
12	Observational studies	Serious[d]	Serious[e]	Serious[f]	Serious[g]	None	38/292 (13.0%)	Not pooled	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	CRITICAL
Flap versus mesh, case series												
3	Observational studies	Serious[h]	Serious[i]	Serious[j]	Serious[k]	None	6/51 (11.8%)	–	–	–	⨁◯◯◯ VERY LOW	CRITICAL

[a]Downgraded by 1. The allocation to mesh and primary closure was not randomized.

[b]Downgraded by 1. The type of patients who had mesh reconstruction and primary closure may be different. Two studies did not make the selection criteria between mesh and primary closure explicit [92,104] whilst one study chose mesh when the defect was too large for primary closure [93].

[c]Downgraded by 1, due to inadequate sample size in all studies.

[d]Downgraded by 1. The risk of bias is serious as the included studies were series of mesh reconstruction only.

[e]Downgraded by 1. The rate of morbidities varied between 0% and 43%.

[f]Downgraded by 1 as there was no control treatment.

[g]Downgraded by 1. All studies were small case series with mesh reconstruction only.

[h]Downgraded by 1. The risk of bias is serious as the use of flap and mesh were in two different periods in two studies. One study did not reveal the method of choice between mesh and flap.

[i]Downgraded by 1. The rate of morbidities varied in both flap (6%, 20% and 25%) and mesh (17%, 20%, 76%) groups.

[j]Downgraded by 1 as two reconstruction methods were performed in two different time periods; hence they were not compared directly. In all studies, the selection criteria for closure method were unclear.

[k]Downgraded by 1 as the size of the studies was small.

TABLE 25 Occurrence of hernia: mesh compared to primary closure/flap for perineal reconstruction

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	Primary closure/flap	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Primary closure versus mesh, randomized controlled trials												
2	Randomized trials	Not serious	Serious[a]	Not serious	Serious[b]	None	12/85 (14.1%)	19/87 (21.8%)	OR 0.60 (0.27–1.32)	75 fewer per 1000 (from 148 fewer to 51 more)	⨁⨁◯◯ LOW	IMPORTANT
Primary closure versus mesh, comparative studies												
2	Observational studies	Serious[c]	Not serious	Serious[d]	Serious[e]	None	4/86 (4.7%)	–	–	–	⨁◯◯◯ VERY LOW	IMPORTANT
Primary closure versus mesh, case series												
9	Observational studies	Serious[f]	Not serious	Serious[g]	Serious[h]	None	3/250 (1.2%)	Not pooled	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	IMPORTANT
Flap versus mesh												
2	Observational studies	Serious[i]	Not serious	Serious[j]	Serious[e]	None	0/34 (0.0%)	0.0%	OR 0.04 (0.00–0.79)	0 fewer per 1000 (from 0 fewer to --)	⨁◯◯◯ VERY LOW	IMPORTANT

[a]Downgraded by 1. Two included studies showed inconsistent results.

[b]Downgraded by 1. The study size was probably inadequate as the OR overlapped 1.

[c]Downgraded by 1 as the method of allocation to mesh reconstruction or primary closure was not randomized.

[d]Downgraded by 1. The types of patients who had mesh reconstruction and primary closure were different.

[e]Downgraded by 1 as the power of the studies was inadequate.

[f]Downgraded by 1 as the included studies were series of mesh reconstruction only.

[g]Downgraded by 1 as there was no control treatment.

[h]Downgraded by 1. All studies were small case series with mesh reconstruction only.

[i]Downgraded by 1. The risk of bias is serious as the use of flap and mesh were in two different periods in both studies (not randomized).

[j]Downgraded by 1 as two reconstruction methods were performed in two different time periods; hence they were not compared directly and the timing of outcome assessment was considerably different.

Outcome

Q13. What are the effects and adverse effects of adding mesh to sphincter repair compared with conventional sphincter repair in treating anal sphincter injury?

In all, 350 references on mesh used in repairing the anal sphincter mechanism were screened for relevance; six papers were retrieved and four papers were included.

Two studies were case series with a small number of patients (16 and 13) [116,117] with no control group, so data from these studies were not analysable. One retrospective study [118] compared 12 patients with mesh to eight age-matched control patients without mesh, and one prospective study [119]compared 10 patients with mesh to 10 age-matched patients without mesh [117]. The selection criteria were not explained and each of the four studies used different types of mesh (polypropylene, Dacron, Permacol™, Surgisis®). The Wexner incontinence score was used in three of the studies and the score was reduced from 15.7 (18–14) to 8 (7–10), pre versus post repair. It was not possible to collate the scores for GRADE as only the median and range were reported. The follow-up was not specified in two studies and was up to 17 months in the other two studies. The overall reporting of complications was 4.5% (1 out of 22) in the mesh group versus 10% (1 out of 10) in the no mesh group (OR 0.83, 95% CI 0.11–5.94).

13.1 Complications: mesh versus no mesh, case series

Risk of bias: Downgraded by 1 as the risk of bias is serious as all studies were observational studies.

Inconsistency: Downgraded by 1. There was only one complication in each of the two studies, one in the mesh group and another in the control group, so there was a degree of inconsistency. It was also downgraded because the meshes used were different in all included studies.

Indirectness: Downgraded by 1. Control patients were age matched but selection bias is possible, so comparison may not be highly applicable. Outcomes were reported as cross-sectional with no long-term outcome.

Imprecision: Downgraded by 1 due to significant underpowering of the studies and a wide confidence interval.

Overall, the quality of evidence was very low combining the above assessments.

Q14. What are the effects and adverse effects of adding mesh to repairing ano/rectovaginal fistulas compared with conventional repair in treating ano/rectovaginal fistulas?

In all, 174 references on mesh used in repairing ano/rectovaginal and rectourethral fistulas were assessed and 18 articles were reviewed. Of these, 10 papers were excluded as they were case reports or had fewer than five patients included. Eight papers were selected for final review.

Six papers reported results of anovaginal fistula repair, one on a combination of anovaginal and rectourethral fistulas and one paper on rectourethral fistulas. Three studies were comparative studies and the others were case series and database studies. There were four studies that used Surgisis® mesh (88 patients) [120-123], two studies used Strattice™ mesh (13 patients) [124,125], one study used Permacol™ mesh (12 patients) [126] and one study used an unspecified biomesh (five patients) [127]. Outcome was reported as fistula healing or as recurrence of fistula. The length of follow-up was between 3 and 26 months. Healing rate was between 50% and 100% for ano/rectovaginal fistulas and 0% for rectourethral fistulas treated with mesh.

Recurrence was reported to be between 0% and 80%. No standardized scoring of functional status was performed but one study reported that there was no change in functional outcome after the procedure. Only four studies reported minor complications [123-126]; four studies did not report complications.

14.1 Recurrence: mesh versus no mesh, comparative studies and case series

Risk of bias: Downgraded by 1. Only two out of six studies reported outcomes for comparative groups. All studies had small numbers of patients.

Inconsistency: Downgraded by 1. Four of six studies had no comparators, the rate of recurrence varied from 4% to 80% and the meshes used differed in all included studies.

Indirectness: Downgraded by 1. Four of six studies had no comparators; thus comparison may not be highly applicable. Outcomes were reported as cross-sectional with no long-term outcome.

Imprecision: Downgraded by 1 as the effect was not estimable due to lack of comparators.

Overall, the quality of evidence was very low combining the above assessments.

14.2 Complications: mesh versus no mesh, case series

Risk of bias: Downgraded by 1. All studies were case series without comparators.

Inconsistency: Downgraded by 1. Two studies had no comparators. In the remaining two studies, there was only one complication in each, one in the mesh group and another in the control group, so there was a degree of inconsistency. Downgraded also because the meshes used differed in all included studies.

Indirectness: Downgraded by 1. Four of six studies had no comparators. Outcomes were reported as cross-sectional with no long-term outcomes.

Imprecision: Downgraded by 1 as the effect was not estimable due to the lack of comparators.

Overall, the quality of evidence was very low combining the above assessments.

Q15. What are the effects and adverse effects of using mesh to recreate the anorectal angle compared with conventional postanal repair for FI?

Sixty-one references on mesh used to recreate the anorectal angle as a treatment for FI were evaluated and six papers were reviewed in detail. One paper was excluded and five were included in the final review [128-132]. There were no comparative studies. Three studies were prospective series, one was an unselected cohort study and one was classified as a pilot study. Different surgical techniques were performed and different mesh material was inserted. In three studies [128,130,131] a polypropylene mesh was used (29 patients, six patients, 152 patients); in one study [132] a polyester mesh was used (eight patients) and in the cohort study [129] a simple silicone band (Jackson-Pratt™ drain) was used (33 patients). The length of follow-up varied from 6 to 180 months. The Wexner incontinence score was used to evaluate functional outcome in all studies. The score was reduced from 15 (18–13) to 7.8 (5–10) and the success rate of the treatment was indicated to be between 50% and 69%. However, none of the data was extractable for pooled analysis.

The complication rate was poorly recorded. In the papers that reported on complications, 21/228 (11.9%) patients with complications were registered.

15.1 Complications: mesh versus no mesh, case series

Risk of bias: Downgraded by 1 as all the studies were observational studies.

Inconsistency: Downgraded by 1. All studies used different types of mesh and surgical techniques.

Indirectness: Downgraded by 1 as there was no comparator.

Imprecision: Downgraded by 1 due to significant underpowering of the study.

Overall, the quality of evidence was very low combining the above assessments.

Q16. What are the effects and adverse effects of placing mesh through a transperineal approach compared with conventional repair in repairing rectocoele?

Ninety-six references were identified relating to mesh placed through a transperineal approach. After evaluation, 16 full papers were assessed in detail. Review articles (three) were excluded, and other studies were excluded because mesh was placed transvaginally (one), mesh was placed transanally (one) or the paper was not relevant (one). Of the 10 included articles [86,121,133,134,135,136,137,138,139,140], four were retrospective and six were prospective case series. There were no comparative studies. Different surgical techniques were performed and different mesh materials were inserted. There were three studies that used exclusively biological mesh (Surgisis®/Permacol™) and six that used synthetic mesh (polypropylene, polyglycolic acid mesh, Vipro, Marlex and an unspecified absorbable mesh). One study did not specify the mesh type used.

The length of follow-up varied from 2 to 120 months. The outcome measures assessed were variable in type and quality; nine of the studies used non-validated clinical measures of success—with 160/195 patients deemed to have had 'successful' treatment (82.1%). The Birmingham Bowel and Urinary Symptoms Questionnaire score was used in one study in which a significant improvement in symptoms was identified, but as the data were only reported using the average of the scores it was not possible to extrapolate data for improvement of function.

Across all studies the reported recurrence rate was 3/32 (9.4%) and the complication rate was 29/204 (14.2%)—four patients with urinary retention/infection, six with bleeding, nine with superficial wound infection, three with dyspareunia, seven with wound dehiscence, one with delayed wound healing, one mesh erosion, one reoperation for mesh trimming. The rate of mesh complications accounted for 2/204 (0.9%) of the total reported complications.

16.1 Recurrence: mesh versus no mesh, case series

Risk of bias: Downgraded by 1. The risk of bias is serious, as all studies were observational.

Inconsistency: Downgraded by 1. In one study [134], mesh was used in <10% of patients included in the study and the selection criteria for different procedures were not clear. Different meshes were used: one study did not clarify the mesh used and another study used two different types of mesh.

Indirectness: Downgraded by 1 as there was no comparator.

Imprecision: Downgraded by 1 as the power of the study was inadequate.

Overall, the quality of evidence was very low combining the above assessments.

16.2 Complications: mesh versus no mesh, case series

Risk of bias: Downgraded by 1. The risk of bias is serious, as all studies were observational.

Inconsistency: Downgraded by 1. None of the studies had comparators and complication rates ranged from 6% to 40%. Mesh type used differed between studies.

Indirectness: Downgraded by 1 as there were no comparators.

Imprecision: Downgraded by 1 as the power of the study was inadequate.

Overall, the quality of evidence was very low combining the above assessments.

Research gaps

In general, for Q13, Q14, Q15 and Q16 there is considerable heterogeneity in terms of surgical techniques, numbers of patients, types of meshes, outcome measures and reporting of complications. Further research would ideally be in the form of RCTs and must use validated outcome measures with long-term follow-up (Tables 26–29).

TABLE 26 Mesh compared to no mesh for anal sphincter repair

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Complications												
2	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[d]	None	1/22 (4.5%)	1/10 (10.0%)	RR 0.83 (0.11–5.94)	17 fewer per 1000 (from 89 fewer to 494 more)	⨁◯◯◯ VERY LOW	IMPORTANT
								0.0%		0 fewer per 1000 (from 0 fewer to 0 fewer)		

Abbreviation: RR, risk ratio.

[a]Downgraded by 1. Both studies were observational studies with no specific patient selection criteria.

[b]Downgrade by 1. In the two included studies, there was only one complication each, one in the mesh group and another in the control group; thus there was a degree of inconsistency. Downgraded also because the meshes used were different in the included studies.

[c]Downgraded by 1. Control patients were age matched but selection bias is possible; thus comparison may not be highly applicable. Outcomes were reported as cross-sectional with no long-term outcome.

[d]Downgraded by 1 due to significant underpower of the studies and wide CI.

TABLE 27 Mesh versus no mesh for repair of anorectovaginal fistula

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence												
6	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[e]	None	23/69 (33.3%)	–	–	–	⨁◯◯◯ VERY LOW	NOT IMPORTANT
Complications												
4	Observational studies	Serious[f]	Serious[g]	Serious[d]	Serious[e]	None	18/43 (41.9%)	Not pooled	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 1. Only two out of six studies reported outcomes for comparative groups. All studies had only a small number of patients.

[b]Downgraded by 1. Four of six studies had no comparators, and the rate of recurrence varied from 4% to 80%; meshes used were different in all included studies.

[c]Included heterogeneous patients (mixture of idiopathic and Crohn's fistula).

[d]Downgraded by 1. Four of six studies had no comparators; thus comparison may not be highly applicable. Outcomes were reported as cross-sectional with no long-term outcome.

[e]Downgraded by 1. Effect was not estimable due to lack of comparators.

[f]Downgraded by 1. All studies were case series with no comparators.

[g]Downgrade by 1. Two studies had no comparators. In the remaining two studies, there was only one complication each, one in the mesh group and another in the control group; thus there was a degree of inconsistency. Downgraded also because meshes used were different in all the included studies.

TABLE 28 Mesh compared to no mesh for recreating anorectal angle

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	No mesh	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Complications												
5	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[d]	None	21/228 (9.2%)	0/0	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	NOT IMPORTANT

[a]Downgraded by 1. All studies were case series of a small number of patients.

[b]Downgraded by 1. Studies used different types of mesh and surgical techniques.

[c]Downgraded by 1. All studies had no comparators.

[d]Downgraded by 1 due to significant underpower of the study.

TABLE 29 Should mesh be placed though a transperineal approach?

Certainty assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Q16	Placebo	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Recurrence												
2	Observational studies	Serious[a]	Serious[b]	Serious[d]	Serious[e]	None	3/32 (9.4%)	Not pooled	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	NOT IMPORTANT
Complications												
9	Observational studies	Serious[a]	Serious[c]	Serious[d]	Serious[e]	None	29/204 (14.2%)	Not pooled	Not pooled	refer main outcome	⨁◯◯◯ VERY LOW	

[a]Downgraded by 1. The risk of bias is serious as all studies were observational studies.

[b]Downgraded by 1. In one study [134], use of mesh was for <10% of all patients included in the study and the selection criteria for different procedures were not clear.

[c]Meshes used were different in included studies.

[d]Downgraded by 1 as there were no comparators.

[e]Downgraded by 1 due to significant underpower of the study.

[f]Downgraded by 1. None of the studies had comparators and complication rates ranged from 6% to 40%.

Management of complications of mesh used in the pelvis by colorectal surgeons

Q17. What are the effects, adverse effects and techniques to deal with mesh complications (conservative treatment, mesh removal, diversion), compared with no intervention?

Recommendations

- Detachment of mesh associated with symptoms of recurrence of full-thickness rectal prolapse could be considered for reoperation to reattach the mesh.
- Treatment of mesh erosion depends on the site. Surgical removal of mesh could be considered if it is technically feasible. This may require a defunctioning stoma.
- Re-intervention for mesh-related complications presents a significant clinical challenge and requires expertise and technical proficiency. This should only be performed at centres with experience of performing rectopexies with a robust system of outcome audit. It could be recommended that these cases are discussed at in-house multidisciplinary meetings but are carried out after discussion with an external network of urogynaecologists and colorectal surgeons. Outcomes should be recorded and rigorously monitored.

These are *conditional recommendations* based on expert opinion.

Rationale for the recommendations

There were only 10 studies that mention management of mesh complications related to rectopexy. It is uncertain whether this is due to an extremely low incidence of complications or under-reporting. Due to the paucity of complication data in the long term, the group has formulated recommendations based on available but limited data combined with their clinical experience.

Methods

PubMed and Embase search identified 2779 records. Titles and abstracts were screened permissively to include all possibly relevant studies. One hundred and ten full articles were screened and 10 articles were included.

Outcome

There was no RCT that directly compared different methods of handling mesh complications following rectopexy. There were 10 case series that mentioned complication management [16,28,42,71,80,81,141,142,143,144].

The most common reported mesh-specific complication was mesh detachment. It is difficult to ascertain the true incidence of mesh detachment. Badrek-Al Amoudi et al. [71] reported specifically on a series of mesh complications and identified a 10% (5/50) incidence of mesh detachment, while another study estimated the rate of mesh detachment as 2.7% at 10 years using Kaplan–Meier analysis [16]. The most common symptom associated with mesh detachment was recurrence of prolapse.

The second most frequently reported mesh complication was mesh erosion. The incidence is reported to be approximately 2% [28,81,141]. Sites of mesh erosion varied between studies, vaginal erosion being the most common, followed by rectal and rarely bladder erosion.

The most commonly reported management was transabdominal mesh removal (open or laparoscopic). Transanal or transvaginal removal could also be performed, depending on the site and extent of erosion. A defunctioning stoma was performed at the surgeon's discretion [71,81,141,142,144]. Rectal erosions were managed either by direct repair, anterior resection, or washout and defunctioning stoma. Jallad et al. [28] reported management of mesh exposure in the vagina with topical vaginal oestrogen cream alone.

Other reported complications included rectal stricture, rectovaginal fistula [42], stitch sinus [143] and discitis. Discitis was related to mesh fixation. There is one report of successful treatment by excision of the sacral portion of the mesh and a prolonged course of antibiotics.

There are conflicting opinions as to whether specific types of mesh are associated with a greater risk of mesh-specific complications. There is a report that more complications occur with use of synthetic mesh [81] whilst another reported the opposite with more complications with a biological mesh (Surgisis®, Biodesign®) [28]. The latter study performed concomitant sacrocolpopexy or sacrohysteropexy which may have affected the outcome.

Research gaps

There have been very few studies that systematically reported adverse events and their management. The follow-up was generally short or studies were cross-sectional and the possibility of missing data due to lost patients cannot be ignored.

As per the discussion in other sections, the definition of a complication needs to be established.

Although it has been advocated that the mesh for rectopexy placed transabdominally should have lower risk compared with transvaginal mesh, due to lack of contamination by vaginal bacterial flora, this may only be confirmed once long-term outcomes become available.

It is clear that this is a field still in its infancy. Patients' perspectives of their symptoms, intervention and outcome after re-intervention should also be explored.

DISCUSSION

General discussion

The group endeavoured to collate currently available evidence on the use of mesh in the pelvis in colorectal surgery with robust analysis using GRADE. Although there have been a few 'position

statements' such as those by ACPGBI on rectopexy [145] and perineal reconstruction [146] or systematic reviews analysing data using meta-analysis [147,148], the current guidance analysed all available data through GRADE so that the strengths and limitations are transparent, and the grade of recommendation is based on these analyses.

The guidance is only as good as the available data and some of the limitations include poor quality of data due to a shortage of RCTs. The bulk of the available studies were case series without controls; there was significant heterogeneity of included patients with regard to indications and lack of definition when reporting complications.

The majority of studies were case series or cross-sectional with variable follow-up periods. In most studies, short- and long-term outcomes were reported with median months used to define short- or medium- or long-term outcomes, without consideration for length time bias. Some studies did not report on complications and, when they did, details regarding complications were not always explicit.

There were significant challenges to extract data on complications as definitions of complications were variable. Reporting on mortality was very poor. Considering the increasing incidence of prolapse in an ageing population, it is important that perioperative mortality is reported clearly, regardless of whether it was directly related to the surgery or not.

There was also possible bias and selective reporting of other elements of the operations and consequences; some cited the 'D'Hoore' technique as VMR but also described some modifications that did not adhere to the techniques originally described.

Techniques of how mesh was applied, and whether rectal mobilization was performed, whether the lateral ligaments were divided may all impact on functional outcomes and complications, but these differences were difficult to extrapolate from most of the cross-sectional studies when various techniques were grouped together and outcomes were not reported separately.

There has been significant increase in the use of VMR for internal rectal prolapse and most of the studies included a mixture of external and internal rectal prolapse as indications. For external full-thickness prolapse, the primary goal of treatment is physical with the anatomical reduction of the prolapse, while that for internal prolapse is primarily functional. When the results for 'recurrence' are reported it is difficult to see to what extent there was recurrence of physical prolapse and how much a functional deterioration was defined as 'recurrence' for the internal prolapse group. Some studies defined postoperative occurrence of 'mucosal prolapse' as different from recurrence which required surgical intervention. Whether it was truly de novo or residual mucosal prolapse was difficult to interpret from the available literature.

As a limitation, the group acknowledges the fact that the extensive literature review led both historical and latest procedures to be included. LVMR has benefitted from much progress made in the understanding of pelvic floor disorders during the evolution of historical procedures. Most of these historical procedures have largely been abandoned (such as the Ripstein procedure) or modified accordingly. Therefore pooled data in some parts of the guidance have to be taken cautiously, as very different approaches are mixed and combined (laparoscopy vs. open, anterior vs. posterior mobilization and fixation, and other technical details that impact the final outcome).

Quality of life and functional outcome were often reported using quality of life scales/scores or bowel symptoms that may not be universally applicable. Use of manometric data as an outcome should be discouraged unless it correlates with functional outcomes. Equally, reporting of function should not just be the number of those with incontinence or ODS before and after, but how many had improvement, no change or worsening of the most troublesome symptom.

De novo constipation was a common complication following rectopexy with full mobilization. Despite the supposed benefit of VMR there were limited reports on whether there was reduction or less frequent de novo constipation. The results were often grouped as median and range of the constipation score and it was difficult to see how many patients truly improved. Instead, there were reports on restoration of anatomy as seen on defaecography that may not reflect improvement of individual symptoms. Future studies should report on de novo constipation or change in defaecatory function in more detail. For internal rectal prolapse, the current literature does not give clear guidance on the place of mesh rectopexy in the treatment of internal prolapse or intussusception.

Previous surgical history is important in relation to adhesiolysis and the possibility of bowel and organ injury. Related complications and conversion to open surgery need to be reported separately. Likewise, any combined operation (hysterectomy, hysteropexy etc.) and its outcome needs to be reported separately (often studies reported concomitant operations that had been done but outcomes for those who had combined operations were not reported separately).

There were very few RCTs regarding the use of mesh for pelvic reconstruction. There was little information regarding patient selection or decision making when the same procedure was performed (ELAPE or abdominoperineal resection), and these would have been helpful to identify issues not only of using mesh but also those who may benefit from the use of mesh.

There has been no study to compare whether mesh is superior to primary closure with any of the new vacuum-assisted devices or dressings and this is something that could be considered in the future. Consideration needs to be given to the possible issues associated with the use of mesh and whether omentum or other native tissue may be needed to protect the bowel from coming into direct contact with the vacuum-assisted device.

The number of studies on the use of mesh for other indications in the pelvis was limited and of low quality. Should the use of mesh be considered for any new indication in future, it should be introduced with the rigour of adequate training and supervision, prospective audit, and monitoring of long-term outcomes and complications.

Balance between innovation and patient safety

There are discrepancies between the extent of problems reported by patients who have suffered complications as a result of mesh

implantation in the pelvis and those reported in the literature. Patients have identified lack of information and an unsatisfactory consent process as highlighted by ACPGBI's position statement and the Mesh Oversight Group Report (https://www.england.nhs.uk/publication/mesh-oversight-group-report/). It is important that suggested registries and training contribute to safe introduction of new techniques/innovations in the wider community. When it comes to the use of expensive meshes it was not always clear whether there was a conflict of interest of the authors in their reports. In future, it is mandatory ethically to describe links between investigators and companies providing meshes and devices. Patient safety is paramount but may become evident only after long-term outcome is available. Awareness of long-term quality of life issues will increase understanding of the true picture of mesh in the pelvis.

RESULTS OF PUBLIC CONSULTATION AND PATIENTS' SURVEY

A website dedicated for international public consultation and patients' survey was launched in March 2020. The survey was offered in different languages and the guidelines were sent to dedicated patient organizations. The initial plan was to run the public consultation and patients' survey for 2 months.

Due to the COVID-19 pandemic, the consultation period was extended until the end of August 2020 to allow adequate time for people to respond. A limited number of responses from professionals and patients was received. Most of the patients' responses were provided by those who had undergone rectal prolapse surgery. The patient organization Meshedup emphasized that the period of follow-up in clinical studies as well as the relatively low number of patients and events could be hampering our ability to detect serious mesh-related complications. The group felt that it could gain more knowledge and receive responses if the process of public consultation and patients' survey were extended further into 2021, given the ongoing COVID-19 pandemic. In addition there was a technical issue of the site being spammed, which compromised some of the input from participants (unreadable).

In the light of this, the full results of the public consultation and patients' survey will be shared on the interactive ESCP Guideline website (https://www.escp.eu.com/guidelines) in due course once the extended consultation is completed.

UPDATE OF THIS GUIDANCE

The guidance should be updated in 7 years (2027).

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This project did not require approval by ethics committee.

AUTHOR CONTRIBUTION

Yasuko Maeda, Paul-Antoine Lehur, Lilli Lundby, and Carolynne J. Vaizey contributed to the conception of this guidance. All authors participated in data analysis, drafting manuscript and approving the final version.

DATA AVAILABILITY STATEMENT

All data are fully disclosed in the article.

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SUPPORTING INFORMATION

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