ESCP Guidance on use of mesh in pelvis in colorectal surgery

Yasuko Maeda, Eloy Espin, Kim Gorissen, Mia Kim, Paul-Antoine Lehur, Lilli Lundby, Ionut Negoi, Gregor Norcic, P. Ronan O'Connell, Tero Rautio, Bart van Geluwe, Gabrielle H. van Ramshorst, Andrea Warwick, Carolynne Vaizey

What does this paper add to the literature?

This is a comprehensive and rigorous review of currently available data on 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.

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DISCLAIMER

This guidance was formulated based on current published evidence.

The guidance is intended to provide information that may assist colorectal surgeons and other healthcare professionals and recommendations are targeted at clinicians only.

The recommendations in this guidance do not replace the need for clinical decision making to each individual presentation nor variations based on locality, facility and resource availability. Ultimately, doctors or other healthcare professionals must make individual decisions regarding particular clinical procedures or treatment plans taking into consideration clinical information presented by the patient and the diagnostic and treatment options available, using their knowledge and expertise. The guidance is unlike protocols or guidelines issued by employers, as the recommendations are not intended to be prescriptive defining a single or exclusive course of action, management or standard of care.

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EXECUTIVE SUMMARY

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

The outcome of 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 becomes more common, concerns have been raised, particularly in relation to 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

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 possibility of long-term mesh complications such as post-operative 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 defecation 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 of the remit of this guidance.

Use of mesh for external full-thickness 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]*
- 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 (SRUS). *[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 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 biologic 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 randomised controlled trials (RCTs) that report conflicting results concerning pelvic floor reconstruction using mesh. One showed no benefit of using mesh compared to primary closure following abdomino-perineal resection, whilst the second study did show benefit. The former study reported no difference in complication rate whilst the latter study indicated that post-operative 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 1/4 to 1/3 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. 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.

Recommendation

- 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 in this regard, as mesh-related complications in colorectal surgery were not explicitly reported, or some symptoms were attributed to

other conditions or stated ‘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 complications rates when mesh was not used.

Recommendation

- 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]*
- Reintervention 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 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 RCTs. There are many challenges to running a well-designed RCT with adequate power and randomisation 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 biologic 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 polytetrafluorethylene. 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 has been few RCTs, case-series have been largely of 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, have 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 widely been used in colorectal surgery and benefits and risks of such use have not been thoroughly assessed.

The European Society of Coloproctology (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 & 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 pelvis in colorectal surgery.

A call for other experts and stakeholders to take part was announced by ESCP e-newsletters and invitations by emails. 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 AGREE II tool[1] and in line with the guidance by the European Commission (Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR, '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 organisations in EU countries)
- Statutory organization (e.g. MHRA (Medicines and Healthcare products Regulatory Agency, UK) and equivalent organisations in EU countries)
- Organisations representing patients (e.g. Meshies United, Scottish MESH Survivors, TVT MUM (The Voices Today on Messed up Mesh), meshedup.eu, and similar organisations in other EU countries)
- Healthcare professional organisations (e.g. IUGA/ICS/ACPGBI/RCS and similar organisations in EU countries)
- Biomaterial specialists
- Surgical mesh manufacturers and industry representatives

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

Scope of guidance

The guidance defined a mesh as a sheet of synthetic or biologic material, manufactured to be implanted in humans. As such, it did not cover other types of implants such as neurostimulators, artificial sphincter devices, or injectable implants. The guidance aimed 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 aimed 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 other than full thickness rectal prolapse (e.g. internal prolapse/intussusception, anterior/posterior rectocoele, enterocoele, solitary rectal ulcer syndrome)

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

Use of mesh for full-thickness prolapse and obstructive defaecation symptoms

4. Does the use of mesh increase the risk of adverse events?
5. Do specific types of mesh increase the risk of adverse events?
6. Do certain surgical techniques (open/laparoscopic/robotic, fixation methods, concomitant resection, concomitant repair of other pelvic organ prolapse) reduce recurrence of prolapse or carry more risks of complications with the use of mesh?
7. 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

8. Is using a mesh in perineal reconstruction better than classical reconstruction (primary closure with mesh versus no mesh, transpositioned/interpositioned flap with/without mesh)?
9. Is one mesh better than others when used for perineal reconstruction?
10. Does the use of mesh increase the risk of adverse events?
11. Do specific types of mesh increase the risk of adverse events?
12. 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

13. Should a mesh be used in repairing the anal sphincter?
14. Should a mesh be used in repairing ano/rectovaginal fistula?
15. Should a mesh be used to recreate the anorectal angle for faecal incontinence?

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

16. Do any approaches (transabdominal/transvaginal) to implant mesh carry more risks?
17. 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 break down, 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/obstructive defaecation/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 supplementary material.

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 1) mesh in pelvis 2) 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 were solicited for refining search strategy and extracting relevant publications (please see *Acknowledgement*).

Study eligibility assessment and selection

The group identified all studies, both those fully published and in abstract form. Controlled and observational (prospective & 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 Grading of Recommendations Assessment, Development and Evaluation (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 were 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 4 groups to collate evidence from literature and draft statements.

The details of group members and process is presented as Supplement.

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 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 web site. Patients' views and experiences of mesh in 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 were 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 trans-perineal and trans-anal 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) all have been reported.

Since D'Hoore described the 'ventral mesh rectopexy (VMR)' procedure in 2004[5], it rapidly has become the most frequently performed intervention in Europe and Australia due to the attractive combination of the 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

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 vs no mesh, RCT

There were three RCTs assessing the efficacy of abdominal mesh rectopexy against a controlled intervention [Lundby 2016][Emile 2016][Luukkonen 1992].[2-4] Studies by Emile and Lundby used laparoscopic ventral rectopexy with polypropylene mesh as per the technique advocated by D'Hoore. The control group for the study by Emile was Delorme's procedure and that of Lundby's study was laparoscopic suture rectopexy. The study by Luukkonen 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 was deemed not serious. All 3 studies used sealed envelope methods. Methods of blinding were not clear in two studies (Emile and Luukkonen) but the overall risk of bias was low.

Inconsistency: There was no inconsistency among the included studies.

Indirectness: Downgraded by 1. Intervention of two studies were ventral/anterior mesh rectopexy whilst that of third study was posterior mesh rectopexy. The control intervention was different in all 3 studies.

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

Other considerations: Upgraded by 1. 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 vs no mesh, comparative studies

There were 7 studies which had a control group: however, 4 studies ([Benoist 2001][Formeijne Jonkers 2014][Makineni 2014][Sahoo 2014])[6-9] had no recurrence in either the mesh rectopexy group or the control groups, hence the effect was not estimable. The pooled data are from the remaining 3 studies ([Bishawi 2016][Lechaux 2005][Marchal 2005]).[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 I^2 statistic of 64% representing substantial heterogeneity.

Indirectness: Downgraded by 1. Three included studies had different interventions as control: one study [Bishawi 2016] was a cross-sectional study (mesh technique not specified), the second study was a mesh Orr-Loygue repair against suture rectopexy with sigmoid resection [Lechaux 2005], and the third study was an Orr-Loygue repair compared with Delorme's procedure [Marchal 2005].

Imprecision: 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 and beta=0.2 and power of 0.8, n=848 for each arm is needed for an adequately powered study. CI (0.13-1.96) overlaps no effect (included 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 vs mesh, observational studies

There were 38 studies reporting the outcome of use of mesh with rectopexy [Albayati 2017][Bjerke 2014][Boccasanta 1998][Consten 2015][Douard 2003][Dulucq 2007][Dyrberg 2015][Faucheron 2012][Fu 2017]]Gravie 2015][Gurland 2017][Haahr 2014][Himpens 1999][Holmstrom 1986][Inaba 2017][Jallad 2017][Launer 1982][Lechaux 2001][Madbouly 2018][Maggiori 2013][Makela-Kaikkonen 2014][McLean 2017][Mehmood 2014][Notaras 1973][Ogilvie 2014][Portier 2006][Randall 2014][Rautio 2016][Roberts 1988][Schultz 2000][Silveira 2017][Solomon 1996][Stevenson 1998][Swain 2018][Tjandra 1993][van Iersel 2017][Verdaasdonk 2006][Yang 2017][Zittel 2000] and one study reporting outcome of resection suture rectopexy [Stevenson 1998].[13-51] 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 was 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. Recurrence of full-thickness external rectal prolapse: mesh compared vs no mesh

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	mesh	no mesh	Relative (95% CI)	Absolute (95% CI)		
Recurrence: mesh vs no mesh RCT												
3	RCT	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 1,000** (from 71 fewer to 41 more)	⨁⨁⨁◯ MODERATE	IMPORTANT
Recurrence: mesh vs 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 1,000** (from 75 fewer to 77 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Recurrence: mesh vs 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	see comment	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **RR:** Risk ratio

Explanations

a. Downgraded by 1. Control intervention was different in 3 studies: Delorme's (Emile), abdominal suture rectopexy (Lundby) and abdominal rectopexy with sigmoid resection (Luukkonen).
b. Downgraded by 1 due to the power of all studies being inadequate and CI included RR of 1. With relative risk reduction RRR of 67% from the current analysis, with alpha= 0.05 and beta=0.2 and power of 0.8, n=285 for each arm is needed for an adequately powered study. CI overlaps no effect (included 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 included 3 studies with I2 statistic of 64% representing substantial heterogeneity.
e. Downgraded by 1. Three included studies had either no direct comparator or had different intervention as control: one study (Bishawi 2016) was a cross-sectional study (mesh technique not specified), second study was mesh Orr-Loygue against suture rectopexy with sigmoid resection (Lechaux 2005), and third study was Orr-Loygue compared against Delorme's procedure (Marchal 2005).
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 and beta=0.2 and power of 0.8, n=848 for each arm is needed for an adequately powered study. CI (0.13-1.96) overlaps no effect (included RR of 1).
g. Downgraded by 2. None of the studies had control arm.
h. Downgraded by 2. Number of participants were 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.

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.

Rationale for the recommendation

There was one study that compared absorbable and non-absorbable mesh and one study comparing biologic and synthetic mesh. Neither study was randomised. 30 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

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 vs non-absorbable mesh, comparative studies

One study directly compared absorbable (polyglycolic acid) and non-absorbable (polypropylene) mesh [Galili 1997].[53] 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, the method of randomisation nor blinding was not 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 vs synthetic mesh, comparative studies

There was only one case-matched study that compared non-cross linked biologic mesh

(Biodesign®, Cook Medical, Bloomington, IN, USA) and non-absorbable (polypropylene) mesh [Ogilvie 2014].[37] In both groups, the mesh was fixed posteriorly to the rectum. There was one recurrence among 14 patients (7%) in the biologic 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 due to the power of the study being inadequate. With relative risk reduction RRR of 66% from the current analysis (biologic mesh group recurrence 1/14=7% vs non-absorbable mesh group recurrence 4/19=21%, with alpha= 0.05, beta=0.2, and 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 vs synthetic mesh, observational studies

There were 30 studies that reported the outcome of use of mesh with rectopexy [Albayati 2017][Benoist 2001][Bjerke 2014][Boccasanta 1998][Consten 2015][Douard 2003][Dulucq 2007][Dyrberg 2015][Faucheron 2012][Formeijne Jonkers 2014][Gravie 2015][Himpens 1999][Holmstrom 1986][Inaba 2017][Lechaux 2001][Lechaux 2005][Maggiori 2013][Makela-Kaikkonen 2014][Makineni 2014][Marchal 2005][McLean 2017][Mehmood 2014][Notaras 1973][Portier 2006][Roberts 1988][Silveira 2017][van Iersel 2017][Verdaasdonk 2006][Yang 2017][Zittel 2000].[13,6,14-20,7,22,25-27,11,30,32,33,8,12,34-36,38,41,43,48,49,54,51]

The pooled recurrence rate in the biologic 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 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. 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 biologic (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. Recurrence of full-thickness external rectal prolapse: one mesh compared to another mesh

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	one mesh	another mesh	Relative (95% CI)	Absolute (95% CI)		
Recurrence: Absorbable vs non-absorbable												
1	observational study	serious [a]	not serious	not serious	serious [b]	none	1/20 (5.0%)	-	-	-	⨁◯◯◯ VERY LOW	CRITICAL
Recurrence: biological vs 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 1,000** (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	CRITICAL
Recurrence: biological vs 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	see comment	⨁◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. Although patients were randomly allocated to either mesh, the method of randomisation nor blinding was not clear.
b. Downgraded by 1 due to significant underpower of the study and CI overlaps no effect (included 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 relative risk reduction RRR of 66% from the current analysis (biologic mesh group recurrence 1/14=7% vs non-absorbable mesh group recurrence 4/19=21%, with alpha= 0.05 and beta=0.2 and power of 0.8, n=85 for each arm is needed for an adequately powered study. CI (0.03-2.92) overlaps no effect (included OR of 1).
e. Downgraded by 2. The risk of bias is very serious as none of the studies had control arm with no blinding and have potential selection bias.
f. Downgraded by 1. Number of participants were variable (9-242) with recurrence rate range of 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 biologic (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.

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 mobilisation has changed, as has the type of mesh, over time 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.[52] 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 randomised trials had patient input. The group feels this is crucial in future trials given recent adverse publicity regarding urogynaecological use of mesh.

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

Q3. Is mesh rectopexy effective for obstructive defaecation/faecal incontinence symptoms with internal prolapse/intussusception, anterior/posterior rectocoele, enterocoele, or 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*]. 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 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 recognises that the most important safety concern is long-term complications, such as major component mesh infection/erosion and pelvic pain. The panel emphasises 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, solitary rectal ulcer syndrome (SRUS) or a combination of the above mentioned.

Indications for surgery of these anatomical conditions are less well defined as reported symptomatic indications are variable including faecal incontinence (FI), obstructed defecation (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 is, however, outside of 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 and/or robotic ventral mesh rectopexy (LVMR and/or 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 lack of specification in the individual studies, results for these 3 subgroups were 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 obstructed defecation and constipation, observational studies

Seventeen studies reported on change in constipation and/or ODS with laparoscopic rectopexy for non-external rectal prolapse. [Albayati 2017][Borie 2014][Collinson 2010] [Consten 2015] [Formeijne Jonkers 2013] [Franceschilli 2015][Gosselink 2013 DCR][Gosselink 2015][Mantoo 2013][McLean 2018][Owais 2014][Portier 2011][Sileri 2012] [Tsunoda 2015][Wahed 2012][Wong 2011 DCR][Wong 2011 CD] [13,57,16,58-61,34,62-70]

There are limitations in interpreting the data. The paper by Consten *et al.* [Consten 2015] did not use any validated score and reported the number with new onset constipation and change of proportion of patients with presence of outlet obstruction as an outcome which may or may not co-exist with constipation. The paper bundled ERP and non-ERP patients, hence outcome specifically for non-ERP could not be extrapolated. Reporting results of mixture of ERP and non-ERP patients were also seen

in the papers by Albayati *et al.* [Albayati 2017], Formijne Jonkers *et al.* [Formijne Jonkers 2013], Mantoo *et al.* [Mantoo 2013], McLean *et al.* [McLean 2018] and Owais *et al.* [Owais 2014]. Assessing from the inclusion period of the cases, there is a concern that the paper by Formijne Jonkers *et al.* is likely to be completely overlapping with data presented in the paper by Consten *et al.* [Consten 2015]. Another two papers by the same author [Gosselink 2013 DCR] and [Gosselink 2015] are likely also to be overlapping, as one paper's inclusion period is August 2009 and July 2011 [Gosselink 2013 DCR] whilst the other paper's inclusion period is June 2010 to October 2012 for the same indication (LVMR for faecal incontinence)[Gosselink 2015]. The inclusion period and indication of rectopexy also overlapped in two papers by the same group of authors (Franceschilli *et al.* and Sileri *et al.*), hence only the latest paper [Franceschilli 2015] was included. The paper by Wahed *et al.* was excluded as the dataset was completely overlapping with the latest publication by the same group of authors [McLean 2018]. Wong published two papers on an overlapping group of patients: one paper [Wong 2011 DCR] compared the outcome of robotic vs laparoscopic ventral mesh rectopexy for complex rectocoele (63 patients) between March 2008 to December 2009, and the second paper on the outcome of laparoscopic mesh rectopexy for complex rectocoele (84 patients) between January 2004 and December 2008 [Wong 2011 CD]. As the former paper focused on operative and technical aspects with no functional outcome, only the latter was included.

As a result, only 8 out of 17 studies that reported on constipation and ODS specifically for non-ERP patients [Borie 2014][Collinson 2010][Franceschilli 2015][Gosselink 2013][Gosselink 2015] [Portier 2010][Tsunoda 2015] [Wong 2011 CD] were included, bearing in mind that four of these papers may contain overlapping data.

Five papers used Wexner or Cleveland Clinic Constipation score as an assessment tool while Borie *et al.*, Portier *et al.*, and Wong *et al.* used other scores or simply symptom descriptions.

The paper by Collinson *et al.* 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.* 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 median 20 months (range 6-54 months). Two studies

by the same group of authors ([Gosselink 2013][Gosselink 2015]) have overlapping inclusion periods of LVMR for faecal incontinence: the paper published in 2013 reported reduction of Wexner constipation score from a median of 13 to 8 at one year, whilst the paper published in 2015 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.* reported the proportion of patients with >50% reduction in their score (9 patients, 41%) and overall score change reported in median and range.

Borie *et al.* reported on functional outcome of LVMR for recto-anal intussusception and rectocoele, compared against Stapled Trans-Anal Rectal resection (STARR) using the Altomare's ODS score. The selection of STARR or rectopexy was not randomised and was based on whether the external sphincter was intact (for STARR) or not (rectopexy). Mean ODS score improved in both groups (16 to 7.6 in LVMR group and 15 to 6 in STARR group).

The paper by Portier *et al.* was a selective report of 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 2 patients with new onset constipation, but 13 of 20 patients with preoperative constipation were cured.

Wong *et al.* 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 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 faecal incontinence (FI), observational studies

Twenty studies reported information regarding FI. [Albayati 2017][Borie 2014][Collinson 2010][Consten 2015][Evans 2014][Formeijne Jonkers 2013][Franceschilli 2015][Gosselink 2013][Gosselink 2015][Makela-Kaikkonen 2014][Mantoo 2013][McLean 2018][Owais 2014][Portier 2010][Powar 2013][Sileri 2012][Slawik 2008][Wahed 2012][Tsunoda 2015][Wong 2011 CD]

In total, 12 studies were excluded. As stated in outcome 3.1.1, some studies did not report outcome separately for non-ERP patients ([Albayati 2017][Consten 2015][Formeijne Jonkers 2013][Mantoo 2013][McLean 2018] and [Owais 2014][Slawik 2008]). A paper by Wahed *et al.* was excluded as the dataset completely overlapped with the latest publication by the same group [McLean 2018] which was excluded as above. The inclusion period and indication of rectopexy also was overlapping in two papers by the same group of authors (Franceschilli *et al.* and Sileri *et al.*), hence only the latest paper [Franceschilli 2015] was included.

Study by Borie *et al.* reported on the incidence only of FI postoperatively. In contrast, a study by Powar *et al.* reported the number of patients with FI pre-operatively but did not report FI as one of the outcomes of their study. [Powar 2013] A RCT by a Finnish group mentioned preoperative FI in 2 patients randomised to RVMR and 1 patient in LVMR. [Makela-Kaikkonen 2014 Tech Coloprocto]

There were six studies that used Fecal Incontinence Severity Index (FISI) as an outcome assessment. [Collinson 2010][Evans 2014] [Franceschilli 2015][Gosselink 2013][Gosselink 2015] [Tsunoda 2015]
Collinson *et al.* 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.* looked into a cohort of patients with solitary rectal ulcer 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.* included 100 patients with internal rectal prolapse. Their definition of improvement was 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 20 months (range 6-54 months). It is worth noting that according to their definition, less than 50% of patients (n=43) suffered from FI with a FISI ≥10 pre-operatively.

Two studies by the same group of authors [Gosselink 2013][Gosselink 2015] have overlapping inclusion periods of laparoscopic VMR for FI: the paper published in 2013 reported on 74 patient 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 one year after VMR and 21 patients (29%) were reported to be completely continent one year after surgery. The paper published in 2015 included 43 patients with high-grade internal prolapse diagnosed by proctogram and 7 patients diagnosed by examination under anaesthesia. Their median preoperative FISI score was 42 (30-61), which improved to 25 (0-56) at one year ($p<0.01$) with 11 patients (22%) being completely continent.

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

One study used Cleveland Clinic (or Wexner) Incontinence Score. [Portier 2010] Portier *et al.* 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 CCIS was 13.3 (SE 4.25) preoperatively, which improved to 3 (SE 3.44) postoperatively (P=0.001) at mean follow-up of 22 months (SE 21). 27 patients complained of urgency preoperatively which improved to 8 postoperatively. Twenty-six patients felt their FI was cured.

A study by Wong *et al.* [Wong 2011 CD] performed VMR for rectocoele. They did not use a validated score but used questionnaires and VAS scale. Twenty patients had symptoms of FI preoperatively and 16 patients suffered from persistent FI post-operatively ($p>0.05$).

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 intra-rectal, 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 6 studies used FISI, the scores were evaluated at various different follow-up points and could not separately be 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. 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		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	rectopexy	[comparison]	Relative (95% CI)	Absolute (95% CI)		
Improvement in symptoms of obstructive defection 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

Explanations

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. Number of included patients was small.
f. Patients with mixed pathologies (intra-rectal/intra-anal prolapse and solitary rectal ulcer) and relationship between these pathologies and symptom severity were 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.

3.2 New onset or worsening symptoms of constipation/obstructive defaecation, faecal incontinence or dyspareunia

Overall, published data were not sufficiently explicit to identify new onset symptoms of constipation/OD 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 [Albayati 2017][Consten 2015][Formeijne Jonkers 2013][Mantoo 2013][McLean 2018] and [Owais 2014][Slawik 2008]. The paper by Wahed *et al.* was excluded as the dataset overlapped with the latest publication by the same group [McLean 2018] 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.* and Sileri *et al.*), hence only the latest paper [Franceschilli 2015] was included.

3.2.1 New onset or worsening of constipation and obstructive defaecation

There were three studies reporting worsening of constipation and ODS. Tsunoda *et al.* assessed patients with evacuation proctography post-laparoscopic ventral rectopexy for rectoanal intussusception. Of 26 patients included in the study, 2 experienced worsening of ODS and one developed de novo constipation. [Tsunoda 2015] Other studies have reported similar occurrence of worsening symptoms of ODS [Makela-Kaikkonen 2014 Tech Coloprocto] or new onset of constipation. [Portier 2010]

Four studies reported no new onset of constipation. [Collinson 2010][Franceschilli 2015][Gosselink 2015][Wong 2011 CD]

3.2.2 New onset or worsening of faecal incontinence

Two studies reported on persistent FI but details were not available as to whether symptoms had deteriorated: One study reported that 12 patients (24%) with high rectal internal prolapse had persistent FI at one-year follow-up. The second study reported 4 out of 21 with persistent FI. [Gosselink 2015][Tsunoda 2015]

Four studies reported no new onset of FI. [Collinson 2010][Evans 2014][Franceschilli 2015][Wong 2011 CD]

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 laparoscopic VMR. [Collinson 2010] However, most studies did not report on this outcome as either a primary or secondary endpoint.

3.3 Recurrence

Recurrence is one of the outcomes considered an important endpoint in treatment for rectal prolapse. However, there appears to be significant under-reporting of this endpoint 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.* reported 4 patients (5%) who had recurrence of IRP on proctography, two of whom benefitted from reattachment of mesh.[57][Collinson 2010] Another study reported recurrence on post-operative proctography: Gosselink *et al.* reported that 3 of 43 patients with high grade internal rectal prolapse had persistent internal rectal prolapse (IRP) on postoperative proctography and experienced recurrent or persistent symptoms.[61][Gosselink 2015]

Two studies each reported a single recurrence without further details.[33,66] [Makela-Kaikkonen 2014 Tech Coloprocto [Portier 2011] No long-term follow-up data were available.

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

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

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

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

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

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

Six studies reported the healing rate of SRUS. [Badrek-Amoudi 2012][Evans 2013][Kargar 2011][Marchal 2001][Tweedie 2005][Slawik 2007][71-76]. Two of these papers [Badrek-Amoudi 2012][Slawik 2007] were from the same centre with overlapping inclusion periods, hence only the most recent paper [Badrek-Amoudi 2012] was included.

Badrek-Amoudi *et al.* reported the outcome of 48 patients with SRUS and is the largest published series of laparoscopic VMR 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 one month to 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.* reported on 30 patients with SRUS who underwent LVMR. Of these, 21 healed, 9 had non-resolution and required further interventions (6 posterior STARR).

Kargar *et al.* 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.* reported outcomes of various interventions (excision, stoma, Delorme's) for SRUS. Of 13 patients, 3 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.* reported a case series of patients who underwent laparoscopic VMR for SRUS. The rectal ulcer healed in all 11 patients and in 7 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, studies having small numbers included, being retrospective in nature and the absence of 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. Timings of follow-up were variable with no consistent outcome measures.

Indirectness: Downgraded by 1. One study had 3 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. 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 SRUS

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	rectopexy	[comparison]	Relative (95% CI)	Absolute (95% CI)		
Healing of SRUS												
5	observational studies	serious [a]	serious [b]	serious [c]	serious [d]	none		not pooled	not pooled	see comment	⨁◯◯◯ VERY LOW	IMPORTANT

Explanations

a. The included studies were not randomised nor had control groups.
b. Three of the five studies used ventral mesh (D'Hoore technique), one study used ventral mesh (Orr-Loygue technique) and one study posterior mesh. Timings of follow-up were variable with no consistent outcome measure.
c. One study had 3 interventions (stoma, Delorme's and Orr-Loygue) and the selection to each intervention was unclear. One study used surrogate outcome measure.
d. The sample size of all studies was small and total number of participants in the five studies is less than the number of participants required for a single adequately powered trial.

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 chapter was hindered by the lack of 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 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 (*NB: Influence of (types of) mesh will be discussed in other chapters*). The group recognises 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 [Mackenzie 2014][Pucher 2017].[55,56]

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 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 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, with relatively short follow-up, thereby providing GRADE evidence of very low quality. There is an absolute need for RCTs, although the panel also recognises that a randomised controlled comparison of VMR versus conservative management will have many problems of its own.

Use of mesh for external full-thickness rectal prolapse and obstructive defaecation: 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 7 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 makes it difficult to translate it to the complication rate of anterior/ventral mesh rectopexy.

- There was only one randomised study which showed occurrence of de novo constipation or exacerbation of constipation with mesh rectopexy in 1/3 of patients, compared with the control group (resection rectopexy) which 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

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 vs no mesh, randomised controlled studies

Three randomised controlled studies reported the incidence of all complications that occurred [Emile 2016][Lundby 2016][Luukkonen 1992].[2,77,4] 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 3 studies used sealed envelope methods. Methods of blinding were not clear in two studies (Emile and Luukkonen) 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 3 studies.

Imprecision: Downgraded by 2 due to the power of all studies being inadequate.

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

4.2 Overall complication: mesh vs no mesh, comparative studies

There were 7 studies that reported complications with the use of mesh rectopexy against rectopexy without mesh [Benoist 2001][Formijne Jonkers 2014] [Lechaux 2005] [Makineni 2014] [Marchal 2005] [Rose 2002] [Sahoo 2014].[6,7,11,8,12,78,9] 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 [Formijne Jonkers 2014] used an anterior mesh rectopexy giving 31.1% weight in the total effect analysis. The rest were posterior in two, Orr-Loygue (2), Ripstein technique (1) and in one study the technique was not clear [Rose 2002].

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 I^2 statistic of 61% representing substantial heterogeneity.

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

Imprecision: Downgraded by 2 due to the power of all studies being inadequate. CI (0.76-1.94) overlaps no effect (included OR of 1).

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

4.3 Major and minor complication: mesh vs no mesh, randomised controlled studies

There was only one randomised controlled study that specifically reported on major and minor complications separately [Emile 2016]. The incidence of major complications in both mesh rectopexy and in the control group was 0%, thus the effect was not estimable.

Minor complications occurred in 5 of 25 patients (20%) in the mesh rectopexy group while 3 of 25 patients (12%) had minor complications in the control group.

Risk of bias: The risk of bias was 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 OR of 1).

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

4.4 Major and minor complications: mesh vs 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 [Formijne Jonkers 2014]. Major complications occurred in 2 of 40 patients (5%) in the mesh group, (both myocardial ischaemia (Clavien-Dindo Grade IV)) while one of 28 patients (3.6%) 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 2 of 40 patients (5%) in the ventral rectopexy group versus 8 of 28 (28.6%) 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 where 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 vs no mesh, randomised controlled studies

Three randomised controlled studies reported on the incidence of mortality [Emile 2017][Lundby 2016][Luukkonen 1992]. 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 3 studies used sealed envelope methods. Methods of blinding were not clear in two studies (Emile and Luukkonen) 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 3 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 vs no mesh, comparative studies

There were 3 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). [Benoist 2001][Makineni 2014][Marchal 2005].

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, RCT

There was only one study [Luukkonen 1992] 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 5 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 was 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. ([Benoist 2001][Dulucq 2007][Dyrberg 2015][Formeijne Jonkers 2014][Gravie 2015][Himpens 1999][Lechaux 2005][Maggiori 2013][Makineni 2014][Marchal 2005][McLean 2017][Portier 2006][Roberts 1988][Schultz 2000][Verdaasdonk 2006] [Zittel 2000]. [6,18,19,7,22,25,11,32,8,12,34,38,41,42,49,51]

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 4 studies ([Benoist 2001] [Formijne Jonkers 2014][Lechaux 2005][Marchal 2005]) had a comparative group to estimate the true effect.

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

Risk of bias: Downgraded by 2. The risk of bias is very serious as no study was randomised 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 generalise 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.

Table 5. Does the use of mesh increase the risk of adverse events?

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)		
Overall complications: randomised controlled studies												
3	randomised trials	not serious	not serious	serious [a]	very serious [b]	none	9/78 (11.5%)	10/77 (13.0%)	**OR 0.88** (0.33 to 2.31)	**14 fewer per 1,000** (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 to 1.94)	**0 fewer per 1,000** (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 to 16.48)	**14 more per 1,000** (from 31 fewer to 343 more)	⨁◯◯◯ VERY LOW	IMPORTANT
								0.0%		**0 fewer per 1,000** (from 0 fewer to 0 fewer)		
Minor complications: randomised controlled study												
1	randomised trials	not serious	not serious	serious [j]	very serious [k]	none	5/25 (20.0%)	3/25 (12.0%)	**OR 1.83** (0.39 to 8.67)	**80 more per 1,000** (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 to 0.68)	**236 fewer per 1,000** (from 72 fewer to 274 fewer)	⨁◯◯◯ VERY LOW	IMPORTANT
Mortality: randomised controlled studies												

3	randomised trials	not serious	not serious	serious [a]	serious [b]	none	0/78 (0.0%)	1/77 (1.3%)	**OR 0.31** (0.01 to 8.28)	**9 fewer per 1,000** (from 13 fewer to 85 more)	⨁⨁◯◯ LOW	IMPORTANT
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 to 3.29)	**0 fewer per 1,000** (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. The control intervention was different in all 3 studies, including both perineal and abdominal intervention.
b. Downgraded by 1 due to the power of all studies being inadequate. CI overlaps no effect (included 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 I2 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. CI (0.76-1.94) overlaps no effect (included OR of 1).
g. Downgraded by 1. The risk of bias is serious as the study did not randomise patients and was data amalgamation of two centres with each centre exclusively performing one procedure. As such, there was no blinding and have potential selection bias.
h. Downgraded by 1 due to different techniques were used.
i. Downgraded by 1 due to the power of the study being inadequate and CI overlaps no effect (included OR of 1)
j. Downgraded by 1. The control intervention was perineal approach, thus patient selection and nature of complications are different. This study may not provide direct answer to the clinical question.
k. Downgraded by 1 due to the power of the study being inadequate. CI overlaps no effect (included 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							№ of patients		Effect		Certainty	Importance
№ 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 RCT												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	5/15 (33.3%)	0/15 (0.0%)	**OR 16.24** (0.81 to 325.88)	**0 fewer per 1,000** (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

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1 due to significant underpower of the study and CI overlaps no effect (included RR of 1).
b. Downgraded by 2. The risk of bias is very serious as none of the studies was randomised studies with no blinding and have potential selection bias.
c. Downgraded by 2. Although I2 statistic was 0%, odd ratios ranged from 0.69 to 4.8 with no significant overlap of CI and CI including 1, suggesting substantial heterogeneity.
d. Downgraded by 2. Techniques (D'Hoore, Orr-Loygue, Posterior, Wells) of investigated arm rectopexy and control group (suture rectopexy, posterior, suture rectopexy with resection, Delorme's) were variable and different, which makes it difficult to generalise the findings.
e. Downgraded by 1 due to the power of all studies being inadequate.

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

Recommendation

- Either biologic 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 biologic mesh may be superior in preventing mesh related complications.
- There were more overall complications seen with the use of biologic mesh (28%) compared with synthetic mesh (14%). Mesh specific complications occurred less frequently with the use of biologic 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.

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-text articles were screened and 5 articles were included.

Outcome

5.1 Overall complications: biological vs synthetic mesh, comparative studies

There was no randomised study. There were two studies that reported complications following mesh rectopexy for both biologic and synthetic mesh [Ogilvie 2014][Swain 2018].[37,46] The study by Ogilvie *et al.* used non-cross linked biologic mesh (Biodesign®) and polypropylene mesh, while Swain *et al.* used Prolene and Permacol™ mesh. In both studies, the technique was ventral rectopexy.

The study by Swain *et al.* reported no complications in either group (possibly due to short follow-up), hence the effect was not estimable. Ogilvie *et al.* reported 28% (8/29) complications in the biologic 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 Complication: absorbable vs non-absorbable mesh, randomised controlled trial

There was one study [Galili 1997][53] 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 it 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, the method of randomisation nor 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 vs synthetic mesh, comparative studies

There were 2 studies reporting the outcome of the use of mesh with rectopexy [Borie 2016][Evans 2015].[79,80]

Borie *et al.* 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 while that of polypropylene it was 1.1%. There was no significant statistical difference.

Evans *et al.* pooled data of ventral rectopexies done in 5 centres (3 in UK, 1 in Australia, 1 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 biologic mesh was 0.7%.

Risk of bias: Downgraded by 1. The risk of bias is serious as none of the studies were randomised 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 biologic and synthetic meshes. The selection criteria for use of a specific type of mesh was 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: Do specific types of mesh increase the risk of adverse events?

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	One mesh	another mesh	Relative (95% CI)	Absolute (95% CI)		
Complications: biologic vs 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 to 9.03)	**123 more per 1,000** (from 40 fewer to 429 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Complications: absorbable vs non-absorbable												
1	randomised trial	serious [c]	not serious	not serious	serious [b]	none	5/20 (25.0%)	4/17 (23.5%)	**OR 1.08** (0.24 to 4.90)	**14 more per 1,000** (from 167 fewer to 366 more)	⨁⨁◯◯ LOW	IMPORTANT
Mesh specific complications: biologic vs 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

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. The studies were cross-sectional with no blinding and have potential selection bias.
b. Underpowered.
c. The method of randomisation nor blinding was unclear
d. None of the studies was a randomised controlled and they were retrospective in nature.
e. One study compared the outcome between two different synthetic meshes, whilst the other study looked into both biologic and synthetic meshes. The selection criteria for the use of a specific type of mesh was not clear in both 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.

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 (laparoscopy/open/robotic) is superior in preventing recurrence.

One randomized controlled trial 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 onto modern practice.

Available data were generally of low or very low quality. There was no study that directly compared 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 impact on recurrence or complication.

Outcome

6.1. Laparoscopy versus open

6.1.1. Laparoscopy versus open: Recurrence

There was one randomised controlled study [Solomon 2002] and 2 observational comparative studies [Boccasanta 1998][Solomon 1996].[81,15,44]

The randomised controlled study was focused on technical feasibility, recovery from surgery and non-inferiority of laparoscopy. The study by Boccasanta *et al.* used Wells rectopexy with polypropylene mesh while the study by Solomon *et al.* 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 RCT. The only randomised controlled study was single-blinded (assessors) and the method of randomisation was not made explicit in the paper. Downgraded by 1 for two comparative studies as there was no randomisation and selection criteria for allocating treatment were not clear.

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

Indirectness: No concern for RCT. Downgraded by 1 for observational studies as the techniques used were different and type of used mesh 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: Laparoscopy compared to open for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	laparoscopy	open	Relative (95% CI)	Absolute (95% CI)		
Recurrence: Laparoscopy vs open, randomised controlled study												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	0/20 (0.0%)	1/19 (5.3%)	**OR 0.30** (0.01 to 7.85)	**36 fewer per 1,000** (from 52 fewer to 251 more)	⨁⨁◯◯ LOW	IMPORTANT
Recurrence: Laparoscopy vs open, comparative studies												
2	observational studies	serious [c]	not serious	serious [d]	serious [e]	none	0/29 (0.0%)	not pooled	not pooled	see comment	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. Single-blinded and randomisation method unclear.
b. Downgraded by 1 as the power of study was not adequate.
c. Downgraded by 1 as there was no randomisation and selection criteria for each group was not clear.
d. Downgraded by 1 as techniques and used mesh were variable.
e. Downgraded by 1 as the studies were inadequately powered and effect was not estimable because of null values in both groups.

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. [81,15,44]

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. Pooled analysis of both comparative observational studies, including posterior mesh rectopexy [Solomon 1996] and Wells rectopexy with polypropylene mesh [Boccasanta 1998], 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. [Boccasanta 1998][Solomon 1996] No conclusion could be drawn.

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

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

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

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

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

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Table 9: Open compared to laparoscopy in complication

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Open	laparoscopy	Relative (95% CI)	Absolute (95% CI)		
Overall complications: randomised controlled studies												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	14/19 (73.7%)	6/20 (30.0%)	**OR 0.20** (0.04 to 0.90)	**221 fewer per 1,000** (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 to 2.94)	**0 fewer per 1,000** (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	
Major complications: open vs lap RCT												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	4/19 (21.1%)	0/20 (0.0%)	**OR 0.07** (0.00 to 1.34)	**0 fewer per 1,000** (from 0 fewer to --)	⨁⨁◯◯ LOW	
Mortality: open vs lap												
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 to 9.43)	**17 fewer per 1,000** (from 27 fewer to 181 more)	⨁◯◯◯ VERY LOW	

CI: Confidence interval; **OR:** Odds ratio

Explanations

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

6.2. Laparoscopy versus robotic

6.2.1. Laparoscopy versus robotic: Recurrence

There were three comparative studies comparing a robotic to a laparoscopic approach [Brunner 2018][Makela-Kaikkonen 2014][Mehmood 2014].[82,33,35]

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 (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 [Haahr 2014][Inaba 2017][Swain 2018][van Iersel 2017]. 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.* stated that the treatment was allocated randomly in a 2:1 ratio, but the method of randomisation was not stated.

Inconsistency: There was no inconsistency as only 0 or 1 recurrence in each arm.

Indirectness: Downgraded by 1. All studies used the VMR technique, however Brunner *et al.* used biologic mesh while Makela-Kaikkonen *et al.* included rectopexy for rectal intussusception. This makes it difficult to generalise interpretation of the results.

Imprecision: Downgraded by 2. All studies were underpowered and reported outcome were of short-term.

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

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Table 10: Robot compared to laparoscopy for full-thickness external rectal prolapse

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	robot	laparoscopy	Relative (95% CI)	Absolute (95% CI)		
Recurrence: robot vs laparoscopy, 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 to 5.55)	**15 fewer per 1,000** (from 31 fewer to 126 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. Two studies were cross-sectional studies with no randomisation. One study stated laparoscopic or robotic approach was randomly allocated 2:1 but method of randomisation 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 biologic mesh, making the findings difficult to compare directly.
c. Downgraded by 2. All studies were underpowered with short-term results only.

6.2.2. Laparoscopy versus robotic: Complications

One randomized controlled trial [Makela-Kaikkonen 2016] and four observational studies [Brunner 2018][Makela-Kaikkonen 2014][Mantoo 2013] [Mehmood 2014] analyzed complications of patients following robotic and laparoscopic VMR, including patients with either external or internal rectal prolapse.[83,82,33,65,35]

While both studies by Makela-Kaikkonen *et al.* showed a non-significant, but higher risk for complications after a robotic procedure, the study by Mantoo *et al.* 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 randomisation method was clearly explained.

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

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

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

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

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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 [Makela-Kaikkonen 2014] [Mantoo 2013].

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

Table 11: Laparoscopy compared to robot for complication

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Laparoscopy	robot	Relative (95% CI)	Absolute (95% CI)		
Complications: a randomised controlled study												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	3/16 (18.8%)	1/14 (7.1%)	**OR 3.00** (0.27 to 32.75)	**116 more per 1,000** (from 51 fewer to 644 more)	⨁⨁◯◯ LOW	IMPORTANT
Complications: observational studies												
4	observational studies	serious [b]	serious [c]	serious [d]	serious [a]	none	9/104 (8.7%)	37/228 (16.2%)	**OR 0.50** (0.23 to 1.09)	**74 fewer per 1,000** (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	see comment	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. The power of the study was inadequate.
b. These were not randomised 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.

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 [Lechaux 2005].[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)[Eftaiha 2017].[84] Use of biologic 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 randomisation.

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

Indirectness: Downgrade by 1. The study by Lechaux et al. 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.

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

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	with sigmoid resection	without sigmoid resection	Relative (95% CI)	Absolute (95% CI)		
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 to 1.00)	**211 fewer per 1,000** (from 270 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 2. No randomisation. 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 vs suture rectopexy with resection.
d. Downgraded by 2. The study was significantly underpowered.
e. Downgraded by 2. No randomisation. The study was a retrospective review of patients.

6.3.2. With or without sigmoid resection: Complications

Two relevant papers were also included in the previous section. Eftaiha *et al.* 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.* 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 [Rose 2002].[78] The methods of rectopexy were variable, as some patients had suture only, while 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 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 was 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 procedure.

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: With resection compared to without resection in complication

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	With resection	without resection	Relative (95% CI)	Absolute (95% CI)		
Complications: with resection vs 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 to 3.87)	**22 fewer per 1,000** (from 203 fewer to 319 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

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.

6.4. With or without concomitant repair of other pelvic organ prolapse

One study reported outcomes without a control arm [Jallad 2017],[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 lateral ligament [Benoist 2001].[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 (3 studies: [Maggiori 2013][Notaras 1973][Zittel 2000])[32,36,51] or preserved the lateral ligaments (14 studies: [Bjerke 2014][Boccasanta 1998][Douard 2003][Dryberg 2015][Faucheron 2012][Gravie 2015][Inaba 2017][Lechaux 2001][Lechaux 2005][Makineni 2014][Marchal 2005][Van Iersel 2017][Verdaasdonk 2006][Yang 2017]).[14,15,17,19,20,22,27,30,11,8,12,48,49,54] The pooled results from the 3 studies showed recurrence to be 2% after division while those of the 17 studies with ligament preservation showed 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 randomisation.

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. 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: Lateral ligament divided compared to preserved for full-thickness external rectal prolapse

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	lateral ligament divided	preserved	Relative (95% CI)	Absolute (95% CI)		
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	see comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 2. All studies were cross-sectional studies with no randomisation.
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.

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) [Benoist 2001].[6] As there was only one mesh group with divided lateral ligaments, 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 randomisation.

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

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ 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)		
Q6 Complications: with vs 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 to 5.69)	**4 fewer per 1,000** (from 120 fewer to 348 more)	⨁◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. No randomisation.
b. Reporting outcomes at short-term
c. Underpowered study and 95% CI overlapped 1.

6.6. With or without peritoneal closure: Recurrence and complications

24 studies reported whether the peritoneum was closed after rectopexy: two studies showed outcomes of not closing and closing the peritoneum ([Dyrberg 2015][Lechaux 2001]).[19,30] Other studies reported outcomes following closure of the peritoneum ([Albayati 2017][Bjerke 2014][Emile 2017][Faucheron 2012][Formijne Jonkers 2014][Gravie 2015][Inaba 2017][Lechaux 2005][Maggiori 2013][Makela-Kaikkonen 2014][McLean 2017][Mehmood 2014][Notaras 1973][Ogilvie 2014][Portier 2006][Rautio 2016][Sahoo 2014][Silveira 2017][Swain 2018][Van Iersel 2017][Verdaasdonk 2006][Yang 2017]).[13,14,85,20,7,22,27,11,32-38,40,9,43,46,48,49,54]

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 randomisation.

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.

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

Certainty assessment							No. of patients		Effect		Certainty	Importance
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)		
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	see comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 2. All studies were cross-sectional studies with no randomisation.
b. There was 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		Certainty	Importance
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)		
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	see comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. No randomisation; no comparison.
b. Estimates widely varies across studies.
c. Highly heterogeneity of the included patients.
d. Large 95% confidence intervals.

6.7. Type of mesh fixation

6.7.1. Type of mesh fixation: Recurrence

24 studies reported mesh fixation methods: ten studies used sutures ([Boccasanta 1998][Douard 2003][Lechaux 2001] [Lechaux 2005][Makineni 2014][Notaras 1973][Roberts 1988][Sahoo 2014] [Yang 2017][Zittel 2000]) [15,17,30,86,8,36,41,9,54,51] and the remaining studies (14) used ProTack™, spiked chromium or staplers ([Albayati 2017][Benoist 2001][Bjerke 2014][Dryberg 2015][Emile 2017][Faucheron 2012][Formijne Jonkers 2014] [Makela-Kaikkonen 2014][Mehmood 2014][Rautio 2016][Solomon 1996][Swain 2018][Van Iersel 2017][Verdaasdonk 2006]). [13,6,14,19,85,20,7,33,35,40,44,46,48,49]

One observational study compared use of glue and suture for mesh fixation [Silveira 2017].[43]

The pooled results showed 4.9% recurrence with the use of ProTack™/staples compared with 3.9% following suture fixation of mesh. 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 randomisation.

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.

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 6.7.1 were analysed.[15,17,30,85,8,36,41,9,53,51, 13,6,14,19,84,20,7,33,35,40,44,46,48,49, 43] The pooled results showed 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 [Silveira 2017].[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% versus 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 randomised.

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

Indirectness: Downgraded by 1. The study comparing glue with suture fixation by Silveira et al 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.

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

Certainty assessment							No. of patients		Effect		Certainty	Importance
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)		
Recurrence: mesh fixation using ProTack™/staple vs 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 vs 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 to 6.01)	**38 more per 1,000** (from 111 fewer to 376 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 2. All studies were cross-sectional studies with no randomisation.
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 observational cohort study with no randomisation. 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		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	suture	ProTac/stapler	Relative (95% CI)	Absolute (95% CI)		
Complications: suture vs. 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	see comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. No randomisation; no comparison.

b. Estimates widely varies 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							№ of patients		Effect		Certainty	Importance
№ 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 vs 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 to 2.87)	**6 fewer per 1,000** (from 57 fewer to 122 more)	⨁◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. No randomisation.
b. The reported outcomes were short-term only.
c. Significantly underpowered study.

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) vs Orr-Loygue, or VMR vs Ripstein or VMR vs posterior mesh. One study compared the outcome of VMR and Wells rectopexy [Madbouly 2018].[31]

Risk of bias: Downgraded by 2. The study was a retrospective review, hence no randomisation. 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 analyzed VMR in comparison to posterior sling rectopexy (Wells procedure) [Madbouly 2018].[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 retrospective design and small sample size.

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

Inconsistency: Not applicable as only one study was included.

Indirectness: Not considered serious. The reported outcomes at various time point.
Imprecision: Downgraded by 2. The study was significantly underpowered.
Overall quality of evidence was considered very low.

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

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	D'Hoore	Wells	Relative (95% CI)	Absolute (95% CI)		
Recurrence: D'Hoore vs 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 to 13.29)	**6 fewer per 1,000** (from 29 fewer to 263 more)	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 2. The study was 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 vs 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 to 4.52)	**62 more per 1,000** (from 87 fewer to 319 more)	⨁◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Retrospective study.
b. Underpowered study and 95% CI overlapped 1.

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 post-operative complications. Definitions varied, some included complications only during the peri-operative period, 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 pre- and post-operatively 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 other?

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].
- 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% versus 21.8%). One study reported that mesh was more cost effective than using 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 a 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 compared directly biological mesh with synthetic mesh, or one biological mesh against another. As there were no comparative data, it was not possible to analyze 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 APR 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 post-operative 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

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 4 abstracts

were deemed relevant to address the themes in this chapter. Only papers reporting on perineal reconstruction with mesh or flap were included.

Two RCTs compared primary closure with closure using biological mesh [Han 2012, Musters 2017].[88,89] 13 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) [Moreno-Sanz 2011],[90] HADM (human acellular dermal matrix mesh, Qingyuanweiye Bio-Tissue Engineering)[Chi 2013][Han 2010][Han 2014],[91-93] Permacol™ (a porcine dermal cross-linked collagen, Covidien) [Abhinav 2009], [Dinnewitzer 2015], [Harries 2014], [Jensen 2014], [Kipling 2014],[94-98] Surgisis®/Biodesign® (a porcine decellularised small intestine submucosa, Cook Medical)[Balla 2015], [Ge 2017], [Peacock 2014],[99-101] Strattice (a porcine-derived acellular dermal matrix, Allergan) [Bhandari 2015][102], and Tutomesh® (an avital, acellular, xenogenic collagen membrane made from bovine pericardium, RTI Surgical) [Buleje 2015][103]. Four studies provided data for comparison of some of the outcomes ([Chi 2013][Harries 2014][Han 2014][Tharakan 2013]).

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™ [Christensen 2011][104], a retrospective study by Peacock *et al.* that compared vertical rectus muscle flap and Surgisis®/Biodesign® [Peacock 2012],[105] and an abstract by Tharakan *et al.* that compared inferior gluteal artery perforator (iGAP) flap or vertical rectus abdominus (VRAM) flap against primary closure or biological mesh (product name or type not specified)[Tharakan 2013].[106]

Jones *et al.* [Jones 2017][107] reported from a registry and a large series but outcomes for primary closure vs mesh vs flap could not be extrapolated separately. The same issue was noted with the paper by Sayers *et al.* [Sayers 2015].[108]

The two papers by the same author group ([Han 2010] and [Han 2014])[92,88] 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 ([Bhalla 2015] [Peacock 2012] [Peacock2014]).[99,105,101]

Four studies ([Jones 2017][Pande 2014][Sayers 2015] [Tharakan 2013])[107-109,106] 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 [Jensen 2013].[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 [Dalton 2012][Palmer 2014][Pande 2014][Sayer 2015][Vaughan-Shaw 2012][West 2010].[111,112,109,108,113,114]

Outcome

8.1. Wound healing: primary closure vs mesh

8.1.1 Wound healing: primary closure vs mesh, RCT

There were two randomized controlled studies. Han *et al.* [Han 2012] compared cylindrical APER with human acellular dermal matrix (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.* [Musters 2017] 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 web site preoperatively.

Inconsistency: Not applicable as only one study 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 a relative risk reduction 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 RR of 1).

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

8.1.2. Wound healing: primary closure vs mesh, comparative studies

There were 3 studies [Chi 2013][Han 2014][Tharakan 2013] 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 [Han 2014]. Two remaining studies reported the numbers of wound dehiscence [Chi 2013][Tharakan 2013].

Among the case-series studies, Harries *et al.* reported healing as an outcome [Harries 2014], 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% vs primary closure group healing 19/25=76%, with alpha= 0.05 and beta=0.2 and 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 vs mesh, comparative studies

There were no randomized controlled studies that compared closure with fascio- or musculo-cutaneous flap and mesh.

There were 3 observational studies that compared flap and mesh after APER. A study by Christensen *et al.* compared gluteal flap with closure with Permacol™ [Christensen 2011], a study by Peacock *et al.* compared vertical rectus muscle flap (VRAM) and closure with Surgisis®/Biodesign® [Peacock 2012], 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)[Tharakan 2013].

There was no difference in wound healing rates (mesh 92.9% vs flap 83.6%, RR 1.08 (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 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 3 studies.

Imprecision: Downgraded by 1 due to the power of the study being inadequate. With mesh group healing of 39/42=92.9% vs flap group healing 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 randomised 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 randomized controlled studies [Han 2012][Musters 2017], one comparative observational study [Han 2014], and five case series using mesh [Chi 2013][Ge 2017][Han 2010][Moreno Sanz 2011][Peacock 2014] that reported on overall morbidity. One observational study that compared use of flaps and meshes [Peacock 2012] reported on non-specific overall morbidities. The overall morbidity rate was 25.3% in 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 vs mesh, RCT

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 web site preoperatively.

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

Indirectness: No concern for the study by Musters *et al.* as it directly compared the current standard approach (primary closure) against mesh closure. The study by Han et

al. used different surgical techniques for rectum excision (cylindrical, extralevator versus 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 OR of 1).

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

10.1.2 General morbidity: primary closure vs 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 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 vs 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 vs 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 [Han 2012][Musters 2017] and three observational studies [Chi 2013][Han 2014][Tharakan 2013] comparing primary closure with mesh implantation, and twelve case series [Abhinav 2009][Bhalla 2015][Bhandari 2015][Buleje 2015][Dinnewitzer 2015][Ge 2017][Han 2010][Harries 2014] [Jensen 2013][Kipling 2014][Moreno Sanz 2011][Peacock 2014]. There were three observational studies that compared the use of flap and mesh [Christensen 2011][Peacock 2012][Tharakan 2013].

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

10.2.1. Perineal septic complications: primary closure vs mesh, RCT

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

Inconsistency: Han *et al.* reported a septic complication rate of 11% for the mesh group and 19% for the primary closure group while Musters *et al.* 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 the definitions were different in the two studies.

Indirectness: There is no concern for the study by Musters *et al.* as it directly compared the current standard approach (primary closure) against mesh closure. The study by Han *et al.* used different surgical techniques for rectum excision (cylindrical,

extralevator vs conventional). However, the risk of influence on indirectness is negligible.

Imprecision: The OR did overlap 1 but with 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 vs 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 use of mesh. The septic complication rates of the mesh group were 0-25%, while those of primary closure 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 [Han 2014][Tharakan 2013] while one study chose mesh only when the defect was too large for primary closure [Chi 2013].

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

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

10.2.3. Perineal septic complications: primary closure vs 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 vs 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 [Christensen 2011][Peacock 2012]. 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 was unclear.

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

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

10.3. Perineal hernia

There were two randomized controlled studies [Han 2012][Musters 2017] and two observational studies comparing primary closure and mesh implantation [Chi 2013][Han 2014]. There were nine case series using mesh [Bhalla 2015][Dinnewitzer 2015][Ge 2017][Han 2010][Harries 2014][Jensen 2013][Kipling 2014][Moreno Sanz 2011][Peacock 2014]: eight of these studies reported that there was no perineal hernia. There were two observational studies that compared the use of flap and mesh [Christensen 2011][Peacock 2012]. Two studies [Pande 2014][Sayers 2015] were not included as the reported perineal hernia complications were a combination of the flap and mesh patients.

The two randomized controlled studies 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 (CI 0.27 to 1.32)[moderate quality evidence]. Other analyses yielded very low-quality evidence only.

10.3.1. Perineal hernia: primary closure vs mesh, RCT

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 web site preoperatively.

Inconsistency: Downgraded by 1. Han et al. reported perineal hernia rates of 14% for the mesh group and 12% for primary closure while Musters et al. 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 I2 index was 29% indicating only small heterogeneity. The study by Musters assessed perineal complication up to 12 months post-surgery.

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

Imprecision***:*** The OR 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 vs 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 randomised.

Inconsistency: Effectively, there was only one study for analysis as the study by Chi *et al.* had no perineal hernia in either group. In the study by Han *et al.*, perineal hernia was seen in 4 out of 83 patients (5%) in the mesh group and 2 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.* 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 [Chi 2013].

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 vs 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 9 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 vs mesh, comparative studies

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 both studies (not randomised).

Inconsistency: Effectively, there was only one study for analysis as the study by Peacock *et al.* 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.*, perineal hernia was seen in 0 out of 24 patients (0%) in the mesh group and 7 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 impact on the outcome assessment.

Imprecision: Downgraded by 1 as the size of 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 [Han 2012] 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, CI 3.28-76.91). Another randomized study [Musters 2017] 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 reconstruction.

There was only one comparative study comparing mesh and primary closure [Han 2014].

There were 6 case series that reported on the incidence of perineal pain [Ge 2017][Han 2010][Harries 2014][Jensen 2013][Moreno-Sanz 2011][Peacock 2014]. The follow-up or assessment timing was around 12 months, some studies reported that pain was transient [Jensen 2013] or minor [Ge 2017], while others reported chronic pain [Han 2010][Moreno-Sanz 2011][Peacock 2014].

There was only one study that compared flap and mesh closure [Peacock 2012], which was a retrospective case series with longer follow-up for the musculocutaneous flap group.

10.4.1. Perineal pain: primary closure vs mesh, RCT

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 vs 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 randomised.

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) vs 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 vs 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 2-33%. One of the studies, which reported 2% perineal pain, had 42% of patients from the original cohort missing from follow-up [Jensen 2013]. Two studies had a considerable range in the timing of follow-ups (Harries *et al.*: between 1 and 85 months

[Harries 2014]; Peacock *et al.*: between 1 and 54 months). There was also a study with no clear follow-up timing [Ge 2017].

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 vs 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 for both studies (not randomised).

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 APE. There was no report of the use of mesh for ischioanal APE 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 that received neoadjuvant therapy without clarifying its effect on perineal wound healing. In one paper ([Jones 2017]) 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.* [Musters 2017] reported a similar incidence of postoperative perineal wound complications (about 1/3) 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 extralevator APE 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 APE 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 BMI of their patients. The role of smoking on perineal wound healing and perineal hernia formation after APE 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 APE for rectal cancer was rarely reported. In one publication ([Sayers 2015]) 6 out of 54 analyzed patients after ELAPE had diabetes, the incidence of diabetes in those who had perineal wound complications was 3 out of 24.

In the randomized study by Musters *et al.,* occurrence of perineal hernia after one year was significantly lower in the biological mesh closure cohort. However, as the authors pointed out, the results were only at one year and the data do not reflect the long-term occurrence of perineal hernia ([Blok 2019][115]).

Data interpretation and limitations

Most studies were case series with correspondingly low level of evidence (low or very low). Two randomized controlled trials were included, one of which was rated as high quality and the other as moderate [Musters 2017, Han 2012].
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 vs deep, or requiring surgery or other interventions. The site of infection (perineal, abdominal or donor site in 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 different reconstruction methods used at different time periods [Christensen 2011, Peacock 2012, Peacock 2014]. 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 occurence. Cost-effectiveness should also be evaluated, including costs of the operation, hospitalization, re-operation (if needed) and postoperative recovery. Sub-group analysis should also be included for risk factors such as smoking, diabetes, obesity, preoperative stage and treatment (radio 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 biologic, cross-linked 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 three trials registered in the public domain to evaluate perineal reconstruction using mesh at the point of writing. 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 vs. Primary Perineal Wound Closure’ (NCT02841293) comparing primary closure and mesh closure (type of biologic mesh unspecified). A study entitled ‘"Cross" Closure for Reconstructing the Perineal Wound of Abdominoperineal Resection (CCRPWAR)’ comparing two different methods of primary closure (NCT03731754) in China, and Collagen Implant (Biological Mesh) Versus GM Flap for Reconstruction of Pelvic Floor After ELAPE in Rectal Cancer (NEAPE, NCT01347697).

Table 23. Wound healing: Mesh compared to primary closure/flap for perineal reconstruction

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	mesh	primary closure/flap	Relative (95% CI)	Absolute (95% CI)		
Primary closure vs mesh RCT												
1	randomised trials	not serious	not serious	not serious	serious [a]	none	30/48 (62.5%)	33/50 (66.0%)	**OR 0.86** (0.38 to 1.96)	**35 fewer per 1,000** (from 235 fewer to 132 more)	⨁⨁⨁◯ MODERATE	IMPORTANT
Primary closure vs mesh, comparative studies												
3	observational studies	serious [b]	not serious	serious [c]	serious [d]	none	0 cases 0 controls		not estimable	-	⨁◯◯◯ VERY LOW	IMPORTANT
							-	0.0%				
Flap vs mesh, comparative studies												
3	observational studies	serious [e]	not serious	serious [f]	serious [g]	none	39/42 (92.9%)	46/55 (83.6%)	**RR 1.08** (0.93 to 1.24)	**67 more per 1,000** (from 59 fewer to 201 more)	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **OR:** Odds ratio; **RR:** Risk ratio

Explanations

a. Downgraded by 1, as the study was underpowered.
b. Downgraded by 1, as the method to allocate mesh or primary closure wed not clear.
c. Downgraded by 1, as the used mesh were different in 3 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 meshes used were different in all 3 studies.

Table 24. Perineal septic complication Mesh compared to primary closure/flap for perineal reconstruction

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mesh	Primary closure/flap	Relative (95% CI)	Absolute (95% CI)		
Primary closure vs mesh RCT												
2	randomised trials	not serious	not serious	not serious	not serious	none	27/85 (31.8%)	32/86 (37.2%)	**OR 0.81** (0.42 to 1.59)	**48 fewer per 1,000** (from 173 fewer to 113 more)	⨁⨁⨁⨁ HIGH	CRITICAL
Primary closure vs mesh, comparative studies												
3	observational studies	serious [a]	not serious	serious [h]	serious [c]	none	7/94 (7.4%)	16/44 (36.4%)	**OR 0.29** (0.10 to 0.87)	**221 fewer per 1,000** (from 310 fewer to 32 fewer)	⨁◯◯◯ VERY LOW	CRITICAL
Primary closure vs mesh, case series												
12	observational studies	serious [d]	serious [e]	serious [f]	serious [g]	none	38/292 (13.0%)	not pooled	not pooled	see comment	⨁◯◯◯ VERY LOW	CRITICAL
Flap vs mesh, case series												
3	observational studies	serious [i]	serious [j]	serious [k]	serious [k]	none	6/51 (11.8%)	-	-	-	⨁◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. The allocation to mesh and primary closure was not randomised.
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 [Han 2014][Tharakan 2013] whilst one study chose mesh when the defect was too large for primary closure [Chi 2013].
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 was unclear.
k. Downgraded by 1 as the size of studies was small.

Table 25: Occurence of hernia: Mesh compared to primary closure/flap for perineal reconstruction

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	mesh	primary closure/flap	Relative (95% CI)	Absolute (95% CI)		
Primary closure vs mesh, RCT												
2	randomised trials	not serious	serious [a]	not serious	serious [b]	none	12/85 (14.1%)	19/87 (21.8%)	**OR 0.60** (0.27 to 1.32)	**75 fewer per 1,000** (from 148 fewer to 51 more)	⨁⨁◯◯ LOW	IMPORTANT
Primary closure vs mesh, comparative studies												
2	observational studies	serious [c]	not serious	serious [d]	serious [e]	none	4/86 (4.7%)	-	-	-	⨁◯◯◯ VERY LOW	IMPORTANT
Primary closure vs mesh, case series												
9	observational studies	serious [f]	not serious	serious [g]	serious [h]	none	3/250 (1.2%)	not pooled	not pooled	see comment	⨁◯◯◯ VERY LOW	IMPORTANT
Flap vs mesh												
2	observational studies	serious [i]	not serious	serious	serious [k]	none	0/34 (0.0%)	0.0%	**OR 0.04** (0.00 to 0.79)	**0 fewer per 1,000** (from 0 fewer to --)	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. Two included studies showed inconsistent results.
b. Downgraded by 1. the study size was probably inadequate as OR overlapped 1.
c. Downgraded by 1 as the method of allocation to mesh reconstruction or primary closure was not randomised.
d. Downgraded by 1. The type 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 randomised).
k. 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.

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 faecal incontinence?

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 (sphincteropasty) 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 very low quality of available evidence. *[Conditional recommendation]*
- Placing a mesh transperineally for rectocoele repair could not be recommended due to 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 is 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 use of mesh for recreating the anorectal angle for faecal incontinence 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 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 transperineally mesh. Rectocoele is an anatomical finding but is not necessarily related to functional abnormality. Further trials are needed with a comparative arm without 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 inserted as a sling behind the rectum to create an anorectal angle between the axis of the rectum and the anal canal and thereby facilitating the normal closing mechanism to keep stool in the rectum.

Outcome

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

350 references on mesh used in repairing the anal sphincter mechanism were screened for relevance, 6 papers were retrieved and 4 papers included.

Two studies were case series with a small number of patients (16 and 13) [Horn 1985][Zutshi 2012][116,117] with no control group, so data from these studies were not analysable. One retrospective study [Elton 2002][118] compared 12 patients with mesh to 8 age-matched control patients without mesh and one prospective study compared 10 patients with mesh to 10 age-matched patients without mesh [Zutshi 2011, age-matched].[119] The selection criteria were not explained and each of the four studies used different type of meshes (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 2 studies and was up to 17 months in the other 2 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 (odds ratio 0.83 (0.1 1–5.94)).

13.1 Complications: mesh vs no mesh, case series

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

Inconsistency: Downgrade by 1. There was only one complication in each of the 2 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 CI.

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

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

174 references on mesh used in repairing ano/rectovaginal and rectourethral fistulas were assessed and 18 articles reviewed. Of these, 10 papers were excluded as they were case reports or had fewer than 5 patients included. 8 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 4 studies that used Surgisis® mesh [Borowiec 2012][Ellis 2008][Schwandner 2009(Tech)] [Schwandner 2009(Surg Inov)] (88 pts),[120-123] 2 studies used Strattice™ mesh [Mege 2015] [Serra-Aracil 2017] (13 pts),[124,125] one study used Permacol™ mesh [Gottgens 2014] (12 pts),[126] and one study used an unspecified biomesh [Milito 2017] (5 pts).[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 50-100% for ano/rectovaginal fistulas and 0% for rectourethral fistulas treated with mesh.

Recurrence was reported to be between 0-80%. No standardised 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; [126,124,123,128] four studies did not report complications.

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

Risk of bias: Downgraded by 1. Only 2 out of 6 studies reported outcomes for comparative groups. All studies had small numbers of patients.

Inconsistency: Downgraded by 1. Four of 6 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 6 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 Complication: mesh vs 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 6 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.

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

Sixty-one references on mesh used to recreate the anorectal angle as a treatment for faecal incontinence were evaluated and 6 papers were reviewed in detail. One paper was excluded and 5 were included in the final review [Brochard 2017][Devesa 2014][Mellgren 2016][Rosenblatt 2014][Yamana 2004].[129-133] 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 [Rosenblatt 2014 [Brochard 2017] [Mellgren 2016] a polypropylene mesh was used (29, 6, 152 patients each); in one study [Yamana 2004] a polyester mesh was used (8 pts) and in the cohort study [Devesa 2014] a simple silicone band (Jackson-Pratt™ drain) was used (33 pts). 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 indicated to be between 50-69%. However, none of the data were extractable for pooled analysis.

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

15.1 Complication: mesh vs 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.

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

96 references were identified relating to mesh placed through a transperineal approach. After evaluation, 16 full papers were assessed in detail. Review articles (3) were excluded, and other studies were excluded because mesh was placed transvaginally (1), mesh was placed transanally (1) or the

paper was not relevant (1). Of the 10 included articles,[134,121,135,86,136-141] 4 were retrospective and 6 prospective case series. There were no comparative studies. Different surgical techniques were performed and different mesh materials were inserted. There were 3 studies that used exclusively biological mesh (Surgisis®/ Permacol™), 6 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, 9 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 (BBUSQ) score was used in 1 study in which a significant improvement in symptoms was identified but as the data were only reported using 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%) – 4 patients with urinary retention/infection, 6 with bleeding, 9 with superficial wound infection, 3 with dyspareunia, 7 with wound dehiscence, 1 with delayed wound healing, 1 mesh erosion, 1 reoperation for mesh trimming. The rate of mesh complications accounted for 2/204 (0.9%) of the total reported complications.

16.1 Recurrence: mesh vs 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 [Hirst 2005], mesh was used in <10% of patients included in the study and the selection criteria for different procedures was 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 Complication: mesh vs 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 6-40%. 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 randomised controlled trials and must use validated outcome measures with long-term follow up.

Table 26: Mesh compared to no mesh for anal sphincter repair

Certainty assessment							No. of patients		Effect		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			Relative (95% CI)	Absolute (95% CI)		
Complication												
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 to 5.94)	**17 fewer per 1,000** (from 89 fewer to 494 more)	⨁◯◯◯ VERY LOW	IMPORTANT
								0.0%		**0 fewer per 1,000** (from 0 fewer to 0 fewer)		

CI: Confidence interval; **RR:** Risk ratio

Explanations

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 mesh group and another in control group, thus there was a degree of inconsistency. Downgraded also because used meshes 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		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			Relative (95% CI)	Absolute (95% CI)		
Recurrence												
6	observational studies	serious [a]	serious [b]	serious [c,d]	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	see comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. Only 2 out of 6 studies reported outcomes for comparative groups. All studies had only small number of patients.
b. Downgraded by 1. Four of 6 studies had no comparators, and the rate of recurrence varied from 4 to 80% and used meshes were different in all included studies.
c. Included heterogenous patients (mixture of idiopathic and Crohn's fistula).
d. Downgraded by 1. Four of 6 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 mesh group and another in control g group, thus there was a degree of inconsistency. Downgraded also because used meshes were different in all included studies.

Table 28 Mesh compared to no mesh for recreating anorectal angle

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)		
Complication												
5	observational studies	serious [a]	serious [b]	serious [c]	serious [d]	none	21/228 (9.2%)	0/0	not pooled	see comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT

CI: Confidence interval; **RR:** Risk ratio

Explanations

a. Downgraded by 1. All studies were case series of 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		Certainty	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Q16	placebo	Relative (95% CI)	Absolute (95% CI)		
Recurrence												
2	observational studies	serious [a]	serious [b,c]	serious [d]	serious [e]	none	3/32 (9.4%)	not pooled	not pooled	see comment	⨁◯◯◯ VERY LOW	NOT IMPORTANT
Complication												
9	observational studies	serious [a]	serious [c,f]	serious [d]	serious [e]	none	29/204 (14.2%)	not pooled	not pooled	see comment	⨁◯◯◯ VERY LOW	

CI: Confidence interval; **OR:** Odds ratio

Explanations

a. Downgraded by 1. The risk of bias is serious, as all studies were observational studies.
b. Downgraded by 1. In one study [Hirst 2005], use of mesh was in <10% of all patients included in the study and the selection criteria for different procedures was not clear.
c. Used meshes were different in included studies.
d. Downgraded by 1 as there was 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 6-40%.

CI: Confidence interval; **OR:** Odds ratio

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 re-attach 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.
- Reintervention 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 not only at in-house multidisciplinary meetings but 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 recommendation

There were only 10 studies that mentioned management of mesh complications related to rectopexy. It is uncertain whether this is due to 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 randomised controlled study that directly compared different methods of handling mesh complications following rectopexy. There were 10 case series that mentioned complication management [Badrek-Al-Amoudi 2013][Borie 2016][Consten 2015][Evans 2015][Jallad 2017][Makela-Kaikkonen 2018][Matthew 2014][Schultz 2000][Shalaby 2017][Tranchart 2013]. [71,79,16,80,28,142,143,42,144,145]

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%.[80,28,142]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. [71,80,142,143,145] Rectal erosions were managed either by direct repair, anterior resection, or washout and defunctioning stoma. Jallad *et al.* 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[144] 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[80] whilst another reported the opposite with more complications with a biologic 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 [146] and perineal reconstruction [147] or systematic reviews analysing data using meta-analysis,[148,149] 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 randomised controlled studies. The bulk of the available studies were case series without controls, there was significant heterogeneity of included patients with regards 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 increasing incidence of prolapse in an aging population, it is important that perioperative mortality is reported clearly, regardless of whether it was directly related to the surgery or not.

There also was possible bias and selective reporting of other elements of the operations and consequences; some cited 'D'Hoore' technique as ventral mesh rectopexy but also described some modifications that did not adhere to the techniques originally described. Techniques of how mesh was applied, and whether rectal mobilisation 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 to include both historical and latest procedures. LVMR has benefited 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 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 (lap. vs open, anterior vs posterior mobilisation 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 obstructive defaecation 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 mobilisation. 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, 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 randomised controlled trials 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 APR), 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 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 as to 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 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 organisations. 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 were received. Most of the patients' responses were provided by those who had undergone rectal prolapse surgery. The patient organisation 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 light of this, the full results of 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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