Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Recommendation
December 2021

In response to an enquiry from the Scottish Government

Elective surgery using mesh to repair primary and incisional hernias in adults

Recommendation for NHSScotland

Surgical mesh is used in hernia repair, a common surgical procedure in both men and women. Following the impact on women of using surgical mesh for prolapse repair, it is timely and appropriate to consider the use of mesh to repair hernias. The Scottish Government asked the Scottish Health Technologies Group (SHTG) to review the evidence for using surgical mesh in the elective repair of abdominal and groin hernias in all adults.

The evidence supports the continued availability of surgical mesh as an option for elective repair of primary ventral hernias, incisional hernias, and primary inguinal hernias, in adults in Scotland.

Patient preference may be for a non-mesh (suture) hernia repair and access to alternative hernia management options should be available to accommodate this.

All elective hernia repairs should be preceded by a detailed discussion between the patient and the surgeon as part of an informed consent process. Points for discussion include:

- the benefits and risks of surgical and non-surgical approaches to hernia management, including the fact that neither mesh nor non-mesh repair are risk-free procedures
- the risk of developing chronic pain following hernia repair, especially for patients with pain as their main presenting symptom, and
- the uncertainty around long-term outcomes from hernia surgery, using mesh or non-mesh repair, given the few studies that followed up with patients beyond 1 year.

Patients should be provided with detailed information on hernia repair in a variety of accessible formats, including verbal and written.

The decision to use laparoscopic or open mesh repair should be based on the patient's medical history, the characteristics of their hernia, and surgical expertise. The decision on which mesh fixation technique to use in elective hernia repair should be based on surgical expertise, the type and size of hernia, laparoscopic or open repair, and the type of mesh used.

It is important that data on long-term outcomes from hernia repair in Scotland are recorded at a national level to inform future decision-making. This should be aligned with the UK Medical Device Information System and include collection of patient reported outcomes.

NHSScotland is required to consider SHTG recommendations.

What were we asked to look at?

SHTG was asked by the Scottish Government to explore a series of questions relating to the use of surgical mesh in the elective repair of abdominal and groin hernias in all adults. The research questions included a series of comparisons: mesh versus suture repair, laparoscopic versus open repair, and synthetic mesh versus biological mesh. We were also asked to compare mesh fixation techniques, to assess potential sex-specific differences in outcomes, and to explore patient experiences. Primary ventral hernias, incisional ventral hernias, umbilical hernias, inguinal hernias, and femoral hernias, were selected as being representative of the majority of hernias treated in NHSScotland.

Why is this important?

The use of surgical mesh has become an important topic in the last few years following women's experiences of severe, chronic pain after mesh was used to treat pelvic organ prolapse. Hernia repairs are one of the most common surgical procedures performed globally, with an estimated 20 million hernia repair procedures each year. Following the impact on women of using mesh for prolapse repair, there is a need to consider the evidence in relation to using mesh to repair hernias in both men and women.

What was our approach?

We produced an SHTG Recommendation based on a review of published evidence on the clinical effectiveness, cost effectiveness, safety and patient aspects of using surgical mesh for hernia repair. Our recommendation incorporated a public engagement exercise we conducted using a survey to elicit the views of patients and the public on hernia repair. The work was undertaken in the context of the Cumberlege First do no harm report (2020), and the recommendation takes into account gaps in the published evidence, including the lack of long-term safety data. Information on our SHTG Recommendations product can be found on our SHTG website.

What next?

The Scottish Government will use the SHTG Recommendation to inform NHSScotland about the evidence base for using mesh in hernia repair. The SHTG Recommendation will be made available to surgeons and the public via the SHTG website.

Evidence review key points

Synthetic mesh versus non-mesh repair in all adults

1. Meta-analyses comparing mesh with non-mesh repair found a statistically significant reduction in hernia recurrence rate and an increased risk of seroma formation with mesh repair.
    - **Ventral hernia:** hernia recurrence relative risk (RR) 0.13, 95% confidence interval (CI) 0.04 to 0.39, p=0.0003.
    - **Incisional hernia:** hernia recurrence RR 0.44, 95% CI 0.31 to 0.62, p<0.00001; seroma RR 2.88, 95% CI 1.52 to 5.42, p<0.001.
    - **Umbilical hernia:** hernia recurrence RR 0.48, 95% CI 0.30 to 0.77, p=0.002; seroma RR 2.37, 95% CI 1.45 to 3.87, p<0.001.
    - **Inguinal hernia:** hernia recurrence RR 0.46, 95% CI 0.26 to 0.80, p=0.0055; seroma RR 1.63, 95% CI 1.03 to 2.59, p=0.038.
2. Chronic pain was reported as an outcome in comparisons of mesh and non-mesh repair in patients with an umbilical or inguinal hernia.
    - **Umbilical hernia:** no meta-analyses reported on chronic pain due to high heterogeneity. Of four primary studies reporting chronic pain at median follow-up of 5 years, two found less chronic pain with mesh repair, one found more chronic pain with mesh repair, and one study found no difference in chronic pain between mesh and non-mesh repair.
    - **Inguinal hernia:** one meta-analysis found a statistically significant reduction in the odds of persistent pain 1 year after surgery with mesh repair (odds ratio (OR) 0.60, 95% CI 0.42 to 0.84) while another found no statistically significant differences at median follow-up of 1 year.
3. A UK cost-effectiveness study comparing open mesh repair with non-mesh repair of inguinal hernias demonstrated that, over a 5 year time horizon, open mesh repair resulted in fewer people experiencing hernia recurrence or persistent pain, and more time spent performing usual activities, all based on a cumulatively lower cost (mean saving £134, 95% CI £81 to £192).
4. Gaps in the published literature on mesh compared with non-mesh hernia repair were:
    - No secondary literature on repair of femoral hernias.
    - No secondary literature on chronic pain outcomes in primary ventral or incisional hernia repair.
    - No cost-effectiveness evidence on primary ventral, incisional, or umbilical hernias.

Biological versus synthetic mesh repair in all adults

5. **Ventral hernia:** a meta-analysis with high heterogeneity (I^2=82%) compared biological mesh with synthetic mesh and found no statistically significant differences in hernia recurrence rates: OR 0.76, 95% CI 0.21 to 2.76, p=0.67. Wound infection was statistically significantly less likely in patients treated with biological mesh: OR 0.18, 95% CI 0.09 to 0.37, p<0.00001.
6. **Inguinal hernia:** a meta-analysis comparing biological mesh with synthetic mesh in men found no statistically significant differences in hernia recurrence risk (OR 2.15, 95% CI 0.39 to 11.74, p=0.38) but an increased risk of seroma with biological mesh (OR 2.67, 95% CI 1.12 to 6.35, p=0.03).
7. A meta-analysis found no statistically significant differences in chronic pain lasting more than 3 months in comparisons of biological and synthetic mesh repair of groin hernias: OR 0.54, 95% CI 0.29 to 1.02, p=0.06.
8. Economic studies were identified that compared biological and synthetic mesh for primary ventral and incisional hernias.
    - **Ventral hernia:** two cost-utility analyses, that both took a societal perspective (direct hospital costs and indirect costs to patients), estimated that synthetic mesh was more effective and less costly than biological mesh in clean-contaminated primary ventral hernia repairs over a time horizon of 5 and 30 years, respectively.
    - **Incisional hernia:** a cost comparison estimated direct medical costs associated with treatment using biological mesh to be statistically significantly more expensive (£14,247 versus £4,364) for incisional hernia repair at 1-year follow-up. These findings should be interpreted with caution since only complex cases were assigned to receive biological mesh.
9. Gaps in the published literature on biological mesh compared with synthetic mesh were:
    - No secondary evidence for umbilical or femoral hernia repairs.
    - No secondary evidence based on comparative studies in patients with incisional hernias.
    - No cost-effectiveness evidence on inguinal, femoral, or umbilical hernias.

Laparoscopic versus open mesh repair in all adults

10. In comparisons of laparoscopic and open mesh repair, a pairwise meta-analysis and a network meta-analysis found no significant differences in hernia recurrence rates and an increased risk of surgical site infection with open mesh repair.

- **Ventral hernia:** hernia recurrence rate OR 0.95, 95% CI 0.46 to 1.98, p=0.89; surgical site infection OR 4.17, 95% CI 2.03 to 8.55, p<0.001.
- **Incisional hernia:** hernia recurrence risk OR 1.14, 95% CI 0.81 to 1.60, p=0.47; surgical site infection OR 5.16, 95% CI 2.79 to 9.57, p<0.001.
- **Inguinal hernia** (81.5% male patients)**:** hernia recurrence risk (transabdominal preperitoneal (TAPP) versus open) RR 0.96, 95% credible interval (CrI) 0.57 to 1.51; hernia recurrence (totally extraperitoneal (TEP) versus open) RR 1.0, 95% CrI 0.65 to 1.61; wound infection risk (TEP versus open) OR 0.33, 95% CrI 0.09 to 0.81.

11. Chronic pain was reported as an outcome in comparisons of laparoscopic and open mesh repair in patients with a ventral or inguinal hernia.
    - **Ventral hernia:** in a meta-analysis of two studies, there was no statistically significant difference in chronic pain (undefined) following laparoscopic versus open repair.
    - **Inguinal hernia** (81.5% male patients)**:** a network meta-analysis found no significant differences in chronic pain (undefined) for comparisons of open, TAPP and TEP inguinal hernia repair.
12. Evidence comparing the cost of laparoscopic versus open mesh repair reached varying conclusions.
    - **Ventral hernia:** a cost comparison estimated laparoscopic repair to be associated with a reduction in costs of £2,481 (p<0.001) 1 year after surgery.
    - **Inguinal hernia:** a cost-minimisation analysis estimated that TEP repair was associated with increased costs of up to £691 (p<0.01) compared with open repair, 5 years after surgery. A cost comparison estimated TEP and TAPP repair techniques to be £308 and £140 less costly relative to open mesh repair (p<0.001 and p<0.05, respectively).
13. Gaps in the published literature on laparoscopic compared with open hernia repair were:
    - No secondary evidence for umbilical or femoral hernias.
    - No cost-effectiveness evidence for primary umbilical, incisional, or primary femoral hernias.

Mesh fixation techniques in all adults

14. Secondary evidence compared mesh fixation techniques including permanent tacks, fibrin glue, suture fixation, permanent tacks plus suture fixation, staples, absorbable tacks, self-gripping mesh, and no fixation.
    - **Ventral hernia (laparoscopic repair):** a network meta-analysis reported no significant differences in hernia recurrence between permanent tack fixation, fibrin glue, suture

fixation, or permanent tacks plus suture fixation. Lower recurrence rates were found for permanent tacks compared with absorbable tacks (RR 1.37, 95% CI 1.03 to 1.81).

- **Inguinal hernia (open repair):** a network meta-analysis found no significant differences in hernia recurrence for comparisons of fibrin glue or suture fixation with self-gripping mesh.
- **Inguinal hernia (laparoscopic repair):** a network meta-analysis found no differences in hernia recurrence between no fixation, absorbable tack fixation, suture fixation, and glue fixation, during TEP repair of inguinal hernias. Pairwise meta-analysis of fibrin glue versus staple fixation in TAPP inguinal hernia repair found no statistically significant differences in hernia recurrence.

15. Chronic pain was reported as an outcome in comparisons of mesh fixation for ventral and groin hernia repair.
    - **Ventral hernia:** no statistically significant differences in chronic pain at 3–6 months follow-up were reported in meta-analyses comparing tack and suture mesh fixation, or absorbable and non-absorbable tack fixation.
    - **Groin hernia:** two network meta-analyses found no significant differences in chronic pain at 1-year follow-up in comparisons of mesh fixation techniques.
16. Gaps in the published literature comparing mesh fixation techniques were:
    - No secondary evidence for umbilical or femoral hernia repair.
    - No cost-effectiveness evidence on any hernia type.

Synthetic mesh safety in all adults

17. In 2015–2020 Public Health Scotland recorded 161 cases of surgical mesh removal, 55 in women and 106 in men. The average annual rate of mesh removal was 32 procedures during this period. The reasons for mesh removal were not reported.
18. A meta-analysis of cohort studies found that mesh-related infections occurred in 7.2% of ventral hernia repairs (119/1,657) and 0.3% of groin hernia repairs (2/761). Statistically significant risk factors for mesh-related infections included smoking, needing an emergency repair, increased patient age, and higher American Society of Anaesthesiologists (ASA) score.

Patient and social aspects (all adults)

19. A qualitative study in patients who had a ventral hernia repair described hernias and hernia repairs as having an impact on activities of daily living including lifting heavy objects, working, engaging with children, and socialising.

20. A survey of patients presenting for hernia surgery in the USA found that patient perceptions of mesh were most strongly influenced by the media (37%) and personal experience of prior surgeries (35%).
21. The information needs of patients centred around the benefits and risks of mesh, and hernia management options. Patient views on the value of online information seeking varied, with some finding it informed decision making while others found it increased anxiety.
22. Two cohort studies found that women were statistically significantly less likely to receive laparoscopic groin hernia repair compared with men: 33% women versus 62.6% men ($p=0.001$); OR 0.70, 95% CI 0.67 to 0.73 ($p<0.001$). Neither study was conducted in the UK nor could either study offer an explanation for why women were less likely to receive laparoscopic hernia repairs.
23. SHTG conducted a 5-week engagement exercise in April 2021, using a survey to gather the experiences of patients in Scotland who had a hernia repair. The results of this exercise are reported in a supplement to this review.

Outcomes of hernia repair in women

24. A registry study (8,138 matched pairs) in patients who had an incisional hernia repair found that women were more likely than men to experience intra-operative complications and chronic pain at 1-year follow-up.
25. Two systematic reviews of mainly single-arm observational studies found that groin hernia recurrence was lower in women after laparoscopic hernia repair compared with open repair. Two comparative observational studies within these systematic reviews found no difference in groin hernia recurrence between mesh and non-mesh repair in women.
26. No studies reported on sex-specific effects or outcomes in women who had a primary ventral or primary umbilical hernia.

SHTG Council considerations

1. In reaching their recommendation, the Council took into account the range of information and evidence that was gathered as part of the health technology assessment (HTA) process, including published literature and public and patient experiences.
2. The Council discussed the importance of offering a non-mesh (suture) hernia repair option for patients across NHSScotland. The clinical experts at the Council meeting were uncertain how much surgical expertise on non-mesh repair was available in the boards, but agreed with the Council that there should be suitable access to non-mesh repairs. Equal access to non-mesh repairs may require transferring patients to a different board for treatment.
3. The Council recognised that chronic pain is an important issue for patients, based on patient engagement work conducted by SHTG and the published patient experience literature.
4. As part of a discussion on the safety of hernia mesh, the Council noted there may be other relevant adverse effects of mesh, such as inflammatory reactions or meshomas, which were not reported in the literature reviewed. The importance of known and unknown 'unknowns' should be acknowledged during discussions between patients and clinicians.
5. The Council discussed with the clinical experts at the Council meeting, the risks involved in hernia mesh removal. The clinical experts informed the Council there was a risk of collateral damage to surrounding tissues, such as the bowel, when attempting to remove hernia mesh.
6. The Council discussed the generalisability of the key findings from the Cumberlege First do no harm report (2020) and the My Path, My Health, My Life report (2021), both of which investigated the experiences of women who had a mesh repair for pelvic organ prolapse or urinary incontinence. Key themes that are applicable to hernia mesh include having a registry of procedures and outcomes, the importance of keeping patients informed and engaged in their treatment, and open, frank discussions between patients and clinicians as part of a shared decision making process.
7. Council members highlighted the importance of clear and accessible patient information on hernia repair. The national It's OK to Ask campaign – encouraging patients to ask questions of healthcare professionals – was deemed a valuable tool that should be promoted to patients requiring hernia repair.
8. The Council highlighted potential equality considerations. These related to hernia repair and gender equality, religious or other beliefs impacted by the use of biological mesh, and equality of access to treatment.

9. The Council discussed the issue of unrecorded long-term outcomes following hernia mesh repair and stressed the importance of future data capture. The Medicines and Medical Devices Act 2021 provides an opportunity to facilitate data collection as part of the UK Medical Device Information System.
10. The Council acknowledged that the British Hernia Society were in the process of developing a hernia repair registry in the UK. One of the clinical experts informed the Council that this registry was part funded by industry.

Contents

Definitions

Strangulated hernia	The blood supply to tissues trapped in the hernia is cut off. This can lead to tissue necrosis and tissue death, and is considered a medical emergency.[1]
Seroma	A mass or lump caused by a build-up of clear fluid in a tissue, organ or body cavity.[2] Most will resolve without requiring intervention.
Lichtenstein technique	An open hernia repair technique using tension-free polypropylene surgical mesh.[3]
Transabdominal preperitoneal repair (TAPP) & totally extraperitoneal repair (TEP)	Two laparoscopic hernia repair procedures involving the use of surgical mesh. The terms differ in the location of mesh implantation.
Ventral hernia	For the purposes of this evidence review, ventral hernia is used as a term that encompasses epigastric, umbilical, para-umbilical, and incisional abdominal hernias.

A list of abbreviations and definitions of key statistical terms used in the review are provided in *Appendix 1* and *Appendix 2* respectively.

Research questions

In order to facilitate the provision of recommendations for Scotland, the evidence review sought to address a series of research questions.

Primary research question:

1. What is the clinical effectiveness, safety and cost effectiveness of using surgical mesh compared with non-mesh (suture) techniques for elective hernia repair in adults?

If evidence supports the availability of surgical mesh for elective repair of a particular hernia type, then the following questions are considered:

2. What is the most clinically effective, safe and cost-effective type of mesh (synthetic, biological, absorbable) to use for elective hernia repair in adults?
3. Should surgeons use open or laparoscopic surgery for elective mesh repair of hernias in adults?
4. What is the most clinically effective, safe and cost-effective way of fixing mesh in place during elective hernia repair in adults?

Two overarching questions on patient aspects are considered:

5. Are there any differences in clinical and safety outcomes following elective hernia repair in women compared with men?
6. What are patients' experiences and views on elective repair of hernias and use of surgical mesh?

Literature search

A systematic search of the secondary literature was carried out between 5 and 12 October 2020 to identify systematic reviews, health technology assessments and other evidence-based reports. Medline, Embase, Cinahl, and Web of Science Core Collection databases were searched for systematic reviews and meta-analyses. The Medline database was systematically searched to identify economics studies, using the Scottish Intercollegiate Guidelines Network (SIGN) economics filter.

The primary literature was systematically searched between the 18 and 19 January 2021 to identify studies describing patient experiences, including qualitative studies. Medline, PsycInfo and Web of Science Core Collection databases were searched using adapted versions of the qualitative research filter by DeJean et al (2016) and a filter for patient experiences literature developed by combining terms from papers by Selva et al (2017) and Wessels et al (2016).

Key websites were searched for guidelines, policy documents, clinical summaries, economic studies, and patient issues reports. Websites of organisations related to this topic, for example the British Hernia Society, were also searched.

All results were limited to English language. All secondary literature and economic studies were limited to studies published after 2010. The patient experiences search was limited to studies published from 2016 onwards.

Concepts used in all searches included: hernia, herniorrhaphy, surgical mesh. A full list of resources searched and terms used are available on request.

Introduction

A hernia occurs when an organ, intestine or fatty tissues protrude through a hole or weak spot in the surrounding muscle or connective tissue.[4] The majority of hernias are a result of a combination of increased internal pressure and an opening or weakness in the surrounding tissue. A hernia can be uncomfortable or can be accompanied by intense pain which gets worse during a bowel movement, urination, heavy lifting or straining.[5]

Hernia repairs are one of the most common surgical procedures performed globally, with an estimated 20 million hernia repairs each year.[5] Surgical repair can be performed either using mesh – biological or synthetic – to reinforce the body tissues, or using sutures to draw connective tissues together (multiple suture techniques are available). Repairs using mesh can be performed either as open or laparoscopic surgery, and the mesh is held in place using one of a number of fixation techniques.[4] Suture hernia repair is generally an open procedure. Currently, surgeon preference, patient characteristics, and features of the individual hernia guide the mode of hernia repair.[6]

Health technology description

Surgical mesh is a class II(b) medical device designed to provide support to weakened or damaged tissues where a hernia has protruded.[4] Mesh products can be made of synthetic materials, such as polypropylene, or organic animal-derived tissues.[5] Synthetic mesh is available in a variety of materials, sizes, shapes, weights and pore sizes. Synthetic mesh can be non-absorbable, partially absorbable, or completely absorbable.[4] Biological mesh is made from collagen scaffolds derived from tissues extracted from human cadavers, pigs or cows. Biological mesh is intended to be absorbed into the body over time.

The use of biological mesh may raise equality issues for certain patient groups. For example, patients may not wish to have tissues from pigs or cows implanted in their body due to their religious beliefs. The implantation of human tissues may present problems for Jehovah's witnesses. Ethical vegetarians or vegans may prefer not to have any animal tissues used in their procedure.

Procedures involving implantation of mesh generally require use of a fixative to keep the mesh in place. There are a number of fixatives available, including absorbable tacks, non-absorbable (metal or plastic) tacks, sutures, and fibrin glue.[7] Modern mesh can be designed to be self-gripping and does not require additional fixation.

The suture material used in non-mesh repair of hernias is made of polypropylene, the same material as synthetic mesh.

Six suppliers have been awarded a contract by National Procurement Scotland to provide synthetic mesh products for hernia repair in NHSScotland: B Braun, Bard Ltd, Covidien (UK) Ltd, Elemental Healthcare Ltd, Johnson & Johnson Medical Ltd and PFM Medical UK Ltd (Mr P Hornby, Head of Strategic Sourcing & Commercial, National Procurement. Personal communication, 08 May 2019). Organic mesh products are no longer within the scope of this national contract, but can be purchased separately if required. Covidien (UK) Ltd, Bard Ltd, and Johnson & Johnson Medical Ltd have also been contracted by National Procurement to provide absorbable and/or non-absorbable mechanical fixatives for mesh used in hernia repair (Mr P Hornby, Head of Strategic Sourcing & Commercial, National Procurement. Personal communication, 08 May 2019).

Available data from NHS England show that the majority of hernias are repaired using synthetic mesh (*Table 1*).[8, 9] The percentage of hernias repaired using mesh varies depending on the type of hernia, with 95% of inguinal hernias repaired using mesh, compared with 50% of umbilical hernias and 82% of incisional hernias.

Table 1: Materials used for hernia repairs in NHS England 2017–2018[9]

Hernia type (primary repair only)	Synthetic mesh	Biological mesh	Non-mesh
Inguinal	60,350	154	2,402
Femoral	1,571	8	1,486
Umbilical	10,491	66	10,994
Incisional	6,962	124	2,016
Ventral	4,047	47	3,146

Epidemiology

Two groups of hernias are of interest to this review: abdominal (ventral) hernias and groin hernias. The abdominal hernias of interest are primary ventral hernias that occur along the vertical midline of the abdominal wall and encompass most abdominal hernia types, primary umbilical hernias that occur in the vicinity of the umbilicus (a subset of ventral hernias), and incisional hernias that occur at the site of a previous surgical incision.[10] These types of hernia are representative of the majority of abdominal hernias. Groin hernias occur at the top of the inner thigh and are either inguinal or femoral.

The most common type of hernia requiring repair is the inguinal hernia. The estimated lifetime risk of a groin hernia (inguinal or femoral) is 27% in men compared with 3% in women.[11] The incidence of groin hernias – both inguinal and femoral – increases with age.[3, 12]

The second most common type of hernia is the umbilical hernia, which accounts for an estimated 6–14% of abdominal hernias in adults.[13, 14] The incidence of umbilical hernias is increased in obese, multiparous women and patients with cirrhosis of the liver.[15]

Incisional hernias are one of the most frequent complications after abdominal surgery, with an estimated incidence of 20% of abdominal surgery patients.[16] Approximately 15% to 47% of incisional hernias can be defined as large.

Over the 5-year period 2015 to 2020, there have been 32,487 hernia repairs using mesh in NHSScotland (Ms N Cameron, Information Analyst, Public Health Scotland. Personal communication,

10 February 2021). There are approximately 6,500 hernia mesh procedures each year within this 5-year period.

Tables 2 and 3 present Scottish data on abdominal and groin hernia repairs using mesh and non-mesh (suture) techniques in the financial year 2019–2020. Based on these data, incisional and inguinal hernia repairs generally include mesh. In the case of umbilical hernias, the use of mesh and non-mesh is approximately 50:50. Men and women appear to have similar likelihoods of a mesh-based repair for all hernia types.

Table 2: Groin hernia repairs in Scotland in the financial year 2019–2020 (Ms N Cameron, Information Analyst, Public Health Scotland. Personal communication, 10 February 2021)

	Mesh repair	Non-mesh repair	Total
Inguinal hernia			
Male	4,374 (98%)	91 (2%)	4,465
Female	245 (86%)	40 (14%)	285
Femoral hernia			
Male	21 (78%)	6 (22%)	27
Female	45 (63%)	27 (37%)	72

Table 3: Abdominal hernia repairs in Scotland in the financial year 2019–2020 (Ms N Cameron, Information Analyst, Public Health Scotland. Personal communication, 10 February 2021)

	Mesh repair	Non-mesh repair	Total
Ventral hernia			
Male	144 (59%)	99 (41%)	243
Female	128 (64%)	72 (36%)	200
Umbilical hernia			
Male	545 (57%)	411 (43%)	956
Female	168 (49%)	173 (51%)	341
Incisional hernia			
Male	185 (92%)	17 (8%)	202
Female	257 (83%)	53 (17%)	310

Ventral hernias (primary or incisional)

Synthetic mesh versus non-mesh repair in all adults

A robust systematic review with meta-analysis and trial sequential analysis compared non-absorbable synthetic mesh with suture repair in adult patients with a primary ventral hernia or an incisional hernia.[17] Randomised controlled trials (RCTs) included in the analysis were appraised by the review authors using the Cochrane Collaboration tool, with studies that did not report randomisation methods and blinding rated as low quality. Pre-planned subgroup analyses assessed mesh compared with suture repair for primary ventral hernias and incisional hernias separately. Trial sequential analysis was used to determine whether the volume of published data was sufficient to form robust conclusions on the effectiveness and safety of mesh-based hernia repair.

The meta-analysis incorporated ten RCTs (n=1,270), six of which were considered by the analysis authors to be high quality, with four considered low quality. Five trials reported on patients with a primary ventral hernia and five on patients with an incisional hernia. Two trials in patients with ventral hernias included emergency repairs. Follow-up in individual trials ranged from 6 to 81 months. Results from the meta-analysis are reported in *Table 4*. The risk of hernia recurrence (primary ventral and incisional combined) was statistically significantly lower for patients treated with synthetic mesh compared with those treated using suture repair: relative risk (RR) 0.39, 95% confidence interval (CI) 0.27 to 0.55, p<0.00001. There was no statistically significant difference between treatment groups in the risk of wound infection, haematoma, and overall adverse events. The risk of developing a seroma statistically significantly increased in patients treated with surgical mesh: RR 2.44, 95% CI 1.43 to 4.14, p<0.001. Limiting the analysis to high quality studies did not affect the findings. Trial sequential analysis indicated there was sufficient published RCT data to form robust conclusions on the effectiveness of mesh versus suture repair in preventing recurrence of primary ventral hernias and incisional hernias combined (312% of required information size) but insufficient evidence to reliably comment on adverse event risk (22.4% of required information size).

Results from the subgroup analyses comparing synthetic mesh with suture repair for primary ventral hernias and incisional hernias separately are presented in *Table 4*. For patients with a primary ventral hernia, the relative risk of recurrence was statistically significantly lower for patients treated with mesh compared with suture repair. No other statistically significant differences were detected between treatment groups in patients with a primary ventral hernia. In patients with an incisional hernia, the relative risk of hernia recurrence was statistically significantly lower for patients treated with synthetic mesh compared with suture repair. There was also a statistically significant increase in the risk of seroma and overall adverse events in patients with an incisional hernia treated with mesh compared with patients treated with suture repair.

The meta-analysis authors noted a number of limitations to their analysis. Only two trials reported long-term results, therefore no conclusions could be reached on the long-term effectiveness or safety of mesh repair. Due to the characteristics of the included trials, the results of the meta-analysis cannot be generalised to biological or absorbable mesh, or to emergency hernia repair. Post-surgical pain was not analysed due to a lack of data on this variable. The analysis made no allowance for different mesh locations, hernia characteristics, or suture types, due to a lack of reported data.

Table 4: Clinical effectiveness and safety of synthetic mesh compared with suture repair of primary ventral hernias and incisional hernias in adults[17]

Outcome	n patients (n studies)	n events (mesh)	n events (non-mesh)	RR (95% CI)	p value	I^2
Primary ventral and incisional hernias						
Hernia recurrence	1,270 (10)	61	155	0.39 (0.27 to 0.55)	<0.00001	20%
Wound infection	NR (9)	–	–	1.26 (0.83 to 1.91)	0.28	0%
Haematoma	NR (7)	–	–	0.58 (0.24 to 1.37)	0.21	21%
Seroma	NR (7)	–	–	2.44 (1.43 to 4.14)	<0.001	0%
Overall adverse events*	906 (9)	139	69	1.31 (0.94 to 1.84)	0.12	27%
Primary ventral hernias only						
Hernia recurrence	426 (5)	2	25	0.13 (0.04 to 0.39)	0.0003	0%
Wound infection	NR (5)	–	–	0.69 (0.33 to 1.49)	0.34	0%
Haematoma	NR (3)	–	–	0.42 (0.11 to 1.64)	0.21	0%
Seroma	NR (4)	–	–	1.66 (0.63 to 4.36)	0.30	0%
Overall adverse events*	426 (5)	25	28	0.82 (0.49 to 1.37)	0.44	0%
Incisional hernias only						
Hernia recurrence	844 (5)	59	130	0.44 (0.31 to 0.62)	<0.00001	26%
Wound infection	NR (4)	–	–	1.62 (0.99 to 2.67)	0.06	0%

Haematoma	NR (4)	–	–	0.58 (0.16 to 2.11)	0.41	38%
Seroma	NR (3)	–	–	2.88 (1.52 to 5.42)	<0.001	0%
Overall adverse events*	480 (4)	114	41	1.75 (1.31 to 2.33)	0.0001	0%

**Overall adverse events consists of wound infection, haematoma and seroma combined. RR = relative risk; CI = confidence interval; NR = not reported.*

Large incisional hernias

Two poorly reported systematic reviews present results from mainly single-arm studies exploring the use of mesh and non-mesh repair techniques for large or giant incisional hernias.[16, 18] In both reviews, the authors draw conclusions about the effectiveness of mesh compared with non-mesh repair based on results from non-comparative studies.

The most recent review (2015) assessed hernia recurrence and complication rates for mesh and non-mesh repair of large incisional hernias.[16] A large incisional hernia was defined as a fascial defect of 10 cm or more in any direction, or a defect surface area of 100 cm^2 or more. Fifty-five studies (n=3,945) were included in the review, the majority of which appear to be retrospective case series. No patient or study characteristics are reported in the review, therefore it is not possible to determine the extent of overlap with studies in the review by Manuel et al (2018)[17] described above. Studies with less than 1 year of follow-up or fewer than ten patients were excluded. The review authors calculated recurrence hazards – the risk of hernia recurrence per year – for each mesh and non-mesh repair technique. This calculation was based on an assumption of equal risk of developing a hernia recurrence in each month following repair. Results from the systematic review are summarised in *Table 5*. Higher rates of mortality, wound infection and hernia recurrence were described in patients with complex large incisional hernias (data not reported). All open mesh techniques had lower annual recurrence hazards compared with open non-mesh repairs. Due to the assumptions in the hazards model, these hazards likely do not reflect the true risk of hernia recurrence.

The second review evaluated mesh and non-mesh repair of giant incisional hernias.[18] A giant incisional hernia was defined as having a mean or median hernia defect of at least 15 cm or 225 cm^2. The review incorporated 14 heterogeneous studies (n=1,198) the majority of which were retrospective case series. One study from this review was incorporated in the review by Manuel et al (2018)[17] reported above. It was not possible to determine whether any of the 14 studies were included in the large incisional hernia review.[16] In five small (n<40) studies the open component separation technique (CST) without mesh had high levels of morbidity within 30 days (23% to 74%), wound infection (9% to 21%), and clinical recurrence within 15 to 52 months (5% to 53%). Three small studies on open CST with mesh reported high levels of morbidity (15% to 100%), wound infection (6% to 33%) and recurrence over 15 to 37 months follow-up (4% to 32%).

Table 5: Data from a systematic review of mainly retrospective single-arm case series on mesh and non-mesh repair of large incisional hernias[16]

Repair type	n studies (n patients)	Mortality (%)	Wound infection or necrosis (%)	Mesh infection (%)	Seroma / haematoma	Recurrence (%)	Mean follow-up (years)	Recurrence hazard per year (%)
Open without mesh								
CST	7 (219)	1.3	20	–	8/9	16	1–4	4.6
Aponeuroplasty	3 (195)	–	–	–	6 (combined)	2.2	4–10	5.5
Open with mesh								
Sublay (Rives-Stoppa)	11 (762)	2.1	11	4.7	9/7	3.6	1–8	0.5
Aponeuroplasty + IPOM	2 (630)	0.5	4	1.3	5 (combined)	3.2	3–8	0.5
IPOM (bridging)	10 (514)	0.2	9	3.5	10 (combined)	8.3	1–6	2.5
Modified CST	8 (511)	1.8	33		11/4	10	1–5	2.5
Onlay	6 (454)	0	31	1.7	19/unknown	11.1	1–6	3.4
Sandwich	5 (131)	–	17	–	5/unknown	0.8	1–7	0.3
Laparoscopic mesh								
IPOM (bridging)	8 (483)	–	8	0.2	6/unknown	5.6	1–5	3.1

CST = component separation technique; IPOM = intraperitoneal onlay mesh.

Biological versus synthetic mesh repair in all adults

Ventral hernias

A systematic review with a meta-analysis, published in 2014, compared any biological mesh with any synthetic mesh for the repair of ventral hernias.[19] The literature search reported in the systematic review included terms for ventral, incisional and umbilical hernias. The review does not report the type of hernia being repaired in the included studies, whether surgery was open or laparoscopic, or patient characteristics. The systematic review authors found that all studies were at high risk of selection bias and eight out of 11 studies did not address incomplete reporting of results. The review authors did not justify the use of meta-analysis in the presence of moderate-to-high study heterogeneity (I^2 51% to 82% for selected outcomes).

Eight studies (n=889) included both biological and synthetic mesh treatment groups. All eight studies were retrospective comparisons, with small samples and heterogeneous populations. Mean or median follow-up ranged from 5.4 to 66 months. The majority of studies assessed the AlloDerm® biological mesh (91.5%). The other biological meshes assessed were Surgisis® and Permacol™. Types of synthetic mesh are not described. The average hernia recurrence rate was 18.6% with biological mesh compared with 15.7% with synthetic mesh: odds ratio (OR) 0.76, 95% CI 0.21 to 2.76, p=0.67, six studies contributed data, I^2=82%. Wound infection was statistically significantly less likely in patients treated with biological mesh (10.9%) compared with synthetic mesh (36.5%): OR 0.18, 95% CI 0.09 to 0.37, p<0.00001, three studies contributed data, I^2=0%. The chances of non-infectious wound complications were not statistically significantly different between the two groups: OR 0.35, 95% CI 0.09 to 1.40, p=0.88, two studies contributed data, I^2=57%.

Four studies (n=235) compared ventral hernia repair using human-derived biological mesh versus porcine-derived biological mesh. No statistically significant differences were found for hernia recurrence (p=0.21), wound infection (p=0.75), or non-infectious wound complications (p=0.69).

Incisional hernias

A well reported systematic review evaluated the evidence on use of biological mesh to repair incisional hernias.[20] Studies included in the review were single-arm studies published between 1990 and 2011 that reported on the use of commercially available biological mesh alone to repair an incisional hernia. A meta-analysis was not performed due to the heterogeneity of study populations, repair techniques, outcome measures, and follow-up periods. The quality of included studies was assessed using an adapted version of the methodological index for non-randomised studies (MINORS) tool. Studies were found by the review authors to be of generally poor quality, with a high risk of selection and information biases. The average weighted MINORS score was 9.7/12 (range 5 to 12); only four studies scored the maximum 12 points and 40% were rated as low quality.

Sixty studies were included in the review, reporting on 1,212 incisional hernia repairs with follow-up data. No studies directly compared biological mesh with synthetic mesh. Over half (56.7%) of the included studies were small case series with less than 30 patients. The majority of studies reported on the use of AlloDerm® (27 studies) or Permacol™ (18 studies) biological mesh. Follow-up duration ranged from 5 days to 60 months, with a mean of 13.6 months. Results from the review are summarised in *Table 6*. The overall weighted hernia recurrence rate across all studies was 15.2% for biological mesh repair. Postoperative infection was reported in 16.9% of patients and seroma or haematoma in 12.0%. Forty-four patients (4.7%) reported surgical site pain. In 25 patients (2.0%) the biological mesh had to be removed, most commonly due to infection or poor mesh incorporation. Mesh reaction or rejection and poor mesh integration were both reported in 0.9% of patients. Mesh disintegration was reported for 0.3% of patients. The review authors noted a significant risk of publication bias in the literature on biological mesh.

Table 6: Systematic review data on biological mesh repair of incisional hernias in single-arm studies[20]

Material	n repairs with follow-up data	Hernia recurrence, n (%)	Average follow-up (months)
Human-derived cadaveric dermis			
AlloDerm®	732	170 (23.2)	14.6
FlexHD®	2	0	6.0
Small intestinal submucosa from pigs			
Surgisis®	135	10 (7.4)	15.4
Xenogenic dermis (from pigs or cattle)			
Permacol™	160	12 (7.5)	10.7
Strattice™	112	16 (14.3)	10.1
XenMatrix™	16	1 (6.3)	16.5
Collamed®	19	8 (42.1)	5.2
SurgiMend®	4	0	10.0
Xenogenic pericardium (from cattle)			
Tutomesh®	2	0	54.0
Veritas®	30	5 (16.7)	22.0

Laparoscopic versus open mesh repair in all adults

Primary ventral and incisional hernias

A systematic review compared laparoscopic with open repair of both primary ventral hernias and incisional hernias.[21] Included studies consisted of RCTs, case-control studies, and retrospective or prospective cohort studies. All studies were required to have at least ten participants in each treatment group. Study quality was assessed by the review authors using the Down and Black 26-item checklist. Any studies with a high risk of bias were excluded. The majority of included studies (17 of 19) were described as having moderate risk of bias, and two studies had low risk of bias. Five studies reported on primary ventral hernia repair and 15 studies on incisional hernia repair. Meta-analyses were performed separately for primary ventral and incisional hernias.

The studies on primary ventral hernia repair consisted of two RCTs, two case-control studies, and one retrospective cohort study. There were a total of 439 laparoscopic repairs and 423 open repairs across all five studies. The pooled hernia recurrence rate was 3.6% (16/439) at mean follow-up of 44 months for laparoscopic repair and 4.3% (18/423) for open repair at a mean follow-up of 62 months. There was no statistically significant difference in hernia recurrence rate between laparoscopic and open repair of primary ventral hernias: OR 0.95, 95% CI 0.46 to 1.98, p=0.89, I^2=0%. The pooled surgical site infection rate was 2.3% (10/439) for laparoscopic repair and 9.2% (39/423) for open repair. The risk of surgical site infection was statistically significantly higher with open repair of primary ventral hernias: OR 4.17, 95% CI 2.03 to 8.55, p<0.001, I^2=0%.

For incisional hernia repair, there were five RCTs, four prospective cohort studies, four retrospective observational studies (including one case-control study) and two studies of mixed design. A total of 832 laparoscopic hernia repairs and 996 open repairs were reported across the 15 studies. The pooled hernia recurrence rate was 8.5% (71/832) at a mean follow-up of 22.8 months for laparoscopic repair and 10.1% (101/996) at a mean follow-up of 27.9 months for open repair. There was no statistically significant difference in the risk of hernia recurrence between laparoscopic and open repair of incisional hernias: OR 1.14, 95% CI 0.81 to 1.60, p=0.47, I^2=19.4%. The pooled surgical site infection rate was 1.6% (11/685) for laparoscopic repair and 10.1% (75/742) for open repair. The risk of surgical site infection was statistically significantly higher with open repair of incisional hernias: OR 5.16, 95% CI 2.79 to 9.57, p<0.001, I^2=0%.

A second systematic review with a meta-analysis compared laparoscopic with open mesh repair of incisional hernias based on RCTs only.[22] Five out of six RCTs were the same as in the analysis reported in the paragraph above. Mean follow-up in the trials ranged from 2 to 35 months. The meta-analysis reported 12 outcomes, which may have introduced bias from multiple outcome assessment. As in the analysis above, there was no statistically significant difference in hernia recurrence rate between laparoscopic and open repair of incisional hernias. However, in this meta-analysis there was no statistically significant difference in the risk of wound infection: OR 0.49, 95%

CI 0.09 to 2.57, p=0.41, I^2=74%. There were 22/373 (5.9%) surgical site infections in the laparoscopic group compared with 32/378 (8.5%) in the open surgery group. Additional pertinent outcomes from this meta-analysis are presented in *Table 7*. Heterogeneity was high for wound infection, overall complications and haematoma or seroma outcomes.

Table 7: Meta-analysis comparing laparoscopic versus open repair of incisional hernias[22]

Outcome	n studies (n patients)	n events / n patients (laparoscopic)	n events / n patients (open)	OR (95% CI)	p value	I^2 (%)
Bowel complications	6 (751)	22/373	8/378	2.56 (1.15 to 5.72)	0.02	0
Overall complications	6 (751)	145/373	157/378	1.07 (0.33 to 3.42)	0.91	90.64
Haematoma / seroma	6 (751)	57/373	48/378	1.54 (0.58 to 4.09)	0.38	74.03
Neuralgia	2 (303)	5/150	10/154	0.48 (0.16 to 1.46)	0.20	0

Bowel complications = enterotomies, serosal tears and postoperative small bowel obstruction.

Component separation technique

A systematic review with a meta-analysis compared laparoscopic component separation using mesh with open component separation, with or without mesh, for the repair of ventral hernias.[23] It is not specified whether the ventral hernias were primary, recurrent, or incisional. The review authors used the Newcastle-Ottawa scale to assess study quality and planned to exclude studies scoring less than five points. Five retrospective observational studies (n=162) were included in the meta-analysis. No studies were excluded on the basis of their quality score. The primary studies used a variety of biological and synthetic mesh. There was no statistically significant difference in hernia recurrence between the laparoscopic (10/78) and open (13/82) surgery groups: OR 0.76, 95% CI 029 to 1.98, p=0.57, three studies contributed data, I^2=0%. Mean follow-up was a maximum of 15 months; therefore, the hernia recurrence rate may be underestimated. Laparoscopic hernia repair using component separation with mesh was associated with a reduced risk of wound complications (14/78) compared with open repair (36/84): OR 0.27, 95% CI 0.12 to 0.58, p<0.001, I^2=0%. The most commonly reported wound complication in both groups was surgical site infection: 6% in laparoscopic versus 13% in open repair. No seroma formation was reported with laparoscopic repair compared with 11 cases (13%) in the open repair group. Results of the meta-analysis were not affected when one study at a time was excluded.

Mesh fixation techniques in all adults

A poorly reported network meta-analysis (NMA) compared mesh fixation using permanent tacks, absorbable tacks, permanent tacks plus sutures, fibrin glue, or sutures alone, in the repair of ventral hernias.[24] The NMA report incorporated a systematic review of 44 single-arm studies, a direct pairwise meta-analysis of three studies comparing permanent tacks with suture fixation, and a small NMA based on six studies (five RCTs and one prospective cohort study). Each comparison within the NMA was underpinned by a maximum of two studies. The type of ventral hernia repaired in the primary studies was not stated. Studies were excluded if they reported on the use of Physiomesh™ – which has been withdrawn from the market – or included more than 5% emergency hernia repairs. All included studies were required to have a minimum follow-up of 6 months and cohort studies had to have at least 50 participants. The NMA authors used the Cochrane tool for RCTs and the Newcastle-Ottawa scale for observational studies to assess risk of bias. The included RCTs were considered to have overall low risk of bias, with evidence of detection bias. The cohort studies were considered to have generally low risk of bias. The limited description of the NMA states that it was a frequentist analysis that assumed transitivity – that patients in each study could have received any of the mesh fixatives – and calculated surface under the cumulative ranking (SUCRA) scores as estimates of the probability each fixation technique was best.

The systematic review incorporated 51 studies (n=6,950) in total, although two studies incorporated an overlapping set of patients. Median follow-up in primary studies was 22 months (range 6 to 64 months). The review authors noted that crude hernia recurrence rates were generally lower in patients who had suture mesh fixation (1.3% to 1.6%) and groups who had absorbable tacks plus suture fixation (0% to 0.9%) compared with other fixatives. The direct pairwise meta-analysis comparing permanent tack fixation with suture fixation found no statistically significant difference between groups in the risk of ventral hernia recurrence: RR 3.07, 95% CI 0.71 to 13.33, p=0.68, I^2=0%.

Permanent tacks were used as the reference fixative in the NMA, with each fixation method compared with the reference technique. Results from the NMA are presented in *Table 8*. Compared with permanent tack fixation, there were no significant differences in the risk of ventral hernia recurrence with fibrin glue, suture fixation, or permanent tacks plus sutures. In comparisons of permanent tacks with absorbable tacks, the permanent tacks seemed to be associated with a lower risk of hernia recurrence. The SUCRA probability scores suggested that suture fixation had the highest probability of being better than other fixatives for prevention of hernia recurrence.

Table 8: Results of frequentist NMA comparing mesh fixation techniques in ventral hernia repair[24]

Fixation technique	Hernia recurrence RR (95% CI)	SUCRA score (hernia recurrence)
Permanent tacks	Reference	0.73
Fibrin glue	5.00 (0.64 to 38.87)	0.12
Sutures	0.41 (0.09 to 1.89)	0.93
Absorbable tacks	1.37 (1.03 to 1.81)	0.43
Permanent tacks plus sutures	2.64 (0.43 to 16.22)	0.27

A direct, pairwise meta-analysis of RCTs compared permanent tack mesh fixation with suture fixation in laparoscopic ventral hernia repair.[25] Nine trials were identified by the systematic literature search, but only five (n=466) were used in the meta-analysis in order to maintain homogeneity of study characteristics. Four out of these five trials were included in the NMA described above; however, this pairwise analysis reported additional outcomes. Trials recruited patients with either primary (37%) or incisional (63%) ventral hernias. Mean follow-up ranged from 3 to 32 months. All five RCTs compared the same type of permanent tack with non-absorbable suture fixation, and recorded chronic postoperative pain using the same measurement scale. The review authors assessed study quality using the Cochrane risk of bias tool. All included studies were judged to be of moderate or high quality.

Results from the pairwise meta-analysis are presented in *Table 9*. As in the NMA, there was no statistically significant difference in the risk of hernia recurrence between mesh fixatives. There were also no statistically significant differences between fixatives for chronic pain, or development of a seroma or haematoma.

Table 9: Direct pairwise meta-analysis comparing permanent tacks with suture mesh fixation in laparoscopic ventral hernia repair[25]

Outcome	n events / n patients (tack)	n events / n patients (suture)	OR (95% CI)	p value	I^2 (%)
Hernia recurrence	5/188	5/187	1.11 (0.34 to 3.62)	0.86	0
Chronic pain (3 months after surgery)	19/142	11/125	1.52 (0.68 to 3.38)	0.30	53
Seroma and haematoma	13/182	20/183	0.60 (0.29 to 1.26)	0.18	0

A second direct pairwise meta-analysis compared absorbable and non-absorbable tack fixation of mesh during laparoscopic ventral hernia repair.[26] Observational studies and RCTs were eligible for inclusion if they incorporated patients with primary or incisional ventral hernias. The meta-analysis authors assessed risk of bias using the Cochrane tool for RCTs and the Newcastle-Ottawa scale for observational studies. Included studies were judged to be of moderate quality. If more than 25% of studies reported zero events in both groups, the meta-analysis authors calculated the risk difference (RD) rather than the relative risk or odds ratio. The meta-analysis incorporated five studies (n=1,149) consisting of three RCTs, one prospective cohort study, and one retrospective cohort study. Two of the included studies were reported in the NMA described above. One study focused on umbilical hernia repair, while the other four included patients with unspecified ventral hernias. Mean follow-up was 30 months and median follow-up was 13 months. Results from the meta-analysis are presented in *Table 10*. There were no statistically significant differences in comparisons of absorbable with non-absorbable tack fixation for the outcomes of hernia recurrence, chronic pain lasting 6 weeks or longer, seroma formation, or haematoma. The review findings were not affected by restricting the analysis to RCTs.

Table 10: Direct pairwise meta-analysis comparing absorbable and non-absorbable tack fixation in ventral hernia repair[26]

Outcome	n studies (n patients)	n events / n patients (absorbable)	n events / n patients (non-absorbable)	Finding (95% CI)	p value	I^2 (%)
Hernia recurrence	5 (1,149)	81/442	99/707	RD 0.03 (-0.04 to 0.09)	0.47	86
Chronic pain (≥6 weeks)	4 (1,098)	47/416	94/682	OR 0.91 (0.62 to 1.33)	0.64	0
Seroma	4 (333)	8/167	8/166	OR 0.98 (0.37 to 2.60)	0.96	0
Haematoma	3 (243)	2/122	2/121	RD -0.00 (-0.04 to 0.04)	0.99	0

RD = risk difference.

Guidelines

The European and American Hernia Societies produced guidance on the treatment of umbilical and epigastric hernias based on a systematic literature search and consensus among clinicians.[27] Both primary and incisional hernias were included. Only studies of high or acceptable quality according to the SIGN appraisal checklists were used in the guideline. The following recommendations were relevant to the research questions in this review:

- ‘It is recommended that mesh is used for repair of umbilical and epigastric hernias to reduce the recurrence rate. Sutured repair can be considered in shared decision-making and for small hernia defects of less than 1 cm.’ Strength of recommendation: strong.
- ‘It is suggested that slowly resorbable or non-absorbable sutures are used for sutured repair of umbilical and epigastric hernias. The suture technique can be chosen by the surgeon. It is recommended not to use quickly absorbable sutures.’ Strength of recommendation: weak.
- ‘If the mesh is fixed for an umbilical or epigastric hernia repair, it is suggested that a non-absorbable suture is used.’ Strength of recommendation: weak.
- ‘It is suggested that laparoscopic repair is considered for large umbilical or epigastric hernias, or if the patient has an increased risk of wound infection.’ Strength of recommendation: weak.
- ‘Although most umbilical and epigastric hernias can be repaired with an open preperitoneal flat mesh, it is recommended that the repair is tailored based on patient and hernia characteristics and local resources. Patient and surgeon preferences should also be taken into account.’ Strength of recommendation: strong (upgraded).

Summary on ventral hernia repair (primary and incisional) in all adults

- A robust meta-analysis comparing mesh with non-mesh repair of primary ventral hernias and incisional hernias found a statistically significant reduction in risk of hernia recurrence with mesh for both primary and incisional hernias, alongside an increased risk of seroma in patients with an incisional hernia.
- Comparison of biological and synthetic mesh repair of ventral hernias suggests no statistically significant differences in hernia recurrence risk or non-infectious complications, with a lower risk of wound infection associated with biological mesh.
- Meta-analyses comparing laparoscopic with open repair of primary and incisional ventral hernias found no statistically significant differences in hernia recurrence rate, but an increased risk of surgical site infection with open repair.
- An NMA reported no significant differences in hernia recurrence between permanent tack fixation, fibrin glue, suture fixation, or permanent tacks plus suture fixation. Lower hernia recurrence rates were found for permanent tacks compared with absorbable tacks. Direct meta-analyses of permanent tacks versus suture fixation, and absorbable tacks versus permanent tacks, found no statistically significant differences in hernia recurrence, seroma or haematoma outcomes.
- Chronic pain was not reported as an outcome in secondary evidence comparing mesh with non-mesh repair of ventral hernias. In comparisons of laparoscopic and open repair of ventral hernias, there was no statistically significant difference in chronic pain (two

studies). No statistically significant differences in chronic pain were reported in direct pairwise meta-analyses comparing tack and suture mesh fixation, or absorbable and non-absorbable tack fixation.

Primary umbilical hernia

Synthetic mesh versus non-mesh repair in all adults

A well-reported systematic review with meta-analysis compared open synthetic mesh with open suture repair of primary umbilical or para-umbilical hernias in adults.[13] A pooled meta-analysis was performed using both RCTs and cohort studies, with sensitivity analyses using RCTs and cohort studies separately. Fourteen studies (n=2,361) were included in the systematic review: six RCTs, one prospective cohort and seven retrospective cohort studies. Studies in the review reported on umbilical hernias up to 9 cm in size, with median follow-up ranging from 6 to 82 months. The review authors appraised cohort studies using the Newcastle-Ottawa scale and RCTs using the Cochrane risk of bias tool. One RCT was considered to have low risk of bias; the other five RCTs had unclear or high risk of bias due to a lack of reporting of randomisation and other methodological features. The cohort studies scored between four and eight out of nine points on the Newcastle-Ottawa scale.

Results from the pooled meta-analysis, and for RCTs and cohorts separately, are presented in *Table 11*. In the pooled analysis, there was a statistically significant reduction in the risk of umbilical hernia recurrence for patients treated with mesh compared with suture repair: RR 0.48, 95% CI 0.30 to 0.77, p=0.002, I^2=30%. The number needed to treat (NNT) to prevent one umbilical hernia recurrence was 19, 95% CI 14 to 31. There was a higher risk of seroma developing following mesh repair compared with suture repair in the pooled analysis: RR 2.37, 95% CI 1.45 to 3.87, p<0.001, I^2=0%. The number needed to harm (seroma developing) was estimated as 30, 95% CI 17 to 86. There were no statistically significant differences in the risk of surgical site infection or haematoma in the pooled analysis. In the sensitivity analyses, hernia recurrence was statistically significantly lower with mesh repair in the RCT analysis but there was no statistically significant difference in the meta-analysis of cohort studies. Both surgical site infection and seroma risk were statistically significantly increased with mesh repair in the cohort study meta-analysis but not in the analyses of RCTs.

Seven studies in the meta-analysis reported on chronic pain; no statistical analysis was attempted for this outcome due to high heterogeneity in pain measures and definitions of chronic pain. Three studies were excluded from the review for having less than 7 days follow-up or for not providing pain scores separately for patients treated with mesh and suture repair. Of the remaining four studies, two reported less chronic pain in patients treated with mesh, based on finding chronic pain only in patients who had suture repair (2.8% of patients) and fewer analgesics being used by patients with a

mesh repair. In one study, patients undergoing mesh repair reported more pain at rest (16%) and during physical activity (47%), compared with patients who had a suture repair (4.3% and 23.5%, respectively). The fourth study found no statistically significant differences in postoperative pain between mesh and suture repair groups (67.8% versus 70.3%). This lack of statistical significance remained at 2-years follow-up: 94.5% versus 93.5% pain free, p=0.45.

Table 11: Meta-analysis results for open mesh repair versus open suture repair of primary umbilical hernias in adults[13]

Outcome	n patients (n studies)	n events / n patients (mesh)	n events / n patients (non-mesh)	RR (95% CI)	p value	I^2
RCTs and cohort studies						
Hernia recurrence	2,316 (14)	43/1,000	126/1,316	0.48 (0.30 to 0.77)	0.002	30%
Seroma	1,432 (9)	39/600	26/832	2.37 (1.45 to 3.87)	<0.001	0%
Haematoma	1,040 (8)	8/474	19/566	0.58 (0.25 to 1.34)	0.20	0%
Surgical site infection	2,132 (13)	81/882	71/1,250	1.57 (0.93 to 2.65)	0.09	41%
RCTs only						
Hernia recurrence	742 (6)	9/383	39/359	0.23 (0.12 to 0.46)	<0.001	0%
Seroma	742 (6)	17/383	9/359	1.67 (0.79 to 3.54)	0.18	0%
Surgical site infection	741 (6)	14/383	17/359	0.76 (0.38 to 1.52)	0.44	0%
Cohort studies only						
Hernia recurrence	1,574 (8)	34/617	87/957	0.70 (0.42 to 1.16)	0.17	23%
Seroma	690 (3)	22/217	17/473	2.91 (1.57 to 5.38)	<0.001	0%
Surgical site infection	1,390 (7)	67/499	54/891	2.46 (1.38 to 4.38)	0.002	35%

A second meta-analysis that compared open mesh repair with open suture repair of primary umbilical hernias, based only on RCTs, presented very similar effect estimates and reached similar conclusions.[28]

Biological versus synthetic mesh repair in all adults

No secondary evidence was identified comparing types of mesh for repair of primary umbilical hernia in adults.

Laparoscopic versus open mesh repair in all adults

No secondary evidence was identified comparing laparoscopic and open repair of primary umbilical hernia in adults.

Mesh fixation techniques in all adults

No secondary evidence was identified that compared mesh fixation techniques for repair of primary umbilical hernia in adults.

Summary on primary umbilical hernia repair

- In a meta-analysis of RCTs and cohort studies comparing open mesh repair with open suture repair, there was a statistically significant reduction in the risk of hernia recurrence and an increased risk of seroma formation in patients treated with mesh. Analysis focusing only on the RCTs confirmed the reduced hernia recurrence risk, but found no statistically significant difference in seroma risk.
- No statistical analysis on chronic pain was presented in the meta-analysis on umbilical hernia repair due to high heterogeneity in pain measures and definitions of chronic pain. Of four studies reporting chronic pain in comparisons of mesh and non-mesh repair, two reported less chronic pain with mesh repair, one reported more chronic pain in patients with mesh repair, and one study found no difference in postoperative pain between mesh and non-mesh repair.

Groin hernias

Synthetic mesh versus non-mesh repair in men

SHTG published advice on mesh versus non-mesh repair of inguinal hernias in men in January 2020.[29] The advice recommended that surgical mesh should be used for elective repair of primary inguinal hernias in men in Scotland. The recommendation was based on the following key evidence:

- A Cochrane systematic review comparing inguinal hernia repair using any mesh technique with any non-mesh technique (n=6,293; approx. 96% male).
  - Compared with non-mesh repair, patients treated with mesh were statistically significantly less likely to have a hernia recurrence: RR 0.46, 95% CI 0.26 to 0.80, p=0.0055.
  - Patients treated with mesh were statistically significantly less likely to experience neurovascular or visceral injury (RR 0.61, 95% CI 0.49 to 0.76) or to suffer from urinary retention (RR 0.53, 95% CI 0.38 to 0.73) compared with non-mesh repair.
  - There was a statistically significant greater risk of developing a seroma (RR 1.63, 95% CI 1.03 to 2.59, p=0.038) or postoperative wound swelling (RR 4.56, 95% CI 1.02 to 20.48) in patients treated with mesh compared with non-mesh repair.
- Two meta-analyses evaluated chronic pain after inguinal hernia repair using surgical mesh compared with non-mesh repair.
  - An individual patient data meta-analysis (n=11,174; data from 58 studies) of mesh versus non-mesh repair reported statistically significant lower odds of persistent pain with mesh repair: OR 0.60, 95% CI 0.42 to 0.84.
  - The second meta-analysis compared individual mesh and non-mesh techniques – maximum of three studies in each analysis – and found no statistically significant differences in risk of chronic pain in any comparison.

Given the recent SHTG publication on inguinal hernia repair in men, no further evidence was sought on mesh versus non-mesh repair for this indication. Groin hernia repair in men accounts for >90% of all groin hernia repair (*Table 2*).

Biological versus synthetic mesh repair in all adults

A well reported meta-analysis compared biological mesh with synthetic mesh for Lichtenstein open repair of primary inguinal hernias in men.[30] Only RCTs were eligible for inclusion. The review authors used the Cochrane risk of bias tool to assess the quality of included studies. Overall risk of bias was judged to be low for included trials, and all studies had an unclear risk of bias in relation to selective reporting of results. Chronic pain was defined in this analysis as pain that persisted for 3 months or

more after surgery. Five trials were identified and four were used in the meta-analysis (n=382); one trial was reported in two papers with different lengths of follow-up. The number of events was low in both treatment groups. Median follow-up was 3 to 36 months.

Results of the meta-analysis are presented in *Table 12*. There were no statistically significant differences between biological and synthetic mesh for the outcomes of inguinal hernia recurrence, chronic groin pain, or haematoma. The risk of seroma formation was statistically significantly greater in patients treated with biological mesh: OR 2.67, 95% CI 1.12 to 6.35, p=0.03, I^2=0%. The meta-analysis findings did not change when the authors reanalysed the data after accounting for different weights of synthetic mesh. The meta-analysis authors noted three limitations that might affect their results: the follow-up duration in trials was not long enough to reliably detect hernia recurrence; trials differed in how they defined and measured chronic pain; and variations between brands of biological mesh suggest results from this analysis may only apply to Surgisis® biological mesh.

Table 12: Meta-analysis comparing biological and synthetic mesh for the repair of inguinal hernias[30]

Outcome	n studies	n events/ n patients (biological)	n events/ n patients (synthetic)	OR (95% CI)	p value	I^2 (%)
Hernia recurrence	4 (2 provide data)	3/179	1/203	2.15 (0.39 to 11.74)	0.38	52
Chronic groin pain	4	17/179	31/203	0.54 (0.29 to 1.02)	0.06	0
Seroma	4	17/179	7/203	2.67 (1.12 to 6.35)	0.03	0
Haematoma	4	15/179	11/203	1.62 (0.73 to 3.62)	0.23	17

A second meta-analysis compared absorbable mesh (biological mesh) with synthetic mesh for Lichtenstein open inguinal hernia repair.[31] Based on a literature search conducted at the same time as for the meta-analysis described above, the authors of this analysis included one additional RCT and evidence from six case series in their meta-analysis and reached similar conclusions.

Laparoscopic versus open mesh repair in all adults

A well reported NMA compared open Lichtenstein, transabdominal preperitoneal (TAPP), totally extraperitoneal (TEP), and robotic TAPP repair of primary unilateral inguinal hernias.[32] This Bayesian NMA assessed the three core assumptions of NMA: consistency between direct and indirect evidence; similarity in characteristics of patients in included studies; and heterogeneity. There was

no evidence of inconsistency in the NMA and heterogeneity was low or moderate for all outcomes. The NMA authors assessed the quality of included studies using the Cochrane risk of bias tool for RCTs and the ROBINS-I tool for observational studies. Sixteen studies (n=51,037) were included in the NMA: 12 RCTs, three prospective observational studies, and one retrospective observational study. The majority of study participants (81.5%) were male and follow-up ranged from 1 to 60 months. Results of the NMA are presented in *Table 13*. There were no statistically significant differences between any of the laparoscopic or open procedures for the outcomes of inguinal hernia recurrence, haematoma, seroma, or chronic pain (undefined).

Table 13: NMA comparing open Lichtenstein, TAPP and TEP repair of primary unilateral inguinal hernias[32]

Outcome	n studies (n patients)	TAPP vs. Open RR (95% CrI)	TEP vs. Open RR (95% CrI)	TEP vs. TAPP RR (95% CrI)
Hernia recurrence	9 (111,197)	0.96 (0.57 to 1.51)	1.0 (0.65 to 1.61)	1.10 (0.63 to 2.10)
Haematoma	5 (54,044)	0.68 (0.40 to 1.30)	0.67 (0.43 to 1.20)	1.01 (0.51 to 1.80)
Seroma	5 (51,438)	0.91 (0.50 to 1.62)	0.64 (0.32 to 1.33)	0.70 (0.39 to 1.31)
Chronic pain	6 (36,724)	0.53 (0.27 to 1.20)	0.86 (0.48 to 1.16)	1.70 (0.63 to 3.20)

CrI = credible interval.

A second NMA compared the same three approaches to hernia repair (Lichtenstein, TAPP and TEP) for inguinal hernias.[33] A greater number of trials were included in this analysis, likely due to less strict inclusion criteria. The NMA reached the same conclusions as the analysis reported above for the outcomes of hernia recurrence, haematoma, seroma, and chronic pain. An additional outcome was reported in this NMA: wound infection. The risk of wound infection after Lichtenstein open repair was significantly greater than for TEP: OR 0.33, 95% credible interval (CrI) 0.09 to 0.81. There were no significant differences in wound infection risk in comparisons of Lichtenstein open repair compared with TAPP, or for TAPP versus TEP.

Mesh fixation techniques in all adults

Mesh fixation (open repair)

A Bayesian random effects NMA compared self-gripping mesh, suture fixation, and fibrin glue fixation, for open repair of inguinal hernias.[34] The analysis included only RCTs and excluded studies where the trial methodology or the surgical and mesh fixation techniques were not clearly reported. The authors tested the assumptions of NMA. Where it was possible to test for consistency, no inconsistency was detected for any outcome. Heterogeneity was low in all analyses. Quality of

included trials was assessed using the Cochrane risk of bias tool. The NMA authors considered the trials to have an overall low or unclear risk of bias. In the NMA, chronic pain was defined as pain that persisted for at least 3 months after surgery or discomfort affecting daily life for at least 3 months after surgery.

Twenty-eight RCTs were included in the NMA (n=5,495). The follow-up periods in individual studies were not specified. The majority of trial participants (94.5%) were male in those trials that reported patient sex. The risk of hernia recurrence, chronic pain, surgical site infection, haematoma, and seroma were not significantly different for fibrin glue or suture fixation compared with self-gripping mesh at 1-year follow-up (*Table 14*).

Table 14: NMA comparing self-gripping mesh, fibrin glue fixation, and suture fixation of mesh during open repair of inguinal hernias at 1-year follow-up[34]

Outcome	Self-gripping mesh vs. fibrin glue RR (95% CrI)	Self-gripping mesh vs. suture fixation RR (95% CrI)
Hernia recurrence	1.5 (0.52 to 4.70)	0.65 (0.36 to 1.20)
Chronic pain (≥3 months)	0.63 (0.36 to 1.12)	1.1 (0.69 to 1.60)
Surgical site infection	1.9 (0.35 to 11.0)	1.1 (0.60 to 1.80)
Haematoma	0.83 (0.50 to 1.30)	1.0 (0.72 to 1.40)
Seroma	1.80 (0.54 to 6.50)	1.0 (0.62 to 1.50)

Mesh fixation (laparoscopic repair)

One NMA, that also reported a direct pairwise meta-analysis, compared mesh fixation techniques for laparoscopic TEP inguinal hernia repair.[7] Only RCTs were included in the analysis. Adverse events were reported as a composite outcome (postoperative complications) because seroma, haematoma, surgical site infection, urinary retention, and intra-operative injury were all considered rare events. Quality of included studies was assessed using the Cochrane risk of bias tool. The NMA authors found most included trials (>80%) had a high risk of attrition bias, detection bias, and selective reporting bias. More than half the trials had an unclear risk of bias relating to blinding. The NMA authors do not state how, or if, they tested the transitivity assumption. No inconsistency was detected in the analyses.

Fifteen RCTs (n=1,783) were included in the NMA. Mean follow-up was 8 to 41 months. The proportion of males in the included studies ranged from 70% to 100%. No trials assessed self-gripping mesh in TEP inguinal hernia repair.

Results from the direct pairwise meta-analysis within the NMA, that compared no fixation and fibrin glue fixation with metallic tack fixation, are presented in *Table 15*. Compared with metallic tack fixation, no mesh fixation was associated with a lower risk of chronic pain: RR 0.64, 95% CI 0.47 to 0.88. There were no statistically significant differences in the risk of hernia recurrence or postoperative complications for no mesh fixation compared with metallic tack fixation. In the analysis of glue fixation compared with metallic tack fixation, there were no statistically significant differences for any outcome.

Table 15: Direct pairwise meta-analysis comparing mesh fixation techniques in laparoscopic TEP inguinal hernia repair[7]

Outcome	No fixation vs. metallic tack	Glue fixation vs. metallic tack
Hernia recurrence	RR 1.43 (95% CI 0.41 to 4.98)	RR 0.35 (95% CI 0.06 to 1.89)
Chronic groin pain	RR 0.64 (95% CI 0.47 to 0.88)	RR 0.56 (95% CI 0.30 to 1.02)
Postoperative complications	RR 0.83 (95% CI 0.52 to 1.31)	RR 1.04 (95% CI 0.62 to 1.73)

Results from the NMA of mesh fixation techniques in TEP laparoscopic inguinal hernia repair are presented in *Table 16*. There were no significant differences between mesh fixation techniques for the outcomes of hernia recurrence, chronic groin pain, or postoperative complications. Based on SUCRA ranking, fibrin glue fixation was likely to be best for reducing the risk of hernia recurrence, followed by suture fixation. Absorbable tacks were ranked worst for hernia recurrence. Fibrin glue was ranked best for reducing the risk of chronic groin pain, followed by no fixation, metallic tacks, and suture fixation. Ranking for postoperative complications suggested that absorbable tacks had the lowest rate of complications, followed by no fixation, and fibrin glue fixation.

Table 16: NMA comparing mesh fixation techniques for laparoscopic TEP repair of inguinal hernias. All results are RR (95% CrI)[7]

	No fixation	Absorbable tack	Suture fixation	Glue fixation
Hernia recurrence (15 RCTs)				
No fixation	1.57 (0.49 to 5.07)	4.64 (0.10 to 221.24)	0.18 (0.00 to 12.94)	0.19 (0.03 to 1.02)
Absorbable tack		7.30 (0.13 to 414.04)	0.04 (0.00 to 12.40)	0.04 (0.00 to 2.74)
Suture fixation			0.29 (0.00 to 18.81)	1.02 (0.02 to 51.21)
Glue fixation				0.29 (0.07 to 1.30)

	No fixation	Absorbable tack	Suture fixation	Glue fixation
Chronic groin pain (11 RCTs)				
No fixation	0.75 (0.33 to 1.68)	-	3.45 (0.12 to 95.33)	0.71 (0.21 to 2.41)
Suture fixation			2.58 (0.11 to 61.71)	0.20 (0.01 to 4.47)
Glue fixation				0.53 (0.25 to 1.12)
	No fixation	**Absorbable tack**	**Suture fixation**	**Glue fixation**
Postoperative complications (13 RCTs)				
No fixation	0.95 (0.47 to 1.89)	0.66 (0.03 to 15.79)	1.46 (0.24 to 9.01)	1.09 (0.44 to 2.72)
Absorbable tack		0.63 (0.02 to 16.13)	2.21 (0.06 to 85.36)	1.64 (0.06 to 44.58)
Suture fixation			1.38 (0.24 to 8.00)	0.74 (0.15 to 3.59)
Glue fixation				1.03 (0.47 to 2.25)

Data in grey cells are the results of each fixation technique versus metallic tack (reference). Data in white cells are results for the column fixation technique versus the row fixation technique.

In addition to NMA evidence comparing mesh fixation techniques, a pairwise meta-analysis comparing fibrin glue fixation with staple fixation provided evidence on mesh fixatives during laparoscopic TAPP repair of inguinal hernias.[35] The systematic review incorporated both RCTs and 'non-RCTs' but only the former were used in the meta-analysis. Quality of included studies was assessed using the Cochrane risk of bias tool for RCTs and the Newcastle-Ottawa scale for observational studies. The review authors determined that the RCTs included in the analysis had an unclear risk of selective reporting bias. All trials had low risk of bias for blinding and sequence generation. The observational studies generally had a low risk of bias, scoring 7–9 out of 9 on the Newcastle-Ottawa scale.

The meta-analysis incorporated four RCTs (n=430). Trial follow-up duration was either 6 or 12 months. The majority of patients (84.9%) were male and one trial included patients with recurrent hernias. There were no statistically significant differences in hernia recurrence risk between glue (7/215) and staple (3/215) mesh fixation for TAPP inguinal hernia repair: OR 2.10, 95% CI 0.61 to 7.22, p=0.24, I^2=0%. There was no statistically significant difference in seroma and haematoma risk between fibrin glue (16/171) and staple (5/170) fixation for TAPP inguinal hernia repair: OR 0.55, 95% CI 0.27 to 1.14, p=0.11, I^2=0%.

A visual analogue scale (VAS) was used to measure pain in three of the included trials; however, variation in the point in time at which chronic pain was measured prevented pooling of results. One study found the difference in pain scores was not statistically significant 1 month after surgery ($p<0.07$) and no patients experienced pain in either treatment group after 6 months. Another study found statistically significantly lower VAS pain scores in the fibrin glue group at 1, 3 and 6 months follow-up compared with staple fixation. The third study found no statistically significant difference in pain scores at 3 months follow-up, with a statistically significant reduction in pain scores for the fibrin glue group at 12 months follow-up.

Summary on groin hernia repair

- The majority of patients incorporated into meta-analyses on inguinal or groin hernia repair were men.
- Based on the evidence reviewed in the previous SHTG advice on inguinal hernia repair in men, mesh repair of inguinal hernia is associated with a lower risk of hernia recurrence, neurovascular or visceral injury, and urinary retention, compared with suture repair. There is a statistically significant increase in the risk of seroma or postoperative swelling with mesh repair.
- In a meta-analysis comparing biological mesh with synthetic mesh for open repair of primary inguinal hernias, there were no statistically significant differences between groups for the outcomes of hernia recurrence, chronic pain, or haematoma. There was a statistically significant increase in the risk of seroma with biological mesh.
- In an NMA comparing open, TAPP and TEP repair of inguinal hernias there were no significant differences between laparoscopic and open procedures for the outcomes of hernia recurrence, haematoma, seroma, or chronic pain. A second NMA found a significantly higher risk of wound infection after open repair compared with TEP.
- For open mesh repair of inguinal hernias, an NMA found no significant difference in hernia recurrence, chronic pain, or surgical site infection, for fibrin glue and suture fixation compared with self-gripping mesh.
- For laparoscopic TEP repair of inguinal hernias an NMA found no significant differences between no fixation, absorbable tack fixation, suture fixation, and glue fixation, for the outcomes of hernia recurrence, chronic pain, and postoperative complications. Direct pairwise meta-analysis of fibrin glue fixation versus staples in TAPP inguinal hernia repair found no statistically significant differences between groups for hernia recurrence or seroma/ haematoma.

Outcomes of hernia repair in women

The use of surgical mesh has become an important topic in the last few years following women's experiences of severe, chronic pain after mesh was used to treat pelvic organ prolapse. This review explored the evidence on hernia repair specifically in women.

Ventral hernias

No secondary evidence was identified on the repair of primary or incisional ventral hernias in women.

A single primary study, based on the Herniamed registry, used propensity score matching to compare outcomes following elective incisional hernia repair in men and women.[36] The Herniamed registry contains prospectively collected data on hernia repairs in Germany, Austria and Switzerland. This study retrospectively analysed data on postoperative outcomes at 30 days and 1 year after surgery for patients who had an elective incisional hernia repair between September 2009 and January 2018. Laparoscopic mesh, open mesh, and suture repair procedures were all included in the analysis. Studies on repairs using Physiomesh™ (since withdrawn from the market) or patients with a recurrent hernia were excluded. Patients were propensity matched based on their American Society of Anesthesiologists (ASA) status, age, body mass index (BMI), preoperative pain, hernia size, hernia location, mesh size, use of a surgical drain, risk factors such as diabetes, and operative procedure.

Out of 22,895 patients in the original incisional hernia repair cohort – 11,480 women (50.1%) and 11,415 men – propensity score matching was achieved for 8,138 patient pairs. Statistically significant differences in baseline patient characteristics between male and female patients prior to matching were reduced to below 10% for all variables after matching. Systematic sex-specific differences (*Table 17*) were identified for the outcomes of intra-operative complications, pain at rest at 1-year follow-up, pain on exertion at 1-year follow-up, and chronic pain requiring treatment at 1-year follow-up. No statistically significant differences between male and female patients were reported for postoperative complications or complication-related reoperation rates. Subgroup analyses comparing pairs of patients who underwent the same type of mesh repair found similar differences in pain outcomes between men and women for all open and laparoscopic procedures.

Table 17: Results of a propensity matched comparison of outcomes from elective incisional hernia repair in men and women[36]

Outcome	n pairs	Men (%)	Women (%)	OR (95% CI)	p value
Intra-operative complications	4	1.6	2.0	0.78 (0.61 to 0.99)	0.04
General complications	NR	3.2	3.6	0.88 (0.75 to 1.05)	0.16
Postoperative complications	NR	7.4	7.2	1.03 (0.92 to 1.16)	0.64
Complication-related reoperation	NR	3.6	3.2	1.12 (0.95 to 1.33)	0.19
Pain on exertion at 1-year follow-up	284	11.7	18.3	0.64 (0.59 to 0.69)	<0.001
Pain at rest at 1-year follow-up	65	7.5	11.1	0.68 (0.61 to 0.75)	<0.001
Chronic pain requiring treatment at 1-year follow-up	39	5.4	9.1	0.59 (0.52 to 0.67)	<0.001

NR = not reported.

Umbilical hernias

No studies were identified that reported results specifically for umbilical hernia repair in women or separately by sex in adults undergoing umbilical hernia repair.

Groin hernias

Two systematic reviews explored the evidence on groin hernia repair in women.[12, 37] The better quality of the two reviews reported on hernia recurrence rates after repair of primary inguinal hernias in women, with a focus on laparoscopic versus open repair.[37] Studies that focused solely on femoral hernia repair were excluded. Included studies consisted of trials or cohort studies with at least 20 female participants and more than 6 months follow-up. Crude recurrence rates were calculated as the number of recurrences divided by the number of women, thereby assuming no bilateral hernias. Heterogeneity between studies was not taken into consideration by the review authors. Quality of included studies was assessed using the Cochrane risk of bias tool for RCTs and the Newcastle-Ottawa scale for cohort studies. The review authors concluded the RCTs were of low or unclear risk of bias and the cohort studies of low or moderate risk of bias.

The systematic review included 55 studies incorporating 43,870 female patients. There were five RCTs, 14 prospective cohort studies, seven prospective database studies, and 29 retrospective cohort studies. Median follow-up was 28 months; range from 6 months to over 10 years. Eight studies reported on both laparoscopic and open hernia repair. Nine studies involved only female patients. The overall hernia recurrence rate in women treated for a primary groin hernia was 2.6% (1,134/43,353); when only RCT evidence was considered, the hernia recurrence rate was 0.5% (1/199). Pooled analysis of recurrence rates across RCTs and prospective observational studies found that the overall hernia recurrence rate was lower in women following laparoscopic repair compared with open repair: 1.2% (18/1,525) versus 4.9% (490/10,058), p<0.001. This result should be treated with caution since only eight studies were comparative.

Twenty studies (2,525 women) reported an overall hernia recurrence rate of 1.2% (27/2,257) with laparoscopic hernia repair over a mean follow-up of 12 to 72 months. Thirteen studies reported no hernia recurrence in female patients after laparoscopic repair. Six studies were solely in women, five of which were retrospective, and recurrence rates reported for laparoscopic repair in these studies ranged from 0% to 3%. Thirty-seven studies (34,127 women) reported an overall hernia recurrence rate of 2.4% (818/33,971 patients) with open hernia repair over a mean follow-up of 6 months to 10 years. Of 496 recurrences in one study, 203 (40.9%) were femoral hernias. Eighteen studies reported no hernia recurrence in women after open surgery. Seven studies reported only on women, six of these were retrospective, and the recurrence rate ranged from 0% to 12.5%.

Eight studies described an open suture repair, with recurrence rates ranging from 0% to 10.7%. Four studies reported both mesh and non-mesh repair. Two of these studies, both database studies, found there was no difference in the risk of reoperation (a surrogate for hernia recurrence) after open suture repair compared with open mesh repair in female patients.

The second systematic review was of low quality, with the methodology poorly reported.[12] The review authors included 80 publications of unknown design. Two studies on open non-mesh repair of groin hernias reported hernia recurrence rates of 2.8% and 2.4% respectively. Two studies reporting on mesh-based hernia repair found no recurrence of hernia during follow-up. Three studies reported lower hernia recurrence rates after laparoscopic repair compared with open repair:

- In a study of 13,945 primary groin hernia repairs in women, reoperation rates were statistically significantly lower after laparoscopic repair compared with open repair for both inguinal hernias (1.8% versus 6.3%, p<0.001) and femoral hernias (2.2% versus 5.5%, p=0.005).
- In a multivariate adjusted analysis of 5,893 female patients with a groin hernia, laparoscopic repair was associated with a statistically significant reduction in the risk of recurrence compared with Lichtenstein open repair: hazard ratio (HR) 0.57, 95% CI 0.43 to 0.75, p<0.001.

- In a multivariate adjusted analysis of 3,970 female patients with a femoral hernia, laparoscopic repair led to a statistically significant reduction in risk of reoperation for recurrence compared with open repair: HR 0.33, 95% CI 0.09 to 0.95.

One study reported that the proportion of hernias recurring after inguinal hernia repair that turned out to be femoral was 25% after laparoscopic repair compared with 47% after Lichtenstein open repair, p<0.001. In a study of the Swedish Hernia Registry, femoral hernias were found during recurrence operations in 41.6% of women compared with 4.6% of men. In five studies, women had higher postoperative pain than men.

A registry study explored factors that influenced outcomes in women who underwent elective, unilateral, primary groin hernia repair.[38] Data from the Herniamed registry were extracted for all women who had a groin hernia repair between September 2009 and July 2017 (n=15,601). Patients underwent TAPP repair (40.2%), TEP repair (23.5%), Lichtenstein open repair (27.9%), or Shouldice suture repair (8.4%). Statistically significant increases in the risk of postoperative complications were driven by older age, the presence of risk factors, a larger hernia, higher ASA score, and having a purely femoral hernia. The risk of complication-related reoperation was statistically significantly increased by the presence of risk factors, having a femoral hernia, and Lichtenstein open repair. Older age or a larger hernia reduced the risk of pain at rest, while preoperative pain or a higher BMI increased the risk of pain at rest. Older age or larger hernia size reduced the risk of pain on exertion. Preoperative pain, higher BMI, a femoral hernia or both a femoral and inguinal hernia, and use of Lichtenstein open mesh repair, statistically significantly increased the risk of pain on exertion. Older age and larger hernia size reduced the risk of pain requiring treatment, while higher ASA score or a femoral hernia increased the risk of pain requiring treatment.

Hernia repair and pregnancy

A well-conducted systematic review of observational studies explored the repair of ventral hernias prior to, during, and after pregnancy.[39] Hernias classed as umbilical, epigastric, ventral, or incisional, were included. Case studies were excluded, as were case series with less than 100 participants. The nine studies included in the review therefore consisted of four cohort studies, four case-control studies, and one case series. Eight out of nine studies were retrospective. The duration of follow-up is not reported. Studies were appraised using the Newcastle-Ottawa scale for cohort and case-control studies, and the Institute of Health Economics checklist for case series. The majority of studies were judged by the review authors to be of acceptable or better quality. Results presented in the systematic review from the nine primary studies are reported in *Table 18*.

An older systematic review on abdominal hernia repair and pregnancy was identified in our literature search.[40] The studies included in the review were mainly case studies and focused on emergency repair of hernias, and therefore the review is not described further.

Table 18: Results from nine observational studies in a systematic review on ventral hernia repair prior to, during, or after pregnancy[39]

Study	Study design	Population	n patients	Outcome/exposure	Results	Follow-up
Pre-pregnancy ventral hernia repair						
Oma, 2017	Retrospective cohort	Umbilical, epigastric or incisional hernia	3,578	Subsequent pregnancy n=267 (7.5%)	Risk of hernia recurrence in subsequent pregnancy: HR 1.56 (95% CI 1.09 to 2.25) No difference between mesh and suture repair	–
Lappen, 2016	Retrospective cohort	Incisional hernia	11,020	Subsequent pregnancy n=840 (7.6%)	Risk of hernia reoperation in subsequent pregnancy: OR 1.73 (95% CI 1.40 to 2.14)	–
Oma, 2016	Retrospective cohort	Primary umbilical or epigastric hernia with subsequent pregnancy	224	Mesh (n=49) vs. suture (n=175)	Risk of hernia recurrence with mesh versus suture repair prior to pregnancy: HR 2.77 (95% CI 0.98 to 7.85)	Median 3.8 years
Umbilical hernia and umbilical hernia repair during pregnancy						
Huskins, 2017	Retrospective case series	Umbilical hernia repair during pregnancy	126	73 incarcerated or strangulated (emergency repairs)	Six laparoscopic and 120 open repairs (three with mesh) Minimal 30-day morbidity	–
Oma, 2017	Retrospective cohort	Umbilical hernia during pregnancy	20,714	17 (0.08%) with umbilical hernia	No repairs during pregnancy five elective postpartum repairs	Median 4 years

Umbilical hernia repair in combination with caesarean section						
Steinemann, 2013	Retrospective case-control	Undergoing caesarean section (CS)	14 vs. 140	CS plus suture umbilical hernia repair vs. CS only	Four recurrences No increased risk of postoperative complications	–
Gabriele, 2010	Retrospective case-control	Undergoing CS	9 vs. 100	CS plus mesh umbilical hernia repair vs. CS only	Zero recurrences No difference in risk of complications	Up to 1 year
Ghnnam, 2009	Prospective case-control	Undergoing caesarean section	48 vs. 100	CS plus umbilical hernia repair vs. CS only	36 suture repair, 12 mesh repair One recurrence after suture repair	Mean 22 months
Ochsenbein-Kolbe, 2004	Retrospective case-control	Undergoing CS	3 vs. 305	CS plus umbilical hernia repair vs. CS	Zero recurrences No difference in postoperative complications	Mean 4.7 years

Guidelines

International guidelines, endorsed by hernia societies from five continents, have been published on the management of groin hernias, including treatment of these hernias in women.[41] No systematic reviews or RCTs were available to inform the guidance on groin hernia repair in women, hence the recommendations are based on observational evidence. The three recommendations made on groin hernia repair in women are as follows:

- 'Provided that expertise is available, women with groin hernias are recommended to undergo laparo-endoscopic repair with mesh implantation.' Strength of recommendation: strong (upgraded).
- 'Timely hernia repair is recommended in women with groin hernias.' [This is due to an increased frequency of incarcerated and strangulated groin hernias in women.] Strength of recommendation: strong (upgraded).
- 'Watchful waiting is suggested in pregnant females with groin swelling.' Strength of recommendation: weak.

A commissioning guide from the British Hernia Society and the Royal College of Surgeons recommends laparoscopic repair of groin hernias in women.[42] This guidance recommends that all groin hernias in women should be classed as urgent referrals.

In 2020, the European and American Hernia Societies published a guideline on the treatment of primary ventral hernias in special circumstances, including pregnancy.[43] The guidance on ventral hernia repair and pregnancy is based on two systematic reviews and three primary studies included within the reviews. The guideline group of 12 surgeons (11 general and one plastic) used a grading of recommendations assessment, development and evaluation (GRADE) approach to develop the guidance. Studies were identified through systematic literature searching and appraised using the SIGN checklists. The following recommendations are made in relation to ventral hernia repair and pregnancy:

- 'Elective umbilical and epigastric hernia repair should, if possible, be postponed until after pregnancy and preferably until after last pregnancy in women of childbearing age.' Strength of recommendation: strong (upgraded).[43]
- 'If hernia repair cannot be postponed until after the last pregnancy, a suture repair is suggested for umbilical and epigastric hernias in women of childbearing age. A mesh repair could be performed after the last pregnancy.' Strength of recommendation: weak.[43]

Summary of hernia repair in women

- A registry study in patients with incisional ventral hernia repairs found that women were more likely than men to experience intra-operative complications, pain at rest at 1-year follow-up, pain on exertion at 1-year follow-up, and chronic pain requiring treatment at 1-year follow-up.
- Two systematic reviews of mainly single-arm studies found that groin hernia recurrence was lower in women after laparoscopic repair compared with open repair. Two database studies within these systematic reviews found no difference in recurrence between mesh and non-mesh repair in women.

Cost effectiveness

Primary ventral hernias in all adults

Synthetic mesh versus non-mesh repair

No economic evidence was identified comparing mesh with non-mesh repair for primary ventral hernias.

Biological versus synthetic mesh repair

The economic evidence comparing biological and synthetic mesh consisted of two cost-utility analyses,[44, 45] a cost and outcome comparison,[46] and two cost comparisons.[47, 48]

The most recent cost-utility analysis, from the US, assessed the economic value of three different types of surgical mesh for use in ventral hernia repair: biological, biosynthetic, and synthetic.[45] This study was based on a synthesis of data from the American Hernia Society Quality Collaborative for short-term complication rates and patient demographics, and long-term complication rates from the published literature. The base-case population was assumed to be a 57-year-old female undergoing open, elective, retromuscular, midline ventral hernia repair for a defect 14 cm long and 9 cm wide. The analysis took a societal perspective, assessed complications up to 5 years after the initial operation, and compared interventions in terms of cost per quality-adjusted life-year (QALY) gained. In the model, patients underwent surgery and could experience short-term complications (or not) lasting 1 month, or experience long-term complications (or not) lasting 1 year. The probability of short- and long-term complications used in the base-case were 13% and 5.6% respectively and assumed to be identical across mesh types.

In the base-case, synthetic mesh dominated – that is, was less expensive than but equally effective as – biosynthetic and biological mesh (*Table 19*).[45] The results were sensitive to long-term complication rates and costs for the different mesh types. Specifically, biosynthetic and biological

mesh became more favourable as their cost decreased and the relative complication rate for synthetic mesh increased. Biosynthetic and biological mesh became cost effective compared with synthetic mesh when long-term complication rates for synthetic mesh increased to 15.5% and 26.2%, respectively.

Table 19: Base-case cost-utility comparison of synthetic, biosynthetic, and biological mesh in ventral hernia repair[45]

Type of mesh	Total cost	Incremental cost	Effectiveness (QALY)	ICER ($/QALY)
Synthetic	$15,620 (£11,227)	–	18.85	–
Biosynthetic	$23,030 (£16,554)	$7,410 (£5,327)	18.85	Dominated
Biological	$31,056 (£22,323)	$8,026 (£5,769)	18.85	Dominated

USD($) to GBP(£) conversion rate: 0.72 (28 April 2021). QALY = quality-adjusted life-year; ICER = incremental cost-effectiveness ratio.

A second US cost-utility analysis compared synthetic mesh with biological mesh for use in clean-contaminated ventral hernia repair.[44] The analysis was based on a synthesis of patient demographics and post-surgery complication rates from a systematic review of retrospective studies. A societal perspective was adopted for the analysis, incorporating direct hospital costs and indirect costs to the patient, over a lifetime time horizon of 30 years. In the model, patients underwent surgery and either had a successful repair or experienced a complication that could require a subsequent repair or medical management. The probabilities of a successful repair and of different complications varied depending on the type of mesh used. The utilities associated with a successful repair and various complications were estimated using a survey of the general public, and the cost of different mesh types was derived using the average retail cost of a 10 x 25 cm^2 piece of mesh across a variety of manufacturers. The costs of the procedure and resolution of complications were based on national average data from 2013 hospital diagnosis-related group classifications obtained from Medicare and Medicaid services.

The base-case results indicated that synthetic mesh dominated – that is, was less expensive but more effective than – biological mesh (*Table 20*).[44] The robustness of this result was assessed using a one-way deterministic sensitivity analyses (OWDSA) and a probabilistic sensitivity analysis (PSA). No single parameter in the OWDSA was found to result in a change in decision-making based on a willingness-to-pay threshold of $50,000 (£36,148) per QALY. The PSA estimated a probability of 54% for synthetic mesh dominating biological mesh.

Table 20: Base-case results in a cost-utility analysis of synthetic versus biological mesh for ventral hernia repair[44]

Type of mesh	Total cost	Incremental cost	Effectiveness (QALY)	ICER ($/QALY)
Synthetic	$15,776 (£11,340)	–	21.03	–
Biological	$23,844 (£17,139)	$8,068 (£5,799)	20.94	Dominated

USD($) to GBP(£) conversion rate: 0.72 (28 April 2021). QALY = quality-adjusted life-year; ICER = incremental cost-effectiveness ratio.

A cost and outcome comparison, based on a retrospective case review, assessed synthetic mesh compared with biological mesh for repairing ventral hernias.[46] This study analysed the data of patients (n=72) who underwent ventral hernia repair by a single surgeon at a US hospital over the period 2007 to 2012. A multivariate regression analysis of outcomes found prior failed hernia repair (OR 4.1, 95% CI 2.1 to 6.1, p<0.05) and use of biological mesh (OR 3.4, 95% CI 1.9 to 4.9, p<0.05) to be independently associated with hernia recurrence. In addition, treatment with biological mesh was calculated to be statistically significantly more costly ($25,542/£18,322, p<0.001) than synthetic mesh at 1 year post-surgery.

The conclusions of the two cost comparisons supported the findings above, estimating that the total cost of treatment with biological mesh was higher than synthetic mesh.[47, 48] It was noted within the analyses that biological mesh use was more common in patients with a higher risk of surgical site infection as judged by their ventral hernia working group (VHWG) classification.

Laparoscopic versus open mesh repair

The economic evidence regarding the use of laparoscopic versus open surgery for ventral hernia repair consisted of a single cost and outcomes comparison.[49] The study examined the differences in long-term outcomes and costs with laparoscopic repair compared with open repair.[49] US hospital discharge data from California and New York were analysed, for patients (n=13,567) who underwent an elective ventral hernia repair between 2007 and 2011 to estimate complication rates, incidence of reoperation, and costs for each surgical technique. Laparoscopic repair was associated with a statistically significant lower rate of perioperative complications (OR 0.72, 95% CI 0.64 to 0.80) and incidence of reoperation (OR 0.75, 95% CI 0.64 to 0.88) after controlling for patient characteristics. Laparoscopic repair was associated with lower total costs 1 year after surgery ($3,451/£2,481, 95% CI $1,892/£1,360 to $5,011/£3,602, p<0.001).

Mesh fixation techniques

No economic evidence was identified that assessed cost effectiveness of using different mesh fixation techniques in ventral hernia repair.

Incisional hernias repair in all adults

Synthetic mesh versus non-mesh repair

No economic evidence was identified comparing mesh with non-mesh repair for incisional hernias.

Biological versus synthetic mesh repair

A single cost analysis compared biological mesh with synthetic mesh for incisional hernia repair.[50] The study estimated the total cost of incisional hernia repair with synthetic and biological mesh according to complexity of care as defined by patients' VHWG classification. Patients with VHWG class I or II were assigned to receive synthetic mesh, while those with VHWG class III or IV received biological mesh. The study analysed the data of patients (n=76) who underwent incisional hernia repair at an Italian hospital between January 2012 and November 2014 to estimate total direct and indirect costs associated with the procedures. The study found that the total costs for VHWG class I and II were comparable €5,544 (£4,819) and €5,021 (£4,364) while repair of VHWG class III or IV hernias using biological mesh was statistically significantly more expensive €16,397 (£14,247). The disaggregated costs indicate that increased costs associated with biological mesh are primarily due to more preoperative investigations, staff costs and longer hospital stays.

Laparoscopic versus open mesh repair

No economic evidence was identified comparing laparoscopic with open repair for incisional hernias.

Mesh fixation techniques

No economic evidence was identified that assessed cost effectiveness of using different mesh fixation techniques in incisional hernia repair.

Umbilical hernia repair in all adults

No economic evidence was identified that explored cost effectiveness in patients with primary umbilical hernias.

Groin hernia repair

Synthetic mesh versus non-mesh repair in men

No additional economic evidence beyond that summarised in the previous SHTG advice on inguinal hernia repair in men was identified.[29] The key economics point from this advice is as follows:

- A UK cost-effectiveness study comparing open mesh repair with non-mesh repair demonstrated that, over a 5-year time horizon, open mesh repair resulted in fewer hernia recurrences (180 less per 1,000 patients, 95% CI 145 to 293) or persisting pain (45 less per 1,000, 95% CI 6 to 73) and more time spent performing usual activities (10.7

days, 95% CI 9.3 to 12), all based on a cumulatively lower cost (mean saving £134, 95% CI £81 to £192).

Biological versus synthetic mesh repair in all adults

No economic evidence was identified comparing biological with synthetic mesh for inguinal hernia repair.

Laparoscopic versus open mesh repair in men

The economic evidence comparing laparoscopic repair with open repair of inguinal hernias consisted of a cost-minimisation analysis[51] and a cost-comparison study.[52]

The cost-minimisation analysis, based on a multi-centre RCT, compared TEP laparoscopic repair with open repair using the Lichtenstein technique.[51] The study cohort consisted of Swedish males aged 30 to 70 who were diagnosed with a primary unilateral inguinal hernia between December 1996 and May 2001. Following surgery, patients were observed at regular intervals and details of hernia recurrences, pain, and other complications were recorded over a period of 5 years. The cost of the TEP procedure was estimated to be €711 (£618) higher than the Lichtenstein repair ($p<0.001$). The higher cost was primarily due to increased anaesthesia time and the purchase of non-reusable laparoscopic equipment. The difference in costs increased to €795 (£691, $p<0.001$) after adjusting for hernia recurrences and complications, but decreased to €292 (£254, $p<0.05$) when community costs such as sick leave were considered, reflecting the shorter recovery time associated with TEP.

The cost-comparison study explored the impact of TAPP, TEP, and open mesh repair of inguinal hernias on hospital costs and length of stay.[52] This study used routine administrative data from 15 German hospitals (n=1,398) during 2008 to estimate differences in total cost by surgical technique. After controlling for patient characteristics, the total costs of TEP (-€354/-£308) and TAPP (-€161/-£140) repairs were statistically significantly lower than for open mesh repair ($p<0.001$ and $p<0.05$, respectively).

Mesh fixation techniques in all adults

No economic evidence was identified that assessed cost effectiveness of using different mesh fixation techniques in groin hernia repair.

Synthetic mesh safety

The most common adverse events following surgical repair of hernias, with or without mesh, include pain, wound infection, hernia recurrence, adhesion, intestinal obstruction, bleeding, fistula formation, seroma, and tissue perforation.[4] The most common complications relating to mesh-based hernia repair are pain, wound infection, hernia recurrence, adhesion, and bowel obstruction.

Chronic pain, wound infection, hernia recurrence, and seroma formation, were considered in the preceding sections of this review and are therefore not described here.

Scottish and UK data in all adults

Over a period of 5 years (2015–2020) Public Health Scotland recorded 161 cases of surgical mesh being removed – approximately 32 procedures per year – from patients who had a prior hernia repair (Ms N Cameron, Information Analyst, Public Health Scotland. Personal communication, 10 February 2021). This equates to 0.5% of the 32,487 hernia repairs (approximately 6,500 per year) performed using mesh during the same 5 year period. Fifty-five mesh removal operations were in women and 106 in men. Data were not available for removal of surgical mesh following repair of individual types of hernia due to the small numbers in any given year. Nor were data available on the reasons for mesh removal.

In 2017–2018 NHS England recorded 91,673 procedures to repair hernias using prosthetic materials, including all types of mesh.[9] In the same year, 342 procedures were performed to remove mesh following a prior hernia repair (*Table 21*). This equates to 0.37% of the hernia mesh procedures in 2017–2018. Data were not available on the reasons for mesh removal. Procedures to remove mesh were slightly more common following incisional, ventral and umbilical hernia repairs compared with groin hernia repairs.

Table 21: Removal of synthetic mesh following prior hernia repairs in NHS England 2017–2018[9]

	n procedures	n removals	% mesh removal*
Inguinal hernia	65,535	96	0.15
Femoral hernia	1,713	5	0.29
Umbilical hernia	11,544	99	0.85
Incisional hernia	8,327	101	1.21
Ventral hernia	4,554	41	0.90
Total	**91,673**	**342**	**0.37**

**This column is calculated as n removals/n procedures x 100. The mesh removal procedures are unlikely to be for patients treated in the same year therefore this is a rough approximation.*

Data collected by the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card scheme in Scotland 2015–2020 are reported in *Table 22*. It should be noted that the Yellow Card scheme is voluntary and patients can report the same adverse event more than once. The data may not reflect true adverse incident rates. Data relate to the surgical procedure and may not correspond with a fault in a specific mesh product.

The Incident Reporting and Investigation Centre (IRIC) collate adverse event data for NHSScotland. All of the data on incidents relating to hernia mesh held by IRIC were from the MHRA Yellow Card scheme.

Table 22: Data from the MHRA on hernia mesh repair incidents reported in Scotland using the Yellow Card scheme 2015–2020 (Mr G Moore-Arthur, Medical Device Specialist, MHRA. Personal communication, 12 February 2021)

	2015	2016	2017	2018	2019	2020	Total
Hernia mesh for unknown indication	–	–	–	3	2	4	**9**
Collagen mesh	–	–	–	1	–	–	**1**
Polypropylene mesh	–	2	–	2	–	–	**4**
All surgical mesh for hernia repair	–	2	–	6	2	4	**14**

SHTG inguinal hernia advice in men

In the previous SHTG advice on inguinal hernia repair in men, two registry studies using data from 2002–2010/11 reported statistically significant reductions in the rate of serious adverse events for hernia repair using surgical mesh compared with non-mesh repair.[29] These adverse events included cardiovascular complications, deep infections, severe neuropathic pain, and injuries requiring additional surgery or having long-term consequences.

Infected mesh in all adults

A meta-analysis of cohort studies explored risk factors for the development of mesh-related infections following hernia repair surgery.[53] The meta-analysis was based on a limited literature search of two databases in 2011 and studies relating to biological mesh were excluded. The authors of the meta-analysis defined mesh infections as 'deep incisional (DIS) surgical site infections (SSI) that involve the mesh prosthesis'. The authors accepted definitions of mesh infection used in individual studies, even though these definitions varied. Risk factors were identified by comparing cohorts of patients who developed a mesh infection with those who did not.

Six cohort studies – five retrospective and one prospective – were included in the meta-analysis. Not all risk factors were assessed in all six studies. The included studies reported on 1,657 ventral hernia mesh repairs (six studies) and 761 groin hernia mesh repairs (one study): one study incorporated both ventral and groin hernias. Mesh infection occurred in 119/1,657 (7.2%) ventral hernia repairs and 2/761 (0.3%) groin hernia repairs. Results from a univariate analysis of risk factors for development of mesh-related infections are reported in *Table 23*. Statistically significant risk factors for development of mesh-related infections were smoking, an ASA score ≥3, and needing an emergency hernia repair. Mesh-related infection was statistically significantly correlated with increased patient age, ASA scores, and longer duration of surgery. A subgroup analysis that excluded the study incorporating groin hernia repairs reached similar conclusions, although the association with emergency repair of hernias was not statistically significant in this analysis: RR 1.58, 95% CI 0.58 to 4.29, n=506 hernia repairs.

Table 23: Univariate analysis of risk factors for development of mesh-related infections after ventral or groin hernia repair[53]

Risk factor	n studies	n repairs	Findings (95% CI)	p value
Patient demographics				
Age	5	2,364	WMD 2.63 (0.22 to 5.04)	0.03
Female sex	3	1,682	RR 1.02 (0.84 to 1.23)	0.87
Diabetes mellitus	5	2,362	RR 1.34 (0.90 to 2.01)	0.15
Obesity	3	1,171	RR 1.41 (0.94 to 2.11)	0.09
Smoking	4	2,243	RR 1.36 (1.07 to 1.73)	0.01
BMI	3	803	WMD 1.12 (-2.06 to 4.30)	0.49
Immunosuppression or steroid use	2	795	RR 1.56 (0.83 to 2.92)	0.16
Preoperative variables				
Recurrent hernia	4	2,158	RR 1.02 (0.36 to 2.90)	0.97
ASA score ≥3	3	1,682	RR 1.40 (1.15 to 1.70)	<0.001
ASA score	3	1,682	WMD 0.23 (0.08 to 0.38)	0.002
Clean surgical wound	3	1,103	RR 1.02 (0.95 to 1.09)	0.58
Operation details				
Resident vs. consultant surgeon	2	9,82	RR 1.18 (0.99 to 1.40)	0.06

Emergency vs. elective repair	2	1,561	RR 2.46 (1.56 to 3.91)	<0.001
Placement of drains	2	682	RR 1.05 (0.90 to 1.21)	0.55
Duration of operation	3	833	WMD 44.92 (25.66 to 64.18)	<0.001
Mesh type				
Polypropylene (all)	3	1,704	RR 0.31 (0.04 to 2.38)	0.26
Polypropylene (heavy-weight)	3	1,650	RR 0.25 (0.04 to 1.66)	0.15
Combined polypropylene and expanded polytetrafluoroethylene	2	1,349	RR 2.88 (0.09 to 90.35)	0.55
Expanded polytetrafluoroethylene	2	1,230	RR 4.79 (0.34 to 68.01)	0.25

RR = relative risk; WMD = weighted mean difference

Mesh migration in all adults

Mesh migration/erosion is a rare clinical event, the definition of which has not yet been standardised. A narrative review, reported in the previous SHTG advice on mesh repair of inguinal hernia, collated published cases of mesh migration in patients who had undergone an abdominal hernia repair.[29, 54] In the narrative review, mesh migration/erosion was defined as 'mesh invasion of any anatomical region other than the area intended for repair'. Eighty-nine cases were reported in 84 publications between 1996 and 2017. Patients were mainly men (76.2%), with an average age of 59.8 (standard deviation (SD) 13.8). Inguinal hernias represented 62.9% of cases of mesh migration; however, this finding is likely due to the high volume of inguinal hernia repair procedures, rather than a high incidence of mesh migration/erosion in this patient group. Mesh plugs were implicated in 35.7% of cases of mesh migration in patients with inguinal hernias. Multiple organs were affected in 31.5% of mesh migration/erosion cases; the small bowel in 25.8% of cases, the colon in 16.9% of cases, and the bladder in 16.9% of cases. Most mesh migration cases (91.0%) were managed operatively, with 79.0% requiring resection of an organ.

Patient and social aspects (all adults)

Patient perceptions of mesh

One study carried out a survey to explore patient perceptions of surgical mesh in hernia repair.[55] One hundred patients presenting for hernia repair surgery and 100 patients registered for non-hernia surgery at a single centre in the US were enrolled in the study. Participants were asked to complete an unvalidated 16-item questionnaire about hernia repair using mesh. Patients who had not heard of surgical mesh were excluded. The median age of study participants was 59. Approximately one-third of patients had previous experience of hernia repair surgery, which may have affected their views on mesh. More patients presenting for hernia repair (74%) were aware of the use of surgical mesh in this procedure compared with patients presenting for other surgeries (55%), p=0.008. Patients in the two groups were equally likely to consider having a mesh-based hernia repair: 78% of hernia group versus 86% non-hernia group, p=0.39.

Patients in the hernia surgery group were statistically significantly more likely to have heard that mesh reduced hernia recurrence (p=0.034), caused complications (p=0.031) and caused chronic pain (p=0.018) compared with the non-hernia group. In the hernia group, the most common opinions relating to mesh use were 'I don't know' (31%); 'its safety depends on the doctor' (22%); 'it is a safe product' (15%); 'its safety depends on other factors related to the patient' (14%); 'it is not a safe product' (11%); and 'its safety depends on what type of mesh is used' (7%). The most common influences on patient perceptions of mesh in the hernia group were the media (37%) and personal experience (35%).

In univariate analyses, variables that had a statistically significant positive influence on patient perceptions of hernia mesh included hearing mesh had been safely used for years, hearing that benefits outweighed the risks and that scientific studies showed mesh to be safe, and not hearing that mesh caused complications. When asked about their information needs regarding surgical mesh, the most common responses were information about the benefits and risks of mesh (74%), the surgeon's experience (66%), alternative management options (56%), and scientific study results (33%).

Patient experiences of hernia repair

Ventral hernias

A qualitative study used interviews and focus groups to explore patient experiences of ventral hernia repair.[56] Semi-structured interviews were conducted by telephone or in person. A set of codes for the thematic analysis were generated prior to the interviews and focus groups, and developed into additional codes as the study progressed. Analysis continued until data saturation or until no new

themes emerged. Twenty-two patients were enrolled in the study: 16 in-depth interviews and two focus groups with three participants in each. Eight participants were male and 14 female, all from the US. Mean age of participants was 54. The type of hernia repair included 12 incisional hernias, seven umbilical hernias, one Spigelian hernia, and one epigastric/umbilical hernia. Five patients had had a prior hernia repair. Seventeen participants (77%) reported having complications after their surgery.

Patients described an inability to work, lift heavy objects, engage with their children, or perform previously enjoyable activities, such as gardening. They also spoke of the social impact of having a hernia repair, where they felt less able to engage socially due to feelings of embarrassment, mental and physical exhaustion, and pain. There was a common fear of recurrence and a state of worry associated with performing daily activities. Patients described feelings of helplessness and despair, with many experiencing chronic postoperative pain. Experiences of pain varied in terms of severity, duration, and fluctuation. Some patients found a probable cause for their pain after undergoing additional procedures. Other participants felt uncertain about taking pain medication due to fears over addiction or poor pain management. Many patients expressed a sense of trust in their doctor's judgement, while other patients felt disappointed not to have better communication and participation in the treatment process. Most patients felt under-informed about the risks and benefits of mesh repair, and were uncertain about alternative treatment options. Decisions about treatment were influenced by patient anxiety about the hernia recurring or the procedure, uncertainty about treatment options, and competing comorbidities. Support from family, friends, support groups, or clinicians was widely acknowledged as being important to patient wellbeing.

Groin hernias

In the previous SHTG advice on inguinal hernia repair using mesh in men, a qualitative study exploring patient experiences of inguinal hernia repair in Scotland 2006–2008 found that pain gave rise to concern when it differed from expectations.[29, 57] Patients demonstrated considerable diversity in how postoperative pain was experienced, but all sought to interpret their pain and assess what was within normal parameters.

A retrospective study published after the SHTG advice on inguinal hernia repair, conducted a survey to explore patient experiences of chronic pain after mesh repair of an inguinal hernia.[58] Study participants underwent inguinal hernia repair between October 2017 and September 2018 in NHS England. An unvalidated questionnaire was sent to 373 patients. Pain was measured subjectively through patient self-assessment. The response rate was 68% (n=253), although not all questionnaires were complete. Twenty-two respondents were female and 231 were male. Mean age of female participants was higher than males, but the difference was not statistically significant. The mean age of patients who did not respond to the survey was statistically significantly lower than those who responded (53.2 ± 17.9 years versus 67.2 ± 12.6 years, $p<0.0001$). Among survey respondents, patients who experienced preoperative pain had statistically significantly higher levels

of postoperative pain, p=0.0001. There was no statistically significant difference between men and women in average pain 28 days after surgery (p=0.72), the mean number of GP visits (p=0.71), and the number of weeks until patients returned to work or normal activity (p=0.28). The type of mesh used in the procedure also did not affect pain experiences. Twenty-five percent of participants reported still experiencing pain at mean follow-up of 47.85 (SD 15.55) weeks after surgery.

Health-related quality of life

Groin hernias in men

In the previous SHTG advice on inguinal hernia repair, a single comparative study reported quality of life outcomes for men with inguinal hernias treated using surgical mesh versus non-mesh repair (2001–2006).[29, 59] The study found statistically significant short-term improvements in quality of life in the mesh group. Non-comparative studies suggested that experiencing pain after hernia repair using mesh was associated with statistically significant reductions in quality of life and limitations on daily activities, irrespective of mesh type or pain severity.

Ventral hernias in all adults

A survey was conducted at a single centre in the US to assess health-related quality of life in patients who had a ventral hernia repair.[60] The Hernia-Related Quality of Life Survey (HerQLes) tool was used to assess quality of life in patients who had a ventral hernia repair using sutures, synthetic mesh, or biological mesh, between 1998 and 2017. The survey was emailed to 974 patients; 175 patients (25.5%) responded. There were 89 female and 86 male respondents. Mean age of participants was 54 (age range 22 to 81). The majority of patients (n=115) had undergone a mesh-based repair – 91 with synthetic mesh and 23 with biological mesh – and 60 had undergone non-mesh suture repairs. Patients who had a mesh repair had statistically significantly larger hernias compared with patients who had a suture repair: 118.86 ± 145.01 cm^2 versus 32.78 ± 65.30 cm^2, p<0.05. Hernias were also statistically significantly larger in patients who had a biological mesh repair compared with a synthetic mesh repair: 240.46 ± 204.51 cm^2 vs 89.58 ± 109.09 cm^2, p<0.001.

Quality of life scores were statistically significantly lower in patients with a BMI ≥30 (p=0.002), patients with a hernia ≥50 cm^2 (p=0.02), patients who had previous abdominal surgery (p=0.0008), patients with hernia recurrences (p=0.004), and patients with postoperative complications (p=0.000003). No statistically significant difference in quality of life score was found for women compared with men (p=0.32). Quality of life scores did not differ significantly between patients treated with laparoscopic compared with open ventral hernia repair (p=0.40), or between patients undergoing a mesh repair compared with non-mesh repair (p=0.19). After adjusting for hernia size and hernia recurrence, quality of life scores remained statistically significantly lower with biological mesh compared with synthetic mesh (p=0.02). Quality of life scores were also lower for biological

mesh compared with non-mesh repair, p<0.01. No statistically significant difference in quality of life was found between patients treated with synthetic mesh compared with non-mesh repair, p=0.75.

Patient information seeking behaviour and information needs

Two studies explored patient information seeking behaviour and information needs in relation to hernia repair.[61, 62]

One study in the US looked at patients' use of the internet and the impact online information about surgical mesh had on treatment decisions.[61] Thirty patients (15 men and 15 women) who presented for preoperative consultations prior to inguinal or ventral hernia repair in July 2018 completed surveys before and after their consultation appointment. Patients who went on to have hernia repair surgery filled in an additional survey at or after the postoperative visit. The mean age of participants was 58.8 ± 12.8 years and 16 patients (53%) had prior surgery using mesh. Almost all study participants (93%) had heard of surgical mesh in the media.

Eight patients had a negative attitude to surgical mesh, 12 were neutral, and ten were positive about mesh. Twenty patients (67%) had consulted the internet as their primary source of information about mesh. Information found on the internet raised concern levels for eight patients (27%), helped seven patients understand conversations with the surgeon (23%), and helped eight patients ask questions at their appointment (27%). Seventeen patients (53%) stated they intended to conduct further research prior to their operation. Additional sources of information included healthcare providers (47%) and the media (37%). Twenty-one patients wanted to know more about mesh before the consultation appointment (70%), while 22 patients (73%) felt their knowledge increased after the consultation.

No statistically significant associations were found between patient information seeking and their decision to go ahead with hernia repair surgery. Patients with a negative attitude to mesh had the highest perceived knowledge of mesh risks, p=0.013. Positive attitudes to mesh were more common among patients who had prior surgery without complications compared with those who experienced complications (p=0.01) or who had not had previous surgery (p<0.001). Patients who had not had hernia repair surgery before and patients with complications following prior surgery were four times more likely to conduct internet research compared with patients who had no complications after prior surgeries. Half of the study participants who researched hernia mesh repair on the internet reported differences from what they learned from the surgeon consultation. Patients who conducted research because of what they had heard in the media had the most negative average impression scores concerning mesh.

The second study explored the pre-surgical information needs of patients with an inguinal hernia.[62] This qualitative study used semi-structured interviews to explore the views of Dutch patients who

had undergone, or were scheduled to undergo, laparoscopic hernia repair between September and December 2018. Patients were given the opportunity to watch a 3-minute 360-degree video of the surgery experience on a virtual reality headset. Data collection and thematic analysis stopped after data saturation. Twenty-one patients were contacted and 17 participated in the study. Participants had a mean age of 56 (range 35 to 79) and 16 were male. Eleven participants had previous surgery for hernia repair (64.7%). The authors identified three themes from their analysis:

- 'being seen as a unique person' rather than a number reflected a more personal connection with healthcare staff
- 'being seen as a partner' highlighted the value of being viewed as a partner or equal in treatment decision making, and
- 'seeing is understanding' referred to insights into whether visual tools helped patients to better understand information about hernia surgery.

Patients preferred personal contact with clinicians, meeting face-to-face, and receiving advice tailored to their specific circumstances. Keeping patients informed and up-to-date using online contact led to patients feeling they were being taken seriously in the treatment process. Views on the value of patient research, using for example the internet, were varied. Some participants felt doing research helped them feel more like an equal partner in treatment decisions and more in control of their care. Others felt the internet provided too much or misleading information, and did not feel it would help in providing them with the confidence to participate in decision-making. After watching the virtual reality video, some patients felt it helped them formulate relevant questions to ask their consultant, and others felt more at ease on the day of surgery as they knew what to expect. Some patients did not feel it was necessary to experience the surgery in virtual reality. General information from brochures, the internet, or doctor's assistants, were not considered sufficiently tailored to individual patients' situations.

Inequalities

Two studies described inequalities between men and women in the use of laparoscopic techniques for groin hernia repair.[63, 64] The most recent study compared rates of laparoscopic groin hernia repair in men and women in Germany who underwent elective surgery at a single hospital between January 2013 and December 2016.[63] Patients undergoing emergency hernia repair or repair of a recurrent hernia were excluded. Data were from unilateral hernia repairs and the open surgery group included both mesh and non-mesh repairs. Non-mesh repairs comprised 12.1% of male procedures and 44.8% of female procedures. The study cohort consisted of 846 consecutive patients: 94 women and 752 men. The female cohort was statistically significantly older compared with the male cohort: median age 74 versus 68, p=0.021. Laparoscopic repair was performed statistically significantly more often in the male cohort: 31 women (33.0%) versus 471 men (62.6%),

p=0.001. The study authors noted that the characteristics of women in their study were representative of the female groin hernia population described in the literature.

The second study was based on data from the American College of Surgeons National Surgical Quality Improvement Project database.[64] The database stores surgical data from 400 hospitals, although submitting data to the database is voluntary which may mean the data are not representative of all hernia repair surgeries in the US. Data were extracted for laparoscopic groin hernia repairs between 2005 and 2014. Pregnant women were excluded. Data from 141,490 patients were analysed; 13,325 (9.4%) patients were women and 10.1% of patients had a recurrent hernia repair. Overall, 38,604 (27.3%) patients had their groin hernia repaired laparoscopically. Men were statistically significantly more likely to undergo laparoscopic groin hernia repair than women: 28.0% versus 20.2%, p<0.001. In a multivariate analysis controlling for age, comorbidities, and year of operation, women remained less likely to have an elective laparoscopic repair compared with men: OR 0.70, 95% CI 0.67 to 0.73, p<0.001. Subgroup analyses for primary unilateral and primary bilateral hernia repairs produced similar results. The rate at which laparoscopic groin hernia repairs increased over the duration of the study (10 years) was statistically significantly greater in men compared with women which suggests a sex-specific disparity in laparoscopic groin hernia repair may continue.

Neither study were able to explain, based on patient characteristics, why the levels of laparoscopic repair of groin hernias were lower in women compared with men, despite international guidelines recommending use of this approach for groin hernia repair in women.

SHTG public engagement exercise summary (full report available here)

A 5-week public engagement exercise to gather views and experiences of hernia repair in Scotland was conducted using a survey to aid the SHTG Council in developing recommendations on hernia repair using surgical mesh. Sixty-eight relevant responses were received from patients, the public, family members, organisations, and healthcare workers. Survey responses described a range of positive (n=3) and negative (n=30) experiences, with chronic postoperative pain being a key theme amongst the negative responses. Twenty-nine people gave a neutral response or described both positive and negative experiences. Both having a hernia and having hernia repair surgery affected many aspects of patients' lives, including employment, exercise, mental health and relationships.

For a more detailed summary of the results of the engagement exercise, and a complete listing of relevant comments received, please see the Hernia Repair Public Engagement Survey Feedback Report and Appendix.

Organisational issues

Two studies explored variations in surgeons' approaches to the management of hernias.[65, 66] In the most recent study, an electronic survey was used to consult members of the British Hernia Society on their approach to elective primary inguinal hernia repair.[66] The survey was sent to 660 surgeons in the UK in March 2019. Of the 364 people (55%) who responded, 318 (87%) would use an open mesh repair technique for a primary inguinal hernia. Ninety-five percent (344/364) reported they rarely or never performed open suture repairs for primary inguinal hernias. *Table 24* presents the survey results in relation to patient sex. 51% of surgeons responding to the survey preferred a Lichtenstein open mesh repair. The study authors compared their findings with those from a similar UK survey in 1999 and concluded that although there was a trend towards increased use of laparoscopic repair for inguinal hernias, there still appeared to be obstacles, perhaps greater technical difficulty, to using this operative technique.

Table 24: Operative approaches to elective repair of primary inguinal hernias by patient sex[66]

	Open Lichtenstein repair n (%)	Open preperitoneal repair n (%)	Laparoscopic TAPP n (%)	Laparoscopic TEP n (%)
Male	212 (58)	9 (2)	72 (20)	71 (20)
Female	184 (51)	12 (3)	92 (25)	76 (21)

The second study, conducted in Denmark, explored surgeons' approaches to the management of incisional hernias.[65] Five hernia experts were presented with 25 clinical cases of incisional hernia. The 25 patients attended a consultation interview with a medical student, which was video-recorded. A 5–6 minute video of each consultation was standardised for setting, questions asked, and clinical examinations, before being presented to the surgeons. The surgeons then completed a questionnaire on whether they would operate, whether they would use open or laparoscopic techniques, whether they would use the CST, what mesh fixation they would use, and the mesh placement they preferred.

The surgeons had previously performed a median of 253 incisional hernia repairs (range 164 to 450). The experts agreed on all aspects of patient management for five patients (20%). Agreement on whether surgery was necessary was achieved for 14 patients (56%) and agreement on the use of the CST was reached for 21 patients (81%). Surgeons agreed in 40% of cases (10 patients) on the operation technique – laparoscopic or open – and the mesh fixation technique they would use. The decision on operative technique depended on the size of the hernia, with open procedures preferred for large hernias (>15 cm) and laparoscopic for smaller hernias (<10 cm). Maximum disagreement between experts arose for medium-sized hernias (10–15 cm). For mesh fixation, the surgeons preferred suture fixation for open repairs and non-absorbable tack fixation for laparoscopic repairs.

Conclusion

Robust secondary evidence comparing mesh with non-mesh repair of primary ventral hernias, incisional hernias, primary umbilical hernias, and primary inguinal hernias, found statistically significant reductions in the risk of hernia recurrence after mesh-based repairs. For incisional hernias and primary inguinal hernias, there was also a statistically significant increase in the risk of seroma formation. No consistent evidence of a statistically significant difference in chronic postoperative pain was found in comparisons of mesh and non-mesh repair for any hernia type.

Comparisons of biological and synthetic mesh found no statistically significant differences in hernia recurrence rates for primary ventral or inguinal hernias. Use of biological mesh was associated with a lower risk of wound infection in ventral hernia repairs and an increased risk of seroma in inguinal hernia repair.

Evidence from pairwise meta-analyses and network meta-analyses found no statistically significant differences in hernia recurrence rates for laparoscopic versus open repair of primary ventral hernias, incisional hernias, or primary inguinal hernias. Open repair was associated with a statistically significant increase in the risk of wound infection compared with laparoscopic repair. No statistically significant differences were reported for chronic postoperative pain in comparisons of laparoscopic and open hernia repair.

Direct pairwise and network meta-analyses compared mesh fixation techniques for hernia repair. No statistically significant differences in hernia recurrence rates were found in most comparisons of fixation techniques for laparoscopic ventral hernia repair and open or laparoscopic inguinal hernia repair. One NMA reported lower hernia recurrence rates with permanent tack fixation compared with absorbable tack fixation in ventral hernia repair. In a pairwise meta-analysis on ventral hernia repair, and an NMA on inguinal hernia repair, there were no statistically significant differences in chronic pain between fixation techniques used in laparoscopic surgery.

There are a number of limitations to the review of clinical effectiveness evidence that need to be considered. Firstly, each research question posed in the review relates to potential effect modifiers for the other questions. For example, laparoscopic versus open repair, type of mesh used, and mesh fixation technique, may all influence the outcome in comparisons of mesh and suture-based repairs. Secondly, there is heterogeneity across studies in patient characteristics, hernia characteristics, and outcome definitions (particularly for chronic pain). Variations in mesh placement and surgical technique have not been considered. Thirdly, most outcomes reported in the published literature are relatively rare occurrences in practice. The length of follow-up in primary studies is generally around 1 year, which may not be long enough to detect hernia recurrence or other chronic outcomes. Finally, the outcomes reported in the literature may not be the most important outcomes for patients.

Methodologically limited secondary evidence, a registry study, and two guidelines, provided data on hernia repair specifically in women. The registry study suggested that women were more likely than men to experience chronic pain after incisional hernia repair regardless of operative technique or use of mesh. Systematic reviews of low quality study designs suggest that groin hernia recurrence is lower in women after laparoscopic repair compared with open repair, and two studies found no difference in hernia recurrence rates between mesh and suture repair of groin hernias in women. Guidelines suggest, based on a small number of observational studies, that women of childbearing age should wait until after their last pregnancy before seeking a hernia repair. Two primary studies found that women were statistically significantly less likely to receive laparoscopic groin hernia repair compared with men.

No additional economic evidence, beyond that summarised in the previous SHTG advice on inguinal hernia repair in men, compared mesh with non-mesh repair of inguinal hernias. The previous SHTG advice found that, for inguinal hernia repair, open mesh repair was more effective and less costly than non-mesh repair over a 5-year time horizon.

Two cost-utility analyses found that synthetic mesh was less costly and more or equally effective compared with biological mesh for primary ventral hernia repair. In addition, a cost-comparison study estimated that treatment with biological mesh was statistically significantly more expensive than synthetic mesh for incisional hernia repair. These figures should be interpreted with caution given that only complex cases were assigned to biological mesh.

A cost comparison estimated that laparoscopic repair was associated with lower costs one year after surgery for primary ventral hernia repair. Findings for inguinal hernia repair were mixed: a cost-minimisation analysis estimated that TEP repair was associated with increased costs compared to open repair at 5 years post-surgery, whereas a cost-comparison study estimated TEP and TAPP repair to be less costly relative to open mesh repair.

In the published literature, patients described the impact of having a hernia or a hernia repair on activities of daily living including lifting heavy objects, working, engaging with children, and their social lives. Patient perceptions of mesh were most strongly influenced by the media and personal experience. Information needs of patients centre on the benefits and risks of mesh, and hernia management options. Patient views on the value of seeking information online varied, with some finding this helpful to inform decision making and others finding it resulted in increased anxiety.

In an SHTG survey of patients and the public, 68 people described how having a hernia and having hernia repair surgery affected many aspects of their lives, including work, exercise, mental health and relationships.

Identified research gaps

Meta-analyses comparing mesh types (biological versus synthetic), laparoscopic and open repair, and mesh fixation techniques, for umbilical hernia repair would add to the evidence base.

Robust comparative analyses of outcomes from hernia repair in women compared with men would be useful for informing sex-specific hernia management.

Other gaps in the existing published evidence include:

- repair of femoral hernias
- how best to approach repair of large hernias
- when to consider using non-mesh (suture) repair, and
- hernia repair in the presence of a contaminated surgical field.

About SHTG Recommendations

SHTG Recommendations are produced to inform a decision at a particular point in time and therefore is not routinely updated. The recommendations will however be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the advice given. For further information about the SHTG Recommendations process see our webpage on the range of products we provide.

To request advice from SHTG please do email his.shtg@nhs.scot

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network www.knowledge.scot.nhs.uk, or by contacting your local library and information service.

A glossary of commonly used terms in Health Technology Assessment is available from htaglossary.net.

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Appendix 1: abbreviations

ASA	American Society of Anaesthesiologists
BMI	body mass index
CI	confidence interval
CrI	credible interval
CST	component separation technique
DIS	deep incisional
GRADE	grading of recommendations assessment, development and evaluation
HADS	Hospital Anxiety and Depression Scale
HerQLes	Hernia-Related Quality of Life Survey
HR	hazard ratio
IH	incisional hernia
ICER	incremental cost-effectiveness ratio
IPOM	intraperitoneal onlay mesh
IRIC	Incident Reporting and Investigation Centre
MD	mean difference
MHRA	Medical and Healthcare products Regulatory Agency
MINORS	methodological index for non-randomised studies
NMA	network meta-analysis
NNT	number needed to treat
NR	not reported
OR	odds ratio
OWDSA	one-way deterministic sensitivity analyses
PCS	Pain Catastrophising Scale
PSA	probabilistic sensitivity analysis
PVH	primary ventral hernia
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RD	risk difference

RR	risk ratio/relative risk
SD	standard deviation
SHTG	Scottish Health Technologies Group
SIGN	Scottish Intercollegiate Guidelines Network
SSI	surgical site infection
SUCRA	surface under the cumulative ranking
TAPP	transabdominal preperitoneal
TEP	totally extraperitoneal
VAS	visual analogue scale
WMD	weighted mean difference

Appendix 2: definitions of statistical terms

95% confidence interval (CI)	A range (interval) in which we can be 95% confident that the true population value lies.[67] For example, if we measure blood pressure reduction after treatment we can work out the mean (average) change in blood pressure. This mean would only be true for our group of patients. If we took another group of patients, we would likely get a different mean value due to chance. The 95% confidence interval gives the range in which the true value – the mean change in blood pressure if we measured it in all patients – is likely to be found 95 times out of 100.
95% credible interval (CrI)	A range in which we believe the true value lies with a probability of 95%.[68]
Hazard ratio (HR)	The chance of a harmful event (hazard) happening in group A divided by the chance of a harmful event in group B. A hazard ratio of 1 implies no difference in risk between the two groups. A hazard ratio of 2 implies double the risk in group A. A hazard ratio of 0.60 implies a 40% reduction in risk in group A.[67]
Mean	The average.
Mean difference	The absolute difference between the mean value in two groups.[68]
Number needed to treat (NNT)	The number of patients that need to be treated for one person to benefit.[67]
Odds and the odds ratio (OR)	Odds are calculated by dividing the number of times an event happens by the number of times it does not happen. The odds ratio is calculated by dividing the odds of an event in group A with the odds of an event in group B. An odds ratio of 1 indicates no difference in odds between the groups – the odds in each group are the same. If the odds ratio is greater than 1, the rate of the event is increased in patients in group A. If the odds ratio is less than 1, the rate of that event is reduced in group A.[67]
Risk difference	The actual difference in the observed risk of an event in two groups.[68]
Risk and the risk ratio/relative risk (RR)	Risk is the probability that an event will happen. It is calculated by dividing the number of events by the number of people at risk. The risk ratio is calculated by dividing the risk in group A by the risk in group B. A risk ratio of 1 indicates no difference in risk between the groups. If the risk ratio is greater than 1, the risk of that event is greater in group A. If the risk ratio is less than 1, the risk of that event is lower in group A.[67]
Standard deviation	An indicator of how much a set of values is spread around the mean. It is normally shown as one standard deviation above and below (±) the mean value.[67]