



The Risk of Adverse Events Associated with Mesh and Non- Mesh Repair of Groin Hernias: A literature review

Office of the Chief Science Advisor

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Executive summary

In light of the pause on use of mesh in urogynaecology procedures in New Zealand and the hernia mesh report in Australia (Health Issues Centre 2019), the Ministry of Health began a review of the literature on the use of mesh in inguinal hernia repair. This showed that use of mesh in groin hernia repair was associated with reduced rates of hernia recurrence, neurovascular injury and urinary retention (with no gender difference) and reduced or similar rates of post-operative pain, operative time, hospital stay length and time to return to usual activities compared to non-mesh groin hernia repair. Non-mesh repair was associated with a lower risk of seroma formation (fluid collection). Ongoing pain affecting activities of daily living was self-reported in a proportion of patients in whom mesh was used in groin hernia repair.

Abstract

Background

Hernias represent one of the most common medical problems globally. Groin hernias (inguinal and femoral) are the most common form of abdominal wall hernias. Abdominal wall hernias usually occur due to a weakness or attenuation of the fascia of the abdominal wall. Groin hernia repair can be performed with or without mesh. Groin hernias can be repaired either with an open technique or laparoscopically. Changes in surgical technique, such as in the use of mesh, surgical approach or type of mesh fixation, may be associated with changes in the risk or rate of complications. Therefore, it is important to continually monitor clinical outcomes and patient experiences to identify changes to the risk-benefit profile associated with new technologies or methodologies.

Objectives

We aimed to evaluate the current literature investigating the risks and benefits of mesh versus non-mesh groin hernia repair, in the context of both clinically assessed outcomes and patient experiences. This literature review aims to provide a contemporary evidence base on which a discussion of the implications of these outcomes might occur in Aotearoa New Zealand.

Methods

Our scoping review sought systematic reviews and randomised controlled trials (RCTs) published within the last five years comparing mesh and non-mesh repair for groin hernias. We searched the following databases: MEDLINE, Embase, Cochrane Reviews and Scopus. We analysed the systematic reviews to identify the range of clinical complications. We undertook a further review focusing on laparoscopic versus open hernia repair techniques, emergency groin hernia repair and patient-reported outcomes not identified in the initial search.

Results

We included three systematic reviews investigating clinical outcomes after mesh versus non-mesh groin hernia repair in our analysis, along with two systematic reviews investigating laparoscopic versus open groin hernia repair and mesh versus non-mesh in emergency operation. We also included four studies and one report discussing patient experiences after mesh/non-mesh groin hernia repair. We analysed 25 RCTs separately and tabulated their results. Analysis of the literature showed that use of mesh in groin hernia repair was associated with reduced rates of hernia recurrence,

neurovascular injury and urinary retention (with no gender difference) and reduced or similar rates of post-operative pain, operative time, hospital stay length and time to return to usual activities compared to non-mesh groin hernia repair. Non-mesh repair was associated with a lower risk of seroma formation (fluid collection). Ongoing pain affecting activities of daily living was self-reported in a proportion of patients in whom mesh was used in groin hernia repair.

Conclusions

Mesh use in groin hernia repair is associated with a low overall rate of complications and may produce superior post-operative clinical outcomes to non-mesh groin hernia repair. However, for those who do experience complications or pain post-operatively, the impact can be profound.

Background

The use of mesh in surgical procedures has been the subject of much public discussion worldwide in recent years. In New Zealand, the majority of adverse event reports relating to surgical mesh implants have been in the combined group of patients suffering from urinary incontinence and pelvic organ prolapse (Medsafe 2019). Mesh injured patients who received mesh for abdominal hernia repair comprise another group within the adverse events reported and compensated by ACC (Medsafe 2019). The use of mesh in groin hernia repair is the specific subject of this literature review.

The context within which this literature review took place is crucial to understanding the impetus for the review.

In 2019, The Ministry of Health initiated a restorative justice approach to exploring the harm caused by surgical mesh in Aotearoa New Zealand (Wailling et al 2019).¹ This was in response to growing concern, within New Zealand and internationally, about the impact of surgical mesh on the lives of those who had undergone a surgical procedure utilising mesh. The process was co-designed by the advocacy group Mesh Down Under, the restorative justice team at Te Herenga Waka – Victoria University of Wellington and the Ministry of Health. The approach incorporated three phases: listening and understanding, planning and acting, and reporting and evaluation. In the latter part of 2019, over 600 mesh injured people shared their stories (based on a public survey identifying people affected). Facilitated listening circles were held between those harmed by surgical mesh and the Chief Medical Officer, Chief Nursing Officer and their Principal Advisor from the Ministry of Health. Representatives of other agencies identified by consumers as having a share in the responsibility for the harm were also invited to attend.

Organisations that agreed to participate included ACC, the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal New Zealand College of General Practitioners and the Medical Council.

In light of the number of patient safety issues involved, the Health Quality & Safety Commission was also invited to attend. Listening circles were provided in all the major centres identified by survey respondents. ACC provided financial support for participants' travel and accommodation to attend listening circles. For those too sick to travel, interviews were conducted in hospital or in people's homes. A Victoria University researcher transcribed stories. As a summary of this process, in December 2019, the research team dedicated to the surgical mesh project at the Chair produced a report titled: *Hearing and Responding to the Stories of Survivors of Surgical Mesh: Ngā kōrero a ngā mōrehu – he urupare* (Wailling et al 2019). The report concluded with 19 actions that would be taken to address the harm caused, including (but not limited to) an apology, the establishment of a credentialling process for surgeons performing mesh-related procedures, advocacy and psychosocial support, more research and the

¹ In January 2014, the Diana Unwin Chair in Restorative Justice, Victoria University of Wellington was established to serve as a focus for research and teaching on restorative justice theory and practice.

Therapeutics Products Bill. In 2020, an evaluation report of the restorative justice process was written (Wailing J 2020). It was released in May 2022. Subsequently, in 2023, the Ministry of Health convened the Surgical Mesh Roundtable, an oversight and monitoring group tasked with responding to harm from the use of mesh and investigating a pause on the use of surgical mesh. The Roundtable's assessment was that the balance of benefit and harm from the use of mesh in the treatment of stress urinary incontinence would be improved by 'additional measures' related to the 19 actions stipulated by the restorative justice process.

In August 2023, a time-limited pause on the use of mesh for stress urinary incontinence came into effect to give time for those measures to be put in place (Ministry of Health 2023).²

A similar process to the restorative justice process in New Zealand has taken place in Australia, focused specifically on mesh use in hernia repair. In February 2019, the Health Issues Centre in Australia produced a report titled *Adverse Outcomes from Hernia Mesh: A report on the consumer experience of mesh implants used for treatment of hernia* (Health Issues Centre 2019). In a process similar to the listening circles in New Zealand, mesh injured patients had an opportunity to identify themselves and have their concerns heard by medical regulatory communities. Patient concerns included lack of informed consent, adverse outcomes including chronic pain, negative responses from clinicians to patient complaints and lack of appropriate remediation. The authors of the report spoke of the broader implications of the findings: regardless of the procedure or outcome, the health system must always act to minimise risk, provide informed consent, validate patient experiences, respond empathetically, and provide remediation when harm occurs.

Hernias are protrusions of all or part of an organ through the body wall. Hernias occur when the fascia encompassing a body cavity becomes weak or develops an opening through which the contents of that body cavity can protrude. Groin hernias (inguinal and femoral) are the most common subset of hernias. Inguinal hernia is the most common type of hernia in both men and women. The lifetime risk of developing inguinal hernias is 27% for men and 3% for women (Fitzgibbons and Forse 2015). Inguinal hernia can be congenital, due to a failure of the processus vaginalis to close, or acquired, caused by a weakening or disruption of the abdominal wall. Femoral hernias are the other type of groin hernia; they can occur when the herniated sac passes through the femoral canal. Femoral hernias are much less common than inguinal hernias overall but are more frequent in women and more likely to develop complications such as obstruction or strangulation. The definitive treatment for groin hernia is surgery. Open operation techniques for the treatment of groin hernias were developed in the late 19th century. Techniques using surgical mesh to augment the strength of the groin hernia repair were first utilised at the beginning of the 20th century (Hori and Yasukawa 2021). Currently, both mesh and non-mesh hernia repair methods are employed in clinical practice. The international HerniaSurge guidelines for groin hernia management recommend laparoscopic mesh repair as the first choice for groin hernia treatment (Stabilini et al 2023).

² By January 2018, all surgical mesh used for urogynaecologic procedures had been removed from the market in New Zealand.

However, open non-mesh procedures may be preferred in some situations, particularly in low-income settings, as the cost of laparoscopic mesh repair of hernias is significantly higher than open non-mesh repair techniques (Bittner et al 2005). All surgical procedures are associated with a risk of complications. Changes in surgical procedures over time may alter the risk of complications associated with the procedure. In the context of hernia repair, the use of mesh, a laparoscopic approach and the urgency of the procedure (emergency or elective) may all influence outcomes. Therefore, there is a need to evaluate the potential benefits and harms of mesh and non-mesh hernia repair methods to establish a baseline understanding of the risk of associated complications.

Objectives

The primary objective of this report is to summarise the current peer-reviewed literature on the risks and benefits of mesh versus non-mesh surgical repair of groin hernias, as well as patient experiences after mesh and non-mesh groin hernia repair. The clinical outcomes assessed included complications reported after mesh and non-mesh repairs.³ In addition to the medical complications from surgery, we identified patient-reported outcomes.⁴ The secondary objective of this report is to investigate the impact of an open versus laparoscopic approach and the use of mesh in an emergency setting.

³ General rate of post-operative complications, post-operative pain, chronic pain, hernia recurrence rate, wound infection, wound swelling, hematoma, seroma, neuralgia, testicular complications, scrotal swelling and oedema, analgesic requirements, operative time, hospital stay length and mortality.

⁴ Patient satisfaction, time to return to work, time to resumption of usual activities, self-reported physical functioning, social functioning, role limitations because of physical problems, role limitations because of emotional problems, mental health, energy, vitality, pain and general health perception.

Methods

Literature search

We identified systematic reviews and randomised controlled trials (RCTs) comparing mesh and non-mesh surgical approaches to hernia repair, the use of mesh in emergency hernia repairs and comparisons of open compared to laparoscopic hernia repair through a search of peer reviewed literature. Appendix 1 provides details of our search criteria. We examined the references from the original studies within the systematic reviews to identify further relevant publications. We identified reports or trials of patient-reported qualitative outcomes after groin hernia repair through the original search criteria to identify non-randomised trials or registry data evaluating patient experiences.

Criteria for study inclusion

In searching randomised trials, our criteria included:

- hernia repair with mesh or non-mesh closure of groin hernias
- published in the last five years
- English language.

Analysis

We reviewed all the RCTs we identified and extracted the outcomes they reported, then entered them into an Excel database (see Appendix 2). We compared the results of the meta-analyses. We recorded a significant difference between the mesh and non-mesh repair method for a given outcome when the 95% confidence intervals of the reported outcomes did not cross the value of 1.0.

Results

After excluding all duplicates and false drops, we identified 55 studies for inclusion in our review. From these, we identified three systematic reviews containing 25 English language RCTs. We did not identify any RCTs published in the last five years that were not included within these systematic reviews.

Systematic reviews and meta analyses of mesh versus non-mesh groin hernia repair

A comprehensive systematic Cochrane Review and meta-analysis of the risks of mesh versus non-mesh inguinal hernia repairs was published in 2018 (Lockhart et al 2018). It included 25 RCTs involving a total of 6,293 patients who had either an inguinal or femoral hernia repair. The RCTs analysed included a range of studies performed in both low- and high-income settings. The meta-analysis reported that for mesh repair compared to non-mesh repair, there was a statistically significant reduction in the risk of hernia recurrence,⁵ neurovascular or visceral injury,⁶ and urinary retention;⁷ a shorter mean duration of surgery;⁸ a shorter mean length of hospital stay;⁹ and a shorter mean time to return to usual activities¹⁰ when compared with non-mesh repair. However, the review noted that the quality of evidence, excluding the risk of neurovascular or visceral injury (high quality) and the risk of recurrence and the risk of urinary retention (moderate quality), was considered low. Compared to non-mesh repair, mesh repair resulted in a statistically significant increase in the rate of post-operative seromas¹¹ and wound swelling.¹²

The meta-analysis did not find a statistically significant difference in rates of testicular complications,¹³ wound infection,¹⁴ hematoma,¹⁵ or wound dehiscence¹⁶ after mesh versus non-mesh repair.

⁵ 21 studies, 5,575 patients; RR 0.46, 95% CI 0.26 to 0.80, I² = 44%, moderate-quality evidence.

⁶ 8 studies; RR 0.61, 95% CI 0.49 to 0.76, I² = 0%, NNTB = 22, high-quality evidence.

⁷ 8 studies, 1,539 patients; RR 0.53, 95% CI 0.38 to 0.73, I² = 56%, NNTB = 16, moderate-quality evidence.

⁸ 20 studies, 4,148 patients; 95% CI -6.85 to -1.60, I² = 97%, very low-quality evidence.

⁹ 12 studies, 2,966 patients; 95% CI -0.86 to -0.34, I² = 98%, low-quality evidence.

¹⁰ 10 studies, 3,183 patients; 95% CI -4.42 to -1.32, I² = 96%, low-quality evidence.

¹¹ 14 studies, 2,640 patients; RR 1.63, 95% CI 1.03 to 2.59, I² = 0%, NNTB = 72, moderate-quality evidence.

¹² 2 studies, 388 patients; RR 4.56, 95% CI 1.02 to 20.48, I² = 33%, NNTB = 72, moderate-quality evidence.

¹³ 14 studies, 3,741 patients; RR 1.06, 95% CI 0.63 to 1.76, I² = 0%, NNTB = 2000, low-quality evidence.

¹⁴ 20 studies, 4,540 patients; RR 1.29, 95% CI 0.89 to 1.86, I² = 0%, NNTB = 200, low-quality evidence.

¹⁵ 15 studies, 3,773 patients; RR 0.88, 95% CI 0.68 to 1.13, I² = 0%, NNTB = 143, low-quality evidence.

¹⁶ 2 studies, 329 patients; RR 0.55, 95% CI 0.12 to 2.48, I² = 37% NNTB = 77, low-quality evidence.

Finch et al (2019) was a systematic review and meta-analysis of open inguinal hernia repair. The study included six RCTs and involved 1,480 patients treated either with open darn repair (non-mesh) or open mesh repair. The three largest RCTs included Finch et al included were also included in Lockhart et al (2018). The studies included were carried out in a range of low- and high-income countries. Meta-analysis of the six reported no statistically significant difference in any of the outcome measures.

Öberg et al (2018) performed a systematic review and meta-analysis of 23 RCTs involving a total of 5,444 patients presenting with inguinal hernia and treated with a variety of mesh and non-mesh repair methods, and included studies from both low- and high-income settings. Seven of the RCTs included in Öberg et al (2018) were also included in Lockhart et al. (2018); 16 were not. The primary outcome Öberg et al investigated was chronic pain after hernia repair with mesh or without mesh insertion. The median follow-up was 1.4 years (range 0.5–10). The median (range) prevalence of pain after non-mesh repairs was 3.5% (0%–16.2%), compared to a median of 2.9% (0%–27.6%) for mesh repairs. The meta-analysis reported that the difference between the median prevalence of pain after mesh and non-mesh repair methods was not statistically significant.

Mesh versus non-mesh emergency repair of groin hernia

Sæter et al (2022) carried out a systematic review and meta-analysis of 15 RCTs comparing mesh and non-mesh emergency groin hernia repair, involving 1,241 patients presenting with obstructed, strangulated or incarcerated groin hernias requiring emergency surgical repair. The RCTs included in this systematic review were conducted in China, the Middle East and South Asia.

The meta-analysis reported no statistically significant difference in the risk of post-operative wound infection within 30 days of repair,¹⁷ post-operative wound infection within 90 days of repair,¹⁸ mortality¹⁹ or hernia recurrence²⁰ after emergency mesh repair of groin hernias when compared with emergency non-mesh repair of groin hernias. However, the authors assessed the evidence to be of a low-quality, and therefore concluded that the effect of mesh versus non-mesh emergency groin hernia repair was uncertain for the outcomes investigated.

¹⁷ 2 studies, 454 patients; RR 1.66, 95% CI 0.96 to 2.88, I² = 21%.

¹⁸ 1 study, 30 patients; RR 1.00, 95% CI 0.15 to 6.64.

¹⁹ 1 study, 208 patients; RR 1.38, 95% CI 0.58 to 3.28.

²⁰ 2 studies, 104 patients; RR 0.19, 95% CI 0.04 to 1.03, I² = 0%.

Systematic review of laparoscopic versus open repair of groin hernias

Bittner et al (2005) conducted a systematic review and meta-analysis of 27 RCTs comparing clinical outcomes after laparoscopic groin hernia repair methods (trans-abdominal preperitoneal (TAPP) and totally extraperitoneal repair (TEP)), with Shouldice repair or other (non-Shouldice) open groin hernia repair methods. Fifteen of these RCTs compared TAPP/TEP with Shouldice repair. Meta-analysis of these 15 RCTs found a significant reduction in chronic pain²¹ and time to return to work²² with laparoscopic TAPP/TEP repair when compared with open Shouldice repair. Nine of the RCTs compared TAPP/TEP with non-Shouldice open groin hernia repair methods. Meta-analysis of these nine also found a significant reduction in chronic pain²³ and time to return to work²⁴ with TAPP/TEP repair.

Across all the RCTs, Bittner et al found no significant difference between operating times with laparoscopic versus open hernia repair methods after accounting for the experience difference between different surgical teams. There was no statistically significant difference in mortality between the laparoscopic hernia repair methods when compared with open hernia repair methods, largely due to the very small number of mortality events recorded across the RCTs.

Studies investigating patient reported outcomes

Forester et al (2022) investigated prospectively collected patient-reported outcomes for 1,720 patients who underwent mesh hernia repair for inguinal hernia between 2008 and 2019 at a single institution in the United States. All operations were performed by four board-certified surgeons of similar experience.

Patients were surveyed on the impact of pain on their life quality, level of chronic pain (pain quality), fatigue and physical functioning using the Surgical Outcomes Measurement System (SOMS) questionnaire. Experiences were assessed pre-operatively and again at three weeks, six months, one year, two years, three years, four years and five years post-operatively. In SOMS, a decrease in reported scores for pain impact on quality of life, pain quality and fatigue indicates an improvement, while an increase in the reported score for physical functioning indicates improvement. The study found that the pain impact on the quality-of-life score reported by patients improved after inguinal hernia mesh repair when compared to the pre-operative baseline.²⁵ Patient-reported pain quality scores also improved after inguinal hernia mesh repair when compared to

²¹ OR 0.41, 95% CI 0.26 to 0.63, P < 0.00007.

²² WMD -6.23 (days), 95% CI -7.47 to -5.00, P < 0.00001.

²³ POR 0.40, 95% CI 0.30 to 0.53, P < 0.00001.

²⁴ WMD -6.53 (days), 95% CI -7.46 to -5.61, P < 0.00001.

²⁵ Mean \pm SD; 9.9 \pm 4.9. at 3 weeks (9.6 \pm 4.6), 6 months (7.3 \pm 2.9), 1 year (7.3 \pm 3.2), 2 years (7.2 \pm 2.9), 3 years (6.7 \pm 2.1), 4 years (7.0 \pm 2.3) and 5 years (7.9 \pm 2.5) post-operatively (for all scores; p < 0.05).

the pre-operative baseline.²⁶ Patient-reported fatigue scores improved significantly after inguinal hernia mesh repair when compared to the pre-operative baseline.²⁷

Furthermore, Forester et al found that patient-reported physical functioning scores also improved significantly after inguinal hernia mesh repair when compared to the pre-operative baseline.²⁸ At five years post-operatively, 3.9% of patients reported severe/disabling sensation of mesh, 3.2% reported significant pain and 31% of patients reported movement limitations. Forester et al (2022) thus concluded that patients generally reported a significant improvement in their life quality, impact of pain, chronic pain level, fatigue and physical functioning after undergoing inguinal hernia mesh repair. However, a minority of patients did report severe or disabling symptoms at the five-year follow-up.

Matikainen et al (2021) was an RCT of 625 patients who underwent Lichtenstein mesh hernioplasty (a tension-free mesh repair typically performed laparoscopically) for inguinal hernia with a cyanoacrylate glue ($n = 216$), self-gripping mesh ($n = 202$) or non-absorbable 3-0 polypropylene suture fixed mesh ($n = 216$). The study investigated patient-reported outcomes after mesh hernia repair based on the type of mesh and the method of mesh fixation. It employed a standardised telephone interview or postal questionnaire at five-years post-operation. The patient-reported outcomes measured included chronic pain, analgesic need and sensation of a foreign object. The results reported no statistically significant difference in any of these measures between the different mesh types and methods of mesh fixation.

Melkemichel et al (2020) was a prospective study of 23,259 patients in the Swedish Hernia Register who underwent open inguinal hernia repair with regular polypropylene lightweight mesh (LWM-PP), composite (poliglecaprone-25) polypropylene lightweight mesh (LWM-PP/PGC) or polypropylene heavyweight mesh (HWM-PP). The study investigated patient-reported chronic pain at one year post-operation. Patients who met the eligibility criteria were sent a questionnaire asking them to 'Grade the worst pain you have felt in the operated groin during the past week'.

Pain was graded on a scale from 1 to 7, as follows:

- level 1 – no pain
- level 2 – pain present but easily ignored
- level 3 – pain present, cannot be ignored, but does not interfere with everyday activities
- level 4 – pain present, cannot be ignored and interferes with concentration on everyday activities
- level 5 – pain present, interferes with most activities
- level 6 – pain present, necessitating bed rest
- level 7 – pain present, prompt medical advice sought.

²⁶ Mean \pm SD; 9.3 \pm 4.1, at 3 weeks (8.0 \pm 3.1), 6 months (5.8 \pm 2.7), 1 year (5.8 \pm 2.6), 2 years (5.8 \pm 2.5), 3 years (8.0 \pm 3.1), 4 years (5.5 \pm 2.2) and 5 years (6.0 \pm 3.0) post-operatively (for all scores; $p < 0.05$).

²⁷ Mean \pm SD; 13.2 \pm 5.8, at 3 weeks (13.7 \pm 5.5), 6 months (11.3 \pm 4.5), 1 year (11.2 \pm 4.2), 2 years (11.8 \pm 4.5) and 5 years (12.4 \pm 5.5) post-operatively (for all scores; $p < 0.05$).

²⁸ Mean \pm SD; 32.7 \pm 4.8, at 3 weeks (32.5 \pm 4.3), 6 months (34.4 \pm 3.6), 1 year (34.0 \pm 4.1), 2 years (34.2 \pm 3.7) and 5 years (33.5 \pm 5.2) post-operatively (for all scores; $p < 0.05$).

The study found no statistically significant difference in the odds of developing chronic pain at one year post-operation with HWM-PP (OR 1.00) compared with LWM-PP²⁹ or LWM-PP/PGC.³⁰ Therefore, the study concluded that the type of mesh used did not significantly change the rates of chronic pain at one year post-operation. The study also reported that 15.9% of patients reported persistent pain at one year post-operation and 6.9% reported severe chronic pain at that time.

Lawrence et al (1997) was a RCT of 140 patients who underwent inguinal hernia repair with an open ($n = 73$) or laparoscopic technique ($n = 67$). The study investigated patient-reported outcomes recorded using the Short Form 36 (SF36) questionnaire. The questionnaire was completed pre-operatively and at three and six months post-operation. The SF36 is a 36-item questionnaire that measures eight dimensions of patient health and wellbeing on multi-item scales: physical functioning, social functioning, role limitations because of physical problems, role limitations because of emotional problems, mental health, energy/vitality, pain and general health perception. A further dimension is on a single-item scale and measures change in health over the last year. The study found no statistically significant difference in the reported mean SF36 scores after laparoscopic versus open hernia repair. However, it did find a statistically significant increase in reported mean SF36 scores for health perception,³¹ physical mobility,³² social functions,³³ physical role limitations,³⁴ mental role limitations,³⁵ pain,³⁶ mental health³⁷ and vitality/energy level³⁸ between the pre-operative baseline and six months post-operation. These results suggest that, regardless of technique, surgical repair for inguinal hernia resulted in a significant improvement in patient-reported health and wellbeing.

²⁹ OR 0.97, 95% CI 0.89 to 1.06, P = 0.535.

³⁰ OR 0.95, 95% CI 0.87 to 1.04, P = 0.295.

³¹ MD 4, 95% CI 1 to 7, P = 0.005.

³² MD 11, 95% CI 8 to 14, P < 0.0001.

³³ MD 4, 95% CI 1 to 7, P = 0.004.

³⁴ MD 20, 95% CI 12 to 27, P < 0.0001.

³⁵ MD 6, 95% CI 2 to 11, P = 0.006.

³⁶ MD 17, 95% CI 12 to 22, P = 0.0001.

³⁷ MD 5, 95% CI 2 to 8, P = 0.001.

³⁸ MD 7, 95% CI 4 to 11, P < 0.0001.

Discussion

Mesh versus non-mesh repair of groin hernias

To investigate clinical outcomes after mesh versus non-mesh repair of groin hernias, we analysed and discussed three systematic reviews: Lockhart et al (2018), Finch et al (2019) and Öberg et al. (2018). These reviews involved a total of 14,781 participants across both high- and low-income countries.

Lockhart et al a systematic review and meta-analysis of 25 RCTs ($n = 6,293$), found a statistically significant decrease in hernia recurrence, neurovascular or visceral injury and urinary retention, with a high quality of evidence. The review also found a statistically significant decrease in operating time, hospital stay length and time to return to usual activities with mesh repair when compared with non-mesh repair; however, the quality of evidence was very low–medium. Lockhart et al found a statistically significant decrease in seroma and wound swelling with non-mesh repair when compared with mesh repair. It found no statistically significant difference for all other post-operative complications. The evidence for rates of mortality, post-operative pain and chronic pain was uncertain. The quality of evidence for the lower rate of neurovascular or visceral injury with mesh repair was assessed to be high. The quality of evidence for all other outcomes was assessed to be very low–moderate, due to a lack of blinding in many studies, wide confidence intervals, heterogeneity and inconsistencies within studies. However, the overall methodological quality of the RCTs investigated in Lockhart et al. (2018) was assessed to be strong.

Finch et al (2019) was a systematic review and meta-analysis of ten studies ($n = 3,044$), including six RCTs ($n = 1,480$). The meta-analysis found no significant difference in rates of any of the assessed outcomes (hernia recurrence, hematoma, wound infection, urinary retention, neuralgia, testicular atrophy, length of hospital stay, time to return to usual activities and operative time) after mesh repair versus non-mesh repair. The risk of chronic pain with mesh versus non-mesh repair was uncertain. The certainty of these results was assessed to be moderate–high; there was low heterogeneity between the analysed RCTs.

Although the studies in Finch et al did not show a significant statistical difference in any outcomes after mesh repair versus non-mesh in open hernia repair, the three RCTs included by Finch et al that were not included by Lockhart et al were small, involving only 301 patients in total. Furthermore, Finch et al only investigated outcomes after open mesh and open darn repair of groin hernias; no laparoscopic techniques were included in the analysis. Therefore, it is probable that a portion of the complications reported in the RCTs analysed in Finch et al were related to the type of incision made and not to whether mesh or non-mesh was used. This may be the reason behind the differing results between Finch et al and Lockhart et al.

Öberg et al (2018) was a systematic review and meta-analysis of 23 RCTs ($n = 5,444$) investigating rates of chronic pain after mesh versus non-mesh repair of groin hernias. The study found no significant difference in these rates. A significant weakness in the evidence presented by Öberg et al was the different definitions and standards for measuring pain used in the RCTs analysed. This reduced the certainty of the evidence. However, Öberg et al assessed a low level of attrition, reporting bias and selection bias in the RCTs that were analysed.

Confounders – method of entry and emergency repairs

We analysed two systematic reviews that investigated emergency groin hernia repair with and without mesh (Sæter et al 2022) and outcomes after laparoscopic versus open groin hernia repair (Bittner et al 2005) respectively to establish the impact of recognised confounders on clinical outcomes after hernia repair.

Sæter et al (2022), a systematic review and meta-analysis of 15 RCTs ($n = 1,241$), found no statistically significant difference in the rates of wound infection, hernia recurrence or mortality after emergency mesh repair versus emergency non-mesh repair. However, this evidence was assessed to be of low quality, and therefore the study concluded that the rates of post-operative complications of emergency mesh repair versus emergency non-mesh repair were unclear.

Bittner et al's investigation into the impact of operative approach (laparoscopic or open) on post-operative clinical outcomes showed that the rates of chronic pain and time to return to work were significantly reduced after laparoscopic repair of groin hernias when compared with open repair of groin hernias, regardless of the method of open repair used. This is likely a result of the lower invasiveness of laparoscopic procedures. Operating time was shorter with laparoscopic repair when compared with open repair; however, Bittner et al attributed this to skill differences between surgical teams. Current literature does not report a significant difference in rates of hernia recurrence between laparoscopic and open repair of hernias. The evidence of rates of mortality is unclear due to the very low incidence of mortality across RCTs investigating groin hernia repairs.

Patient-reported outcomes

Our investigation of patient-reported outcomes found significant improvement across a wide variety of patient-reported quality-of-life outcomes after repair of groin hernias with mesh when compared to a pre-operative baseline. These outcomes include self-reported pain level, impact of pain on wellbeing, mental and physical health perception, fatigue and impediment caused to work and social interactions. Forrester et al (2022) concluded that, for patients with inguinal hernias, mesh repair would produce a significant improvement in their quality of life. The results of Lawrence et al (1997) concur.

Matikainen et al (2021) and Melkemichel et al (2020) reported that the type of mesh and the method of mesh fixation used had no significant impact on any of the assessed clinical outcomes. These studies noted, however, that some proportion of patients (between 3 and 18%) did report significant ongoing pain or impact on their daily living after a mesh repair.

Treatment of groin hernias – HerniaSurge 2023 guidelines

The European Hernia Society publishes a widely referenced guideline on hernia management, initially published in 2018 (HerniaSurge Group 2018) and updated in October 2023 (Stabilini et al 2023). With a strong level of evidence, the HerniaSurge guidelines recommend a 'mesh-based repair technique for the majority of patients undergoing inguinal hernia repair'. The guidelines also recommend (noting a weak level of evidence) that 'a non-mesh repair for inguinal hernia repair can be suggested after careful patient selection and shared decision-making if expertise is available'. Of note, the guidelines recommend, with a strong level of evidence, that the Shouldice technique (a four-layered non-mesh technique using two separate sutures) should be used for non-mesh inguinal hernia repair. The guidelines also note that the Shouldice technique has a long learning curve, and this should be taken into consideration depending on local/country-specific training environments. In terms of type of mesh, the recommendation (with a strong level of evidence) is for lightweight mesh in Lichtenstein repair to reduce the occurrence of chronic post-operative pain and foreign body sensation. However, in laparo-endoscopic repair, a heavyweight mesh is recommended (especially in large or direct hernias), to reduce the risk of recurrence. The guidelines note that, in this case, lightweight mesh increases the risk of recurrence without reducing post-operative pain. The guidelines also make recommendations on the use of antibiotics, anaesthetic choice, surgical approaches, diagnostic imaging, pain control, emergency treatment of acute hernias and predictors of bowel ischaemia.

Conclusion

Our investigation found that there does not appear to be a substantial difference in clinical outcomes after mesh groin hernia repair when compared with non-mesh groin hernia repair. Mesh repair does reduce the rate of hernia recurrence, urinary retention and neurovascular or visceral complications (with RRs of 0.46, 0.53, and 0.61 respectively). Mesh repair increases the rate of seroma formation (RR 1.63). However, the poor quality of a large portion of the current evidence on this subject makes the margin of difference between outcomes after mesh versus non-mesh repair uncertain. Our investigation also found that there is evidence to suggest that the use of laparoscopy in groin hernia repair produces significantly superior outcomes for patients. Although, from a quantitative and qualitative perspective, outcomes after mesh repairs are probably similar or marginally superior to outcomes after non-mesh repairs of groin hernias, those who do suffer complications post-operatively after mesh groin hernia repair face a significant impediment to their quality of life. This highlights the importance of informed consent, patient voice and the value of lived experience in any consideration of mesh use for groin hernia repair.

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Appendix 1: Search criteria

This appendix presents details of our search criteria.

Databases

Ovid MEDLINE(R) and Epub ahead of print, in-process, in-data-review and other non-indexed citations, daily and versions <1946 to November 03, 2023>

Search strategy

1. *Surgical Mesh/ae [adverse effects]
2. *surgical mesh/
3. exp *postoperative complications/
4. *Pain/ or *Chronic Pain/
5. *Seroma/
6. *Hematoma/ or haematoma.mp.
7. *Wound Infection/
8. *Recurrence/ or recurrence.mp.
9. 3 or 4 or 5 or 6 or 7 or 8
10. 2 and 9
11. exp hernia/ or hernia.mp.
12. (nonurogyn* or non-urogyn*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]
13. (nonuro or non-uro or nongyn or non-gyn*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]
14. ((bone or dental or 'soft tissue') and surger*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]
15. 11 or 12 or 13 or 14
16. (1 or 10) and 15
17. Prevalence/ or prevalence.mp.
18. incidence.mp. or Incidence/

19. registries/ or registry.mp. or registries.mp. or hernia database*.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]

20. (rate* adj7 (complication* or 'adverse event*')).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]

21. surgical mesh/sn

22. ((prospective* adj7 (complication* or 'adverse event*')) or (retrospective* adj7 (complication* or 'adverse event*'))).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]

23. 17 or 18 or 19 or 20 or 21 or 22

24. 16 and 23

25. limit 24 to (english language and yr='2018 -Current')

Appendix 2: Outcome tables

This appendix presents the outcomes we identified and extracted in the course of our review.

General key

=: No Notable Difference Between Mesh/Non-Mesh
NM: Non-Mesh [Produced Better Result]
M: Mesh [Produced Better Result]
LMR: Lichtenstein Mesh Repair
MDR: Modified Darn Repair
BRT: Bassini Repair Technique
Shld: Shouldice Repair
Mesh: Mesh (Not Specified Further)
DR: Darn Repair (General)
MPR: Mesh-plug Repair
DRM: Desarda Repair Method
MBR: Modified Bassini Repair
Non-Mesh: Non-Mesh (Not Specified Further)
LTFH: Lichtenstein Tension-Free Hernioplasty
TAAP: Trans-Abdominal Preperitoneal Mesh Repair
TFMR: Tension Free Mesh Repair
TDS: Traditional Darn Suture
LH: Laparoscopic herniorrhaphy
MDR: Moloney Darn Repair
LP: Lichtenstein Patch
PHSR: Prolene Hernia System Repair
MR: Marcy Repair
MPTFR: Mesh-plug Tension Free Repair
PMR: Propylene Mesh Repair

Table 1: Outcomes reported by 25 RCTs comparing mesh and non-mesh hernia repair

RCT Studies:	Yr(Pub)	n =	Year	Country	Age Range	No. M (%)	No. F (%)	HR	WI	WS	H	S	N	Mesh Procedure (1)	Mesh Procedure (2)	Non-Mesh Procedure	KEY:
Abd-El	2014	227	08-09	Egypt	18-60	227 (100%)	0 (0%)	=	=					LMR		MDR	HR: Hernia Recurrence
Barth	1998	105	93-95	United Kingdom	>18	104 (99%)	1 (1%)							Mesh		Shld	WI = Wound Infection
Butters	2004/07	280	N. R.	United Kingdom	46-60	280 (100%)	0 (0%)							LMR	TAPP	Shld	WS = Wound Swelling
Chakraborty	2007	240	01-03	India	18-76	240 (100%)	0 (0%)							TFMR		TDS	H = Hematoma
Elsebae	2008	54	04-06	Egypt	>18	54 (100%)	0 (0%)	=	=					LMR*		BRT	S = Seroma
Kaynak	2007	651	00-06	Turkey	18-87	612 (94%)	39 (6%)							LMR		MDR	N = Neuralgia
Kucuk	2010	306	03-08	Turkey	N. R.	248 (81%)	58 (19%)							LMR		DR	
Manylirah	2011	101	09	Uganda	>18	88 (88%)	13 (13%)							LMR		DRM	
McGillcuddy	1998	672	90-95	United States	20-90	672 (100%)	0 (0%)							LMR		Shld	
Nakagawa	2013	91	02-07	Japan	49-80	82 (90%)	9 (10%)							PHSR		MR	
Naveen	2014	70	11-13	India	Mid-Eld	N.R.	N.R.							LMR		MBR	
Nordin	2002	300	94-98	Sweden	25-75	300 (100%)	0 (0%)							LMR		Shld	
Panda	2012	40	09-10	India	20-65	N.R.	N.R.							LMR		BRT	
Prieto-Diaz	2009	106	02-03	Mexico	18-65	84 (79%)	22 (21%)							MPTFR		Shld	
Prior	1998	80	N.R.	United Kingdom	>18	N.R.	N.R.							LMR		MBR	
Shi	2010	552	01-06	China	N. R.	537 (98%)	15 (2%)	M						TFMR		BRT	
Vrijland	2002	300	93-96	Netherlands	>18	292 (92%)	8 (3%)	M						Mesh		Non-Mesh	
Witowski	2000	140	94-98	Poland	>14	113 (81%)	27 (19%)							MPR		BRT	
Zieren	1998	240	94-96	Germany	>18	219 (92%)	21 (8%)							LH	TAPP	Shld	
Berndsen	2005/07	1183	93-96	Sweden	30-70	1183 (100%)	0 (0%)							LH		Shld	
Koukourou	2001	105	94-98	Australia	18-90	105 (100%)	0 (0%)							PMR		MDR	
Al-Saiegh	2009	104	07-08	Iraq	16-72	102 (98%)	2 (2%)							LTFF		MDR	
Memon	2017	92	14-15	Pakistan	20-60	92 (100%)	0 (0%)							LMR		TFDR	
Dirksen	1998	175	93-95	Netherlands	20-80	173 (99%)	2 (1%)	M						TAPP		BRT	
Juul	1999	268	94-97	Denmark	18-75	268 (100%)	0 (0%)							TAPP		Shld	

Table 2: Outcomes reported by 25 RCTs comparing mesh and non-mesh hernia repair

RCT Studies:	Yr(Pub)	n =	Year	Country	Age Range	No. M (%)	No. F (%)	TC	SS/E	UR	AN	PS	N/V-I	Mesh Procedure (1)	Mesh Procedure (2)	Non-Mesh Procedure	KEY:
Abd-El	2014	227	08-09	Egypt	18-60	227 (100%)	0 (0%)	=						LMR		MDR	TC: Testicular Complications
Barth	1998	105	93-95	United Kingdom	>18	104 (99%)	1 (1%)							Mesh		Shld	SS/E: Scrotal Swelling & Edema
Butters	2004/07	280	N. R.	United Kingdom	46-60	280 (100%)	0 (0%)					M		LMR	TAPP	Shld	UR: Urinary Retention
Chakraborty	2007	240	01-03	India	18-76	240 (100%)	0 (0%)							TFMR		TDS	AN: Analgesic Requirements
Elsebae	2008	54	04-06	Egypt	>18	54 (100%)	0 (0%)							LMR*		BRT	PS: Patient Satisfaction
Kaynak	2007	651	00-06	Turkey	18-87	612 (94%)	39 (6%)							LMR		MDR	N/V-I: Neurovascular/Visceral Injury
Kucuk	2010	306	03-08	Turkey	N. R.	248 (81%)	58 (19%)							LMR		DR	
Manylirah	2011	101	09	Uganda	>18	88 (88%)	13 (13%)							LMR		DRM	
McGillcuddy	1998	672	90-95	United States	20-90	672 (100%)	0 (0%)							LMR		Shld	
Nakagawa	2013	91	02-07	Japan	49-80	82 (90%)	9 (10%)							PHSR		MR	
Naveen	2014	70	11-13	India	Mid-Eld	N.R.	N.R.							LMR		MBR	
Nordin	2002	300	94-98	Sweden	25-75	300 (100%)	0 (0%)							LMR		Shld	
Panda	2012	40	09-10	India	20-65	N.R.	N.R.							LMR		BRT	
Prieto-Diaz	2009	106	02-03	Mexico	18-65	84 (79%)	22 (21%)							MPTFR		Shld	
Prior	1998	80	N.R.	United Kingdom	>18	N.R.	N.R.							LMR		MBR	
Shi	2010	552	01-06	China	N. R.	537 (98%)	15 (2%)							TFMR		BRT	
Vrijland	2002	300	93-96	Netherlands	>18	292 (92%)	8 (3%)							Mesh		Non-Mesh	
Witowski	2000	140	94-98	Poland	>14	113 (81%)	27 (19%)					M		MPR		BRT	
Zieren	1998	240	94-96	Germany	>18	219 (92%)	21 (8%)							LH	TAPP	Shld	
Berndsen	2005/07	1183	93-96	Sweden	30-70	1183 (100%)	0 (0%)						M	LH		Shld	
Koukourou	2001	105	94-98	Australia	18-90	105 (100%)	0 (0%)							PMR		MDR	
Al-Saiegh	2009	104	07-08	Iraq	16-72	102 (98%)	2 (2%)							LTFF		MDR	
Memon	2017	92	14-15	Pakistan	20-60	92 (100%)	0 (0%)							LMR		TFDR	
Dirksen	1998	175	93-95	Netherlands	20-80	173 (99%)	2 (1%)				M			TAPP		BRT	
Juul	1999	268	94-97	Denmark	18-75	268 (100%)	0 (0%)							TAPP		Shld	

Table 3: Outcomes reported by 25 RCTs comparing mesh and non-mesh hernia repair

RCT Studies:	Yr(Pub)	n =	Year	Country	Age Range	No. M (%)	No. F (%)	TRW	TRUA	HSL	OT	Mesh Procedure (1)	Mesh Procedure (2)	Non-Mesh Procedure	KEY:
Abd-El	2014	227	08-09	Egypt	18-60	227 (100%)	0 (0%)		=	=	M	LMR		MDR	KEY: TRW: Time To Return to Work TRUA: Time To Return To Usual Activities HSL: Hospital Stay Length OT: Operative Time
Barth	1998	105	93-95	United Kingdom	>18	104 (99%)	1 (1%)		M		M	Mesh		Shld	
Butters	2004/07	280	N. R.	United Kingdom	46-60	280 (100%)	0 (0%)						TAPP	Shld	
Chakraborty	2007	240	01-03	India	18-76	240 (100%)	0 (0%)				M	TFMR		TDS	
Elsebae	2008	54	04-06	Egypt	>18	54 (100%)	0 (0%)			NM	M	LMR*		BRT	
Kaynak	2007	651	00-06	Turkey	18-87	612 (94%)	39 (6%)	=	NM	=	=	LMR		MDR	
Kucuk	2010	306	03-08	Turkey	N. R.	248 (81%)	58 (19%)				=	LMR		DR	
Manylirah	2011	101	09	Uganda	>18	88 (88%)	13 (13%)		=		NM	LMR		DRM	
McGillcuddy	1998	672	90-95	United States	20-90	672 (100%)	0 (0%)					LMR		Shld	
Nakagawa	2013	91	02-07	Japan	49-80	82 (90%)	9 (10%)				NM	PHSR		MR	
Naveen	2014	70	11-13	India	Mid-Eld	N.R.	N.R.			=	M	LMR		MBR	
Nordin	2002	300	94-98	Sweden	25-75	300 (100%)	0 (0%)		M	=	M	LMR		Shld	
Panda	2012	40	09-10	India	20-65	N.R.	N.R.			M	M	LMR		BRT	
Prieto-Diaz	2009	106	02-03	Mexico	18-65	84 (79%)	22 (21%)	M	M	M	M	MPTFR		Shld	
Prior	1998	80	N.R.	United Kingdom	>18	N.R.	N.R.				=	LMR		MBR	
Shi	2010	552	01-06	China	N. R.	537 (98%)	15 (2%)			M		TFMR		BRT	
Vrijland	2002	300	93-96	Netherlands	>18	292 (92%)	8 (3%)		=	=		Mesh		Non-Mesh	
Witowski	2000	140	94-98	Poland	>14	113 (81%)	27 (19%)		M	M	M	MPR		BRT	
Zieren	1998	240	94-96	Germany	>18	219 (92%)	21 (8%)		M	M	M	LH	TAPP	Shld	
Berndsen	2005/07	1183	93-96	Sweden	30-70	1183 (100%)	0 (0%)		M		NM	LH		Shld	
Koukourou	2001	105	94-98	Australia	18-90	105 (100%)	0 (0%)		=			PMR		MDR	
Al-Saiegh	2009	104	07-08	Iraq	16-72	102 (98%)	2 (2%)			M	M	LTFH		MDR	
Memon	2017	92	14-15	Pakistan	20-60	92 (100%)	0 (0%)					LMR		TFDR	
Dirksen	1998	175	93-95	Netherlands	20-80	173 (99%)	2 (1%)	M	M		NM	TAPP		BRT	
Juul	1999	268	94-97	Denmark	18-75	268 (100%)	0 (0%)					TAPP		Shld	

Table 4: Outcomes reported by 25 RCTs comparing mesh and non-mesh hernia repair

RCT Studies:	Yr(Pub)	n =	Year	Country	Age Range	No. M (%)	No. F (%)	PO-O	PO-C	PO-P	Mesh Procedure (1)	Mesh Procedure (2)	Non-Mesh Procedure	KEY:
Abd-El	2014	227	08-09	Egypt	18-60	227 (100%)	0 (0%)			NM	LMR		MDR	KEY: PO-O: Post-Operative Outcomes PO-C: Post-Operative Complications PO-P: Post-Operative Pain
Barth	1998	105	93-95	United Kingdom	>18	104 (99%)	1 (1%)	=			Mesh		Shld	
Butters	2004/07	280	N. R.	United Kingdom	46-60	280 (100%)	0 (0%)	=			LMR	TAPP	Shld	
Chakraborty	2007	240	01-03	India	18-76	240 (100%)	0 (0%)	=			TFMR		TDS	
Elsebae	2008	54	04-06	Egypt	>18	54 (100%)	0 (0%)						BRT	
Kaynak	2007	651	00-06	Turkey	18-87	612 (94%)	39 (6%)		=	=			MDR	
Kucuk	2010	306	03-08	Turkey	N. R.	248 (81%)	58 (19%)				=		DR	
Manylirah	2011	101	09	Uganda	>18	88 (88%)	13 (13%)				=		DRM	
McGillcuddy	1998	672	90-95	United States	20-90	672 (100%)	0 (0%)	=					Shld	
Nakagawa	2013	91	02-07	Japan	49-80	82 (90%)	9 (10%)						MR	
Naveen	2014	70	11-13	India	Mid-Eld	N.R.	N.R.			M			MBR	
Nordin	2002	300	94-98	Sweden	25-75	300 (100%)	0 (0%)		=				Shld	
Panda	2012	40	09-10	India	20-65	N.R.	N.R.			M			BRT	
Prieto-Diaz	2009	106	02-03	Mexico	18-65	84 (79%)	22 (21%)			M			Shld	
Prior	1998	80	N.R.	United Kingdom	>18	N.R.	N.R.			M			MBR	
Shi	2010	552	01-06	China	N. R.	537 (98%)	15 (2%)			M			BRT	
Vrijland	2002	300	93-96	Netherlands	>18	292 (92%)	8 (3%)		=	=			Non-Mesh	
Witowski	2000	140	94-98	Poland	>14	113 (81%)	27 (19%)		=	M			BRT	
Zieren	1998	240	94-96	Germany	>18	219 (92%)	21 (8%)			M			Shld	
Berndsen	2005/07	1183	93-96	Sweden	30-70	1183 (100%)	0 (0%)			M			Shld	
Koukourou	2001	105	94-98	Australia	18-90	105 (100%)	0 (0%)		=				MDR	
Al-Saiegh	2009	104	07-08	Iraq	16-72	102 (98%)	2 (2%)						MDR	
Memon	2017	92	14-15	Pakistan	20-60	92 (100%)	0 (0%)						TFDR	
Dirksen	1998	175	93-95	Netherlands	20-80	173 (99%)	2 (1%)			M			BRT	
Juul	1999	268	94-97	Denmark	18-75	268 (100%)	0 (0%)						Shld	

Appendix 3: Relevant international information

This appendix sets out some relevant information from the international context:

- policies and guidelines on the use of mesh for groin hernia repair
- guidelines on the use of mesh for other hernias
- peripheral guidelines of interest
- new trends in the approach to hernia repair.

Policies and guidelines on use of mesh for groin hernia repair

The Welsh Government (Welsh Government 2019) sought opinions and advice from the Royal College of Surgeons, which was supported by review of evidence by Deputy Chief Medical Officer. It found the following.

- ‘Mesh based technique should be performed for adults with inguinal hernias.’
- ‘The clear opinion and advice from the Royal College of Surgeons, which is supported by the available evidence, international guidance and practice, is that we must continue to be vigilant and listen to patient feedback as well as examine any new evidence, but at present, there is no indication to put a pause on the use of mesh in hernia repair.’
- There was acknowledgment that for those who do suffer adverse outcomes, the impact can be severe. Considering this, those who suffer ‘should raise these concerns through NHS Wales’ Putting Things Right arrangements’.

The Royal College of Surgeons of England published a statement in 2019 (Royal College of Surgeons of England 2019) that:

- stated ‘A recent 2018 study [referring to Öberg et al (2018)] found that both mesh and non-mesh hernia repairs were effective for patients and are not associated with different rates of chronic pain’. We note that Öberg et al (2018) do not make a clear statement in support of the continued use of mesh; but imply that support
- stressed the importance of reporting adverse events, being vigilant of the literature and listening to patients’ experiences.

The American Hernia Society published a statement in 2018 (American Hernia Society 2018) that:

- stated that the Society 'supports the use of appropriately selected mesh reinforcement for the vast majority of both inguinal and ventral hernias to reduce the risk of hernia reoccurrence'
- endorses shared decision making between surgeons and patients with respect to benefits and potential risks.

The United States Food and Drug Administration published a statement in 2023 (US Food and Drug Administration 2023) that:

- stated that 'it is generally accepted that most hernia repair surgeries in the U.S. use mesh'.
- references literature from 2013.

A Canadian report on surgical mesh for inguinal hernia repair (Tumasz-Jordan et al 2019):

- concluded that 'analyses of recurrence rates suggest that synthetic mesh is similar to suture repair (however, these results are associated with moderate-to-substantial heterogeneity after 1 year) and is comparable to porcine mesh. Risk profile of complications is similar and not significant across synthetic mesh and its comparators.'
- commented on the need for ongoing monitoring of reported adverse events and noted that Health Canada was in the process of establishing such a monitoring system.

The Australian Government's report *Reclassifying Surgical Mesh Devices* (Therapeutic Goods Administration 2018) noted that in October 2017, the Therapeutic Goods Administration had reclassified surgical mesh from Class IIb (medium) to Class III (high risk), due to 'serious concerns about the risk associated with the use of these devices'.

Guidelines on use of mesh for other hernias

The European Hernia Society and Americas Hernia Society guidelines for treatment of umbilical and epigastric hernias (Henriksen et al 2020):

- recommended repair of umbilical and epigastric hernias by 'an open approach with a preperitoneal flat mesh'
- strongly recommended that sutured repair be considered for hernias of < 1cm, with shared decision making (due to the lack of evidence concerning hernias of this size)
- contained recommendations regarding antibiotics, anaesthetic choice, method of mesh fixation, type of mesh, surgical approach, emergency hernia repair, cost and learning curves.

Most of the recommendations in this guideline, however, were classified as weak due to low-quality evidence.

European Hernia Society guidelines on other abdominal wall hernias (Henriksen et al 2020):

- The European Hernia Society has regularly updated guidelines on multiple other hernias: incisional, parastomal, scrotal inguinal, ventral and rectus diastasis.

Peripheral guidelines of interest

The British National Institute for Health and Care Excellence (NICE) guidance on the use of glue to secure mesh in inguinal hernia operations (NHS Supply Chain 2022):

- recommended that clinicians 'consider' the use of glue to secure mesh in inguinal hernia repair, rather than traditional tacks (plastic or metal)
- cited three systematic reviews and two randomised controlled trials (involving a total of 1,374 people) who were randomised to cyanoacrylate glue groups. These studies showed that cyanoacrylate glue was as effective as alternative methods of mesh fixation. The evidence does not show any advantage, however, of cyanoacrylate glue for the incidence of post-operative chronic pain.

New trends in the approach to hernia repair

Robotics

Over the past decade, there has been an increase in the use of robotics in a broad range of surgical procedures, including hernia repair. However, there is a cost-benefit issue to be considered, as well as issues related to early adoption of robotic approaches in the absence of sufficient evidence to support its superiority (American College of Surgeons (nd)).

Machine learning

Machine learning is being used in some surgical settings to predict the risk of adverse outcomes; for example, the Surgical Risk Calculator used by the American College of Surgeons (Hassan et al 2022).

Validation studies are being done to evaluate the accuracy of machine learning tools for hernia repair (McCartney (nd)).

Shared video learning technology

Video learning to teach surgical techniques is a growing trend. There is, however, a need for a peer-review process to evaluate the quality of the wide range of videos available (Poulose et al 2020).

Holistic approach to hernia care

There is a growing movement to broaden the approach to hernia care to encompass the idea of abdominal core health (Wailling et al 2019).

The holistic approach incorporates preventive strategies, core muscle strength and the interaction between pulmonary function, core strength and pelvic floor function.

Appendix 4: Glossary of terms used in footnotes

Terms used in footnotes are as follows.

CI	Confidence interval
MD	Mean difference
NNTB	Number needed to benefit
OR	Odds ratio
RR	Risk ratio
SD	Standard deviation
WMD	Weighted mean difference