



Llywodraeth Cymru
Welsh Government

Deputy Chief Medical Officer Review

Use of Hernia Mesh

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Background

- A hernia occurs when an internal part of a body pushes through a weakness in the muscle or surrounding tissue wall. It usually takes the form of a lump, or swelling with or without some discomfort that may limit daily activities, including the ability to work.
- There are different types of hernia, inguinal hernias are the most common and the majority of these (approximately 98%) are found in men due to their particular anatomical structure.
- Other types include femoral (also in the groin), umbilical and incisional (this type occurs following surgery in the upper abdomen where an incision has caused weakness in tissue)
- Hernias cannot be treated medically and often require surgical repair if the patient is fit enough. Without surgery, there are risks of strangulation, bowel obstruction and incarceration, which could require emergency surgical intervention.

Management

- Hernia repair is a very common surgical intervention and significantly more patients have undergone hernia mesh procedures than have undergone vaginal mesh procedures [with approximately 70,000 inguinal hernia repairs performed every year in England and 6,000 each year in Wales].
- Until the 1950's, the repair took the form of a suture technique at the site of weakness or defect. The stitching of such weak areas did not result in long lasting repair which led to the recurrence of the hernia.
- The use of prosthetic mesh has become increasingly common since then as a 'tension-free' or patching method for strengthening and reinforcing weak tissue, resulting in longer lasting repair.
- There has been significant change in the design and manufacture of synthetic mesh over the years, with a move to larger pore, lighter weight mesh, with early data suggesting better tolerance of such implants by the patient.
- There are broadly two techniques for mesh hernia repair - open or laparoscopic.

- In an open repair, the defect through which the hernia is protruding is identified and mesh placed over the defect and stitched in place, in effect creating a scaffold for the tissue to grow through to strengthen the weak area.
- In a laparoscopic repair, a small incision is made near the umbilicus as well as two small incisions in the lower abdomen. Carbon dioxide is used to inflate the abdomen and a camera is inserted via one of the incisions so that the defect is viewed from the interior abdominal wall and mesh introduced.
- As with all types of surgery, there are associated risks. These include inter-operative complications such as bleeding or damage to surrounding structures as well as post-operative complications such as infection, pain (which can become chronic), thromboembolic complications as well as hernia recurrence.

NICE Guidance

- Guidance was published in 2004 on laparoscopic hernia repair which states that a laparoscopic repair should only be carried out by trained surgeons who perform the procedure regularly.
- The use of mesh in hernia repair is considered by NICE to be an 'Interventional Procedure', and therefore is not 'approved' as may be the case for a drug or procedure subject to technology appraisal. NICE do not examine interventional procedures which are considered established practice unless there are data demonstrating uncertainty about their efficacy or safety.
- The guidance with regard to laparoscopic repair was reviewed in 2016 but there was no new evidence to suggest a change in the guidelines was required.

MHRA view

- Our understanding is the MHRA broadly agrees with NICE's position outlined above and considers that the main determinant of success of an operation seems to be patient selection and surgical technique rather than choice of device. MHRA continues to encourage the reporting of adverse events following the use of surgical mesh.

Use of mesh for hernia repair in Wales

- Data in relation to the number of patients undergoing hernia procedures in Wales over the period 2011/12 to 2017/18 was obtained and is set out in the table below. It is based on PEDW data provided by NWIS, but it should be noted it is of mixed quality due to potential inaccuracies in coding, the varied interpretation of the code by clinicians and some patients may have undergone more than one procedure. However, it provides a snap shot of the available data to establish the broad scale of the activity involved. .

Year	Hernia repair with other materials	Hernia repair with prosthetic materials	Removal of prosthetic material	Total number of patients	Percentage of those requiring mesh removal
2011/12	1,102	5,062	31	6,195	0.006
2012/13	1,135	4,655	22	5,812	0.005
2013/14	1,226	5,043	39	6,308	0.008
2014/15	1,186	4,693	40	5,919	0.009
2015/16	1,406	5,020	36	6,462	0.007
2016/17	1,470	5,315	35	6,820	0.007
2017/18	1,498	4,597	35	6,130	0.008
Total	9,023	34,385	238	43,646	0.007
% total	20.7	78.8			

- The table records three categories of hernia procedures:
 - Those involving only the use of non-prosthetic materials such as sutures, such as carried out for the repair of the abdominal wall.
 - Hernia repairs using synthetic, prosthetic material. This covers all of the operations using the more contentious non-absorbable meshes, usually, but not exclusively made of polypropylene.
 - Patients who have undergone procedures involving the removal of prosthetic mesh, for operations treating inguinal, femoral, umbilical, incisional and ventral hernias.
- The table demonstrates that in Wales between 2011/12 and 2017/18, 43,646 patients had a hernia repair
- Of those, 78.8% underwent a mesh-based technique

- As mentioned above, a small number of patients will require removal of mesh due to complications, for example, chronic infection.
- Our data demonstrates that a very small minority of patients suffer complications that necessitates removal and those figures do not change dramatically on an annual basis
- Obviously some patients will have complications that do not warrant mesh removal but the interpretation is that those who undergo mesh removal suffer the most severe complications. The likelihood of the mesh being removed appears to be around 0.007%, consistent with international data and extremely low for any surgical complication. This is a rate which appears to have been largely consistent over the 5 year period of this review.

Correspondence/complaints

- In addition to reviewing the PEDW data we looked at the information recorded by NHS Wales on serious incidents relating to the use of hernia mesh and whether there were any on-going legal cases recorded. There were no serious incidents reported or legal cases.
- In addition, there have been only been a small number (4 - 5) of letters from patients about hernia mesh to Welsh Government Health Ministers, one of which praised the benefits of mesh. The letters outlining the problems experienced with hernia mesh, most of which were received after the women's mesh group raised the issue as a concern, contained little information on where and when the surgery took place.

Literature review (Please see Annex 1)

- As part of this exercise, an on-line literature review was undertaken using the keywords 'hernia', 'mesh' and 'complications'.
- A Cochrane systematic review was published in 2018 comparing mesh procedures and non-mesh procedures for the repair of inguinal and femoral hernias (which included 6,293 participants)
- It found that mesh repairs are associated with a reduced rate of hernia recurrence (hence reduced amount of patients needing more surgery) as well as reduced risk of visceral and neurovascular damage but non-mesh procedures carried a lower risk of seroma (pocket of serous fluid) formation.

- In terms of chronic pain a large systematic review published in 2018 found no statistical difference in the rates of chronic pain between mesh and non-mesh procedures in the first post-operative year. There is no evidence that the use of mesh increases the risk of pain
- There are reports that moderate-severe chronic pain can affect 10-12% post-operatively, but that the risk is less with mesh than non-mesh repair. Reports from England also noted that up to 5 per cent of those undergoing inguinal hernia repairs can experience long-term discomfort or pain, lasting for more than three months after their operations.
- An original piece of research looked at the rate of chronic infection following mesh insertion with only 0.005% requiring mesh removal due to chronic infection, similar to rates seen in NHS Wales.

International Guidelines

- **International guidelines for groin hernia management (HERNIASURGE)**
 - These guidelines were published in 2018, taking into account evidence and expertise from across the world, as well as patient perspectives
 - They acknowledged that there is debate about the best surgical approach and ultimately, this depends on surgical and patient choice
 - However, the international consensus was that the evidence supports a 'strong' recommendation to use a mesh-based technique
- **Danish Hernia Database**
 - This database records all hernia procedures performed in Denmark along with outcomes
 - Their recommendation is that in all male patients, the preferred method is mesh-based
 - Almost 100% of patients in Denmark having inguinal hernia repair undergo a mesh-based procedure

Royal College of Surgeons (RCS), London, position statement.

- The matter has been considered by the RCS and based, on their conclusions, they have issued the following statement:

"It is clearly tragic if even a single patient suffers horrible complications from any type of surgery, not just hernia operations. Unfortunately the nature of surgery in general, not just mesh surgery, carries with it an inherent risk of complications which surgeons will always seek to assess, and will discuss

with patients according to their individual clinical circumstances before surgery takes place.

There have already been a number of scientific studies looking at the use of different types of mesh in hernia and we should continue to review the evidence and patients' experiences to make sure the right advice is given and the right action is taken. Along with the regulatory authorities, we will continue to listen to patients' experiences. Patients suffering complications or pain need help, not silence. There must also be an ongoing review of the data to make sure that previous studies have not missed any serious, widespread issue. It remains vital that surgeons continue to make patients aware of all the possible side effects associated with performing a hernia repair."

Summary and conclusion

The use of mesh for hernia repair is one of the most common surgical procedures carried out worldwide. Since the introduction of mesh for hernia repair, there has been a significant reduction in the numbers of patients suffering hernia recurrence and therefore, a reduction in numbers of those needing further surgery. Recent papers have suggested that the risk of chronic pain is similar regardless of method used (mesh versus non-mesh).

The expert led review of vaginal mesh use highlighted a significant problem that we are responding to whilst we continue to take account of the ongoing work of the Cumberledge review. In contrast, the available statistical and clinical evidence does not support the view that the routine use of mesh in hernia repair is a serious problem for the population of Wales.

There are risks of complications associated with these operations, as there is with any interventional medical procedure, but the current evidence and available statistics do not support the concern the complications are in excess of what would be expected.

My recommendation is that there is presently no evidence to suggest that further work is necessary but of course, the situation needs to be observed and would need a further review if the evidence changes or in any way suggests the need.

I therefore advise we follow the cautionary approach proposed by the Royal College of Surgeons.

Annex 1

Systematic reviews/meta-analyses:

**Laparoscopic techniques versus open techniques for inguinal hernia repair
Cochrane Systematic Review - Intervention Version. Published 20 January
2003.**

**Kirsty McCormack, Neil Scott, Peter M.N.Y.H Go, Sue J Ross, Adrian Grant:
Collaboration the EU Hernia Trialists**

Inguinal hernia repair is the most frequently performed operation in general surgery. Our findings relating to hernia recurrence are consistent with those in the review of open mesh versus open non-mesh repair of groin hernia (Scott 2001). That review provides evidence that the use of mesh in open repair is associated with a substantial reduction in the risk of hernia recurrence. In this review both of the subgroup comparisons of laparoscopic groups (which use mesh) with non-mesh open methods favour the laparoscopic method (although not statistically significantly so for the TEP versus non-mesh comparison).

**Repair of Groin Hernia with Synthetic Mesh. Meta-Analysis of Randomized
Controlled Trials. Ann Surg. 2002 Mar; 235(3): 322–332.**

EU Hernia Trialists Collaboration.

The Collaboration identified data for 11,000 randomized patients, 10 times more than the single largest trial. These data indicate that the use of synthetic mesh reduces the risk of groin hernia recurrence by around 50%, regardless of method of placement. Persisting pain was also less frequent among the groups allocated to mesh repair, and apparently less common after laparoscopic than after open placement of mesh.

Mesh versus non-mesh for inguinal and femoral hernia repair.

Cochrane Database Syst Rev. 2018 Sep 13;9

This is an update of a Cochrane Review first published in 2001. Mesh (hernioplasty) and the traditional non-mesh repairs (herniorrhaphy) are commonly used, with an increasing preference towards mesh repairs in high-income countries.

OBJECTIVES: To evaluate the benefits and harms of different inguinal and femoral hernia repair techniques in adults, specifically comparing closure with mesh versus without mesh.

CONCLUSIONS: Mesh and non-mesh repairs are effective surgical approaches in treating hernias, each demonstrating benefits in different areas. Compared to non-mesh repairs, mesh repairs probably reduce the rate of hernia recurrence, and reduce visceral or neurovascular injuries, making mesh repair a common repair approach. Non-mesh repair is less likely to cause seroma formation and has been favoured in low-income countries due to low cost and reduced availability of mesh materials.

**Chronic pain after mesh versus non-mesh repair of inguinal hernias: A
systematic review and a network meta-analysis of randomized controlled trials
Surgery: Official Journal of the Society of University Surgeons, Central
Surgical Association, and the American Association of Endocrine Surgeons,
2018-05-01, Volume 163, Issue 5, Pages 1151-1159**

Stina Öberg, Kristoffer Andresen, Tobias W. Klausen and Jacob Rosenberg

- Several guidelines recommend mesh techniques when treating inguinal hernias in adults. Prior to mesh techniques, repairs were performed without mesh and with sutures only, i.e., non-mesh techniques. These techniques leave less foreign material in the groin compared with mesh techniques, which may decrease the inflammatory response, but suturing the defect creates more tension on the tissue, which is hypothesized to increase the risk of chronic pain
 - We included 23 RCTs
 - Regarding postoperative complications, the majority reported no statistical difference between mesh and non-mesh repairs
 - The median crude pain rate (including mild, moderate, and severe pain) at last follow-up was 6.4% (0%–51.4%) for the non-mesh group and 7.4% (0%–47.6%) for the mesh group
 - We found no difference in chronic pain in the first postoperative year when comparing non-mesh with mesh techniques, both with the meta-analyses and the network meta-analysis. The network meta-analysis could not be conducted 1 to 5 years postoperatively, but meta-analyses were possible after 1 to 5 years comparing open mesh techniques with non-mesh techniques, which again indicated that there was no difference in chronic pain
- Mesh may be used without fear of causing a greater rate of chronic pain.

International Guidelines:

Danish Hernia Database recommendations for the management of inguinal and femoral hernia in adults. Dan Med Bull. 2011 Feb;58(2):C4243. (Denmark)

- In male patients with primary unilateral or bilateral groin hernia the preferred method is mesh repair, either at open surgery (Lichtenstein) or laparoscopically, irrespective of age.

European Hernia Society guidelines on the treatment of inguinal hernia in adult patients, August 2009, Volume 13, Issue 4, pp 343–403

Primary unilateral: Mesh repair: Lichtenstein or endoscopic repair are recommended. Endoscopic repair only if expertise is available.

Primary bilateral: Mesh repair: Committee's recommendation: Lichtenstein or endoscopic.

Recurrent inguinal hernia: Mesh repair: Committee's recommendation: modify technique in relation to previous technique.

If previously anterior: Consider open preperitoneal mesh or endoscopic approach (if expertise is present).

If previously posterior: Consider anterior mesh (Lichtenstein).

International guidelines for groin hernia management, HerniaSurge

Guidelines published in 2018, to standardise management of groin hernias with collaboration from European Hernia Society, International Endo Hernia Society and European Association for Endoscopic Surgery, with input from experienced clinicians worldwide as well as patients.

Presently, the majority of surgeons in the world favour mesh repair of inguinal hernias. In Denmark, with its complete IH repair statistics in a national database,

mesh use is currently close to 100%. One single standard technique for all hernias does not exist. In most situations a mesh repair is preferred. When considering the results from the systematic review, large databases and guideline conclusions, we conclude that Shouldice is superior to other non-mesh techniques especially when considering recurrence rates. Compared to non-mesh techniques mesh-based techniques have a lower recurrence rate and an equal risk of postoperative pain. Although the level of evidence seems only moderate, by consensus in HerniaSurge the recommendation to use a mesh-based technique in inguinal hernia repair is upgraded to “strong”. Given the limitations of the literature on this subject, no conclusions can be reached regarding mesh removal sans neurectomy.

Original Research:

Outcome of the patients with chronic mesh infection following open inguinal hernia repair

J Korean Surg Soc. 2013 May; 84(5): 287–291 (Korea)

- In our clinic, between the years 2000 and 2012, 2,940 hernia repairs were performed and in 4 of these patients, graft infection is observed
- During the study period, 15 mesh removals were performed because of chronic infections in 14 males and one female with a median age of 52 years (0.005%)

Outcome of patients with severe chronic pain following repair of groin hernia British Journal of Surgery 2002, 89, 1310±1314

Courtney CA1, Duffy K, Serpell MG, O'Dwyer PJ.

Between April 1998 and March 1999 data were gathered on patients who underwent repair of a groin hernia in Scotland. Details were obtained on 5506 patients who had a groin hernia repair in Scotland in 1998, of whom 4062 (74 percent) returned the modified SF-36 questionnaire. Severe or very severe pain was reported in 3 per cent of patients at 3 months after groin hernia repair in Scotland. At a median follow-up of 30 months 26 per cent still reported severe or very severe pain which had profound effects on daily activities and quality of life. While there have been no comparative studies in hernia repair, use of absorbable suture materials has consistently been shown to cause less chronic pain after abdominal wall closure than non-absorbable materials

Long-term Recurrence and Complications Associated With Elective Incisional Hernia Repair.

JAMA. 2016 Oct 18;316(15):1575-1582. Kokotovic D, Bisgaard T, Helgstrand F.

To investigate the risks of long-term recurrence and mesh-related complications following elective abdominal wall hernia repair in a population with complete follow-up. Among patients undergoing incisional repair, sutured repair was associated with a higher risk of reoperation for recurrence over 5 years compared with open mesh and laparoscopic mesh repair. With long-term follow-up, the benefits attributable to

mesh are offset in part by mesh-related complications. There are several limitations to this study. These results were not based on randomized data, so selection bias and imbalance between the groups at baseline cannot be fully controlled for. Another limitation to our analysis is that our registry did not include other factors such as body mass index and smoking habits, which are known to influence the risk of complications from hernia repair.

Long-term Follow-up of a Randomized Controlled Trial of Suture versus Mesh Repair of Incisional Hernia

Ann Surg. 2004 Oct; 240(4): 578–585. Burger JW, Luijendijk RW, Hop WC, Halm JA, Verdaasdonk EG, Jeekel J.

Between March 1992 and February 1998, we randomly assigned 200 adult patients with a primary or first recurrent incisional hernia to suture repair or mesh repair. Twenty-seven percent of suture repair patients had experienced scar pain during the last month, compared with 20% of mesh repair patients ($P = 0.53$). Our study provides evidence that in the long-term mesh repair of incisional hernia is superior to suture repair. Recurrence is more frequent after suture repair, while the incidence of hernia repair–related complications, scar pain, cosmetic result, and patient satisfaction is comparable for both groups.

Chronic postoperative pain: the case of inguinal herniorrhaphy

**British Journal of Anaesthesia. Volume 95, Issue 1, July 2005, Pages 69-76
Aasvang E, Kehlet H.**

Poobalan and colleagues published a review in 2001 where data on chronic pain after inguinal herniorrhaphy until 2000 were analysed, and found that chronic pain was observed in about 10% of patients undergoing inguinal herniorrhaphy. The review by Poobalan and colleagues found three articles in which there was less pain after mesh-repair compared with non-mesh. The EU Hernia Trialists review also concluded that mesh repair caused less pain than non-mesh repair. In conclusion, the overall data suggest that there is less chronic pain after a mesh repair compared with non-mesh, which may be explained by an easier suture technique with the repair and thus a smaller risk of nerve damage. It appears from this updated review that even a relatively small operation such as inguinal herniorrhaphy may be followed by a risk of a chronic pain state in about 12% of patients.

National Guidance:

RCS commissioning guideline hernia repair

Groin hernia repairs are amongst the most commonly performed general surgical operations with over 71,000 inguinal and femoral hernias repairs carried out in England in 2014/15. All adult inguinal hernias should be repaired using flat mesh (or non-mesh Shouldice repair, if experience is available). A cost effective 'so called lightweight' (large pore) mesh should be used

NICE Guidance Laparoscopic surgery for inguinal hernia repair (published 2004)

Laparoscopic surgery for inguinal hernia repair by TAPP or TEP should only be performed by appropriately trained surgeons who regularly carry out the procedure. Recently, the availability of prosthetic meshes has led to an increase in the number of 'tension-free' methods of reinforcing the inguinal region. This guidance was reviewed in 2016 but no new evidence was produced that would necessitate a change in guidance.