Briefing for the Citizen Participation and Public Petitions Committee

Petition Number: PE1865

Main Petitioner: Roseanna Clarkin, Lauren McDougall and Graham Robertson

Subject: suspension of use of certain types of surgical mesh and fixation medical devices

Calling on the Scottish Parliament to urge the Scottish Government suspend the use of all surgical mesh and fixation devices while—

- a review of all surgical procedures which use polyester, polypropylene or titanium is carried out; and
- guidelines for the surgical use of mesh are established.

Background

The petitioners wish to raise awareness of complications that have arisen from the use of synthetic mesh in surgical repairs. The petitioners make it clear that this petition is not about transvaginal tape (TVT) or pelvic mesh implants, but about mesh and other devices and fixings used in surgery elsewhere in the body, particularly in hernia repair.

Transvaginal tape (TVT) 'mesh', is used for stress urinary incontinence (SUI) and pelvic organ prolapse and (POP). These two conditions, and their treatment with mesh, have been the subject of much controversy, debate and a wide review internationally, as well as the production of new clinical guidelines over recent years.

Routine use of mesh for treatment of SUI and POP ceased in Scotland in 2014. This suspension was tightened in 2018 until a restricted use protocol was established. See also PE 1517.

The petitioners are highlighting that similar problems with these other synthetic meshes, such as infection, pain and adhesion can occur with mesh after it is used for hernia and other repairs, and are calling for a suspension of its use. They want this suspension so that a review can done on existing guidelines and evidence. They also wish to see the introduction of bespoke services for removal if complications occur, and argue that specialist training of surgeons is required. Removing TVT is not the same as removing mesh from the digestive tract for example. The petitioners want the same attention that has been given to treatment by mesh for SUI and POP given to the use of mesh in other parts of the body.

The petitioners are also calling for similar caution to be applied to other devices, such as titanium staples that are used in securing mesh, because of a reported cancer risk.

Repairs where mesh and mesh stitches might be used

A common use for surgical mesh is for hernia repair. There are several types of hernia, that occur in the abdominal area, but the most common is an inguinal (groin) hernia. Such hernias most commonly affect men, when part of the bowel or fatty tissue pokes through the muscle wall into the groin area causing painful swelling. Treatment is by open or laparascopic (key hole) surgery. NHS Inform say that the operation is routine and can be carried out as day-surgery. Mesh is used to strengthen the muscle wall. In keyhole surgery, there are two methods used:

- Transabdominal preperitoneal (TAPP) – instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum). A flap of the peritoneum is peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

- Totally extraperitoneal (TEP) – this is the newest keyhole technique. It involves repairing the hernia without entering the peritoneal cavity.

NHS Inform goes on to describe the pros and cons of all three methods, including open surgery, which remains the most common.

Clinical Guidelines for hernia repair

The mesh in use for hernia and other abdominal repair has been in use since the 1970s. It was later approved for use in pelvic repair surgery. The National Institute for Health and Care Excellence (NICE) published guidance for a certain type of hernia repair that dates from 2004, and was reviewed in 2016 with no changes deemed necessary. However, more recent guidance for the treatment of a different type of hernia with mesh was published in 2019, and recommends caution and fully informed consent and the involvement of clinical governance leads.

Other guidelines:

Society of American Gastrointestinal and Endoscopic Surgeons guidelines (2016)

Scottish Needs Assessment Programme, Hernia Repair 1996

How are medical devices and materials regulated?

Regulation of medicines and medical devices is reserved to the UK Parliament. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for issuing licences to manufacturers and wholesalers to enable licensed products to be used in the UK. This SPICe briefing provides more information. Once licensed, health boards and clinicians are able to order and use the products and devices.

In 2017, NHS England set up a Mesh Working Group to address concerns. However, the focus was only on evidence related to vaginal mesh implants for Pelvic Organ Prolapse (POP) and Stress urinary incontinence (SUI).

In June 2021, NHS National Services Scotland published Guidance on the Management of medical Devices and Equipment in Scotland's Health and Social Care Services. This brings together MHRA guidance (as the competent authority) with Scotland specific guidance so that there is alignment between UK and Scottish public bodies and government, partly as a consequence of the UK leaving the European Union.

How are adverse events reported?

Adverse events are occasions when a procedure or treatment has cause harm to individuals or groups of people. NHS Healthcare Improvement Scotland has led work in learning from adverse events over recent years, and in reviewing how such events are managed. The report of the transvaginal mesh short-life working group recommended to:

- Mandate the use of a national database to record the details of the mesh removal surgery, report adverse events to MHRA and audit the outcome in patients' own terms of success and failures

The Guidance published in June 2021 explains the processes for reporting adverse events in NHS Scotland, updating guidance with changes to duty of candour and adverse event reporting procedures in Scotland.

The SPICe briefing that accompanied PE 1517 also describes the processes for reporting adverse incidents by clinicians and manufacturers. Adverse events must be reported by manufacturers, and CEL 43 (2009) sets out reporting and monitoring arrangements for health professionals in Scotland. Individuals can also report issues through the MHRA 'yellow card' reporting scheme.

When a product is suspected or known to be faulty, the MHRA works with the manufacturer and wholesaler to agree the most appropriate action to take. In serious circumstance, the product has to be recalled and taken out of the supply chain. The MHRA oversees:

- Field Safety Notices (FSNs) - sent out by medical device manufacturers or their representatives outlining actions they are taking in relation to a product.
- Medical Device Alerts (MDAs) - issued by the MHRA to communicate safety information to device users in health and social care.

The MHRA also operates the Yellow Card Scheme which monitors the safety of medicines and devices in the UK. Reports can be made by healthcare professionals and patients about safety concerns on products via the Yellow Card Scheme.

Issues raised about mesh for hernia treatment and repair

This article, published by the Royal College of Surgeons discusses the materials used and types of mesh used for hernia repair. This more recent US website describes in some detail the use of hernia mesh and some of the types of mesh used. It also discusses complications. It also highlights lawsuits filed in the US against a number of manufacturers. It should be noted that brands licensed in the US will not necessarily be licensed for use in the UK. However, hernia mesh claims have been made in the UK with a number of solicitors advertising their services for such claims.

In 2018, the BBC conducted an investigation into hernia mesh use in England, highlighting the complication rate. Hernia affects about 10% of the population according to the report.

Commenting on the Victoria Derbyshire programme's claim that hernia
mesh complications 'affect more than 100,000' people, the Royal College of Surgeons issued a statement seeking to contextualise the BBC report and end by supporting the introduction of a UK mesh implant registry to monitor the safety and effectiveness of mesh implants and to allow early intervention when problems are identified.

The British Hernia Society issued a mesh safety leaflet for patients in 2018.
This states that:

> **"Surgical mesh, regulations and safety**
> The use of mesh to repair the majority of hernias has been the preferred method in the UK and worldwide for over 25 years. There is a large volume of data on the outcome of various hernia operations and different meshes. Indeed when surgeons themselves have hernias they opt for mesh repairs. Meshes used in surgery are tightly regulated…
>
> **Is a repair with mesh a 'gold standard?'**
> Many patients who develop a hernia, have a 'tissue weakness' which doesn't hold stitches well. This explains why repairs with stitches have a higher failure rate than those with additional mesh. For the vast majority of patients,

> mesh poses little if any additional risk, and coupled with a lower recurrence rate, has resulted in the use of mesh becoming the gold standard in hernia repairs."

How many people in Scotland have experienced post-operative complications?

According to an answer given on 16 July 2020 by the then Cabinet Secretary for Health and Sport, Jeane Freeman:

> "routine health data records hernia operations, bladder operations, etc., using prosthetic implants, not those specifically using mesh implants. … NHS Information Services Division (ISD) confirmed that reported complications or problems following surgery cannot accurately be established..."

Mesh fixation devices (eg titanium ProTacks™)

Sometimes repairs will involve the use of metal staples. Titanium has not been regarded as a serious allergen, although clinical experience shows that it can induce allergic reactions. The petitioners say that cancer risks have been reported in connection with titanium. Titanium is a metal that has been used extensively in medicine, along with many other metals. The US Food and Drug Administration published a wide-ranging review Biological Responses to metal Implants in September 2019. Page 52 of this report reviews research and evidence on carcinogenic effects of metals, but makes no mention of titanium. However, the review says that 'the clinical response to metal implants is complicated and no simple explanation for the wide variety of reported adverse responses is available'.

This academic article compares different fixation methods used in hernia repair, including titanium ProTacks™, and tested for adhesion and mechanical strength. They are fitted with a fixation device in 'key-hole' surgery. The titanium staples are designed to stay in the body permanently as part of the repair. This research article says that they have been associated with the formation of

‘dense adhesions’ erosion and cause of the formation of so-called ‘tack hernias’. The most clinically important aspect though, it says, is acute and chronic post-operative pain.

Scottish Government Action

In answer to a Parliamentary question about research into hernia mesh, put by Neil Findlay MSP in February 2020, the then Cabinet Secretary for Health and Sport, Jeane Freeman responded:

> “In 2019, the Scottish Government asked the Scottish Health Technologies Group (SHTG) to undertake an assessment of the evidence on the use of surgical mesh for elective repair of primary inguinal hernia in male patients, comparing such repairs with those carried out without surgical mesh (for example, suture repair). In particular, the SHTG was asked to consider safety and patient aspects relating to mesh repair of inguinal hernias.
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> The SHTG published its report last week, and it can be viewed here . Health Boards are expected to give consideration to the SHTG's findings.
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> Officials will now consult the Chief Scientist's Office on whether any further research into hernia repair is required and, separately, will approach Healthcare Improvement Scotland to ask that it considers whether a guideline on clinical care, including using recently published international studies, would be helpful for NHS Scotland.”

The SHTG reported the following in its report:

- Around 5000 inguinal hernia repairs are carried out each year using mesh.
- Use of mesh meant that men were less likely to have their hernia return (compared to having surgical stitches).
- Use of mesh meant that the men were less likely to suffer urinary retention, injury to nerves, blood vessels or internal organs.
- They were more likely to develop a build up of fluid or swelling soon after surgery.

- Between 2013 and 2018 there were 70 operations in Scotland to remove surgical mesh after hernia repair. (This represents 0.3% of the 25,188 patients where mesh was used).

- There was no difference (or slightly lower risk) of developing chronic pain whether stitches or mesh was used.

- Detailed discussion with patients should precede surgery regarding risks of surgery and of not repairing the hernia.

- Systems should be in place to routinely collect data from all hernia repairs to inform practice and to generate data on new types of mesh.

The Scottish Government are in the process of procuring a specialist mesh removal service for SUI and POP procedures for those seeking treatment outwith the NHS in Scotland. They are also proposing legislation to reimburse women who have paid for private treatment to remove transvaginal mesh.

The petitioners in the case of this petition believe that any specialist mesh removal service should also offer specialist expertise for the removal of other mesh devices and fixings, not only for TVT and POP devices.

Scottish Parliament Action

Numerous parliamentary questions have been asked about hernia mesh over recent years. These have covered topics such as efficacy, complications, restriction of use, adverse events and the number of people affected by complications.

UK Parliament Action

Research briefing on surgical mesh implants, including hernia mesh. Section 8 of the briefing provides statistics for England on hernia procedures involving mesh, as well as statistics on removal operations of both prosthetic mesh and mesh or stitches made from natural materials. More recent data for NHS England procedures has been published (via FOI request for waiting times for femoral hernia surgery).

A debate was held on surgical mesh in April 2018, one on medical devices in February 2019, and one specifically on hernia mesh in men on 5 September 2019.

Key Organisations and relevant links

British Hernia Society – According to a brief patient information leaflet on their website, the Society, created by a group of surgeons with an interest hernia surgery in 2003, seeks to reassure patients on the use of mesh.

British Journal of Surgery Vol 106 Issue 7 June 2009 In support of mesh for hernia repair
https://onlinelibrary.wiley.com/doi/full/10.1002/bjs.11240

Cochrane review Comparing surgical groin hernia repair performed with or without mesh September 2018
https://www.cochrane.org/CD011517/COLOCA_comparing-surgicalgroin-hernia-repair-performed-or-without-mesh

Past Present and Future of Surgical Meshes: A Review, Baylon et al, 2017.

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