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Review

Vaginal mesh in prolapse surgery

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Key content
- Mesh used in gynaecology can be permanent or absorbable.
- According to the Amid classification, there are four types of permanent synthetic mesh. In gynaecology, type 1 monofilament polypropylene mesh is used.
- Autologous, cadaveric (allograft) or porcine/bovine (xenograft) meshes are more correctly termed 'grafts'. All are prepared so they are acellular, and free of antigens and viruses.
- Mesh usage has seen a rise and subsequent decline.
- When using mesh in practice, it is imperative to adhere to criteria recommended by the National Institute for Health and Care Excellence.

Learning objectives
- To gain an overview of the types of mesh used in gynaecological surgery and their characteristics.
- To understand the origins of the use of meshes in practice, and their advantages and disadvantages.
- To understand the criteria that must be fulfilled before using mesh to avoid litigation.

Ethical issues
- Informed consent through shared decision making is perhaps the most important ethical issue associated with the use of vaginal mesh in prolapse surgery.
- The characteristics of some patients might preclude them from accessing the best surgical approach for their problems, even if it involves the use of mesh.
- The use of mesh is associated with greater litigation than native tissue repair.

Keywords: Litigation / prolapse / synthetic mesh / vaginal mesh

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Introduction

The use of vaginal mesh in the surgical management of pelvic organ prolapse (POP) is controversial. Since 2004 we have witnessed a rise followed by a decline in the use of vaginal mesh after potential adverse events were realised. This has caused several high-profile lawsuits and intense public scrutiny. Although mesh has been used abdominally for many years (and more recently laparoscopically) for the treatment of vault prolapse, this review focuses on vaginal mesh insertion. The aim of this review is to summarise how vaginal mesh is used in POP surgery, and to outline the important issues of legislation, clinical evidence, recommendations from national bodies, and involvement of patient groups.

History of mesh

Bakelite, the first synthetic plastic, was made in 1907 by Belgian chemist Leo Baekeland.[1] Many more synthetic plastics had been invented by the 1930s, and the war effort led to enormous growth in the industry. When the war ended in 1945, plastic production for the consumer market significantly increased. In 1951, Hogan and Banks[2] polymerised propylene to polypropylene and in 1954, Nobel prize-winning Italian chemist Giulio Natta developed a large-scale production method by polymerising propylene to a crystalline isotactic polymer. Polypropylene was the first synthetic plastic that could withstand an autoclave and thus be used in the manufacture of medical devices.[3]

The concept of using nylon mesh for hernia repair was introduced by French surgeons Acquaviva and Bourret in 1948,[4] followed by the introduction of polypropylene mesh to repair inguinal hernias by the 1960s.[5] In 1987, Lichtenstein reported results[6] from over 6000 inguinal hernia repairs with recurrence of 0.7% after 2–14 years of follow-up. This study provided the clinical evidence to support the use of mesh in inguinal hernia repair. In 2002, a systematic review of 58 trials[7] involving 11 000 patients reported a 50% reduction in the risk of groin hernia recurrence with

synthetic mesh compared with traditional fascial plication (Shouldice repair).

In 1962, Lane[8] described the technique of abdominal sacrocolpopexy to manage vaginal vault prolapse using an arterial graft and in 1992, Timmons[9] described the technique using a synthetic mesh. Vaginally placed synthetic mesh was introduced around the same era.[10] The earliest description of mesh to treat stress urinary incontinence (SUI) was in 1968 by Chassor Moir.[11]

Gynaecologists began to use mesh designed for hernia repair by cutting it into shapes that could be used in the vagina. Manufacturers soon began to develop devices specifically designed for SUI and POP repair. In 1996, the US Food and Drug Administration (FDA) cleared the first surgical mesh for treatment of SUI, and in 2002, the first surgical mesh for treatment of POP was cleared.[12]

Mesh classification

The principle of using graft or mesh materials in POP surgery is to reinforce weakened and torn native tissue. Biological materials are typically referred to as 'grafts', whereas synthetic materials are referred to as 'mesh' (Table 1).[13]

Biological grafts

Autologous grafts

Autologous grafts are harvested from the patient's own tissues; most commonly the rectus sheath and fascia lata.[14,15]

Table 1. Graft and mesh materials (prostheses) used for reconstructive pelvic floor surgery[13]

Prosthesis*		Example
Graft#	Autologous	Rectus sheath, fascia lata
	Allograft	Cadaveric fascia lata
	Xenografts	Porcine dermis, Porcine small intestinal submucosa, bovine pericardium
Synthetic~	Absorbable	Polyglactin
	Non-absorbable	Polypropylene
	Other non-resorbable	Polytetrafluoroethylene, polyester, polyethylene terephthalate

*A fabricated substitute to assist a damaged body part or to augment or stabilise a hypoplastic structure

#Any tissue or organ for transplantation. This term refers to biological materials inserted

~Synthetic prostheses can be:

i). Mesh – a (prosthetic) network fabric or structure
ii). Implant – a surgically inserted or embedded (prosthetic) device
iii). Tape (sling) – a thin strip of synthetic material

The most significant risk is potential donor site morbidity (wound infection, scar, nerve damage and hernia).[16]

Allografts

Allografts are cadaveric tissues that have been sterilised and undergone a process to remove immunogenic material. Use of allografts avoids the morbidity of harvesting tissue and saves time during the operation.

Xenografts

Xenografts consist of acellular extracts of collagen, harvested from nonhuman donors; typically porcine or bovine.

Use of biological grafts is limited by the theoretical risk of infectious disease transmission and inconsistency of tissue strength. In a 2-year follow-up study of women with stage 2 or greater anterior compartment prolapse randomised to synthetic mesh, biological mesh or native tissue repair, women in the biological mesh group had a significantly higher anatomic failure rate compared with those in the synthetic mesh group (46% versus 18%, $P = 0.015$).[17] A 2016 Cochrane review found insufficient evidence to compare biological grafts with native tissue repair.[18] More recently, evidence for biological grafts came from the graft trial in the 2016 PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials) study, which included 368 women who underwent primary anterior or posterior repair augmented with porcine acellular collagen matrix, porcine small intestinal submucosa, or bovine dermal grafts. Although objective outcomes were similar at 1 year, at 2 years women in the graft group were significantly more likely to report a feeling of 'something coming down' than women who underwent standard native tissue repair.[19]

Synthetic mesh

Transvaginal mesh can be sutured across the fascial defect as an 'inlay', surround the vagina as a 'total mesh', or be inserted into pelvic spaces with introducer 'kits'.

Synthetic absorbable mesh

Synthetic absorbable mesh is typically composed of polyglactin or polyglycolic acid and undergoes replacement by collagen-rich connective tissue. Animal models of hernia repair using absorbable mesh have demonstrated poor long-term tensile strength and early recurrence.[20,21]

Synthetic partially absorbable mesh

The use of collagen-coated polypropylene mesh and native tissue repair was evaluated in a randomised controlled trial (RCT) of women with anterior compartment prolapse. At follow-up after 12 months, women in the mesh group had a significantly greater objective cure rate cystocele at 88.1% (95% confidence interval [CI] 80.7–95.6%) versus 39.8% in

the native tissue repair group (95% CI 28.6–50.9%; $P < 0.001$). There was no difference in recurrence of rectocele between the two groups and mesh exposure rate was 13.3% in the mesh group.[22] In the same study, at follow-up after 3 years, a sustained superior anatomical cure rate was reported in the mesh group but there was no impact on subjective outcomes,[23] which were similar in both groups with no difference in reoperation rates for recurrent prolapse. To date, there is insufficient evidence to support the use of partially absorbable synthetic mesh in POP repair.

Synthetic non-absorbable

Synthetic non-absorbable mesh avoids the risk of infectious disease transmission posed by biological grafts and, in theory, should provide more consistent and durable tissue strength than absorbable mesh. The most significant limitation of synthetic non-absorbable mesh is reaction by the host to the foreign body, as well as related complications such as infection and mesh contracture and/or exposure. The first classification system for synthetic non-absorbable mesh was proposed by Amid in 1997 and is based on pore size (Table 2).[24]

Pore size significantly influences mesh density and flexibility, infiltration by macrophages and bacteria, and subsequent risk of infection and mesh exposure. Type 1 mesh materials are composed of polypropylene monofilaments with a pore size greater than 75 µm (macroporous). This pore size permits infiltration by fibroblasts, blood vessels, collagen fibres and macrophages, which promotes tissue incorporation and reduces the risk of infection. Type 1 mesh is the current preferred choice for POP repair. All vaginal and abdominal meshes in use at the time of writing are type 1 meshes. Bacteria (<1 µm) can infiltrate type 2 mesh materials (pore size <10 µm); however, these meshes cannot be infiltrated by macrophages (20–80 µm), so their use increases the risk of infection. Collagen fibres are also unable to penetrate the mesh, which minimizes incorporation into the host tissue. Type 3 meshes are braided or multifilamentous with both macroporous and microporous components and thus behave similarly to type 2 meshes. Type 4 meshes are rigid and therefore unsuitable for use in the vagina.

Table 2. Amid classification[36] of synthetic non-absorbable mesh

Mesh type	Pore size	Description	Example
Type 1	>75 µm	Completely macroporous and monofilametous; all pore sizes greater than 75 µm.	Prolene® (Ethicon, Somerville, NJ)
Type 2	<10 µm	Totally microporous: pore size smaller than 10 µm in at least 1/3 dimensions.	GORE-TEX® (GORE, Flagstaff, AZ),
Type 3	>75 µm	Macroporous with either multifilametous or microporous components.	IVS Tunneler™ (Covidien, Dublin)
Type 4	<1 µm	Submicronic pores	Not used in vaginal prolapse surgery.

Host response

The implantation of any foreign body generates a host response that is characterised by seven stages: injury, protein absorption, acute inflammation, chronic inflammation, foreign body reaction, granulation tissue formation and tissue encapsulation. Mesh implanted in the vagina appears to be more susceptible to host reaction than abdominally placed mesh. Evidence from animal studies suggests host response could be reduced by using lightweight mesh with large pores and reducing the surface area of the implanted material.[25] Furthermore, coating polypropylene with collagen could control inflammatory reactions better and potentially reduce mesh exposure.[26] Mechanical properties such as mesh density, stiffness and response to physiological loading are increasingly recognised as important factors in host integration. Further discussion is beyond the scope of this review.

History of vaginal mesh

How vaginal mesh was approved for prolapse surgery

Between 1985 and 1995, several surgical meshes, including Trelex Natural Mesh (Boston Scientific, Marlborough, MA), Supple Peri-Guard® (Synovis, St Paul, MN), GORE-TEX® Soft Tissue Patch (GORE, Flagstaff, AZ), Mersilene® mesh (Ethicon, Somerville, NJ) and Marlex® mesh (C. R. Bard, Inc., Murray Hill, NJ), were cleared by the FDA for uses including hernia repair; however, none were cleared for use as vaginal meshes. In 1996, Boston Scientific's ProteGen® mesh, the first vaginal mesh for the surgical treatment of SUI, was approved under the FDA 510(k) pre-market notification process. The 510(k) ruling allows manufacturers to bring a new product to market without rigorous testing if it is deemed to be 'substantially equivalent' and 'at least as safe and effective' to a legally marketed device. ProtoGen 510K (K963226) was predicated on mesh devices previously approved for hernia repair (GORE-TEX®, Marlex® and Mersilene®) and no further testing was deemed necessary, despite a lack of clinical safety trials for transvaginal placement. The chain of events demonstrating how the 510 (k) pathway led to approval of mesh use in surgery for POP is shown in Figure 1.[27,28]

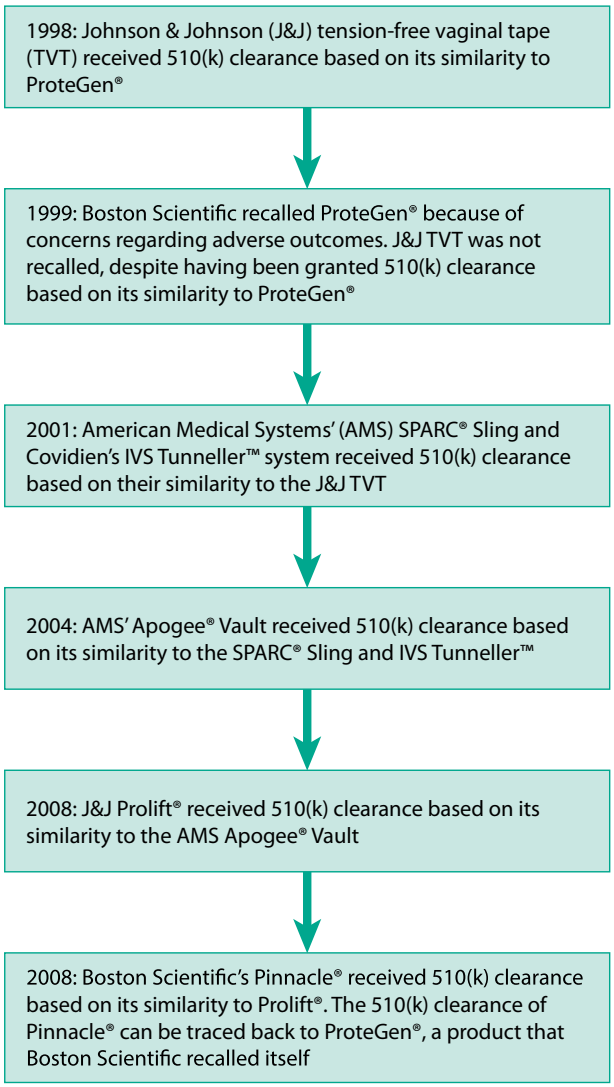

Figure 1. Cascade of events leading to the approval of transvaginal mesh in practice.

The rise and fall of vaginal mesh for prolapse surgery

The rise in vaginal mesh use was driven by a hypothetical belief that it reduced the risk of recurrent prolapse, estimated to affect 30–50% of women undergoing native tissue POP repair.[29–31] In 2010, approximately 300 000 prolapse operations were performed in the USA, of which one-third used mesh.[32] The true incidence of repeat prolapse surgery varies between studies and populations. Studies now suggest that the risk of recurrent prolapse after native tissue repair may have been overestimated.[33–36] In a record linkage study of 47 000 women, Abdel Fattah et al. showed that the lifetime risk of women undergoing repeat prolapse surgery in the UK was 15.8% and the median time interval (IQR) between primary and repeat surgery for prolapse was 3 (1.00–8.25) years.

In October 2008, the FDA issued a Public Health Notification (PHN) alerting clinicians to over 1000 cases of 'rare' adverse events associated with transvaginal placement of surgical mesh to treat POP and SUI. The PHN made recommendations on training and informed consent.[37] Between 2008 and 2010, the FDA identified 2874 further reports of mesh complications (1503 associated with POP and 1371 associated with SUI), which had been reported to the Manufacturer and User Device Experience (MAUDE) database. The most common complications associated with mesh devices for prolapse repair were mesh exposure, pain, infection, bleeding, dyspareunia, organ perforation and urinary problems.

In 2011, the FDA conducted a systematic review of the literature (1996–2011), which showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair. Furthermore, it showed that mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair. The FDA concluded that adverse events are 'not rare' and issued a second safety communication. It announced that it was considering a reclassification of mesh for transvaginal POP repair from class II to a class III medical device, which would require manufacturers to submit pre-market approval applications including clinical data. In response, the four largest mesh manufacturers (Ethicon, Bard, Boston Scientific and American Medical Systems) formed the Transvaginal Mesh Working Group and proposed collaboration between industry and societies to develop training programmes and improved regulation, with the caveat that mesh devices used in POP surgery remain in class II. At this time, the International Urogynecological Association (IUGA) and International Continence Society also issued a joint terminology document on the classification of complications related to prosthesis and graft use in female pelvic floor surgery.[13]

In 2012, under Section 522 of the Federal Food, Drug, and Cosmetic Act, the FDA ordered 34 manufacturers of surgical mesh for POP to conduct post-market surveillance studies, which became known as '522 studies', to address safety and effectiveness concerns. Bard and Ethicon subsequently withdrew their products from the US market and, since then, the use of vaginal mesh in prolapse surgery has significantly declined.[38] In January 2016, the FDA reclassified surgical mesh for transvaginal repair of POP from class II to class III and ordered manufacturers to submit pre-market approval applications to support the safety and effectiveness of surgical mesh for this use.[39]

Current use of transvaginal mesh in surgery for pelvic organ prolapse

In 2015, a survey of IUGA members revealed that following the FDA's safety announcement, 45% of respondents

reported a decreased use of mesh, and 7% of respondents use transvaginal mesh for primary repair and 58% for recurrence.[40] Current UK usage is difficult to gauge because of problems with the specifics of coding; however, hospital episode statistics (HES) data for England and the National UK Prolapse Survey: 10 years on[41] suggests a significant decline in usage. A cohort study published in 2017, which describes mesh procedures carried out for SUI and POP in Scotland between 1997 and 2016, also reports a decline in the use of mesh in the preceding 2–3 years.[42] At the time of writing this review, the only vaginal prolapse mesh product currently available is Boston Scientific's Uphold™ LITE vaginal support system.

Current evidence for the use of vaginal mesh

In 2012, the Medicines and Healthcare Products Regulatory Agency (MHRA) funded the report *Summaries of the safety/adverse effects of vaginal tapes/slings/meshes for stress urinary incontinence and prolapse*, otherwise known as the *York Report*.[43] Led by the York University Health Economics Consortium, this was an independent review of up-to-date published evidence (at that time) to inform our understanding of vaginal mesh implant-related issues, including safety. Two systematic reviews were evaluated for women undergoing anterior or posterior mesh repair. At follow-up after 6 months, 5.5% of patients reported pain and 15.3% (range: 12.8–17.7%) reported deterioration in sexual function. Organ damage occurred in 2.1% (0.9–2.8%) and the average rate of mesh exposure was 6.5% (0.9–19.6%), with the highest rate of mesh exposure reported by the study with the longest follow-up (3.2 years). Two systematic reviews evaluated the safety and efficacy of mesh in vault/uterine prolapse surgery. Postoperative pain at 6 months affected approximately 2% of women undergoing synthetic mesh repair and de novo dyspareunia rate was 14.5% (although this was based on small patient numbers from a single centre). Mean mesh exposure rate was 5.5% with a wide variance (0.0–25.6%), suggesting that patient and/or surgical factors might play a role in mesh exposure risk.

In 2016, Maher et al.[18] published a meta-analysis of 37 RCTs comparing women who underwent transvaginal graft repair (n = 1986) and traditional native tissue repair (n = 2037). Compared with women who underwent native tissue repair, women who received synthetic non-absorbable mesh repair were less likely to be aware of prolapse after 1–3 years (relative risk [RR] 0.66, 95% CI 0.54–0.81), less likely to have recurrent prolapse on examination (RR 0.40, 95% CI 0.30–0.53) and less likely to require repeat prolapse surgery (RR 0.53, 95% CI 0.31–0.88). However, more women in the mesh group required repeat surgery for the combined outcome of prolapse, stress incontinence, or mesh exposure (RR 2.40, 95% CI 1.51–3.81). Permanent mesh was associated with higher rates of de novo stress incontinence (RR 1.39, 95% CI 1.06–1.82) and bladder injury (RR 3.92, 95% CI 1.62–9.50) and there was no difference between the groups in rates of de novo dyspareunia (RR 0.92, 95% CI 0.58–1.47). While there is evidence of efficacy associated with mesh-based surgery, this is offset by increased morbidity. Furthermore, there was insufficient evidence to comment on the effects on quality of life between the two groups. This review therefore concluded that there was no evidence to support the use of synthetic non-absorbable mesh in primary prolapse surgery. There was also insufficient evidence to draw any comparison between absorbable mesh or biological grafts with native tissue repair.

A further meta-analysis of 30 RCTs[44] compared different surgical techniques to manage apical prolapse, including six RCTs comparing vaginal surgery with mesh versus vaginal surgery without mesh (n = 598, 1–3 year follow-up). There was no difference between the groups in awareness of prolapse, recurrence of prolapse or repeat surgery for prolapse or stress urinary incontinence. The mesh exposure rate was 18%. Evidence from this meta-analysis does not support the use of transvaginal mesh in the management of apical prolapse.

In December 2016, a Scottish population-based cohort study (1997–2016)[42] reported 5-year outcomes on 18 986 women who underwent primary anterior or posterior repair, of which 7% used mesh. This study found that the use of mesh in anterior and posterior compartment surgery was associated with an increased risk of complications and lower effectiveness than native tissue repair. The study concluded that mesh procedures for anterior and posterior compartment prolapse could not be recommended for primary prolapse repair.

The PROSPECT study was published in January 2017.[45] This was a UK-based multicentre study that randomised 1352 women undergoing primary anterior or posterior repair to standard native tissue repair or repair augmented with synthetic mesh or biological graft. The primary outcome measures were Pelvic Organ Prolapse Symptom Score (POP-SS) and a generic quality of life score (EQ-5D-3L). After 1 year, the scores for prolapse symptoms, quality of life and dyspareunia (around 5%) were similar between the groups. Objective assessment after 1 year using the Pelvic Organ Prolapse Quantification system (POP-Q) showed no difference in objective failure between the groups. After 2 years, 6% of women had undergone further prolapse surgery and the synthetic mesh complication rate was 12%. Apart from mesh complications, a similar number of women required further treatment. The study concluded that in the first 2 years after surgery, women do not benefit from having their first prolapse repair reinforced with synthetic mesh or a biological graft, either in terms of prolapse symptoms or

anatomical cure. PROSPECT represents the most robust and up-to-date evidence for the use of mesh and grafts in vaginal POP surgery.

Recommendations on the use of vaginal mesh

Letters from Government

In a letter written in November 2012, Sir Bruce Keogh (NHS Medical Director for England) and Professor Keith Willet (NHS Commissioning Board) brought the York Report to the attention of all NHS medical directors and informed them of plans by the NHS, MHRA and professional associations (the British Society of Urogynaecology [BSUG] and the British Association of Urological Surgeons [BAUS]) to reduce rates of adverse events with the use of mesh.[46] Another letter followed in December 2013, this time to all practitioners involved in the management of incontinence and POP with regard to the use of surgical of mesh.[47] The letter outlined recommendations on the importance of multidisciplinary team decision making, trust governance procedures, the appropriate consent process, regular audit and use of national databases (BSUG and BAUS), adverse event reporting and surgery for mesh removal.

Medicines and Healthcare Products Regulatory Agency

In 2014, the MHRA published *A summary of the evidence on the benefits and risks of vaginal mesh implants*[47] at the request of the Chief Medical Officer for England. Vaginal mesh implants were reportedly associated with a 6.5% risk of adverse events and a 15.3% risk of deterioration of sexual function. The MHRA stated that, for most women, the use of vaginal mesh implants is safe and effective; indeed, current evidence shows that when mesh is used correctly it can help to alleviate symptomatic prolapse. However, the MHRA acknowledged that many uncertainties remain and its position might be affected by the results of the Scientific Committee on Emerging and Newly Identified Health Risk (SCENHIR) report[48] (discussed below) and the PROSPECT study.[19]

NHS England established the Mesh Working Group to address patient and clinician concerns. This led to the publication of the Mesh Oversight Working Group report,[49] which has been endorsed by the MHRA, BSUG, BAUS, the Royal College of Obstetricians and Gynaecologists (RCOG) and the National Institute for Health and Care Excellence (NICE).

Scientific Committee on Emerging and Newly Identified Health Risks

In 2015, SCENHIR (the European Union's equivalent of the FDA) published an opinion paper on 'the safety of surgical meshes used in urogynaecology'.[48] Several recommendations were made based on a thorough review of the published literature. The committee acknowledged that vaginally implanted mesh for POP is associated with increased risks compared with abdominally placed mesh for POP and mesh implantation for SUI. Transvaginal mesh for POP repair should only be used when other procedures have failed or are expected to fail. Patients should be appropriately selected and comprehensively counselled regarding the performance and risks of using mesh, based on clinical evidence. Type 1 polypropylene mesh is the most appropriate synthetic mesh for vaginal implantation. Factors influencing outcome include overall mesh surface area, material properties of the mesh (e.g. tissue integration, flexibility), mesh pore size, patient factors (e.g. age, obesity, smoking), associated procedures (e.g. hysterectomy) and surgeon's experience.

The SCENHIR report recommended further improvements in the composition and design of synthetic meshes in POP surgery, the development of a certification system for surgeons in cooperation with relevant European surgical associations, the establishment of European guidelines and implant registries, and scientific studies to assess long-term (5+ years) safety and performance of synthetic non-absorbable mesh.

Scottish Government report

The Scottish Independent Review was published in March 2017 and made several recommendations on the use of surgical mesh in urogynaecology.[50] With reference to surgery for POP, the report recommends that robust clinical governance must surround treatment, the decision to use mesh and the surgical approach used. To support decision making, management of individual patients should take place in the context of multidisciplinary team assessment, audit and review. Informed consent is a fundamental principle underlying health care and all information provided to patients should be improved. In line with the Montgomery ruling and guidance from the General Medical Council (GMC), patients should be made aware of all their treatment options, including conservative and expectant management. The lack of long-term follow-up data, including information on quality of life and activities of daily living, should be addressed. The GMC recommends that adverse events are reported to the MHRA, which is the responsibility of the surgeon,[49] and use of the BSUG database in this context is advisable. Finally, the independent review reported that some women with adverse events were not believed, adding to their distress and delaying diagnosis. Awareness of the possible symptoms of mesh-related complications must be improved in both primary and secondary care.

Views from patients

The interim report from the NHS England Mesh Working Group[51] included the views of a group of patients who were adversely affected by the use of mesh. The patients

interviewed firmly believed that the use of mesh devices should be suspended until clinical evidence is available for their safety and efficacy. Furthermore, patient groups have strongly criticised the consent process. They state that they were not given choice or the time to consider their treatment options, and were not given full information on the possible severity of complications. These patients want a thorough scientific study to establish exactly what happens when mesh is implanted. This, they say, should include a comprehensive analysis of the composition of the polypropylene mesh, whether chemicals can leach from it into the body once implanted, and what happens to implanted mesh over time. A recent review has addressed this topic and suggests that the main issue is host response rather than the inherent toxicity of materials.[25]

Future research

There is an urgent need for research into prosthetic devices that do not cause the same adverse effects seen with the use of current meshes, and which reduce the host–tissue response. There has been increased interest in the use of tissue engineering to find the ideal remodelling material and continuing research into bioactive materials containing compounds to enhance the integration of new tissue.

Ethical issues

The mesh debate encompasses all ethical principles, the most important of which is the issue of informed consent. Respect for patient autonomy and truthfulness through appropriate counselling of expected benefits and risks, based on clinical evidence, ensures that informed consent is obtained through a shared decision-making process.

The principles of beneficence and non-maleficence are relevant in keeping the patient at the centre of care and providing the best possible treatment without exposing the patient to harm.

It is likely that some patients may derive more benefit from mesh repair than native tissue repair; for example, patients with congenital connective tissue disorders such as Ehlers–Danlos syndrome, or women with recurrent prolapse. The decision to ban the future use of vaginal mesh may ultimately deny some patients the best treatment, thereby raising issues of justice and fairness.

As in all areas of treatment, each individual must consider the risk–benefit profile of a proposed procedure. Conservative measures such as a pessary may be sufficient for some women, while others might consider surgical treatment that may or may not include vaginal mesh. Though the adoption of vaginal mesh was initially enthusiastic, there is now a lack of confidence in the product from both clinicians and patients. However, over time its correct place among all the treatment options available will ensure its correct usage to maximise benefit and minimise potential harm.

Disclosure of interests

There are no conflicts of interest.

Contributions to authorship

SJ conceived and developed the project. PC and SJ conducted the literature review. All authors helped to write the manuscript, and approved the final version.

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