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Vaginal mesh and the implications of the current reluctance to use it in surgery

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Abstract
Pelvic organ prolapse and stress urinary incontinence are common conditions, and one in 10 women will undergo surgery for one of these complaints during their lives. The use of vaginal mesh was intended to reduce the recurrence rates of these conditions, and shorten the period of recovery from the associated symptoms, but this approach has failed to live up to expectations, especially with regard to prolapse surgery. Regulatory bodies appear to have been sluggish in responding to concerns about mesh-related complications. This has resulted in a sharp decline in its use as a result of a combination of manufacturers withdrawing their products, a rise in litigations and complaints, and intervention by central governments. This paper aims to provide an overview of mesh, the rationale for its use and how it was introduced, the complications that ensued, why there has been a change in its use in clinical practice, and what implications this could have for patients and clinicians.

Keywords: complications, pelvic organ prolapse, stress urinary incontinence, vaginal mesh.

Introduction

Pelvic floor dysfunction is a common condition that has a multifactorial aetiology (Dietz 2008). It is likely that combinations of anatomical, physiological, genetic, lifestyle and reproductive factors interact throughout a woman's lifespan to contribute to pelvic floor dysfunction (Delancey *et al.* 2008).

On objective clinical examination, the incidence of pelvic organ prolapse (POP) in the general population is approximately 40% of women aged between 45 and 85 years. However, only 12% of these individuals are symptomatic (Slieker-ten Hove *et al.* 2009). Stress urinary incontinence (SUI) is also a common problem in women, with an estimated incidence of 29% in the community (Norton & Brubaker 2006).

Those who are symptomatic suffer increased physical and emotional distress (Subak *et al.* 2001). There is a significant impact on their quality of life and day-to-day productivity, and costs to both the individual and the healthcare system as a whole (Wu *et al.* 2009).

Symptomatic POP and SUI can be managed conservatively with either pelvic floor muscle exercises, or vaginal inserts to support the prolapsing tissue (i.e. pessaries). It has been reported that the lifetime risk in the general female population, up to the age of 80 years, of needing surgery for POP/SUI is 20% (Wu *et al.* 2014). Surgery for POP is known to have a high reoperation rate (Olsen *et al.* 1997; Clark *et al.* 2003), which is why mesh was initially introduced in order to increase the longevity of surgical interventions for this condition. With respect to SUI, the established procedures were thought to be invasive, which is why the use of mesh was introduced because this had a shorter recovery time, but similar outcome rates.

Therefore, with this in mind, the present paper will primarily focus on vaginal mesh for urological and urogynaecological indications, to the exclusion of abdominal mesh for prolapse and mesh used in hernia surgery.

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A brief history of mesh

A review by Baylón *et al.* (2017) summarized the history of surgical meshes.

In 1890, Theodor Billroth suggested that prosthetic substance could be used to close hernia defects (Billroth 1924). Numerous materials were tested, but all failed as a result of infections, rejections and recurrences (Chowbey 2012). It was believed that the main problem was the multifilament material used for suturing, which has been proven to be unsuitable in many other surgical procedures (Greenberg & Clark 2009).

In 1955, Dr Francis Usher studied the suitability of other materials (e.g. nylon, Orlon, Dacron and Teflon), but these all had problems, such as: foreign body reaction, sepsis, rigidity, fragmentation, loss of tensile strength and encapsulation (Usher *et al.* 1959a). Usher subsequently developed a woven mesh (Usher *et al.* 1959b), and then the Marlex prostheses were implemented. Marlex had large pores that facilitated incorporation regardless of infections. The growth of tissue through its interstices was the main difference when compared to previous materials. After a few days of surgical incorporation, fibroblast activity noticeably increased, more collagen was induced without giant cells and the whole system became stronger (Klinge *et al.* 2002).

Usher continued the search for better systems, and found that knitted polypropylene had many more advantages: it could be autoclaved, had firm borders coupled with two-way stretching, and could be rapidly incorporated. In 1959, Usher published his surgical technique employing a polypropylene mesh (Usher *et al.* 1959a, b), and 30 years later, the Lichtenstein repair (known today as "tension-free" mesh technique) was popularized for hernia repair (Klinge *et al.* 2002).

The rationale for introducing mesh into urogynaecological and urological practice

The use of mesh for hernia surgery gradually evolved over the 2 decades following the late 1950s. In the 1970s, transabdominal mesh began to be used for POP repair in the urogynaecological treatment of vault prolapse. In the 1990s, mesh was introduced for transvaginal repair.

The initial rationale for the use of mesh for transvaginal pelvic floor dysfunction repair was the high risk of a recurrence of prolapse after native tissue repair. It was a less-invasive procedure than transabdominal repair, and repairs augmented with abdominal hernia mesh were known to be superior to native tissue repairs (Glazener *et al.* 2017).

Retropubic procedures, specifically the Burch colposuspension (which had been available for several decades with high subjective cure rates of 80–90%), were thought to be too invasive and associated with well-documented complication rates (Stanton 1990; Leach *et al.* 1997; Corcos *et al.* 2006). Hence, when tension-free vaginal tape (TVT) was introduced by Ulmsten *et al.* (1996), it was hailed as being less invasive and associated with shorter recovery times. A subsequent randomized controlled trial (RCT) comparing the use of TVT with colposuspension (Ward & Hilton 2004) showed that both procedures were equally effective. This resulted in the widespread adoption of synthetic midurethral slings. Subsequent reviews have suggested that synthetic slings maintain or improve efficacy, and decrease recovery time relative to traditional abdominal approaches or autologous fascial slings (Jakus *et al.* 2008).

How was mesh introduced into clinical practice

In order to be marketed in the USA and EU, mesh products had to be passed by the relevant regulatory bodies, i.e. the Food and Drug Administration (FDA) and the European Medicines Agency, respectively.

The FDA has three categories of medical devices that range from Class I (lowest risk) to Class III (highest risk). Class III devices require a scientific review demonstrating the efficacy and safety of each product prior to approval for use. This review is also known as a premarket approval (PMA), the FDA's most stringent device approval pathway (Moskowitz 2019).

The US (FDA) 501(k) Premarket Notification approval system for Class II medical devices (FDA 2002) requires manufacturers to demonstrate only that a new device is similar enough to an existing or predicate device to anticipate similar results. Hence, transvaginal mesh was initially approved as a Class II device because it was thought to carry the same level of risk as mesh used for hernia repair in 2002 (Moskowitz 2019).

In the EU, the introduction of mesh required that all vaginal mesh implants marketed in the European Economic Area had a CE mark, which indicates that the manufacturer is declaring that the product conforms to the essential requirements set out in the relevant Medical Devices Directive. This is reliant on the manufacturer having made a "declaration of conformity" that their product meets the relevant essential requirements

that apply. This would include demonstrating that the following factors have been satisfactorily assessed:

(1) the benefits outweigh any risks;
(2) clinical evaluation;
(3) biological/toxicological safety data; and
(4) sterilization validation data.

Vaginal mesh implants are generally classified as medium risk (Class IIb), but some biological meshes are classified as high risk (Class III) because these have an absorbable component. The level of assessment that such products undergo before being awarded a CE mark will be in line with how these are classified, and new clinical investigations may have to be undertaken. However, as part of their postmarket surveillance activities, manufacturers are expected to gather clinical data on devices that are already in use. This is not only to ensure the safety of those devices, but also to inform the development and clinical evaluation of future products.

Notified bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, would then assess the clinical evaluation made by manufacturers as part of the conformity assessment to ensure that appropriate clinical investigations have taken place (MHRA 2014). For higher-risk devices, notified bodies would assess the documentation for the product. All of the vaginal mesh implants are CE marked, and the majority are Class IIb medical devices. This means that a notified body will have taken samples from across the range of a manufacturer's products and processes to ensure that the essential requirements of the Medical Devices Directive are being met. The manufacturer's technical files will also be sampled, a process that will include a review of the risk management file.

The above-mentioned methods of surveillance and medical device conformity allowed over 100 mesh products to be introduced between 2001 and 2010. Coupled with a rapid uptake of trocar-based vaginal mesh POP "kits", unprecedented direct-to-surgeon marketing, and a lack of training and credentialing oversight for these products, this led to these procedures being quickly adopted (Moskowitz 2019).

What were the complications being reported?

Although these procedures were initially thought to be as efficacious as previous surgeries, but less invasive and associated with a shorter recovery time, concerns were gradually raised within the medical community about the safety and morbidity of mesh and graft use in prolapse and incontinence surgery. The symptoms reported included pain, dyspareunia, and mesh-specific complications such as exposure within the vagina, extrusion and perforation (Haylen *et al.* 2011).

In 2012, the MHRA commissioned the University of York, York, UK, to review the published literature on the most frequently reported adverse events in light of the concerns expressed by patient groups about TVT and mesh procedures (Mahon *et al.* 2012). Although this report concluded that the rates of adverse events were generally low, the authors acknowledged that their findings were not straightforward. Mahon *et al.* (2012) noted that increased rates of adverse events were associated with surgical techniques involving TVT for SUI, which were generally in the 1–3% range, although a 9% rate of deterioration of sexual function was recorded for one technique. In comparison, the equivalent rates were 2–6% for surgical techniques involving vaginal meshes for POP, and 14–15% for deterioration of sexual function.

The complications reported in the MHRA summary of the evidence for the benefits and risks of vaginal mesh implants (MHRA 2014), and the frequency of these events are outlined in Table 1.

Table 1. Percentage ranges of the rates of occurrence of complications derived from systematic reviews

	Rates of occurrence (%)	
Complication	Vaginal mesh implants for stress urinary incontinence	Vaginal mesh implants for pelvic organ prolapse
Pain/discomfort after an operation	0.0–22.0	1.0–25.0
Sexual difficulties	3.0–10.0	6.0–57.0
Vaginal erosion	0.0–5.0	–
Mesh/tape erosion	0.6–7.0	0.0–10.0
Bladder perforation	0.0–9.0	–
Urinary tract infection	0.2–76.0	–
Haematoma	0.0–4.0	1.0–3.0
Prolapse	0.0–16.0	–
Recurrent prolapse	–	0.0–15.3

The timeline of mesh issues being raised and action being taken by regulatory authorities

A 2007 Cochrane Review analysed 22 RCTs of transvaginal mesh for POP repair (Maher *et al.* 2007). Standard repair was associated with more prolapse recurrences than mesh-based surgery. The data on morbidity and complications related to transvaginal mesh for POP were too limited for comparisons to native tissue repair, and therefore, no conclusions were drawn with regard to safety by Maher *et al.* (2007).

However, an FDA notification in 2008 stated that the complications caused by transvaginal mesh were greater than would have been expected on the basis of previous data (FDA 2008). In addition, it recommended mitigating the risks of surgery, and carefully counselling patients regarding the outcomes and complications of mesh surgery (FDA 2002).

In 2011, the FDA released a white paper and safety communication on transvaginal mesh for POP (FDA 2011). On the basis of the data available at that time, it was determined that there was not enough evidence to establish a strong risk–benefit profile. The products were subsequently allocated to a higher risk category (from Class II to Class III) that requires PMA. A device panel was then convened to evaluate the safety and efficacy of transvaginal mesh.

The 2011 FDA (2011) notification recommendations were:

(1) Most cases of POP can be treated successfully without mesh.
(2) Mesh-based repairs should be used only after weighing the associated risks and benefits.
(3) Mesh surgery is more complex than other options, and multiple operations may be required in order to address its possible complications.
(4) Patients should be notified that mesh will be used to repair their POP.

In 2012, a new FDA notification (Moskowitz 2019) ordered manufacturers of vaginal mesh for POP to conduct postmarket surveillance. In response, 66% removed their products from the market.

In 2016, an updated Cochrane Review included 37 RCTs evaluating the use of mesh for transvaginal POP repair (Maher *et al.* 2016). Levels of awareness of prolapse and rates of repeat prolapse repair were both better in patients in the mesh groups. However, significantly more of these patients required repeat surgery for the combined outcomes of prolapse recurrence, SUI and mesh exposure. The conclusion of this review was that mesh was of limited utility in primary repairs (Maher *et al.* 2016).

The PROSPECT study compared the outcomes of prolapse repairs involving either non-absorbable synthetic mesh inlays (the mesh trial) or biological grafts (the graft trial) against standard repairs (native tissue without mesh or graft) in women who had undergone either a primary anterior or posterior transvaginal repair (Glazener *et al.* 2017). The primary focus was on patient-reported outcomes (i.e. the women's symptoms of prolapse) and their experience of adverse effects, which is in keeping with international recommendations (Barber *et al.* 2009; Toozs-Hobson *et al.* 2012). This study showed that vaginal repair with mesh did not improve outcomes in the short term, and more than one in 10 of the participants had experienced mesh-related complications. Glazener *et al.* (2017) also highlighted that long-term follow-up was vital to identify any longer-term potential benefits and serious adverse effects.

The following national and international reports on the use of mesh were published between 2012 and 2018:

(1) the NHS England (2017) Mesh Oversight Group review (2014–2017);
(2) the MHRA (2014) review;
(3) the European Commission review (SCENIHR 2015);
(4) the Scottish Government (2017) review (2013–2017); and
(5) the Welsh Government (2018) review (2017–2018).

The main points of most of these reports were as follows:

(1) The evidence suggests that there is a higher level of morbidity after surgery for POP because this involves a much larger amount of mesh than that for SUI.
(2) Mesh must not be offered routinely for POP.
(3) Reporting of all procedures and adverse events should be mandatory.
(4) Extra steps need to be taken to ensure that patients can make informed choices.
(5) In the case of surgical treatment for SUI, all appropriate treatments should be available, subject to informed choice and assessment.
(6) Improved training is needed for clinical teams involved in transvaginal mesh surgery.
(7) Further research into the safety and effectiveness of the products is required.

A change of practice

In the UK, NHS Digital published experimental statistics on procedures that used surgical mesh or tape to treat SUI and urogynaecological prolapse from 2008–2009 to 2016–2017 (Barber 2018). The data confirm a gradual decline in the incidence of mesh implantations over the past decade, which fell by almost 30% for vaginal mesh and 50% for tapes in SUI surgery:

(1) A total of 100 516 patients had a tape insertion procedure for SUI during this period. The number of procedures declined year on year from 13 990 in 2008–2009 down to 7245 in 2016–2017.
(2) A total of 27 016 patients had a mesh insertion procedure for urogynaecological prolapse between 2008–2009 and 2016–2017. The number of procedures increased from 3073 in 2008–2009 to 3413 in 2011–2012, but subsequently, fell year on year to 2680 in 2016–2017.

A review by Cohn *et al.* (2016) found that 41% of all women in the USA undergoing surgical repair of POP in 2009 had mesh or a graft implanted at the time of surgery (Khan *et al.* 2015), and the use of synthetic material increased significantly throughout that year (Reynolds *et al.* 2013). Furthermore, institutional data provided by one of the largest healthcare systems in the USA demonstrated that there had been a decrease in mesh usage in transvaginal prolapse repairs. This dropped from 27% in early 2008 to 15% at the time of the first FDA notification (FDA 2008), 5% at the time of the 2011 FDA notification (FDA 2011) and then just 2% at the end of that year (Skoczylas *et al.* 2014).

Cohn *et al.* (2016) also noted that a survey of American Urogynecologic Society members found that 40% of respondents decreased their use of vaginal mesh for POP after the 2011 FDA update, and 12% stopped using it entirely (Clemons *et al.* 2013). A multi-institutional study of specialty-trained urologists at eight major academic centres employing data extending to the end of 2013 also reported a marked decrease in transvaginal mesh usage (Cohn *et al.* 2016; Younger *et al.* 2016).

Reasons for the reluctance to implant mesh

The statistics described above clearly show that there has been a decline in the use of mesh for urogynaecological procedures. The reasons for the reluctance to implant mesh are as follows:

(1) There are concerns about the potential for litigation, and complaints against surgeons and medical institutions. In the USA, the legal community also responded to the FDA notifications (FDA 2008, 2011), and after 2011, legal filings against mesh manufacturers increased from 100 per year to 32 296 per year. By 2015, a total of 74 512 product liability lawsuits had been filed, 14% of which were for mesh used in POP repair alone, 63% for SUI, and 23% for the combined use of mesh for SUI and POP (Moskowitz 2019).
(2) Mesh manufacturers have suffered major financial repercussions as a result of litigation associated with both slings and prolapse repair (Cohn *et al.* 2016), and the inability of some companies to provide postmarket surveillance data. In 2012, a new FDA notification ordered manufacturers of transvaginal mesh for POP to conduct postmarket surveillance. In response, 66% of companies removed their products from the market (Moskowitz 2019).
(3) Influenced by the media and other sources, patients are increasingly reluctant to undergo mesh-related operations (P. Bhal, personal communication).
(4) Externally imposed restrictions by governing bodies, especially in the UK and, more recently, in the USA, are also a factor.

On 10 July 2018, the Secretary of State for Health and Social Care and the Chief Medical Officer announced a "pause" in the use of synthetic mesh/tape for SUI and vaginal mesh for POP. The recommendations of the Mesh Pause Clinical Advisory Group to Medical Directors and Surgical Teams were as follows (NHS Improvement & NHS England 2018):

"A. Recommend the mesh and tape procedures to be included in the restriction of use.
"B. Recommend and justify any mesh/tape procedures that should be excluded from the restriction, with or without increased vigilance.
"C. Recommend any alternative non-mesh procedures that should be subject to increased vigilance, given the change in practice caused by the restriction on mesh/tape use."

The following measures were also put in place (NHS Improvement & NHS England 2018):

"D. Advise on high vigilance processes which must be followed by NHS [National Health Service] and private hospitals for any mesh/tape surgery defined in (A) but deemed clinically essential during the restriction, and for the procedures defined in (B) and (C). This requires provider trust/hospital Medical Directors to be accountable for ensuring that procedures are in place to:

   i. Ensure the necessity and appropriateness of any procedure covered by the restriction of use and high vigilance period.
   ii. Ensure that all appropriate surgical options have been offered, including where secondary referral would be required.
   iii. Ensure that appropriate information and consenting processes are in place in all cases.
   iv. Provide assurance of a surgeon's competence for any procedure offered.
   v. Ensure there is documenting and registering of included procedures.

"E. Recommend how Trusts and GPs should support patients with advice, including patients newly referred or diagnosed, patients on the waiting list, and patients who have had previous mesh surgery who may have concerns."

Finally, it was recommended that biological mesh should not be used because there was insufficient evidence to support its routine use.

Dr Alvaro Lucioni's presentation in February of this year (Moskowitz 2019) confirmed that an advisory committee was convened by the FDA to obtain input from patients and experts on how best to evaluate transvaginal mesh used to treat POP. It was concluded that, in order to support a favourable risk–benefit profile for transvaginal mesh, there had to be evidence that:

(1) transvaginal repair with mesh is superior to native tissue repair at 36 months; and
(2) safety outcomes were similar.

Then, on 16 April 2019, the FDA (FDA 2019; Moskowitz 2019) ordered that the remaining manufacturers of transvaginal mesh for apical/anterior compartment prolapse stop selling and distributing these products. This decision was made prior to the completion of 36-month follow-up data. There were concerns about what this would mean for slings and sacrocolpopexy mesh. It should be noted that the FDA made a distinction between transvaginal mesh for POP repair, and that used for slings and sacrocolpopexy. The FDA is now requiring the completion of studies of 36-month follow-up data, and the panel will reconsider this decision once this information becomes available.

In the UK, Baroness Julia Cumberledge has led the Independent Medicines and Medical Devices Safety Review on the use of mesh since July 2018. It is anticipated that the review will publish its findings and various recommendations later this year. Although the National Institute for Health and Care Excellence (NICE 2019) clinical guidelines for urinary incontinence and POP continued to include the surgical use of mesh as one option for women with particular conditions, the mesh pause is set to continue until the Cumberledge report is published, and probably for the foreseeable future. The NICE (2019) guidelines state that surgery should only be offered to women for whom non-surgical approaches have failed or been rejected. These also stress that women must be counselled about the possible complications, and that both short- and long-term outcomes must be recorded in a national registry. However, the new guidelines on the use of vaginal mesh have been met with anger by campaigners, who say that these do not sufficiently reflect the experiences of women who have been left with serious complications after such procedures.

What's next?

Cohn *et al.* (2016) reported that, although improved informed consent processes have been a welcome and necessary change, the use of transvaginal mesh has decreased significantly. Hence, these authors predicted that its use for prolapse and/or SUI is likely to continue to dwindle since its availability from manufacturers will also be affected by financial risks outpacing potential gains. The pause in mesh surgery in the UK since 2018 and the latest FDA guidance have confirmed this.

Given the limited number of healthcare providers who are capable of achieving satisfactory results with mesh, women with POP may benefit from this change. However, those tasked with treating the most challenging cases may struggle to find other options, leaving some patients with little hope after failed repairs. In addition, owing to similarities with regard to materials, manufacturers, surgeons and the transvaginal

surgical approach, the availability of synthetic midurethral slings may be endangered (Cohn *et al.* 2016).

Furthermore, the number of surgeons who are willing to use synthetic slings in procedures may decrease because even those with low complication rates may be intimidated by the potential for litigation if the outcome is not optimal (Cohn *et al.* 2016). This is also likely to have an impact on training for future surgeons, and what procedures established clinicians will be offer to their patients for these conditions. This is because the use of mesh has been so prevalent in some clinical quarters that surgeons have become completely deskilled in native tissue repairs for incontinence surgery. In the UK, the British Society of Urogynaecology and the British Association of Urological Surgeons offer new training programmes for both established and newly qualified surgeons in which mentors share their knowledge of native tissue procedures.

It is now widely accepted that conservative treatment options for these urogynaecological conditions need to be fully explored before considering surgical solutions. This is especially pertinent because quality of life issues are associated with these conditions. There is a risk of failure associated with surgical treatment, and patients can develop new and unwanted symptoms and complications.

A multidisciplinary approach to managing these conditions is another step in the right direction. It is hoped that mandatory reporting of all procedures to national databases and complications to the relevant notification bodies will reduce similar issues recurring in the future.

New research into the use of stem cell therapy shows some promise; however, full application of this approach in the clinical stream is still a long way off. There are also cost implications, as well as a need to assess the efficacy and practicality of using human progenitor cells in the treatment of pelvic floor disorders (Cohn *et al.* 2016). Finally, we have to accept that it is inevitable that the adoption of any new materials and the surgeons implanting them will both be subject to much greater scrutiny in the future (Cohn *et al.* 2016).

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