Pelvic mesh in colorectal pelvic floor surgery—implications of recent developments
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ABSTRACT
The use of mesh prostheses in pelvic surgery is under significant scrutiny. There are justifiable concerns around the transvaginal use of mesh products for POP surgery. The latter part of 2017 saw the announcement of wide-ranging regulatory actions relating to transvaginal mesh products, by the Therapeutic Goods Administration in Australia and subsequently Medsafe in New Zealand. In colorectal surgery, pelvic mesh is predominantly used in the treatment of rectal prolapse, with ventral mesh rectopexy (VMR) becoming popularised in recent years. The available evidence suggests that despite the current mesh controversy, VMR is an acceptable procedure, with functional advantages over other colorectal prolapse procedures. With only short-term outcome data available however, comparative studies and longer follow-up are required to answer the question of long-term mesh safety. In the meantime, there are areas where surgical practice can be optimised, in particular around reporting, training and patient education. The aims of this paper are to summarise the current status of pelvic floor mesh surgery and examine how this will impact colorectal pelvic floor surgery.

The use of mesh prostheses in pelvic surgery is under significant scrutiny. Recent developments in gynaecological pelvic floor surgery have led to a broad reappraisal of mesh-related procedures in many health jurisdictions worldwide. Gratifyingly for patients and surgeons, we are now entering a phase of greater accountability, clearer surgical indications, more collaborative decision-making, and prospective monitoring of outcomes. The overall goal remains the successful treatment of patients with pelvic organ prolapse (POP) with the most effective, durable and safe techniques available.

A major Australasian shift in the latter part of 2017 was the announcement of wide-ranging regulatory actions relating to transvaginal mesh products, by the Therapeutic Goods Administration (TGA) in Australia and subsequently Medsafe (New Zealand Medicines and Medical Devices Safety Authority) in New Zealand. Widely reported as a ‘ban’ on surgical mesh implants for POP, there has been uncertainty among colorectal surgeons regarding the implications of this.

This perspective paper has two aims. The first is to summarise the current status of pelvic floor mesh surgery and put it into a New Zealand practice context. The second is to examine how this will impact colorectal pelvic floor surgery. The paper is not a systematic review of the literature, but an appraisal of what are considered by the authors to be the most salient recent publications for those working in this field.

Use of mesh in colorectal pelvic floor surgery
Products described as surgical ‘mesh’ fall broadly into two categories—synthetic or biologic. The commonest synthetic product in use is polypropylene—widely utilised in hernia surgery, abdominal wall reconstruction and pelvic floor surgery including suburethral slings. Biological products (often referred to as ‘graft’ rather than ‘mesh’) are generally an acellular allograft or xenograft
collagen matrix, with the latter being the most commonly-used variant (usually of porcine or bovine origin). Most of the publications discussed in the next section do not make a distinction between these products, unless stated in this paper.

In colorectal surgery, pelvic mesh is predominantly used for the treatment of rectal prolapse. In particular, ventral mesh rectopexy (VMR) is an operation performed by some colorectal surgeons to correct the posterior pelvic compartment disorders which form part of the POP spectrum. This includes rectal prolapse (both external and internal), enterocele and rectocele. There are technical similarities to gynaecological sacrocolpopexy. VMR in New Zealand is currently performed with either a synthetic mesh (usually polypropylene) or a biologic graft situated between the rectum and the vagina, and sutured to the anterior rectal wall and sacral promontory, and to the vagina in some cases. The mesh is placed from an abdominal approach (usually laparoscopic), with no breach of the vagina, and is completely covered with peritoneum, thus isolating it from the viscera of the peritoneal cavity. While first described using synthetic mesh in 1971,1 the procedure has been popularised over the last 15 years, as it appears to address some of the undesirable functional bowel sequelae of other procedures, based on reports of uncontrolled case series from high-volume centres.2–6 As part of the POP spectrum, it is unsurprising that VMR is most commonly performed on women (>90%), and the median patient age is in the range of 50–60 years old,7,8 although the operation is considered suitable for patients over 80 years of age who are fit for general anaesthesia.9 While there are two randomised studies comparing mesh with non-mesh rectal prolapse repairs, they focus on functional outcomes, and are not powered to address the question of mesh safety.10,11

Background to the current pelvic mesh situation

The global reappraisal of surgical mesh usage has come about through the persistence of patients and their advocates—clinicians, consumer groups, media and government agencies. The process was given momentum in 2011 when the US Food and Drug Administration (FDA) published its report into the safety and effectiveness of transvaginal mesh placement for pelvic organ prolapse (POP), based on adverse event reports and a review of the literature.12 This report made two broad points, which challenged the enthusiasm for pelvic mesh repairs:

- “serious complications associated with surgical mesh for transvaginal repair of POP are not rare”; and
- “it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair”.

The report made the following observations about safety:

- “Based on data from 110 studies including 11,785 women, approximately 10% of women undergoing transvaginal POP repair with mesh experienced mesh erosion within 12 months of surgery.”
- “More than half of the women who experienced erosion from non-absorbable synthetic mesh required surgical excision in the operating room.”
- “Transvaginal surgery with mesh to correct vaginal apical prolapse is associated with a higher rate of complication requiring reoperation and reoperation for any reason compared to traditional vaginal surgery or sacral colpopexy.”
- “Abdominal POP surgery using mesh (sacrocolpopexy) appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh...”

The report makes the distinction that the problems with pelvic mesh seem to be associated with mesh placed via a transvaginal route. It also casts doubt on the benefit of mesh repair over traditional native tissue repair of POP. In the most recent (2016) Cochrane review of this,13 the authors concluded that “The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there is currently no evidence to support this position.” It went on to recommend “…newer transvaginal meshes should be utilised under the discretion of the ethics committee”.

VIEWPOINT
In 2014 the Scottish Government declared a suspension of all mesh surgeries pending the results of its own enquiry. The release of this report in March 2017 made some broad recommendations, but stopped short of a continued ban on mesh usage.\textsuperscript{14} In England, the National Institute of Health and Care Excellence (NICE) produced their updated guideline in December 2017.\textsuperscript{15} This concluded that transvaginal mesh repair of anterior or posterior vaginal wall prolapse should be used only in the context of research, effectively banning its routine use. It is unclear in the document whether this also includes urethral sling procedures.

The Australian TGA was widely praised when it issued its own actions on 28 November 2017.\textsuperscript{16} Based on a review of the latest published international studies and the 2014 TGA review into urogynaecological surgical mesh implants, the TGA concluded that “the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients. As a result, the TGA has taken a series of regulatory actions in relation to transvaginal mesh products and single incision mini-slings”.

In practical terms, these actions constitute a ‘ban’ on the use of some POP mesh products (cancellation from the Australian Register of Therapeutic Goods (ARTG)), and tighter conditions around the use of others, effective January 2018. A full list appears on the TGA website. Some examples of permitted products with tighter controls include:

- the polypropylene Upsilon Y-Mesh Kit (Boston Scientific Pty Ltd), which cannot be used transvaginally, but can still be used transabdominally for sacrocolpopexy.
- Biologic grafts, such as the bovine dermis allograft Xenform Tissue Repair Matrix (Boston Scientific Pty Ltd), which must alter its instructions for use and labeling to include “This device is not intended for any pelvic organ prolapse repair via a transvaginal approach”. Biodesign 4 Layer Tissue Graft (Cook Biotech Inc) has had its conditions of use limited to non-urogynaecological procedures
- A number of polypropylene mid-urethral slings used for stress urinary incontinence (SUI). They remain on the ARTG on the basis that they include additional precautions in the instructions for use and labeling, effective 17 January 2018.

Medsafe in New Zealand issued a statement of its own regulatory action following the TGA announcement.\textsuperscript{17} It has taken the view that the “Australian outcome has given sufficient reason to consider that the products involved in the Australian action may not be safe. As a consequence, continued use of these products is considered inadvisable”. To this end, the Medsafe position is fundamentally the same as that of the TGA.

Background to the New Zealand mesh situation

In 2014 the New Zealand Parliament Health Select Committee considered a petition submitted by Carmel Berry and Charlotte Korte, two patients who had experienced adverse outcomes from pelvic mesh surgery, requesting an inquiry into the use of surgical mesh in New Zealand. The petition raised several issues around the quality of surgical mesh, the standards of care for patients and the need for a surgical mesh registry. Among those who provided submissions were the petitioners, the Accident Compensation Corporation (ACC), Pharmaceutical Management Agency (PHARMAC), the Ministry of Health, and the Royal Australasian College of Surgeons (RACS) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). The Select Committee’s report in June 2016 included seven recommendations in three areas:\textsuperscript{18} the investigation of options for a surgical registry, improvement in medical practice and the role of the regulator in pre-market medical device approval. The Government supported all of the Committee’s recommendations in a response tabled in August 2016,\textsuperscript{19} specifically recommending:

- That the Government work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry.
• That the Medical Colleges review best practice around informed consent for mesh procedures. That health providers are encouraged to ensure that coding for mesh surgery is consistent.

• That the Government encourages utilisation of the adverse events reporting system as applicable to medical devices.

• That the Government endorses the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery.

• That the Government considers expanding Medsafe’s role over time to assess the quality and safety of a medical device before it can be used in New Zealand.

Following the Government support of the above recommendations New Zealand has had a general election and a change of Government, and it remains to be seen what priority will be given to these, in particular the establishment of a surgical mesh registry.

The scope of the problem within New Zealand has been difficult to quantify, in part due to a lack of a prospective registry, and a reliance on adverse event reports. The 2015 ACC Surgical Mesh Review states that 56,508 mesh devices were sold in New Zealand between 1 January 2005 and 31 October 2014. Fifty-eight percent were sold for hernia repair, while 30% were for POP repair and 11% were for SUI repair.

The 2017 ACC review (Surgical Mesh-Related Claim Data Report) provides a breakdown of surgical mesh-related claim data, covering claims over 12 fiscal years from 1 July 2005 to 30 June 2017. The report covers adverse events reported following the use of mesh for POP and SUI surgery (470 claims), hernia surgery—including inguinal and ventral (290 claims), and others (50 claims). Of the 470 claims for POP/SUI surgery, 91% were in the gynaecology treatment context, followed by Urology (7%) and General Surgery (eg, VMR) eight cases (2%). Two-thirds of 470 POP/SUI claimants presented with the primary symptom of mesh erosion, with the commonest secondary symptoms being sexual dysfunction, pain and infection.

**Mesh safety in colorectal pelvic floor surgery**

Where does this leave VMR? What can we tell our patients about mesh safety?

Three systematic reviews of VMR have been published since 2010, and demonstrate a mesh-related complication rate of 0.5–3.1%. Three studies compared pre- and post-operative sexual function for 152 patients. There was no statistically significant between-study heterogeneity. Pre-operatively 98 patients (64.5%) were considered to have sexual dysfunction, compared with 21 (13.8%) post-operatively. In the review by Samaranayake, the rate of chronic abdominal and pelvic pain after VMR is <1%.

Two case series are useful to discuss, as they have large numbers with adequate follow-up, from recognised high-volume centres. The first is 919 consecutive patients (869 women; 50 men) in a combined Belgian and Dutch series. Median follow-up was 34 months. Mesh-related complications were recorded in 18 patients (4.6%). However, in nine patients this represented mesh detachment from the sacral promontory, a mechanical failure presenting with deterioration of initial good functional result. These cases were treated by reoperation and mesh reattachment. Erosion of the mesh to the vagina occurred in seven (1.3%) patients. In five of these patients, VMR had been combined with a perineotomy to suture the mesh to the perineal body, a modification of technique which the authors no longer advocate. This leaves two cases only of true vaginal erosion from what is considered to be standard technique, representing an erosion rate of <1%. The rate of chronic abdominal or pelvic pain was <1%.

The second study is the pooled experience of five centres, over a 14-year period. A total of 2,203 patients underwent VMR, 80% of whom received a synthetic mesh and 20% of whom received a biologic graft. At the time of data analysis, median length of time since operation was 36 months (range, 0–162 months). Forty-five patients (2.0%)
had mesh erosion. Of these 45 patients, 50% required minor treatment for minor erosion morbidity and 40% required major revisional surgery such as mesh removal for major erosion morbidity. Erosion occurred in 2.4% of synthetic meshes and 0.7% of biological meshes. The median time to erosion was 23 months, but up to a quarter of erosions were documented to occur 40–80 months after surgery. Using the Kaplan-Meier method the erosion rate for synthetics was 2.3% at five years. There were three patients with erosion after use of the biological graft, a rate of 0.7% at five years. Synthetic mesh was not significantly associated with an increased incidence of erosion compared with biological graft.

The study was limited by its retrospective nature, and included some patients with very short-term follow up.

In summary, when these studies are considered, the risk of a major mesh-related complication with VMR would seem to be in the 1–2% range. This is significantly less than that of transvaginal mesh surgery. It also compares favourably with what is considered the analogous gynaecological procedure (sacrocolpopexy). In the systematic review of Jia et al (27 studies involving nearly 3,000 patients), the risk of a mesh erosion with sacrocolpopexy was 0–12%, median 5.4%. In the case of VMR, the ideal mesh prosthesis is not clear, as synthetic and biologic products have differing characteristics. This is an area where practice is certain to evolve in the next decade as further data become available.

An international perspective on the current status of VMR

In the UK, The Pelvic Floor Society (TPFS) is an affiliate of the Association of Coloproctology of Great Britain and Ireland (ACPGBI), and is a surgical special interest group with a multidisciplinary membership. TPFS has recently released a position statement on the use of mesh in VMR, authored by recognised authorities in the field and endorsed by TPFS. The summary recommendations are consistent with much of the foregoing commentary. They make the following conclusions:

- Mesh morbidity for VMR is far lower than that seen in transvaginal procedures, and lower than laparoscopic sacrocolpopexy.
- Ventral mesh rectopexy should be performed by adequately trained surgeons who work within a multidisciplinary team framework.
- Clinical outcomes of surgery and any complications should be recorded in a registry.
- There should be a move towards accreditation of UK units performing VMR and an enhanced structured training programme.
- Enhanced consent forms and patient information booklets are being developed.
- It may be possible to optimise technical aspects of the procedure to reduce morbidity rates, eg, suture material choice.

Why VMR?

VMR has been popularised for two main reasons. Firstly it may improve some aspects of post-operative bowel function compared to other procedures, as in the case of external rectal prolapse. Second, it offers a treatment option where previously these were lacking, ie, in high-grade internal rectal prolapse, particularly where it relates to faecal incontinence. However, it represents only one treatment option, and is by no means a ‘gold standard’ procedure. The choice between use of synthetic material or a biologic may ultimately come down to a balance between the risks of erosion and recurrence. This must form the basis of an informed discussion between the operating surgeon and the patient. It must be recognised however that we do not have high-quality long-term safety data for synthetic mesh in this procedure, as it is possible that mesh complications could occur over 10 years after mesh implantation. This is particularly relevant to patients who are contemplating VMR at a young age. Similar question marks surround the long-term recurrence rate with the use of biologic grafts.
Conclusion

There are justifiable concerns around the transvaginal use of mesh products for POP surgery, and the international reappraisal of this is important and timely. However, there are significant differences between this type of surgery and the use of abdominally-placed pelvic mesh for VMR. Available evidence suggests that VMR is an acceptable procedure, with some functional advantages. Comparative studies and long-term follow-up however are required to answer the question of long-term mesh safety. The current regulatory environment does not contraindicate the use of synthetic mesh in VMR, but recommendations around its optimal use have been developed. These are centred around reporting, training and patient education. This will ultimately be to the advantage of both patients and surgeons, with the shared aim of effective, durable and safe treatment of pelvic organ prolapse.

Competing interests: Nil.

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