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Use of mesh in gynaecological surgery

C. Mahoney & A. R. B. Smith
Institute of Human Development, Faculty of Medical and Human Sciences, University of Manchester, and The Warrell Unit, St Mary's Hospital, Central Manchester University Hospitals NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK

Abstract
Mesh is used in gynaecological surgery to treat pelvic organ prolapse and stress urinary incontinence. One in three women in the UK will develop symptoms of pelvic floor weakness during their lifetimes, and one in 10 of these individuals will require surgery. Unfortunately, the rate of surgical failure is high and one-third of women who have undergone a mesh procedure will need another operation. Mesh was introduced to overcome the inherent weakness of the natural tissue. However, its use is associated with complications that can cause significant morbidity in women. The type of mesh used and the location of insertion can have an impact on the nature and severity of any problems. Since the discovery of the complications of mesh, support groups have been established in order to provide support for women, and also lobby for the removal of all mesh implants. It is to be hoped that the situation will prompt regulatory agencies and health professionals to implement more robust approvals processes for medical implants and devices in the future.

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

Introduction
Mesh is used in gynaecological surgery to treat both pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The US National Institutes of Health defines POP as the descent of any vaginal segment "to within 1 cm of the hymen or lower" (Weber *et al.* 2001, p. 181). Pelvic organ prolapse and SUI are caused by weakness in the pelvic floor, which can be congenital, or connective tissue disorders, pregnancy or childbirth, and age-related weakness.

Pelvic organ prolapse can be treated conservatively with pelvic floor muscle (PFM) training (PFMT), and pessaries to correct the anatomy and surgery. The type of POP depends on the vaginal compartment that is prolapsing (i.e. anterior, posterior or apex/vault), and can involve repair with native tissues or the use of mesh to provide additional strength.

Stress urinary incontinence can also be treated with PFMT, pessaries to provide mechanical support to the urethra and surgery. Operations for SUI generally focus on providing additional mechanical support to the urethra so as to restore the continence mechanism. These can involve bulking agents, which are injected sub-urethrally, a sub-urethral sling (which is typically made from mesh, but can also be made from the rectus sheath), and a colposuspension (open or laparoscopic), which elevates the tissue alongside the urethra.

The present paper discusses the reasons for using mesh rather than native tissues, the benefits and potential complications that can ensue, and the social and ethical ramifications of mesh use in gynaecological surgery.

Correspondence: Dr Charlotte Mahoney, The Warrell Unit, St Mary's Hospital, Central Manchester University Hospitals NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester M13 9WL, UK (e-mail: charlotte.mahoney@cmft.nhs.uk).

The pelvic floor
The pelvic floor is a complex structure containing the muscles and fascia of the pelvic diaphragm, the perineal membrane, and the superficial vaginal muscles. A fascia is a muscle attachment to bone that provides both strength and support. The pelvic diaphragm contains the levator ani and coccygeus muscles, and is pierced by the urethra, bowel and vagina. The

perineal membrane consists of the deep transverse perineal muscles, the external urethral sphincter and a layer of fascia. It is perforated by the urethra and vagina. The superficial vagina includes the ischiocavernosus, bulbospongiosus and superficial transverse perineal muscles, which form the perineal body.

In addition to providing mechanical support, the PFMs have a functional interaction with the bladder, bowel and vagina. It is important to note that any surgical procedure will not improve muscle function, although it may make muscle contraction more effective.

Why use mesh?

In hernia surgery, failure or recurrence has been shown to be reduced when the repair is augmented with mesh, and this approach is now recommended practice. With regard to the surgical treatment of SUI, the 2006 National Institute for Health and Clinical Excellence guidelines on urinary incontinence in women considered the mid-urethral sling, which is a 1-cm-wide piece of polypropylene mesh, to be the gold standard surgical treatment for this condition (NCWCH 2013).

Pelvic floor weakness is extremely common and will affect approximately one in three women in the UK during their lifetimes (Davis & Kumar 2003), with one in 10 of these individuals requiring surgery for their condition (Olsen *et al.* 1997). However, the risk of surgical failure is high, and one in three women who undergo surgery will need a further operation (Olsen *et al.* 1997). One possible explanation for the high rate of surgical failure is that women who experience symptoms of pelvic floor dysfunction have inherently weak tissues that are naturally predisposed to a recurrence of their condition. This has led to the use of mesh in an attempt to overcome the deficiency of the natural tissue.

Mesh in practice

A wide variety of mesh implants have been developed since this technique was introduced, including both animal tissue and synthetic materials, which can be absorbable or non-absorbable in nature. A synthetic material can vary in terms of the polymer type, density or weight, pore size, filament, tensile strength, and elasticity (Table 1). Each of these factors helps to determine the host's response, and in turn, has an impact on the risk of infection and the potential of the mesh to erode into an adjacent area of the body.

Another factor affecting the likelihood of mesh complications is the location of the insertion. Mesh that is inserted through the vagina has a 19% chance of exposure (Fayyad *et al.* 2011), whereas mesh which is attached onto the vagina via the abdomen has a 9% chance of exposure (Iglesia *et al.* 1997). Transvaginal mesh for prolapse is also associated with a five times higher risk of mesh complications than mesh inserted for SUI (ACC 2015).

Problems with mesh

As discussed above, there are possible issues with mesh that can cause significant morbidity in women. Some of the problems that have been reported to be associated with mesh use have also been described after prolapse surgery without mesh, and therefore, it is not yet clear how much morbidity is produced by the mesh itself.

Table 2 details the potential complications of mesh. However, this list is not exhaustive, and does not include the additional psychological and social implications of living with a long-term complication.

The more severe mesh complications may take a number of years to develop, by which time women have usually been discharged from secondary or tertiary care.

Table 1. Types and properties of synthetic mesh

Polymer	Product	Filament	Pore size	Type
Polypropylene	Marlex Surgipro SPMM Prolene Gynemesh PS	Lightweight or heavyweight monofilament	Macro	I
	Vypro	Multifilament		
Expanded polytetrafluoroethylene	Gore-Tex	Multifilament	Micro	II
Polyethylene polypropylene	Mersilene Surgipro SPM	Multifilament	Micro/macro	III
Polypropylene sheet	Cellgard	Monofilament	Sub-micro	IV

Table 2. Potential mesh complications and associated symptoms

Complication	Symptom
Nerve damage	Genital, pelvic groin or thigh pain Urinary incontinence Dyspareunia
Recurrence	Symptoms of pelvic organ prolapse Stress urinary incontinence
Fistulae	Urinary incontinence Faecal incontinence
Vaginal scarring, shrinkage or shortening	Dyspareunia
Mesh degradation	Offensive discharge Genital, pelvic groin or thigh pain Dyspareunia
Recurrent infections	Recurrent urinary tract infections
Voiding dysfunction	Vaginal discharge Difficult micturition
Organ perforation	Bladder/urethra: haematuria dysuria Bowel: blood in stool pain on evacuation sepsis death
Mesh exposure	Offensive discharge Dyspareunia "Hispareunia" (partner dyspareunia) Genital pain, scratching and/or discomfort

Evidence on mesh use in pelvic organ prolapse surgery

A Cochrane Review evaluated 37 randomized controlled trials (RCTs) involving 4023 women that had investigated transvaginal native tissue versus mesh repair for vaginal prolapse (Maher *et al.* 2016). The authors reported that transvaginal mesh was associated with a lower objective recurrence of prolapse and patient-reported symptoms, but there was a significantly higher risk of intraoperative bladder injury, as well as reoperation for mesh complications and SUI when compared to native tissue repair. Overall, the risk–benefit profile meant that they could not recommend the use of transvaginal mesh for primary prolapse surgery.

However, Maher *et al.* (2016) included a number of RCTs involving many of the heavier non-absorbable transvaginal meshes that were discontinued in 2011 because of the developing awareness of the complications associated with these products. This highlights the need for a high-quality RCT comparing lightweight mesh to native tissue repair.

To answer the question about whether mesh should be used in prolapse repair, a multicentre RCT called PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials) was designed (CHaRT 2016). This involved 35 centres in the UK and over 2000 women. Although PROSPECT has now completed recruitment and randomized over 1200 women, the results have not yet been published.

The current climate

There has been extensive coverage in the national and international press of both positive and negative stories since the discovery of mesh complications. One article suggested that doctors were deliberately concealing the risks from patients, and an examination of the National Health Service (NHS) surgical procedures numbers revealed that one in 20 women had tension-free vaginal tape exposure surgery with "disastrous results" (Rogers 2012). Support groups have been established that provide support for those living with complications, and lobby for the removal of all mesh implants. In Scotland, the use of mid-urethral slings using mesh was suspended pending an inquiry into the use of such implants (Crothers 2015), and the rest of the UK has also set up the Mesh Working Group to evaluate the risk to patients. The Medicines and Healthcare Products Regulatory Agency reported

that the evidence did not support the withdrawal of mesh, but its use needed more evaluation.

Responsibility

As healthcare providers, we should not underestimate the potential loss of trust from our patients that this situation has caused. There is some concern that the scrutiny of new medical devices and implants by the regulatory authorities is not sufficiently robust, and that more research should be performed before devices are introduced and marketed.

In the USA, the mesh manufacturing companies have been found negligent for failing to inform doctors and patients of the risks of mesh complications. Over US$3.5 billion has been awarded in compensation already, and there is no sign of a reduction in the number of lawsuits (Klein 2016).

It is to be hoped that this situation will prompt regulatory agencies to develop a more robust approval process that incorporates the need for long-term safety data, including post-marketing surveillance.

The future

The impact of the newer lightweight meshes has yet to be assessed, particularly from a long-term perspective. Further research is needed into the techniques and materials that could be used to strengthen native tissues without causing the morbid complications of the older types of mesh. One option is to use stem cells to build a stronger natural collagen scaffold onto which the host cells could grow. Finally, the role of physiotherapy must be explored to find the optimum regime for women with pelvic floor dysfunction, both to prevent the need for surgery, and as a way of maximizing surgical outcomes for those who "go under the knife".

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References

Accident Compensation Corporation (ACC) (2015) *ACC Surgical Mesh Review: Analysis of Treatment Injury Claims, 1 July 2005 to 30 June 2014.* [WWW document.] URL http://www.acc.co.nz/PRD_EXT_CSMP/groups/external_providers/documents/reference_tools/wpc138053.pdf

Centre for Healthcare Randomised Trials (CHaRT) (2016) *PROSPECT: PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials.* [WWW document.] URL https://w3.abdn.ac.uk/hsru/prospect/

Crothers E. (2015) Suspension of mesh surgery: the Scottish experience. *Journal of Pelvic, Obstetric and Gynaecological Physiotherapy* **116** (Autumn), 76–77.

Davis K. & Kumar D. (2003) Pelvic floor dysfunction: a conceptual framework for collaborative patient-centred care. *Journal of Advanced Nursing* **43** (6), 555–568.

Fayyad A. M., North C., Reid F. M. & Smith A. R. B. (2011) Prospective study of anterior transobturator mesh kit (Prolift™) for the management of recurrent anterior vaginal wall prolapse. *International Urogynecology Journal* **22** (2), 157–163.

Iglesia C. B., Fenner D. E. & Brubaker L. (1997) The use of mesh in gynecologic surgery. *International Urogynecology Journal and Pelvic Floor Dysfunction* **8** (2), 105–115.

Klein S. (2016) *Transvaginal Mesh Settlement Costs J&J $120 Million.* [WWW document.] URL http://surgicalwatch.com/2016/02/transvaginal-mesh-settlement-costs-jj-120-million/

Maher C., Feiner B., Baessler K., *et al.* (2016) Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079.

National Collaborating Centre for Women's and Children's Health (NCCWCH) (2013) *Urinary Incontinence in Women: The Management of Urinary Incontinence in Women*, 2nd edn. NICE Clinical Guideline 171. Royal College of Obstetricians and Gynaecologists, London.

Olsen A. L., Smith V. J., Bergstrom J. O., Colling J. C. & Clark A. L. (1997) Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstetrics and Gynecology* **89** (4), 501–506.

Rogers L. (2012) *The Scandal of Women Who STILL Aren't Told the Risks of Bladder Operations.* [WWW document.] URL http://www.dailymail.co.uk/health/article-2197850/The-scandal-women-STILL-arent-told-risks-bladder-operations.html

Weber A. M., Abrams P., Brubaker L., *et al.* (2001) The standardization of terminology for researchers in female pelvic floor disorders. *International Urogynecology Journal and Pelvic Floor Dysfunction* **12** (3), 178–186.

Dr Charlotte Mahoney is an NIHR doctoral research fellow. Professor Anthony Smith is a consultant urogynaecologist and honorary senior lecturer. Both work at the Institute of Human Development, Faculty of Medical and Human Sciences, University of Manchester, and The Warrell Unit, St Mary's Hospital, Central Manchester University Hospitals NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK.