Polypropylene Vaginal Mesh Implants for Vaginal Prolapse

Produced by Executive of the Urogynaecological Society of Australasia (UGSA)

Introduction

Very little robust information is available on the efficacy and long term safety of polypropylene mesh kits marketed for use in the surgical management of pelvic organ prolapse.

The Food and Drug Administration (FDA) in the United States approved the first mesh implant for vaginal use in 2002. Over the last decade a number of polypropylene mesh “kits” have been developed by industry for use by gynaecological surgeons in vaginal prolapse repairs. The introduction of vaginal mesh augmented repairs was driven by a pervasive perception that conventional native tissue repairs had unacceptably high anatomical failure rates in the short to medium term.

On October 20th 2008 the FDA, after reviewing complaints made to the agency in the USA, issued a statement regarding vaginal mesh. They recommended that surgeons should undertake specialized further training before attempting vaginal mesh repairs and that they should notify patients that mesh is a permanent implant and complications can occur which may not resolve even with further corrective surgery. However they still considered these serious complications “rare”.

With the increasing use of vaginal mesh, the report of 2008 was followed by more reported adverse events resulting in the organization issuing an update to its 2008 report on 13 July 2011. This FDA update stated that adverse events with the use of vaginal mesh were no longer considered rare. An accompanying literature search concluded that most cases of pelvic organ prolapse could be treated without mesh and there was no compelling evidence that the use of vaginal mesh showed greater success rates or durability over conventional surgery, particularly with regard to the vault and the posterior vaginal compartment. However, they accepted there was some evidence of greater efficacy in the use of mesh in the anterior compartment. They recommended that all patients be advised that convincing long term data on the safety of mesh was limited and that all alternatives to the use of mesh should be also discussed in detail with patients prior to its use. This update, its highly critical conclusions and the literature search on which they were based have been subsequently criticized by some clinicians – but even the most outspoken critics have agreed on the need for full preoperative evaluation, informed patient consent and improved surgeon training.

In January 2012, the FDA introduced to industry mandatory post market surveillance of all mesh implanted in the vagina – so called “522 studies”, together with the gathering of comparative data between mesh kits and conventional surgery. Since then, some 88 post market study orders have been issued to 33 manufacturers of vaginal mesh kits. Given the financial burden of performing such studies, some manufacturers have withdrawn wholly (Johnson and Johnson) or partially
(Boston Scientific) from the market and anecdotally the overall use of vaginally implanted mesh in the USA has fallen by 40 – 60% since the FDA update announcement of July 2011.

**UGSA and RANZCOG Recommendations**

**Informed Patient Consent**

The consent process should be wide ranging and cover issues such as:

1. The patient should be informed that very limited robust data is available on the efficacy and safety of many of the transvaginal mesh products available in Australasia.

2. Potential benefits and complications of prolapse surgery generally versus the status quo or using conservative treatments (e.g. pelvic floor exercises or vaginal pessary). Patients with mild to moderate (pelvic organ prolapse quantification; POP-Q stage 1&2) asymptomatic prolapse do not necessarily require surgical management. The decision to operate should be based upon symptomatic bother from the prolapse defined by the patient. There is little longitudinal data in the literature on untreated asymptomatic prolapse to inform a decision for surgery in this situation.

3. Potential benefits and complications of transvaginal mesh specifically (see below).

4. Alternatives to surgical management, including non surgical options such as pelvic floor muscle training and vaginal support pessaries.

5. Other alternative surgical treatments such as conventional native tissue repair, as well as abdominal sacrocolpopexy (open or laparoscopic).

6. Complications discussed of transvaginal mesh must include mesh exposure/ erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and/or pelvic pain which may require additional intervention and may not be completely resolve even with mesh removal. The possibility of mesh surgery resulting in unprovoked pelvic pain at rest should be discussed.

**Surgical Training**

1. Transvaginal placement of surgical mesh for pelvic organ prolapse should only be performed by surgeons who have requisite knowledge, surgical skills, and experience in pelvic reconstructive surgery. When intending to introduce the use of a new mesh technique into their practice, individual surgeons should keep a clear record of all relevant training and experience. This knowledge and experience should be objectively demonstrable either by completion of the CU fellowship or by attendance and close involvement at surgical workshops, conferences, and peer to peer training. It is essential that such training should be “hands on” training on multiple occasions. Simple observation of theatre cases is insufficient to demonstrate adequate expertise in performing these surgical procedures.

2. Specific knowledge for a particular procedure should be obtained. Different mesh kits demand different skills and specific training. It is essential that surgeons should keep themselves up to date with reported results and complications of particular procedures that they use.

3. Surgeons performing vaginal mesh surgery should ensure that they perform pelvic floor surgery (both with and without mesh) regularly enough to maintain expertise. Experienced surgeons have fewer mesh complications arising from transvaginal placement of surgical mesh for pelvic organ prolapse than those with less experience.
4. Surgeons should be able to demonstrate experience and competence in non-mesh vaginal repair of prolapse including anterior colporraphy, posterior colporrhaphy, and vaginal colpopexy (e.g. uterosacral or sacrospinous ligament fixation) prior to training in and performance of vaginal mesh surgery.

5. Surgeons should demonstrate experience and expertise to perform intraoperative cystoscopy to evaluate for bladder and ureteral integrity.

6. Surgeons should demonstrate knowledge of the management of intra and post operative complications of vaginal mesh surgeries.

**Monitoring of efficacy and safety of implants**

The ideal method of evaluating long term efficacy and safety of vaginal mesh implants is by randomized control trial with long term systematic follow up. Because such trials are very limited in number the following interim strategy is suggested:

1. The outcomes and complications of transvaginal placement of surgical mesh for pelvic organ prolapse should be monitored longitudinally – preferably using a statewide or national data collection mechanism so that peer comparison may be obtained.

**Who would benefit from a transvaginal mesh implant?**

This is not an easy question to answer since clear evidence is lacking and no guidance can be given regarding which specific mesh implant should be used since there is simply no robust comparative data available. A recent useful consensus statement has been published in the International Urogynaecology Journal.

A broad summary of the International Urogynecological Association (IUGA) recommendations would be:

Exercise caution in using transvaginal mesh implants in:

1. Primary prolapse cases.
2. Patients younger than 50.
3. Lesser grades of prolapse (POP-Q ordinal grade 2 or less).
4. Posterior compartment prolapse without significant apical descent.
5. Patients with chronic pelvic pain.
6. Postmenopausal patients who are unable to use vaginal oestrogen therapy since this will be first line therapy for erosion.

These suggestions on patient selection are not intended to be exclusive or all encompassing and do not preclude the necessity of a broad based wide ranging discussion with the patient regarding her specific situation.

**References**


5. Davila W, Baessler K, Cosson M, Cardozo L. Selection of patients in whom vaginal graft use may be appropriate. Int Urogynecol J Pelvic Floor Dysfunct 2012. Published online 7 March 2012.

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