



Polypropylene vaginal mesh implants for vaginal prolapse

This statement has been developed and reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

A list of Women's Health Committee Members can be found in [Appendix A](#).

Disclosure statements have been received from all members of this committee.

Disclaimer This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

First endorsed by RANZCOG: July 2007
Current: November 2016
Review due: November 2019

Objectives: To provide advice on the use of polypropylene vaginal mesh implants for the treatment of vaginal prolapse.

Target audience: Gynaecological surgeons performing vaginal prolapse repairs, and patients.

Values: The evidence was reviewed by the Women's Health Committee (RANZCOG), and applied to local factors relating to Australia and New Zealand.

Background: This statement was first developed by Women's Health Committee in July 2007 and reviewed in November 2016.

Funding: The development and review of this statement was funded by RANZCOG.

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1. Patient summary

Vaginal prolapse can affect the anterior (bladder), posterior (bowel) and/or apical (uterine or post hysterectomy prolapse) vaginal sites. The current evidence does not support the use of polypropylene mesh as a first line treatment for anterior, posterior or apical prolapse. In the anterior compartment there are some advantages to utilising polypropylene mesh as compared to the traditional native tissue repair. These included a reduction in prolapse symptoms and re-operation for prolapse. However, these advantages are offset by significant problems including a higher combined re-operation rate for prolapse, urinary incontinence or mesh exposure and higher rates of bladder injury, stress urinary incontinence and prolapse in other vaginal sites. The mesh becomes exposed in the vagina in 8-15% of patients. The data relating to utilisation of polypropylene mesh in the treatment of recurrent prolapse is lacking.

2. Summary of recommendations

Recommendation 1	Grade
Transvaginal polypropylene mesh is not recommended as the first line treatment of any vaginal prolapse ¹	A Reference 1
Recommendation 2	Grade
When using the newer light weight, transvaginal permanent meshes, consider recruiting into a clinical trial as these meshes have not been evaluated within a RCT. At a minimum, extensive discussion regarding other options and referral for a second opinion should be considered. Clinical audit of all mesh procedures is encouraged.	Good Practice Point Reference 1

3. 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 2002.² 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.³

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 specialised 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 organisation 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 criticised 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. Ethicon (Johnson and Johnson) and American Medical Systems have both withdrawn their transvaginal mesh kits from the market. In January 2016, the FDA reclassified transvaginal mesh as a Class III “high risk device”.

As a consequence of these changes, much of the scientific evidence used to justify the use of early transvaginal mesh for prolapse is not applicable to the newer, lightweight transvaginal permanent meshes. The review by Maher et al (Cochrane Database) has noted that the lightweight transvaginal permanent meshes currently available have not been evaluated within a RCT. Where possible, patients who will have these meshes implanted should be recruited into clinical trials to determine the efficacy of these meshes. ¹

4. Discussion and recommendations

4.1 Informed patient consent

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

1. Due to the withdrawal of some of the commonly performed and studied transvaginal mesh products from the market, the patient should be informed that very limited robust data is available on the efficacy and safety of the transvaginal mesh products available in Australasia.
2. Patients with 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 for mild prolapse and vaginal support pessaries.
5. Other alternative surgical treatments including conventional native tissue repair and abdominal sacrocolpopexy (open or laparoscopic).
6. Complications of transvaginal mesh must include mesh exposure/ erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and/or unprovoked pelvic pain at rest. The possibility of mesh surgery resulting in unprovoked pelvic pain at rest that can be difficult to treat should be discussed. That these complications may occur some years after implantation and can be difficult to treat should be discussed.

7. If mesh complications arise, this may require additional surgical intervention and the complications may not completely resolve even with mesh removal. Complete removal of the mesh implant may not always be possible.

4.2 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.^{4,5}
4. Surgeons should be able to demonstrate experience and competence in non-mesh vaginal repair of prolapse including anterior colporrhaphy, 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.

4.3 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 ⁶ 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.
2. All gynaecologists should be aware of and be encouraged to make full use of the ability to report adverse events from mesh surgery to the Australian Therapeutic Goods Administration at: www.tga.gov.au The link appropriate to reporting problems with a medical implant is: <http://www.tga.gov.au/safety/problem.htm>
3. In New Zealand, this should be done to the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE). The link is: <http://www.medsafe.govt.nz/safety/report-a-problem.asp>

4.4 Who would benefit from a transvaginal mesh implant?

This is not an easy question to answer since clear evidence is lacking. Similarly, no guidance can be given regarding which specific mesh implant should be used as there is no robust comparative data available. The data are not supportive of the use of transvaginal mesh for any primary repair procedure. There is no robust data on its use in recurrent prolapse.

However, patients at increased risk for recurrent prolapse such as the obese, the young, those with chronically raised abdominal pressure (severe asthma, constipation) and those with stage 3 and 4 prolapse may find the risk benefit profile of transvaginal mesh procedures acceptable.⁷

Ideally, transvaginal mesh procedures would be performed in the setting of a properly conducted clinical trial with appropriate ethical oversight. Therefore, referral to a centre with such a trial in process should be considered and discussed with these women. At the minimum, a detailed and exhaustive consent and audit process is required and consideration of a second opinion from an independent gynaecologist who is experienced in pelvic reconstructive surgery should also be discussed prior to surgery.

5. References

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2. KOHLI N. Controversies in utilization of transvaginal mesh. Current opinion in obstetrics & gynecology 2012;24:337-42.
3. FRAZER M. Transvaginal Mesh. O&G Magazine 2014;14:28-31.
4. WITHAGEN MI, VIERHOUT ME, HENDRIKS JC, KLUIVERS KB, MILANI AL. Risk factors for exposure, pain, and dyspareunia after tension-free vaginal mesh procedure. Obstetrics and gynecology 2011;118:629-36.
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6. ALTMAN D, VAYRYNEN T, ENGH ME, AXELSEN S, FALCONER C, NORDIC TRANSVAGINAL MESH G. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. The New England journal of medicine 2011;364:1826-36.
7. DAVILA GW, BAESSLER K, COSSON M, CARDOZO L. Selection of patients in whom vaginal graft use may be appropriate. Consensus of the 2nd IUGA Grafts Roundtable: optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery. Int Urogynecol J 2012;23 Suppl 1:S7-14.

6. Links to other College statements

Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)

[https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Evidence-based-medicine,-Obstetrics-and-Gynaecology-\(C-Gen-15\)-Review-March-2016.pdf?ext=.pdf](https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Evidence-based-medicine,-Obstetrics-and-Gynaecology-(C-Gen-15)-Review-March-2016.pdf?ext=.pdf)

Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair
Dr Joseph Sgroi	Deputy Chair, Gynaecology
Dr Lisa Hui	Deputy Chair, Obstetrics
Associate Professor Ian Pettigrew	EAC Representative
Associate Professor Rosalie Grivell	TAC Representative
Dr Tal Jacobson	Member
Dr Ian Page	Member
Dr John Regan	Member
Dr Craig Skidmore	Member
Associate Professor Janet Vaughan	Member
Dr Bernadette White	Member
Dr Scott White	Member
Associate Professor Kirsten Black	Member
Dr Greg Fox	College Medical Officer
Dr Kiarna Brown (TBC)	Chair of the ATSI WHC
Dr Martin Byrne	GPOAC Representative
Ms Catherine Whitby	Community Representative
Ms Sherryn Elworthy	Midwifery Representative
Dr Michelle Proud	Trainee Representative

Appendix B Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in July 2007 and was most recently reviewed in November 2016. The Women's Health Committee carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.
- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the March 2016 face-to-face committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise. Recommendations were graded as set out below in Appendix B part iii)

ii. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of the Women's Health Committee.

A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. The Women's Health Committee members were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement.

iii. Grading of recommendations

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines. Where no robust evidence was available but there was sufficient consensus within the Women’s Health Committee, consensus-based recommendations were developed or existing ones updated and are identifiable as such. Consensus-based recommendations were agreed to by the entire committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire committee.

Recommendation category		Description
Evidence-based	A	Body of evidence can be trusted to guide practice
	B	Body of evidence can be trusted to guide practice in most situations
	C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
	D	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available
Good Practice Note		Practical advice and information based on clinical opinion and expertise

Appendix C Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.