CATEGORY: CLINICAL GUIDANCE STATEMENT

# 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: March 2021
Review due: March 2026

**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 March 2021.
**Funding:** The development and review of this statement was funded by RANZCOG.

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# 1. Plain language 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] | Evidence based recommendation<br><br>Grade A<br><br>Reference 1 |
| **Recommendation 2** | |
| Due to the removal from the Australian Register of Therapeutic Goods (ARTG), and Therapeutic Goods Administration (TGA), from 4 January 2018, transvaginal permanent meshes can only be used within the context of the TGA Special Access Scheme as part of a clinical trial. Clinical audit of all mesh procedures is encouraged. | Consensus-based recommendation |

# 3. Introduction

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 women 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", with the consequence that the manufacturers were required from then on, to submit and obtain premarket approval (PMA) applications, the agency's most stringent device review pathway, in order to continue marketing their devices.

An FDA convened advisory committee meeting in Feb 2019, concluded that, to support a favourable benefit/risk, surgical mesh for transvaginal repair of prolapse need to be superior to native tissue repair at 36 months and the safety outcomes for surgical mesh for transvaginal repair of prolapse should be comparable to native tissue repair. Since then, the FDA did not receive sufficient evidence to assure that the probable benefits of these devices outweigh their probable risks, which led them to conclude the products do not have reasonable assurance of safety and effectiveness. In April 2019, the FDA ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse to stop selling and distributing their products immediately (in USA).

https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/fdas-activities-urogynecologic-surgical-mesh

https://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants

Much of the scientific evidence used to justify the use of early transvaginal meshes 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]

From 4 January 2018, the Therapeutic Goods Administration (TGA) has removed transvaginal mesh kits for transvaginal prolapse repair from the Australian Register of Therapeutic Goods (ARTG). This change does not affect the Mid Urethral Slings for stress urinary incontinence with the exception of Single Incision Slings. It does not affect the use of trans-abdominal mesh procedures for prolapse. Further, in their communique in April 2019, the FDA believes that the benefit-risk profile of mesh placed abdominally to treat POP and mesh used to treat SUI remains favourable.

It is of interest that Health Canada updated its safety review and published its conclusions in July 2019. Whilst it found the benefit-risk profile to be unfavourable for transvaginal mesh to treat posterior compartment prolapse (eg rectocele), the benefit-risk profile *was favourable* for anterior and/or apical compartment prolapse, though transvaginal mesh should only be used for patients who have significant risk factors for recurrence of POP or recurrent POP, or for whom alternative surgical treatments are not appropriate.

Due to the changes to the ARTG, transvaginal mesh devices for prolapse can only be accessed via the Special Access Scheme. This will be to an Approved Prescriber and within the context of a clinical trial.

https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00229

# 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 transvaginal mesh for prolapse from the ARTG by the TGA, 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. Women who are at risk of recurrent vaginal prolapse and who are considered suitable for transvaginal mesh should be recruited into a clinical research trial for management and follow up of efficacy and safety of these devices.
3. 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.
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. Potential benefits and complications of transvaginal mesh including: mesh exposure/ erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and/or unprovoked pelvic pain at rest. That these complications may occur some years after implantation and can be difficult to treat should also 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. 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 compartment repair, posterior compartment repair, and apical support procedures (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.
7. The American Urogynecologic Society has retracted its credentialing guidance for transvaginal placement of mesh for POP, because its use is no longer approved, following FDA's communique on 16th Apr 2019.[6, 7]

## 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 [8] 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 is 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]

As transvaginal mesh procedures are no longer on the ARTG, they are now only available on Special Access Scheme and should only 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 encouraged and consideration of a second opinion from an independent gynaecologist who is experienced in pelvic reconstructive surgery should also be discussed prior to surge

## 5. References


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2. Kohli N. Controversies in utilization of transvaginal mesh. Current opinion in obstetrics & gynecology. 2012;24(5):337-42.
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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(3):629-36.
5. Kelly EC, Winick-Ng J, Welk B. Surgeon Experience and Complications of Transvaginal Prolapse Mesh. Obstetrics and gynecology. 2016.
6. "Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: " Retraction. Female pelvic medicine & reconstructive surgery. 2020;26(5):349.
7. Committee AUSsGD. Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: Retracted. Female pelvic medicine & reconstructive surgery. 2012;18(4):194-7.
8. 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(19):1826-36.


## 6. Links to other relevant college statements

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

Position statement on midurethral slings (C-Gyn 32)

# Appendices

## Appendix A Women's Health Committee Membership

| Name | Position on Committee |
|---|---|
| Professor Yee Leung | Chair and Board Member |
| Dr Gillian Gibson | Deputy Chair, Gynaecology |
| Dr Scott White | Deputy Chair, Obstetrics and Subspecialties Representative |
| Dr Jared Watts | Member and EAC Representative |
| Dr Kristy Milward | Member and Councillor |
| Dr Will Milford | Member and Councillor |
| Dr Frank O'Keeffe | Member and Councillor |
| Professor Sue Walker | Member |
| Dr Roy Watson | Member and Councillor |
| Dr Susan Fleming | Member and Councillor |
| Dr Sue Belgrave | Member and Councillor |
| Dr Marilyn Clarke | ATSI Representative |
| Associate Professor Kirsten Black | Member |
| Dr Thangeswaran Rudra | Member |
| Dr Nisha Khot | Member and SIMG Representative |
| Dr Judith Gardiner | Diplomate Representative |
| Dr Angela Brown | Midwifery Representative, Australia |
| Ms Adrienne Priday | Midwifery Representative, New Zealand |
| Ms Ann Jorgensen | Community Representative |
| Dr Ashleigh Seiler | Trainee Representative |
| Dr Leigh Duncan | Maori Representative |
| Prof Caroline De Costa | Co-opted member (ANZJOG member) |
| Dr Christine Sammartino | Observer |

## 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 1992 and was most recently reviewed in February 2021. 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 September 2021 teleconference, 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.[13] 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

### Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning polypropylene vaginal mesh implants 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 person. 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 person while providing vaginal prolapse care and circumstances of each case.

### Quality of information

The information available in polypropylene vaginal mesh implants (C-Gyn 20) is intended as a guide and provided for information purposes only. The information is based on the Australian/New Zealand context using the best available evidence and information at the time of preparation. While the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) had endeavoured to ensurethat 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. The use of this information is entirely at your own risk and responsibility.

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These terms and conditions will be constructed according to and are governed by the laws of Victoria, Australia

| Version | Date of Version | Pages revised / Brief Explanation of Revision |
|---|---|---|
| v1.1 | Jul / 2007 | Developed by WHC working party (previous title : The use of mesh in gynaecological surgery) |
| v2.1 | Jun / 2009 | WHC |
| v3.1 | Mar / 2013 | Reviewed by UGSA Executive/ WHC |
| v4.1 | Nov/2016 | Reviewed by CU/WHC |
| V5.1 | Dec/2017 | Reviewed by CU/WHC (TGA ban) |
| V6.1 | Dec/2019 | Reviewed by CU/WHC |

| | |
|---|---|
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| Review of Policy: | Mar / 2026 |