

Clinical Guidance Statement Sacrocolpopexy

This statement has been developed and reviewed by the Urogynaecology Committee (CU) and approved by the Women's Health Committee, RANZCOG Council and Board.

A list of the Women's Health Committee membership can be found in <u>Appendix A</u>, and the Urogynaecology Committee (CU) membership can be found in <u>Appendix B</u>.

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.

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Objectives: To provide advice on the use of grafts for the abdominal treatment of vaginal prolapse. Target audience: Gynaecological surgeons performing abdominal prolapse repairs, and patients. Values: The evidence was reviewed by the RANZCOG Urogynaecology Committee (CU) and Women's Health Committee (WHC) and applied to local factors relating to Australia and New Zealand. Background: This statement was first developed by CU Committee in March 2022 Funding: The development and review of this statement was funded by RANZCOG.



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1. Plain language summary

Pelvic organ prolapse (POP) is the abnormal descent of one or more vaginal walls and accompanying pelvic organs (uterus, cervix, bladder, or bowel). Bothersome POP is common and in some developed countries around 1 in 10 women will undergo surgery for POP during their lifetime. Treatment options for POP include expectant management such as by observation, conservative management such as by vaginal pessary or pelvic floor muscle training, and surgical management. Surgery may be performed through the vagina, through the abdomen, or sometimes by both approaches.

Sacrocolpopexy is the optimal surgical procedure to treat POP in some women. Sacrocolpopexy uses a "graft" to suspend the upper part of the vagina from the sacrum (a bone in the back of the pelvis) to keep it from falling down. The graft used may be made from a synthetic mesh (weaved polypropylene), the patient's own tissue, donated human tissue, or animal tissue. In some cases, part or all of the uterus is also removed (hysterectomy) or the uterus is suspended using graft (hysteropexy). Sacrocolpopexy is performed through the abdomen by either an open incision, keyhole surgery (laparoscopy), or robotic surgery (laparoscopy using a specialised robot controlled by the surgeon).

Sacrocolpopexy for select cases of POP is supported by robust scientific evidence with several studies concluding that sacrocolpopexy with synthetic mesh is the optimal surgical treatment for vaginal apical/vault prolapse (weakness of the upper part of the vaginal wall).¹

While the grafts used could include tissues from the patient's own body, or human donor, or another animal, the graft used and studied the most, and which seems to be more successful, is synthetic mesh. Unlike vaginal prolapse repairs where mesh has been inserted via vaginal incisions (transvaginal mesh), sacrocolpopexy mesh is applied over the top of the vagina without breaching the vaginal skin. Compared to vaginal approaches to prolapse surgery, sacrocolpopexy is associated with lower risk of persistent prolapse symptoms, recurrent prolapse on examination, repeat surgery for prolapse, postoperative urinary leakage with coughing and other activity, and pain during sex.

Companies producing mesh have been steadily withdrawing from Australia and New Zealand but not from other countries. The potential loss of mesh availability will affect the possibility of curing women with severe or recurrent prolapse. Such women may have to opt for a vaginal procedure that closes the vagina to resolve their discomfort.

Whilst the sacrocolpopexy procedure has good success and safety profiles, surgical complications and failures are possible. Different management options, alternative surgical procedures should be discussed between the patient and her treating surgeon. The Australian Commission on Safety and Quality in Health Care (ACSQHC) has resources for patients as well as care pathways for General Practitioners and Gynaecologists/Surgeons for the treatment of vaginal prolapse.



2. Summary of recommendations

Recommendation 1	LoE (Grade)
Sacrocolpopexy, using type 1 synthetic mesh, is a recommended treatment	Evidence based
of post-hysterectomy vaginal vault prolapse, and is especially important for	recommendation
women suffering from severe prolapse or recurrent prolapse following	I (A)
previous surgery.	



Compared with open sacrocolpopexy, laparoscopic sacrocolpopexy has less blood loss, longer operating time, shorter hospital stay with no clinically significant difference in objective or subjective cure rates.Evidence based recommendation 1 (A)Recommendation 3LoE (Grade)If a synthetic mesh is used, a lightweight type 1 mesh is recommended.Evidence based recommendation
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II (B)
Recommendation 4 LoE (Grade)
For women wishing to avoid mesh, autologous fascia, xenograft, or Evidence based
allograft may be used. Outcomes of such procedures are less well studied, recommendation
where mesh is used
Recommendation 5 LoE (Grade)
Only surgeons trained and credentialed for open Japaroscopic, or robot-
assisted sacrocolponexy should perform this procedure. Surgeons who
perform sacrocolpopexy should frequently see women with POP and III (C)
commonly both recommend conservative treatments and perform a
variety of prolapse surgeries reserving sacrocolpopexy procedures for
appropriate cases.
Recommendation 6 LoE (Grade)
Surgeons should be familiar with the ACSQHC or NZ Ministry of Health Evidence based
recommendations, patient pamphlets, and treatment algorithms for POP. recommendation
III (C)
Recommendation 7 LoE (Grade)
Patients should undergo a minimum of six months of follow up, including Evidence based
collecting patient outcomes, which should be clearly recorded through recommendation
properly maintained logbooks, other suitable documentation, or a secure III (C)
surgical database. To evaluate post-operative data, appropriate pre-
operative data should be collected, including the collection of demographic
data.
Good Practice Point
As of mid-2022, the Australasian Pelvic Floor Procedure Registry (APFPR)
will include mesh procedures for vaginal prolapse. Surgeons and
healthcare operators (including New Zealand based surgeons) should be

3. Introduction

3.1 Surgery for Pelvic Organ Prolapse

Pelvic Organ Prolapse (POP) is the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix), or the apex of the vagina (vaginal vault or cuff scar after hysterectomy). The presence of such signs should be correlated with prolapse symptoms.^{2, 3}

The lifetime risk of undergoing surgery for pelvic organ prolapse is estimated to be 19%⁴ with re-operation rates of up to 25%.⁵ Re-operation rates were substantially reduced if a concomitant apical support procedure was undertaken, ⁶ given at least half of anterior compartment support can be explained by apical support.⁷ Comparative trials are needed to assess these procedures further.



There are several options for surgical correction of apical compartment prolapse and they can be broadly categorised into vaginal or abdominal approaches. The abdominal approach can be performed via laparotomy, conventional laparoscopy, or robotic-assisted procedures. The vaginal approach tends to be most commonly performed.⁸

Known risk factors for prolapse recurrence includes parity, vaginal birth, age, high BMI, preoperative clinical stage,⁹ preoperative symptom severity as measured using Pelvic Floor Disability Index (PFDI 20),¹⁰ family history,¹¹ connective tissue disorders, and presence of levator avulsion.¹¹ Other patient-related factors include a woman's own surgical history, her goals/expectations, co-existent pelvic floor symptoms, and individual risks for surgical complications as well as prolapse recurrence. Surgeon-related factors includes prior training, overall experience, as well as current relevant caseload. Institution-related factors includes existence of national guidelines or care pathways, and local credentialing factors.

Companies producing meshes that can be used for sacrocolpopexy have been steadily withdrawing these devices from Australia and New Zealand, but not from other countries. The potential loss of surgical mesh availability will affect the possibility of curing women with severe or recurrent prolapse.

3.2 Sacrocolpopexy

Sacrocolpopexy is the suspension of the vaginal apex to the anterior longitudinal ligament of the sacrum using a graft, with possible incorporation of the graft into the fibromuscular layer of the anterior and/or posterior vaginal walls.¹² Although the use of suture to attach the uterine fundus to anterior longitudinal ligament was described in 1957,¹³ the use of a graft to bridge the vaginal vault to the sacrum was first reported in 1962.¹⁴ Suturing to the anterior longitudinal ligament at level of the sacral promontory had been recommended to minimise bleeding and to avoid lumbosacral discitis.¹⁵ An early description of graft placement described placing graft from sacral promontory along rectovaginal septum, ¹⁶ but a later study proposed attaching graft on both anterior and posterior vagina in addition to the vaginal apex to improve vaginal support across all compartment, ¹⁷ and the latter is now commonly performed.

Sacrocolpopexy can be performed via laparotomy, laparoscopy or robotically and the minimum sets of steps in the procedure were recently published. ¹² Sacrohysteropexy is the procedure when graft is attached to cervix during a similar sacrocolpopexy vault suspension while conserving the uterus. Sacrocervicopexy is undertaken concomitantly with subtotal hysterectomy. Peritoneal closure over the graft is frequently undertaken for the theoretical prevention of bowel obstruction, although there is heterogeneity in this procedural step amongst reported RCTs for sacrocolpopexy. Of note, a single retrospective series of 128 cases reported no postoperative complications when peritoneum was not closed over the graft.¹⁸

Despite standardisation of procedural steps,¹² technique variations in sacrocolpopexy remain. A variety of grafts have been used, including non-absorbable synthetic (usually type 1 macroporous polypropylene),¹⁹ absorbable synthetic (e.g., polyglactin), and biologic (e.g., autologous rectus fascia). Grafts may be either preformed or individually crafted, in either one or two pieces, and fixed to the anterior longitudinal ligament with either non-absorbable or absorbable sutures or with tacking/fixation devices. The graft can be attached to the anterior and/or posterior fibromuscular layers of vagina as well as the vaginal apex (sacrocolpopexy) or the anterior posterior cervix (sacrocervicopexy – replacing sacrohysteropexy). Vaginal graft attachment can be achieved using non-absorbable, delayed absorbable, or barbed sutures with varying number of sutures in each compartment. Although graft can be placed transvaginally prior to being attached to sacrum through and open abdominal or laparoscopic approach,²⁰ this could run into conflict with the TGA's position on transvaginally placed graft.²¹



4. Evidence & Care Pathways

4.1 Sacrocolpopexy compared to other prolapse surgery

Overall, sacrocolpopexy is associated with lower risk of recurrent prolapse symptoms, recurrent prolapse on examination, repeat surgery for prolapse, postoperative stress urinary incontinence, and dyspareunia when compared broadly with vaginal prolapse repairs with or without mesh augmentation.^{1, 22}

Compared with sacrospinous ligament suspension, sacrocolpopexy has a higher anatomical success rate, less stress urinary incontinence, and less postoperative dyspareunia, but has greater surgical morbidity ²¹ including operating time, inpatient stay, and slower return to daily activities, as well as higher cost.²³

Compared with vaginal uterosacral ligament suspension in a single RCT, sacrocolpopexy has greater anatomical success, fewer re-operations, and greater perioperative complications but no difference in prolapse symptoms or quality of life at 12 months.²⁴

Compared with vaginal hysterectomy with uterosacral suspension, uterine preservation in the form of laparoscopic sacrohysteropexy improves anatomical outcomes (C point and vaginal length on the pelvic organ prolapse quantification), estimated intraoperative blood loss, postoperative pain and functioning, and hospital stay, but open abdominal sacrohysteropexy was associated with worse outcomes in terms of bothersome urinary symptoms, operative time, and quality of life. ²⁵ Nevertheless, current evidence-based algorithms suggest vaginal-based native tissue interventions for primary uterine prolapse and reserving sacrocolpopexy for post-hysterectomy and recurrent prolapse as outlined by ACSQHC.^{1,26}

Recommendation 1	LoE (Grade)
Sacrocolpopexy, using type 1 synthetic mesh, is a recommended treatment	Evidence based
of post-hysterectomy vaginal vault prolapse, and is especially important for	recommendation
women suffering from severe prolapse or recurrent prolapse following	I (A)
previous surgery. ^{1, 26}	

4.2 Sacrocolpopexy technique variations, outcomes, and complications

Laparoscopic sacrocolpopexy is associated with lower blood loss, longer operating time, and shorter hospital stay than the open abdominal route, with no difference in objective or subjective cure rates.^{1, 22} Robotic sacrocolpopexy is associated with longer operating times and greater costs than the laparoscopic route with similar anatomic success and adverse events.^{1, 22}

For women wishing to avoid mesh, autologous fascia, allograft (including cadaveric fascia lata), or xenograft may be used. The outcomes of such procedures are less well studied with only comparative trials with small sample sizes having been undertaken. Thus far biological grafts have not shown equivalence or superiority compared to mesh.^{27,28} Further comparative trials are needed to assess these procedures further.

Sacrocolpopexy has often been combined with concurrent total or subtotal hysterectomy ²⁹ or performed with uterine conservation.^{30, 31} The confidence in surgical outcomes relating to sacrocolpopexy is largely derived from post hysterectomy prolapse data and there is a paucity of data relating to the outcomes of sacrocolpopexy with concurrent hysterectomy.



Mesh exposure was nearly six times lower (1.5% vs 8.5%) when the uterus was preserved compared with concomitant hysterectomy during sacrocolpopexy.³² Concurrent subtotal hysterectomy together with sacrocolpopexy had been advocated to reduce mesh exposure rates,²⁹ although powered morcellation [detailed in the RANZCOG statement <u>C-Gyn 33</u>: Tissue extraction at minimally invasive procedures] is often required during laparoscopic/robotic routes. A recent RCT with follow up to 24 postoperative months showed no difference in anatomical outcomes between subtotal hysterectomy/sacrocolpopexy and total hysterectomy/sacrocolpopexy, but showed more mesh exposures in the total hysterectomy group.³³

Recommendation 2	LoE (Grade)
Compared with open sacrocolpopexy, laparoscopic sacrocolpopexy has less blood loss, longer operating time, shorter hospital stay with no clinically significant difference in objective or subjective cure rates ^{1, 22}	Evidence based recommendation
Recommendation 3	LoE (Grade)
If a synthetic mesh is used, a lightweight type 1 mesh is recommended.	Evidence based recommendation II (B)
Recommendation 4	LoE (Grade)
For women wishing to avoid mesh, autologous fascia, xenograft, or allograft may be used. Outcomes of such procedures are less well studied, but recurrent prolapse may be higher in these procedures than in those where mesh is used.	Evidence based recommendation III (C)

5. Discussion and recommendations

5.1 Informed patient consent

The consent process should adhere to the principles of shared decision-making and include wide-ranging discussion of issues such as the following.

- 1. Informed consent should be recorded, supported by explicit information that should include specifically a discussion around the use of mesh.
- Women with asymptomatic prolapse do not necessarily require surgical management. The decision to
 operate should be based upon symptomatic bother from the prolapse as defined by the patient.
 There are little longitudinal data in the literature on the natural history of untreated asymptomatic
 prolapse to inform a decision for surgery in this situation.
- 3. Alternatives to surgical management, including options such as pelvic floor muscle training for mild prolapse and vaginal support pessaries.
- 4. Other alternative surgical treatments including obliterative vaginal procedures (colpocleisis), conventional vaginal native tissue repair such as sacrospinous fixation or uterosacral vault suspension, or other abdominal procedures including abdominal uterosacral vault suspension.
- 5. Surgeons performing sacrocolpopexy should have current experience in treating women with pelvic organ prolapse which includes commonly recommending conservative treatments and commonly performing a variety of prolapse surgeries. Surgeons should reserve sacrocolpopexy for women with the most severe prolapse, women with recurrent prolapse following prior vaginal surgery, or women with significant risk factors for prolapse recurrence using vaginal approaches.
- 6. Patients considering sacrocolpopexy should be provided sufficient information regarding the broad nature and effects of sacrocolpopexy. The RANZCOG patient information pamphlet on <u>pelvic organ</u> <u>prolapse</u> provides broad information, including treatment options for prolapse. The International Urogynaecological Association (IUGA) & UroGynaecological Society of Australasia (UGSA) has patient information pamphlet on sacrocolpopexy. Information is also available from ACSQHC and NZ Ministry of Health respectively.

- 7. The risks of sacrocolpopexy should be discussed in detail. General risks associated with surgery include wound infections, urinary tract infection, bleeding requiring transfusion, deep vein thrombosis, chest infection, and heart problems. Specific risks of sacrocolpopexy include exposure of mesh (3%), injury to bowel (1.4%), bladder (1.8%), or ureter, osteomyelitis and sacral discitis (<1%), conversion from laparoscopy to laparotomy, general pelvic pain or pain during intercourse (2-3%), as well as changes to bowel motions or urination. ²²
- 8. There are risks of *de novo* or occult stress urinary incontinence after any apical vault suspension procedure. These risks are higher in older women (>66 years), those with positive pessary (urine leakage) test, and those with low maximum urethral closure pressure (MUCP).³⁴ The possibility of "new" exertional/stress urinary incontinence should be discussed, including that further treatment may be needed.
- 9. 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. Potential benefits and complications of transvaginal mesh specifically are detailed in the RANZCOG statement: <u>C-Gyn 20</u>: Polypropylene vaginal mesh implants for vaginal prolapse (2022).
- 10. Complications of transvaginal mesh to be discussed must include mesh exposure/erosion, vaginal scarring/stricture, fistula formation, dyspareunia, and 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 also be discussed.
- 11. 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.

5.2 Perioperative management

The following issues should be taken into consideration in the perioperative management of women undergoing sacrocolpopexy in accordance with Enhanced Recovery after Surgery (ERAS) principles.

- 1. In women with significant medical comorbidities, preoperative medical optimisation may be useful as "poor functional status", as defined by higher ASA physical status classification system, is associated with longer hospital stays.
- 2. The use of mechanical bowel preparation should be reviewed in light of evidence that there was no sustained benefit for surgical field visualisation quality or perioperative patient comfort. ³⁵
- 3. Although preoperative IV acetaminophen does not reduce postoperative pain, combined general plus spinal anaesthesia improves pain scores with reduction in analgesic drug requirements when compared with general anaesthesia alone.³⁶
- 4. Single dose antibiotic prophylaxis has similar postoperative infection/urinary tract infection (UTI) rates, compared with multi-dose regimens.³⁷
- 5. Urinary catheter removal should be considered after at least one day, given earlier removal could lead to a higher risk of urinary retention and decreased time to first void with no difference in UTI rates.³⁸
- 6. Time to first bowel movements is reduced with regimen involving multiple laxatives (e.g. Ducosate, polyethylene glycol) and suppositories (bisacodyl) compared with single medication or placebo.³⁹





5.3 Surgical training

Sacrocolpopexy is not an isolated surgical skill. Clinicians require extensive knowledge and experience in pelvic anatomy and physiology, evaluation of urinary incontinence and bowel function, and general reconstructive pelvic surgery including all conservative and surgical management options. This includes specific supervised training in sacrocolpopexy technique, including via laparotomy in case open conversion is required.

For credentialing standards, this procedure is considered a RANZCOG Level 6 procedure. This requisite knowledge and experience for sacrocolpopexy is met through the RANZCOG Urogynaecology Subspecialty training program and in trainees who have frequently performed this procedure during their training. Skills in cystourethroscopy are also required. Furthermore, surgeons require knowledge of intraoperative and postoperative complications and their management.

Whilst there are no studies looking at the association between POP recurrence and a surgeon's training and work load, there is evidence to suggest that subspecialisation and high work load might be associated with a better outcome in terms of success and failure in relation to continence surgery ⁴⁰ and other conditions, such as hernia.⁴¹ A multivariate logistic regression analysis of the outcome of vaginal wall mesh repair showed that a surgeon's experience, defined as having performed 50 or more mesh repairs, is significantly associated with a reduced risk of POP recurrence.⁴²

The learning curve for sacrocolpopexy is substantial. Using indicators such as duration of surgery, conversion to laparotomy and operative complications, the literature describes a range of 18 to 93 cases before a steady state in competency is reached. Some of these reports include the initial training period, albeit for experienced prolapse surgeons. The Royal College of Obstetricians and Gynaecologists (RCOG) curriculum suggests a minimum of twenty supervised cases as the primary operator for a trainee to reach a safe standard.⁴³

5.4 Credentialing

Only surgeons trained and credentialed for open, laparoscopic, or robot-assisted sacrocolpopexy should perform this procedure.

Credentialing of clinicians practising in Australia remains the responsibility of individual institutions which must have clear mechanisms to determine a clinician's capacity to provide safe and effective care based on demonstrated procedural and non-procedural skill acquisition and maintenance. RANZCOG recommends that the following points are considered by institutions for credentialing in sacrocolpopexy.

- 1. Transabdominal 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 RANZCOG Urogynaecology Subspecialty training program or equivalent.
- 2. 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 abdominal mesh surgery.
- 3. Surgeons should demonstrate experience and expertise to perform intraoperative cystoscopy to evaluate for bladder and ureteral integrity.



- 4. Surgeons should demonstrate knowledge of the management of intraoperative and postoperative complications of abdominal surgeries.
- 5. Surgeons performing prolapse surgery should ensure that they perform pelvic floor surgery (any route) regularly enough to maintain expertise.
- 6. Surgeons should be familiar with ACSQHC or New Zealand Ministry of Health guidance on the management of prolapse, including patient information resources and treatment algorithms.⁴⁴⁻⁴⁶
- 7. Surgeons are encouraged to undertake regular audit of their cases through mesh registry or surgical databases. Patients should undergo a minimum six-month follow up (consistent with ACSQHC guidance) and outcomes should be clearly recorded through properly maintained logbooks, other suitable documentation, or a secure surgical database. To evaluate post-operative data, appropriate pre-operative data, including demographic data, should be collected.

Recommendation 5	LoE (Grade)
Only surgeons trained and credentialed for open, laparoscopic, or robot- assisted sacrocolpopexy should perform this procedure. Surgeons who perform sacrocolpopexy should frequently see women with POP and commonly both recommend conservative treatments and perform a variety of prolapse surgeries, reserving sacrocolpopexy procedures for appropriate cases.	Evidence based recommendation III (C)
Recommendation 6	LoE (Grade)
Surgeons should be familiar with the ACSQHC or NZ Ministry of Health recommendations, patient pamphlets, and treatment algorithms for POP. ⁴⁴⁻⁴⁶	Evidence based recommendation III (C)
Recommendation 7	LoE (Grade)
Patients should undergo a minimum of six months of follow up, including collecting patient outcomes, which should be clearly recorded through properly maintained logbooks, other suitable documentation, or a secure surgical database. To evaluate post-operative data, appropriate pre-operative data should be collected, including the collection of demographic data.	Evidence based recommendation III (C)
Good Practice Point	
As of mid-2022, the Australasian Pelvic Floor Procedure Registry (APFPR) will include mesh procedures for vaginal prolapse. Surgeons and healthcare operators (including New Zealand based surgeons) should be encouraged to enter their data into the registry.	

As of mid-2022, the Australian Pelvic Floor Procedures Registry (APFPR) will include mesh procedures for prolapse (<u>www.apfpr.org.au</u>). The APFPR collects pre-operative and validated patient reported outcome measures, with capability for >6 month patient follow up data. Once mature, the APFPR will provide both public and surgeon level information on devices inserted, complications and outcomes to inform clinical practice. The registry will publish publicly available annual data reports. 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: <u>http://www.tga.gov.au/safety/problem.htm.</u> In New Zealand, this should be done through the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE). The link is: <u>http://www.medsafe.govt.nz/safety/report-a-problem.asp</u>



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7. 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

Polypropylene vaginal mesh implants for vaginal prolapse (<u>C-Gyn 20</u>)

https://ranzcog.edu.au/getattachment/Statements-Guidelines/Gynaecology/Polypropylene-Vaginal-Mesh-Implants-for-Vaginal-Pr/Polypropylene-vaginal-mesh-implants-for-vaginal-prolapse-(C-Gyn-20).pdf?lang=en-AU&ext=.pdf

Tissue Extraction at Minimally Invasive Procedures (C-Gyn 33)

https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-

MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20Gynaecology/Tissue-

Extraction-at-Minimally-Invasive-Procedures-(C-Gyn-33)-review-March-2017.pdf?ext=.pdf

Pelvic Organ Prolapse Patient Information Pamphlet

https://ranzcog.edu.au/RANZCOG SITE/media/RANZCOG-

MEDIA/Women%27s%20Health/Patient%20information/Pelvic-Organ-Prolapse-KK19.pdf?ext=.pdf



Appendices

Appendix A: Women's Health Committee Membership

Name	Position on Committee
Dr Scott White	Chair
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Anna Clare	Deputy Chair, Obstetrics
Associate Professor Amanda Henry	Member and Councillor
Dr Samantha Scherman	Member and Councillor
Dr Marilla Druitt	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Dr Kasia Siwicki	Member and Councillor
Dr Jessica Caudwell-Hall	Member and Councillor
Dr Sue Belgrave	Member and Councillor
	Aboriginal and Torres Strait Islander
Dr Marilyn Clarke	Representative
Professor Kirsten Black	SRHSIG Chair
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 Leigh Toomey	Community Representative
Dr Rania Abdou	Trainee Representative
Dr Philip Suisted	Māori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Steve Resnick	Co-opted member

The Women's Health Committee acknowledges the significant contribution of the RANZCOG Urogynaecology Committee (CU) in the development of the statement.

Appendix B: Urogynaecology Committee Membership

Name	Position on Committee
A/Prof Emmanuel Karantanis	Chair
Dr Alex Mowat	Deputy Chair
Dr Peta Higgs	Elected Subspecialist
Dr Fay Lin Chao	Elected Subspecialist
Dr Salwan Al-Salihi	Elected Subspecialist
Dr Bernadette Brown	Elected Early Career Subspecialist
A/Prof Joe Lee	Written Exam Coordinator
Dr Tim Dawson	NZ Fellow (co-opted)
Dr John Regan	Chair Subspecialties Committee
Dr Elizabeth Gallagher	Deputy Chair Subspecialties Committee



Appendix C: Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in early 2022 by the Urogynaecology committee and was most recently reviewed by the Women's Health Committee in March 2022. 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 2022* 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 level of evidence and 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. Level of evidence reflects the best study types for the specific type of question. The most appropriate study design to answer each type of clinical question (intervention, diagnostic accuracy, aetiology or prognosis) is level II evidence. Level I studies are systematic reviews of the appropriate level II studies in each case. Study designs that are progressively less robust for answering each type of question are shown at levels III and IV.

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	А	Body of evidence can be trusted to guide practice
	В	Body of evidence can be trusted to guide practice in
		most situations
	С	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 D: Full Disclaimer

Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning surgical treatment of pelvic organ prolapse 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 and the particular circumstances of each case.

Quality of information

The information available in this statement 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) has endeavoured 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. The use of this information is entirely at your own risk and responsibility.

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Version	Date of Version	Pages revised / Brief Explanation of Revision
v1.1	Mar-May / 2022	Dr Joe Lee/ RANZCOG Urogynaecology Committee / RANZCOG Women's Health Committee

Policy Version:	Version 1.1
Policy Owner:	Women's Health Committee
Policy Approved by:	RANZCOG Council/Board
Review of Policy:	March / 2027