



Position statement on midurethral slings

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.

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Current: July 2020
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Background: This statement was first developed by RANZCOG in March 2014 and most recently reviewed in July 2020.

Funding: This statement was developed by RANZCOG and there are no relevant financial disclosures.

1. Plain language summary

Stress urinary incontinence (SUI) is an extremely common¹, burdensome and costly condition for women in Australasia, with a negative impact on a woman's quality of life. SUI is the type of urinary leakage associated with physical exertion, such as coughing, laughing and sneezing. SUI is caused by a weakness in the urethra or neck of the bladder, which means it cannot keep fully closed during exertion, allowing urine to escape.

Non-surgical, conservative measures such as pelvic floor muscle training and behavioural modifications are first line treatment options for SUI.² If conservative treatments are not successful, surgery may be offered. For those with severe stress urinary incontinence, mid urethral surgery may be a more effective option.³

There are a number of different types of surgery for SUI. Midurethral sling (MUS) surgery is the most common surgery performed for SUI in women. Many studies have shown this surgery to be highly effective and to improve women's quality of life overall.

There are three different insertion methods for these slings currently available in Australia

- Retropubic (RP) MUS: This is the oldest and most studied MUS. The incisions are in the vagina and just above the pubic bone.
- Transobturator (TO) MUS: This sling has incisions in the vagina and in the groin area.
- Single incision (SIS) MUS: This is the newest and least studied MUS. The only incision is in the vagina.

For the purposes of the rest of this statement, the term Midurethral Sling (MUS) refers only to Retropubic and Transobturator slings.

These procedures have good success and safety profiles, however surgical failures and complications are possible. The different approaches have different risks and their use depends on patient factors and surgical experience. The type of MUS, risks and success rates should be discussed by the treating surgeon with any woman considering surgery.⁴ Alternative surgical procedures should also be discussed.

2. Summary of recommendations

Recommendation 1	Grade and references
MUS surgery is a recommended surgical procedure for SUI in routine cases.	Grade A

Recommendation 2	Grade
Local credentialling, provision of written information (particularly from the Australian Commission of Safety and Quality in Health Care); Clinical Audit (logging of cases and follow-up) and Patient Reported outcomes are essential for gynaecologists undertaking MUS procedures ^{5,6} .	ACSQHC Guideline
Recommendation 3	Grade
Single Incision Slings (SIS) should be performed <i>only</i> within the context of a properly conducted clinical trial or where arrangements are in place for clinical governance such as long-term prospective audit. <i>Although several comparative trials are ongoing, currently available Single Incision Slings (SIS) have not yet demonstrated equivalence to MUS.</i> ^{7,8}	Consensus-based recommendation

3. Introduction

This position statement by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) supports the use of mid-urethral slings (MUS) in the surgical management of female stress urinary incontinence (SUI). Mid-urethral slings are minimally invasive procedures developed in the early 1990s to treat female SUI. These slings are narrow, synthetic polypropylene mesh tapes that are surgically placed beneath the middle part of the urethra to provide dynamic support to the urethra, preventing urinary leak during physical exertion.

The USA Food and Drug Administration (FDA) released a white paper⁹ and safety communications¹⁰ regarding safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. A prolapse is where the pelvic organs bulge downwards giving rise to symptoms of an uncomfortable vaginal lump. Media attention on this totally distinct and separate issue of mesh use in women for pelvic organ prolapse (not stress urinary incontinence) has the potential to cause unnecessary confusion and fear in women considering MUS for treatment of stress urinary incontinence. RANZCOG strongly emphasise that the US FDA publications clearly state that traditional MUS were not the subject of their safety communication.

There is an extensive body of literature, including comparative trials on synthetic slings. MUS surgery is highly effective in the short and medium term for treatment of urinary stress incontinence. This recommendation is supported by the International Cochrane review Group on Urinary Incontinence.⁴ (Grade A). It is also supported by the European Safety Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR); to which a member of the Australian Therapeutic Goods Administration (TGA) contributed as an external advisor.¹¹ The MUS carries less risk than most other available major continence surgeries.^{11,12} This has resulted in MUS becoming the operation of choice in Europe, Australasia^{13,14} and the USA¹⁵ for treatment of SUI.

Further opinions from the European Commission and NHS Scottish review as well as the ACSQHC of current gynecological practice and of the literature regarding vaginal mesh have both supported the use of traditional MUS for stress urinary incontinence with both the RP and TO approaches demonstrating efficacy for the treatment of SUI with fewer adverse outcomes than from other available continence surgeries such as colposuspensions and fascial bladder neck slings.^{11,12}

The most recent of all the published reviews, the NHS Scottish review, notes that the two approaches have different types and rates of complications. The TO approach can result in persistent groin and pelvic pain which may require removal of the mesh. The RP approach has higher rates of visceral injury. They therefore recommended the RP approach as routine surgery for SUI unless the presence of other risk factors have a significant effect on the implications of visceral injury.¹² However, other reviews including the Cochrane review, European Commission and NICE guidance have not recommended one approach over the other at this stage.^{4,8,11}

Surgeons practicing in Australia need to be aware of the current guidance from the Australian Commission on Safety and Quality in Health Care (see link below), which recommends RP MUS as the preferred approach.

<https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/resources/care-pathway-sui>

Comparison of Retropubic and Transobturator MUS Outcomes:

Outcome	Retropubic (RP)	Transobturator (TO)
Subjective and objective success rates (short-medium term)	Similar	Similar ⁴
Longer-term (>5 years) success	Possibly higher ⁴ – more data is required	
Effectiveness in Intrinsic Sphincter Deficiency (low midurethral closure or valsalva leak point pressure)	More effective	Higher failure rate ^{8,16}
Visceral injury (including bladder perforation, major injury blood loss)	Higher rates	Lower rates ⁴
Length of hospital stay	Longer	Shorter ⁴
Post-operative voiding dysfunction and risk of need for re-intervention	Higher	Lower ⁴
Post-operative pain	Suprapubic - lower rate	Groin - higher rate – may become chronic ^{4,11,12}
Mesh exposure rate	Approx. 2%	Approx. 2% ⁴

Potential for complete mesh removal	Usually possible	More difficult, often incomplete ^{8,12}
Re-operation for recurrent SUI in the mid- to long-term	Lower rate	Higher rate ^{4,11,12}

- On the basis of this comparison, the TO approach may be preferred: in women with extensive previous abdominal surgery.
- in women who are unable to cease anti coagulation.
- In women with compromised voiding pre-operatively (although in these women, not performing MUS or any continence surgery should be discussed, as all continence surgeries may further compromise voiding function).

Complete removal of RP mesh (if needed) is usually achievable in a combined vaginal and laparoscopic-open procedure. The ACSQHC stipulates guidelines on who can remove mesh¹⁷. Mesh removal centres have been established.

Complete removal of TO mesh can be far more difficult and in the longer-term mesh removal is often incomplete.^{8,12} It can be a morbid procedure that requires bilateral groin incisions. Pain may not resolve. These women may require multidisciplinary team care, including physiotherapy with an experienced practitioner who can address pelvic pain symptoms and pain clinic team.

Single incision MUS (SIS):

There has been the introduction of single incision slings (SIS) or “mini-slings”. These slings are also placed at the mid urethra, with less dissection and a smaller length of mesh, *but are heterogeneous in their tape characteristics as well as anchorage*. Studies of these slings, to date, have not shown them to be as successful as RP or TO MUS. A number of SIS have recently been withdrawn from the market. There are ongoing comparative trials of SIS against RP/TO slings but their longer-term data have not matured. Until such data exist, RANZCOG recommends the use of single incision slings only within the setting of a properly conducted clinical trial or under strict institutional clinical governance such as a long-term prospective audit. ^{7,8}

4. Considerations prior to surgery

1. All women should be recommended to undertake pelvic floor physiotherapy and/or see a continence nurse advisor for pelvic floor exercises and bladder retraining as first line of treatment.²
2. Women who fail conservative treatments can be offered continence surgery including MUS.

3. Gynaecologists need to be transparent and make clear, prior to surgery, that polypropylene tapes are mesh materials, though used in much smaller amounts than when used for vaginal prolapse surgery. Some mention of the recent class action between Shine Lawyers and Johnson and Johnson is needed, in particular to highlight that many companies make similar polypropylene meshes, and that Johnson and Johnson meshes are not different to these.
4. Women contemplating continence surgery should be aware of the other surgeries available to them, including their success rates, recovery time, longevity, and complications. Women contemplating surgery should read the relevant documents to their country, as below:

Australian Commission on Safety and Quality in Health Care

<https://www.safetyandquality.gov.au/sites/default/files/migrated/Treatment-Options-SUI-Consumer-Info.pdf>

New Zealand Ministry of Health

<https://www.health.govt.nz/system/files/documents/publications/considering-surgical-mesh-to-treat-stress-urinary-incontinence-aug2019.pdf>

5. Prior to proceeding with surgery, urodynamic study should be considered to exclude other causes of urinary incontinence, exclude voiding dysfunction and evaluate for ISD. However, the evidence regarding improvement in outcomes after urodynamic studies is lacking.¹⁸
6. Individual patient needs and preferences must be taken into account. Patients must have adequate opportunity to make informed decisions in partnership with health care professionals.
7. Success rates for obese women who undergo MUS are significantly lower compared to women of normal BMI and weight loss strategies should be discussed pre and post operatively with these women.^{19,20}
8. Success rates must be discussed with women considering surgery including the different success rates associated with each MUS route.
9. Complications must be discussed with women considering surgery including the different complications associated with each MUS route. Discussion must include bleeding, damage to the bladder and urethra, bowel and major vessel perforation. Voiding difficulties which may require catheterisation, loosening or even division of the sling at a later stage, which may result in recurrent SUI.²¹ De novo urge incontinence or worsening of pre-existing overactive bladder symptoms can occur. Sling insertion can cause pain and dyspareunia and with the TO sling, groin pain can occur. This is usually short lived but may become intractable.⁴ In some women these long-term adverse outcomes have had severe effects on everyday activities and their quality of life.¹² The mesh is a permanent material that can result in mesh exposure and infection or vaginal pain or burning which usually will develop soon after surgery or in some cases many years later.

10. A particular procedure chosen by a woman cannot be provided by the gynaecologist or health service, referral is needed to a doctor or department where such treatment can be provided.

5. Mesh Erosion

In the recent Federal Court of Australia ruling, chronic pain was judged to occur in up to 5% of women having a synthetic mesh midurethral sling.²² The range of severity of the chronic pain, however, is variable. For some of these 5% of women, the pain is debilitating and disabling, and can take place in the long term. The court ruling highlighted that the mesh material can produce an oxidative reaction, which is potentially ongoing. We presume that this reaction in the majority of these women is mild, but in a small fraction of the 5% of women, the reaction is severe, causing pain and mesh exposure. The pain could also occur with sexual intercourse (including to the partner).

It is impossible to predict which women will have an erosion. Removal of the midurethral sling for severe debilitating pain occurs in about 1 per 150 women in the long term.²³ Mesh in RP MUS can be entirely removed in most cases, with a recent systematic review indicating resolution of pain in 81% of cases.²⁴ However, a fifth of patients undertaking mesh removal, which may be difficult or associated with its own complications, may not experience resolution of their symptoms.

Women need to be informed that the incidence of chronic long-term pain or dyspareunia from Burch colposuspension and pubovaginal slings is unknown, as data is sparse, and these operations have not been performed often enough in recent times. However, chronic pain following these conditions has been reported.²⁵

6. Surgical Training

1. As with all surgical procedures, adequate supervised training should be obtained in the particular surgical technique and device to be performed. Studies show a learning curve for all urogynaecological procedures and surgical complication rates are higher during this time. MUS surgery should only be undertaken by those regularly carrying out MUS surgery.^{8,26,27} To understand credentialing requirements for performing MUS, gynaecologists are required to read the ACSQHC document titled "Guidance for Hospital Credentialling for Senior Medical Practitioners to undertake Transvaginal Mesh Surgery for Stress Urinary Incontinence"⁶. Importantly a surgeon performing less than 10 continence cases per year requires another period of supervision (though this requirement pertains to Australia and credentialing guidelines are currently underway in New Zealand).
2. Surgeons should demonstrate experience and expertise to perform intraoperative cystourethroscopy to evaluate for bladder and urethral integrity, and this is recommended practice for insertion of all types of MUS.

3. Surgeons should demonstrate knowledge of the management of intra- and post-operative complications of MUS surgery.
4. Surgeons need to be aware of the surgical complications of MUS including the different risks of the various approaches. The RP approach of MUS carries a higher risk of bladder, visceral and vascular injury during insertion and voiding dysfunction post operatively while the TO approach of MUS has a higher risk of groin pain and reoperation for SUI in the longer term.⁴ The TO approach has a higher risk of failure in women with ISD and the RP approach should be performed in these women.^{8,16} The TO approach is more appropriate if there is the risk of intra-abdominal organ injury due to extensive abdominal surgery.¹²

7. Monitoring of Efficacy and Safety

1. As for all surgical procedures, regular clinical audit is a powerful tool to monitor efficacy and safety. It is recommended that surgeons performing MUS log their MUS outcomes onto a recognised database or registry (such as the UGSA or IUGA Databases) and advise regulatory bodies of adverse events.^{8,11} At the time of preparation of this document, the Australian Pelvic Floor Procedures Registry is being developed.

2. All gynaecologists should take responsibility for auditing and reporting adverse events from mesh surgery.

In Australia this is via the Therapeutic Goods Administration. The link appropriate to reporting problems with a medical implant is: <http://www.tga.gov.au/safety/problem.htm>

In New Zealand, this is via the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE). The link is: <http://www.medsafe.govt.nz/safety/report-a-problem.asp>

3. Women undertaking MUS surgery should receive information for use of the product from the manufacturer, the product details and batch number.
4. ACSQHC mesh insertion credentialling Guidelines⁶ have recommended a minimum 6 month follow up for women undergoing MUS surgery with clear documentation. Documentation includes:

1. Patient reported level of improvement and satisfaction
2. Objective measures of incontinence
3. Urinary retention
4. Overactive bladder
5. Persistent Groin or pelvic pain

A pre-op and post-op (6 weeks and 6 months) patient-completed questionnaire for incontinence symptoms and pain is recommended.

8. Conclusion

There is robust evidence to support the use of traditional MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated surgical procedure for female stress urinary incontinence.^{4,8,11} In Australia and New Zealand, the MUS has become the operation of choice for female SUI. RANZCOG supports the use of synthetic MUS for surgical treatment when conservative treatment has been unsuccessful.

There are different risks and long-term outcomes from different surgical approaches which need to be discussed and tailored to each individual woman.

Surgeons who perform MUS need to be aware of the risks and benefits of each approach and appropriately trained to perform these surgeries and manage the possible complications.

9. References

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10. Patient information

A range of RANZCOG Patient Information Pamphlets can be ordered via:

<https://www.ranzcog.edu.au/Womens-Health/Patient-Information-Guides/Patient-Information-Pamphlets>

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
Associate Professor Ian Pettigrew	Member and EAC Representative
Dr Kristy Milward	Member and Councillor
Dr Will Milford	Member and Councillor
Dr Frank O'Keefe	Member and Councillor
Professor Sue Walker	Member
Professor Steve Robson	Member
Dr Roy Watson	Member and Councillor
Dr Susan Fleming	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	ATSI Representative
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 Rebecca Mackenzie-Proctor	Trainee Representative
Dr Leigh Duncan	Maori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Christine Sammartino	Observer

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 March 2014 and was most recently reviewed in July 2020. 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.
- At the May 2020 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.¹⁷ 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 D 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.