



**The Royal Australian
and New Zealand
College of Obstetricians
and Gynaecologists**
Excellence in Women's Health

College House
254–260 Albert Street
East Melbourne Victoria 3002
Australia
telephone: +61 3 9417 1699
facsimile: +61 3 9419 0672
email: ranzocg@ranzocg.edu.au
www.ranzocg.edu.au
ABN 34 100 268 969

Senate Community Affairs Reference Committee

RANZCOG Submission to the Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) welcomes the opportunity to provide this submission to the Senate Community Affairs Reference Committee regarding the Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters.

This submission is based on the RANZCOG statements on consent and the provision of information to patients[1], mid urethral slings (MUS) in women with stress urinary incontinence (SUI)[2] and the use of transvaginal mesh in women with pelvic organ prolapse (POP).[3]

RANZCOG acknowledges the very distressing problems that some women have experienced following transvaginal mesh surgery. As with all patients who experience complications from their treatments, RANZCOG extends its utmost sympathy.

Introduction

Urinary incontinence and pelvic organ prolapse are both common and distressing conditions affecting women, particularly following vaginal birth and in the post-menopausal period. These conditions, while not life threatening, may be very distressing. While conservative treatments may be helpful, in many cases surgical intervention is requested or required to relieve the woman's symptoms. It has long been recognised that surgical treatments for these conditions (especially POP) are not always successful, particularly in the long term, and surgeons have tried many different surgical approaches in the attempt to minimise the disappointment and distress of women having a premature recurrence of their prolapse that might need further surgery.

It is important to understand that urinary incontinence and pelvic organ prolapse are **different conditions**, with each condition requiring separate assessment. Both conditions are often present in the same woman and the surgeries for the two conditions may be performed concurrently. While sling implants for urinary incontinence and the transvaginal mesh implants used for the treatment of POP are usually made of the same synthetic polypropylene mesh, the surgeries for each condition are distinctly different from each other. MUS for SUI use a smaller strip of mesh than the transvaginal meshes used for POP. MUS are located under the urethra while transvaginal meshes for POP are deeper in the vagina. For this reason, it is important to present findings about these conditions and their meshes separately rather than under one umbrella.

Stress Urinary Incontinence (SUI) and Midurethral Slings (MUS)

SUI is the condition of involuntary urinary leakage which occurs with events such as coughing, sneezing, and exercise. It is very common with one in three women experiencing urinary incontinence after childbirth.[4] When conservative (non-surgical) treatments are unsuccessful, there are a number of surgical treatments available. In the early 2000's, synthetic mesh mid-urethral slings (MUS) were introduced to Australia for the treatment of SUI. These are 1 cm wide strips of mesh, and placement of MUS is now regarded as the "gold standard" for SUI surgery.

Success rates for use of MUS are high with rates of complete cure or significant improvement of 80-90%.[5, 6] The majority of women who undergo these surgical treatments have improved quality of life. A PubMed literature search of the term "Tension Free Vaginal Tape (the most commonly used MUS) reveals over 3,000 publications on this procedure in the literature. A PubMed literature search of the term 'Midurethral Slings' produces more than 2,600 publications making these procedures the most extensively researched continence procedures. High quality clinical studies have demonstrated their effectiveness in the short to medium term with increasing evidence for their effectiveness in the long term.[6]

Review of the MUS compared to previously available surgeries for SUI (open colposuspension, urethral injection, suprapubic surgery (non-mesh)) have shown that the MUS has a lower complication rate overall compared to the previous surgical treatments for SUI and/or higher efficacy.[5] Recently published information regarding Burch colposuspension which was the operation previously performed most commonly for SUI prior to introduction of the MUS, reported 12 year follow up data. This published information showed the cumulative recurrence rate in women with pre-operative SUI was significantly higher after the Burch procedure than MUS. There were no significant differences in rates of perioperative and late complications. At 12 years, there was a significant increase in rates of repeat surgery for incontinence and prolapse in women after the Burch procedure.[7] This is why MUS is now viewed as the "gold standard", although we note that is not always 100% effective in the short or long-term.

There are complications which are specific to MUS including mesh erosion/exposure. Some types of MUS procedures can cause groin pain. RANZCOG strongly encourages surgeons who perform these surgeries to discuss the risks and benefits of these procedures with women considering continence surgery, to obtain appropriate training in each procedure performed, and to be aware and able to manage complications if and when they arise.[2]

Pelvic Organ Prolapse (POP) and Transvaginal Mesh for POP

POP is a condition of weakness of the supporting tissues of the vagina and uterus. Women experience a sensation of lump in the vagina, discomfort, and a 'dragging' sensation in the pelvis. This can result in functional changes affecting the bladder and bowel, as well as sexual function. There are many surgical procedures available for treatment of POP. The use of a woman's own tissues (native tissue repair) has a recognised failure rate and commonly a need for repeat surgery, especially in the long term. The theory of using mesh reinforcement to improve outcomes has been supported by the use of synthetic mesh in abdominal sacral colpopexy. This surgery involves synthetic mesh attached to the upper vagina and attached to the sacral promontory through an abdominal approach. This approach has been shown to improve objective success rates compared to the vaginal approach in the treatment of upper vaginal prolapse.[8] Transvaginal mesh was therefore introduced with the aim of better success rates than the traditional native tissue repairs and initial trials were promising. There has been an evolution and refinement in the types of mesh used, with woven macroporous monofilament polypropylene now the standard mesh type.

Subsequent studies have shown that the use of transvaginal mesh is associated with lower rates of awareness of POP by women and less POP on examination compared to native tissue surgery. However, use of mesh in repair of POP is associated with higher rates of complications. For this reason, the use of transvaginal mesh is not recommended for routine POP surgery. [3] Although most women treated using transvaginal mesh for POP have not had significant problems and excellent results, the overall the rate of mesh complications has been reported as 12%.[9] The impact of the complications varies from minimal to severe.

Many mesh products have now been voluntarily withdrawn from the market by the manufacturers. Gynaecologists are now advised to use the currently available devices only in specific circumstances where there is anticipated to be a higher rate of recurrence with native tissue surgery, and ideally only in the setting of a clinical trial.[6,3] As with all surgical procedures, RANZCOG strongly encourages surgeons to discuss the potential risks and benefits of procedures with women considering POP surgery, to discuss other alternative surgical approaches, to obtain appropriate training in each surgical technique, and to be aware of and able to manage complications that may arise.[3]

1 a. The number of women in Australia who have had transvaginal mesh implants

We have attempted to provide separate data on the number of women having Midurethral Slings for SUI and women having transvaginal meshes for POP.

The main limitation to accurately tracking mesh usage is that most coding is procedure based and does not capture data on whether a mesh device or native tissue was used as part of the procedure. Possible sources of data to inform the response to how women in Australia with mesh implants include Medicare item numbers, Australian Institute of Health and Welfare ICD-10 codes, the UroGynaecological Society of Australia Voluntary database or mesh companies. The limitations of data from each of these sources are explored below.

Midurethral Slings for SUI

Studies have investigated the trends in SUI surgery in Australia and found that from 1994 to 2009, the overall number of female SUI operations has increased, almost doubling over a 3-year period following the introduction of the MUS.[11] The per capita rate increase in all SUI surgery is most prominent in women over the age of 55 years, compared with younger women, over the 15-year period.[11] MUS have overtaken Burch colposuspension as the most utilised operation for female SUI across all age groups, accounting for 85.5% of all procedures performed in 2009 with 14 MUS for every one colposuspension.[11]

It is estimated that in 2012, one out of 1000 women in Australia underwent continence procedures and the majority of these would have been MUS surgery.[12]

Data regarding the use of MUS are available from the Australian Institute of Health and Welfare (AIHW), as they have separate coding according to ICD-10 coding system, however there are caveats when interpreting this data. The data for use of MUS, and follow-up procedures associated with MUS surgery – either revision or division of the sling – are presented in the table below. These data should be interpreted with caution as AIHW may be over-estimating the numbers because division/excision of POP vaginal mesh may also use the 37340 number. AIHW uses the Australian Modification of the ICD-10 and this is largely based on MBS item numbers, to make coding of private procedures easier. AIHW does however list every surgical procedure done in Australia, both in public and private settings. Another concern is that AIHW data is collected by medical administrators (coders) who come from a non-clinical background and therefore there can be errors in interpretation of the procedures.

Table 1: ICD-10 coding of Sling Procedures (source AIHW data cubes)

	35599-00 Sling Procedure	35599-01 Sling Revision	37340-00 Sling Division
2002-03	5558	152	242
2003-04	6353	180	344
2004-05	7745	235	392
2005-06	7921	239	369
2006-07	7861	230	300
2007-08	8433	231	309
2008-09	8860	245	373
2009-10	9029	251	370
2010-11	9225	262	403
2011-12	9240	259	409
2012-13	8834	280	416
2013-15	17091	494	792
TOTAL	106,150	3058	4719

This data demonstrates a 7.3% incidence of sling revision or division in the 2002-2015 time period which is higher than would be expected compared to published data. There may be an overestimation from these figures as the coding may have been used in mesh revision for POP cases as there is no ICD coding number for this procedure. More rigorous auditing of the data would be required for conformation of these figures.

Medicare item numbers have been considered as a means of tracking numbers of non-MUS transvaginal mesh procedures performed. However, MBS data are only collected from the private sector and do not include operations performed in public hospitals, which make up almost half of surgery performed in Australia.

The UroGynaecological Society of Australasia (UGSA) houses a voluntary database on urogynaecological procedures. The information from this database is not really helpful for the overall mesh picture as it has data predominantly from sub-specialists whose practice is skewed to the more complex patients. However upon request, UGSA were able to obtain reasonably accurate estimations from sources here and overseas. From 1999 when the first midurethral slings were performed in Australia, approximately 120,000 women have had a mid-urethral sling procedure. These numbers seems consistent with the AIHW figures.

Transvaginal mesh in prolapse

The exact number of women who have had transvaginal mesh placed as part of a procedure for treatment of POP in Australia is unknown.

In 2012, it was estimated that 2.3 out of 1000 Australian women underwent surgery for prolapse (POP) but the percentage of these with transvaginal mesh is unknown. Again in Australia, coding of surgery for prolapse procedures does not distinguish whether mesh or native tissue repair was used for so we can't make any conclusions locally about how much mesh has been used in prolapse surgery in Australia. However, internationally we know that in this time period, other countries reported that the rate of mesh usage was 15.7% and it would be reasonable to expect that Australian usage was similar.[12]

Again the use of Medicare item numbers is problematic with regard to POP surgery. The significant limitation of Medicare item numbers is that the item numbers for POP repair do not specify whether mesh was used in the repair. In order to accurately track mesh usage, possible complications and removal, there should be consideration in future of separate MBS item numbers for native tissue repair and transvaginal mesh repair and for the removal of mesh following prolapse repair.

Data obtained from UGSA sources estimate that after 2004-5 when the mesh kits were available, approximately 33,000 women had a vaginal mesh repair for prolapse. Some of these women may of course have had both a sling and a prolapse repair. Rates of mesh usage varied over this time with the major decline seen this decade. On average for the whole period, one in eight prolapse repairs utilised mesh. Unfortunately it is not possible to know how many of these were cases of recurrent prolapse and/or patients with other comorbidities.

The mesh companies could be individually contacted to report on number of sales of transvaginal mesh products. However with up to 100 different companies being suppliers of mesh at various points in time, (some of which have now been withdrawn from the market), this information is difficult to accurately capture. Additionally, the suppliers can provide data on how many mesh products were sold but this would not be completely accurate as some mesh kits would have been opened and discarded, some women may have had a number of kits implanted either concurrently (e.g. for SUI and POP) or at different times. It would, however, provide a rough estimate of the number of mesh kits used.

Mesh surgeries for SUI and POP

The New Zealand Accident Compensation Corporation (ACC) Surgical Mesh Review used data relating to the number of mesh devices sold in New Zealand for the period of January 2009 to October 2014.[13] The number of mesh devices sold in this period for POP, SUI and hernia surgery was 56,508 devices. The percentage of claims made to the ACC for POP was 3.3% and for SUI was 0.7%. It is likely that there was an under-reporting of surgical complications, however it would be reasonable to expect that the Australian and New Zealand experience with mesh is similar.

Estimating numbers of Australian women would also be possible in Australia by contacting each mesh company and requesting these numbers. This would not be completely accurate as some mesh kits would have been opened and discarded, some women may have had a number of kits implanted either concurrently (e.g. for SUI and POP) or at different times. It would, however, provide a rough estimate of the number of mesh kits used.

In Australia, while all implanted devices are recorded, this is currently the responsibility of each hospital and how these data are collected and stored varies between hospitals and states. These data are not easily accessible with some data collected electronically while some data is paper based.

Future considerations

For future planning, inclusion of implanted devices onto the Medicare personal health record could be considered. Each individual patient would be able to access their electronic health record and have access to the type and number of implanted devices.

A system of coding for both SUI and POP surgery, with and without mesh and the coding of mesh complications in both public and private sectors with development of separate Medicare item numbers for native tissue repair and transvaginal implants should also be considered.

There is no registry in Australia of mesh device implants. This makes it difficult to provide consistent details on the scale and scope of complications for mesh implants. The establishment of a mandatory 'mesh registry' has also been suggested by overseas reviews.[6, 13] This would provide prospective data on implanted mesh devices, similar to current databases used for both orthopaedic and cardiology implanted devices. The creation of a mandatory 'mesh registry' would require funding from an independent source, consultation with an expert group as to what data should be captured, and overseeing of the data to enable analysis of efficacy and safety of these devices.

In 2014, the New Zealand Health Select Committee undertook an inquiry into the use of surgical mesh in New Zealand (https://www.parliament.nz/resource/en-NZ/50DBSCH_SCR56932_1/7ad991cdbaa6a3fbdcf738603bfc2a8a7a285c1b). One of the main recommendations was the establishment of a centralised, mandatory surgical mesh registry. Following extensive contributions from a range of relevant individuals and organisations, this inquiry concluded that the registry should be informed by the International Urogynaecological Association (IUGA) classifications, to enable comparisons between surgeons internationally. During this inquiry, it was noted that the Royal Australian College of Surgeons are concerned about the registry being specific for pelvic floor as surgical mesh is used in other sites in the body (e.g. hernia repairs) so it is important that if a registry is established, that it should be centralised to encourage general surgeons to use the registry as well urogynaecologists.

If a mandatory registry is established, allocation of item numbers to specific procedure such as retropubic sling, transobturator sling and single incision sling (as examples for MUS surgery) would allow collection of more accurate data reflecting the current practice.

1b. The number of women in Australia who have had transvaginal mesh implants who have experienced adverse side effects

This number is also unknown as again this data has not been collected, other than in clinical trials.

There is a recognised under-reporting of adverse events to the TGA with 99 adverse events reported between July 2012 and June 2016 relating to transvaginal mesh implants. (<https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications>). This most commonly reported events were pain and mesh erosion. RANZCOG encourages all gynaecologists to report adverse events to the TGA.

There are no item numbers specific to removal of mesh implants and therefore repeat surgeries for mesh complications are not monitored via Medicare claims. Again the limitation that these data would only be captured within the private sector is noted.

RANZCOG has sought advice from UGSA on the number of women in Australia who have had transvaginal mesh implants who have experienced adverse side effects. UGSA reported that in terms of complications they are aware that perhaps 5-6% of sling patients have sling division or excision for voiding difficulty or superficial mesh extrusion however these problems tend to be easily resolved.

The data from the AIHW figures in the table above suggest that between 2002-2015, 7,777 women underwent sling division or revision. As previously stated, these figures should be interpreted with some caution. This indicates an incidence of 7.3% of the slings in that time period requiring further intervention. It should be noted that some of these sling revisions or divisions would have been for the MUS inserted prior to this time frame and may also include non-synthetic mesh slings.

There are reports to the TGA regarding more serious or chronic problems for approximately 200 women while the Australasian mesh support groups list 800 members. There may be women who have yet to notify of their problems but even so the rate of more serious complications is well under 1%. So the majority of women have had a good outcome from their surgery. The challenge remains to try to determine why some women are at risk of chronic post-operative pain, how we can prevent this and how we can help those women already suffering.

International and local data suggest that complications with mesh for POP surgery are higher than complications following MUS.[6, 13-15] It is noted from consumer reports, however, that more women are presenting with complications after placement of an MUS. There could be a number of reasons for this apparent discrepancy. It is likely that more slings have been placed as this mesh became available a number of years before the mesh kits for POP. In addition, some of the early MUS meshes were more prone to complications due to the type of mesh used and these meshes are now withdrawn.[11] It is considered that the Australian experience will be similar to published reports where MUS mesh is less likely overall to cause complications than mesh for POP.[6, 13] It is difficult to demonstrate this currently, due to the lack of data on the number of each type of procedure that has been performed. The capture of these data via a 'mesh registry' could be considered for the future.

One specific mesh kit device, the Tissue fixation systems (TFS) used mesh with anchors. This mesh kit device was withdrawn from the market by TGA in November 2014. Tissue anchors in this particular device were used to affix mesh products into pelvic tissue but are no longer used as there was demonstration of complications related to migration of tissue anchors after vaginal surgery for prolapse and/or urinary incontinence.[10] It is possible that some patients who had mesh surgery using tissue anchors prior to 2014 and are experiencing adverse events are affected by the tissue anchor rather than mesh and this should be noted.

1c. The number of women in Australia who have made attempts to have the mesh removed in Australia or elsewhere.

This number is unknown. There are reports of women traveling overseas to have complete mesh removal. In Australia, there are urogynaecologists and gynaecologists who have experience in mesh removal - see item 7.

2. Information provided to women prior to surgery about possible complications and side effects.

Informed consent must be obtained before any treatment is conducted.[1] This includes warning a woman of material risk inherent to any proposed treatment or surgery. In some cases, standard consent forms are used. However, consent is more the process of consultation between the individual woman and her treating doctor rather than simply signing a consent form. Written or audio-visual information may be used and would complement any information a doctor provides to a woman verbally.[1] It should also be noted that the consent discussion will include the potential consequences of doing nothing.

In the case of transvaginal mesh, it would be expected that the treating surgeon explains the treatment options, both non-surgical and surgical, the permanent nature of synthetic mesh and the likely success rates considering the individual woman's clinical factors. It would also be expected that possible risks be explained including general surgical risks and the risks specific to mesh implants - see section 5.

Patient information sheets on SUI and POP were previously available through RANZCOG, and these outlined various treatment options. There are now freely available patient information sheets on the International Urogynaecology Association (IUGA) website that include specific information sheets on MUS and vaginal repair with mesh.[16] These resources are commonly used by urogynaecologists and general gynaecologists prior to surgery.

3. Information provided to doctors regarding transvaginal mesh implants and possible complications and side effects.

Surgeons are expected to obtain appropriate surgical training and experience in any procedure they are intending to perform independently. While RANZCOG provides a framework to support training and ongoing professional development, it is expected that individual surgeons practice due diligence to maintain and/or acquire appropriate surgical skills. This includes the knowledge of appropriate patient selection and indication for any particular surgical technique, the performance of the surgical technique and the possible complications and their management.

RANZCOG provides statements on transvaginal mesh for SUI and POP however, these are guidelines only and clinicians are expected to understand the current literature regarding these procedures if they are performing these procedures. RANZCOG also recommends clinical audit of these procedures and encourages this practice via Continuing Professional Development (CPD). CPD is compulsory for all Fellows of RANZCOG.

4. Any financial or other incentives provided to medical practitioners to use or promote transvaginal mesh implants.

RANZCOG does not have access to this information. Any financial arrangements between mesh companies and individual practitioners would be kept by the individual companies.

Doctors who do have a financial relationship with a company are expected to declare any interest as recommended by the *Code of conduct for doctors in Australia*. [17] It could be considered that any research funds provided by companies are kept at "arm's length" by elected bodies such as RANZCOG and educational societies arranging open and transparent tendering for work to evaluate new devices.

The Physician Payment Sunshine Act of 2010 mandates that all financial interaction between physicians and Pharmaceutical and device companies be entered in a publicly scrutinised database by September 2014.

However, the vast majority of surgeons do not have any financial incentive to use transvaginal mesh products, and use these products with the aim of improving outcomes for women affected by pelvic floor dysfunction.

5. The types and incidence of health problems experienced by women with transvaginal mesh implants and the impact these health problems have had on women's lives.

Overall, the use of mesh in SUI and POP has improved the symptoms and quality of life in the majority of women who have had these procedures. Again, it is important to understand that different mesh procedures have been performed for these two different conditions. It is important to note that MUS is a much smaller piece of mesh in a different location to vaginal mesh for prolapse.

MUS for SUI

In the case of SUI and the use of MUS, this surgery has been extensively reviewed with numerous high quality studies. Overall, the safety profile has been found to be very good with high success rates. In most cases, women's quality of life and sexual function improves significantly after this surgical intervention.[5]

All surgical procedures have the risk of complications. Overall, MUS for SUI has been found to have a lower complication rate than other surgical procedures performed for female SUI. Other procedures, such as Burch/open colposuspension, urethral injection and suprapubic sling without mesh have been analysed in the Scottish review.[6] When compared to these procedures, the MUS carries a lower overall risk of complications such as recurrent SUI, damage to bladder, difficulty passing urine, excessive bleeding, infection, and pain.[6]

However, there are complications that are specific to the MUS, including mesh erosion and pain; particularly groin pain. The incidence of mesh erosion/exposure is around 1-2% and can usually be managed with relatively minor surgery. Groin pain in the long term can occur in approximately 1.6% of women depending on the approach of MUS insertion.[6] This can be more difficult to treat and the removal of the mesh from the groin area is often incomplete.[5] The recent RANZCOG statement on MUS reflects advice to gynaecologists regarding counseling of women on complications following MUS and the various approaches.[2]

Transvaginal mesh for POP

Compared to native tissue repair for POP, the use of transvaginal mesh: decreases the awareness of POP post-operatively; improves the objective finding of POP on examination; and, reduces the need for repeat surgery for POP. However there are higher rates of complications overall following transvaginal mesh repair, with increased rates of: combined repeat surgery for POP; *de novo* SUI; chronic pain and, mesh exposure/erosion. Currently, many of the transvaginal permanent meshes which have been studied have been voluntarily removed from the market. As a consequence the meshes available in Australia have not been evaluated with good quality trials. Native tissue vaginal repair is the procedure of choice for routine POP surgery.[2, 6, 9]

It is important to remember that native tissue surgery for POP also carries risks which include bleeding, infection, damage to bladder, bowel and rectum, fistulae, change in urinary and bowel function, sexual difficulty, pain and recurrent POP.

Again, the majority of women who underwent transvaginal mesh surgery for POP did not have complications and most women have had good outcomes and improved quality of life. However, complications unique to transvaginal mesh for POP include:

- vaginal exposure
- mesh erosion into the urinary tract
- mesh erosion into the bowel or rectum
- pain requiring mesh removal

The overall incidence of mesh complications is estimated to be approximately 12%, with approximately 8% of women requiring surgery for mesh exposure and up to 18% of women requiring repeat surgery for either POP, SUI, or mesh exposure combined (compared to 7% after native tissue repair).[9]

Chronic pain from these procedures while uncommon, is extremely distressing and debilitating, with an enormous impact on women's quality of life

The removal of mesh following these procedures can be complex as a larger area of mesh is implanted compared to the MUS. The removal of this mesh can require a combined vaginal and abdominal approach. If the mesh has eroded into bladder and/or bowel, a combined surgical team with urogynaecologist/gynaecologist and urologist and/or colorectal surgeon may be required. Whilst the mesh can be removed, it cannot always be safely removed completely, and the long-term pain associated with mesh may not be completely resolved despite mesh removal. Hence, a stage can be reached where the risks of mesh removal exceed the possible benefit. This has been the experience in the Independent Scottish review on mesh, in keeping with the experience in Australia.[6]

6. The Therapeutic Goods Administration's:

- a. role in investigating the suitability of the implants for use in Australia;
- b. role in ongoing monitoring of the suitability of the implants; and
- c. knowledge of women suffering with health problems after having transvaginal mesh implants.

The TGA will address these questions.

7. Options available to women to have transvaginal mesh removed.

Urogynaecologists have specialised experience in vaginal mesh removal surgery, and this is part of the curriculum for RANZCOG subspecialist Urogynaecology training. Some general gynaecologists have sought to further specialise and therefore undertaken extra training in mesh removal techniques.

For many women the mesh complications they experience are minor and a small area of mesh can be removed as a day procedure/surgery. In many cases a general gynecologist is well suited to performing this surgery.

As noted previously, however, in some cases, the mesh complication requires a more complicated assessment and treatment. In these complex cases where there is significant pain and the requirement for larger mesh removal it is acknowledged that mesh removal is not always complete and even following mesh removal symptoms of pain may be ongoing. Therefore, a multidisciplinary approach is highly recommended. This can include pelvic floor physiotherapy for 'down-regulation' of pelvic floor muscle spasm and trigger point therapy; chronic pain specialists including psychological support, urogynaecology/gynaecological and/or urology and colorectal surgeons.

This type of team approach may not be available in many centres, and referral to another region or tertiary centre may be required. There may also be a substantial waiting time to access a sub-specialist urogynaecologist as there are currently only 37 urogynaecologists practising in Australia with no urogynaecologist in Tasmania or the Northern Territory. RANZCOG would welcome more funding for urogynaecology training in Australia as many accredited training units have availability for a sub-specialist trainee but lack the funding to be able to offer a position to an Australian trainee.

It is realistic to say the not insignificant risks of complete mesh removal often exceed the possible benefit. If that is deemed to be the case it is appropriate to inform the women the mesh cannot be safely removed. Some women may misconstrue this advice as meaning that the mesh cannot be removed because Australian Urogynaecologists are not trained in mesh removal, and believe they must seek a surgical solution overseas or wait for an overseas trained Urogynaecologist to come to Australia to perform and teach mesh removal. We wish to emphasise that this perception, whilst understandable, is incorrect.

It is not known whether complete mesh removal provides better outcomes than partial removal, despite aggressive internet advertising from overseas mesh removal surgeons asserting that complete removal is the only appropriate surgical option and is routinely achievable. This is driving unrealistic expectations among the Australian community that the only viable surgical option is complete removal. In contrast, the FDA warnings state complete mesh removal may not be achievable. This, in conjunction with the often extremely high surgical risks of complete removal, drives the rationale in Australia to more frequently offer partial mesh excision targeted at the area of concern. We believe this to be a more balanced and realistic approach to mesh removal.

Suggestions and Recommendations:

1. RANZCOG supports the use of MUS surgery for women who have SUI and who have not had success with conservative non-surgical treatment. As with all surgical procedures, specific training in the patient selection process, surgical training and the understanding and management of complications is essential. The understanding of the different approaches for insertion of MUS and their specific complications and clinical use is the responsibility of the treating surgeon and the recent RANZCOG statement on MUS is a useful guide to gynaecologists.
2. RANZCOG recommends that transvaginal mesh should not be used as the primary surgical treatment for POP. The currently available meshes have not been evaluated within robust clinical trials. If use of these devices is considered appropriate due to patient factors which increase the risk of POP recurrence, the woman ideally would be recruited into a clinical trial to assess safety and efficacy. However, there are currently very few of these trials in progress and extensive discussion of other options and/or a referral for a second opinion is recommended in the current RANZCOG statement on polypropylene vaginal mesh implants for POP.
3. Consent for all surgical procedures relies upon good communication between the treating surgeon and the woman. There are particular risks with mesh surgery that need to be discussed, and the use of written patient information regarding the surgery and the product used may be helpful for this process. This is a freely available resource and surgeons should be encouraged to make these available to each patient prior to decision regarding the type of surgery performed.
4. Adverse event reporting is recommended as per section 1 (b) and via the RANZCOG position statements. Improvements in the TGA reporting pathways for adverse events associated with medical devices would be welcomed. This would allow more accurate analysis and better clinical care.
5. In order to accurately track mesh usage, possible complications and removal, there should be consideration of separate MBS item numbers for native tissue repair and transvaginal mesh repair and for the removal of mesh following prolapse repair. There is also an urgent need for introduction of mesh-related ICD numbers in the ACHI handbook, for both insertion and removal. A review of data collection regarding SUI and POP surgery with and without mesh and removal of mesh within both public and private sectors should also be considered.
6. The consideration of development of a 'mesh registry' to enable data capture on the number of women undergoing transvaginal mesh and abdominal mesh surgery for SUI and POP is encouraged. This would also be used to capture data on complications rates for these surgeries. This practice is already in place in other specialties such as the *Australian Orthopaedic Association National Joint Replacement Registry*. The establishment and ongoing financial support to administer a 'mesh registry' would need financial support from Government. Any registry needs to ensure complete confidentiality for all women included.
7. Improvement on data collection for all medical devices should be considered. The current system where data is collected within individual hospitals by various means is outmoded in the current technological age. A system which allows efficient recall of a device for reasons of safety and/or efficacy is required across all medical device usage.

8. Improvement to access to multidisciplinary teams for women who have complex mesh complications is required. Those women who have suffered severe life changing complications should be able to access a team approach within Urogynaecological units including access to specific pelvic floor physiotherapy specialists, colorectal and urology specialists and pain teams. The communication regarding the availability of these units within Australia is also required. Funding to establish these types of clinics within major tertiary centres may be required to enhance the existing resources.
9. In the future, new devices coming to market for the treatment of SUI and POP need detailed scrutiny from regulatory bodies such as the TGA, and demonstration of pre-market safety and efficacy as is required for pharmaceuticals. Clinicians need to be vigilant prior to the introduction of new technologies. When appropriate safety and efficacy data are not available, the use of new devices should only be performed in the setting of a clinical trial with ethics committee approval and surveillance. The relationship between clinicians and industry is required for development of better surgical procedures for pelvic floor dysfunction but this should be at "arm's length" to ensure transparent funding with grants being supervised through RANZCOG or other educational societies.

Summary

SUI and POP are common and distressing conditions for women. RANZCOG is committed to improving the health and wellbeing of women and endeavours to support its trainees and Fellows in striving for excellence, aiming for the best treatment outcomes for women. While many women have had good results from transvaginal mesh surgery for SUI and POP, some women have had life changing complications. RANZCOG acknowledges these complications and sincerely thanks those women who have brought this into sharp focus. In response to these concerns and updated evidence RANZCOG has improved the guideline recommendations to their gynaecologists with the aim of minimising future complications. [2,3]

References

1. RANZCOG. *Position statement on consent and provision of information to patients in Australia regarding proposed treatment. C-Gen 2(a)*. July 2016.
2. RANZCOG. *Position statement on midurethral slings C-Gyn 32*. May 2017.
3. RANZCOG. *Position statement on polypropylene vaginal mesh implants for vaginal prolapse. C-Gyn 20*. November 2016.
4. Thom, D.H. and G. Rortveit, *Prevalence of postpartum urinary incontinence: a systematic review*. Acta Obstet Gynecol Scand, 2010. **89**(12): p. 1511-22.
5. Ford, A.A., et al., *Mid-urethral sling operations for stress urinary incontinence in women*. Cochrane Database Syst Rev, 2015(7): p. CD006375.
6. Scottish Government, *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women. Final Report March 2017*. 2017.
7. Holdo, B., et al., *Long-term clinical outcomes with the retropubic tension-free vaginal tape (TVT) procedure compared to Burch colposuspension for correcting stress urinary incontinence (SUI)*. Int Urogynecol J, 2017.
8. Maher C, F.B., Baessler K, Schmid C., *Surgical management of pelvic organ prolapse in women*. Cochrane Database of Systematic Reviews, 2013. Issue 4. Art. No.: CD004014.
9. Maher C, F.B., Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J., *Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse*. Cochrane Database of Systematic Reviews, 2016. Issue 2. Art. No.: CD012079.
10. Atherton, M.J., et al., *Complications associated with tissue anchor migration after vaginal surgery using the tissue fixation system - a case series*. Aust N Z J Obstet Gynaecol, 2012. **52**(1): p. 83-6.
11. Balakrishnan, S., et al., *Sling distress: a subanalysis of the IVS tapes from the SUSPEND trial*. Aust N Z J Obstet Gynaecol, 2007. **47**(6): p. 496-8.
12. Haya, N., et al., *Prolapse and continence surgery in countries of the Organization for Economic Cooperation and Development in 2012*. Am J Obstet Gynecol, 2015. **212**(6): p. 755 e1-755 e27.
13. The Accident Compensation Corporation (ACC), *ACC Surgical Mesh Review Analysis of Treatment Injury Claims 1 July 2005 to 30 June 2014*. 2015.
14. Lee, J.K., et al., *Randomized trial of a single incision versus an outside-in transobturator midurethral sling in women with stress urinary incontinence: 12 month results*. Am J Obstet Gynecol, 2015. **213**(1): p. 35 e1-9.
15. Maher, C.F., et al., *Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial*. Am J Obstet Gynecol, 2011. **204**(4): p. 360 e1-7.
16. www.iuga.org
17. Medical Board of Australia. *Good Medical Practice: A Code of Conduct for Doctors in Australia*. March 2014.