Submission to Senate Community Affairs Reference Committee

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

by the Urogynaecological Society of Australasia

As the major organisation representing Australian and New Zealand pelvic floor reconstructive surgeons, the Urogynaecological Society of Australasia (UGSA) is instrumental in education, research and training for the treatment of pelvic organ prolapse and urinary incontinence. Management of pelvic floor disorders may involve the placement of transvaginal mesh which has led to reports of adverse outcomes in some women.

However, pelvic floor disorders, especially with our increasingly elderly population, can be very complex to treat. UGSA believes it is important that surgeons who regularly manage advanced and / or recurrent prolapse are able to offer patients a complete range of surgical and non-surgical options. No one procedure is appropriate for all patients and for some women a transvaginal mesh procedure may be the most effective and durable treatment. We therefore appreciate the opportunity to make a submission to this committee.

Background to transvaginal mesh placement for pelvic floor reconstructive surgery

Traditionally vaginal surgery for prolapse or incontinence has made use of the patient's own tissues (known as a fascial repair). Techniques generally involved excision of the weaker tissues with plication and resuturing of the remaining vaginal wall. However pelvic floor dysfunction is a result of weakened, torn or overstretched connective tissue with the ongoing impact of aging, menopause, upright posture, heavy lifting etc. It is not surprising that recurrent problems can occur and we have known for well over 100 years that our repair procedures have a significant failure rate.

Over many decades surgeons have trialled different mesh products, especially in incontinence surgery, in an attempt to improve the outcome for the patient. However these products tended to be made of thicker or more dense mesh which did not incorporate well into the tissues and so were no more effective than standard fascial procedures. Vaginal mesh use became widespread initially in incontinence surgery following the development of the minimally invasive mid-urethral sling. This sling utilised a lighter, monofilament polypropylene mesh which was well-incorporated into the vaginal connective tissue.

Developed in Europe in the early 1990s, the mid-urethral sling was first available in Australia in 1998. Previous standard incontinence procedures required major abdominal surgery with several days hospitalisation and a prolonged recovery period . Due to its efficacy and reduced morbidity, within a few years the MUS superseded all previous continence procedures (1). Another real benefit from the introduction of the mid-urethral sling is that older women who previously could not have tolerated major surgery, can have their incontinence treated. The proportion of women seventy

years and over having a mid-urethral sling procedure has risen steadily each year and this rise is even more marked in women over 85 years (2).

There is extensive data to support the use of the MUS from over 2000 publications including multiple, high quality randomised controlled trials making this the most extensively investigated incontinence procedure ever (3,4). Long term follow up over 17 years has also confirmed its excellent safety and efficacy (5). Over the last decade in Australia the MUS has been performed up to 20 times more frequently than the previous abdominal procedures and the quality of life benefits for women of all ages have been immense (2).

Following the huge improvement in continence management gained with the mid urethral sling, attention turned to the use of vaginal mesh for prolapse repair. This was a time of real disillusionment with the patient outcomes from fascial repair surgery. Research had shown that almost one third of traditional prolapse repairs failed with patients requiring further surgery. Studies of anterior repair techniques reported a failure of fascial repairs in 58 - 70% of patients within one to two years (6,7). General surgeons had had similar difficulty with hernia repairs but by 2000 the use of synthetic mesh reinforcement for abdominal hernia repairs had become the gold standard in management (8). So with the introduction of vaginal mesh kits in 2004-5 there was optimism this would similarly transform the treatment of pelvic floor prolapse.

<u>The number of women in Australia who have had transvaginal mesh implants; who have experienced adverse side effects; who have made attempts to have the mesh removed in Australia or elsewhere</u>

Precise data is difficult to obtain largely because to date the MBS item numbers for pelvic floor reconstructive procedures do not distinguish between mesh and non-mesh repairs. Also numbers are not readily available for public hospital procedures although we know two-thirds of all elective surgery is performed in private hospitals so this would presumably apply to pelvic floor surgery. All mid-urethral sling procedures obviously involved a mesh sling however we can only estimate overall numbers based on overseas experience. Data from Scotland where mesh procedures have been separately identified since 2006 shows 7% of primary vaginal repair procedures involved a mesh implant (9). In the USA at the peak time of mesh use in 2011, 23% of vaginal repairs utilised mesh (10).

Since 1998 with the introduction of the mid-urethral sling, over 80,500 procedures have been performed in the private sector (MBS statistics online). This would extrapolate to approximately 120,000 women Australia wide.

From 2004-5 when vaginal mesh for prolapse repair was readily available almost 186,000 vaginal prolapse procedures were performed in private hospitals. This suggests approximately 90,000 procedures in the public hospital sector. Rates of vaginal mesh usage have varied over time. Peak usage in Australia was probably in 2010 similar to international experience with a fall of over 90% in transvaginal mesh usage after 2011. It is estimated 33,000 women had vaginal mesh implants for prolapse up to 2016, a rate of one in 8-9 vaginal prolapse repairs.

This means over 150,000 Australian women have had transvaginal mesh procedures for urinary incontinence or prolapse. It is important to note that the vast majority of these women have not experienced complications from their surgery and on longer term follow up remain very satisfied with their management.

We know 5-6% of women following a mid-urethral sling require sling division or excision for extrusion or voiding difficulty (11). However voiding dysfunction can occur with any bladder surgery and with the previous abdominal procedures was extremely difficult to correct leaving up to 20% of patients having to perform self-catheterisation to empty their bladders. Even allowing for specific mesh complications, the morbidity and efficacy for mid-urethral slings is significantly better than for the older colposuspensions and pubovaginal slings(9,12).

Mesh extrusion is the process where mesh fibres can protrude through the vaginal skin and occurs in 1-2% of sling cases. This is often asymptomatic but may cause bleeding or discomfort with intercourse. It can resolve with vaginal oestrogen creams but may need minor surgery to remove. Vaginal mesh extrusion is more common when mesh is used for prolapse repair due to the larger area of mesh reinforcement compared with a sling procedure. Most studies report an incidence of around 8 - 10% although again not all of these need treatment.

Of most concern are those distressing cases where patients experience severe and / or chronic pelvic pain and where mesh erodes internally into pelvic organs requiring major surgical correction. The true incidence of these complications is uncertain and Australia would benefit from a mesh registry or surgical database such as the UGSA pelvic floor database. Recent UK data reports moderate or severe adverse events in 800 of 92,000 patients having transvaginal mesh surgery, ie less than 1%. This compares well with all types of surgery. Unfortunately resolution of pain symptoms is not always achieved by mesh removal as chronic post-operative pain is a significant problem with all forms of surgery, with or without the use of implants. Between 10 and 50% of surgical patients suffer with persistent pain thought to be secondary to inflammation and neurogenic damage. In up to 10% of these patients, the pain is severe (13). The International Association for the Study of Pain reports chronic pain occurs in approximately 20% of patients undergoing total knee replacement and 10% of those requiring hip replacement (14).

UGSA has no accurate information on women who have sought mesh removal in Australia or overseas. As individual surgeons we have all have treated patients requiring mesh removal but this is typically for small areas of superficial extrusion. Requests for complete mesh removal are, in our experience, relatively rare. We have only anecdotal reports of patients travelling overseas for such treatment.

As in any area of medicine, clinicians have to try to balance the benefits of a treatment against the possibility of uncommon adverse events. Even without mesh, pelvic floor reconstructive procedures can be complicated by pain, vaginal scarring, bladder symptoms and difficulties with intercourse. For example, a recent large randomised trial demonstrated no significant difference in serious adverse events including dyspareunia between those with native tissue and those with mesh repair (15). And the rate of all intra and post-operative complications is increased if repeat surgery is required due to failure. Mesh reinforcement can reduce the rate of surgical failure and recurrent prolapse. So for some women, for example those with significant medical comorbidities or at high risk of recurrence, the smaller risk of a mesh complication may outweigh the risks of redo surgery which is then more likely to need mesh implants.

Information provided pre-operatively to patients about possible complications and side effects

Australian urogynaecologists and gynaecologists generally provide patients with information leaflets developed by UGSA, the Royal Australian & New Zealand College of Obstetricians and Gynaecologists (RANZCOG) or by the International Urogynaecological Association (IUGA). Two of these from RANZCOG covering 'Surgical Treatment of Pelvic Floor Prolapse' and 'Urinary Incontinence' are attached as are the IUGA pamphlets on 'Stress Urinary Incontinence', Anterior Vaginal Repair', Posterior Vaginal Wall Repair' and 'Vaginal Repair with Mesh' plus UGSA patient information leaflets on conservative and surgical treatment options for urinary incontinence. Alternative management options, surgical procedures and complications with mesh and non-mesh procedures are carefully covered.

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

Information on new procedures or surgical products is gained predominantly from the scientific literature and medical meetings. This generally consists of data from the initial animal histological studies and then from early patient trials. Techniques which appear to offer improved patient outcomes are then used more widely allowing the collection of increasing data on safety and efficacy. This generates further research and publication. In the case of transvaginal mesh implants for prolapse repair information was also gained from the use of similar products in other surgical procedures specifically hernia repair.

Monitoring of international experience and events is also important in influencing practice. For example after the 2011 FDA announcement on possible complications associated with vaginal mesh, surgeons responded with a marked reduction in the use of vaginal mesh implants for prolapse.

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

No UGSA board member or any of our urogynaecological colleagues have any knowledge of such a practice.

Many pelvic floor reconstructive surgeons in teaching hospitals have of course been part of ethics committee approved clinical trials of vaginal mesh products. Funding from industry is usually available for study costs such as research staff however this is paid to the involved hospitals, not to individual surgeons. Such studies are essential for us to monitor short and long term patient outcomes.

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

This has been covered above in the section on mesh adverse side effects.

The role of the Therapeutic Goods Administration

This is not strictly within UGSA's area of expertise however we are aware of the previous 2014 TGA review into urogynaecological surgical mesh products. The TGA also has an online reporting system for adverse events with a specific link to report problems with medical implants.

Options available to women to have transvaginal mesh removed

Complete mesh removal can be technically very complex but this can generally be performed by experienced pelvic floor surgeons. There is certainly adequate expertise in Australia available to women seeking mesh removal. There is emerging evidence that partial mesh removal can be adequate to relieve symptoms and any mesh removal surgery needs to be very thoroughly discussed (16). It is important to note that patients with pre-existing vaginal or pelvic pain, particularly younger patients appear to have more risk of post-operative pain and hence mesh removal will not necessarily resolve all pain symptoms.

The use of vaginal mesh implants has provided excellent anatomical and quality of life results for the silent majority of women who have undergone surgery for incontinence and pelvic organ prolapse. In particular the introduction of the minimally invasive mid urethral sling has brought major benefits to women, young and old, suffering from urinary incontinence. All surgery can result in complications and understandably patients are anxious and unhappy in this situation. Generally there are multiple factors involved but it is easy for the vaginal mesh implant to become the focus of the patient's distress.

Research and audit into the safest and most effective use of transvaginal mesh implants for pelvic floor disorders continues worldwide including large multicentre 522 studies mandated by the American FDA. The data from these studies will help immensely in better identifying those patients most likely to benefit from transvaginal mesh and those in whom the risk of a mesh complication may be greater.

UGSA believes transvaginal mesh is an important tool in the management of prolapse and urinary incontinence. We need to ensure our patients are thoroughly counselled and carefully selected. We need to monitor surgical outcomes through detailed audit and to continue high quality research. In this way we are able to offer each patient the optimal treatment for her condition with the best possible outcome.

Appendices

1. UGSA patient information leaflet on Stress Urinary Incontinence
2. UGSA patient information leaflet on pelvic floor muscle training
3. UGSA patient information leaflet on Mid-urethral Slings
4. UGSA patient information leaflet on Burch colposuspensions
5. UGSA patient information leaflet on Pubovaginal Slings
6. Joint UGSA RANZCOG statement 2013 on Polypropylene vaginal mesh implants for vaginal prolapse
7. Joint UGSA RANZCOG Position statement 2014 Mid-urethral slings
8. IUGA patient information leaflet on Stress Urinary Incontinence
9. IUGA patient information leaflet on Anterior Vaginal Wall Repair
10. IUGA patient information leaflet on Posterior Vaginal Wall Repair
11. IUGA patient information leaflet on Vaginal Repair with Mesh
12. RANZCOG patient information leaflet on Surgical Treatment of Pelvic Floor Prolapse
13. RANZCOG patient information leaflet on Urinary Incontinence

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