EDITORIAL

The mid-urethral sling: current issues

Female stress urinary incontinence (SUI) is a common problem that entails leakage of urine with coughing, straining, and physical activity. SUI has a significant effect on a woman's quality of life (QoL), causing physical discomfort, psychological distress, self-consciousness and sexual dysfunction[1]. First-line treatment for SUI should include conservative measures such as lifestyle, physical therapy such as pelvic floor muscle training, behavioural therapy[2] and the consideration of vaginal estrogen or continence rings. If unsuccessful, then surgical options, such as insertion of a mid-urethral sling (MUS), autologous pubovaginal fascial sling, bulking agents or colposuspension may be considered[3].

While the use of synthetic MUS is supported by extensive level 1 evidence, with high success rates and a low risk of complications, the current attention on vaginal mesh has led to a perception they are unsafe or ineffective. Tension-free MUS surgery has occasionally been linked to complications associated with the use of vaginal mesh for pelvic organ prolapse (POP). The United States Food and Drug Administration (US-FDA) issued a communication in 2008 outlining potential complications of vaginal mesh for POP use, including urinary tract erosion, vaginal extrusion, infection, pain, urinary symptoms, incontinence and recurrence of POP[4]. Legal services have widely advertised to women who have had a vaginal mesh procedure, and while this has heightened community awareness of mesh it may have also instigated unwarranted fear of complications in many who are not experiencing issues[5].

A REVIEW OF THE LITERATURE

The aim of this review was to evaluate the current evidence on the safety and efficacy of MUS surgery for female urinary incontinence. A PUBMED search was undertaken to find relevant English language publications from January 1995 to July 2017 using the terms 'mid-urethral' and 'vaginal sling' or 'vaginal mesh'. A total of 261 papers were found and abstracts were reviewed to establish specific relevance to MUS surgery. Research articles, systematic reviews, guidelines and position statements and conference abstracts were referenced and incorporated to highlight key considerations. Publications that represented low-volume follow-up, reports that were already included in systematic reviews, guidelines or position statements were excluded. A total of 35 documents were included for this summary narrative review.

USE OF MESH IN SUI AND POP SURGERY

The introduction of vaginal mesh transformed surgical intervention for SUI and POP. Anti-incontinence surgeries have been shown to improve subjective symptoms of SUI[6,7], with tension-free MUS placement being better tolerated than colposuspension or autologous fascial sling insertion[8]. Risks associated with interventions do exist and it is imperative to consider the risks and benefits when contemplating surgery for urinary incontinence[9]. Proper assessment of this important issue can be challenging due to the oft-encountered confusion between vaginal mesh for POP and tension-free MUS for SUI. Though vaginal mesh for POP and the markedly smaller tension-free MUS are inserted transvaginally, mesh used in POP surgery requires a larger graft and more extensive dissection for placement. Mesh-related complications have been extensively publicised in non-medical media, and the accuracy of this information is unclear[5]. Litigation-driven advertising has had implications regarding mesh use[10], and it is increasingly important for all health care practitioners to be fully informed of the literature surrounding the use of mesh and the reasons for concern and potential dissatisfaction[11].

WHAT IS MESH?

Non-absorbable surgical mesh is composed of macroporous monofilament polypropylene (classified as "type 1" mesh). Other combinations of porosity and

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filament correspond to different "types" of mesh. Type 1 mesh is the recommended and most widely used synthetic material in continence surgery and is, to date, the synthetic mesh most compatible for implantation in the human body and with the lowest tendency to cause infections due to its admission of macrophages and the consequent fibroplasia and angiogenesis[2]. The polypropylene from which type 1 mesh is made is the same material that sutures are made of and this has been used for many years.

This non-absorbable monofilament is generally considered inert and safe[12]. Despite this, mesh can be associated with infection, seroma formation, extrusion and shrinkage[13]. Nevertheless, it is used by surgeons across specialities for augmentation of tissue in reconstructive techniques[14].

IS MESH EFFECTIVE AT REDUCING SYMPTOMS OF SUI?

Surgical intervention is often considered after trialling conservative management through lifestyle, physical, behavioral and, sometimes, pharmacological agents. Tension-free mesh MUS, which can be placed via a retropubic (RP) or a transobturator (TO) approach, is the most commonly performed anti-incontinence surgery worldwide and is considered by many to be the 'gold standard' surgical solution for SUI[12,15]. The mesh, which allows tissue ingrowth, supports the urethra, thereby augmenting the mid-urethral continence mechanism[16]. The MUS procedure tends to have less morbidity, shorter recovery and reduced length of hospital stay than other primary surgical procedures such as the autologous fascial pubovaginal sling[17].

The MUS for treatment of urinary incontinence has been extensively studied[2,6,12,14,18]. A 2016 systematic review and meta-analysis of eight randomised controlled trials (399 women) found that use of type 1 polypropylene MUS achieves a subjective cure rate of SUI of 77.5–82.5%[19]. Other reports conversely describe a 15% failure rate that includes persistent variable urinary incontinence[2]. As demonstrated in Table 1,continence success from treatment using either the RP or TO route is similar but the complication profile is different[20]. It should be noted that there is insufficient evidence for the long-term effectiveness of single-incision slings also known as "mini-slings".

INFORMING PATIENTS ABOUT MESH SAFETY

Current literature supports the safety and efficacy of tension-free MUS surgery[3,4]. In 2011, the FDA re-classed vaginal mesh for POP from class II to class III, requiring premarket approval before marketing. The FDA requires that biocompatibility testing for inertness be completed before marketing[21]. Pacemakers and other medical devices are also in class III. The same FDA statement clarified that type 1 mesh used for MUS was excluded from said communication[2]. Since the change in classification of such products, the number of mesh repairs for prolapse have decreased significantly, with a return to traditional native tissue techniques[22]. This is considered due in part to patient and physician reaction to the FDA notification. This has also been observed for incontinence procedures. Despite autologous pubovaginal fascial sling surgery being more invasive and associated with a higher incidence of voiding symptoms than the MUS procedure, the autologous sling remains a method of choice of intervention for complex patients, including those where previous surgery has failed and for patients who have concerns about the use of transvaginal mesh[8].

While all surgeries have inherent risks, there are additional risks specific to mesh that must be discussed with women[3]. The fact that the true complication rate of anti-incontinence surgery may be under-reported is acknowledged in the literature[23]. A recent Cochrane meta-analysis (Table 1), comprehensively captures reported complications in the literature[2]. In decreasing order of frequency, the following complications of MUS have been reported to the FDA: pain, extrusion, infection, urinary problems, recurrent incontinence, dyspareunia, bleeding, organ perforation, neuromuscular problems and vaginal scarring. A smaller proportion of the overall cohort can have residual issues, not all of which are specifically due to the mesh material. Additionally, differences in the types of complications and the ease of removing mesh completely may differ between the RP and TO route dependent upon the location of the offending mesh (Table 1). While the RP route has higher rates of bladder or urethral perforation, supra-pubic pain and voiding dysfunction, the TO route has a higher incidence of groin pain but lower risks of bladder/vaginal perforation and storage symptoms[1,2,24].

Despite postings on social media and non-medical, online communities publishing concerns about systemic complications such as toxicity and carcinogenicity, there is currently insufficient data to conclude that mesh causes malignancy or other systemic issues[1,20,21,25,26].

Table 1: Outcomes and complications of MUS for both transobturator (TO) and retropubic (RP) insertion

Outcome	Rate (%) Retropubic	Rate (%) Transobturator
Subjective cure short term (<1 year)	84.4	82.7
Subjective cure medium term (1–5 years)	88.1	85.4
Subjective cure long term (>5 years)	70.7	67.1
Bladder or urethral perforation	4.9	0.6
Voiding dysfunction	7.2	3.8
New onset urgency or incontinence	8.2	8.0
Groin pain	1.4	9.2
Suprapubic pain	2.9	0.8
Tape erosion/extrusion	2.0	2.2

Table adapted from *Mid-urethral sling operations for stress urinary incontinence in women,* a 2015 Cochrane Meta-Analysis[2] and the 2017 update[24].

INFORMED CONSENT AND HEALTH LITERACY

It is of critical importance that patients are provided with adequate information and realistic expectations about possible therapeutic outcomes to help make choices that work best for their specific situation[10]. Consent issues have become complicated but should not deter from open discussion about how best to manage what can be complex clinical situations[10,27]. In the current medico-legal environment, clinicians must commit to meticulously explaining the disease process, treatment options and potential complications of any intervention[3]. Information on which consent is based should carefully balance the potential risks and the possible benefits of the procedure[9].

With patients accessing information from a wide variety of sources, it is understandable that confusion may ensue. Patients need to be informed that while the material and route of insertion is similar to that used for POP, the risk–benefit ratio differs significantly[16]. Evidence exists for a dose-response relationship between the volume of vaginal mesh and subsequent complications or repeat interventions. This is most often seen in combination use of vaginal mesh for both POP and SUI[28].

Information is obtained from many online sources and YouTube™ remains a common 'go to' source for health and medical communication, but is skewed by information posted by legal firms highlighting the FDA warning and offering less comprehensive and potentially unbalanced content[5]. Internet-based information and media content may be disproportionately focused on lawsuits and patient dissatisfaction. Despite this, research has shown that patients still prefer and take note of unbiased, scientifically accurate information when making choices[29]. This emphasises the importance of individualised information about the risks and benefits of treatment options that should occur in a clinical consultation. This clinical consultation is critical given the evidence suggesting that patients consider litigation because of a sense of not being heard and in situations in which their QoL has been affected adversely with regard to urinary and sexual health[11].

Despite controversy, current evidence supports type 1 mesh as a safe, durable and effective choice for tension free MUS[18,30]. MUS remains the most extensively studied continence restoring procedure, with a good safety profile and is a reasonable option for treatment of SUI, but the search for the ideal material continues[12,24,27].

CONCLUSION

Key take-home points are outlined in Box 1. Women with uncomplicated SUI will generally benefit from conservative measures attended to by a continence service. Those who have no relief of symptoms may consider surgery as a reasonable next step. Index patients who have demonstrable SUI without concomitant issues such as POP may be offered an MUS. In women with significant POP, repair of the prolapse in addition to a tension-free MUS or other anti-incontinence technique may be considered. Continence success from treatment using either the RP or TO route is similar but the complication profile is different[20].

Consent should include discussion of current data that suggests that most women will do well with no long-term adverse effects[31]. Nevertheless, it is imperative to explain that some women do experience problems following MUS placement, most of which can be corrected with additional treatment[3].

Optimising consent processes, education, and information dissipation should benefit women who seek care for SUI. The search for better materials continues[27]. Greater scrutiny by regulators and the profession should improve industry standards with an ultimate goal of safer patient care[32].

Proper guidance from health care providers is imperative in helping women make appropriate, informed choices for their circumstances. Finally, there may be new considerations for manufacturers, regulators and practitioners following the class action[33] and Australian Senate inquiry[34,35] under way at the time of compiling this review.

Box 1: Key points

Key points
There is a common misconception that the risk of complications with tension-free mid-urethral mesh used for stress urinary incontinence and transvaginal mesh used for pelvic organ prolapse repair are equivalent[6].
Tension-free MUS surgery remains extensively studied and a reasonable option in the management of stress urinary incontinence[6,12].
Type 1 polypropylene (mesh) has been demonstrated to be safe[30].
Mesh is an effective material for use in surgery for stress incontinence[3,18].
Informed consent prior to placement of a mesh sling requires careful explanation of the disease process, the purpose of the sling, and the risks, benefits and alternatives available to the patient[9,10,12].
Type 1 polypropylene MUS remains the most studied anti-incontinence procedure in the history of treating SUI[12].

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