

POSITION STATEMENT ON THE USE OF MID-URETHRAL SLINGS (MUS) IN THE SURGICAL MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI)

The Urological Society of Australia and New Zealand acknowledges that the evidence suggests that use of mid-urethral slings (MUS), sometimes called TVT, in the surgical management of female stress urinary incontinence (SUI), which is the type of urinary leakage associated with physical exertion and coughing, laughing, exercise is reasonable procedure.

Stress urinary incontinence is a common¹, burdensome and costly condition for women with a negative impact on quality of life. Non-surgical measures such as pelvic floor muscle training (PFMT) are useful treatment options in alleviating symptoms, although many women may proceed with surgery if these are not successful. Surgery is generally a more effective treatment than PFMT.² Mid-urethral slings are minimally invasive procedures developed in Europe in the early 1990s to treat female stress urinary incontinence. These slings are narrow, synthetic polypropylene tapes that are surgically placed beneath the middle part of the urethra (water pipe) to provide dynamic support to stop leakage from the bladder. They have been shown to be as effective as more invasive traditional surgery with major advantages of shorter operating and admission times, and a quicker return to normal activities, together with lower rates of complications.³ This has resulted in MUS becoming the operation of choice in Europe, the United Kingdom, Asia, South America, South Africa, Australasia⁴ and the USA⁵ for treatment of SUI.

The US Food and Drug Administration (FDA) in the USA released a white paper⁶ and safety communications⁷ regarding safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. A prolapse is where some of the pelvic organs bulge downwards giving rise to symptoms of an uncomfortable vaginal bulge. Media attention⁸ on this totally distinct and separate issue of mesh use in women has the potential to cause unnecessary confusion and fear in women considering MUS for treatment of stress urinary incontinence. The FDA publications clearly state that MUS were not the subject of their safety communication.

There is robust evidence⁹⁻¹¹ to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use. These scientific publications studied all types of patients, including those with other conditions such as prolapse, overweight/high BMI, and other types of bladder dysfunction. It is, however, acknowledged that any operation can cause complications and for MUS, these include bleeding, damage to the bladder and difficulties passing urine¹². Nevertheless, the results of a recent large multi-centre trial¹³ have again confirmed the excellent outcomes and low risks of complications to be expected after treatment with MUS. Additionally, long term effectiveness of up to 80% has been demonstrated in studies following patients for up to 17 years.¹⁴⁻¹⁵

As a result, USANZ acknowledges that the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence is a reasonable treatment option.

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References

1. <http://www.aihw.gov.au/publication-detail/?id=60129543605> [accessed 23 Feb 14]
2. Labrie J, Berghmanns BL, Fischer K et al, Surgery versus physiotherapy for stress urinary incontinence. N Engl J Med, 2013. 369(12): p. 1124-33. doi: 10.1056/NEJMoa1210627. PMID 24047061
3. Cody J, Wyness L, Wallace S et al. Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence. Health Technol Assess 2003; 7 (21): iii, 1–189.
4. Lee J, Dwyer PL. Age related trends in female Stress Urinary Incontinence Surgery in Australia – Medicare data 94 – 09. Aust N Z J Obstet Gynaecol 2010; 50: 543 - 549. doi:10.1111/j.1479-828X.2010.01217.x PMID:21133865
5. <http://www.augs.org/d/do/2535> [accessed 25Feb14]
6. FDA, Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Vaginal Placement for Pelvic Organ Prolapse. 2011: <http://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/UCM262760.pdf>.
7. FDA, FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm> . 2011.
8. <http://www.bjuinternational.com/bjui-blog/midurethral-tape-surgery-for-incontinence-a-possible-victim-of-the-vaginal-mesh-crisis/> [accessed 23 Feb 14]
9. Ogah J, Cody JD, & Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst. Rev. CD006375 (2009).
10. Rehman H, Bezerra CC, Bruschini H, Cody JD. Traditional suburethral sling operations for urinary incontinence in women. Cochrane Database Syst. Rev. CD001754 (2011).
11. Novara, G., et al., Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol, 2010. 58(2): p. 218-38.
12. <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%93M%E2%80%93T/Syntheticvaginaltapesforstressincontinence/Summariesofthesafetyadverseeffectsofvaginaltapeslingsmeshesforstressurinaryincontinence/index.htm> [accessed 25Feb14]
13. Richter H E et al. Retropubic versus transobturator midurethral slings for stress incontinence. N. Engl. J. Med. 362, 2066–2076 (2010).
14. Nilsson CG, et al., Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J, 2013. 24(8): p. 1265-9.
15. Liapis A, Bakas P, Creatsas G. Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. Int Urogynecol J Pelvic Floor Dysfunct 2008; 19:150

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