

Evaluation and management of the patient with a failed midurethral synthetic sling

E. Ann Gormley, MD

Professor of Surgery (Urology), and Urology Residency Program Director, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Cite as: *Can Urol Assoc J* 2012;6(5):S123-4. <http://dx.doi.org/10.5489/cuaj.12198>

Abstract

While most women will do well following placement of a midurethral sling (MUS), a substantial minority do experience surgical failure. There are several risk factors that can help identify a patient at higher risk for failure, including body mass index greater than 25 kg/m², mixed incontinence, previous continence surgery, intrinsic sphincter deficiency, and diabetes. At the present time, there is no evidence-based guidance for which intervention to use following failure. Careful evaluation of patient characteristics will help guide subsequent management.

Surgical failure of a midurethral sling (MUS) is defined as a postoperative patient experiencing incontinence the same or worse than it was preoperatively. The patient may ultimately be found to have persistent or recurrent stress urinary incontinence (SUI), persistent or *de novo* urgency incontinence or, rarely, a fistula.

Failure can be defined by the surgeon's or patient's assessment of cure or improvement at the last follow-up visit, or it can be strictly assessed using subjective or objective criteria, including patient satisfaction at a minimum follow-up of 12 months.

This review will discuss the frequency of MUS failure, how to identify a patient at risk for failure, and provide suggestions on how to manage patients following failure.

Frequency of MUS failure

The 2010 update of the American Urological Association (AUA)'s Guidelines for the Surgical Treatment of SUI¹ included a review of the literature on MUS. Using the various authors' definitions, the rate of failure for synthetic slings at the mid urethra was 16% at 12 to 23 months (among 1215 patients in 14 groups). The numbers were substantially smaller for the analysis at 24 months; among the 483 evaluable patients, the failure rate was 19%.

The guideline authors concluded that MUS had comparable efficacy to autologous slings but that some MUS procedures did not have similar long-term efficacy data.

There have been some direct comparisons of the different types of MUS using strict objective and subjective criteria for failure. Perhaps most notable is the Trial of Midurethral Slings (TOMUS) from the Urinary Incontinence Treatment Network (UITN) in which a retropubic midurethral sling (RMUS) was compared to two transobturator midurethral slings (TMUS) in 597 women with SUI.² Objective cure was defined as a negative stress test, a negative 24-hour pad test and no retreatment (behavioural, pharmacologic or surgical) for SUI. Subjective cure was defined as no self-reported symptoms of SUI, no leakage on three-day voiding diary and no retreatment for SUI (same as objective criteria).

At one year, the objective failure rates for the RMUS group was 19.2% and 22.3% for the TMUS group (Fig. 1). These rates were similar and met the predefined criteria for equivalence. The subjective failure rate for the RMUS was 37.8%, and 44.2% for TMUS (Fig. 1). The difference between these rates was not statistically significant, nor did it meet the predetermined criteria for equivalence. These failure rates are higher than those reviewed in the AUA Guidelines because of the very strict definitions of failure. Patient dissatisfaction rates, which are more in keeping with the definitions of failure used in earlier studies, were 14% in the RMUS group and 10% in the TMUS group (not statistically significant).

Identification of patients at risk for failure

Researchers have attempted to identify significant risk factors for failure of MUS. In 2012, Stav et al examined data from 1225 consecutive women with SUI receiving an MUS (955 retropubic and 270 transobturator) at their institution between 1999 and 2007.³ Multivariate analysis showed that body mass index greater than 25 kg/m², mixed incontinence, previous continence surgery, intrinsic sphincter deficiency, and diabetes are significant independent predictors for MUS failure. Conversely, patients undergoing concomitant prolapse surgery were at significantly lower risk of MUS failure (Table 1).

In the TOMUS trial clinical predictors for MUS failures included previous urinary incontinence surgery, maximum Q-time excursion <30 degrees, MESA score for urge >10, increased pad weight, increased age, higher scores on certain incontinence questionnaires and concomitant surgery.⁴

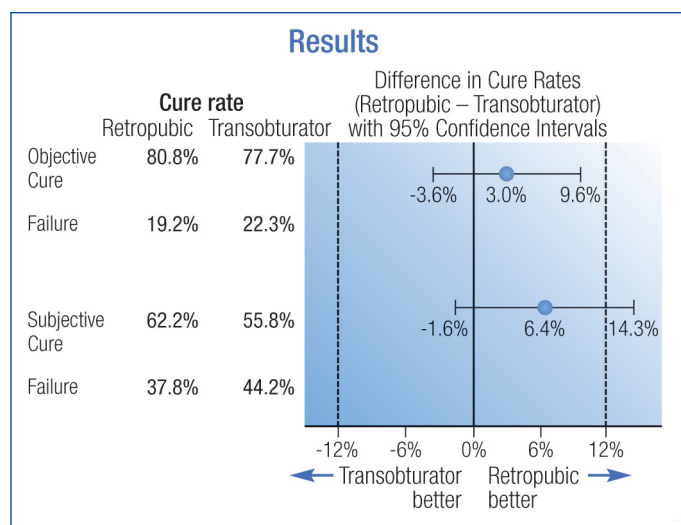


Fig. 1. Success or failure of retropubic versus transobturator midurethral slings for stress urinary incontinence (Trial of Midurethral Slings [TOMUS]).

Evaluation of the patient post-MUS failure

A patient with a MUS failure should undergo a careful evaluation in an attempt to determine the reason for the failure. History should include a review of onset, severity, characterization (stress/urge/mixed) of the postoperative incontinence. One should determine if these characteristics are different from the preoperative incontinence and, if so, how they differ.

The review of records should include consideration of the type of mesh used, the location of the mesh, and any operative difficulties encountered. Urodynamic results obtained prior to the first surgery if available should also be reviewed.

The physical examination should include an assessment of urethral mobility, a stress test and examination for other potential vaginal pathologies (e.g., atrophy, pelvic organ prolapse, scarring, extrusion). One should also assess for the presence of pain, tenderness or numbness (vaginal and/or abdominal) associated with the prior sling.

Urinalysis should also be performed, with further investigations as necessary. Evaluation may also include a post-void residual (PVR), cystoscopy and urodynamics. Cystoscopy can be useful to help determine if there is mesh in the urethra and/or bladder, and can also identify other bladder pathology (e.g., stone, tumour, chronic inflammation, fistula). The American¹ and European⁵ guidelines both recommend urodynamics for complicated patients, to demonstrate incontinence (mobility, intrinsic urethral sphincter deficiency), assess compliance/capacity, and rule out obstruction/voiding dysfunction.

Management

The overall goal of the evaluation is to attempt to determine the reason for failure, which may include one or more of the following: wrong procedure, wrong material, technical surgical issues, or a change in the patient's medical condition. In some patients a reason may not be determined.

Table 1. Risk factors for failure of midurethral slings

Variable	Odds ratio	95% CI	P value
BMI >25	2.9	1.8 to 4.5	<0.001
Urodynamic mixed incontinence	2.4	1.6 to 3.6	<0.001
Previous continence surgery	2.2	1.5 to 3.2	<0.001
Intrinsic sphincter deficiency	1.9	1.2 to 2.9	<0.01
Diabetes	1.8	1.2 to 2.7	<0.05
Concomitant prolapse surgery	0.6	0.4 to 0.8	<0.05

CI: confidence interval; BMI: body mass index.

There is no clinical trial evidence available to guide the selection of the subsequent treatment. A patient who has failed a MUS may be treated with a repeat MUS, either retropubic or obturator, a pubovaginal sling, or an injectable at the bladder neck. No one procedure is ideal for all patients. The selection of the procedure depends on the evaluation, which procedure the patient failed previously and the assessment of why the patient failed. Regardless of the intervention chosen after failure of a previous MUS, women should be warned that the outcome of second-line surgical procedures is likely to be inferior to first-line treatment, both in terms of reduced benefit and increased risk of harm.

Conclusions

There are minimal data to tell us how to treat a MUS failure. Ideally, a randomized trial between a RMUS, a TMUS and a PV sling with adequate pre- and post-procedure characterization of the patients and long-term follow-up is needed to answer this important question.

Competing interests: Dr. Gormley is a paid consultant for Astellas, the National Institutes of Health, and National Institute of Diabetes and Digestive and Kidney Diseases.

References

1. Dmochowski RR, Blaivas JM, Gormley EA, et al. Update of AUA guideline on the surgical management of female stress urinary incontinence. *J Urol* 2010;183:1906-14. <http://dx.doi.org/10.1016/j.juro.2010.02.2369>
2. Richter HE, Albo ME, Zyczynski HM, et al. Retropubic versus transobturator midurethral slings for stress incontinence. *N Engl J Med* 2010;362:2066-76. <http://dx.doi.org/10.1056/NEJMoa0912658>
3. Stav K, Dwyer PL, Rosamilia A, et al. Risk factors of treatment failure of midurethral sling procedures for women with urinary stress incontinence. *Int Urogynecol J* 2010;21:149-55. <http://dx.doi.org/10.1007/s00192-009-1020-9>
4. Richter H, Litman H, Lukacz, et al. Demographic and Clinical Predictors of Treatment Failure One Year After Midurethral Sling Surgery. *Obstet Gynecol* 2011;117:913-21. <http://dx.doi.org/10.1097/AOG.0b013e31820f3892>
5. Lucas MG, Bosch JL, Cruz FR, et al. Guidelines on Urinary Incontinence. European Association of Urology, 2012. http://www.uroweb.org/gls/pdf/18_Urinary_Incontinence_LR.pdf (Accessed July 30, 2012).

Correspondence: Dr. E. Ann Gormley, Dartmouth-Hitchcock Medical Center, Urology, One Medical Center Drive, Lebanon, NH 03756; elizabeth.a.gormley@hitchcock.org