



## Review Article

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# Twenty-Five Years of the Midurethral Slings: Lessons Learned

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Midurethral slings (MUS) are widely accepted for the surgical treatment of stress urinary incontinence (SUI) in cases where conservative treatment has failed. They have been shown to be a safe and effective surgical treatment for the management of SUI. However, there have recently been growing concerns regarding the safety profile of mesh procedures, generating international debate and leading to national inquiries into the effectiveness and safety of mesh implants. A multitude of clinical, technical, manufacturer-related, and other health jurisdictional factors are involved in the outcomes of MUS. Appropriate patient selection and informed consent to all treatment options, with proper guidance from healthcare providers, are critical for empowering women to choose an appropriate treatment option based on a personalized decision.

**Keywords:** Urinary incontinence; Stress; Midurethral sling; Mesh complication; Suburethral slings; Urodynamic stress incontinence

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## INTRODUCTION

Urinary incontinence (UI) has been estimated to have a prevalence between 10% to 39% [1]. Stress UI (SUI) is defined as the involuntary loss of urine upon effort or physical exertion or upon sneezing or coughing [2].

A conservative strategy using pelvic floor muscle exercises (PFME) should be the first-line approach to managing SUI [3]. Surgery may be offered to women in whom conservative management has failed. In 1996, Ulmsten et al. [4] introduced a procedure that involved the placement of a retropubic midurethral mesh sling for the treatment of SUI. Compared to the Burch colposuspension and the autologous rectus fascial sling, which were the reference standards at the time, these midurethral slings (MUS) were less invasive. Overall, the reported therapeutic success rate of this technique ranged from 80% to

90% [5].

MUS aims to restore urethral support by enhancing the pubourethral ligament, which according to the integral theory of female urethral incontinence, is deficient [6]. This leads to anterior vaginal wall laxity during increased abdominal pressure, such as coughing or straining. However, Chan and Tse [7], using transperineal ultrasonography, showed that another possible mechanism of action is dynamic compression of the midurethra during abdominal straining. In general, these slings share the common characteristics of using monofilament type 1 polypropylene synthetic mesh that is inserted at the level of the midurethra and applied without tension [8].

## PRIMARY STRESS URINARY INCONTINENCE

MUS are currently widely accepted for the surgical treatment of

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SUI in cases where conservative treatment has failed. There have recently been growing safety concerns regarding these procedures, generating international debate and legal cases against the manufacturers of mesh tapes. Since these concerns had been raised, there has been a decline in the number of procedures, with a return to traditional native tissue techniques. The recent National Institute for Health and Care Excellence guidelines on the management of female UI and pelvic organ prolapse (POP) state that women should be offered a choice of colposuspension, retropubic MUS, and autologous fascial slings [3]. The committee also recommended the retropubic approach rather than the transobturator approach due to evidence of a higher short-term cure rate and the greater ease of removing retropubic MUS if complications do occur.

The effectiveness of MUS for treatment of UI has been extensively studied. A Cochrane review with evidence from 55 randomized controlled trials found subjective short-term cure rates of 62% to 98% for those undergoing the transobturator approach and 71% to 97% for those undergoing the retropubic approach [8]. At a 5-year follow-up, the subjective cure rates were similar between the transobturator (43% to 92%) and the retropubic (51% to 88%) approaches. A retropubic bottom-to-top route was found to be more effective than the top-to-bottom approach (risk ratio [RR], 1.10; 95% confidence interval [CI], 1.01–1.19), with significantly less voiding dysfunction, bladder perforation, and mesh erosion.

A recent ESTER systematic review that examined surgical treatments for women with SUI included 175 studies and found that fascial sling and retropubic MUS were more likely to cure women of SUI (89.4% and 89.1%, respectively), followed by open colposuspension (76.6%), transobturator MUS (64.1%), laparoscopic colposuspension (48.9%), single-incision sling (39.8%), bladder neck needle suspension (26.9%), anterior vaginal repair (12.5%), and PFME (2.6%) [9]. The authors also found that over a lifetime, retropubic MUS was less costly and more effective than the other surgical techniques. The rate of mesh exposure was higher after transobturator MUS than after retropubic MUS or single-incision sling (8.6% vs. 2.8%; 95% CI, 1.02%–10.36%).

Urethral function may be an important consideration when selecting a surgical approach. In a randomized trial of 597 women, a Valsalva leak point pressure (VLPP) less than 86 cm H<sub>2</sub>O and a maximal urethral closure pressure (MUCP) less than 45 cm H<sub>2</sub>O were associated with a 2-fold increase in the odds of objective failure [10]. It has been suggested that patients with

urethral dysfunction have better success rates with retropubic MUS than with transobturator MUS because the vector forces provided by a retropubic sling may be more compressive. A study by Schierlitz et al. [11] found that women with poor urethral function (MUCP < 20 cm H<sub>2</sub>O, VLPP < 60 cm H<sub>2</sub>O) had lower rates of failure if they underwent MUS than if they underwent transobturator MUS.

## RECURRENT STRESS URINARY INCONTINENCE

Recurrent SUI is reported in 2% to 16% of women after MUS [12]. Risk factors for failure include an immobile urethra, usage of 2 or more pads per day prior to treatment, high body mass index, weight greater than 80 kg, and more than 1 L of intraoperative blood loss [13]. At present, no consensus exists on how to manage women with recurrent SUI following failed MUS surgery; there are no randomized controlled trials, and a Cochrane analysis was inconclusive [14].

A number of non-randomized studies considered specific approaches to the management of failed MUS surgery. Periurethral bulking agents (Macroplastique, Uroplasty Inc. Geleen, The Netherlands; and Durasphere, Coloplast, Minneapolis, MN, USA) have been evaluated in women in whom MUS procedures have failed [15]. The cure rate was 34.8% after a median follow-up of 10 months, which is in keeping with the primary success rates of bulking agents. Ninety-two percent of patients reported a benefit and 77% of patients were satisfied with their treatment. The authors concluded that periurethral bulking agents for failed MUS provided a low cure rate, but achieved high patient satisfaction.

Tape shortening was compared to repeat MUS after a failed primary MUS procedure in a retrospective study [16]. The authors found that among patients with a VLPP < 60 cm H<sub>2</sub>O, the cure rate was significantly higher in those who underwent repeat MUS than in those who underwent tape shortening (76.5% vs. 40.0%). Colposuspension has also been shown to offer subjective cure rates of 92.9% and 85% after laparoscopic and open procedures, respectively [17,18].

The efficacy of repeat synthetic MUS after failed MUS was assessed in a study of 1,225 women with urodynamic SUI [19]. The subjective SUI cure rate was 86% and 62% in the primary and repeat MUS groups, respectively ( $P < 0.001$ ). The repeat retropubic approach was significantly more successful than the repeat transobturator approach (71% vs. 48%,  $P = 0.04$ ). Rates of postoperative complications were similar between the primary

and repeat groups. *De novo* urgency (30% vs. 14%,  $P < 0.001$ ) and *de novo* urge UI (22% vs. 5%,  $P < 0.001$ ) were more frequent in the repeat group than in the primary group. A 2019 meta-analysis also found superiority of retropubic MUS over transobturator MUS in curing recurrent SUI (odds ratio [OR], 2.01; 95% CI, 1.45–2.80;  $P < 0.0001$ ) [20].

The role of autologous fascial pubovaginal slings following failed MUS placement was evaluated in a prospective cohort study of 288 patients [21]. The authors found that prior MUS placement was not associated with a significant difference in objective (55.9% vs. 62.4%) or subjective cure (66.1% vs. 69.0%) when compared to patients undergoing placement of an initial autologous fascial sling. Patients who underwent autologous fascial sling placement after prior MUS had a significantly higher rate of urinary retention requiring intermittent catheterization (8.5% vs. 3.1%,  $P < 0.001$ ).

## MIXED URINARY INCONTINENCE

Approximately 30% of incontinent women experience both SUI and urge UI (UUI) [22]. The surgical management of mixed UI is complex and subject to debate among clinicians.

In a large prospective cohort study, preoperative detrusor overactivity (DO) doubled the risk of both persistent urgency (OR, 2.04; 95% CI, 1.39–3.01) and UUI (OR, 1.86; 95% CI, 1.18–2.93) following MUS procedures in women with mixed UI [23]. In a retrospective study by Lo et al. [24], the authors aimed to determine the outcomes of mixed UI after MUS surgery. Ninety-nine women with urodynamic SUI and urgency and no DO attained an objective cure rate of 82.2%. The remaining 67 women with both urodynamic SUI and DO had an objective cure rate of 55.2%. The type of incontinence surgery did not affect postoperative outcomes in either group. The factors with significant negative effects on cure rates were postmenopausal status, prior hysterectomy, and a preoperative small bladder capacity. A lower MUCP was associated with failure of treatment in the urodynamic mixed UI group and has been previously reported as a predictor of persistent symptoms [25–27].

Other studies have also found that the risk of postoperative overactive bladder (OAB) symptoms is much greater (19%–53%) for women with preoperative urodynamic mixed UI [24–26]. In a retrospective series, patients with preoperative persistent DO had a higher median preoperative opening detrusor pressure than those with no DO (33.0 cm H<sub>2</sub>O vs. 16 cm H<sub>2</sub>O,  $P < 0.05$ ) [28]. Furthermore, only 58% of patients with urody-

amic DO reported OAB symptoms, with the remaining 42% being asymptomatic, emphasizing the value of performing preoperative urodynamic studies.

The type of sling procedure may also impact the rates of storage symptoms postoperatively. One randomized trial of patients with mixed UI showed cure rates of storage symptoms of 31% after retropubic MUS and 55% after transobturator MUS [29].

## STRESS URINARY INCONTINENCE IN PELVIC ORGAN PROLAPSE

SUI may be unmasked or worsen after POP repair in previously asymptomatic women [30]. The decision to perform either concurrent surgical procedures to treat both prolapse and SUI, or a single procedure that addresses only 1 condition requires balancing the risks of incomplete treatment and the potential need for additional future surgery.

### Symptomatic POP and Symptomatic SUI

For women with symptoms of both POP and SUI, evidence supports concurrent procedures for prolapse repair and continence. Cumulative data of women with both symptomatic POP and SUI have shown significantly lower rates of postoperative SUI in women who undergo concurrent POP repair and a continence procedure than in those who undergo POP repair alone [31–36].

A Cochrane analysis included 18 randomized controlled trials (2,717 women) and found that concomitant MUS in women with symptomatic POP and SUI improved the postoperative rates of subjective SUI (RR, 0.30; 95% CI, 0.19–0.48), and decreased the need for further continence surgery (RR, 0.04; 95% CI, 0.00–0.74) [37]. POP repair with concurrent versus staged MUS did not result in different postoperative SUI rates between groups (RR, 0.45; 95% CI, 0.12–1.37). The authors concluded that concurrent MUS in women with POP and symptomatic SUI probably reduces postoperative SUI, but a staged approach would also be reasonable.

A 2,018 meta-analysis found that 40% of women with symptomatic SUI who had POP repair alone required subsequent surgery for postoperative SUI (number needed to treat [NNT] = 2.5) [34]. In continent women with occult SUI, 15% (NNT = 7.1) required subsequent surgery for postoperative SUI.

A combined procedure for POP and SUI should be balanced against the harms of a potentially unnecessary procedure. In a randomized study by Borstad et al. [38], 181 women with POP

and symptomatic SUI had MUS either at the time of prolapse repair or 3 months later. The SUI cure (95% in the concurrent group vs. 89% in the staged group) and complication rates (18% vs. 13%) were similar between groups. In the staged group, only 56% of women who had confirmed SUI at 3 months after prolapse repair ultimately underwent a MUS procedure. Furthermore, one-third of women among those randomized to a staged procedure were cured of SUI after a prolapse procedure alone. This highlights the complexity of the relationship between prolapse repair and continence. While a combined procedure for POP and SUI is reasonable, this approach may expose the patient to perioperative complications in a potentially unnecessary procedure and should be carefully discussed with the patient.

### Symptomatic POP Without Symptomatic SUI

The management of women with symptomatic POP, but without SUI symptoms, remains a matter of debate. Continent women who have stage I POP are unlikely to have urethral obstruction and resultant occult SUI, and they are thus unlikely to benefit from a concurrent continence procedure. The risk of postoperative SUI increases with increasing prolapse severity. Continence surgery may be performed concurrently with POP repair or as a staged procedure. Alternatively, a selective approach may also be adopted. The patient may be assessed preoperatively with prolapse reduction, and if occult SUI is detected, a continence procedure may be offered at the time of the prolapse repair.

The Outcomes Following Vaginal Prolapse Repair and Midurethral Sling (OPUS) trial in 2012 randomly assigned 337 women who had stage 2 or higher anterior prolapse, but without symptoms of SUI, to receive either a MUS or sham incisions during POP surgery [39]. The authors found that the 3- and 12-month rates of postoperative SUI were nearly double for women assigned to POP repair alone compared with women undergoing POP repair and concurrent MUS (3 months: 49% vs. 24%; 12 months: 43% vs. 27%). The NNT to prevent one case of SUI at 12 months was 6.3. The rate of bladder perforation was higher in the sling group than in the sham group (6.7% vs. 0%), as were rates of urinary tract infections (31.0% vs. 18.3%), major bleeding complications (3.1% vs. 0%) and incomplete bladder emptying 6 weeks after surgery (3.7% vs. 0%) ( $P < 0.05$  for all comparisons). Furthermore, only 4.7% of women who did not initially receive MUS elected to have a staged MUS procedure, which suggests a low rate of residual bothersome SUI after prolapse repair alone.

Based on the current evidence, in women with stage II or greater POP and negative preoperative testing for occult SUI, a staged approach is reasonable. It avoids a potentially unnecessary procedure, voiding dysfunction, and mesh complications in patients who are willing to accept a higher risk of postoperative SUI. However, for women who place a high value of avoiding postoperative SUI and are willing to accept a risk of complications, concurrent prolapse and SUI repair may be a reasonable option.

## STRESS URINARY INCONTINENCE IN ELDERLY PATIENTS

In frail and elderly patients, the decision to proceed with a surgical intervention is based on the functional status of the patient, along with the potential risks and benefits of the procedure. Voiding dysfunction in the elderly is multifactorial and includes a reduction in bladder capacity [40], increased bladder sensation [41], and DO [42]. SUI is often associated with weakened supporting tissues, which consequently cause hypermobility of the bladder outlet and urethra.

The outcomes of MUS procedures in older women vary. In a study by Stav et al. [43] of 1,225 women, the authors found no differences in the subjective cure rate between elderly and younger women (81% vs. 85%,  $P = 0.32$ ). There was no significant difference in the cure rate between retropubic and transobturator slings in the elderly group (82% vs. 79.3%,  $P = 0.75$ ). Similarly, a retrospective study of 696 women found no difference in SUI failure rates in patients older than 70 years compared to those younger than 70 years [44].

In contrast, a retrospective study of 688 women found that cure rates decreased with age [45]. The objective cure rates were 91.0% for <64-year-old patients, 80.6% for 65- to 74-year-old patients, and 66.7% for >75-year-old patients. The cure rates were significantly lower in older women than in younger women for all types of MUS, with the exception of retropubic MUS. The authors also demonstrated a lower flow rate, higher postvoid residual, smaller cystometric capacity, and lower maximum urethral closure in the elderly group. There were no significant differences in perioperative complications.

Elderly patients tend to have higher rates of intrinsic sphincter deficiency, which may account for worse outcomes [43,45,46]. Older women also tend to have more persistent UUI and postoperative DO [44,45], and may be at risk of a failed trial of void compared to younger patients in up to a third of cases [43].

## SLINGS AND SEXUAL DYSFUNCTION

It is estimated that more than 60% of women with UI may experience sexual dysfunction [47]. Coital incontinence in women with UI has been shown to range from 10% to 56% [48]. Fear of UI during intercourse, decreased libido, perineal irritation from urine leakage, and dyspareunia are common sexual complaints among women with UI.

The available literature on sexual function of patients who have undergone MUS is mixed, with some authors reporting improvement [49,50] and others showing deterioration [51,52]. A meta-analysis of 23 articles found that two-thirds of MUS procedures resulted in no change or improved sexual function postoperatively [53]. Only one-third of patients showed an overall improvement in orgasm after the MUS procedure. The authors attributed this to the theory that the placement of MUS is likely to compromise the neural integrity of the anterior vaginal wall and periurethral female prostatic tissue [54].

Horosz et al. [55] found that MUS significantly improved coital incontinence, from 56% preoperatively to 8.6% postoperatively. Women who gained continence showed significant improvements in sexual function. In women who were not objectively cured (9.0%), there was no improvement in sexual function. Deterioration in sexual function was associated with persistent SUI, OAB, urgency, and fear of urine leakage during intercourse. The authors concluded that the positive impact of MUS on sexual function is primarily attributable to the resolution of incontinence and voiding difficulties after surgery. Another study of 293 women found similar results, with a decrease in coital incontinence from 51% to 7% postoperatively, and improved sexual function [56]. Furthermore, the authors found that retropubic sling is more effective than transobturator sling for improvement of coital incontinence (OR, 2.04; 95% CI, 1.10–3.80;  $P=0.02$ ).

## MESH COMPLICATIONS

The use of synthetic MUS for SUI is supported by extensive level I evidence, with high success rates and low rates of complications [39,57,58]. While mesh complications may occur following surgery for POP and SUI, they are more common following POP surgery, particularly when the mesh is placed vaginally. In 2019, the U.S. Food and Drug Administration banned surgical mesh for transvaginal POP repair, but has kept the class II (moderate risk) classification for transvaginal mesh used in the

surgical treatment of SUI and for transabdominal mesh for POP [59,60].

The most common complications are mesh exposure, mesh contraction, pain (including dyspareunia), infection, voiding difficulty, and organ perforation [61]. A recent review reported that immediate complications were experienced by 3.7% of women after retropubic MUS procedures, and 2.5% of women after transobturator MUS procedures [62]. A retrospective cohort study of 1,881 women found that the reintervention rate for mesh exposure was 2%–3% at 8 years of follow-up [63]. The results were similar between retropubic and transobturator slings. This was supported by results from a Cochrane review [8]. The risk factors for mesh exposure after MUS placement include trocar injury, type of material (types 2 and 3 are associated with higher risk than type 1), diabetes, bleeding, a vaginal incision length greater than 2 cm, a history of prior prolapse, and prior bariatric or incontinence surgery [64,65].

A Cochrane review found that the incidence of bladder perforations was significantly lower following the transobturator approach than after the retropubic approach (0.6% vs. 4.5%) [8]. On average, the incidence of groin pain across both groups was 4.51%, and this rate was found to be higher with the transobturator approach (RR, 4.12; 95% CI, 2.71–6.27). Most cases of groin pain resolved within the first 6 months following surgery. Postoperative voiding dysfunction was found in 5.53% of patients. In the short term, the average rate of *de novo* urgency/UII was 8.35%. Data from several large, randomized trials have shown that the rate of voiding dysfunction requiring urethrolisis was less than 3% [39,57,58,66].

## THE MESH TAPE SAGA

In recent years, there have been many litigation cases around the world surrounding tapes. It is the authors' view that the issue is not simply related to the mesh material, as many patients have had satisfactory long-term results with tapes that improved their quality of life. Mesh complications and patient dissatisfaction are a result of the interaction of multiple factors. These may include the properties of meshes and their interactions with tissues *in vivo*, surgical technique, the surgeon's experience and knowledge of anatomy, details of informed consent regarding complication profiles, the vigilance of follow-up, and aspects of the surgeon's continuing professional development [67]. Lessons regarding the above factors have to be learned by all parties involved, including clinicians, manufacturers, the le-

gal profession, various government and health jurisdictions, and patients themselves [68]. In Australia, a pelvic floor reconstructive procedure registry was established in 2021 with government support to enhance the tracing of mesh implants and reporting of complications [69].

## CONCLUSION

MUS has been shown to be a safe and effective surgical treatment for SUI. Efficacy decreases over time, but results have been shown to be durable over the long term. The success rates of the retropubic and transobturator routes are similar, but the complication profiles are different. The growing concern regarding the safety profile of transvaginal mesh has generated international debate and litigation, with a decline in the number of MUS procedures being performed. It should be understood that the issue is not simply the mesh material, but many other clinical, technical, manufacturer-related, and other health jurisdictional factors. Appropriate patient selection and informed consent to all treatment options, with proper guidance from healthcare providers, are critical in empowering women to select an appropriate treatment option based on a personalized decision. It is with this patient-focused approach that one can optimize quality of life in women with SUI.

## AUTHOR CONTRIBUTION STATEMENT

- Conceptualization: VT
- Data curation: JY
- Methodology: JY
- Project administration: VT
- Writing-original draft: JY
- Writing-review & editing: JY, VT

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