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3

Surgical management of urinary stress incontinence – Where are we now?



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A B S T R A C T

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Mid-urethral sling procedures (MUS) have been the surgical option of choice for most gynaecologists and urologists treating stress urinary incontinence (SUI) in women around the world for almost 20 years, since their introduction in the late 1990s.

The evidence suggests that the long-term effectiveness of the MUS is good and similar to the Burch Colposuspension and the fascial pubovaginal slings. The bulking agents are now being put forward as another minimally invasive option for the surgical treatment of SUI.

Despite the increasing evidence that the retropubic MUS are more effective in long term and in high failure risk women with recurrent SUI and ISD, the TOT continues to have a high satisfaction and usage worldwide.

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Overview

Mid-urethral sling procedures (MUS) have been the surgical option of choice for most of the gynaecologists and urologists treating urinary stress incontinence in women around the world for almost 20 years, since their introduction in the late 1990s [1–3]. The major differences from previous fascial and synthetic slings was the use of trocar needles passed through small incisions, and the mid-urethral position of the tape instead of under the bladder neck for the traditional autologous slings. Prior to the introduction of the MUS, the Burch colposuspension was the operation of choice for most clinicians. This operation performed through the retropubic space by open incision or by laparoscopy,

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and was a safe and effective procedure. However, the MUS required less dissection and had less postoperative complications, pain and hospital stay, and this resulted in a rapid uptake of (MUSs) from 1998 and a corresponding decline in colposuspension [1–3]. MUS are currently the most commonly performed operations for stress urinary incontinence (SUI), and have proved to be effective and safe in clinical trials [4] and everyday practice. In Australia, since its introduction in 1998, MUS have been the most frequently performed female continence surgery with over 80% of all SUI operations. In a survey of 15 OECD countries in 2012 [3] 82% of all SUI operations were MUS. Other continence surgery including fascial pubovaginal slings, the Stamey needle suspensions, Botox injections, sacral nerve stimulators, and reconstructive bladder interventions accounted for a median rate of 10.6% of continence interventions. There is a considerable geographical variation in incontinence procedures globally. MUS accounts for 90% of SUI operations in Sweden and Canada and only 65% in France [3].

The dominance of the synthetic MUS has been challenged recently, not by the scientific data showing poor efficiency or safety but by medicolegal issues with class actions and large payouts particularly in the United States. This has been accompanied by poor publicity in the lay press and on social media with the public often confusing the use of synthetic mesh for vaginal prolapse and SUI surgery. The commercial sequelae have been that many companies are no longer producing MUSs and more strict government regulation of the synthetic slings. Many of the synthetic MUSs are no longer available and even the original Johnson and Johnson Tension free vaginal tape, which was originally conceived and developed in Australia and Sweden is no longer available for the use in Australia. Opportunities for ongoing development and research have been severely curtailed. The number of women having SUI operations and the type of operation is susceptible to change. Just as there was a 30–40% increase in women having SUI surgery with the introduction of a more minimally invasive day procedure in the late 90's; over the last 7 years between 2010 and 2017 there has been a 40% decrease in MUS procedures performed in England. This is a result of adverse publicity, which has not been reflected in an increase in other traditional procedures or injectables [5].

The choice of surgery will vary according to the clinical situation and no one operation will suit all patients. The adverse publicity has already led some women to request non-synthetic mesh options, so clinicians will need to have other options available to them, such as the Burch colposuspension, fascial pubourethral sling, or the urethral bulking agents. Further, in some clinical scenarios, synthetic slings would be best avoided, for example, if an infection is present, or women having abdominal surgery for another indication may be better suited to a colposuspension or fascial sling. This will have implications for training the next generation of surgeons as at present most doctors have only very limited experience in other procedures to MUS for SUI; hence, retraining will be necessary.

Development of MUS

The MUSs can be classified into three main groups according to the anatomical position and when they were developed. The retropubic MUS are based on the work of Petros and Ulmsten [6] with mid-urethral placement usually inserted vaginally behind the symphysis and passing through 2 small suprapubic incisions. The transobturator sling (TO) was developed in 2001 by Delorme [7] using the obturator foramina approach to place the mid-urethral tape. In contrast to Delorme's outside-in approach, de Leval described an inside-out approach in 2003 [8]. These 2 *trans*-obturator approaches could reduce potential injury to the bladder, bowel, and other major vessels compared to the retropubic approach (RP). Further, a wider vector of urethral support with a broad-based hammock could, in theory, minimize *de novo* urgency or postoperative voiding dysfunction. The third generation of slings was the single incision mini-slings placed mid-urethral and attached to the obturator fascia and muscle but with no exit incisions. The potential advantages of these mini-slings over traditional RP or TO MUSs were avoiding the retropubic space, and limiting the passage of materials through spaces containing known vessels, nerves, and viscera. Recent global data provided by commercial companies in 2017 to the author indicate that 43% of MUS performed use the RP, 45% TO and 12% are single incision mini-slings. However, again there is a geographical variation; in England (2015–16) twice as many retropubic MUS were inserted as TO [5]. The long standing popularity over a long period of the retropubic and TO MUS amongst gynaecologists and urologists does confirm their popularity amongst doctors and patients and the safety and effectiveness of MUS in the real world.

In this review, we will discuss the options available to clinicians in the use of the three generations of mid urethral slings, their advantages and disadvantages and compare these to more traditional surgical procedures. We are now approaching 20 years since the introduction of the TVT MUS so the long-term effectiveness of surgery will be of primary concern as well as the safety and need to further treatment particularly USI surgery. Many factors impact on this not only what operation, but the skill and experience of the surgeon, and how carefully women were assessed preoperatively. Patient expectations are also very important in how they see the outcome of any operation. If they expect to be completely cured of all urinary symptoms, then up to a half of patient may be disappointed. So not only how you assess your patients but also how you counsel them is of the utmost importance. Women with pre-existing frequency, urgency or urge incontinence from detrusor overactivity or hypersensitivity are less likely to be happy with the results of surgery [9]. This is also relevant in women with chronic pelvic pain, where the cause is unknown as post-operative continuation of pre-existing pain may be attributed to surgery by the patient. Preoperative symptoms need to be carefully documented to avoid misunderstanding following surgery.

Retropubic versus trans obturator MUS

Effectiveness of MUS

Comparison between the retropubic and TO slings has been evaluated in numerous RCTs [10–14] and three meta-analyses [15–17]. RCTs are often powered for noninferiority with only short to medium-term follow-up. Meta-analyses combine many RCT studies of different qualities, under powered, varying follow up, entry and outcome criteria, and even diagnoses, with patients with primary and recurrent stress incontinence, ISD, and mixed incontinence. Many meta-analyses and subsequent RCTs [10–17] have showed no significant difference in subjective and objective cure rates for SUI between the RP or TO approaches. A recent Cochrane review by Ford AA et al., in 2016 confirmed no statistically significant difference in subjective and objective cure rates between these two routes irrespective if follow up was less than 12 m or 1–5 years [18]. Data on longer term follow up or more than 5 years are said to be poor and they emphasised the need for longer studies. A systematic review by Fusco et al. [4] reached a different conclusion. They found the *trans*-obturator route has poorer objective (OR 0.82 95% CI 0.70, 0.96) and subjective (OR 0.83 95% CI 0.70, 0.98) cure rates compared with the retropubic route. They concluded that “The available literature suggest that those slings are either more effective or safer than other older surgical procedures. Retropubic tapes are followed with slightly higher continence rates as compared with the *trans*-obturator tapes but are associated with higher risk of intra- and postoperative complications.”

Looking at large databases (e.g. national) with long follow up may provide more accurate information on efficiency and relative risks. Foss Hansen et al. [19] used the Danish National Patient Registry to identify women who had surgery for urinary incontinence from 1998 through 2007 and the outcome was a reoperation within 5 years. A total of 8671 women (mean age, 56.1 years, range 6.7–93.7 years) underwent surgical treatment for urinary incontinence. Among these women, 5820 (67%) received a synthetic MUS at baseline. The cumulative incidence of reoperation after any surgical treatment for urinary incontinence was 10%. The lowest rate of reoperation was observed among women having pubovaginal slings (6%), retropubic mid-urethral tape (6%) and Burch colposuspension (6%) followed by TO tape (9%), and urethral injection therapy (44%). The TO tape carried a 2-fold higher risk of reoperation (HR, 2.1; 95% CI, 1.5–2.9), and urethral injection therapy carried a 12 fold-higher risk (HR, 11.5; 95% CI, 9.3–14.3) compared with retropubic mid-urethral tape.

In a study by Stav et al. [20] in our department, the outcome of retropubic and TOMUS procedures in a large group of women with USI (n = 1112) was evaluated. At a mean follow-up of 50 ± 24 months (range 12–114) the subjective cure rate was 84.7%. Subjective cure was considered in those women who had no further continence surgery and who responded ‘no’ to the question of leaking urine during

physical activity, coughing or sneezing. Multivariate analysis revealed that BMI > 25 (OR 2.9), mixed incontinence (OR 2.4), previous continence surgery (OR 2.2), intrinsic sphincter deficiency (OR 1.9) and diabetes mellitus (OR 1.8) are significant independent predictors for MUS failure. The subjective stress incontinence cure rate was 86% and 62% in the primary and repeat SI group, respectively ($p = 0 < 0.001$). The RP was significantly more successful than the TO approach (71% vs. 48%, $p = 0.04$) for women with recurrent stress incontinence. The preoperative incidence of intrinsic sphincter deficiency was higher in patients who had repeat MUS (31% vs. 13%, $p < 0.001$). The rates of sling-related and general postoperative complications were similar between the primary and the repeat SI surgery group. However, de novo urgency (30% vs. 14%, $p < 0.001$) and de novo urge urinary incontinence (22% vs. 5%, $p < 0.001$) were more frequent in women having repeat USI surgery compared to primary surgery.

Ninety three percent of the patients stated that they would recommend this operation to someone else with SUI reflects a high satisfaction rate. Surprisingly, 63% of the patients in the failure group also stated that they would do the same, possibly, because the severity of the incontinence was reduced after the procedure. This again raises the question of what is success after a SI operation and managing patient expectations.

Operative risks and complications - MUS

The Fusco et al. meta-analysis [4] reported on randomized data comparing the RP and TO approaches. They reported that the TO approach comes with lower odds of bladder perforations, pelvic hematoma, and symptoms of voiding. Nevertheless the TO approach comes with a higher odds of vaginal perforations and groin ache. The 2016 Ford et al. Cochrane review [20] confirmed comparable vaginal mesh exposure rate (2.1%–2.4%), de novo urgency rate (8.1%–8.3%) but have an excess of groin pain (20.8% vs 4.5%) within the TO group compared with retropubic route.

The RP has a higher risk of visceral injury particularly bladder perforation. Injury to bowel by RP is exceedingly rare and in our experience with over 4000 cases of mid urethral slings, we have not encountered any. However, it has been reported, and care particularly needs to be taken when there is a risk of bowel being adherent to the back of the symphysis. Bladder perforations are common during the learning phase or low volume surgeons. In a recent large study of 1136 patients, who underwent MUS [21], the incidence of trocar injury to the bladder during retropubic sling was 3.8% (33/874) compared to 0.4% (1/262) with TO approach. Urethral injury was detected intraoperatively in two women (0.2%); both had retropubic slings. Thirty two (94%) of the 34 perforations involved inexperienced surgeons (fellows or registrars whose experience varied but was less than 50 slings) ($p < 0.0001$). Other risk factors for bladder perforation include a history of previous cesarean section, colposuspension, body mass index (BMI) < 30 kg/m², use of local anaesthesia, and presence of a rectocele. It is important to confirm the integrity of the lower urinary tract by routine cystourethroscopy following any MUS procedures. If bladder perforation is missed intraoperatively, the presence of intravesical mesh in the long term can cause bladder pain, irritative urinary symptoms, recurrent urinary tract infections, and stone formation. If diagnosed, the mesh, tape or suture can be removed by cystourethroscopy with scissors or laser cutting the material flush to the mucosa (Fig. 1). Occasionally, the bladder or urethra will need to be opened either retropubically or vaginally to remove the foreign body.

Vaginal extrusion of synthetic mid urethral slings has been reported to occur in 2–3% of women [5]. This is an important cause of morbidity and litigation despite the overall small risk. In a recent review of 2823 women with urodynamic SUI in our clinic [22] there were 2310 retropubic, and 513 TO and single incision slings performed between 1999 and 2017 with a mean follow-up of 100 months. There were 33 women (1.17%) who had a tape extrusion; 22 post retropubic and 11 post TO MUS. 31 needed surgical management (1.09%) for tape extrusion; any revisions solely performed for pain or voiding difficulty were excluded. Older age, BMI, DM, current smoking, trainee operator, recurrent vaginal/incontinence surgery and RP approach in ISD were independent risk factors for mesh extrusion on multivariate logistic regression analysis.

Surgical management was either by local sling excision and closure or by simple vaginal closure conserving the sling to maintain sling integrity and continence. 19 of the 20 had successful closure following sling excision. One required a further procedure to deal with lateral extrusion detected 6

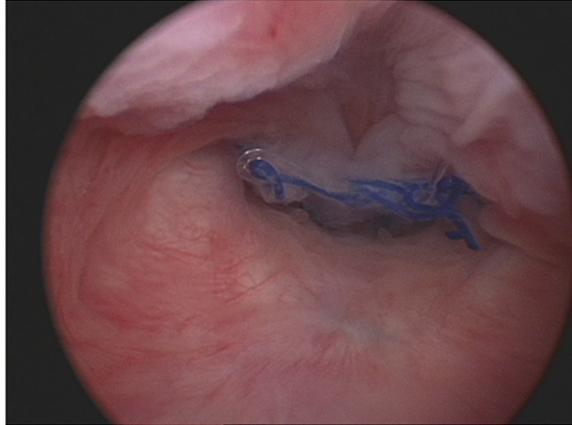


Fig. 1. Sling mesh inside bladder-likely missed during initial placement of mid-urethral sling previously.

months later. Seven out of 11 who had vaginal closure alone with sling conservation needed a second procedure for recurrent extrusion. The vaginal portion of sling was removed and no SUI procedure performed. Two of the 7 required further SUI surgery with 2 reporting persistent pain.

Of the 20 who had sling excision; 5 had concomitant SUI procedure. Five of the 15 who had sling excision alone needed further SUI surgery. Of the 11 women who had sling conservation, 7 required reoperation for recurrent extrusion. Recurrent SUI did not occur in any of the 4 who had successful closure. Of the 22 who had partial/complete excision of sling eventually and did not have a concomitant SUI procedure at time of revision, 7 had further continence procedure (31.82%). Overall of 31 in the series, 7 needed further continence procedure (22.58%).

Vaginal Sling excision and repair has significantly better outcomes compared to vaginal closure with tape conservation. One in 3 women following partial/complete sling removal will redevelop SUI and require further surgery. Placement of another synthetic MUS at time of sling removal will reduce the incidence of further SUI but does run the risk of serious infection.

Another complication more frequent after retropubic slings than TO is bleeding and pelvic hematoma. Although uncommon this complication also is increased in the learning phase. Central retropubic tocar placement to avoid the obturator vessels and more laterally the external iliac vessels is essential. We usually treat these hematomas conservatively unless bleeding continues or the hematoma becomes infected.

Mixed urinary incontinence is common occurring in a third of all women with urinary incontinence and persistence or de novo urgency or urge incontinence is a common cause of dissatisfaction following MUS. Rezapour and Ulmsten [23] reported a subjective cure of 85% in women with MUI 4 years after TVT, although they excluded women with DO [89]. Cure rates are typically lower than for pure SUI. Systematic reviews by Ford et al., 2016 [20] and Fusco et al., 2017 [4] do not show a statistically significant difference in lower urinary tract storage symptoms or de novo (i.e. new onset) urgency rates between retropubic and TO slings. Urinary urgency and urge incontinence is present in 28% and 14% of women at a long-term follow up after MUS in a study by Lee et al. [9] and is a common cause of dissatisfaction following surgery. Intrinsic sphincter deficiency, previous stress incontinence and prolapse surgery, pre-existing detrusor overactivity and OAB symptoms increased the risk of persistent OAB symptoms.

Intrinsic sphincter deficiency

Women with poor urethral function as defined as having Valsalva leak point pressure (VLPP) of less than 60 cm H₂O and/or maximum urethral closure pressure (MUCP) of less than 20 cm H₂O have more severe incontinence and poorer surgical outcomes. The significance of ISD for the MUS is still debated.

In a recent Cochrane review by Ford et al. [18] in 2016 focusing on intrinsic sphincter deficiency, the retropubic route confers greater objective, subjective cure rates compared with TO route, resulting in a higher risk of repeat continence surgery in women who had prior TO sling (RR 14.4 95% CI 2.0–106).

The largest RCT to date examining the effectiveness of RP vs. TO specifically in ISD patients (VLPP < 60 cm H₂O and/or MUCP < 20 cm H₂O) studied at least 164 patients [12]. This RCT demonstrated a clear superiority in efficacy for the RP route in the treatment of female SUI with ISD, compared to the TO approach, as 1 in 16 women requested repeat surgery in the RP group compared to 1 in 6 within the TO group, with the risk ratio of repeat surgery being 2.6 (95% CI 0.9, 9.3).

Single incision mini-slings

Single-incision mini-slings can be inserted through a suburethral vaginal incision either in a TO direction anchored to the obturator internus muscle but without passing through the obturator fascia and muscles or in a retropubic direction secured to the urogenital diaphragm. The tape is of a fixed length with anchors at each end, does not penetrate the retropubic space and has no groin or abdominal exit incisions. The potential advantages are the avoidance of the risks of the retropubic space, less postoperative pain and an easier safer insertion for less experience clinicians.

Early studies of TVT-Secur and MiniArc reported satisfactory short-term cure rates of 70–90% [24,25,26]. All these single incision mini-slings TVT Secur[®], Miniarc[®] (AMS, Minnetonka, MN, USA), Solyx[®] (Boston Scientific, Natick MA, USA), Ajust[®] (Bard, New Providence NJ, USA), Altis[®] (Coloplast, Minneapolis, MN, USA), Ophira[®] (Promedon, Cordoba, Argentina) and TFS (TFS, South Australia) have different anchorage systems. In a review, comparing mini-slings against standard MUSs [27], mini-slings were shown to have inferior efficacy. TVT Secur has the largest sample in this analysis, and possibly has the least “secure” anchorage mechanism. When TVT Secur was excluded efficacy of mini-slings was comparable to standard MUS. A 3 year RCT comparing Monarc with Miniarc by Schellart et al. [28] showed similar objective and subjective cure rates. Another RCT comparing Monarc with Miniarc by Lee et al. [29] with 5 year follow has reported similar efficacy between Monarc and Miniarc, with minimal complications. Similar to the TO slings, the mini-slings may be expected to have a lower cure rates in women with a higher risks for failure, including ISD, obesity and previous failed surgery. Because of medicolegal issues and poor publicity many mini-slings have been withdrawn from the market. Solyx, Ophira and Altis are available at the present time.

Self-made slings

Self-made slings can be made at low costs using cut to measure strips of polypropylene mesh and re-usable sterilised trocars based on the original retropubic TVT or TO slings [30]. These modified inexpensive slings are the predominant surgical treatment of female SUI in developing countries which cannot afford the high costs of the commercial kits. Several studies have explored cutting and tailoring a piece of pre-packaged off-the-shelf mesh and using it to perform a MUS with a tension-free mid-urethral placement and trocar needle introducers (e.g. Stamey needle) to facilitate sling placement.

Rutman et al. [31] reported 5-year results in 69 patients with USI who had polypropylene MUS with a subjective cure rate of 72%, with a further 16.4% who reported improvement. Zhang et al. [32] reported their comparative trial of a self-made sling against commercial kit using same surgical route and showed no significant differences in clinical outcomes at only 1 month. While further RCTs are needed, long-term follow studies are also necessary and becoming a requirement in some countries before they will be approved for general use.

Vaginal laser treatments for SUI

Vaginal laser treatments are being introduced and used worldwide to treat urogenital symptoms including USI. The studies performed to date are using CO₂ or erbium YAG lasers in single centres, small numbers and short-term follow-up with comparative control group. Improvement rates of 62–78% have been reported with minor side effects including vaginal warming, increased vaginal discharge and transient urge incontinence [33]. However recently a case report of a vesicovaginal fistula following laser treatment for USI was reported [34]. Prospective comparative studies are planned; hence, it is

important that the widespread commercial introduction of vaginal laser therapy should not occur until safety and effectiveness are confirmed.

Comparison of MUS to other traditional SUI procedures

With the present adverse publicity against synthetic mesh, we are increasingly being asked by our patients and regulators to consider other options. Even if we do not use other alternatives to the MUS, we are expected by health authorities in the UK and Australia to discuss these options and the relative risks and benefits before coming to an agreed surgical procedure. Other options are the Burch colposuspension, the fascial pubourethral sling using fascia harvested from the abdominal wall or the fascia lata from the leg, or the urethral bulking agents. The RCT by Ward and Hilton [35] showed that the TVT MUS and the Burch colposuspension had similar outcomes in short- to medium-term effectiveness, but the TVT had significant benefits in less pain postop, shorter hospitalisation and morbidity.

Longer term data is now becoming available. Foss Hansen et al. [19] using a large Danish National Registry found a reoperation rate within 5 years among women having pubovaginal slings (6%), retropubic mid-urethral tape (6%) and Burch colposuspension (6%) followed by TO tape (9%), and urethral injection therapy (44%). In a 2015 Cochrane review by Ogah et al. comparing Burch colposuspension and early VD, and shorter operative times and hospital stay, but a significantly higher rate of bladder perforations after TVT surgery than after the Burch procedure [36].

Holdo et al. [37] using a case series design comparing the Burch procedure (n = 127) with the first 5 years of the retropubic TVT procedure (n = 180) found the cumulative recurrence rate of SUI in women with preoperative SUI was significantly higher after the Burch procedure, but no difference was observed in women with MUI. There were no significant differences in rates of perioperative and late complications. At 12 years, there was a significant increase in rates of repeat surgery for incontinence and prolapse in women after the Burch procedure. The Burch had a 3 times risk of prolapse surgery up to 12 years after incontinence surgery.

The evidence suggests that the long-term effectiveness of the MUS slings is good [38] and similar to the Burch Colposuspension and the fascial pubovaginal slings.

Urethral bulking agents

The bulking agents to date have had a reasonable short-term effectiveness but repeated reinjections have been necessary to maintain continence. In a RCT [39] of women with SUI and ISD comparing the pubovaginal sling and transurethral Macroplastique, the symptomatic and patient satisfaction success rates were similar following the sling and Macroplastique with the objective success rate being significantly greater ($P < 0.001$) following the sling (81% vs 9%). Macroplastique had significantly lower morbidity but was more expensive than the sling ($P < 0.001$). Response rate at 62 months follow up was 60% in both groups with the sling group reporting better continence success (69% vs 21%) and satisfaction rates (69% vs 29%, P greater 0.05). Whether the newer bulking agents are more effective remains to be seen. An RCT comparing Bulkamid to TVT sling is presently being conducted which should provide answers.

Conclusion

Despite the increasing evidence that the retropubic MUS are more effective long-term and in high failure risk women with recurrent USI and ISD, the TOT continues to have a high satisfaction and usage worldwide. This is probably related to the avoidance of the retropubic space with its significant risk of visceral injury and bleeding risks. Inexperienced and low volume clinicians frequently feel that the TOT MUS and mini-slings are safer in their hands; hence, these slings which do have good success rates provide an important alternative to the retropubic slings. There is an ongoing need for more comparative trials with longer follow up to look at the different surgical options in primary or recurrent stress incontinence.

Conflict of interest

PD is the head of one of the units which in the past was involved in a multi-centric trial that received funding from AMS in the past. None current disclosures.

DK has no relevant disclosures.

Practice points

- MUS are the surgical option of choice for SUI
- The retropubic MUS are the most likely to work and for longer in intrinsic sphincter deficiency
- Complications with MUS are closely related with the surgeon's surgical experience.
- Cure rates for SUI between the retropubic and TO approaches in the short-term are similar but the retropubic slings are more effective long-term and in high risk women with recurrent SUI, or ISD. The RP has a higher risk of visceral injury particularly bladder perforation than TOT and mini-slings.
- There is current interest in bulking agents in the current climate with negative publicity around mesh devices including MUS

Research agenda

There is a need for comparative trials to look at

- The different surgical options in primary or recurrent stress incontinence
- Optimum surgical options for stress incontinence with intrinsic sphincter deficiency
- Best practice for management of women with no symptoms of stress incontinence but demonstrable SI on examination or with reduction of prolapse
- Routine versus selective use of urodynamics prior to stress incontinence surgery
- The place of bulking agents and vaginal laser treatments for SUI presently being proposed as alternatives to the synthetic MUS.

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