

Review Article

Mid-urethral sling approach for female stress urinary incontinence: benefits versus risks

Yang Shen^{1,2,3}, Yiying Wang^{2,3,4}, Yue Wang^{2,3,4}, Christopher P Geffre⁵, Kenneth D Hatch^{3,5}

¹Department of Obstetrics and Gynecology, Zhongda Hospital, School of Medicine, Southeast University, Nanjing, Jiangsu, China; Departments of ²Pathology, ³Obstetrics and Gynecology, University of Arizona Medical College, Tucson, AZ, USA; ⁴Department of Obstetrics and Gynecology, Henan Province People's Hospital, Zhengzhou, Henan, China; ⁵Arizona Cancer Center, University of Arizona, Tucson, AZ, USA

Received July 15, 2015; Accepted August 18, 2015; Epub December 20, 2015; Published December 30, 2015

Abstract: Stress urinary incontinence (SUI) has a major impact on quality of life and accounts for a large percentage of health-care expenditures. But it seems that there are lots of controversies regarding the mid-urethral sling (MUS) treatment for SUI. Such controversies have caused a significant confusion in the field. The polypropylene mesh MUS is the worldwide recognized standard of care for the surgical treatment of SUI. An unwarranted controversy around MUS has kept a large number of women with SUI from receiving appropriate treatment for SUI and has resulted in a sustained poor quality of life. Overall, the advances in the treatment of SUI, which is supported by the evidence based medical practice, have led to progressively less invasive procedures, high success rates, durable outcomes, and minimal complications. We have systemically reviewed the literature on the topic and conclude that MUS implementation for patients with SUI remains a good choice and the procedure needs to be performed by well-trained surgeons in an individual basis after necessary urodynamic evaluation, detailed discussions with patients about the pros and cons of the procedure, and expected results after the operation.

Keywords: Mid-urethral sling, stress urinary incontinence, pelvic organ prolapse

Introduction

Stress Urinary Incontinence (SUI) is defined as the “complaint of any involuntary leakage of urine on effort of exertion, or on sneezing or coughing” by the International Continence Society (ICS) [1]. SUI has a major impact on quality of life and accounts for a large percentage of health-care expenditures [2]. Various risk factors for SUI development have been identified. The most well-known being vaginal births, obesity, hormonal disorders, and muscle weakness of the pelvic diaphragm [1]. Due to patients' embarrassment and physicians' reluctance to discuss this sensitive subject, many women may go untreated, and in turn, suffer from disruptive symptoms and co-morbid complications associated with urinary incontinence. The prevalence of SUI is estimated to be approximately 25% in young women (14 to 21 years), 44% to 57% in middle-aged and postmenopausal women (40 to 60 years), and 75% in elderly women (≥75 years) [3]. The cost of care associated

with managing SUI is rising, with billions of dollars spent annually in the US for the treatment of SUI [4]. A claims-data analysis shows that the average direct medical cost per patient to treat SUI in 1998 was \$5,642, and the indirect work-place cost of SUI was \$4,208 [5].

Based on the literature published within the field, the current gold standard first-line surgical treatment for women with SUI is the synthetic mid-urethral sling (MUS) inserted through a retropubic or transobturator approach. This method has a higher success rate than the colposuspension and other traditional approaches [6]. To date, the MUS utilizing a macroporous polypropylene mesh is the most frequently used surgical treatment for SUI. In 2010, 260,000 women underwent surgical repair for SUI, and 208,000 of them had mesh mid-slings inserted transvaginally [7].

However, between 2008 and 2010, the U.S. Food and Drug Association (FDA) received mul-

Benefits of mid-urethral sling overweight over risks

multiple reports of medical complications associated with transvaginal placement of MUS [8]. On July 13, 2011 the FDA released a bulletin expressing concern about the number of complications related to the vaginally implanted meshes for Pelvic Organ Prolapse (POP). These vaginally inserted mesh products had a high incidence of erosion, infection and pain. This bulletin warning did not include MUS. However, this prompted studies to see if the MUS procedure is the most appropriate SUI treatment [9]. These complications include unsatisfactory results or without significant improvement, uncomfortable personal feeling such as dyspareunia, infection associated with mesh erosion, etc. Furthermore, it has occasionally been reported that the success rate of the MUS is not clearly superior to that of other surgical approaches [8]. In 2013, the American Urogynecology Society (AUGS) issued a position statement on restriction of surgical options for pelvic floor disorders [10], but they pointed out that the 2011 FDA bulletin did not include MUS.

It seems that there are still lots of controversies regarding the MUS treatment for SUI. Such controversies have caused significant confusion in the field. Patients are worried about the potential complications and surgeons sometimes do not know how to answer the questions patients may raise. In this review we will summarize the available data and discuss the pros and cons of various treatment options including the MUS procedure for SUI. In addition, we will discuss if the MUS procedure remains the gold standard for SUI treatment, hoping the information provided helps to clarify the confusion.

Management of SUI

Many factors should be considered when determining the optimal therapy for a patient with SUI, including the etiology and type of SUI, bladder capacity, and severity of leakage. A progressive approach that begins with the least invasive (behavioral modification) and advances to more invasive (surgery) interventions is recommended [3, 11]. Initial treatment includes lifestyle and behavior modification, as well as pelvic floor strength and bladder training (Kegel exercises). Women who are overweight or obese and who experience stress incontinence should be encouraged to lose weight, which has been shown to reduce the frequency of incontinence symptoms [12]. Pelvic floor muscle exercises are the mainstay of behavioral

therapy for SUI. Increased effectiveness is demonstrated in women undergoing longer training and in those following comprehensive clinic-based training rather than those using self-help booklets. Noninvasive electrical and magnetic stimulation devices are also available for women who have mild SUI. Additional treatments for stress incontinence include vaginal inserts, such as Pessaries and urethral plugs. There is minimal and conflicting evidence for the use of medications for SUI; moreover, there are no medications currently approved by the FDA for this condition. Minimally invasive procedures, including radiofrequency denaturation of the urethra and injection of periurethral bulking agents, can be used if SUI does not respond to less invasive treatments [11].

For women with persistent SUI following conservative therapy, surgical management may be considered. Surgical treatment options have demonstrated significantly better results than conservative treatment in select circumstances. About 30% of women with SUI ultimately elect to undergo surgery [13]. While there are many surgical procedures described for the treatment of SUI, all of them aim to provide a tension-free support to the mid-urethra or bladder-neck, thus, preventing the downward displacement in the setting of stressful provocative maneuvers (e.g., cough, sneeze, valsalva, straining).

The first surgical procedures for incontinence were performed via laparotomy or laparoscopy using the Burch colposuspension in the 1960s, which involves attaching the periurethral fascia to the iliopsoas ligament with multiple sutures to stabilize the urethra. Overall, the Burch colposuspension has been documented to be a safe and effective surgical option for SUI, and can be considered for women already undergoing an open abdominal procedure, such as for pelvic organ prolapse or hysterectomy. However, there is a time-dependent decline of efficacy, with a 63% continence rate at 6 years follow-up and a 44% continence rate at 14 years [14].

The development of minimally invasive, retro-pubic, synthetic MUS procedures has revolutionized SUI surgery and reduced the popularity of 'traditional' procedures, such as colposuspension and autologous fascial sling. The MUS is placed via a small sub-urethral vaginal incision and small incisions in the suprapubic or

Benefits of mid-urethral sling overweight over risks

groin area, depending on the type of tape utilized. Since the introduction of the MUS procedure, a number of modifications have been made to the procedure with the most notable being the transobturator approach [15, 16].

The retropubic tension-free vaginal tape (TVT), designed on the basis of 'integral theory', was the first MUS procedure introduced into clinical practice in 1996 by Ulmsten [17]. The retropubic tape can be placed via a top-down approach (Lynx[®] [Boston Scientific, USA], SPARC (suprapubic arc)[™] [American Medical Systems, USA]) or a bottom-up approach (TVT[™] [Ethicon, USA], IVS Tunneller[®] [Tyco Healthcare, USA], Advantage Fit[™] [Boston Scientific, USA]) [6]. The TVT's mechanism of action in treating SUI is to increase the abdominal to urethral pressure impact ratio (APIR), while the urethral opening pressure at rest (Po-rest) is unchanged [18]. The transobturator approach (based on the "hammock theory" proposed by Delancey in 1994 [19]) was introduced in 2001 with the aim of decreasing the risk of perioperative bladder, bowel, and vascular complications reported rarely with the retropubic approach [20]. The transobturator approach is performed by making an incision in the anterior vaginal wall and then dissecting the periurethral space. The sling is then placed in the horizontal plane under the urethra through the obturator membrane and obturator internus muscles. The transobturator sling can be placed via an outside-in approach (Monarc[™] [American Medical Systems, USA], ObTryx[®] [Boston Scientific, USA], Aris[®], ObTape[®] [Coloplast, USA], Ura tape[®] [Mentor-Porgés, France]) or an inside-out approach (TVT-OTM, Abbrevo[™] [Ethicon, USA]) [6]. Multiple, large randomized controlled studies have demonstrated that the success rates for MUS range from 86-99% [21-23].

The MUS procedure has demonstrated improved objective as well as subjective cure rates compared to colposuspension; including being less invasive and more cost-effective [14, 21]. In a 10-year follow-up study, TVT was more cost-effective (\$1495/quality-adjusted life year [QALY]) than colposuspension (\$1824/QALY) [24]. Given the improved cost-effectiveness and success rate, the MUS procedure has become the treatment of choice for SUI [21]. While the retropubic approach provides a slightly higher success rate, the transobturator approach is associated with fewer overall complications [23]. However, open colposuspension re-

mains an effective treatment modality for recurrent SUI after failed MUS procedures. In the setting of repeated SUI surgery, long-term results (>10 years) demonstrate that the Burch procedure had the lowest 9-year cumulative incidence of repeat SUI surgery [25]. In the past 5 years, in an attempt to further reduce morbidity associated with transobturator injury, less-invasive single-incision slings (SIS), such as the TVT Secur[™] (Ethicon, USA), Solyx[™] (Boston Scientific, USA) and MiniArc[®] (American Medical Systems, USA) [6] have been developed. However, a recent meta-analysis concluded that there was no significant difference in patient-reported or objective measures of success between SIS and standard MUS at midterm follow-up, although SIS is associated with more favorable recovery time. These results should be interpreted with caution due to the heterogeneity of the trials included [26]. Furthermore, clinic observations suggest several complications with SIS, dominated by incontinence, pelvic pain, dyspareunia and obstructive urinary symptoms/urinary retention. These side effects are similar to what has been reported with other suburethral synthetic tapes [27]. However, long-term results for SIS techniques are not available and close monitoring of the adverse event profile is needed [25]. In the future, tissue engineering using autologous stem cells may be the next step in the evolution of pubovaginal slings for the treatment of female SUI [28]. Currently, retropubic and transobturator tension-free MUS slings represent the most effective and popular procedures for the surgical treatment of SUI and as such are currently the gold standard [29].

Pathogenesis of SUI

Urinary continence relies on the integrity of the pelvic floor muscles and connective tissue. Connective tissue (types I and III collagens) are responsible for tensile strength and flexibility, while the cross-linking of proline and hydroxyproline amino acids stabilizes the collagen fibers. Elastin allows for increased compliance and stretching [30]. Pelvic tissue studies have demonstrated differences in collagen and elastin structure between control subjects and women with SUI. While the studies have produced heterogeneous results, there has been a trend towards decreased collagen and elastin content in patients suffering from SUI [31]. One study found that the content of type III collagen was significantly reduced ($P < 0.05$) in patients

Benefits of mid-urethral sling overweight over risks

with SUI when compared to controls, either with or without POP. These findings suggest that women with SUI show an altered collagen profile in the skin, vaginal wall along with the uterosacral, and round ligaments. These findings seem unrelated to secondary damage of the support tissues and degree of pelvic relaxation [32]. Data on collagen metabolism continues to support the hypothesis that increased turnover of extracellular matrix (ECM) proteins and serine proteases plays a role in the development of SUI; although, this complex interplay of enzymes, proteins and their related molecules is not well understood. Epidemiological data indicates a genetic predisposition to abnormal extracellular matrix in affected individuals, while cell culture and animal models have documented the role of transforming growth factor- β pathways in the development of SUI. Additionally, reproductive hormones, trauma, mechanical loads and aging all modulate the metabolism of extracellular matrix proteins [33]. Due to the altered metabolism of the native extracellular matrix (specifically collagen, elastin, and their respective enzymes), repairs using autologous tissue may lead to subsequent failure, despite a higher cure rate of 82%-83% at 3.5-7 years [34, 35]. Based on this concept, it is entirely rational to consider using biomaterials in the treatment of SUI instead of autologous tissue.

Optimal MUS biomaterials for SUI treatment

The purpose of tapes is to perform, supplement, or replace a natural function that is attenuated or lost in patients suffering from SUI. The ideal biomaterial is inert, sterile, non-carcinogenic, mechanically durable, elicits no inflammatory or immune reaction, can withstand modification by the host, be inexpensive, convenient, and easy to use [36, 37]. A multitude of biomaterials, such as allografts, xenografts and synthetic grafts, have been established and used for the treatment of SUI. Safety and serious side effects of incontinence devices must be completely defined with adequate follow-up, especially for use of implantable devices and biologic materials, so that risks can be weighed against efficacy [38]. Currently, none of the available biomaterials completely meets all of the above mentioned criteria, but many come close.

Allografts used in SUI usually consist of fascia. A concern with using allografts is that they are

often donated by the elderly who may already have age related weakening of connective tissues [39]. Additionally, these grafts may lose tensile strength after they are processed by techniques such as freeze drying and solvent dehydration [40]. More importantly, allografts are associated with lower continence rates and have potential poor long-term outcomes [41, 42]. Xenografts used in SUI are often porcine or bovine. These materials undergo extensive processing in order to de-cellularize them and to render them non-immunogenic. Additionally there are FDA regulations on animal source and vaccination status which must be followed [43]. The available clinical studies suggest lower continence rates of about 80% for porcine dermis and increased reoperation rates compared to synthetic tape or autologous fascia [44]. Porcine small intestine submucosa used for the treatment of SUI has shown cure rates ranging from 79 to 93% at 2- and 4-year follow-up, respectively [45]. However, another study has raised concerns that grafts made of small intestine submucosa are not completely acellular and may contain porcine DNA leading to a significant immune response and subsequent graft failure [46].

Absorbable mesh, including Vicryl (polyglactic acid) and Dexon (polyglycolic acid), have been used to reduce the risk of erosion/infection. Their use, however, has been discouraged due to poor tissue integration, poor tensile strength, and high recurrence rates [47].

A range of synthetic non-absorbable meshes have been used for SUI. These materials offer several advantages including no risk of transmittable infectious diseases and ease of availability, as well as sustained tensile strength due to them not degrading *in vivo* [48]. They are classified as type 1 (macroporous, $>75 \mu\text{m}$), type 2 ($<10 \mu\text{m}$), type 3 (microporous with microporous compartments), or type 4 (nanoporous, $<1 \mu\text{m}$) according to their mesh size [49]. The initial clinical experience with type 2 (expanded polytetrafluoroethylene [PTFE]) and type 3 (Mersilene) meshes was mostly negative with excision rates of up to 30% for expanded PTFE [50] and erosion rates of 17% for Mersilene (polyester) [51]. A greater pore size, such as with type 1 meshes, is thought to be advantageous as it allows immune cells, vascular elements and greater collagen ingrowth into the construct [52]. All of these are necessary to anchor the implant within the host, reduce the

Benefits of mid-urethral sling overweight over risks

risk of mesh infection and accelerate and enhance host tissue integration [53]. The filament type and structure are important to mesh function as well. Multifilament meshes have interstices within the filaments, measuring less than 10 μm , which can allow bacteria but not the host immune cells (9-20 μm), to pass through, thereby restricting the host's ability to combat infection within the mesh. It has been shown that multifilament meshes produce more fibrosis and acute inflammation than their monofilament counterparts [54]. In contrast, a solid matrix product as well as one with smaller pores (<50 μm) will likely be encapsulated or have an increased foreign body reaction resulting in inefficient tissue integration [52].

Krambeck et al. compared six different types of suburethral slings (two human cadaveric fascia, porcine dermis, porcine small intestine mucosa, polypropylene and autologous fascia) in a rabbit model in order to compare the histologic response of different graft materials. The findings included a persistent tissue reaction, consisting of an inflammatory infiltrate characterized by foreign-body giant cells, granulocytes, and fibroblasts [55]. Polypropylene mesh showed the lowest degree of inflammatory response [55]. In order to compare the histological response among different synthetic meshes, Boulanger et al. chose the pig model, anatomically and physiologically closer to humans, to analyze the tissue integration and tolerance of five different meshes. The results showed absorbable prostheses made of polyglacin 910 (Vicryl) and non-absorbable prostheses made of polypropylene (Prolene and Prolene soft) induced low levels of inflammation [56]. Tissue integration was best with the polypropylene meshes, which allowed the development of a well-organized, mature fibroconnective tissue. They concluded that that type 1 mesh with macroporous and monofilament material, such as polypropylene, seems to be the best in terms of host integration and tolerance [56]. Additionally, Woodruff et al. compared graft materials removed from 24 women undergoing sling revision (polypropylene mesh in 10, autologous fascia in 5, porcine dermis in 4, cadaveric dermis in 3 and cadaveric fascia in 2). The study found that porcine dermis has the potential to encapsulate, but the degree of host tissue infiltration was greatest with polypropylene, and no degradation of the mesh material had occurred with time [57].

Therefore, based on the evidence presented above, type 1 polypropylene mesh, of macroporous and monofilament, is currently optimal for biocompatibility [58]. Polypropylene induces a limited inflammatory response and allows for advantageous tissue remodeling, which appears to provide better long term success than other biomaterials that induce persistent and significant chronic inflammation, fibrosis, and scar encapsulation.

Efficacy of MUS procedure for SUI treatment

Research looking at different SUI treatments has been carried out for decades [1, 54], and as such long-term data is available for analysis. According to Nilsson et al., the overall objective success rate of the TVT procedure at 17-years was 90%, with an 87% patient satisfaction rate [59]. The cure rates of the transobturator procedure range from 51% to 95%, depending on the definitions used for success or cure, the study instruments, and the size of the patient population [60, 61]. Recent reports demonstrate that the cure rate depends on the starting point of the surgical incision. When using transobturator suburethrel tap (TOT) to surgically treat SUI, incision at the mid-urethra using the 1/2 rule is recommended as it results in better outcomes for most patients, particularly those with normal urethral mobility [62]. To date, many randomized controlled trials (RCTs) comparing long-term efficacy of different types of MUS have been performed and will be discussed below.

TVT vs. other retropubic MUS

Meschia et al. reported the largest trial of 190 women randomly assigned to either TVT or IVS (Intravaginal Slingplasty) with a 1:1 ratio. After two years of follow-up, 87% and 78% of women reported that they were cured, respectively. Objectively, a 1-hour pad test was negative in 85% and 72% of patients, respectively [63]. Therefore, it appears both procedures are effective for the management of SUI [63]. Andonian et al. randomized 84 women to either TVT (n=43) or suprapubic arch sling (n=41). Follow-up at 1, 6 and 12 months assessed complications and cure rates. At 12 months follow-up, there was no statistical difference in objective or subjective cure rates (95% in the TVT and 83% in the SPARC group; P=0.1) [64].

Benefits of mid-urethral sling overweight over risks

Retropubic vs. transobturator MUS

Laurikainen et al. compared the TVT and the tension-free vaginal tap obturator (TVT-O) procedures. The objective cure rates (negative cough stress test at 2 months postoperatively) were 98.5% for the TVT group and 95.4% for the TVT-O group. The subjective cure rates as demonstrated by improvement on questionnaire scores were similarly high in both groups [65]. This indicates there is little clinical difference between the retropubic and transobturator approaches for the treatment of SUI. Lee et al. randomly assigned 120 women to either TVT or TVT-O procedures. The only significant differences between the groups were the mean operative time (TVT 15.2 min; TVT-O 11.5 min) and sling length used (TVT 23.1 cm; TVT-O 16.1 cm). The rates of cure (86.8% of TVT and 86.8% of TVT-O), improvement (6.6% of TVT and 8.2% of TVT-O) and failure (6.6% of TVT and 5.0% of TVT-O) were similar [66]. However, a meta-analysis, from all available RCTs between retropubic and transobturator slings, showed retropubic midurethral slings resulted in better objective and subjective cure rates than transobturator midurethral slings [23]. The disparity likely arises from different clinical evaluation criteria.

Inside-out TVT-O vs. outside-in TOT

There was widespread sentiment that the TOT and TVT-O procedures were equally effective and safe when used to treat female SUI [67]. A prospective RCT to compare the efficacy of the 'inside-out' (TVT-O) and 'outside-in' (TOT) transobturator tape procedures reported that TVT-O and TOT had similar cure rates (73.2% vs. 72.3%) at 3-year follow-up. Although, there was a decrease in the patient-reported success rate compared to the 1-year follow-up data (81.3% vs. 73.1%, $P=0.005$). About 6% underwent further surgical treatment within 3 years. The parameters included in the total King's Health Questionnaire (KHQ) improved significantly in both groups, and there was no statistical difference between the groups [68]. Another study evaluated the long-term safety and efficacy of TOT procedure in the treatment of 48 women with SUI (25 patients treated with TVT-O by Gynecare, Ethicon and the other 23 patients treated with TOT by Monarc Subfascial Hammock, AMS). Follow-up of the studied patients revealed that there was no statistical difference between the groups. At 12 months follow-

up, 39 patients (81.25%) were cured, 5 (10.42%) improved, and 4 (8.33%) were considered a failure. At 71 months follow up, 38 patients (79.15%) were cured, 5 (10.42%) improved, and 5 (10.42%) were considered a failure. Meanwhile, there was significant improvement in the QOL score among the treated patients at both time points and no statistically significant difference between the groups [69].

Single incision approach vs. retropubic or trans-obturator approach

One retrospective, one prospective observational study and one RCT all compared single incision procedures to TVT or TVT-O. None of the studies showed any clinical benefit of the single incision procedures to TVT or TVT-O. Additionally, there was a significantly higher rate of persistent SUI at 6 weeks (OR 9.49, 95% CI 2.8-32.6) and 6 months (OR 8.14, 95% CI 2.7-24.7) with the single incision procedures compared to a retropubic TVT approach [70-72]. One study recently reported 2 year follow-up data comparing TVT-S and TVT-O. The objective cure rates for TVT-S and TVT-O groups were 77.3% and 83.6%, while subjective cure rates were 75.7% and 80.3%, respectively. There was no statistically significant differences between the two techniques [73].

Economics analysis

In addition to the points discussed above, SUI is associated with a substantial economic burden. In view of patient satisfaction from the procedure, the cost/effectiveness ratio still needs to be determined. A study examining the cost of transobturator slings for SUI surgeries determined that the average incremental cost over 1 year for one patient was between \$2,601 and \$3,132. In a hypothetical population of 100 patients, a 10% shift from the most to the least expensive option was associated with reducing hospital expenditures by 2% [74]. With the current transobturator sling market share, the expected expenditure is approximately \$285,533 for a surgical population of 100 patients. Approximately \$105,526 (37%) of this total cost is due to the sling, while the remainder and majority of the costs are related to management of complications [74]. Another study demonstrated that retropubic MUS was more cost-effective than transobturator MUS in the treatment for SUI, while the efficacy of the

Benefits of mid-urethral sling overweight over risks

Table 1. Complications after midurethral sling procedures

Intraoperative	
Major	
Vascular injury	<0.01%
Nerve injury	<0.0005%
Gut injury	<0.007%
Minor	
Bladder injury	0.5-0.7%
Repeated bladder injury	1.2%
Perioperative	
Retropubic haematoma	2-4.3%
Blood loss >200 ml	2.7-3.3%
Urinary tract infections	4.1%
Spondylitis	0.3-0.8%
Postoperative	
Transient urinary retention	1.4-15%
Permanent urinary retention	2.4-2.8%
Vaginal and urethral erosion	0.7-13.79%
De novo urgency	7.2-30.1%
Bladder erosion	0.5-0.6%
Urethral obstruction	3.6-6.4%
Pain	1.5-16%
Sexual dysfunction	Probable improvement
Carcinogenesis	No any human case reported

Note: Ranges are as reported in the literature.

two treatments is potentially affected by surgeons' experience and sling characteristics [75]. Even so, transobturator vaginal tape is still considered a low-cost alternative, particularly for those patients with relatively fewer financial resources who rely on public health systems to obtain medical services [76].

Safety of MUS procedure for SUI treatment

5th International consultation on Continence (Paris, 2013) proposed that the safety and serious side effects of operations must be completely defined with adequate follow-up so that risks can be weighed against efficacy. At a minimum, this requires more use of large scale, independent, prospective, multicenter cohort studies when RCTs are not practical [38]. In 2013, the FDA reported that "the safety and effectiveness of multi-incision slings is well established in clinical trials that followed patients for up to one-year" [77]. In October 2013, the American Urological Association (AUA) reaffirmed the AUA Guideline for the Surgical Management of Stress Urinary Incontinence:

"synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques" [78]. In June 2014, AUGS and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) jointly issued a position statement on midurethral slings stating that the "the procedure is safe, effective, and has improved the quality of life for millions of women" [79]. Given these positions, MUS procedures have gained popularity not only because success rates are high, but also because complication rates appear low. **Table 1** presents the range of complications after MUS procedures, according to the reported data in the English literature [63, 65, 73, 80-87]. **Table 2** summarizes the potential causes of the complications [80, 85-88].

In the next few paragraphs, we will discuss those prominent complications.

Bladder injury

Bladder perforation by needle injury is the primary complication of TVT, occurring in approximately 0.7% of cases, and usually resolved with appropriate medical treatment [63]. Given that the IVS device has blunt plastic ends, this may result in a lower risk of bladder perforation or vessel injury during the surgery. The transobturator technique avoids the retropubic space and addresses clinicians' concerns regarding potential bladder injuries after TVT [88]. Expert recommendations from the AUA state that intraoperative cystoscopy should always be performed, to help minimize the risk of urinary tract injury [89].

Urinary tract infections

A nationwide analysis of complications reported that 4.1% of patients undergoing the TVT procedure had urinary tract infection [81]. Infection-related complications after the TOT procedure included thigh abscesses and infected obturator hematomas, both requiring drainage and probable exploration for management [48]. It was speculated that the presence of localized infection and morbid obesity could be possible risk factors for the development of such infections [88].

Benefits of mid-urethral sling overweight over risks

Table 2. Etiology of midurethral sling-related complications

Complications	Potential causes
Vaginal erosion	Inadequate suturing of vaginal wall
	Extensive dissection
	Early resumption of sexual activity
	Previous vaginal surgery
	Wound infection
	Incorrect vaginal plane
	Rolling of the tape
Urethral erosion	Ischemia
	Excessive tension
	Ischemia
	Extensive dissection around urethra
	Previous surgery
	Infection
Bladder perforation	Incorrect plane of dissection
	Rolling of the tape
	Operative technique
Groin/thigh pain	Hematoma
	Nerve entrapment
	Trauma to the adductor muscle

Vaginal and/or urethra erosion

There is a high rate of erosion (9%) with IVS, due to its multifilament structure, compared with none in the TVT group ($P < 0.01$) [62]. Of the 386 patients who had a sub-urethral sling (TVT-O or TVT Secur) and were studied with a median follow-up of 4 years, the total rate of exposure was 4.32%. TVT Secur gave rise to more exposures (13.79%) than TVT-O (3.51%) ($P = 0.0203$). It seems important not to use the mini-slings of the TVT Secur tape as they induce a higher rate of prosthetic exposure [90]. Eroded material showed a significantly higher accumulation of macrophages around the filaments of the mesh, which may have resulted from persistent post-implantation foreign body reaction. However, no bacterial colonization was found immediately adjacent to the mesh filaments [56, 91]. Another study demonstrated that when organ prolapse repair is done simultaneously, the cure of SUI may be achieved without a higher risk of mesh erosion [89].

De novo urgency

De novo urgency is defined as the appearance of urge urinary incontinence after an anti-incontinence surgery that persists after six months

[92], and was reported by 30.1% and 18.9% of patients after TVT treatment at 3-month and 10-year follow-up, respectively. Recent reports on de novo urgency after a TOT procedure suggests that de novo urgency develops in only 2.5-8% of patients [83]. In a meta-analysis of randomized trials, there was no significant difference in the development of de novo urgency between the transobturator and retropubic approaches [89]. Additionally, another study found that at 12 weeks 43.8% of women given anti-muscarinic drugs for detrusor over activity were non responders [82]. It's worth noting that a maximum detrusor pressure during the filling phase of greater than 9 cm H₂O and a maximum detrusor pressure during the voiding phase of greater than 29 cm H₂O were independent predictors for the recurrence of SUI [82].

Urethral obstruction

The true incidence of obstruction after incontinence surgery is not known. Multifilament mesh, such as IVS, has the advantage of being more flexible and less extensible and is said to be easier to adjust once positioned under the urethra compared to monofilament mesh, which can't be moved once in place. As such there may be a lower incidence of postoperative voiding difficulties or retention with multifilament mesh [63]. Furthermore, trans-obturator tape, theoretically, should carry little if any risk of producing urgency as it is expected to provide a tension-free support and thus minimize the chance of producing any obstruction [93]. Additionally, the TOT sling allows for a less acute angle that is more anatomical and natural compared to TVT, so it also makes sense that there are fewer problems with urinary obstruction [94]. In a recent study involving 48 women with transobturator tape, no patient developed postoperative urinary retention. There was no significant difference in the mean Q max and post-void residual urine measured at 12 months and at 71 months postoperatively [69]. Another study concluded that the severity of obstructive symptoms and post-void residual volumes at 5 years were not improved compared with 1 year postoperatively [83].

Groin or thigh pain

Groin and thigh pain following the MUS procedure is a troublesome complication for both

Benefits of mid-urethral sling overweight over risks

patients and surgeons. Possible causes include hematoma, positioning, retention, and nerve entrapment. When using the transobturator approach, there may also be pain due to trauma to the adductor longus [88]. Studies have demonstrated that postoperative groin/thigh pain was higher ($P < 0.05$) with the TVT-O procedure compared to TVT-S procedure [85]. Laurikainen et al. randomly assigned 267 patients to TVT or TVT-O and reported that postoperative groin pain was significantly more common in the TVT-O group than in the TVT group (16% vs. 1.5%, respectively, $P < 0.001$) [65]. Tommaselli et al. suggested that a more limited dissection and a more medial trocar trajectory of TVT-O seemed to reduce postoperative groin pain at 24 hours after the procedure, but not the analgesic requirement [87].

Sexual dysfunction

No matter what kind of procedure (TVT, TOT, SIS) is used for the treatment of SUI, it appears to negatively interfere with female sexual function [86, 95]. However, one recent study, involving 94 women without concomitant pelvic organ prolapse repairs, reported that the total PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire Short Form) score before surgical operation was 30.9 compared to a mean score of 33.9 at 12 months postoperatively, representing a significant difference ($P = 0.021$) in the TVT-S group. There was no significant difference in PISQ-12 scores before and after the TVT-O procedure [85]. Coital incontinence seems to be a good predictor of an improvement in postoperative sexual parameters; its cure to a large extent explains the sexual benefits reported in one previous study [96].

Carcinogenesis

Polypropylene has been found to be carcinogenic in some laboratory animal models. However, there is doubt whether the results utilizing these animal models are transferable to human [97]. There have been so far no reports of malignancy in human after polypropylene mesh placement. In a recent series of 2,361 polypropylene MUS with a follow-up extending up to 122.3 months, the rate of cancer formation was 0% [98]. Furthermore, the results utilizing the rat model did not show an infiltrative pattern or distant metastasis and as such do not provide convincing proof of the malignant fea-

tures of the tumor-like lesions. Additionally, a post-retrieval study in human looking at 400 explants found a primarily acellular fibrosis after decades of implantation, and no precursor lesions (nuclear dysplasia) similar to the rat model. After a review of all the evidence-based data, there is currently no evidence to suggest that polypropylene MUS is associated with a risk of malignancy [84].

Making clinical decisions for SUI by using MUS

The value of urodynamic studies

Urodynamic studies (UDS) involve the assessment of the function of the lower urinary tract. UDS can be either noninvasive or invasive. The principle methods for UDS are filling the bladder with saline then measuring the water flow as well as pressure with cystometry [38].

It has been well accepted that UDS are necessary, particularly for those patients with complicated SUI. However, some debates about the necessity of using UDS to evaluate all SUI patients exist. The role of UDS has recently been questioned mainly based on the data coming from selected population of uncomplicated (pressure induced) SUI patients. There was a retrospective study, which involved 2,053 women with SUI, including only a minority (about 36%) amount of patients in the study. The majority patients had complicated SUI (67%). Based on the results of this relatively large study, it is necessary to use UDS to evaluate patients with SUI, especially those patients with complicated etiologies [99]. In addition, study from the VALUE trial evaluated the cost of preoperative urodynamics and concluded that it is probably economically beneficial not to perform UDS for patients with uncomplicated SUI [100].

Optimal choice of biomaterials and clinical indications

Despite controversy surrounding vaginal mesh for POP, synthetic slings (MUS) for the treatment of SUI are considered safe and minimally invasive. Complications seen in association with urogenital prolapse surgery utilizing mesh may not be caused by the mesh material itself, although the FDA is alerted. As long as type 1 materials (macroporous, monofilament polypropylene) are used, the complications could be the result of improper training of surgeons

Benefits of mid-urethral sling overweight over risks

who may use inappropriate surgical techniques, operate based on incorrect surgical indications or even select unsuitable patients for the graft procedure [78, 101].

Qualified surgeons using appropriate MUS procedure

In order to ultimately improve the quality of MUS and minimize the risks and complications, we strongly agree with AUGS recommendation [101] on the implementation of credentialing guidelines so that mesh procedures are performed by qualified surgeons. It is critical for a surgeon performing these complex procedures to adequately train with a proctor present for each type of transvaginal mesh procedure they are intending to utilize.

In October 2013, the AUA reaffirmed the AUA Guideline for the Surgical Management of Stress Urinary Incontinence: “synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques”. The AUA also agrees that “surgeons who wish to perform synthetic sling surgery should have undergone rigorous training in the principles of pelvic anatomy and pelvic surgery, should be properly trained in specific sling techniques, and are able to recognize and manage complications associated with synthetic mesh sling placement” [78].

Adequate informed consent, discussion and personalized treatments

Making the decision about surgery is a personal matter involving an interactive process between patients and their physicians. An anonymous survey reported that while nearly two-thirds of new patients had knowledge of vaginal mesh surgery; there was considerable misinformation and aversion to future mesh surgery among these women. There were multiple instances of misinformation among the new patient population including: women reporting that vaginal mesh can cause cancer, might be rejected from the body, needs to be removed immediately due to a recall, or can cause an allergic reaction. Using multivariable logistic regression, level of concern, information from friends/family, and knowledge of class-action lawsuit predicted aversion to mesh surgery [102]. Additionally, Tennstedt et al. identified differences between the subjective and objec-

tive opinions of success. Women reported that improvement in SUI symptoms was more important than the type of surgery or its success rate [103]. Ultimately, the goal is to return the woman to a quality of life that she considers acceptable. Surgeons must weigh the patient's goals against how the “success” of a procedure may be viewed by medical personnel [103]. Therefore, it is important to have a thorough informed consent and discussion prior to SUI surgery [78]. Both surgeon and patients should exchange whether the type of surgery she is considering can meet those expectations, and what she can expect during and after surgery. More importantly, when choosing between surgical procedures, any surgeon must weigh the presumed benefits with the potential risks and adverse effects of these procedures. Balancing those against a specific patient's expectations and desires is an important consideration for SUI treatment. The best-approach is elective based on the degree of bothersome and quality-of-life impact. Additionally, surgeons should evaluate their own personal success and complication rates with the procedures and products they use, as these may differ from published rates [104]. Based on adequate informed consent and discussion, individualized operations tailored to the specific patient would assist in improving subjective satisfaction and success rates.

Conclusions

In view of evidence-based medicine in the field of treatment of SUI, advancements in the past decades have led to progressively less invasive procedures, high success rates, durable outcomes and minimal complications. The polypropylene mesh MUS remains the worldwide recognized standard of care for the surgical treatment of SUI. An unwarranted controversy around MUS has kept a large number of women with SUI from receiving appropriate treatment for SUI and has resulted in a sustained poor quality of life. We have systemically reviewed the literature on the topic and conclude that MUS implementation for patients with SUI remains a good choice and the procedure needs to be performed by well-trained surgeons in an individual basis after necessary urodynamic evaluation, detailed discussions with patients about the pros and cons of the procedure, and expected results after the operation.

Benefits of mid-urethral sling overweight over risks

Disclosure of conflict of interest

None.

Abbreviations

AUA, American Urological Association; APIR, Abdominal to urethral pressure impact ratio; AUGS, American Urogynecology Society; ECM, Extracellular matrix; FDA, Food and Drug Association; ICS, Intravaginal Slingplasty; IVS, Intravaginal Slingplasty; KHQ, King's Health Questionnaire; MUS, Mid-urethral sling; POP, Pelvic Organ Prolapse; SIS, Single-incision slings; SUFU, Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction; SUI, Stress Urinary Incontinence; TOT, Transobturator suburethral tap; TVT, Tension-free vaginal tape; TVT-O, Tension-free vaginal tap obturator; UDS, Urodynamic study.

Address correspondence to: Dr. Kenneth D Hatch, Department of Obstetrics and Gynecology, University of Arizona Medical College, Tucson, AZ, USA. Tel: 520-626-9285; Fax: 520-626-9287; E-mail: khat-ch@obgyn.arizona.edu

References

- [1] Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, Van Kerrebroeck P, Victor A, Wein A; Standardisation Sub-Committee of the International Continence Society. The standardisation of terminology in lower urinary tract function: report from the standardisation subcommittee of the International Continence Society. *Urology* 2003; 61: 37-49.
- [2] Coyne KS, Zhou Z, Thompson C and Versi E. The impact on health-related quality of life of stress, urge and mixed urinary incontinence. *BJU Int* 2003; 92: 731-735.
- [3] Qaseem A, Dallas P, Forcica M, Starkey M, Denberg T and Shekelle P. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2014; 161: 429-440.
- [4] Wilson L, Brown JS, Shin GP, Luc KO and Subak LL. Annual direct cost of urinary incontinence. *Obstet Gynecol* 2001; 98: 398-406.
- [5] Birnbaum HG, Leong SA, Oster EF, Kinchen K and Sun P. Cost of stress urinary incontinence: a claims data analysis. *Pharmacoeconomics* 2004; 22: 95-105.
- [6] Cox A, Herschorn S and Lee L. Surgical management of female SUI: is there a gold standard? *Nat Rev Urol* 2013; 10: 78-89.
- [7] Fabian G, Barcz E, Zwierzchowska A and Kociszewski J. Complications of sub-urethral sling procedures. *Ginekol Pol* 2014; 85: 536-540.
- [8] FDA. Urogynecologic surgical mesh: update on the safety and effectiveness of vaginal placement for pelvic organ prolapse. <http://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/UCM262760.pdf>. 2011.
- [9] Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG; Systematic Review Group of the Society of Gynecologic S. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J* 2011; 22: 789-798.
- [10] AUGS. Position statement on restriction of surgical options for pelvic floor disorders. <http://www.augs.org/d/do/1859>. 2013.
- [11] Carpenter DA and Visovsky C. Stress urinary incontinence: a review of treatment options. *AORN J* 2010; 91: 471-478; quiz 479-481.
- [12] Wing RR, West DS, Grady D, Creasman JM, Richter HE, Myers D, Burgio KL, Franklin F, Gorin AA and Vittinghoff E. Effect of weight loss on urinary incontinence in overweight and obese women: results at 12 and 18 months. *J Urol* 2010; 184: 1005-1010.
- [13] Dmochowski RR, Blaivas JM, Gormley EA, Juma S, Karram MM, Lightner DJ, Lubner KM, Rovner ES, Staskin DR, Winters JC, Appell RA; Female Stress Urinary Incontinence Update Panel of the American Urological Association Education and Research, Inc, Whetter LE. Update of AUA guideline on the surgical management of female stress urinary incontinence. *J Urol* 2010; 183: 1906-1914.
- [14] Parker-Autry CY, Barber MD, Kenton K and Richter HE. Measuring outcomes in urogynecological surgery: "perspective is everything". *Int Urogynecol J* 2013; 24: 15-25.
- [15] Giarenis I and Cardozo L. Managing urinary incontinence: what works? *Climacteric* 2014; 17: 26-33.
- [16] Wood LN and Anger JT. Urinary incontinence in women. *BMJ* 2014; 349: g4531.
- [17] Ulmsten U, Henriksson L, Johnson P and Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1996; 7: 81-85; discussion 85-86.
- [18] Saaby ML, Klarskov N and Lose G. The impact of tension-free vaginal tape on the urethral closure function: Mechanism of action. *Neurourol Urodyn* 2015; 34: 50-4.
- [19] DeLancey JO. Structural support of the urethra as it relates to stress urinary incontinence: the hammock hypothesis. *Am J Obstet Gynecol* 1994; 170: 1713-1723.

Benefits of mid-urethral sling overweight over risks

- [20] Delorme E, Droupy S, de Tayrac R and Delmas V. Transobturator tape (Uratape): a new minimally-invasive procedure to treat female urinary incontinence. *Eur Urol* 2004; 45: 203-207.
- [21] Novara G, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S and Artibani W. Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. *Eur Urol* 2007; 52: 663-678.
- [22] Jain P, Jirschele K, Botros SM and Latthe PM. Effectiveness of midurethral slings in mixed urinary incontinence: a systematic review and meta-analysis. *Int Urogynecol J* 2011; 22: 923-932.
- [23] Seklehner S, Laudano MA, Xie D, Chughtai B and Lee RK. A Meta-analysis of the Performance of Retropubic Midurethral Slings vs. Transobturator midurethral slings. *J Urol* 2015; 193: 909-15.
- [24] Laudano MA, Seklehner S, Chughtai B, Lee U, Tyagi R, Kavalier E, Te AE, Kaplan SA and Lee RK. Cost-effectiveness analysis of tension-free vaginal tape vs burch colposuspension for female stress urinary incontinence in the USA. *BJU Int* 2013; 112: E151-158.
- [25] Mischinger J, Amend B, Reisenauer C, Bedke J, Naumann G, Germann M, Kruck S, Arenas Desilva LF, Wallwiener H, Koelbl H, Nitti V and Sievert KD. Different surgical approaches for stress urinary incontinence in women. *Minerva Ginecol* 2013; 65: 21-28.
- [26] Mostafa A, Lim CP, Hopper L, Madhuvrata P and Abdel-Fattah M. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications. *Eur Urol* 2014; 65: 402-427.
- [27] Coskun B, Lavelle RS, Alhalabi F, Lemack GE and Zimmern PE. Mini-slings can cause complications. *Int Urogynecol J* 2015; 26: 557-62.
- [28] Nikolavasky D, Stangel-Wojcikiewicz K, Stec M and Chancellor MB. Stem cell therapy: a future treatment of stress urinary incontinence. *Semin Reprod Med* 2011; 29: 61-70.
- [29] Lee EW, Nitti VW and Brucker BM. Midurethral slings for all stress incontinence: a urology perspective. *Urol Clin North Am* 2012; 39: 299-310.
- [30] Karlovsky ME, Thakre AA, Rastinehad A, Kushner L and Badlani GH. Biomaterials for pelvic floor reconstruction. *Urology* 2005; 66: 469-475.
- [31] Campeau L, Gorbachinsky I, Badlani GH and Andersson KE. Pelvic floor disorders: linking genetic risk factors to biochemical changes. *BJU Int* 2011; 108: 1240-1247.
- [32] Bergman A, Elia G, Cheung D, Perelman N and Nimni ME. Biochemical composition of collagen in continent and stress urinary incontinent women. *Gynecol Obstet Invest* 1994; 37: 48-51.
- [33] Chen B and Yeh J. Alterations in connective tissue metabolism in stress incontinence and prolapse. *J Urol* 2011; 186: 1768-1772.
- [34] Colaco M, Mettu J and Badlani G. The scientific basis for the use of biomaterials in stress urinary incontinence (SUI) and pelvic organ prolapse (POP). *BJU Int* 2015; 115: 859-66.
- [35] Haab F, Zimmern PE and Leach GE. Female stress urinary incontinence due to intrinsic sphincteric deficiency: recognition and management. *J Urol* 1996; 156: 3-17.
- [36] Karlovsky ME, Kushner L and Badlani GH. Synthetic biomaterials for pelvic floor reconstruction. *Curr Urol Rep* 2005; 6: 376-384.
- [37] Williams DF. On the mechanisms of biocompatibility. *Biomaterials* 2008; 29: 2941-2953.
- [38] Wagg A, Gibson W, Ostaszkiwicz J, Johnson T 3rd, Markland A, Palmer MH, Kuchel G, Szonyi G and Kirschner-Hermanns R. Urinary incontinence in frail elderly persons: Report from the 5th International Consultation on Incontinence. *Neurourol Urodyn* 2015; 34: 398-406.
- [39] Moalli PA. Cadaveric fascia lata. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17: 48-50.
- [40] Lemer ML, Chaikin DC and Blaivas JG. Tissue strength analysis of autologous and cadaveric allografts for the pubovaginal sling. *Neurourol Urodyn* 1999; 18: 497-503.
- [41] Carbone JM, Kavalier E, Hu JC, Raz S. Pubovaginal sling using cadaveric fascia and bone anchors: disappointing early results. *J Urol* 2001; 165: 1605-1611.
- [42] Fitzgerald MP, Mollenhauer J and Brubaker L. Failure of allograft suburethral slings. *BJU Int* 1999; 84: 785-788.
- [43] Amrute KV and Badlani GH. The science behind biomaterials in female stress urinary incontinence surgery. *ScientificWorldJournal* 2009; 9: 23-31.
- [44] Khan ZA, Nambiar A, Morley R, Chapple CR, Emery SJ and Lucas MG. Long-term follow-up of a multicentre randomised controlled trial comparing tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence in women. *BJU Int* 2015; 115: 968-77.
- [45] Jones JS, Rackley RR, Berglund R, Abdelmalak JB, Deorco G and Vasavada SP. Porcine small intestinal submucosa as a percutaneous midurethral sling: 2-year results. *BJU Int* 2005; 96: 103-106.
- [46] Zheng M, Chen J, Kirilak Y, Willers C, Xu J and Wood D. Porcine small intestine submucosa (SIS) is not an acellular collagenous matrix and contains porcine DNA: possible implications in

Benefits of mid-urethral sling overweight over risks

- human implantation. *J Biomed Mater Res B Appl Biomater* 2005; 73: 61-67.
- [47] Sand PK, Koduri S, Lobel RW, Winkler HA, Tomeszko J, Culligan PJ and Goldberg R. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. *Am J Obstet Gynecol* 2001; 184: 1357-1364.
- [48] Gomelsky A and Dmochowski RR. Biocompatibility assessment of synthetic sling materials for female stress urinary incontinence. *J Urol* 2007; 178: 1171-1181.
- [49] Amid P. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* 1997; 1: 15-21.
- [50] Weinberger MW and Ostergard DR. Postoperative catheterization, urinary retention, and permanent voiding dysfunction after polytetrafluoroethylene suburethral sling placement. *Obstet Gynecol* 1996; 87: 50-54.
- [51] Young S, Howard A and Baker S. Mersilene mesh sling: short-and long-term clinical and urodynamic outcomes. *Am J Obstet Gynecol* 2001; 185: 32-40.
- [52] Birch C and Fynes MM. The role of synthetic and biological prostheses in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol* 2002; 14: 527-535.
- [53] Deprest J, Zheng F, Konstantinovic M, Spelzini F, Claerhout F, Steensma A, Ozog Y and De Ridder D. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17: 16-25.
- [54] Winters JC, Fitzgerald MP and Barber MD. The use of synthetic mesh in female pelvic reconstructive surgery. *BJU Int* 2006; 98: 70-76.
- [55] Krambeck AE, Dora CD, Sebo TJ, Rohlinger AL, DiMarco DS and Elliott DS. Time-dependent variations in inflammation and scar formation of six different pubovaginal sling materials in the rabbit model. *Urology* 2006; 67: 1105-1110.
- [56] Boulanger L, Boukerrou M, Lambaudie E, Defossez A and Cosson M. Tissue integration and tolerance to meshes used in gynecologic surgery: an experimental study. *Eur J Obstet Gynecol Reprod Biol* 2006; 125: 103-108.
- [57] Woodruff AJ, Cole EE, Dmochowski RR, Scarpero HM, Beckman EN and Winters JC. Histologic comparison of pubovaginal sling graft materials: a comparative study. *Urology* 2008; 72: 85-89.
- [58] Slack M, Sandhu J, Staskin D and Grant R. In vivo comparison of suburethral sling materials. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17: 106-110.
- [59] Nilsson C, Palva K, Aarnio R, Morcos E and Falconer C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J* 2013; 24: 1265-1269.
- [60] Davila G, Johnson J and Serels S. Multicenter experience with the Monarc transobturator sling system to treat stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17: 460-465.
- [61] Juang CM, Yu KJ, Chou P, Yen MS, Twu NF, Horng HC and Hsu WL. Efficacy analysis of trans-obturator tension-free vaginal tape (TVT-O) plus modified Ingelman-Sundberg procedure versus TVT-O alone in the treatment of mixed urinary incontinence: a randomized study. *Eur Urol* 2007; 51: 1671-1679.
- [62] Viereck V, Kuszka A, Rautenberg O, Wlazlak E, Surkont G, Hilgers R, Eberhard J and Kociszewski J. Do different vaginal tapes need different suburethral incisions? The one-half rule. *Neurourol Urodyn* 2015; 34: 741-6.
- [63] Meschia M, Pifarotti P, Bernasconi F, Magatti F, Viganò R, Bertozzi R and Barbacini P. Tension-free vaginal tape (TVT) and intravaginal sling-plasty (IVS) for stress urinary incontinence: a multicenter randomized trial. *Am J Obstet Gynecol* 2006; 195: 1338-1342.
- [64] Andonian S, Chen T, St-Denis B and Corcos J. Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. *Eur Urol* 2005; 47: 537-541.
- [65] Laurikainen E, Valpas A, Kivelä A, Kalliola T, Rinne K, Takala T and Nilsson CG. Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial. *Obstet Gynecol* 2007; 109: 4-11.
- [66] Lee KS, Han DH, Choi YS, Yum SH, Song SH, Doo CK and Choo MS. A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year followup. *J Urol* 2007; 177: 214-218.
- [67] Chae HD, Kim SR, Jeon GH, Kim DY, Kim SH, Kim JH, Kim CH, Kim YM, Kim YT, Kang BM and Nam JH. A comparative study of outside-in and inside-out transobturator tape procedures for stress urinary incontinence. *Gynecol Obstet Invest* 2010; 70: 200-205.
- [68] Abdel-fattah M, Mostafa A, Familusi A, Ramsay I and N'Dow J. Prospective randomised controlled trial of transobturator tapes in management of urodynamic stress incontinence in women: 3-year outcomes from the Evaluation of Transobturator Tapes study. *Eur Urol* 2012; 62: 843-851.
- [69] El-Eweedy SM, Abd El-Rahim AF, Abd-Alkhalek MA, Abdellatif AH, Anwer AS. Long-term out-

Benefits of mid-urethral sling overweight over risks

- come of transobturator suburethral tape procedure for treatment of female stress urinary incontinence. *Urol Ann* 2014; 6: 235-8.
- [70] Basu M and Duckett J. A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence. *BJOG* 2010; 117: 730-735.
- [71] Bernasconi F, Napolitano V, Natale F, Leone V, Lijoi D and Cervigni M. TVT SECUR™ System: Final results of a prospective, observational, multicentric study. *Int Urogynecol J* 2012; 23: 93-98.
- [72] Kennelly MJ, Moore R, Nguyen JN, Lukban J and Siegel S. Miniarc® single-incision sling for treatment of stress urinary incontinence: 2-year clinical outcomes. *Int Urogynecol J* 2012; 23: 1285-1291.
- [73] Bianchi-Ferraro AM, Jarmy-DiBella ZI, de Aquino Castro R, Bortolini MA, Sartori MG and Girao MJ. Randomized controlled trial comparing TVT-O and TVT-S for the treatment of stress urinary incontinence: 2-year results. *Int Urogynecol J* 2014; 25: 1343-1348.
- [74] Roy S, Bramley TJ, Hinoul P, Migliaccio-Walle K and Li H. Economic considerations for mid-urethral sling procedures among patients with stress urinary incontinence. *J Long Term Eff Med Implants* 2013; 23: 1-8.
- [75] Seklehner S, Laudano MA, Te AE, Kaplan SA, Chughtai B and Lee RK. A cost-effectiveness analysis of retropubic midurethral sling versus transobturator midurethral sling for female stress urinary incontinence. *Neurourol Urodyn* 2014; 33: 1186-1192.
- [76] ElSheemy MS, Elsergany R and ElShenoufy A. Low-cost transobturator vaginal tape inside-out procedure for the treatment of female stress urinary incontinence using ordinary polypropylene mesh. *Int Urogynecol J* 2015; 26: 577-84.
- [77] FDA. Considerations about surgical mesh for SUI. http://www.google.com/url?url=http://www.urogynsavannah.com/forms/Surgical_Mesh_for_SUI.pdf&rct=j&frm=1&q=&esrc=s&sa=U&ei=9h6JVPuGE4bnoATgh4HwDQ&ved=OCC4QFjAE&usq=AFQjCNHoYu3i5k22EjMOnK7UqR22w2qRJA. 2013.
- [78] Association AU. AUA position statement on the use of vaginal mesh for the surgical treatment of stress urinary incontinence. <https://www.auanet.org/about/vaginal-mesh-for-sui.cfm>. 2013 Oct.
- [79] Nager C, Tulikangas P, Miller D, Rovner E and Goldman H. Position statement on mesh midurethral slings for stress urinary incontinence. *Female Pelvic Med Reconstr Surg* 2014; 20: 123-125.
- [80] Costantini E, Lazzeri M and Porena M. Managing complications after midurethral sling for stress urinary incontinence. *EAU-EBU Update Series* 2007; 5: 232-240.
- [81] Kuuva N and Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol Scand* 2002; 81: 72-77.
- [82] Serati M, Ghezzi F, Cattoni E, Braga A, Siesto G, Torella M, Cromi A, Vitobello D and Salvatore S. Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. *Eur Urol* 2012; 61: 939-946.
- [83] Cheng D and Liu C. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. *Eur J Obstet Gynecol Reprod Biol* 2012; 161: 228-231.
- [84] King AB and Goldman HB. Current controversies regarding oncologic risk associated with polypropylene midurethral slings. *Curr Urol Rep* 2014; 15: 1-3.
- [85] Tang X, Zhu L, Liang S and Lang J. Outcome and sexual function after transobturator tape procedure versus tension-free vaginal tape SECUR: a randomized controlled trial. *Menopause* 2014; 21: 641-645.
- [86] Dursun M, Otunctemur A, Ozbek E, Cakir SS and Polat EC. Impact of the transobturator tape procedure on sexual function in women with stress urinary incontinence. *J Obstet Gynaecol Res* 2013; 39: 831-835.
- [87] Tommaselli GA, Formisano C, Di Carlo C, Fabozzi A and Nappi C. Effects of a modified technique for TVT-O positioning on postoperative pain: single-blind randomized study. *Int Urogynecol J* 2012; 23: 1293-1299.
- [88] Nitti VW. Complications of midurethral slings and their management. *Can Urol Assoc J* 2012; 6: S120-122.
- [89] Sung V, Schleinitz M, Rardin C, Ward R and Myers D. Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis. *Am J Obstet Gynecol* 2007; 197: 3-11.
- [90] Bourdy C, Lucot JP, Giraudet G, Ferdynus C and Cosson M. Sling exposure after treatment of urinary incontinence with sub-urethral transobturator slings. *Eur J Obstet Gynecol Reprod Biol* 2014; 176: 191-196.
- [91] Kavvadias T, Kaemmer D, Klinge U, Kuschel S and Schuessler B. Foreign body reaction in vaginally eroded and noneroded polypropylene suburethral slings in the female: a case series. *Int Urogynecol J Pelvic Floor Dysfunct* 2009; 20: 1473-1476.
- [92] Lleberia J, Pubill J, Mestre M, Aguilo O, Serra L and Canet Y. De novo urgency: a review of the literature. *Gynecology & Obstetrics* 2013; 3: 166.

Benefits of mid-urethral sling overweight over risks

- [93] Levin I, Groutz A, Gold R, Pauzner D, Lessing JB and Gordon D. Surgical complications and medium-term outcome results of tension-free vaginal tape: A prospective study of 313 consecutive patients. *Neurourol Urodyn* 2004; 23: 7-9.
- [94] Morey AF, Medendorp AR, Noller MW, Mora RV, Shandera KC, Foley JP, Rivera LR, Reyna JA and Terry PJ. Transobturator versus transabdominal mid urethral slings: a multi-institutional comparison of obstructive voiding complications. *J Urol* 2006; 175: 1014-1017.
- [95] Naumann G, Steetskamp J, Meyer M, Laterza R, Skala C, Albrich S and Koelbl H. Sexual function and quality of life following retropubic TVT and single-incision sling in women with stress urinary incontinence: results of a prospective study. *Arch Gynecol Obstet* 2013; 287: 959-966.
- [96] Fatton B, de Tayrac R and Costa P. Stress urinary incontinence and LUTS in women-effects on sexual function. *Nat Rev Uro* 2014; 11: 565-578.
- [97] Ostergard DR and Azadi A. To mesh or not to mesh with polypropylene: does carcinogenesis in animals matter? *Int Urogynecol J* 2014; 25: 569-571.
- [98] King AB, Zampini A, Vasavada S, Moore C, Rackley RR and Goldman HB. Is there an association between polypropylene midurethral slings and malignancy? *Urology* 2014; 84: 789-792.
- [99] Serati M, Topazio L, Bogani G, Costantini E, Pietropaolo A, Palleschi G, Carbone A, Soligo M, Del Popolo G, Li Marzi V, Salvatore S and Finazzi Agrò E. Urodynamics useless before surgery for female stress urinary incontinence: Are you sure? Results from a multicenter single nation database. *Neurourol Urodyn* 2015; [Epub ahead of print].
- [100] Norton PA, Nager CW, Brubaker L, Lemack GE and Sirls LT. The cost of preoperative urodynamics: A secondary analysis of the ValUE trial. *Neurourol Urodyn* 2014; [Epub ahead of print].
- [101] American Urogynecologic Society Board of Directors. Position statement on restriction of surgical options for pelvic floor disorders: the American Urogynecologic Society Board of Directors. *Female Pelvic Med Reconstr Surg* 2013; 19: 199-201.
- [102] Brown LK, Fenner DE, Berger MB, Delancey JO, Morgan DM, Patel DA and Schimpf MO. Defining patients' knowledge and perceptions of vaginal mesh surgery. *Female Pelvic Med Reconstr Surg* 2013; 19: 282-287.
- [103] Tennstedt SL, Litman HJ, Zimmern P, Ghetti C, Kusek JW, Nager CW, Mueller ER, Kraus SR and Varner E. Quality of life after surgery for stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2008; 19: 1631-1638.
- [104] Schimpf MO, Rahn DD, Wheeler TL, Patel M, White AB, Orejuela FJ, El-Nashar SA, Margulies RU, Gleason JL, Aschkenazi SO, Mamik MM, Ward RM, Balk EM and Sung VW. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. *Am J Obstet Gynecol* 2014; 211: 71.e1-71.e27.