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TOPIC PAPER

Female stress urinary incontinence and the mid-urethral sling: Is obstruction necessary to achieve dryness?

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Abstract
Background Recently, the American Urogynecologic Society and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction released position statements on the use of mid-urethral slings. The statement offers that the polypropylene mesh mid-urethral sling (retropubic and transobturator) is now the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The purpose of the current manuscript is to examine whether the polypropylene mesh mid-urethral sling should be the standard of care.
Methods Data for this review were acquired by a systematic search of the medical literature.
Results The Trial of Mid-Urethral Slings found that retropubic and transobturator slings were associated with a significant rate of adverse events, despite being comprised of surgeons from high-volume, experienced centers. Stress urinary incontinence is not just a urethral disease due to intrinsic sphincteric deficiency. It can also be related to urethral hypermobility, which in turn is caused by anterior vaginal wall laxity. Often both hypermobility and intrinsic sphincter deficiency coexist. Recognizing the role of anterior vaginal wall support is important to understanding the role of procedures (such as Burch or needle suspension procedures) which have the potential of correcting stress incontinence without affecting voiding parameters.
Conclusions As a discipline, we need to conceptualize stress incontinence due to urethral hypermobility or intrinsic sphincter deficiency as separate entities and design our procedures to restore the underlying suspected pathology.

Keywords Female stress urinary incontinence · Mid-urethral sling · Bladder outlet obstruction

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Background

Female stress incontinence and mid-urethral sling: is it time for a new gold standard?

Recently, the American Urogynecologic Society (AUGS) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) released their position statement on the use of mid-urethral slings stating that the polypropylene mesh mid-urethral sling (retropubic and transobturator) is now the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence [1]. The Trial of Mid-Urethral Slings (TOMUS) found that retropubic and transobturator sling had a very high 12-month satisfaction rate (85–90 %) [2], with durability of satisfaction recently demonstrated out to 5-years (79–85 %) as well as a modest 5-year treatment success (43–51 %) [3]; however, this was also associated with a significant rate of serious (13.8 and 6.4 %) and grade I–II (36.9 and 29.8 %) adverse events [2]. The mid-urethral sling is clearly not without risk, even in the most experienced centers participating in the TOMUS trial. Although the mid-urethral sling represents an important option for stress incontinence, it is paramount to not only examine its immediate and long-term impact on our patients, but also investigate alternative approaches to stress incontinence.

Surgical management options for the treatment of female stress urinary incontinence are intended to increase outlet resistance or restore the natural hammock support [4]. Over the years, a number of theories have guided the way we think about stress urinary incontinence and how we address its surgical management. The Integral Theory was introduced by Petros in 1990 and stated that "prolapse and symptoms of urinary stress, urge, abnormal bowel and bladder emptying, and some forms of pelvic pain mainly arise, for different reasons, from laxity in the vagina or its supporting ligaments, a result of altered connective tissue" [5, 6]. In the setting of stressful provocative maneuvers (e.g., cough, sneeze, valsalva, straining), the resulting sudden increase in intra-abdominal pressure should be: (1) augmented by the guarding reflex and (2) mechanically balanced by a dynamic increase in compression of the urethra (which proportionately increases outlet resistance and maintains continence) [7, 8]. In 1996, DeLancey introduced the anatomic backboard concept that stress incontinence is a result of loss of support by the fascia which normally provides a hammock-like support of the bladder neck [9].

It is important to understand that stress urinary incontinence is not just a urethral disease due to intrinsic sphincteric deficiency. It can also be related to urethral hypermobility, which in turn is caused by anterior vaginal wall laxity. Often both urethral hypermobility and intrinsic sphincter deficiency disorders coexist [8]. Recognizing the role of anterior vaginal wall support is important to understanding the role of procedures (such as Burch or needle suspension procedures) which have the potential of correcting stress incontinence without affecting voiding parameters [10, 11]. To begin this dialogue about the optimum surgical treatment of female stress incontinence, without inadvertently causing obstruction, we must first briefly outline the evolution of procedures leading up to the inception of the mid-urethral sling.

Chronology of procedures

In the 1940s, the Marshal Marchetti Krantz (MMK) procedure was originally described and involved suspending the urethral wall and periurethral tissues to the pubic symphysis [12]. The mechanistic defect corrected by this procedure was that as the urethra descends in the absence of support, the transfer of urethral pressure becomes imbalanced with a negative gradient seen on urethral pressure profile and the patient leaks. With MMK suspension, the bladder and urethra were put in the same pressure cavity, so that elevated pressures during cough were transferred similarly to both structures, thus preventing leak. Problems included secondary cystocele, overcorrected urethra, and rarely osteitis pubis [13]. The MMK procedure emphasizes the importance of avoiding fixation close to the urethra with its resultant kinking. In 1987, Raz and Zimmern identified women with urodynamically proven obstruction after MMK and all were treated with simple transvaginal urethrolysis and needle vesicourethral re-suspension [14]. The majority of patients ($N = 12/13$) achieved resolution of obstruction and postoperatively their symptoms improved, while post void residuals returned to normal.

In the 1960s, the Burch retropubic suspension was introduced. The Burch is similar in concept to the MMK but involves anchoring the bladder neck and vaginal wall into Cooper's ligaments bilaterally to provide more reliable anchor sites than the periosteum [15]. The Burch does not typically affect voiding function. However, the abdominal approach, without vaginal access to evaluate the degree of anterior suspension, can lead to overcorrection. The Burch will not support the anterior vaginal wall compartment due to the distal location of the sutures unless one performs a concurrent paravaginal repair. There are few long-term data, but those that exist (reviewed below) are robust.

In the 1980s, the needle suspension procedures were popularized and include a number of subtypes; the Pereyra [16] (small transverse suprapubic incision, blind passage of trocar needle through retropubic space lateral to bladder neck through vaginal wall, stainless steel suture, two passes per side), Bladder Neck Pereyra–Lebherz [17] (addition of Kelly plication), Raz Modified–Pereyra [18] (Inverted U-incision, accessing the retropubic space for mobilization of the bladder neck and fingertip guidance during needle passage, full thickness vaginal wall helical anchoring sutures), Stamey [19] (addition of Dacron pledget to buttress the periurethral tissue, concurrent cystoscopy during needle passage) and Gittes [20] (no-incision, full thickness "autologous pledget" tied suprapubically). Vaginal approaches were developed to reduce morbidity that was previously associated with the Pfannenstiel incision [21]. Debate existed regarding where and how to anchor the sutures to avoid suture pull-through. Pull-through was reduced with the addition of the Dacron pledget and the inclusion of full thickness vaginal mucosa in the suspensory sutures in addition to the pubourethral ligament. Passage also garnered attention and resulted in the development of various needles; the Pereyra, Stamey and dual-prong Raz. Technical consideration existed regarding the need to free the retropubic space to transfer the sutures from the vagina to the suprapubic region using fingertip guidance, therefore decreasing the risk of bladder injury but increasing the risk of retropubic bleeding. These procedures enjoyed good results for stress incontinence with promising results in the short term, however provided no support of the upper anterior vagina [22–24].

In the 1990s, the four-corner bladder neck suspension developed as an evolution of the Raz needle suspension to also incorporate the upper anterior vagina [25]. This

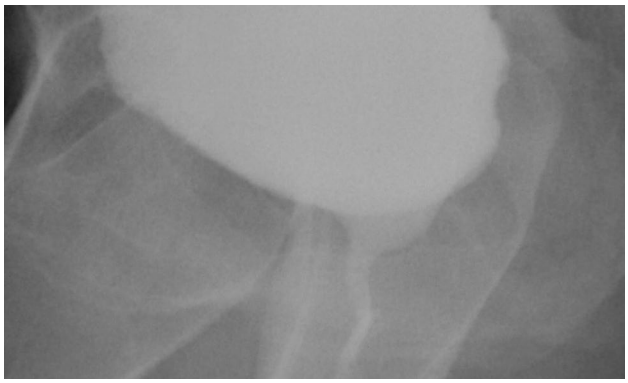

Fig. 1 Voiding cystourethrogram after mid-urethral sling demonstrates urethral distortion with proximal widening of the bladder neck area and vesicourethral junction (Courtesy of Philippe E. Zimmern)

included four anchor sites with each suture passed multiple times at each site. Whereas the procedure had its merits, the multiple passes resulted in a loop cutting effect and tissue pull-through, with modest results overall [26]. Shortly following, the anterior vaginal wall suspension was later introduced as a modification of the four-corner bladder neck suspension [27]. This was based on animal data showing that the best way to prevent tearing of polypropylene suture in the rabbit abdominal wall fascia was to use a helical running pass. Once the anterior vaginal plate has healed in place after a few months, the sutures served no purpose. With this procedure, the sutures are tied loosely to avoid overcorrecting the anterior vaginal wall and the unmasking of potential posterior and apical vaginal wall defects. The operation is well suited as a concurrent repair with laparoscopic assisted vaginal hysterectomy, sling, or after a prior midline anterior colporrhaphy, but is not ideal for an apical or central cystocele defect [28]. It has no impact on voiding function (data reviewed below), and its use is primarily for stress urinary incontinence in the setting of a lateral anterior defect.

At the turn of the twenty-first century, the retropubic and transobturator mid-urethral slings were popularized [29, 30]. These procedures were adopted widely, marketed to non-expert surgeons and enjoyed rapid rates of adoption due to the avoidance of an abdominal incision, quick operative times and promising short-term outcomes, even before long-term data were known [31]. These options can pose a difficult combination, adding the risk of a sling procedure (tension, despite the intent of being tension free) with a synthetic material underneath the floor of the urethral wall at the mid-urethra where the innervation and blood supply arrive. Other subtle factors include the plane of mid-urethral dissection and deviation from intended trajectory of trocar passage which can impact outcomes significantly. The mid-urethral sling can create kinking to provide continence, but as with many other anti-incontinence procedures, gradual proximal urethral and bladder neck distension can develop as seen by voiding cystourethrogram (Fig. 1), as it provides no support of the upper anterior vagina [32]. The goal of treatment with the mid-urethral sling describes defective pubourethral ligaments; however, these ligaments have been shown to insert on the anterior vaginal wall rather than the urethra [33]. It is actually the lateral attachments of the urethra which provide support and are contiguous with support of the vagina [9]. The mid-urethral sling demonstrated promising early success but leaves potential for long-term voiding dysfunction in addition to the short-term rates of extrusion, dyspareunia, erosion, pain along the tape extension arms, and at times irreversible sequelae despite attempts at removal [34, 35]. As a later spinoff, the single incision mini-slings were introduced with the intention to avoid certain risks associated with the retropubic and transobturator approaches. Tensioning, however, is difficult, with a weaker benefit on incontinence and a significant risk of postoperative dyspareunia, extrusion and erosion [36].

Obstruction after sling

Voiding and outlet resistance: how to determine obstruction

Normal voiding relies on relaxation of the pelvic floor muscles, urethra and bladder neck to decrease outlet resistance in the setting of a coordinated bladder contraction (or Valsalva void) [5]. Since women are able to void with relatively low detrusor pressures compared to men, they rely on a low outlet resistance for normal voiding function. Bladder outlet obstruction in women can be either a functional obstruction (e.g., primary bladder neck obstruction, detrusor external sphincter dyssynergia, Fowler's syndrome) or anatomic (e.g., cystocele, obstructing sling, diverticulum).

A few methodologies of identifying women with bladder outlet obstruction exist and the diagnosis of the condition is not standardized. In 2000, Blaivas and Groutz introduced a bladder outlet obstruction nomogram for women with lower urinary tract symptoms based on maximum free uroflow rate and detrusor pressure [37]. They divided patients into four categories: no obstruction versus three grades of obstruction (mild, moderate and severe). Based on the urodynamically measured maximum detrusor pressure and free uroflow maximum flow rate, they differentiated among the presence, absence and degree of obstruction. In general, the Blaivas nomogram discriminates between moderate (Pdet Max > 57 cm H_2O) and severe (Pdet Max > 107 cm H_2O); however, for lower detrusor pressures (Pdet Max < 57 cm H_2O), low

flow rates may be seen in the setting of low detrusor pressures in the absence of clinical obstruction. Other authors have described measurement of cutoff points to determine obstruction, using urodynamic flow rate and detrusor pressure along a receiver operator curve with detrusor pressures markedly lower than those of Blaivas and Groutz. The parameters were reported as follows: Chassagne [38] (Qmax < 15 mL/s and Pdet Qmax > 20 cm H_2O), Lemack and Zimmern [39] (Qmax < 11 mL/s and Pdet Qmax > 21 cm H_2O) and Defreitas [40] (Qmax < 12 mL/s and PdetQmax > 25 cm H_2O). Nitti described the use of fluoroscopic criteria to assist in urodynamic identification of women with bladder outlet obstruction, consistent with findings of higher voiding pressures, lower flow rate and higher postvoid residuals compared to unobstructed patients [41]. These authors explicitly state the difficulty with using strict cutoff criteria to define urinary tract obstruction in women and acknowledge that by simply defining obstruction according to urodynamic parameters alone, there will be an over-assignment of patients without clinical symptoms to the wrong classification. Again, this may be attributed to the unique ability of women compared to men to void by simply relaxing the pelvic floor in the absence of a detrusor contraction. It is only with the entire clinical picture, including an accurate assessment of symptomatic complaints (e.g., straining to void, sensation of incomplete emptying, weak stream and chronology) combined with objective parameters (detrusor pressure, flow rate, post void residual and voiding images identifying an obstruction site), that the diagnosis of clinical bladder outlet obstruction can be assured. It is important to emphasize that no one parameter can predict the diagnosis of obstruction (e.g., the post void residual can be normal) [42].

Postoperative voiding dysfunction after mid-urethral sling is a troublesome complication, and it can be difficult to predict who will be affected the most after surgery. In patients who are able to generate flow on preoperative urodynamics, maximum flow rate of less than 15 mL/s is predictive of postoperative voiding dysfunction after transobturator mid-urethral sling [43]. Postoperative bladder outlet obstruction with concomitant voiding dysfunction can be very bothersome to patients due to symptoms of de novo urgency, incomplete emptying, and elevated post void residual, sometimes necessitating revision surgery or use of a catheter. One important caveat is that it is important to identify patients with preoperative behavioral voiding dysfunction (e.g., high tension pelvic floor muscles on physical exam associated with storage and voiding symptoms) and to intervene on this with biofeedback or physical therapy prior to surgery. When missed, the voiding dysfunction can lead to a diagnostic quandary when trying to distinguish between a sling complication versus functional disorder.

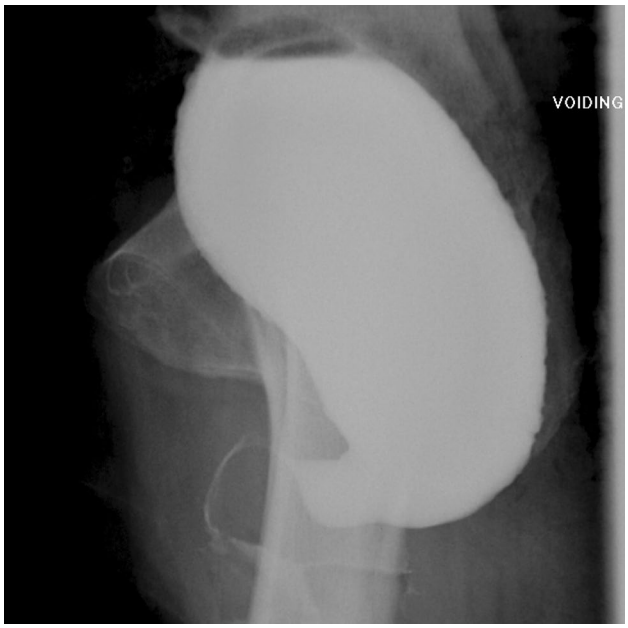

Fig. 2 Classic urethral kinking after mid-urethral sling as demonstrated by ballooning of the proximal urethra and bladder neck on voiding cystourethrogram (Courtesy of Philippe E. Zimmern)

Sling placement and obstruction: not an exact science

The mid-urethral slings have been marketed as "tension free". However, it is well documented that they can obstruct due to tension overlying the urethra as well as a kinking effect on the vaginal wall and proximal urethra cephalad to its placement (Fig. 2). Sling placement is complicated by several factors. Intraoperative adjustment is subjective and approximated in a supine, non-physiologic position and is more of an art than an exact science. Tension can be incorrect and the sling can move from the mid-urethra to the bladder neck. The sling can be placed "tension free" but then as a result of retraction scarring of up to 30 % may develop subsequent tension [44, 45]. As a result, a significant number of patients require urethrolysis or in the case of a sling that is too loose, sling revisions or implantable urethral bulking agents.

SISTEr trial: elevated Pdet at Qmax after sling

After sling placement, patients are at risk for urinary retention or de novo urgency and urge incontinence, with early or delayed presentation. Investigators of the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) demonstrated that urodynamic changes after pubovaginal sling surgery were accompanied by higher postoperative voiding pressures at 2 years, with detrusor pressure at maximum flow rate increased from 16 cm H_2O preoperatively to 27 cm H_2O postoperatively [46]. Upon

closer inspection of the data, successful sling procedures were associated with relative bladder outlet obstruction and accompanied by a mean increase in detrusor pressure at maximum flow of 18 cm compared to 6 cm H_2O for sling failures, with a concomitant decrease in flow. Meanwhile, there was only a 3.8 cm H_2O increase in detrusor pressure noted after successful Burch procedure, and minimal change in bladder outlet obstruction measures compared to Burch failures. Flow rates in the Burch were noted to minimally decrease by a mean range of 2.2–4.6 mL/s in all patients after surgical intervention, regardless of surgical technique or treatment success. In summary, subjective treatment success and resolution of stress incontinence was generally associated with higher voiding pressures postoperatively in the pubovaginal sling group. This study begs the question, were we really just obstructing patients with the sling in order to achieve continence?

Urethral kinking after sling

There is also potential for difficulties due to the fact that the suburethral tape or mid-urethral sling is placed just under the mid-urethra. Sub-urethral kinking during stress maneuvers can occur when only the mid-urethra is supported, as the proximal urethra, bladder neck, and bladder base are left in continuum of the original vaginal wall lateral defect [33]. The bladder changes seen after sling placement are consistent with bladder outlet obstruction as hallmarked by increase in detrusor voiding pressures and decreased flow rates demonstrated in the SISTEr trial [46]. These changes are not observed in procedures supporting the vesicourethral junction and anterior vaginal wall plate as demonstrated by Raz [25], Zimmern [14], Dmochowski [47], Appell [48] and Mikhail [49] (data on vaginal wall suspension reviewed below) and the Burch data from the SISTEr trial [46].

Likewise Klutke reported on 289 women with genuine stress incontinence and genital prolapse who were randomized to Burch, anterior colporrhaphy or modified Pereyra and found that urodynamic changes were not significantly affected after bladder neck suspension and there was no change in pressure-flow over time [50]. These findings were previously described in a smaller cohort of women by Leach [51]. The urethra does not exist in isolation but is actually just a component of a larger dynamic system fused with support of the anterior vaginal wall, as described by the Integral Theory [5, 6].

Restoration of continence can be achieved in a few manners. The mechanisms of action of the available surgical treatments include: providing a backboard to the urethra, compressing the urethra, bulking the urethra or

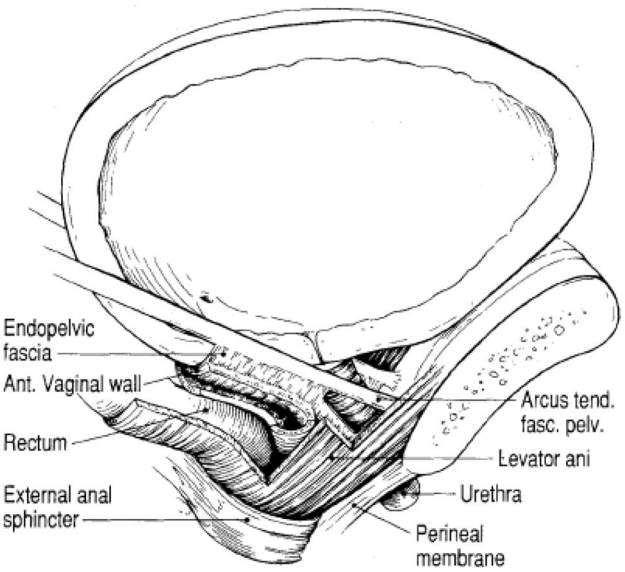

Fig. 3 Structures of the urethral support system. Note the pubourethral ligaments insert on the anterior vaginal wall, not the urethra. Directly reproduced from DeLancey [9] (RightsLink License Number 3481640374975)

restoring anatomic supports surrounding the external urethral sphincter to maximize the physics of its function. All of these corrective measures function with the intent that appropriate outlet resistance will prevent leakage during rise in intra-abdominal pressure. Physiologically, the pubourethral ligament attaches to the vagina cephalad to the urethra bilaterally. Urethral support is actually based on the lateral level III attachments as originally described by DeLancey [52]. These attachments serve as a functional valve during stress maneuvers, allowing a degree of dynamic compression as intra-abdominal pressure increases (Fig. 3) [9]. The intended goal of the mid-urethral sling is to restore the natural hammock support of the vesicourethral junction; however, the continuum of lateral vaginal support is not addressed by the mid-urethral sling alone. Proximal loss of vaginal support (to varying degrees, present or future) allows potential for un-physiologic urethral kinking after mid-urethral sling, putting patients at increased risk for urinary obstruction, retention and voiding dysfunction in the long term [43]. Urethral ultrasound studies have demonstrated dynamic kinking of the urethra accompanied by a rise in intra-abdominal pressure during stress maneuvers after mid-urethral sling placement, with a higher rate of kinking noted after retropubic (86.9 %) compared to the transobturator (23.9 %) approach [34]. This dynamic kinking seems to be the primary mechanism of action of the mid-urethral sling, both at rest and during stress [35]. Is it really necessary to kink the urethra to achieve continence?

Stress incontinence: a vaginal disease

As we move forward it is important we continue to seek procedures for stress incontinence that restore natural support, addressing continence with low potential for complications in the short and long term. Therefore, the entire anterior vaginal wall needs to be addressed as a continuum.

Lateral paravaginal repair

The data on lateral paravaginal repair has not included focus on rates of postoperative stress incontinence, but suggests that the rates are low. Young et al. [53] reported on vaginal paravaginal repair in 100 patients with grade II–IV lateral cystocele. A proportion of patients underwent Burch. The authors described 16 patients with "urinary symptoms" postoperatively (stress incontinence, nocturia or recurrent urinary tract infections). Reid et al. [54] analyzed vaginal and abdominal approaches to the lateral paravaginal repair retrospectively and did not describe concurrent stress incontinence procedures. Forty-three of 52 (82.7 %) women who underwent abdominal paravaginal repair were dry compared to 41 of 59 (69.5 %) after vaginal paravaginal repair. Nine women went on to bulking injection or mid-urethral sling. Whereas the lateral paravaginal repair has been largely abandoned due to high reported complication rates (primarily blood loss and ureteric injuries), the concept that lateral support may impact rates of stress incontinence requires consideration.

Vaginal wall suspension

Just as Petros described the interplay of pelvic organs and the importance of the suspensory ligaments "…problems of bladder, bowel, prolapse, and some types of pelvic pain mainly originate from the vaginal ligaments, not from the organs themselves" [6], stress urinary incontinence is a vaginal disease, not just a urethral disorder. In other words, stress incontinence can be due to vaginal wall and urethral mobility, deriving from a breakdown of lateral vaginal wall support as reported by Zimmern in his 15-year experience with anterior vaginal wall suspension procedures [55]. During pelvic floor relaxation the anterior vaginal wall descends and brings with it the urethra, drawing it open. The non-physiologic mechanism employed by bladder neck and mid-urethral slings can prevent normal proximal opening of the urethra to allow for efficient voiding [32]. Furthermore, due to the sling kinking effect on the urethra in the setting of stressful provocative maneuvers, the vesicourethral junction and proximal bladder neck is left unsupported [33, 34, 56]. The impact on voiding can worsen as the preexisting weak vaginal support deteriorates over time, following its natural history. Surgical approaches to stress urinary incontinence that provide support of the vaginal wall would allow for preservation of long-term voiding function.

The four-corner bladder neck and urethral suspension was described by Raz in 1989 after it was shown that a moderate cystocele treated with Kelly-type plication alone had a high rate of de novo stress urinary incontinence [25]. By restoring the lateral support of the bladder base and repositioning the vesicourethral junction into a high retropubic position, Raz demonstrated excellent results with respect to stress incontinence. Other investigators have also shown that by re-creating support to the entire anterior vaginal plate moderate improvements in stress urinary incontinence could be achieved. Dmochowski demonstrated the role of the four-corner bladder neck suspension in correcting stress incontinence in the setting of mild to moderate cystocele; 83 % of patients were rendered dry at 3 years [47]. Appell showed that by supporting the anterior vaginal wall using a 2-suture repair, a similar result could be achieved [48]. In a prospective analysis by Kaplan of an anterior wall suspension using running suture on the lateral vaginal wall and surrounding paravaginal tissue, postoperatively only 4 % of 373 consecutive women with mean follow-up of 39.8 months had persistent stress incontinence [57]. Likewise, Mikhail found that using a modified vaginal wall suspension technique, 83 % of patients were dry at 5 years with minimal postoperative voiding dysfunction [49]. In Zimmern's recent abstract reporting on long-term results with the anterior vaginal wall suspension (helical sutures through the anterior vaginal wall passed retropubic and tied off-tension overlying the rectus fascia), only 6 % of 213 patients required further intervention for stress urinary incontinence (sling or bulking agent) [55]. As previously mentioned, data suggest that each of these procedures emphasizes the value of reinforcing or recreating the vaginal supports at the vesicourethral junction for the treatment of stress urinary incontinence, while minimizing the obstructive side effects typically seen with the mid-urethral sling.

Conclusion

It is prudent to question the recent AUGS/SUFU position statement that the synthetic mid-urethral sling should be the gold standard for treatment of stress urinary incontinence given all of the negative mechanisms of action on the urethra and lower urinary tract [1]. Bladder outlet obstruction, urgency, and secondary cystocele can develop over time in addition to shorter-term complications related to route of passage and mesh erosion. In effort to restore function to women suffering from stress leakage, the mid-urethral sling is certainly part of the armamentarium we all offer our patients. Many women have been helped by this approach,

and positive outcomes after surgery depend greatly on preoperative expectations and appropriate mid-urethral sling mesh tensioning [58]. If we settle on a simple position statement and accept the negative factors associated with the mid-urethral sling, we will stop pursuing other mechanisms by which to address stress urinary incontinence and the related continuum of vaginal support. If we conceptualize stress urinary incontinence and urethral hypermobility as a vaginal disease, not just as intrinsic sphincteric dysfunction or an isolated disorder of the urethra in all cases, we can strive to design our procedures to restore support and function of the urethra and anterior vaginal wall, either through native or regenerated structural support.

Conflict of interest The authors declare that they have no conflicts of interest in relation to the content of the manuscript.

Ethical standard The manuscript is not a clinical study and does not contain patient data.

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