

Surgery for Post-Prostatectomy Incontinence – A Changing Field

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Abstract

The most common cause of male stress urinary incontinence is intrinsic sphincter deficiency secondary to iatrogenic injury during prostate cancer surgery. While conservative management is typically offered during the first 6-12 months, most efficacious therapeutic options are surgical in nature. The most common treatments include periurethral bulking, artificial urinary sphincter, and various male slings. During the last 15 years, innovations in male sling design and technique have resulted in a substantially greater interest in this particular option. With several choices now available to patients, the number of sling surgeries performed each year is steadily increasing. Recent evidence has demonstrated that male slings are most efficacious in men with mild to moderate stress incontinence, no history of pelvic radiation, and without prior artificial sphincter placement. In this population, high efficacy with very low complication rates can be expected. In men with more severe incontinence, especially following radiotherapy, the artificial urinary sphincter typically offers predictably reliable efficacy, with an acceptably low complication rate. Recent advancements in sling technology may provide improved efficacy even in those with more severe leakage.

Keywords: Intrinsic sphincter deficiency; Artificial urinary sphincter; Sling; Stress urinary incontinence; Prostate cancer

Risk Factors for Post Prostatectomy Incontinence

The surgical technique for radical prostatectomy (RP) has become relatively standardized, with improved instrumentation and visualization, especially following the adoption of robotic assistance. There are, however, recognized risk factors for post prostatectomy incontinence (PPI). And while these risks may not all be modifiable, they may alter cancer treatment choice. These risk factors include age, preoperative continence status, preoperative voiding dysfunction, tumor stage, obesity, prior radiation and transurethral resection of the prostate, vascular disease, preoperative membranous urethral length, and postoperative radiation or cryotherapy [1-9].

The most predictive risk factors for PPI are pre-operative urinary incontinence and voiding dysfunction. Stress urinary incontinence (SUI) in men who had no prostate cancer surgery occurs at a baseline prevalence of 1.3%-4.8% [10,11]. Whereas urgency incontinence and overflow incontinence associated with bladder outlet obstruction may indeed resolve following de-obstructive prostate extirpation [1], pre-operative SUI typically will not improve postoperatively. Baseline intrinsic sphincteric insufficiency (ISD), demonstrated either by the pre-existing clinical sign of SUI or the urodynamic finding of low maximal urethral closure pressure, strongly predicts post-operative stress incontinence [2,3]. Furthermore, pre-operative bladder dysfunction also increases the risk of PPI, especially in those with neurogenic detrusor overactivity secondary to Parkinson's disease, dementia or spinal cord injury [4].

Epidemiology

Most cases of male SUI are secondary to prostate removal for the treatment of prostate cancer. Recent data indicates that prostate cancer is diagnosed in approximately 186,000 men each year in the United States [12], of whom 40% elect RP as their treatment of choice [13]. With the advent of robotic-assisted surgery (accounting for nearly two-thirds of all RP procedures), the utilization of RP has proliferated, and thus the prevalence of post-prostatectomy incontinence (PPI) has risen as well, resulting in an overall increase in the number of patients affected.

While the incidence of PPI varies depending on the definition of incontinence and the precise method of evaluation, reports of large cohort series typically describe urinary control as "total control/perfect

continence/dry", "occasional leakage but no pad", and "less than one daily pad". While a significant minority of men who do not use protective pads will admit to daily leakage of urine [14,15], the use of any pad is an important marker of leakage severity. It turns out that men using even one protective pad per day have a significantly lower quality of life score than do those who wear no pad at all [16]. Finally, not every man who leaks will seek incontinence treatment. In a large longitudinal study following men 2 years after RP, 18.3% required 1-2 pads per day and 3.3% wore 3 or more pads per day to manage their SUI, with 8.4% complaining of no urinary control or frequent leakage [17]. Of all men who undergo RP, an estimated 1% will require surgical management to treat their incontinence [18].

Evaluation

In men with persistent PPI, evaluation should start with a detailed history focusing on duration of symptoms, exacerbating maneuvers, voiding habits, pad use, number of daily incontinent episodes, and symptomatic bother. Physical examination should demonstrate leakage during straining maneuvers and the leakage should cease at the end of the straining maneuver. Cystoscopy is indicated if an anastomotic stricture is suspected. Stricture can occur in 2.7 to 20.5% of men post RP [19,20]. A thorough urodynamic evaluation to characterize the underlying pathophysiology of incontinence should be considered prior to offering invasive surgical treatment. Urodynamics are particularly useful for distinguishing between bladder causes of incontinence (e.g. detrusor overactivity, diminished compliance, overflow incontinence) and outlet causes (e.g. sphincteric insufficiency). In men suffering from incontinence post RP, the vast majority (over 85%) will demonstrate ISD. In addition, detrusor overactivity, bladder outlet obstruction, or

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detrusor hypocontractility may be present in up to 50% of patients with ISD, each of which can affect treatment management decisions [21].

Conservative Management

Conservative measures are usually advised as the initial treatment of PPI, as the majority of patients will regain adequate continence within 12 months of surgery [22]. Conservative treatment usually involves fluid restriction, timed voiding, and pelvic floor exercises. Impaired detrusor contractility can occur in 29%-61% of patients (*de novo* in approximately 47%), and diminished vesical compliance can occur at a rate of 8%-39% (*de novo* in approximately half). And while these abnormalities typically resolve during the postoperative time with conservative treatment, they may persist in a minority of patients, affecting treatment choices [23-25]. Furthermore, the state of the pelvic floor may influence return to continence after RP. While physiotherapy and pelvic floor rehabilitation have been shown to improve or enhance continence (decreased time to final continence level) in the post operative period in two randomized studies, they only appear to be efficacious if such measures are instituted before or immediately after catheter removal [26,27]. Maximum difference between physiotherapy and no treatment is typically realized early in the course of intervention at 3 months. However, at 12 months, there was no clinically significant difference. With respect to delayed physiotherapy, the success of pelvic floor rehabilitation for successfully treating post RP incontinence greater than one year postoperatively has not been well-established [28].

Periurethral Bulking

Transurethral injection therapy

Transurethral injection of bulking agents represents the least invasive, but also the least efficacious surgical treatment for SUI. The proposed mechanism of action is via increasing coaptation at either the bladder neck or at the distal sphincter mechanism. Collagen, calcium hydroxylapatite, polytetrafluoroethylene, zirconium carbon coated beads, and silicone particles have all been used as injectate, generally with similar efficacy rates. Unfortunately, multiple injections are typically required to achieve even short-term improvements in continence. Due to this general lack of efficacy, the International Consult on Incontinence does not recommend injection therapy for treating PPI [29]. In the largest series to date, comprising 323 men over a 4 year time period, the overall improvement following collagen injection was a decrease in pad use of 45%. Improvement lasted a mean of only 6 months, with patients typically needing more than four injections to achieve even this modest level of success [30]. Within the past few years, animal [31] and human [32] studies have demonstrated a potential role for muscle-derived stem cells to restore rhabdosphincter integrity. Injections of myoblasts and fibroblast/collagen suspensions into the peri-sphincteric urethra under ultrasound-guidance demonstrated a short-term cure rate of 65%, with an additional 27% of patients improving. Additionally, there was sonographic evidence of recovery of sphincter function [32]. Unfortunately, there was a retraction of this article issued by the editors of the Lancet secondary to concerns regarding methodological flaws [33]. Current research has focused on adipose derived stem cells, which are simpler to harvest than bone-marrow derived stem cells [34].

Periurethral balloon placement

An alternative method of periurethral bulking involves the transperineal implantation of two inflatable balloons on either side of the proximal urethra, using fluoroscopic, urethrosopic or sonographic guidance. The balloons are incrementally filled post-operatively with

up to 8 cc saline until continence is realized. In the initial report on the ProACT™ (Uromedica, Plymouth, MN) device, 117 patients were followed for a mean 13 months [35]. Two-thirds were considered cured (0-1 pads per day) while another 25% realized at least a 50% improvement in continence. Adverse events were common, affecting 46%. Despite further experience with the technique, in a follow-up study of 50 patients, revision surgery was still necessary in 24%, including 8% due to balloon erosion, infection or malfunction, 6% due to device malposition, and 4% due to urethral or bladder perforation [36].

In their cohort of 64 men, Kocjancic et al. reported an average of 3 (maximum 9) postoperative interventions in 91% of patients at 20 months [37]. Complications included bladder perforation (8%), as well as urethral erosion (8%), infection (3%), migration (3%) and balloon failure (3%) that required removal in 17% of patients. Another contemporary cohort of 62 patients followed for a mean of 2 years, complications occurred in approximately 10%, including 3.2% with urethral erosion, 5.6% with balloon migration, and 1.6% with prolonged urinary retention [38]. In both series, success rates approximated 67% at the latest follow-up. Radiation was identified as an adverse prognostic factor, as was the presence of higher volume incontinence, with only one-third achieving pad-free status [38,39]. While success rates are substantially higher with periurethral balloon implantation than with the transurethral injection of bulking agents, the benefit must be weighed against the frequent need for balloon refilling and the high complication rate necessitating device explantation. Given the low efficacy of injections and the high complication rate of periurethral balloon placement, neither procedure is recommended for the routine treatment of PPI by the 4th International Consult on Incontinence [29].

Artificial Urinary Sphincter

In contrast to the low pressure coaptation of periurethral bulking, the artificial urinary sphincter (AUS, American Medical Systems, Minnetonka, MN) relies on circumferential occlusion of the urethra utilizing a pressurized inflatable cuff (Figure 1). For more than three decades, the AUS has represented the most predictably efficacious treatment for male SUI treatment, with satisfaction rates typically greater than 80%, regardless of the degree of incontinence. Despite revision rates of 8-45% and explantation rates of 7-17% due to mechanical failure, urethral atrophy, infection, and erosion [40,41], the majority of men with PPI are appropriate candidates for AUS placement, with exception of those who may lack the mental faculties and manual dexterity to cycle the scrotal pump necessary to properly work the system.

In the two largest contemporary cohort studies, Lai et al. evaluated

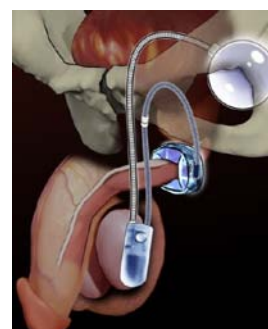


Figure 1: Artificial Urinary Sphincter, with circumferential urethral compression.

218 patients with the AUS over a 13 year period [40]. Overall efficacy was high (69% using 0-1 pads per day), with a surgical revision/removal rate of 27.1% - including an infection rate of 5.5%, erosion rate of 6%, urethral atrophy in 9.6%, and mechanical failure in 6%. At 5 years, the revision rate was 25%, and this revision rate doubled by 8.5 years following initial implantation. In a cohort of 124 men, Kim et al. [41] reported efficacy was 79% (0-1 pad daily), with a complication rate of 37%-infection (5.6%), erosion (8%) and mechanical failure (23.3%)-at a median of 7 years follow-up.

The AUS has been reported to have a predictably high success rate regardless of the degree of incontinence, even in the setting of detrusor dysfunction such as overactivity, or diminished vesical compliance in men with PPI [42]. In men who had presumably normal storage function prior to RP, the urodynamic findings of detrusor overactivity or diminished compliance are most likely due to supraphysiologic fluid infusion into a bladder that has experienced a prolonged under-filled state secondary to continual urinary leakage. Whereas resolution of SUI is not adversely affected by pre-operative detrusor overactivity, persistent overactive bladder symptoms are common. Hence patients must be counselled accordingly [42]. The AUS is cycled to an “open” phase during voiding, with relief of urethral occlusion. Thus detrusor hypocontractility does not adversely affect surgical success [42].

The high cost and high revision rates due to mechanical failure, urethral atrophy, infection, and erosion have inspired the search for less expensive, less invasive, and less complicated devices. The modern male sling has been actively studied and refined over the past decade in an effort to minimize invasiveness, and overcome these hurdles.

Male Slings

The modern male sling is based on the early devices described by Berry, Kaufman and Kishev. Most slings apply pressure to the ventral urethra only, aiming to balance effective continence with spontaneous and efficient voiding. The surgical principles are similar for all slings: 1) elevation and suspension of the pelvic floor muscles; and 2) sufficient sling tension to compress the urethra. Over-correction may precipitate urinary retention, while under-correction may result in recurrent or persistent SUI. Bladder emptying is optimized when implants do not significantly obstruct outflow, especially in the presence of adequate detrusor contractility. Unlike the AUS, detrusor underactivity is a relative contraindication to male sling surgery [43]. Since the sling is designed to prevent leakage during straining maneuvers, then it is logical that abdominal straining will not facilitate efficient bladder emptying. Thus, if the detrusor is unable to sufficiently overcome the fixed resistance of a compressive sling, implantation of an AUS (which can be de-activated during voiding) is preferred.

Non-adjustable pubourethral slings

Interest in slings waned with the emergence of the modern AUS, until Schaeffer et al. reported their novel incontinence device in 1998 [44]. Their device was constructed of suburethral bolsters made of a vascular graft material. They reported a 64% success rate in 64 patients with severe SUI at 18-months follow-up. However, a urethral erosion rate of 8% and infection rate of 2%, as well as persistent perineal pain and/or numbness in up to 18% of patients prevented the widespread adoption of this technique beyond the authors’ institution [45]. A modified version of this bulbourethral sling, involving a polypropylene mesh under the urethra, which is suspended by sutures passed retropubically and secured over the rectus fascia, was described by Migliari et al. [46]. At an average of 3 years follow-up, 63% had significant improvement in SUI. Unfortunately, 96% of patients complained of substantial perineal pain lasting a median of 3.7 months.

Bone anchored perineal sling

The next significant innovation was the introduction of bone screws. The InVance™ (American Medical Systems) perineal bone anchor system transformed sling surgery into a single-incision, minimally invasive outpatient procedure. Three titanium bone screws, each loaded with a looped number 1 polypropylene suture are inserted in the medial aspect of either descending ramus with the most distal suture just beneath the pubic symphysis and the proximal sutures at the level of the bulbous urethra. A 4x7 cm silicone-coated polyester mesh is placed over the urethra and the sutures are then passed through the sling and tied down with enough tension to prevent stress incontinence, but without excessive tension which may cause urinary retention (Figure 2). Several large prospective studies have demonstrated sustained efficacy of the InVance™ (American Medical Systems, figure 1) sling with 3-5 year follow-up. Success rates (cure or >50% improvement) general range from 60-85% [47-53]. Comiter followed 48 patients for a median of 48 months (maximum 60 months) [47]. A 65% pad-free rate and 80% improvement in pad use and in symptom score was realized. Short-term perineal pain occurred in 16-19%, resolving by 3 months post-operatively. Whereas insufficient urethral coaptation can result in early failure, in the properly tensioned sling efficacy is maintained with a low risk of late failure, with a 2%-4% revision rate for dislodged bone anchors over a 4-year period [47,48]. Unlike the AUS, urethral atrophy with loss of coaptation has not been reported.

While excessive sling tightening may predispose to urinary retention, and insufficient tension can lead to persistent ISD, the particular method of sling tensioning is less important. Using a retrograde leak point pressure of 60 cm water is a particularly useful guide to proper fixation, whereby bladder outlet obstruction can be avoided in the patient with normal bladder contractility. Comiter’s group performed urodynamic studies 2 years post-operatively on a cohort of 22 patients who underwent bone anchor sling procedures with tension guided by precise measurement of retrograde leak point pressure (RLPP) [54]. RLPP was noted to improve from 30 cm H₂O preoperatively to 60 cm H₂O postoperatively, confirming the durability of the urethral compression. On the other hand, no significant change in maximum flow rate was seen postoperatively (19.2 vs. 17.7 ml/sec) nor was there a significant change in detrusor pressures at max flow (40.3 vs. 45.8 cm H₂O). With regulated tensioning, no instances of retention occurred, and the average PVR was 17 ml post-operatively, with no cases of PVR >100 ml. There were no instances of *de novo* urgency or urge incontinence.

Fischer et al. advocated a combination of RLPP and cough test at the time of surgery [55]. While success rates were similar to other published series, this particular tensioning method did result in 4

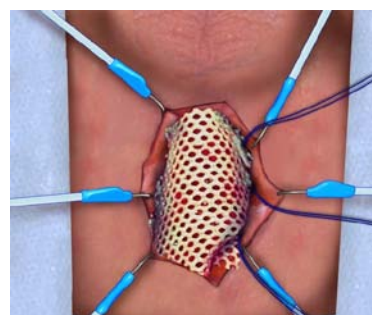


Figure 2: Bone anchored male sling provides compression of the perineal portion of the urethra.

instances of urinary obstruction (6%) with frank retention in 2 patients. And while reports of the bone-anchored sling secured with “maximal tension” did not demonstrate any obvious improvements in efficacy compared to a more measured tightening technique [48,52,53], in one such cohort, patients demonstrated a significantly decreased max flow rate post-operatively compared to pre-operatively (14.6 ml/s versus 23.4 ml/s) consistent with new onset bladder outlet obstruction.

In addition to proper sling tension, adequate tissue compliance is necessary for successful urethral compression. Not surprisingly, radiation and previous AUS explantation are associated with diminished sling efficacy [47,48,50,52]. Moreover, absorbable grafts are less efficacious than are synthetic slings, due to their failure to maintain urethral compression [49]. Samli and Singla reported superior outcomes of bone anchored synthetic grafts versus organic slings [56], where cure (no pads) and improvement (1-2 pads per day) was reached in 56% and 41% of patients respectively in the synthetic group (mean follow-up=18 months) versus cure in only 8% and failure in 92% in the absorbable group. The failures occurred at a mean of 6 months, i.e. at the time of expected sling absorption. Finally, the degree of incontinence impacts efficacy. In a prospectively evaluated cohort of 62 patients with PPI, Fischer et al. demonstrated that men with <423 g leakage per day were six times more likely to have adequate continence compared to those with a higher pre-operative pad weight tests [55].

While the bone-anchored sling has demonstrated durable intermediate-term results in multiple large cohort studies, the theoretical risk of bony complications (osteitis and osteomyelitis) has fostered increased interest in newer sling techniques that do not rely on bone screws.

Trans-obturator perineal sling

First described in 2005 [57], the AdVance™ (American Medical Systems) enables placement of a perineal sling that does not rely on the need for bone anchors. The sling is placed using a suburethral transobturator (T-O) approach, and is thought to improve continence by shifting the membranous urethra proximally and repositioning the sphincteric zone into the pelvis (Figure 3). The bulbar urethra is elevated, and this proximal “repositioning” of the membranous urethra increases the functional urethral length. In fact, in one study following placement of the T-O sling, functional urethral length increased from 31 mm to 40 mm. Just as importantly, there was no significant change in uroflowmetry, or were there any instances of urodynamic bladder outlet obstruction [58]. Thus this retroluminal sling, by repositioning rather than compressing the urethra, affects continence through a non-obstructive mechanism of action.

Based on this mechanism of action, it should not be surprising that the presence of urethral mobility predicts successful T-O sling surgery. Rehder's group demonstrated that the “repositioning test” whereby the abdominal leak point pressure is measured with and without gently pushing the pre-anal midperineum cephalad. Thus the effect of urethral repositioning on the coaptive ability of the sphincteric urethra can be demonstrated preoperatively. This provocative maneuver, by increasing the “zone of coaptation”, augments pressure transmission within the functional sphincteric unit. A positive test predicts successful outcome for the T-O sling [59,60].

Bauer et al. reported on their cohort of 124 patients, 70 of whom were followed for at least one year [61]. At 1 year follow-up, 51% of patients were cured (0-1 pad per day) and 26% noted improvement in continence. Infection and erosion rates were 1% each and 13% of patients were noted to have urinary retention for up to 10 days following

surgery. In a separate study of 102 patients with milder incontinence at baseline (76% requiring 2 pads or less per day preoperatively and no patients using more than 4 pads), similar results were demonstrated [62]. At a median follow-up of 13 months, 63% of patients were cured (0-1 pad per day with no leak) and 18% were improved (>50% improvement in pad use). However, 9% of patients who were pad free at 6 months required 1 pad for mild leakage at later follow-up. Bauer et al. followed up on their previous cohort study, reporting the complications associated with transobturator sling placement (n=230 patients, median follow-up=17 months) [63]. Overall, 21.3% of patients in the study had postoperative urinary retention, for a mean of 27 days. One patient developed long term retention requiring transection of the sling, 1 developed a sling infection, and 1 suffered sling erosion. Similar to other slings, success was lower in patients with a history of radiation (cure rate of 53% vs. 85% in non-radiated patients). In this series, the infection rate was only 2%, with no erosions. A recent study evaluated the urodynamic effects of the transobturator sling [64]. Thirteen patients were evaluated urodynamically before and after surgery. There was no change in voiding pressure, maximum urinary flowrate, or residual urine. Only 1 patient (8%) developed de novo detrusor overactivity.

More recent publications, however, have reported substantially lower success rates over time. Cornel et al. reported that in their cohort of 35 patients, a cure rate of only 9% was achieved at 1 year average follow-up with an improvement rate of 46% based on pad test. In addition 9% were found to have more leakage post-operatively than prior to the sling surgery [65]. In a recent report from the Cleveland Clinic [66] patient determined success was 51% with 29% pad free. This was in contrast to the pad free rate of 51% documented at 3 months. On questioning, only 53% would recommend the procedure to a friend. In a follow-up study, quantitative success decreased from 87.3% to 62.5%, with average daily pad use more than doubling from initial follow-up to 2 years postoperatively [67].

The I-STOP TOMS (CL Medical) is a 45 cm × 1.4 cm 4-armed monofilament poly-propylene bulbar urethral sling with a 2.8 cm central part placed over the urethra. The larger surface of bulbar urethral compression, combined with the fact that the perineal body is not dissected free from the bulbar urethra, proximal mobility of the sphincteric unit is less pronounced than in the Advance sling, and more direct compression of the bulbar urethra is potentially achieved. In 103 patients followed for a year, 59.4% of patients became completely dry, with an additional 20.3% improving to 1 pad per day leakage. A low wound infection rate (2%) occurred, with no instances of urinary retention [68]. An “inside-out” version of the TO sling with bulbar location and subcutaneous attachment of each arm was reported out of Belgium. In 173 men, 49% were cured and an additional 35% improved at a median follow-up of 24 months [69]. Overall, the short-term

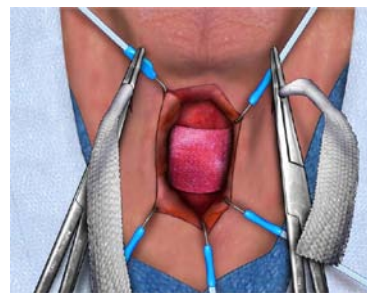


Figure 3: Trans-obturator sling repositions urethral sphincter zone proximally.

results of the T-O sling are comparable to that of the bone-anchored sling [59,61,62,64-66].

Trans-obturator and prepubic quadratic sling

The VIRTUE™ sling (Coloplast, Humlebaek, Denmark) is a new device for treating PPI that consists of a large-pore knitted monofilament polypropylene mesh with two pre-attached inferior (transobturator, TO) extensions and two superior (pre-pubic, PP) extensions. This novel device is designed to relocate the proximal urethra, similar to the transobturator slings, but also to compress the perineal urethra against the genitourinary diaphragm in a manner similar to the bone anchored sling, but without the use of any bone screws (Figure 4). This quadratic design may indeed improve efficacy in patients with more severe incontinence by providing a greater length of urethral compression than the currently available slings. The fixation does not rely on bone anchors, and thereby minimizes the risk of boney complications. In addition, the direct vision inside-out needle passage should substantially decrease the risk of urethral injury that can occur with the outside-in approach [70].

This dual mechanism of action was demonstrated in a cohort of 22 men undergoing placement of the VIRTUE sling. Mean RLPP increased from a baseline of 33.4 cm H₂O to 43.3 cm H₂O with T-O tensioning alone, and to 55.8 cm water with PP tensioning alone. With combined TO and PP tightening, RLPP was even higher, at 68.8 cm water. Each mean RLPP value was significantly higher than the preceding value. Thus both TO and PP components of the quadratic fixation contributed to increasing urethral resistance.

The sling is fixed in position to prevent loosening of the device over time, as can be seen with an unfixed TO sling [66]. The PP sling extensions are sutured in position to the soft tissue over the pubic symphysis, and the TO arms are tunneled back to the midline to prevent sling slippage. Early results of the fixated quadratic sling were recently reported at the 2012 annual meeting of the American Urological Association [71]. In a cohort of 31 patients, most of whom had 1-year follow-up, median 24-hr pad weight decreased from 147 g at baseline to 12.5 g at 1 year ($p < 0.001$ compared to baseline). Overall, there was a median 89% decrease in pad weight, with 85% of men realizing at least a 50% improvement. Using a validated patient global impression of improvement (PGI-I) score, 80% of men reported that they were very much better or much better at 6 weeks and again at 1 year, and an additional 15% reported that they were a little better. No patient was worse at 1 year. The sling was also proven to be safe, with no change in mean PVR following surgery (12.1 ± 19.2 cc baseline vs. 11.2 ± 18.0 cc at 1 year). No patient had urinary retention beyond 1 week, nor were there any serious adverse events.

Adjustable pubourethral slings

The Argus™ (Promedon, Cordoba, Argentina) adjustable pubourethral sling has demonstrated short-term efficacy [72]. The Argus device consists of a silicone foam pad placed under the bulbar urethra, attached to retropubically passed silicone column which are fixed over the rectus fascia with silicone washers. In the event of suboptimal intra-operative tension, sling tightening may be accomplished through a minimally invasive “re-adjustment” technique. In a multicenter trial of 47 patients, 66% became dry and 79% were dry or improved at 45 months mean follow-up. The large silicone burden, however, is prone to complications as 19% underwent sling removal due to erosion (13%) or infection (6%). In another trial of 101 men, with an average follow-up of 2.1 years, 79.2% of men achieved dryness on a short (20 minute) pad weight test. However, adjustment was necessary in nearly 40% of

patients, and 15.8% required explantation due to erosion or infection [73]. A very recent report out of the Netherlands demonstrated a cure rate of 54% and cure/improved rate of 72% in 100 patients at a median of 27 months follow-up. However, the overall complication rate was 55%, with 11% requiring sling explantation, and 12% developing a new urethral stricture, requiring surgical intervention [74]. Similar to what has been seen with the non-adjustable slings, risk factors for surgical failure included prior radiotherapy, and more severe incontinence.

The REMEEX™ (Neomedic, Barcelona, Spain) bulbourethral sling is another adjustable device in which a synthetic mesh is placed under the bulbar urethra and suspended by retropubically passed sutures which are secured to a varitensor, placed anterior to the rectus fascia. A “manipulator” is then used to tighten or loosen the sling to the desired tension. The varitensor may be re-accessed in the future in a minimally invasive tightening procedure. In a small cohort (14 patients) with an average follow-up of 18.6 months, patients required an average of 3.7 adjustments, yet achieved a dry rate of only 36%, with an additional improvement in only 29%. Unfortunately, bladder perforation occurred in 29%, and 21% required sling explantation [75]. Sousa-Escandon et al. reported their results with the REMEEX adjustable sling, achieving a 65% cure and 85% cure/improved rate in 51 patients over 32 months [76]. However, 86% of patients required at least 2 revisions, and the retropubic suture passage was associated with a 10% bladder perforation rate, and 6% infection/erosion rate. Overall, it appears that adjustability does not improve overall efficacy, compared to non-adjustable male slings, and also appears to increase the complication rate.

Sling Efficacy after AUS Failure

The male sling requires adequate urethral compressibility to achieve efficacy. It is not surprising, then, that prior radiotherapy and prior AUS explantation have been associated with decreased sling efficacy. A recent investigation specifically focused on the efficacy of sling surgery following AUS erosion [77]. In this cohort of 16 patients with prior AUS erosion, half underwent placement of a second AUS while half had implantation of an ARGUS adjustable sling. In the AUS group, 63% were dry and an additional 25% were improved (1-2 pads per day). Re-erosion occurred, however, in 25% at 1 year follow-up. In the sling group, only 12% were cured and 12% were improved. Despite re-tensioning, the other 75% failed to improve. It has become evident that a circumferentially placed AUS is more efficacious than a non-circumferential sling in cases of periurethral fibrosis.

AUS Efficacy Following Sling Failure

The effectiveness of the AUS in patients with prior bone-anchored

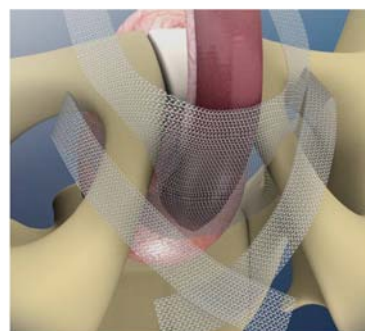


Figure 4: Quadratic sling provides proximal relocation and perineal urethral compression.

sling failure was evaluated in a cohort of 11 patients, of whom 73% were cured (0 pads per day and no leakage), and another 18% were improved (1-2 pads per day) following AUS placement [78]. One patient (8%) developed an infection of the device. It appears that while prior AUS placement diminishes sling efficacy, previous sling surgery does not adversely affect AUS outcome, especially if the bulbospongiosus muscle is left intact during sling surgery. The surgeon may then simply cut the sling, open the muscle, and place the AUS around a relatively unscarred corpus spongiosum.

Conclusion

The generally low success rates for injection of periurethral bulking agents and the high complication rate for periurethral balloon placement limit the role of these minimally invasive treatments for male SUI. The predictable efficacy of the AUS has rendered it the procedure of choice for men with high volume SUI, with success rates generally >80%, countered by an infection/erosion rate of 5%-10%, and a 5-year revision rate of approximately 20-25%. In men with more mild to moderate SUI (<400 g per day), the male sling may be preferable as an initial procedure. Non-adjustable slings are generally associated with generally lower complication and revision rates. In addition, successful AUS implantation can be expected after sling failure, whereas previous placement of an AUS is a relative contraindication to sling surgery. For those with milder leakage, the trans-obturator approach has reported short- and intermediate-term efficacy of 50-85% with very few complications. For men with more substantial incontinence, the bone-anchored or quadratic sling may have better efficacy based on a broader area of urethral compression. While adjustability may theoretically salvage an insufficiently tensioned sling, success rates for the adjustable slings do not appear to be higher than that of properly tensioned non-adjustable slings. On the other hand, complications appear substantially more common with the adjustable slings. Early results of the quadratic sling appear excellent. However, an AUS may be the treatment of choice in those individuals with high volume incontinence or in those with urethral fibrosis that would benefit most from circumferential luminal compression.

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