Surgical management of post prostatectomy incontinence

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ABSTRACT

Post prostatectomy incontinence (PPI) is a well-recognized and bothersome complication following radical prostatectomy. Conservative measures such as pelvic floor physical therapy, biofeedback, and medication are first line management of PPI. When first line therapies fail, patients are offered a variety of surgical procedures based on the degree of incontinence, prior radiation therapy, and comorbidities. Among the various surgical options, placement of an artificial urinary sphincter (AUS) is the gold standard for PPI. However, AUS placement has a high rate of re-operation and requires good manual dexterity. In cases of mild-moderate incontinence, especially in patients without prior radiation therapy, male slings and proACT are a less invasive option. Bulking therapy, although highly successful for female stress urinary incontinence (SUI), is not currently advised in the treatment of male SUI. Regardless of surgical approach used to treat PPI, providers should counsel patients regarding risks of re-operation and have an open an honest discussion regarding the degree of continence that can be restored following each procedure.

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1. Introduction

Prostate cancer is one of the most commonly diagnosed cancers in men, accounting for approximately 1.4 million new diagnoses and 375,000 deaths worldwide.[1] Radical prostatectomy (RP) is the surgical procedure most commonly used to treat prostate cancer. A well-recognized and bothersome complication of RP is post prostatectomy incontinence (PPI), defined as an involuntary loss of urine that occurs after surgery. PPI can be classified as mild, moderate, or severe based on 24-hour pad weight with weight less than 150 g for mild incontinence, between 150 g and 400 g for moderate incontinence, and more than 400 g for severe incontinence.[2,3]

Stress urinary incontinence (SUI) is the primary cause of PPI, although overactive bladder (OAB), with or without urinary incontinence (UI), has also been described. Male SUI is defined as urine leakage with increased intra-abdominal pressure such as coughing, sneezing, laughing. The incidence of PPI in literature is reported as 5%–72%, ranging widely depending on definition (completely dry vs socially continent) and technique (minimally invasive vs open prostatectomy).[4] Surprisingly, although 14%–29%

of men with PPI report significant bother, only 3.6% elect surgical treatment.[5,6]

PPI can improve one to two years following radical prostatectomy, but it often persists and has significant impact on a patient's quality of life.[7,8] This can lead to loss of confidence, social embarrassment, and decreased sexual function.[7,8] First line therapies include conservative measures: pelvic floor physical therapy and biofeedback, and should be offered to all patients following RP. For many men these treatments are either ineffective or provide only partial relief.[9] In these cases, anti-incontinence surgery is a viable treatment option that can be offered 6–12 months post prostatectomy.

The aim of this review article is to provide an overview of the different surgical techniques used in managing SUI in men after RP. Since the role of OAB and urge urinary incontinence in PPI is not well studied or classified, this review focuses primarily on surgical management for SUI. We discuss the indications, techniques, and outcomes of surgical options such as bulking agents, male slings, and compressive devices including artificial urinary sphincter (AUS) and prostate adjustable continence therapy device (ProACT).

2. Etiology of PPI

The etiology of PPI is complex and multifactorial, often influenced by patient characteristics and surgical technique. Patient factors that negatively impact continence include obesity, increasing age, pre-existing intrinsic sphincter deficiency (ISD) and

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neurogenic detrusor activity.[10–12] Mandel et al. noted 93.2% continence rate in men aged <65 years compared to 86.5% in those >75 years old. This could, at least in part, be related to enlarged prostate size in older men, which can impact continence.[12]

Nerve injury and damage to the external urethral sphincter (EUS), bladder neck, or pelvic floor during RP have also been implicated in PPI.[13] It is reported that patients PPI have 31%–35% shorter urethral length and more funneled bladder neck on MRI compared to continent men.[14] Furthermore, although certain surgical techniques such as nerve sparing and posterior reconstruction of the EUS accelerate the return of continence, they do not impact the degree of final continence.[13,15]

3. Bulking agents

Unlike treatment of SUI in women, bulking is not a first line option for male SUI post prostatectomy. Initially widely used in the early 2000s, collagen-based bulking agents fell out of favor due to complications including migration to proximal and distal lymph nodes, systemic absorption, fibrosis, and embolization.[16] Even after the introduction of nonabsorbable, non-migrating bulking agents such as Macroplastique, few studies report good results in men.[17] Furthermore, there is no standardized description of amount of bulking agent that should be used or the urethral location it should be injected in. One bulking agent extensively studied for SUI in women, Bulkamid (polyacrylamide hydrogel), has been shown to have a favorable safety profile.[18,19] Although no current studies assess Bulkamid in men, a study by Toia et al demonstrated that a four-point injection of Bulkamid at the urethral sphincter increased maximum urethral pressure in male cadavers, possibly leading to decreased SUI.[20] Additional studies are needed to assess Bulkamid in a clinical setting. Therefore, bulking agents should be reserved for clinical trials or patients with minimal incontinence who either do not desire or are unfit for surgery.

4. Male sling procedures

Male slings are a minimally invasive first line option in the treatment of mild to moderate male SUI. Slings are placed under the bulbar urethra in a retropubic or transobturator fashion, and are classified as fixed or adjustable depending on the ability to change the sling's compression postoperatively. Benefits of sling implantation, compared to AUS placement, include easier implantation, fewer complications, and not requiring manual dexterity to manipulate a pump. However, the longevity of slings has not been demonstrated in studies. In spite of high success rates, a study by Kumar et al found that 92% of men did not want a mechanical device or a scrotal pump implanted and instead opting for a male sling.[21]

Characteristics of each sling, including implantation technique, continence rate, follow up time, and complications are summarized in Table 1 (fixed slings) and Table 2 (adjustable slings).

5. Fixed slings

Fixed male slings function by repositioning the urethra proximally. These slings do not provide much urethral compression, requiring a partially or fully present urethral sphincter.[22–24] Four polypropylene mesh slings are currently commercially available: AdVance XP (Boston Scientific, USA), I-STOP TOMS (CL Medical, France), Virtue MS (Coloplast, Denmark), and Surgimesh M-SLING (Aspide Medical, France). All slings are placed via a transobturator approach with the Virtue and Surgimesh slings having two additional prepubic arms. AdVance, and its more recent counterpart, AdVance XP, is the most implanted and studied fixed sling to date.[25] Since the release of AdVance XP, the AdVance sling is not commercially available anymore. Updates to the second-generation sling include chevron anchors for better sling stability and a change in introducer needle for easier implantation.[25]

Efficacy and outcomes of AdVance and AdVance XP are well studied. One study of 130 patients who received AdVance or AdVance XP slings with mean follow-up of 42.7 months demonstrated 82.3% continence rate with a 90-day complication rate of 12%.[26] Complications included transient retention, wound infection, and UTI. No sling erosion or chronic pain (lasting >90 days) were reported. The authors found that higher preoperative pad use was associated with increased sling failure, especially use of more than 3 pads per day. Other studies have shown similar promising results. Grabbert et al evaluated 115 patients with Advance XP slings, of which 71.7% were cured at a mean follow up of 48 months.[27] They also reported no erosions/infections in their cohort. Bauer et al. reported a 66% cure rate and 23.4% improvement at 36 months following AdVance XP implantation.[25] The longevity of AdVance is questionable, however, with a recent meta-analysis reporting decreased continence from 81% 3 months postoperatively to 51% at 52 months.[23]

The I-STOP TOMS sling shows similar continence rates as the AdVance XP. At twelve-month follow up, success rates were 77%–87% and cure rates were 40%–59.4%.[28,29] On 58-month follow up, however, success and cure rates dropped to 22% and 15%, respectively, indicating recurrence of leakage.[29] Sequalae of the I-STOP TOMS sling include corpora cavernosa injury, wound infection, UTI, scrotal hematoma, and chronic pain.[28,29]

An alternative to two arm slings, Virtue MS and Surgimesh M are four-armed slings with a TO component and a superior prepubic (PP) component that provides compression in addition to elevation of the bulbar urethra. There are less data on the efficacy and durability of quadratic slings. The Virtue sling has variable success rates ranging from 41.9% at 12 months to 32% at 55 months.[30,31] In one study of 32 patients, including patients who underwent external beam radiation therapy (EBRT) with subsequently implantation of Virtue MS sling, a failure rate of 68% was reported. 7% of patients reported chronic pain and 22% underwent sling explant due to either pain and/or sling failure.[31] The authors have since abandoned implantation of Virtue sling after these findings. Ferro

Table 1
Fixed slings.

Device (citation)	Placement method	Continence rate	Follow-up time	Complications
Advance XP[23,25–27]	TO	51%–83.2%	36–52 months	Wound infections, UTI, transient retention, transient wound pain
I-STOP TOMS[28,29]	TO	22%–87%	12–58 months	Corpora cavernosa injury, wound infection, UTI, scrotal hematoma, chronic pain
Virtue MS[30–32]	Quadratic sling: TO and PP components	31%–41.9%	12–36 months	Short-term paresthesias, temporary perineal pain
Surgimesh M-sling[33]	Quadratic sling: TO and PP components	34.4%	24 months	Transient urinary retention, OAB

PP, prepubic; TO, transobturator.

Table 2
Adjustable slings.

Device (citation)	Placement method	Continence rate	Follow-up time	Postoperative sling adjustment	Complications
ATOMS[36,37]	RP	73%–80%	9–24.3 months	68.4%–70% of patients underwent at least 1 adjustment	Perineal/scrotal pain, scrotal hematoma, port extrusion/infection, epididymitis
Remeex[38]	TO	64.7%	32 months	Performed in 46 pts; 17 pts needed >1 adjustment	Perineal pain, bladder perforation, perineal discomfort
Argus T[39]	TO	53.5% at 5 years	3.2 years[a)]		Retention, hematoma, perineal pain, ED

ED, erectile dysfunction; RP, retropubic; TO, transobturator.
[a)] Median follow up.

at al found high complication rate with overall Clavien I complications in 17/29 (58.6%) patients.[32] Scrotal pain (17%), acute retention (10.3%), and perineal hematoma (10.3%) occurred most often.

Only one study has evaluated outcomes of the Surgimesh M sling. Out of 93 patients, the authors reported a 34.4% cure rate and 27.1% improvement rate at 24 months.[33] The most common complication was transient urinary retention in two patients.

6. Adjustable slings

Adjustable slings offer the benefit of altering tension after the initial placement in cases of persistent incontinence. Examples include ATOMS (A.M.I, Austria), Remeex (Neomedic, Spain), and Argus T (Promedon, Argentina). ATOMS and Argus-T are placed retropubically while Remeex is placed via a transobturator approach. ATOMS, the most studied adjustable sling, compresses the bulbar urethra on one side using a centrally located silicone cushion that is anchored to a two-armed mesh. The cushion is connected to a port that can be filled or emptied postoperatively depending on the patient's symptoms. A systemic review of ATOMS pooled data of 1393 patients, revealing a 67% dryness rate and 90% improvement (including postoperative adjustment). The authors defined dryness as "use of no pad or one safety pad per day."[34] Non-irradiated patients and those who used fewer than 6 pads per day had better results. Complications included urethral erosion, pain, and infection.

A recent systematic review and meta-analysis comparing ATOMS to Remeex in PPI found higher dryness (69.3% ATOMS vs 53.4% Remeex), and improvement (90.8% ATOMS vs 80.2% Remeex) in ATOMS slings. ATOMS also had lower complication rates (18.9%) and explant rate (5.5%) compared to Remeex (35.8% complication rate, 13.9% explant rate).[35] As this study did not directly compare the two slings, randomized controlled trials are needed to verify the superiority of ATOMS to Remeex.

Additional details of adjustable slings, including continence rate and complications, are outlined in Table 2.[36–39]

7. Autologous retropubic sling

In addition to synthetic polypropylene mesh, autologous slings have been reported for use in PPI. Athanasopolous and McGurie conducted a retrospective review of 32 patients who underwent rectus fascia bulbourethral slings for male SUI.[40] Causes of SUI included PPI (46.9%) and neurogenic dysfunction (53.1%).[40] They reported 46.9% of patients were satisfied with the outcome of the operation, with 31.3% of patients being either completely dry or using one pad per day.[40]

Nguyen et al conducted a randomized controlled trial assessing whether placement of a retropubic vas deferens sling during RP results in earlier return of continence. 203 patients were randomized to undergo sling placement during RP or just RP. Authors did not observe an earlier return of continence at 6 months in the sling group and concluded there is no benefit to this approach.[41] Further studies are needed to determine the efficacy of autologous slings and compare them to synthetic slings.

8. Sling complications or failure

In the event of persistent incontinence or infection/erosion after male sling, AUS can be offered. If no sling erosion or infection has occurred, an AUS can be placed with the sling in place.[42] However, in the event of sling erosion or infection, providers should excise as much of the sling as possible and offer AUS no sooner than 3–6 months after explanation.[43] Occasionally, slings can be replaced, however this is associated with high failure rates and should largely be avoided.[44]

9. Compressive devices

Compressive devices can be classified as circumferentially compressive (AUS) or non-circumferential devices (ProACT).

10. AUS

The AUS is the gold standard for the treatment of male SUI and is most commonly used for patients with moderate to severe incontinence following RP. Unlike placement of a male sling, AUS placement is independent of urethral sphincter existence and is therefore preferred for men with urethral stricture disease and history of pelvic radiation.[43] It is a circumferentially compressive device consisting of three components: a cuff, a pump, and a pressure-regulating balloon. The cuff should be placed at the bulbar urethra, proximal to the fusion of the corpora cavernosa. This proximal location ensures the largest diameter of the corpus spongiosum and allows for the safest circumferential urethral dissection. When the patient desires to urinate, they activate the pump, located within the scrotum, which releases pressure on the cuff, allowing the patient to urinate. Once the patient has finished urinating, the cuff is then automatically re-inflated restoring the patient's continence. Post implantation, the device remains deactivated for 6 weeks while the patient heals.

In order to ensure proper AUS function, an appropriately sized cuff must be chosen. Cuff size can be measured with or without a foley catheter in place, although many surgeons believe removing the foley yields a more accurate measurement.[43] For patients with history of radiation therapy (RT), 3.5 cm cuff size should be avoided due to increased risk of urethral erosion.[45] On the other hand, patients with urethral atrophy may benefit from implantation of 3.5 cm cuff.

The AMS800 (Boston Scientific, USA) is the most studied AUS. A review of AMS800 published in 2013 included 12 studies comprising of 623 patients with a pooled social continence rate of 79% and dry rate (0 pads/24 hours) of 43.5%. However, up to 26% of

patients required reintervention, with the most common being erosion or extrusion of device.[46] Younger age, shorter duration of preoperative incontinence, and lower preoperative pad use were all associated with better patient outcomes. Other less studied artificial sphincters include Zephyr (Zephyr Surgical Implants, Switzerland) and Victo (Promedon, Argentina). These devices differ from AMS800 by having the ability to adjust the compression of the device through a port at the bottom of the pump.

In spite of high success rates, the AUS is associated with a higher complication rate compared to male slings. Common complications include mechanical failure (10.5%), infection (1-3%), erosion/migration (5%–35%), pain (7.2%), and urethral atrophy (6%).[47–50] In cases with persistent or significant incontinence post AUS placement, occurring in approximately 10% of men, a subsequent second cuff around the bulbar urethra may be used to provide continence.[51] However, patients should be counseled that use of tandem cuff is associated with higher risk of erosion and can limit bulbar urethral locations if needed to redo AUS.[51]

In cases of urethral atrophy, tandem cuff placement has been successful. DiMarco et al investigated 18 patients who underwent tandem AUS placement for urethral atrophy with follow up of 3.3 years. Daily pad use decreased from 4.3 to 1.6 pads and all but one patient reported they would recommend the procedure. Complications were erosion in two patients, one of whom had three previous AUS revisions.[52]

Several techniques have been developed to decrease erosion risk or urethral injury in high-risk patients, such as those with history of urethral erosion or prior radiation therapy. One such technique involves placing the cuff by transcorporal approach. A retrospective review of 45 patients with AUS placement after RT found fewer device explant, erosion, and revision in the transcorporal group compared to standard AUS placement.[53] Transcorporal implantation is also helpful in salvage situations after erosion for two reasons: the already vulnerable urethra does not need to be dissected thus decreasing the risk of injury, and additional bulk is added in a location where the urethra is small, allowing for better sizing and therefore improved continence.[54] Trost and Elliot developed an alternative to transcorporal implantation which involves using small intestinal submucosa as a "urethral wrap" to provide urethral bulk during salvage AUS placement.[55] All patients experienced transient postoperative urinary retention and three out of eight patients had cuff explant rate for recurrent incontinence or urinary retention. This technique has not been reproduced.

A recent randomized controlled trial was conducted to compare outcomes of AUS and male sling in men with significant SUI post prostatectomy.[56] Men with bothersome SUI were randomized to either male sling or AUS. The primary outcome was defined as "any self-reported urinary incontinence at 12 months." Using this strict definition, incontinence rates were not significantly different in either group (87% male sling, 84.2% AUS). Even after a less strict definition of primary outcome which included leakage less than once a week or a small amount of leakage, no difference was seen in the two surgical methods (66% male sling, 65% AUS). However, AUS showed higher satisfaction with surgical outcome (90.6% AUS vs 72.2% in sling group).

11. ProACT

ProACT is a relatively newer technique that has gained popularity in recent years. It involves the placement of two adjustable balloons placed on either side of the bladder neck, thus increasing outlet resistance. The balloons are connected to a titanium port within the scrotum that can be accessed for adjustment of the balloon volume. ProACT is indicated for me with mild-to-moderate

SUI following prostatectomy and should not be used in men with severe urinary incontinence or urethral stricture.

A systematic review and meta-analysis of 19 studies of 1264 patients reported an improvement in quality of life of 30.8 points with a mean follow-up of 3.6 years.[57] Additionally, 60.2% patients were considered dry while 81.9% of patients noted more than 50% improvement. Men who underwent minimally invasive prostatectomy with subsequent ProACT placement had better success than those who underwent open prostatectomy. The most common adverse events after ProACT placement are erosion (up to 10.9%) and device dislocation (up to 6.2%).[58]

12. Conclusion

Surgical management of post-prostatectomy incontinence is an effective and viable option for patients who have failed conservative management. The different surgical procedures for PPI vary in terms of success rates and potential complications, and the choice of procedure should be individualized based on patient factors such as severity of incontinence, prior radiation therapy, and comorbidities. Among the various surgical options, AUS placement remains the gold standard and has demonstrated high success rates in the management of PPI. Other procedures such as bulking agents, male slings, and proACT can also be used, especially in the treatment of mild-moderate incontinence of lower risk patients. Additional studies should be conducted to assess OAB/UUI as a cause of PPI.

Conflicts of interest

The authors have no conflict of interest and have no disclosures to report.

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