

# Stress Urinary Incontinence: Surgery (Male)

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## 1. Introduction

Stress urinary incontinence (SUI) in men is defined as involuntary leakage of urine secondary to decreased bladder outlet resistance. SUI is associated with significant deterioration of quality in life. Surgical intervention remains at the forefront of the treatment options and is associated with significant improvements in patient satisfaction.<sup>1,2</sup> The burden of the disease goes beyond the physical aspect of incontinence and associated costs. The impact on quality of life as well as the psychological implications of SUI are quite significant. Multiple studies demonstrate a higher incidence of depression in patients who suffer from urinary incontinence after treatment for prostate cancer.<sup>3</sup>

### 1.1 Keywords

Male stress urinary incontinence, Post-prostatectomy incontinence, Artificial urinary sphincter, Male sling, Incontinence after Prostate Treatment

## 2. Risk factors and pathophysiology

**Bladder outlet resistance in men is provided by the internal sphincter (bladder neck and prostate complex) and the external sphincter (rhabdosphincter).** Typically, damage to both mechanisms is required to result in SUI. The most common cause of SUI in men is a radical prostatectomy (RP).<sup>4,5</sup> Other causes of SUI include incompetence of the external sphincter due to pelvic fracture urethral injury (PFUI), transurethral prostate surgery for benign disease, radiation, pelvic surgeries, traumatic and acquired myelopathies, and congenital conditions.

The incidence of SUI in the general male population is low, however, increases following prostate treatments. Post-prostatectomy SUI is estimated to occur in 2-60% of patients with most contemporary series reporting a rate of 10% or under.<sup>6,7,8</sup> Continence is reported to improve for up to 24 months following RP,<sup>9</sup> though **AUA guidelines on Incontinence after Prostate Treatment** suggest offering surgical management at one year if SUI remains bothersome despite conservative therapy. Nerve sparing approaches to RP are associated with improved continence rates.<sup>10,11,12</sup> It is important to note that there is significant variation in the definition of continence among studies as well as variation in the rates of continence reported by patients versus physicians. Patient reported

rates of incontinence are significantly higher than physician reported rates.

Incontinence is less common after radiation for prostate cancer; however, it can be as high as 30-50% in the setting of TURP after brachytherapy or external beam radiation.<sup>13</sup> More contemporary series of prostate cancer treatment shows the persistently high incidence of urinary incontinence after treatment.<sup>14</sup>

### 3. Diagnosis and Evaluation

Initial evaluation of men with stress urinary incontinence starts with a detailed history to establish the type of incontinence, the severity of incontinence and degree of bother. It is important to distinguish the type of incontinence as the treatment differs for stress incontinence and urgency incontinence. Understanding the precipitating factors may help distinguish between the types of incontinence. Stress incontinence occurs during activities that increase intra-abdominal pressure such as walking, coughing, laughing and changing position. The severity of incontinence and the degree of bother add value in the shared decision making process when discussing treatment options ( **Incontinence after Prostate Treatment AUA Guidelines Management Algorithms** ). Identification of urgency symptoms should prompt treatment according to the **AUA Overactive Bladder guidelines**.

A pad weight test and a voiding diary are inexpensive and non-invasive ways of assessing the severity of the incontinence and bladder function. Obtaining pad weight measures over several days increases its accuracy and potentially decreases variability based on differing levels of physical activity. A voiding diary assesses working bladder capacity, frequency and subjective incontinence episodes. Bladder function and storage capacity are important factors to evaluate especially in the presence of neurologic conditions or history of pelvic radiation.<sup>15</sup>

Patient reported pad use is a poor surrogate to the severity of incontinence.<sup>16,17</sup> Pad number is notoriously inaccurate at estimating the severity of incontinence and as such should not be used in describing the patient's degree of leakage.<sup>18</sup> The physical examination should include objective demonstration of SUI, the presence or absence of inguinal hernias, prior surgical incisions, and perineal or groin skin evaluation. The standing cough test is a valuable tool in the assessment of SUI. It has been shown to have a high predictive value for SUI, can stratify patients, and can be performed easily in the office in a noninvasive fashion.<sup>19</sup> Urine analysis and culture should be obtained prior to surgical intervention. Any existing urinary tract infection should be treated.

**Cystoscopy is important to perform prior to surgical intervention for SUI.** Cystoscopy should be completed to detect obstructive lesions, bladder pathology, and to directly visualize the external sphincter coaptation. Any urethral obstruction must be managed with the appropriate intervention (transurethral incision, resection or urethroplasty) prior to proceeding with surgery to correct SUI. Stability or resolution of the condition needs to be documented for a minimum of 3 months before surgical intervention for SUI.

Urodynamics (UDS) testing can be a valuable diagnostic tool to assess bladder function, capacity, and stability. UDS also can help to differentiate between stress and urgency urinary incontinence in

situations where the history and/or voiding diary are not sufficient. UDS play an important role in patients with a history of radiation, prior voiding dysfunction, prior failed incontinence procedure (sling or sphincter) or prior bladder surgery.

## 4. Treatment of Male SUI

Prior to a discussion of surgical therapy, **patients should be informed of non-surgical management options** including absorbent pads, occlusive devices and catheters. In addition, pelvic floor muscle training can be offered to the patient.

### 4.1 Conservative Management

The role of conservative management of stress urinary incontinence in men after bladder outlet surgeries or radical prostatectomy is limited. Treatments range from external devices (absorptive pads, clamps, external catheters...) that aim to collect the urine to pelvic floor muscle training (PFMT) with or without biofeedback. A meta-analysis of 50 trials evaluated the role of conservative management in SUI identified significant variability in the interventions performed as well as the outcome measured. None the less, one of the most striking findings was that incontinence improved over time irrespective of the intervention. In patients with SUI after transurethral resection of the prostate, pooled data from 8 trials showed no benefit for PFMT (57% SUI in PFMT versus 62% in control, RR 0.85 at 12 months with 95%CI 0.60-1.22). In men with SUI following radical prostatectomy, there was evidence of reduction of urinary incontinence by subjective report (relative risk 0.32 with 95% CI 0.2-0.51), however, the findings were not supported by the objective data from the pad test.<sup>20</sup> Further studies aim at better understanding the complex mechanism of continence after radical prostatectomy with the aim of better targeting muscle groups as well as identify barriers for success with PFMT.<sup>21</sup>

### 4.2 Artificial Urinary Sphincter (AUS)

The artificial urinary sphincter (AUS) has been the gold standard for post prostatectomy incontinence (PPI) surgery. The AMS 800 (Boston Scientific, Burlington, MA) has undergone several modifications but has been largely unchanged since the introduction of the narrow-back cuff in the mid-1980s and the maturation of the device into the current day model. The AUS is composed of three components; a cuff that is most commonly positioned circumferentially around the bulbar urethra, a control pump that is implanted in the scrotum, and a pressure regulating balloon (PRB) typically placed in the sub-muscular (sub-rectus) space in the right or left lower quadrant of the abdomen.

#### 4.2.1 Surgical Approach

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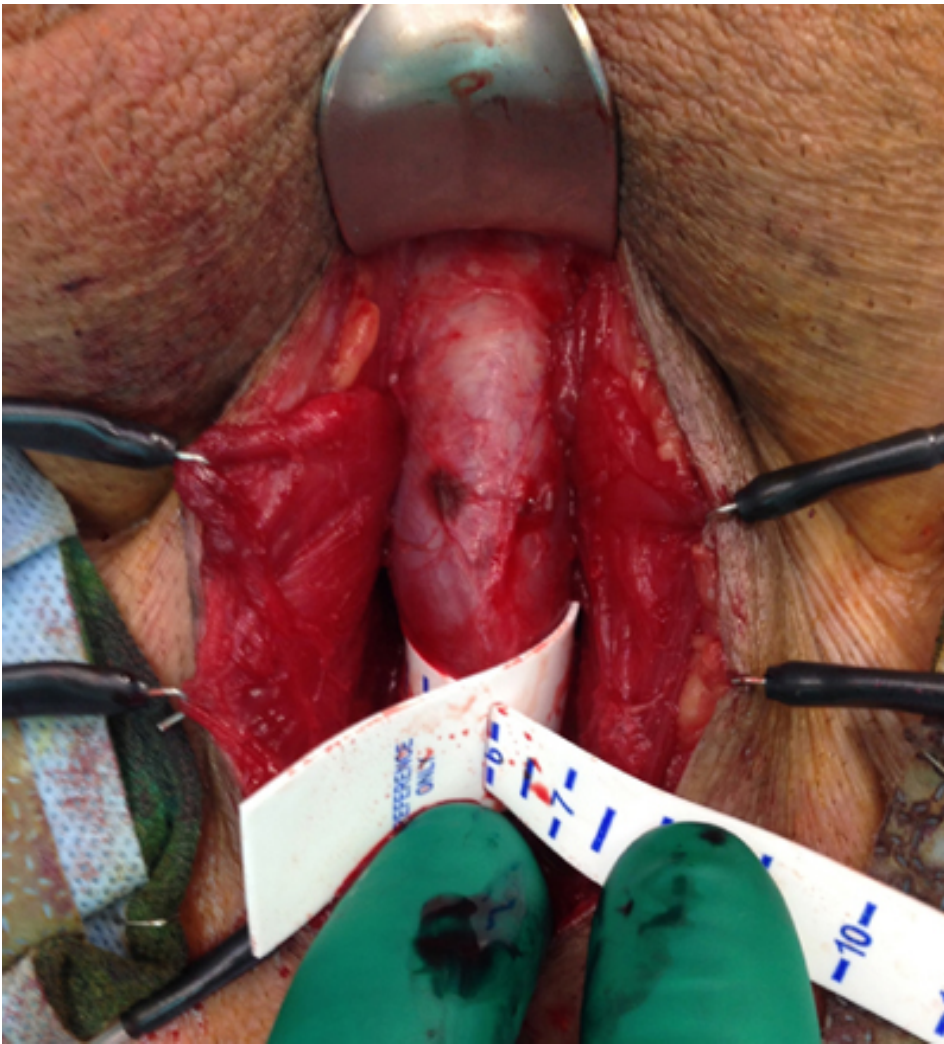


Figure 1: dissection of the urethra and reflection of the bulbospongiosus muscle. Measurement of the urethral bulb without tightening the measuring tape to get a proper assessment of the size.

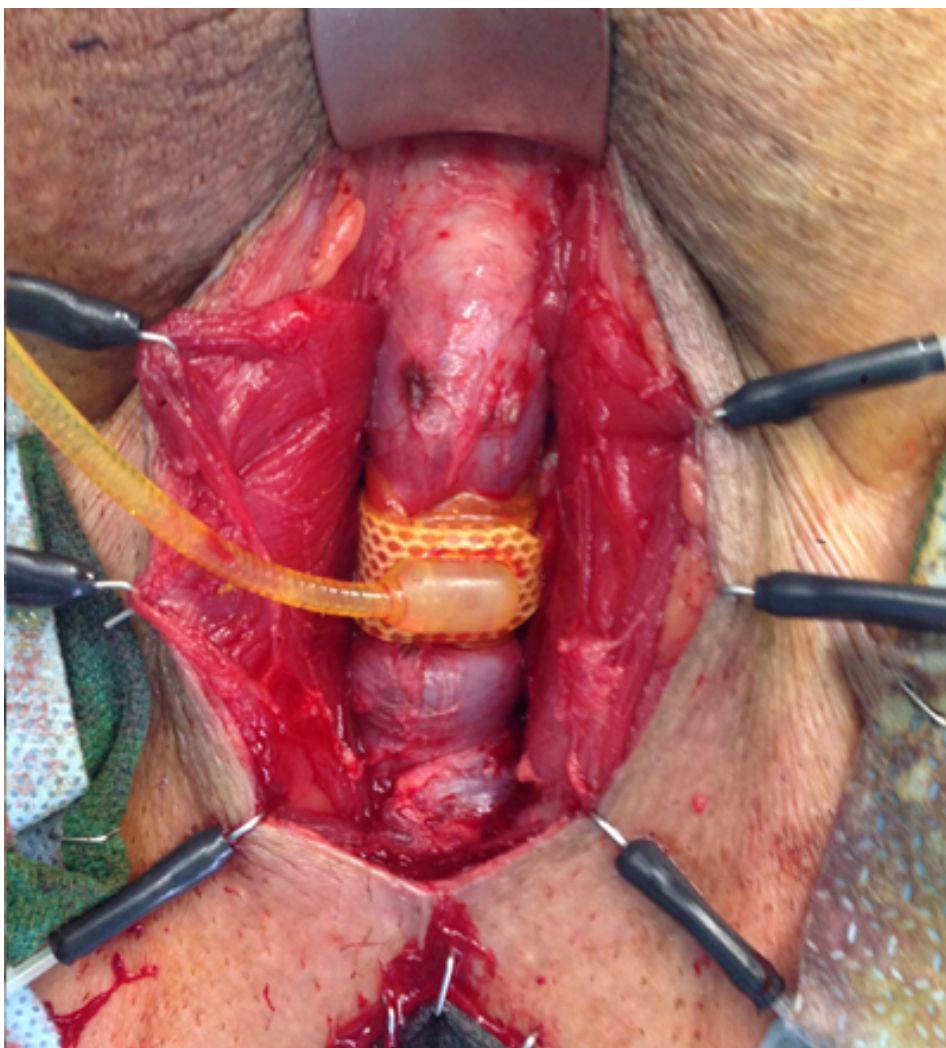


Figure 2: Placement of the urethral cuff around the bulbar urethra.





Figure 3: Placement of the pump through the abdominal incision. Note the sub-dartos placement and the ability to visualize the locking mechanism.

Preoperative preparation of the patient involves discussion of potential complications, informed surgical consent and verification of a preoperative negative urine culture. If placing a device with Inhibizone™ antibiotic coating, it is important to cross reference patient's allergies prior to placement of the device. Administration of IV antibiotics per **AUA Best Practice Statements on Urologic Procedures and Antibiotics Prophylaxis** should be confirmed. After prepping and draping in a sterile fashion, a foley catheter can be placed for bladder drainage.

The surgical approach generally involves two incisions. A midline perineal incision is taken down to the level of the bulbospongiosus muscle, which is divided and reflected off the urethra. A circumferential dissection is performed around the proximal bulbar urethra. The corpus spongiosum is thickest in this area and theoretically offers the most protection against erosion. The proximal location also minimizes urine pooling in the urethra proximal to the cuff. Variations to this approach include placement through a penoscrotal incision, transcorporeal placement (see below), and bladder neck placement.

After circumferential dissection of the urethra (with or without the aid of a 12 or 14 French foley catheter) the bulbar urethra is measured (**Figure 1**) and an appropriately sized cuff is prepared. The

cuff is placed around the urethra and secured (**Figure 2**). If there is a concern for urethral injury during the dissection, cystoscopy or irrigation can be used to verify its integrity. Most “early erosions” are likely due to a missed urethral injury at the time of the urethral dissection.

The PRB and the control mechanism/pump are often placed through a counter incision in the right or left lower quadrant. A dissection is performed through Scarpa’s fascia to the external rectus sheath where a small incision is made along its fibers. Typically, fascial closure sutures are pre-placed, and the muscle is spread bluntly. A sub-muscular space is created that is large enough for placement of the PRB. The sub-muscular space may also be accessed through a high scrotal incision. The PRB is then placed into this sub-muscular space and filled with the appropriate amount of injectable sterile saline or acceptable contrast medium. Blunt dissection is continued under Scarpa’s fascia using either a metal dilator or a ring forceps to reach the sub-dartos space in the lateral aspect of the scrotum. The control pump mechanism is then placed in the scrotal space ( **Figure 3**). The tubing from the cuff is then tunneled from the perineal incision to the counter incision and all connections are made at the counter incision. The device is cycled and deactivated with enough fluid in the pump to allow for reactivation while maintaining the cuff open for urethral healing. A small caliber (12 Fr – 14 Fr) catheter is typically left overnight to avoid post-operative urinary retention.

The PRB determines the amount of pressure applied to the urethra. Prior studies evaluating normal urethral closing pressures in continent men, found a range of 50-80 cm of H<sub>2</sub>O.<sup>22</sup> The three available pressure regulating balloons are 51-60 cm H<sub>2</sub>O, 61-70 cm H<sub>2</sub>O, and 71-80 cm H<sub>2</sub>O. The most commonly used pressure regulating balloon is 61-70 cm H<sub>2</sub>O. The most commonly used cuff sizes for bulbar placement are 4.0 and 4.5 cm.<sup>23,24</sup> The lower pressure balloon can be used in situations where the urethral health is of concern either due to multiple prior procedures or radiation. The higher pressure balloon is typically utilized for bladder neck cuff placement.

The cuff and the control mechanism are available with antibiotic coating (Inhibizone™) of rifampin and minocycline. The pressure regulating balloon is not imbedded with this coating due to concerns about change to the range of pressure generated. Recent data has questioned the added benefit of antibiotic coating.<sup>25,26</sup>

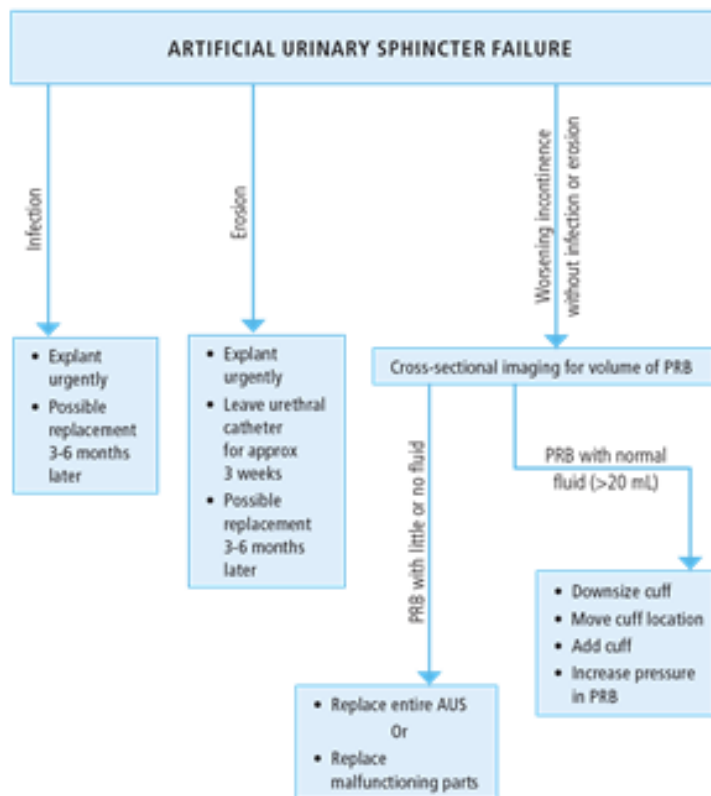
#### 4.2.2 Outcomes

Although backed by over 25 years of successful utilization with numerous publications supporting its use for management of SUI, all the data on the AMS 800 artificial sphincter is retrospective and the definition of continence is inconsistent between studies. A recent systematic review of the literature highlighted the heterogeneous definition of cure and social continence.<sup>27</sup> The most common definition is the use of "no pads" or the use of "one pad for protection". **The combined dry/improved rate of the pooled 12 studies was 79% with a range of 61-100%.**

Infection and erosion rates were consistent and averaged 8.5%. Infection or erosion generally occurred within 2 years of implantation. Urethral atrophy was reported in 7.9% and mechanical failure rates ranged between 2 and 13.8% (11 to 68 months). The re-intervention rate was calculated at 26% with a total of 84-98% of the patients having a functional sphincter at 2 years. The introduction

of the narrow back cuff decreased the rate of mechanical failure to 12% from around 21% for the older model.<sup>28</sup> **Table 1** summarizes the long-term outcome studies of the AMS 800.<sup>23,24,29,30</sup>

The rate of reoperation is based on many factors, including the surgeon's experience. AMS 800 implantation has a very long learning curve that does not plateau even after 200 procedures. Given that 60% of urologists who have implanted sphincters since 1987 have done less than 5 procedures, this number is not achievable for most surgeons in the entirety of their career.<sup>31</sup>



PRB: Pressure Regulating Balloon

AUS: Artificial Urinary Sphincter

Figure 4:

Secondary implantation in patients with a prior failed AUS is feasible and is associated with good results. The **AUA Incontinence After Prostate Treatment** guidelines review the work-up and



algorithm to address a prior failed AUS (**Figure 4**). Several studies have evaluated the outcomes of revision artificial urinary sphincters. Viers et al. surveyed 229 patients with primary AUS placement and 49 with secondary AUS placement and noted similar rates of quality of life improvement, pad use and urinary leakage episodes.<sup>32</sup> Other studies have shown similar success rates with revision/re-implant surgeries; however they have noted a higher degree of subsequent erosions. The rate of future erosion was 4 times higher (14.3% versus 3.6%).<sup>33</sup>

A recent study evaluated over 400 AUS placements. The aim of the study was to evaluate the impact of the 3.5 cm cuff on erosion rates. The mean follow-up was 50 months. The erosion rate was 10.8% in the 3.5cm group (166 pts) and 10.7% in the 4 cm cuff group (244 pts).<sup>34</sup> This study highlights the importance of accurate measurement of the urethral circumference and proper placement of the cuff in the most proximal part of the bulbar urethra. Radiation therapy, but not cuff size, was associated with higher rate of erosion. The effect of previous radiation treatment on the success of AUS placement has not been fully defined. It is generally accepted that patients with history of radiation have a higher complication rate and shorter time to erosion than non-radiated patients.<sup>35</sup>

A recent meta-analysis of male SUI surgical treatments highlights the improvement on the quality of life associated with these procedures.<sup>36</sup> Despite the strong positive impact on quality of life, these surgeries remain sparsely utilized. Patient education, counseling and robust cancer survivorship programs are needed to better address the burden of the disease. With a reported rate of post prostatectomy incontinence as high as 66%, the number of patients seeking treatment for urinary incontinence remains very low. The AUS is the gold standard for the treatment of male SUI, however, the 25% re-operative rate makes this implant less attractive, especially for someone with mild to moderate stress urinary incontinence. This has been highlighted by Kumar et al. reporting that when an AUS has been recommended by the urologist, only 75% of the patient chose it.<sup>37</sup> The remaining 25% elected to go against the recommendations and proceed with a sling to avoid the use of a mechanical device. When both implants were offered as options, 92% chose the male sling.<sup>37</sup>

Sexual dysfunction often coexists with urinary incontinence in post prostatectomy patients. Evaluation of patient's sexual function as well as the modalities for treatment previously attempted is important during the evaluation and planning of interventions for urinary incontinence. The placement of a penile prosthesis at the time of AUS is feasible. An infrapubic approach for placement of the penile prosthesis can serve as the access point for placement of the pressure regulating balloon and the pump for the artificial sphincter. Patients need to be counseled regarding the higher risk of revision surgery, especially for the penile prosthesis.<sup>38</sup> A retrospective review comparing 248 AUS implantations and 118 penile prosthesis/artificial sphincter implantation suggested a higher rate of erosion and subsequent explanation of the AUS in the penile prosthesis/artificial sphincter group.<sup>39</sup> However, these findings were recently contested. A study comparing three groups of patients (793 AUS, 644 penile implants, and 62 double implants) over a follow up period of 61 months showed no increase in complication rate of the double implant group compared to either AUS or IPP.<sup>40</sup>

**Table 1. Long-term outcome studies of the AMS 800**

Study	N	Follow up (mean/median)	Success rate, patient satisfaction (PPD= Pads per day)	Failure rate and complications
Montague et al. 2001 <sup>23</sup>	113	73 months (mean)	32% no pads, 33% 1 PPD, 31% 2-3 PPD  28% very satisfied, 45% satisfied, 18% neutral, 6% dissatisfied, 4% very dissatisfied	12% revision
Gousse et al. 2001 <sup>29</sup>	131	92 months (mean)	27% 0 PPD, 32% 1 PPD for protection, 15% 1-3 PPD, 25% more than 3 PPD  58% very satisfied, 19% satisfied, 23% dissatisfied	4% device erosion, 25% mechanical failure rate (lower in the narrow back cuff population), 1.4% infection rate
Kim et al. 2008 <sup>30</sup>	124	81.6 months (mean)	0-1 PPD use was 76.3% for follow up less than 4 years, 83.3% for follow up 4-8 years, and 88.8% for follow up greater than 8 years.	37% total failure rate  23.4% mechanical failure rate, 8% device erosion, 5.6% infection rate.  Most removals occurred within first 48 months.

Lai et al. 2012 <sup>24</sup>	218	36.5 months (mean)	At 5 years, 75% were free of revision. Median time to infection 3.7 months, 19.8 months for erosion, 29.6 months for atrophy and 68.1 months for mechanical failure	Infection rate 5.5%, erosion 6%, urethral atrophy 9.6%, mechanical failure 6%. Surgical removal 27.1%
Linder et al. 2020 <sup>41</sup>	1154 patients	5.4 years (median)	Revision-free survival rates at 5, 10, and 15 years were 72%, 56% and 41% respectively	404 patients needed secondary surgery: 156 for device malfunction (39%), 105 for urethral atrophy (26%), 99 for infection/erosion (25%) and 44 for erosion/infection (11%)
Radomski et al. 2018 <sup>42</sup>	1632	N/A	N/A Population-based data from the ICES data in Ontario, Canada (Single payer, government funded health system)	10-year revision/removal and reimplantation rates were 34% and 27%  Reimplantation rate lower in hospitals with high volume HR 0.55, 95% CI 0.37-0.82.

Tutolo et al. 2019 <sup>43</sup>	892	32 months (mean)	Retrospective, multicenter (16 centers in US and Europe), Only first time implants for post prostatectomy incontinence	Cure rate of 58%, revision rate of 30.7%. Higher volume centers associated with higher dry rates (OR: 1.18, p=0.005) and freedom from revision (OR:1.51, p=0.001)
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### 4.2.3 Complications

Complications after AUS implant can be immediate or delayed. Immediate complications include urethral injury, urinary retention, wound complications, device infection or damage to the device components during implantation. **Short term complications are typically related to early erosion (likely due to a missed urethral injury) or device infection. Long term complications include mechanical failure of the device, urethral atrophy and erosion.**

In patients with recurrent or persistent incontinence after placement of an AUS, the onset and nature of the incontinence is key to understanding the etiology. Persistent incontinence can be due to the following: device factors (poor coaptation due to an oversized cuff, insufficient fluid in device or fluid leak), urethral injury during dissection of the urethra, or improper location around the urethra (too distal with very little coaptation). <sup>44,45,46,47</sup>

Incontinence occurring after a period of successful continence is most likely due to one of the following: mechanical failure (fluid leak), urethral atrophy, or erosion. Typically, incontinence as a result of mechanical failure presents as acute onset, while incontinence as a result of atrophy is more gradual. Some patients report needing to squeeze the pump more times to be able to empty the cuff as there is more fluid in the cuff due to atrophy of the urethra.

Cuff erosion presents in various ways. Signs may include hematuria, infection, scrotal swelling, recurrent urinary tract infections or simply recurrent incontinence. Risk factors for erosions include compromised urethras after prior urethral surgery (urethroplasty, prior AUS), radiation, or need for urethral instrumentation. <sup>48</sup> It is important to consider using a larger cuff (4.5 cm or larger) in patients requiring intermittent catheterization for neurogenic bladders or frequent endoscopic procedures such as bladder cancer surveillance as the smaller cuffs do not readily accommodate a rigid endoscope without risk of injury.

### 4.2.4 Alternate Surgical Approach

The transcorporal approach is a variation on the previously described surgical technique for cuff placement. Recent data has been accumulating on the benefits of this approach in the setting of a compromised or fragile urethra.

The surgical technique involves a midline perineal incision and dissection of the ventral bulbar urethra without circumferential mobilization. A 2 cm corporotomy is created parallel to the urethra, 1-2 mm lateral to the urethral edge bilaterally. The plane of dissection is dorsal to the urethra through the corporal septum creating a flap of corporal tissue to protect the dorsal urethra from erosion. Closure of the corporotomies can be performed in various fashions. The reported long-term success rates approach 70% with 0-1 pads used daily. <sup>49,50</sup>

### 4.2.5 Post-Operative Pathway (suggested)

POD 0

- Pre-operative IV antibiotics continued for 24 hours post op



- Mobilization of patient
- Regular diet
- Pain assessment and control

## POD 1

- Foley removal and trial of void
  - If patient develops urinary retention, perform gentle catheterization with a 12 or 14 Fr catheter with repeat trial of void within 24-72 hours. Longer catheterization duration can lead to AUS erosion
- If longer duration of catheterization is needed, consider a suprapubic tube placement guided by imaging to avoid damage to device components.
- Discussion of reasons to call for medical attention: fevers, wound drainage, increasing pain, urinary retention, hematuria
- Discharge home\* with appropriate pain management\*\* and stool softeners<sup>51</sup>

\* – With a transition towards same day surgeries in the field of urology, there have been studies assessing the plausibility of outpatient placement of the AUS. In a recent study, rates of immediate postoperative complications, urinary retention, patient phone calls, unplanned clinic visits, ED visits and need for surgery were comparable between the patients who were admitted for observation and those who were discharged on the day of the surgery. Another study reviewed the immediate outcomes along with opioid requirements, identifying minimal narcotic requirements and low complication profile supports same day discharge. <sup>52</sup>

\*\* – Additionally, as the recognition of the opioid epidemic came to the forefront for health care providers, many urologists have evaluated pain management protocols in the perioperative setting to reduce the need for opioid medication and therefore reduce the risk of long-term addiction. <sup>53</sup> Consideration of multi-modal analgesia protocols should be considered given the low narcotic requirements in the postoperative period. <sup>52</sup>

## POD 7- 14

- Follow up in clinic for wound check

Approximately 6 weeks post-op

- Follow up in clinic for AUS activation

## 4.3 Transurethral Injection of Bulking Agents

Numerous bulking agents have been used in the male urethra, all with limited success. Currently, the ones that are most commonly used are pyrolytic carbon microspheres (Durasphere™, carbonmed.com), dextranomer/hyaluronic acid copolymer (Deflux™, q-med.com), and polydimethylsiloxane (Macroplastique™ uroplasty.com). More recent trials utilize stem cells derived from adipose tissue. <sup>54</sup>

Transurethral injection of bulking agents involves submucosal injections at the bladder neck to cause coaptation of the tissues. Most reported studies are retrospective in nature and report variable success rates. Generally, transurethral injection of bulking agents requires more than one procedure and patients with a low abdominal leak point pressure are more likely to have a successful outcome. A randomized controlled trial comparing Macroplastique injection with AUS showed significant differences among patients with moderate to severe incontinence favoring AUS placement. There was no statistically significant difference in change in pre-op and post-op pad weight, use, and quality of life scores among AUS and Macroplastique treated patients with mild incontinence.<sup>55</sup> Generally, there is lack of evidence with this modality of treatment and as a result, it is rarely offered for male patients with SUI.

#### 4.4 Male Perineal Slings

In the late 1990s, bulbourethral sling use became more common in the treatment of male PPI. There are several slings of different designs and different materials, with some being adjustable while others are not.<sup>56,57,58,59</sup>

In general, patient selection is the key for a successful outcome after sling placement. **Good candidates for a sling are patients with mild to moderate stress urinary incontinence with evidence of a functioning rhabdosphincter** (evaluated on cystoscopy, coaptation of the native sphincter), gravitational incontinence (does not leak when lying supine), good functional bladder capacity, no prior pelvic radiotherapy, and absence of/or stable bladder neck contracture.<sup>60,61,62,63,64,65,66</sup>

Utilizing the American College of Surgeons National Surgical Quality Improvement Project, Alwaal et al. evaluated the rate of 30-day complications following sling and sphincter implantation. From among over 1200 incontinence surgeries between 2008 and 2013 (597 sling and 608 AUS), the rates of urinary tract infections and return trips to the operating room were significantly higher among the AUS group. Compared to the sling group, the rate of urinary tract infections in the AUS group within 30 days was 2.0% vs 0.3%. Similarly, the rate of return to the operating room was 3.0% in the AUS group compared to 1% for the sling group. A higher BMI among both groups was associated with an increased rate of complications within 30 days.<sup>67</sup>

##### 4.4.1 AdVance XP Sling

The AdVance XP sling (Boston Scientific, Burlington, MA) is a polypropylene retrourethral transobturator mesh sling that proximally relocates the rhabdosphincter as a mechanism of restoring continence. Urodynamics performed after sling placement do not show a significant increase in obstruction.<sup>60</sup> The AdVance sling provides continence rates of around 60-77% in most reported studies. Li et al. reported an 87.8% quantitative improvement in 66 patients with mild to moderate urinary incontinence following AdVance sling placement. This response rate dropped to 62.5% by 2 years. Cure rates (0 pads) similarly dropped from 50.8% to 39.3% at 2 years.<sup>61</sup> An updated study by the same authors in 2017 showed a cure rate of over 65% and more than 50% improvement rate in

22% patients (excluded patients with radiation and included 112 highly selected patients with no nocturnal incontinence and a sphincter coaptation zone length of more than 0.5 cm). These results were stable over the two year follow up.<sup>68,69,70</sup>

Preoperative preparation involves a discussion of expectations, potential complications, surgical consent and verification of a preoperative negative urine culture. Intraoperative preparation includes administration of IV antibiotics, removal of the hair below the umbilicus including the perineum and the medial thighs.

The AdVance XP Sling is placed through a perineal incision with the patient in lithotomy position. After dissecting the urethral bulb and reflecting the bulbospongiosus muscle, the distal aspect of the perineal body is marked. This is the intended location of the proximal edge of the sling. If the sling is placed too proximally, it is less likely to give the desired continence rate.<sup>71</sup> The perineal body/central tendon is then freed to allow for mobility of the proximal bulbar urethra.

Two stab incisions are performed one finger-breadth below the adductor tendon and one finger-breadth lateral to the inner thigh crease. The trocars are passed outside-in through the obturator foramen to retrieve the arms of the sling. The entry point of the trocar should be as high as possible in the angle formed by the urethra and the crus of the corporal body attached to the ipsilateral pubic ramus. Care should be taken to ensure passing of the trocar through the obturator membrane and behind the pubic ramus as to not injure the urethra or corporal bodies. After placement of the trocar, a cystoscopy can be performed to ensure absence of injury to the bladder or urethra. In the presence of such injury, the procedure should be aborted and the injury must be managed either by catheter drainage or repair.

#### 4.4.2 Virtue Sling

The Virtue sling (Coloplast, Minneapolis, MN) is a quadratic sling with two transobturator limbs and two prepubic limbs. The larger mesh surface spreads the compression along a larger surface area of the urethra. The transobturator limbs proximally reposition the urethra and the prepubic limbs allow compression over the entire length of the bulbar urethra. Common practices include anchoring the prepubic arms to the periosteum of the pubic rami and intraoperative measurement of retrograde leak point pressures (RLPP) to guide the amount of tension on the sling. Studies reporting on success rates of Virtue sling are not consistent. A recent study documents high procedure failure rate of around 68% of 38 patients with mild to moderate incontinence undergoing the procedure. Failure was defined as inability to reduce the preoperative pad use.<sup>72</sup> However, in a multinational clinical trial, they found that objective success rates were 79% with median pad weight reduction of 88% at 12 months in patients who underwent fixation of the prepubic arms.<sup>73</sup>

#### 4.4.3 Other Male Slings

Recent practices have utilized a “mini-sling” or “mini-jupette” placement at the time of penile implant to treat mild stress incontinence and climacturia. The procedure involves using mesh or cadaveric allograft sutured to the corporal bodies across the urethra. Minimal tension is placed on the graft as it

will tighten with the inflation of the prosthesis.<sup>74</sup>

Adjustable slings are not currently available in the United States. There are numerous types and they can be implanted retropubic or via a transobturator approach. A recent study compared Argus T® sling versus the AdVance® sling. Success rates and quality of life improvements were similar. The number of patients in the study was too low to be able to generate significant conclusions.<sup>75</sup>

There are several other adjustable slings available on the market outside the United States.<sup>76,77,78,79</sup> Short<sup>80</sup> and mid-term success rates as well as complication rates from published studies equate those available. Retropubic slings, however, have a significantly higher rate of bladder injury.<sup>81</sup>

#### 4.4.4 Adjustable Balloon Continence Therapy

The ProACT™ device (Uromedica Inc. Plymouth, MN) was FDA approved and became commercially available in the United States in 2017. ProACT is an adjustable device consisting of two balloons implanted on the lateral aspects of the bladder neck using dedicated trocars. The balloons are filled with 1 ml of isotonic contrast solution. The balloons can be filled with additional fluid via subcutaneous ports in a subdartos pouch in the scrotum. Adjustments are made every 6-8 weeks following the initial implantation until the desired continence level is achieved. The procedure for implantation continues to evolve with the use of different imaging modalities for proper placement of the device (ultrasound, fluoroscopy and direct visualization with cystoscopy). The initial safety and efficacy of the device in the United States has been established in a study of over 120 patients showing reduction in pad weights and improved quality of life scores.<sup>82</sup> The device has been utilized in Europe for over 10 years. Noordhoff et al recently published their experience with 143 patients with no prior history of radiation. The patient's degree of incontinence ranged from mild to severe. The success rate (zero pads or 1 pad for security) among all degrees of incontinence was around 47% at 6 months and 51% at 12 months. At 1 year, 78% had significant improvement (more than 50% reduction of pad use).<sup>83</sup> Recent<sup>84</sup> data suggest that the ProACT has similar success rate to the sling in non-irradiated patients. The revision rate, however, can be significantly higher.<sup>85</sup>

## 5. Future Directions

The largest challenges facing the study of the surgical therapy for male SUI remains in standardizing the definitions for the severity of incontinence, success after surgery and the use of urinary incontinence specific patient reported quality-of-life outcomes. In an era with ever increasing healthcare costs, randomized prospective trials are needed to support the use and implementation of increasingly expensive interventions.

## 6. Other Resources

**AUA University: Case modules on Incontinence After Prostate Treatment.**

**AUA Update Series 2019 Volume 38 lesson 4 on Surgical Treatment of Post Prostatectomy Incontinence.**

## Videos

Urethral dissection and cuff placement in transcorporeal approach in 2 patients.

Step-by-Step Placement of the AdVance XP Male Urethral Sling

Step-by-Step Placement of the Artificial Urinary Sphincter

Artificial Urinary Sphincter Surgery: Transcorporeal Approach

## Presentations

SURGERY FOR MALE SUI Presentation 1

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