Review Article on Surgical Management of Stress Urinary Incontinence in Men

Management of male stress urinary incontinence in high-risk patients: a narrative review

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Background and Objective: The artificial urinary sphincter (AUS) remains the gold standard for treatment of stress urinary incontinence (SUI). However, highly complex patients such as those with bulbar urethral compromise, bladder pathology, and lower urinary complications pose a particular challenge for the surgeon. In this article, we will address critical risk factors and synthesize existent data across relevant disease states to support surgeons in successful management of SUI in high-risk patients.

Methods: A comprehensive review of current literature was performed utilizing the search term "artificial urinary sphincter" in conjunction with any of the following additional terms: "radiation", "urethral stricture", "posterior urethral stenosis", "vesicourethral anastomotic stenosis", "bladder neck contracture", "pelvic fracture urethral injury", "penile revascularization", "inflatable penile prosthesis", and "erosion". Guidance is provided based upon expert opinion where existing literature was sparse or nonexistent.

Key Content and Findings: Several known patient risk factors are associated with AUS failure and can ultimately lead to device explantation. Each risk factor requires careful consideration and investigation, or intervention as appropriate, prior to device placement. Optimization of urethral health, confirmation of anatomic and functional stability of the lower urinary tract, and thorough patient counseling are a necessity for these high-risk patients. Several surgical strategies to decrease device complications can be considered: optimization of testosterone, avoidance of 3.5 cm AUS cuff, transcorporal AUS cuff placement, relocation of AUS cuff site, use of lower pressure-regulating balloon, penile revascularization, and intermittent nocturnal deactivation.

Conclusions: A number of patient risk factors are associated with AUS failure and can ultimately lead to device explantation. We present an algorithm for management of high-risk patients. Optimization of urethral health, confirmation of anatomic and functional stability of the lower urinary tract, and thorough patient counseling are a necessity for these high-risk patients.

Keywords: Artificial urinary sphincter (AUS); fragile urethra; incontinence

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Introduction

The American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) have published contemporary guidelines for the management of urinary incontinence after prostate therapy (IPT) (1). There is a myriad of options for patients with stress urinary incontinence (SUI), including observation, absorbent wearables, pelvic floor physical therapy, penile clamps, urinary catheters, adjustable balloons, bulking agents, male slings, artificial urinary sphincters (AUS), and urinary diversion. AUS implantation remains the gold standard for patients with moderate to severe SUI, with longstanding evidence of efficacy and durability (2). In patients with a history of pelvic radiotherapy, the AUS remains the preferred management option regardless of incontinence severity; sling placement in these patients has limited efficacy and poor durability (AUA/SUFU IPT guideline statement 24 (1,3-5).

A number of risk factors have been identified to portend higher failure rates with AUS implantation. The risk factors which lead to a "fragile urethra" (or bulbar urethral compromise) have been previously defined as a history of pelvic radiation, a prior failed/eroded AUS, a prior urethroplasty, and urethral atrophy (6). These risk factors all have a common theme: vascular compromise of the bulbar urethra, whether through endarteritis or scar formation through injury or surgery. Similarly, pelvic fracture resulting in traumatic disruption of vascular flow may result in bulbar urethral compromise, resulting in sequelae for cases of incontinence requiring AUS. Herein we assess risk factors that lead to bulbar urethral compromise, bladder pathology that can yield AUS failure, and lower urinary obstruction that can pose a challenge to long-term success. If urethral or bladder pathology is present, it must be carefully considered when determining a management strategy for concomitant SUI. Preoperative cystourethroscopy is recommended in all cases by the AUA/SUFU guidelines, and it remains a critical component of the preoperative evaluation to screen for underlying posterior urethral stenosis, identify bladder pathology, and evaluate the tissue quality of the lower urinary tract for surgical planning (1). Our objective is to provide urological surgeons with a range of strategies for the evaluation, surgical treatment, and follow-up of high-risk patients undergoing first time or repeat implantation of AUS. We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-727/rc).

Methods

A review of current, English-language literature (see *Table 1* for search strategy summary) was performed in PubMed utilizing the search term "artificial urinary sphincter" in conjunction with any of the following additional terms: "radiation", "urethral stricture", "posterior urethral stenosis", "vesicourethral anastomotic stenosis", "bladder neck contracture", "pelvic fracture urethral injury", "penile revascularization", "inflatable penile prosthesis", and "erosion". Articles were screened by JSL to verify their focus on the population of interest (adult men with SUI after prostate surgery or pelvic injury), and findings from relevant articles were synthesized by JSL, AJS, and JCH; guidance is provided based upon expert opinion where existing literature was sparse or nonexistent.

Results

A total of 920 articles were reviewed: 175 from radiation, 198 from urethroplasty/stricture, 53 from posterior stenosis, 5 from pelvic fracture urethral injury, 54 from inflatable penile prosthesis (IPP), and 387 from AUS erosion. No search results returned for penile revascularization. Twenty-seven articles from radiation, 15 from urethroplasty/stricture, 2 from posterior stenosis, 1 from pelvic fracture urethral injury, 6 from IPP, and 59 from AUS erosions were included. The following is a summary of the relevant findings and our interpretation of existing literature in these disease states. Our knowledge of the pathophysiology of pelvic fracture related injury can be applied to inform care for men with SUI after prostate surgery and/or radiation, another form of injury to the genitourinary organs. In all cases, the blood supply to the urethra may be compromised by prior injuries or treatments and can in turn lead to failure of subsequent interventions in the form of recurrent stricture disease or AUS cuff erosion.

In this manuscript we have divided the discussion into three high-risk disease states: bulbar urethral compromise, bladder pathology, and lower urinary tract complications. We describe the microvascular and macrovascular consequences of AUS erosion, pelvic radiotherapy, pelvic fracture urethral injury (PFUI), urethroplasty, and low testosterone on the bulbar urethra and their consequences on device survival. We highlight important considerations in patients with bladder dysfunction or disease requiring urinary instrumentation. Furthermore, we discuss management of concomitant lower urinary tract

Table 1 Search strategy summary

Items	Specification
Date of search	September 1–20, 2022
Databases and other sources searched	PubMed
Search terms used	"artificial urinary sphincter", "radiation", "urethral stricture", "posterior urethral stenosis", "vesicourethral anastomotic stenosis", "bladder neck contracture", "pelvic fracture urethral injury", "penile revascularization", "inflatable penile prosthesis", and "erosion"
Timeframe	Jan 1, 1985–Sept 1, 2022
Inclusion criteria	English language, all study types were included for review
Selection process	Selection performed by JSL, consensus with AJS and JCH
Any additional considerations, if applicable	Additional consideration and search were performed for concomitant bowel use with artificial urinary sphincter placement, pathophysiology of radiotherapy, and urethral fistula

complications: anterior urethral stricture, prostatic fossa calcifications, and posterior urethral stenosis. Finally, we synthesize the existing literature and propose an algorithm for management of these high-risk patients in *Figure 1* with important considerations for follow-up after AUS implantation.

Discussion/summary

Risk factors

Bulbar urethral compromise

Prior AUS cuff erosion

Prior studies have examined risk factors associated with AUS cuff erosion, with the vast majority being single-center retrospective studies with small cohorts (7-26). Previously described risk factors include diabetes, smoking status, obesity, coronary artery disease, previous urethroplasty, history of radiation, and previous AUS cuff erosion. Pelvic radiotherapy and urethroplasty are risk factors that will be discussed in subsequent sections and other risk factors will be discussed here.

Multiple patient co-morbidities have been identified to increase risk of device failure. In two retrospective studies examining primary AUS placements, diabetes was shown to be independently associated with AUS erosion or infection on multivariable analysis with a hazard ratios ranging from 2.26–2.50. Interestingly, both groups also found increasing body mass index (BMI) to be a protective factor for erosion and infection, in otherwise healthy men (27,28). In the study by Viers *et al.*, this was seen in patients categorized as obese (BMI ≥30.0) with a hazard ratio of 0.39. This finding trended towards significance in overweight patients (BMI between 25–30). They also noted that a greater BMI was associated with a decrease in the proportion of patients with pad use ≤1 pad/day. In the same study, coronary artery disease was found to be an independent risk factor for AUS erosion with a hazard ratio of 1.87 (27). Another study by Ortiz *et al.* found CAD similarly associated with a risk of erosion, with a hazard ratio of 3.7 (29). Multiple other studies have found this association on univariate analysis, however only trended towards significance in multivariate analysis (30,31). Diabetes and CAD are well known to yield chronic systemic microvascular disease, which may compromise the health of the urethra in a similar manner to that seen after pelvic radiotherapy.

Studies have also found increasing age as a factor for increasing AUS erosion (27,28,30) Ziegelmann *et al.* found that particularly patients older than 80 years are at a significantly increased risk of erosion, with a hazard ratio of 4.13 on multivariable analysis. Age was not a factor for mechanical failure or urethral atrophy (28). Concerning smoking as a risk facture, despite its known adverse effects on perioperative outcomes and wound healing (32-34). Godwin *et al.* found that current and previous smoking status did not increase rate of device complications (35).

As with other controllable medical comorbidities, the authors recommend patient optimization prior to AUS placement. Diabetes, coronary artery disease, age/fragility, and smoking affect wound healing and urethral health may be compromised by systemic microvascular disease. These factors may have a compounding effect. Patients have a much higher risk of subsequent AUS removal after a single erosion event, and thus medical optimization is critical with every AUS implant (22,36,37).

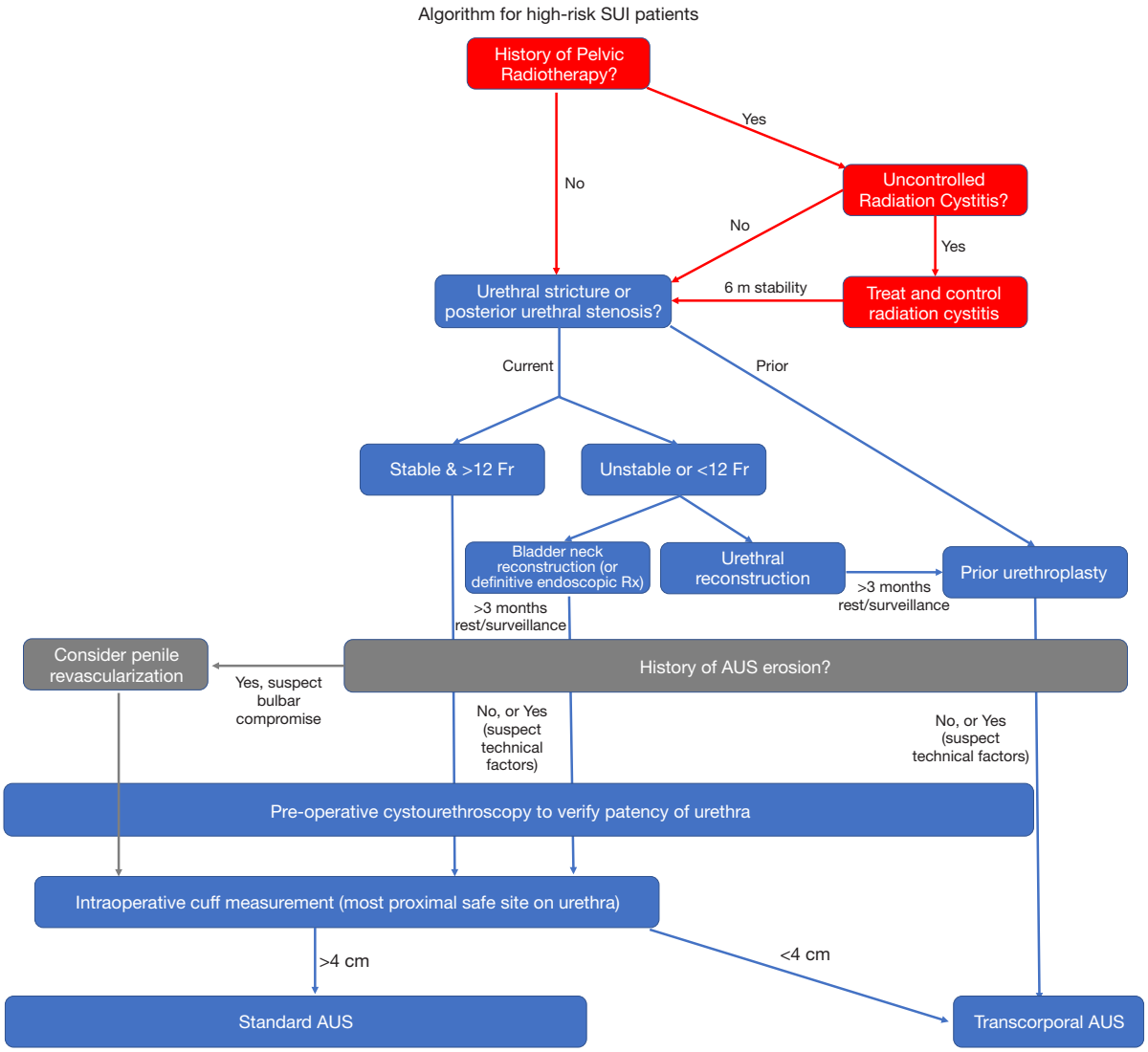

Figure 1 Algorithm for management of high-risk patients undergoing AUS implantation. During the initial evaluation of high-risk patients, first consider a patient's history of pelvic radiotherapy: the patient should be evaluated for radiation cystitis and any bladder storage dysfunction (Section "Radiation induced bladder pathology"). After treatment or stability of bladder pathology, the focus should shift to the urethra with evaluation of urethral stricture or posterior urethral disease. Section "Bulbar urethral compromise" reviews the pathophysiology and associated risks of AUS placement in the compromised urethra, while Section "Lower urinary tract compromise" discusses management concomitant stricture or stenosis. Finally, when the patient is deemed ready for AUS placement, important surgical considerations are reviewed regarding cuff location, cuff sizing, use of transcorporal cuff, PRB pressure, and concomitant IPP in Section "Surgical considerations for high-risk patients". Should a patient have a history of prior failure with demonstrated arterial insufficiency, penile revascularization can be considered prior to AUS replacement (Section "Penile revascularization"). SUI, stress urinary incontinence; AUS, artificial urinary sphincters; PRB, pressure-regulating balloon; IPP, inflatable penile prosthesis.

If an AUS erosion is identified, prompt device explantation and a delay of 3 to 6 months prior to AUS reimplantation is recommend (AUA/SUFU IPT guideline statement 31) (1). During device explantation, it is recommended that full explant be performed. Various studies have reported lower urinary tract sequelae after explantation, including an incidence of urethral stricture ranging from 12–61.5% (38-42). Management of the

urethra varies and multiple studies have compared urethral catheter placement, suture urethrorrhaphy (also referred to as abbreviated urethroplasty or *in situ* urethroplasty), and excisional urethroplasty (primary urethral anastomosis) (38-40). At this time, there is no definitive or high-level evidence suggesting superior outcomes with a particular technique. However, these studies have uniformly shown that increased severity of erosion results in a greater risk of urethral stricture formation, especially with circumferential erosions. Our group recommends surgical repair of the eroded segment when possible in an effort to mitigate the risk of stricture formation.

AUS replacement after erosion is particularly challenging, with a very high risk of repeat erosion and poor long-term device survival (some groups have reported close to 50% 5-year explant-free survival) (7,11). Thus, it is critical to optimize patient factors prior to reimplantation. Cystourethroscopy around 3–6 months after device removal should be performed to confirm complete and circumferential healing of the urethra and to rule out *de novo* urethral stricture disease prior to AUS reimplantation.

During AUS reimplantation, TC-AUS cuff placement can be considered. El-Akri *et al.* have demonstrated a trend towards prolonged explant-free survival compared to bulbar AUS placement in subgroup analysis of patients with previous AUS explantation (2-year explantation-free survival: 61.9% *vs.* 58.2%; P=0.096) (43). Maurer *et al.* compared dual-cuff AUS to TC-AUS cuff in the salvage setting and found comparable perioperative outcomes including infection, erosion, mechanical failure, and explantation. Furthermore, they found equivalent objective and social continence outcomes (44).

Prior pelvic radiotherapy

Despite modern improvements in targeting of radiation delivery, such as high-linear accelerators, conformal radiation delivery, and intensity-modulated radiation therapy, bystander effects of radiation to local structures continue to pose significant challenges in the setting of urinary incontinence (45). Through these mechanisms, pelvic radiation therapy may yield microvascular compromise of bulbar urethral perfusion and have consequences on device survival. The reported incidence of AUS cuff erosion ranges from 1–13% in patients without risk factors (7,46). This erosion risk is higher among patients with a history of pelvic radiation, with rates reported as high as 33.3% (range, 3.4–33.3%) (7-15). Numerous studies have examined AUS revision and erosion in irradiated patients, with mixed results (7-23). The vast majority of these studies are single-center and retrospective in nature and often include patients with multiple comorbidities such as history of urethroplasty or previous AUS erosion, which may further increase their risk of AUS complications.

In a multi-institutional retrospective study, Kaufman *et al.* examined 56 patients who had an idiopathic cuff erosion. Radiated patients were found to have a faster time to erosion. In patients who had an AUS erosion, median erosion-free device survival was 1 year in irradiated patients compared to 3.15 years in non-irradiated patients (23). In another multi-institutional study, Fuller *et al.* examined device revision and explantation (rather than erosion specifically) in radiated and non-radiated patients. Radiated patients had a shorter median time to explant of their first (26.4 *vs.* 35.6 months) and second (30.1 *vs.* 38.7 months) AUS implants compared to non-radiated patients. This difference was not seen with the third AUS explant. Although the group examined any cuff revision or device explantation rather than AUS erosions specifically, they did find that erosion occurred more commonly in radiated patients during the first explant. This difference was not seen for second or third explants. Finally, when adjusted for covariates patients with any urethral risk factor had a compromised revision-free survival; this finding was compounded in those with multiple risk factors. In patients with a 4.0 cm cuff without risk factors, 5- and 10-year revision free survival was 83.1% and 71.9%. For radiated patients, this was reduced to 72.6% and 56.4%, respectively. In those with prior pelvic radiotherapy and urethroplasty, this was reduced further to 46.0% and 24.9% at 5 and 10 years, respectively (22).

Both studies observed that in patients with radiation, device explantation occurred much more rapidly in radiated patients compared to non-radiated patients (22,23). Fuller *et al.* found that regardless of radiation history, there was no significant difference in etiology (infection, erosion, or device malfunction) for patients undergoing device explantation of their second or third AUS implantation. Furthermore, median time to explant was no longer significantly different for the third AUS explant between radiated and non-radiated patients. This finding seems to show that pelvic radiotherapy plays an influential role on AUS survival with the first device implant, whereas other factors, such as prior erosion, likely grow in relative importance among those requiring revision surgeries. Stated differently, with every device revision or explant, a patient's risk of subsequent device explantation cumulatively

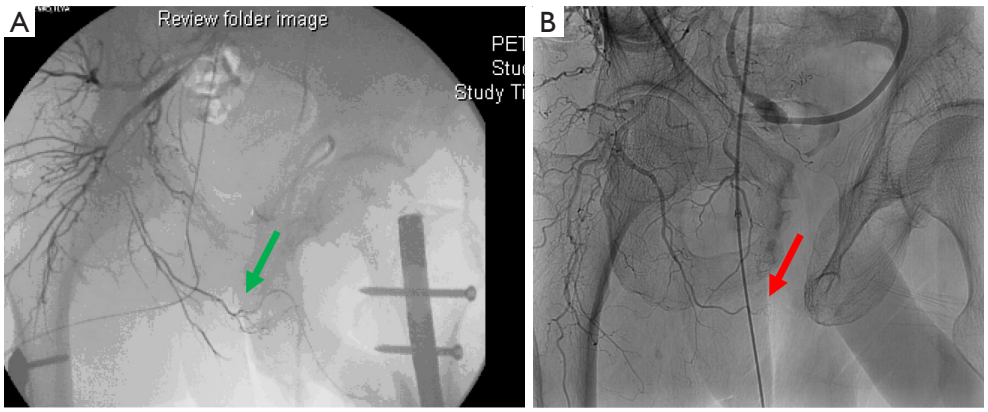

Figure 2 Angiogram demonstrating status of pelvic vascular integrity after pelvic fracture in two patients. (A) An intact right pudendal arterial system. Green arrow points to branching of the pudendal artery with intact perfusion to the dorsal penile artery and right bulbar artery. (B) A truncated right pudendal system with red arrow highlighting area of vascular injury. No perfusion reaches the dorsal, deep, or bulbar arteries.

increases and the role pelvic radiotherapy plays as a risk factor for explantation inversely decreases. This is evidenced by the lack of difference in the median-time to explantation between radiated and non-radiated patients after the first AUS is explanted (22).

Prior pelvic fracture urethral injury

As mentioned above, radiotherapy may induce endarteritis that can potentially lead to microvascular compromise of the bulbar urethra. In contrast, traumatic injury to the urethra can lead to macrovascular compromise of the urethra, which may have consequences to device implantation. After posterior urethroplasty for pelvic fracture urethral injury (PFUI), 1.5% to 8% of patients may develop SUI, with identified risk factors including urethral injuries that extended proximally into the prostatic urethra and bladder neck (47,48). PFUI and subsequent posterior urethroplasty compromise the external urethral sphincter, resulting in a reliance on the function of the internal sphincter/bladder neck for continence. Mundy *et al.* have shown that up to 57% of those with proximal injury extension after urethroplasty have incontinence requiring placement of an AUS (49).

Patients surviving severe pelvic trauma may also have associated injury-related or treatment-related macrovascular compromise involving the internal iliac/internal pudendal arterial system. Cases of bulbar necrosis and early urethroplasty failure are thought to be related to this mechanism of bulbar vascular compromise, and the authors propose that inadequate perfusion in the setting of chronic extrinsic compression with a urinary sphincter cuff underlies a primary mechanism for cuff erosion risk after PFUI. *Figure 2* shows angiography of two patients after pelvic fracture with associated PFUI. One demonstrates an angiogram with an intact right internal pudendal artery and the other with a truncation of the right pudendal vessel. Perfusion may also be further compromised by pelvic embolization or surgical vascular ligation when it is required to control pelvic bleeding after trauma. Several studies have shown that pelvic angioembolization is associated with genitourinary end-organ dysfunction (50-54). There is wide variability in injury patterns after pelvic fracture, and it is critical to consider the trauma, subsequent interventions, and their sequelae when evaluating SUI after PFUI.

AUS placement can be difficult after posterior urethroplasty due to scar tissue from the previous dissection, with potential fixation of the previously mobilized urethra yielding additional risk to the periurethral dissection. Previous operative notes and medical records should be carefully reviewed as maneuvers such as corporal splitting, crural rerouting, gracilis flap interposition, and post-operative urine leak can affect the patient's urethral anatomy and tissue planes. One may consider a bladder neck AUS placement for PFUI patients with complex urethral anatomy. Alternatively, a more distal AUS cuff may be considered, however this may compromise incontinence outcomes. A transcorporal AUS (TC-AUS) cuff can be considered should dorsal dissection prove to be challenging or to avoid placing a 3.5 cm cuff, which may be prone to erosion as seen in patients with history of radiation (55).

Concerning alternative approaches to AUS placement,

surgeons should cautiously weigh the potential limitations against plausible benefits in patients with prior pelvic fracture. While post-pelvic fracture erectile dysfunction (ED) is prevalent in up to 42–62% of patients, many can be managed medically and some will ultimately recover independent erectile function; for those with mild ED or normal postinjury function, TC-AUS placement could contribute to worsened or *de novo* ED due to compromised veno-occlusive function (56). In addition, patients with PFUI are often younger than most other populations undergoing AUS placement, which may prompt greater consideration for device longevity with bladder neck cuff placement if prior pelvic surgeries and associated injuries do not preclude it. Few studies have compared bulbar urethral AUS cuff placement to bladder neck AUS cuff placement, though Khene *et al.* saw a trend towards longer explant-free survival in patients with bladder neck AUS with median explant-free survival of 18.5 years in bulbar urethral AUS cuffs and 24.5 years in bladder neck cuffs (57).

Prior urethroplasty/urethral transection

Urethroplasty remains an independent risk factor for device erosion and failure. Multiple studies have consistently shown patients with a history of urethroplasty to be at a much higher risk of erosion and device removal. Sayedahmed *et al.* prospectively evaluated AUS outcomes after urethroplasty, excluding those with radiation and a previous AUS (58). They reviewed a cohort of 105 patients, with 30 having undergone prior urethroplasty; the overall erosion rate was 12.3%, with a 23.3% erosion rate in those with a history of urethroplasty. On univariable logistic regression analysis, previous urethroplasty conferred a higher risk of device explant with an odds ratio (OR) of 4.18; multivariable analysis was not performed due to a small number of events. The group also noted a trend toward a positive correlation between median stricture length and need for AUS explant. Median stricture length was 3.5 centimeters in the explant group compared to 1.4 in those not requiring explant (P=0.056). Mann *et al.* also found a history of urethroplasty was an independent risk factor for a shorter interval to erosion, with a hazard ratio of 2.12 (24). McGeady *et al.* found that patients with a history of urethroplasty had a higher rate of failure (device malfunction, infection, or erosion) with a hazard ratio of 8.14 when compared to patients without urethral risk factors (11). McKibben *et al.* found that compared to ≥4 cm cuff, in patients with 3.5 cm cuff, patients with history of urethroplasty had a higher risk of erosion with hazard ratio of 5.11 (36). Similarly, Fuller *et al.* found that history of urethroplasty conferred worse all-cause revision-free survival, making it a greater risk factor than radiotherapy. The 5- and 10-year revision free survival was 83.1% and 71.9% for patients without risk factors, 72.6% and 56.4% respectively for patients with a history of radiation, and even lower at 63.9% and 44.9% respectively for patients with prior urethroplasty (22).

While a history of urethral stricture (involving spongiofibrosis of the periurethral vascular sinusoids) and any prior urethroplasty likely represent a risk for AUS failure in all cases, the type of surgical repair may contribute differentially to the risk of AUS failure. Traditional anastomotic repairs disrupt dual antegrade-retrograde urethral perfusion, yielding a distal stump dependent upon retrograde blood flow and a proximal stump still maintained via antegrade perfusion. With AUS cuff placement, a segment of urethra between the prior anastomosis and the cuff site could become ischemic and more prone to breakdown due to cuff compression. Non-transecting anastomotic repairs are thought to maintain dual urethral perfusion by allowing scar excision while preserving healthy spongiosum, and this approach has been shown to yield benefits in the form of preserved sexual function (59-61). Further study is needed to investigate if this technique may decrease the risk of erosion after urethroplasty. The authors acknowledge findings by Sayedahmed *et al.* suggesting an increased erosion risk specifically after substitution urethroplasty. This study included only a small cohort (19 transecting anastomotic and 11 substitution urethroplasties), and the observed correlation may be a surrogate for the severity of stricture and associated spongiofibrotic vascular compromise. Patients undergoing substitution urethroplasty tend to have more complex or longer segment strictures, and Sayedahmed's group noted that median stricture length was longer in those requiring AUS explantation (58). Non-transecting techniques and substitution repairs theoretically stand to mitigate cuff erosion risk through greater arterial preservation, although dedicated investigation is needed.

The studies identifying prior urethroplasty as a risk factor, while small in number, are nevertheless consistent in their findings. They highlight the importance of close follow-up and the continued need for strategies to mitigate failure in these high-risk patients. We recommend more frequent follow-up with cystourethroscopy to evaluate urethral mucosal quality at the cuff site at least in the first year after AUS implantation. This serves to evaluate for both urethral stricture recurrence and the health of the urethra.

Low testosterone

Systemic androgens seem to play a role in urethral health

and the risk of device erosion. In a study of urethral tissue harvested during urethroplasty, patients with low testosterone (LT) were found to have decreased androgen receptor expression and significantly decreased vessel density (62). In a prospective analysis of 53 consecutive patients undergoing AUS implantation at a single-institution, Hofer *et al.* found low testosterone to be a significant risk factor for AUS erosion. Of the 53 patients, 20 patients (37.7%) had an AUS erosion with 90% found to have LT. In contrast, of the 33 patients without erosion, 36.4% had LT on serum assay. On multivariable logistic regression, LT remained the sole independent risk factor for AUS erosion with an odds ratio of 15.78 (95% CI: 2.77–89.92) (63). In a retrospective single-center study, Wolfe *et al.* examined patients with a serum testosterone level within 24 months of AUS placement. When examining patient demographic factors and surgical factors (coronary artery disease, prior AUS, radiation therapy, TC-AUS, and 3.5 cm cuff), again only LT was predictive of AUS cuff erosions on multivariable binary logistic regression analysis (31). It is important to note that these studies did not find a significant difference in the rate of AUS erosion in patients with a history of androgen deprivation therapy (ADT). Bailey *et al.* compared patients with greater than 6 months use of ADT within 2 years of AUS placement and found no difference in device infection, erosion, mechanical failure, or urethral atrophy (64).

While these studies do highlight low testosterone as a significant and independent risk factor for AUS erosion, it is unclear whether testosterone supplementation may prevent cuff erosion or improve device survival. In a retrospective, single-center study, nearly half of patients with preoperative serum testosterone levels had LT prior to AUS placement (65). No studies have examined testosterone supplementation prior to AUS placement. This remains an important area of future study. However, preoperative serum testosterone assays can be informative and can be important in patient counseling regarding individualized risk and device outcomes.

Bladder pathology

Radiation induced bladder pathology

Patients with radiation cystitis and urinary incontinence after pelvic radiotherapy pose a particularly challenging scenario. Management of the radiation cystitis is recommended prior to placement of an AUS. Cystoscopy with clot evacuation and fulguration, hyperbaric oxygen, and intravesical instillation of astringent agents can be utilized based upon patient needs and available resources (66). If possible, the authors pursue sustained resolution of hemorrhagic cystitis for at least 3–6 months prior to AUS placement. Should hemorrhagic cystitis prove refractory, a patient may be better served with cystectomy and urinary diversion to manage both conditions. Management of acute clot retention from radiation cystitis often entails the use of large-bore urethral catheters and endoscopic treatments, all of which can lead to urethral cuff erosion. In cases of clot retention due to radiation cystitis in the setting of an AUS, placement of a suprapubic tube or an open clot evacuation should be considered to protect the AUS cuff. If urethral access is required for intervention, device uncoupling is recommended for prolonged urethral instrumentation. Section "Need for lower urinary tract instrumentation" below provides recommendations for patients requiring urinary instrumentation in the setting of an AUS.

Urinary adverse effects from radiation damage may also include urgency, frequency, decreased bladder storage volumes, and bleeding complications from radiation cystitis. The incidence of adverse effects varies by radiation modality, however it is noted that improvements in radiation delivery have reduced the prevalence of these toxicities (67-69). Following pelvic radiotherapy, the incidence of Grade 2 or higher adverse effects ranges from 7–41%, grade 3 effects specifically ranging from 5–13%, and grade 4 effects in about 0.1% of patients (70-79). Counseling the patient about bladder function, especially radiation-induced overactive bladder is important for postoperative expectation setting (AUA/SUFU Guideline for non-neurogenic overactive bladder) (80).

If a patient has prolonged and severe urinary incontinence after radiotherapy, surgeons should evaluate the bladder capacity. Temporary use of an external penile clamp can serve as a simple screening tool for underlying poor storage function. The penile clamp mimics the basic function of an AUS cuff, allowing the bladder to cycle and potentially unmasking severe storage symptoms in those with limited capacity. Urodynamic studies (UDS) may be helpful to evaluate storage pressures and capacity before finalizing an incontinence treatment plan. Should bladder capacity be found to be severely limited or if the patient cannot tolerate bladder cycling, it is generally not recommended to pursue AUS placement. Alternatives such as chronic suprapubic cystostomy or urinary diversion should be considered. If a patient desires orthotopic diversion, orthotopic neobladder with AUS placement can be considered as described by Patil *et al.* (81).

Pelvic fracture related bladder dysfunction:

In patients who sustained a severe pelvic fracture, exclusion of a neurologic cause of incontinence should also be considered as patients with devastating pelvic injuries can have disruption of the pelvic nerves supplying the bladder. Lefaivre *et al.* prospectively assessed urinary symptoms utilizing the International Consultation Incontinence Questionnaire (ICIQ) at baseline, 6 months, 1, 2, and 5 years after surgical treatment for pelvic fracture. The group found that men had significant worsening and persistent urinary symptoms 5 years after injury. Furthermore, in men, neurologic dysfunction was found to be predictive of worse ICIQ scores (82). In patients with urinary incontinence and history of pelvic fracture, bladder function must be assessed. For example, patients who have suffered from a sacral fracture are at risk for lower motor neuron injury and pressure-flow urodynamics studies should be considered to evaluate for an atonic bladder prior to AUS placement. This is critical for counseling as patients who require clean intermittent catheterization (CIC) may be at risk of erosion.

Need for lower urinary tract instrumentation (bladder cancer, CIC, hemorrhagic cystitis)

The need for CIC or lower urinary tract instrumentation does not necessarily preclude patients from obtaining an AUS. Studies examining CIC have largely been in the pediatric population of mixed genders, with bladder neck AUS cuff implantation and often the creation of catheterizable channels to avoid urethral catheterization (83-85). One study found no erosions in 22 patients requiring CIC, with 50% requiring CIC for >30 months (86). Patients requiring surveillance and treatment for non-muscle invasive bladder cancers represent a similar challenge. Heiner *et al.* have shown safety of cystoscopic surveillance of 14 patients with AUS and non-muscle invasive bladder cancer. With a median follow-up of 7.2 years, only 1 patient (5.6%) experienced an iatrogenic AUS cuff erosion related to urethral manipulation (87). The need for large-caliber scopes, large-bore catheters, or prolonged urethral catheterization are widely thought to place patients at significant risk for iatrogenic AUS erosions. No modern studies have examined device outcomes in patients requiring instrumentation, however, Otis-Chapados *et al.* have examined passage of urinary catheters (12 to 22 Fr) and cystoscopes (19 to 26 Fr) through AUS cuffs (3.5 to 6 cm) *ex-vivo*. They utilized three blind observers to rate the safety of passage, taking into account bulbar urethral thickness and compressibility of urethras (88). These findings can serve as a guide when considering urinary instrumentation and the authors advise caution and careful counseling as these studies have not be studied in the patient setting.

Patients requiring repeat endoscopic resections with large cystoscopes may benefit from temporary cuff uncoupling via a small separate perineal incision to preserve a device *in situ* and prevent urethral injury and subsequent device erosion. This should be performed prior to cystoscopy to prevent contamination of the surgical field. This incision may be closed temporarily, and a barrier applied to the skin while cystoscopy is performed. Device may be recoupled or the device may be left uncoupled depending on the need for repeat intervention or for prolonged urethral catheterization.

Lower urinary tract complications

Anterior urethral stricture

Management of patients with concomitant urethral pathology poses a challenge to both the patient and surgeon. Any urethral surgery prior to AUS placement may compromise the vascularity of the urethra and may place patients at high risk of AUS complications such as urethral injury during device placement and cuff erosion. Furthermore, multiple studies have found that a history of urethroplasty portends a poor prognosis for device survival, and urethroplasty is often classified as a risk factor for a "fragile urethra" (6).

The authors consider the stability and caliber of the urethra when determining initial management, dividing patients into those with stable asymptomatic, non-flow limiting strictures (≥12 Fr) and those with symptomatic or otherwise clinically apparent (<10–12 Fr) strictures. In those with a prostate in situ, it is also important evaluate the prostate/bladder outlet as contributory factors to any baseline lower urinary tract symptoms.

For patients with asymptomatic moderate caliber strictures (≥12 Fr), we ensure adequate bladder emptying and then repeat in-office cystourethroscopy after an interval of 3–6 months to confirm urethral stricture stability. If patients have worsening of stricture disease with a narrower lumen, development of obstructive symptoms, or new elevated post-void residual measurements, repair of the urethral stricture should be performed prior to AUS placement. AUS placement should be deferred for 3–6 months after urethroplasty, and cystoscopy is important before anti-incontinence surgery to verify success of the urethral reconstruction.

For patients with symptomatic or narrow caliber strictures (<10–12 Fr), urethroplasty should be performed

prior to AUS placement. Urethroplasty approach can be determined according to surgeon preference and other patient factors, utilizing the AUA urethral stricture guidelines as a reference (89). A dorsal substitution repair may yield additional challenge with subsequent urethral mobilization, requiring cuff placement at a more proximal/distal site or TC-AUS cuff placement. A non-transecting approach (such as a non-transecting anastomotic urethroplasty or substitution repair) is thought to preserve antegrade urethral perfusion and could limit device erosion risk as noted previously. Non-transecting approaches have been shown to help decrease sexual adverse effects after urethroplasty, such as soft or cold glans, however no studies have extrapolated this for urethral perfusion and its effect on outcomes after AUS placement (90,91).

During AUS placement, difficulty may be encountered after bulbar urethroplasty. Options for alternative cuff location include a more distal bulbar or penobulbar site or a TC-AUS cuff. Transcorporal placement may be the best option after a dorsal substitution graft, as it avoids a second dorsal mobilization and potential graft compromise. If a more distal cuff is placed, some have advocated tandem cuff placement to increase continence; however, this may further contribute to erosion risk in a cohort already prone to such complications due, in part, to their prior urethroplasty (43,44). There are no comparative studies to identify the most appropriate surgical modifications to account for risks from prior urethroplasty. Most studies exploring the aforementioned techniques are retrospective in nature and small in number.

In rare cases, patients may have multiple risk factors and have exhausted their options for stricture repair. For example, a patient with radiation history, prior buccal mucosa graft (BMG) urethroplasty, and previous AUS cuff erosion may develop a new stricture at the area of the previous erosion. Such scenarios illustrate the great importance of patient counseling and understanding the goals of the patient. If continence is the most important goal for them, AUS placement could be cautiously considered with close follow-up, knowing that erosion risk is high. Suprapubic catheter placement perioperatively can establish reliable bladder drainage. This tube can be capped once their AUS is activated and serves as a backup system in case of worsening obstruction due to urethral stricture disease. Some patients might even elect to connect the SP tube to drainage at night (with or without AUS deactivation) to address nocturia or establish a period of cuff site urethral rest when not active. Should such a high-risk patient have an erosion and AUS reimplant deem not an option, permanent urethral ligation as described by VanDyke *et al.* can restore continence and serve as an alternative to a urinary diversion (92).

Another option for a similar patient may be creation of a continent catheterizable channel to establish an alternative urinary drainage mechanism. Some authors have described placing a bladder neck AUS at the same time of the channel creation, although surgeons may pursue AUS placement separately due to concern about bowel surgery contaminating a sterile device. Studies examining synchronous versus staged bowel surgery and AUS placement have been mixed and largely performed in the pediatric population (93-97). Some studies have demonstrated simultaneous AUS implantation and urinary reconstruction to be safe with good bowel prep, ensuring urine sterility, and separation of surgical fields. It is generally recommended to perform the AUS implantation first, with complete device coverage and incision closure prior to opening the bowel. However, several studies have also found higher erosion and infection risk with concomitant bowel surgery during AUS placement in the pediatric population (94,95). Given high morbidity from device infection or erosion, we recommend staging as two separate procedures whenever possible.

Prostatic fossa calcifications

Patients with recalcitrant prostatic fossa calcification (*Figure 3A*) or extensive necrosis (*Figure 3B*) after pelvic radiotherapy should be managed similarly to those with radiation cystitis. Patients should have stable disease without frequent or ongoing need for endoscopic intervention related to cumulative calcification, as repeated treatments could compromise the integrity of the urethra at the AUS cuff. If there is extensive necrosis or calcification, abandonment of the lower urinary tract may need to be considered as endoscopic procedures are likely inadequate to resolve this difficult problem. The dystrophic calcification results from the contact of urine with necrotic tissue. Despite repeated resection of these calcifications, the necrotic tissue remains and will continue to reaccumulate calcifications. These calcifications subject the patient to recurrent urinary tract infections, gross hematuria, and pelvic pain. *Figure 3* highlights patients with urethras devastated from prostate radiation. If the patient elects for non-continent urinary diversion, the authors recommend safe resection of bladder tissue and mucosa. In hostile pelvises, as seen in patients with prior radiation and surgery, a partial cystectomy may be performed with fulguration of

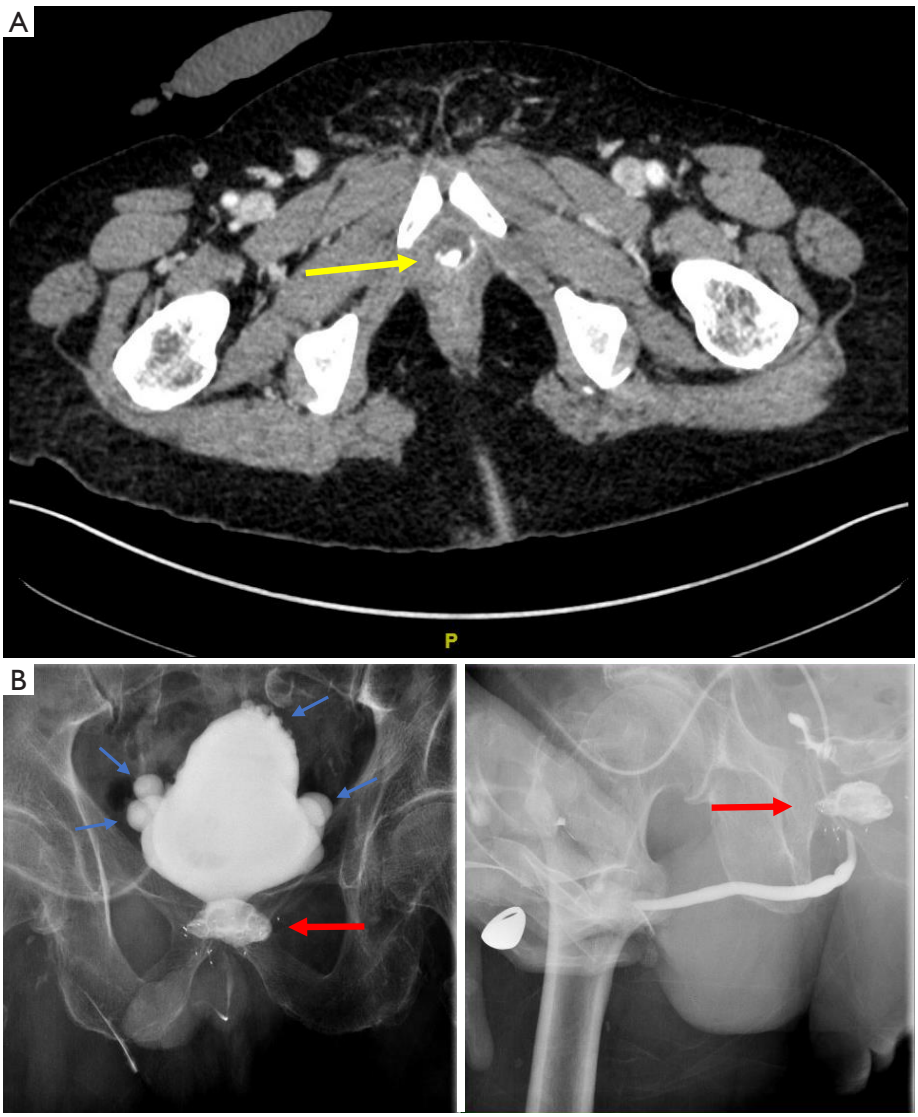

Figure 3 Urethral complications. (A) A 68-year-old male with history of prostate cancer s/p EBRT with pelvic pain, recurrent urinary tract infections, and prostatic urethral calcifications. Computed tomography images show prostatic urethral calcifications (yellow arrow). (B) An 84-year-old male with history of prostate cancer s/p brachytherapy and EBRT with posterior urethral stenosis. Retrograde urethrogram and voiding cystourethrogram images are shown with necrosis of prostate fossa with cavitation (red arrows) and multiple bladder diverticula indicating chronic high pressure voiding due to obstruction (blue arrows). s/p, status post; EBRT, external beam radiotherapy.

any remaining bladder mucosa.

Proposed alternatives include resection of this necrotic tissue through salvage prostatectomy or revision of the vesicourethral anastomosis if the patient had a prior prostatectomy. These procedures have a considerable risk of major morbidity, but subsequent AUS can be considered for those who undergo a successful salvage procedure and establish a stable patent lower urinary tract. If a perineal approach is taken for salvage lower urinary tract reconstruction, surgeons can consider placing a "space-saver" AUS cuff; this may facilitate safe subsequent periurethral access, since repeat perineal dissection may be challenging after prior radiation and extensive prior dissection. In one study, a total of 8 patients underwent salvage cystoprostatectomy with orthotopic neobladder for defunctionalized bladder and recalcitrant posterior urethral stenosis. While 5 of 8 patients underwent placement of a "space-saver" AUS cuff at time of lower urinary tract

Table 2 Patient considerations and intraoperative surgical techniques for the compromised urethra

Patient optimization and surgical techniques for high-risk patients
Preoperative optimization of testosterone (cohort series)
Penile revascularization (expert opinion)
Avoid placement of 3.5 cm AUS cuff (cohort series)
Transcorporal AUS cuff +/– corporal wrap (cohort series)
Preservation of bulbospangiosus muscle (case report)
Relocation of AUS cuff site (expert opinion)
"Space-safer" AUS (case series)
Lower PRB of 51–60 cmH_2O (expert opinion)
Intermittent nocturnal deactivation (case series)

AUS, artificial urinary sphincters; PRB, pressure-regulating balloon.

reconstruction, 3 required explantation due to perineal infection. AUS implantation occurred at a mean of 74 days after reconstruction, with 4 patients experiencing AUS erosion (2 patients with "space-saver" AUS cuff and 2 patients who did not have a "space-saver" placed). At a median follow-up of 58 months, there was no recurrence of stenosis. Fifty percent of patients were completely dry and 50% required 1–2 pads per day (81).

Posterior urethral stenosis

After surgical correction of posterior urethral stenosis, it is critical that patients are monitored for urethral patency. A post-void residual should be measured to ensure the bladder can empty prior to AUS. Kahokehr *et al.* developed an algorithm for treatment of posterior stenoses and recommend stability of >3 months, prior to AUS implantation (98).

If a perineal dissection is to be done for stenosis treatment, one can consider placing a "space-saver" AUS cuff, though a major drawback from this technique is the cost. If SUI is expected after repair, an AUS cuff may be placed at the bulbar urethra during the time of posterior urethroplasty. Then, after adequate urethral rest to allow for neovascularization and to examine for any recurrence of stenosis, AUS implantation may be performed (81). This technique allows surgeons to avoid a challenging dissection of the urethra and avoid urethral injury at the time of perineal dissection for AUS cuff placement. If perineal dissection is not required during stenosis repair, subsequent AUS placement should not be different than in the standard patient.

Surgical considerations for high-risk patients

Patient comorbidities such as diabetes, coronary artery disease, age/fragility, and smoking can play a role in microvascular compromise to urethral health, leading to increased risk of device complications. Similarly, iatrogenic insult such as pelvic radiation can cause microvascular insult to bulbar urethral health. Similarly, pelvic fracture and prior urethral manipulation such as AUS erosion or urethroplasty can result in macrovascular compromise to the urethra. Several surgical techniques have been employed by urologic surgeons to mitigate these risks. *Table 2* lists the preoperative and surgical considerations for such high-risk patients.

Cuff size and transcorporal placement

For patients with a history of prior radiation or other bulbar compromise, surgeons should be conservative when sizing the AUS cuff intraoperatively and select a cuff that is up to 0.5 cm larger than the measured urethral circumference, at the expense of some degree of continence. In addition, implanters should avoid using a 3.5 cm AUS cuff, as it has been associated with a high risk of erosion, especially in the high-risk patient. Simhan *et al.* found that 21% of their radiated patients with a 3.5 cm AUS cuff experienced an erosion, compared to 4% in the non-radiated group. Of the factors examined, history of radiation was the only predictor of erosion with an odds ratio of 6.2 (55). To avoid the placement of a 3.5 cm cuff in these scenarios, the surgeon may need to utilize a TC-AUS placement to increase the circumference of the urethral unit (99,100). This technique can also be utilized to avoid a challenging dorsal urethral dissection, especially in patients with a history of AUS erosion. Several studies have demonstrated TC-AUS to be safe, without additional risk of device erosion (11,25). However, one group compared 3.5 cm standard cuffs to TC-AUS cuffs and found TC-AUS to have a significantly increased risk of erosion on multivariate analysis with a hazard ratio of 6.11 (101). Additionally, Ortiz *et al.* examined location of cuff erosion and found that TC-AUS placement was not protective of dorsal erosion as previously hypothesized. The group found that most AUS cuff erosions occur ventrally after both standard (79.5%) and TC-AUS (66.7%) cuff placement. Lateral erosions occurred at a rate of 20.5% for standard and 33.3% for TC-AUS cuffs. Dorsal erosions were least common with 5.1% for standard and 20% for TC-AUS cuffs (29). Larger multi-institutional studies combine patients with high risk of

erosion, or "fragile urethras": history of pelvic radiotherapy, history of AUS explanation, and history of urethroplasty (24,43,102). Extrapolating from that data, transcorporal cuffs tended to have longer explant-free survival. Thus, it is our recommendation to preferentially attempt transcoporal cuff placement in this patient population to avoid dorsal dissection, especially in those with dorsal substitution grafts.

In patients with incontinence after lower urinary tract fistula repair or posterior urethroplasty, the surgeon has be to aware that gracilis interposition flaps may have been used (103,104). In our experience, gracilis flaps have not interfered with placement of a bulbar AUS cuff, as the flap is located proximal and away from the standard AUS cuff location.

Another consideration in the patient with a "fragile urethra" is intermittent nocturnal deactivation of the device to allow for urethral rest and unrestricted perfusion of the cuff segment. This is extrapolated from previous published data suggesting an association between urethral atrophy and nocturnal deactivation, where patients treated in a practice that utilized nocturnal deactivation had a 10% rate of urethral atrophy while those in a separate practice not utilizing this technique had a 21% atrophy rate (105). However, further studies would be needed to investigate this adjunctive technique in a rigorous manner.

Urethral protection maneuvers to be considered can include a circumferential urethral wrap or preservation of the bulbospongiosus muscle. Vasan *et al.* described wrapping the urethra circumferentially with bilateral 2 cm by 2 cm flaps of corpus cavernosal tissue in the Gullwing technique. This is then secured at the ventral urethra with interrupted suture (106). This may mitigate previous concerns about TC-AUS cuffs, however long-term studies are needed to examine the durability of this technique in preventing erosion in high-risk patients. Other groups have also proposed the preservation of the bulbospongiosus muscle and placing the AUS cuff over it in an effort to protect the urethra from erosion (107,108). Prospectively collected data of 82 patients revealed encouraging results with no intraoperative complications. 4.9% required device revision or explant (erosion, infection, or pump/cuff relocation) and device survival at 60 months was 62.6% (108). However, the bulbospongiosus muscle may be atrophic in the case of previous urethral surgery. If examination of the proximal bulbar urethra suggests urethral atrophy of the corpus spongiosum, the surgeon can consider a more distal location for the AUS cuff and potentially placing a TC-AUS to avoid the use of a 3.5 cm cuff.

AUS and penile prosthesis

Patients with vascular compromise of the bulbar urethra may present with ED in addition to urinary incontinence. If the ED does not respond to medical therapy, they have the option of pursuing a penile prothesis placement. Per AUA/SUFU guidelines, an AUS and IPP placement may be staged or synchronous per surgeon and patient discretion (1). Previous studies examining staged versus synchronous implantation have shown variable results (109-113). Many studies have demonstrated its safety, while others have shown increased erosion risk, increased rates of surgical revision, and lower device survival. However, 2 large retrospective studies have shown similar device survival and device revision in metachronous placement compared to synchronous placement (112,113). Patel *et al.* found that synchronous placement of IPP and AUS did not affect AUS reoperation rate (9.2%) at 3 years when compared to AUS placement alone. However, they did find an increase in IPP reoperation rate at both 1 and 3 years (112). Similarly, Boysen *et al.* found that in 61 patients with synchronous placement, there was no difference in IPP or AUS device survival on Kaplan-Meier analysis. With a median follow-up of 61 months, AUS survival was 84.5% and 81.7% at 5 years in AUS alone and synchronous IPP and AUS, respectively (113). With synchronous placement of AUS and IPP, complications from one device may affect the other, requiring dual device explantation. One benefit from metachronous placement may be a separation of surgical fields which may isolate one device from the other, thus limiting the effect and spread of device infection or erosion to the other device. If synchronous placement is performed, we recommend separating the surgical fields through separate incisions to prevent contamination. We recommend placement of the IPP first with all incisions closed prior to placement of the AUS. The rationale comes from the increase revision and device complication rate from AUS placement. This may stem from a different level of sterility with urethral manipulation during AUS placement. At our institution, we perform metachronous placement of devices. We generally recommend placement of AUS first. In a patient with concomitant ED and SUI, it would be generally desirable to achieve continence prior to improvement of erectile function. Once the AUS has been successfully placed and activated, the placement of a penile prosthesis can be considered. In patients with mild incontinence, placement of IPP first may be considered as the urethral compression from IPP may result in an acceptable improvement in SUI and deem

incontinence surgery such as the AUS unnecessary.

Nevertheless, some patients may have had a penile prosthesis placed for ED prior to becoming incontinent and desire an AUS placement. During placement of an AUS in the setting of a previous penile prosthesis, careful dissection of the dorsal urethra should be done as to avoid entering the corpora cavernosa. Should a transcorporal cuff be needed, we recommend dissection between tunica albuginea of the corpora cavernosa and the IPP pseudo-capsule. If that plane is not easily dissected then the corporotomies can be made onto the cylinders. Some surgeons may leave the corpora cavernosa open, others might use allograft (e.g., Tudoplast) to close the corporotomy window.

Pressure regulating balloon

When choosing the pressure regulating balloon, surgeons should also carefully consider the health of the urethra. Some may select a lower pressure balloon (51–60 cmH_2O) instead of the standard 61–70 cmH_2O balloon in cases with significant radiation change as this theoretically has less pressure transmission to the urethra. The authors acknowledge that this is extrapolated from data regarding pressure-regulating balloon (PRB) pressures, with 2 prior studies indicating improved continence but a higher rate of erosion and revision (especially in radiated patients) with upregulating PRB pressures (114,115). Moses *et al.* identified 22 patients undergoing PRB exchange for SUI persistence or recurrence following AUS placement. Patients had an improvement of their SUI based off pads per day, and Incontinence Symptom Index Score and Incontinence Quality of Life. However, 3 patients (14%) with prior radiation experienced cuff erosion and the explantation/revision rate was 45% at 33.5 months and Kaplan-Meier analysis revealed 41% retained their device for 24 months (114). Loh-Doyle *et al.* similarly identified 55 patients undergoing PRB exchange to 71–80 cmH_2O pressure to treat recurrent SUI. At a median follow-up of 26.4 months, 4 (7.3%) patients developed an erosion with 5 patients showing impending erosion requiring revision surgery (115). Based on this, we postulate that a lower PRB may yield lower rate of erosion (at the expense of some degree of continence) in the high-risk patient. Prolonged urethral rest after AUS placement can also be considered, with delay in device activation up to 10–12 weeks, especially in patients with multiple risk factors such as prior pelvic radiotherapy, history of urethroplasty, and history of AUS cuff erosion (116).

Penile revascularization

In the instance that bulbar vascular compromise is suspected, penile revascularization can also be considered in the salvage AUS setting. Penile revascularization has been utilized in patients with devastating pelvic vascular injury resulting in arterial insufficiency and ED (117,118). There is also a rationale for using revascularization prior to urethroplasty for PFUI to prevent recurrence of stricture disease due to poor blood supply. As in the case of ED, revascularization of the corpus spongiosum should be utilized when the mechanism of injury is vascular disruption and an ischemic etiology is confirmed (*Figure 2* shows angiogram of intact and injured pudendal artery). This may be the case in PFUI or in cases of multiple insults to the urethra, such as concomitant radiotherapy, urethral/prostate surgery, and AUS erosion. Revascularization can be considered after AUS erosion as a salvage procedure prior to AUS replacement or prior to impending AUS erosion with suspected ischemic etiology. This procedure may be used in highly select cases. The work up consists of penile doppler with medically induced erection and pelvic angiography to evaluate for arterial insufficiency and to map out the vascular anatomy (*Figure 2*).

A case at our institution for which revascularization was used to salvage an AUS presented as follows: a 45-year-old male with prostate cancer received external beam radiotherapy followed by salvage radical prostatectomy for recurrence in the prostate. The patient's course was complicated by a vesicourethral anastomotic stenosis requiring posterior urethroplasty, corporal splitting, and inferior pubectomy. The patient had severe SUI and thus underwent AUS placement. He developed an AUS erosion within 9 months. After AUS explantation, penile doppler ultrasound (PDUS) and pelvic angiogram confirmed arterial insufficiency to his dorsal arteries and penile revascularization was performed using the left deep inferior epigastric artery. Following revascularization, the patient was followed with serial PDUS to confirm dorsal artery patency and after appropriate recovery, AUS reimplantation was done at 8 months. A transcorporal 4.0 cm AUS cuff with a 51–60 cmH_2O PRB was implanted. He was most recently seen at 7-year follow-up, with a functional device and acceptable social continence. Revascularization should be reserved for these special circumstances and only offered to a carefully selected patient population.

Follow-up for high-risk patients after AUS implantation

Surgeons may consider delay in device activation for up to

8 weeks or longer after implantation in high-risk patients. Furthermore, a more stringent follow-up regimen should be performed as many patients have had multiple insults to the urethra, which compromise urethral health and predispose the patient to device erosion. Mann *et al.* found most device failures occurred within 2 years of implantation in high-risk patients (24). Though we do not perform routine cystoscopy after AUS implantation in high-risk patients, cystoscopy can be used to inspect the quality of the luminal epithelium, evaluate the urethra to ensure patency of the repair, and exclude gross erosion at about 3–6 months. Patients should be instructed to seek prompt urologic intervention if symptoms of device failure arise, such as hematuria, urinary tract infections, recurrent incontinence, or perineal or penile pain.

During cystourethroscopy, should the urethra underlying the cuff appear thin, a sign of pending erosion, device deactivation with close follow-up can salvage some systems. In this scenario, surgical management with increasing cuff size or placing a lower pressure PRB should be considered after a period of deactivation, and this may prevent erosion while maintaining some level of continence compared to device explanation or complete device deactivation.

Conclusions

A number of patient risk factors are associated with AUS failure and can ultimately lead to device explantation. Each risk factor requires careful consideration and investigation, or intervention as appropriate, prior to device placement. Several surgical strategies to decrease device complications can be considered (*Table 2*) and we present an algorithm for management of high-risk patients (*Figure 1*). Optimization of urethral health, confirmation of anatomic and functional stability of the lower urinary tract, and thorough patient counseling are a necessity for these high-risk patients.

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Footnote

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