SEXUAL MEDICINE REVIEWS REVIEW

A User's Guide for Surgery Involving the Artificial Urinary Sphincter

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ABSTRACT

Introduction: The artificial urinary sphincter (AUS) has long been regarded as the gold standard for surgical correction of male stress urinary incontinence (SUI). Despite impressive rates of initial success for restoration of continence, durability may wane to the point of considering revision surgery.

Aim: To provide a review of existing data as well as personal experience regarding patient selection, surgical technique, and postoperative troubleshooting for the AUS.

Methods: A systematic review of the peer-reviewed literature was performed to identify relevant and contemporary articles regarding perioperative and long-term management of the AUS. Additional input is presented based on clinical experience of the senior author.

Main Outcome Measure: The main outcome measures are durability, patient satisfaction, mechanical failure, and urethral erosion.

Results: In addition to a thorough history and examination, preoperative screening should include office cystoscopy to rule out bladder neck contracture in patients with a history of radical prostatectomy. Perineal cuff placement appears superior to alternative approaches. Prior radiation and use of the 3.5-cm cuff are risk factors for future erosion. Newer findings suggest that subsequent recurrence of SUI may be due to restrictive encapsulation, rather than true atrophy, with implications for revision surgery.

Conclusion: The AUS remains an excellent option for surgical correction of moderate to severe male SUI. Detailed preoperative evaluation and patient selection are critical. The challenge of downstream recurrent SUI after AUS can be effectively managed for most patients with a structured approach. **Chouhan JD, Terlecki RP. A User's Guide for Surgery Involving the Artificial Urinary Sphincter. Sex Med Rev 2018;XX:XX–XX.**

Key Words: Urinary Incontinence; Stress; Urinary Sphincter; Artificial; Urethra; Treatment Outcome; Prostheses and Implants

INTRODUCTION

Since the first application in 1972, the artificial urinary sphincter (AUS) has represented the gold standard option for surgical correction of male stress urinary incontinence (SUI). After introduction, there have been 5 iterations leading up to the current version of the AMS800, which became available in 1987 after development of the narrow-backed urethral cuff (American Medical Systems/Boston Scientific, Boston, MA, USA). The rise in use has been highlighted previously, with a volume of 5 units in 1975 and 3,762 units a decade later.[1]

First described by Scott et al[2] (who developed the device in collaboration with the University of Minnesota), the AUS has been shown to provide durable results up to 15 years, but as many as 43% may require revision surgery at 10 years.[3] Lower-volume experience from a single institution, however, found that as many as 45% of patients required AUS explantation at a median of 5.62 years.[4] Admittedly, a 2012 systematic review found the quality of evidence for long-term efficacy of AUS in men with non-neurogenic SUI to be low.[5] In addition, a Cochrane review could identify only 1 randomized or "quasi-randomized" trial that included surgical treatments for urinary incontinence after prostate surgery.[6]

In this article, we provide a review of existing data regarding patient selection, perioperative considerations, and postoperative troubleshooting. Additional input is offered based on personal experience. Our hope is that this will serve as a practical guide for both new and established surgeons involved in management of male SUI.

DEVICE MECHANICS

The AUS consists of 3 main components: an occlusive cuff, a pressure-regulating balloon (PRB), and a pump for fluid transfer.

Received September 11, 2018. Accepted October 13, 2018.

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https://doi.org/10.1016/j.sxmr.2018.10.004

When activated, the occlusive cuff applies constant circumferential pressure to the urethra. The cuff and pump are made of silicone subsequently impregnated with a combination of rifampin and minocycline (Inhibizone). The PRB, however, remains uncoated, as industry evaluation found that adding Inhibizone affected its pressure regulation characteristics (personal communication with Research and Development, Urology and Pelvic Health, Boston Scientific, August 2018).

Compared with the fluid reservoirs used for inflatable penile prostheses, the PRB is less simple. In an activated system, the PRB creates a pressure equilibrium between itself and the occlusive cuff. This component is available in 6 pressure ranges, but most providers select those rated for 61−70 cm of H_2O.[7] The pressure profile is determined by the wall thickness of the PRB, rather than an alternative fluid capacity, and remains relatively consistent across a range of fill volumes. The manufacturer's manual advises instillation of 22 mL of saline or diluted contrast, but variation in either direction of 1−2 mL will not result in significant pressure differences. It has been suggested that the pressure should remain consistent with filling volumes between 16 and 24 mL.[8,9]

At time of desired voiding, pressure applied to the inferior aspect of the pump opens an internal valve, resulting in fluid movement out of the pump and toward the PRB. Concurrently, the cuff fluid is drawn cephalad toward the pump. Facilitated by an internal flow resistor, the cuff will slowly refill without manipulation. However, the time for this process is variable across patients. Logically, smaller cuff sizes will have shorter times for refilling. In theory, the height of the PRB relative to the cuff would also be a contributing factor in addition to the intrinsic pressure profile. However, the length of tubing provided by the manufacturer or any alteration in the length at time of placement will not significantly alter the time to refill the cuff.[8]

PATIENT SELECTION AND PREOPERATIVE PREPARATION

Most men considered for AUS placement have SUI after radical prostatectomy, although some may be secondary to surgery for benign disease. Preoperative assessment involves a thorough history and physical exam. Based on overall health, patients are risk-stratified appropriately and may require advance clearance by primary care, cardiology, and anesthesia. In our practice, diabetic patients are required to have a hemoglobin A1c <9% before surgery.[10] Routine testing includes urinalysis/urine culture and office cystoscopy. Some providers may require a voiding diary, determination of 24-hour pad weight, or urodynamics (UDS).[11] In our experience, the need for UDS is rare but may be valuable in patients with significant urgency, neurologic disease, or a history of radiation. Of note, in an evaluation of preoperative UDS parameters among AUS patients, Thiel et al[12] found that neither early sensation, overactivity, impaired compliance, nor low bladder capacity conferred worse outcomes in terms of pad usage, urgency, or patient-reported improvement. Thus, considering the cost and potential for patient discomfort/inconvenience, routine UDS for all men considered for AUS seems unnecessary.

Preoperative office cystoscopy allows determination of potential vesicourethral stenosis (bladder neck contracture [BNC]). Although in the past, some had advocated concomitant transurethral bladder neck incision at the time of AUS placement in the setting of a previously undiagnosed stenosis, contemporary data support early identification and management in advance of AUS.[13−15] Some have argued for proceeding to AUS if the bladder neck is patent 6−8 weeks after transurethral incision.[15] Our approach is to proceed if the bladder neck accommodates a flexible cystoscope 3 months after transurethral management.[16]

In line with traditional practice, we believe that a negative urine culture should be documented before placement of an AUS. 1 group has suggested that this practice may be unnecessary based on retrospective review, including patients whose culture results were not addressed before surgery.[17,18] However, any event of subsequent device compromise related to a preexisting infection that could be easily identified and treated at low cost would seem difficult to defend. Because patients with severe SUI are prone to cutaneous candidiasis, severely affected patients should be treated in advance of surgery. For patients with clinically significant hydroceles, we advocate staged management in advance of AUS.

Special attention is given to the patient's list of medications. Antiplatelet agents and other anticoagulants may increase risk for intraoperative bleeding or postoperative hematoma. Consistent with previously published literature, we have patients discontinue aspirin and non-steroidal anti-inflammatory agents 10 days before surgery.[19] Similar advice is given regarding fish oil and high-dose Vitamin E supplements. Periods of cessation for newer anticoagulants are based on their given pharmacokinetics relative to drug clearance. For individuals managed with warfarin, we require that the international normalized ratio be <1.4 on the morning of surgery. Patients on chronic steroids or other immunosuppressive medications should be evaluated carefully for whether these medications can be safely withheld temporarily, or whether their operative risk is prohibitive. Consultation with corresponding providers (cardiologist, hematologist, etc) is often essential.

Patients are advised to avoid shaving the genital region in advance of AUS placement and to perform a chlorhexidine scrub at home, at least twice, beginning the day before surgery. A review of patients following a similar protocol for 5 days ahead of surgery revealed a fourfold reduction in preoperative perineal colonization rate and significant reduction in positive surgical site cultures.[20] It is possible that the longer duration of at-home preparation is superior, but this has not been shown.

PATIENTS WITH HISTORY OF PRIOR SURGERY

Patients who have undergone prior male urethral sling placement and present with persistent or worsening SUI are better

served with an AUS than with a secondary sling. A single-center series of 61 men with sling failure had a nearly even split of men undergoing AUS or secondary sling.[21] Despite the AUS patients having significantly higher rates of prior pelvic radiation (47% vs 17%, $P = .01$) and preoperative pad weight, at 4 months, 100% of AUS patients were continent versus 79% of secondary sling patients. At 10 months, 100% of AUS patients remained continent compared with 35% of those who received a second sling. It has also been shown that prior sling surgery does not increase complications or compromise success after a subsequent AUS.[22]

In the setting of a patient with a history of AUS removal for erosion or prior urethroplasty, serious consideration should be given to a planned transcorporal approach. In the setting of any prior urethral surgery (sling, AUS, or urethroplasty), the surgeon should anticipate scarring and the lack of normal tissue planes. As such, slow and methodical sharp dissection is often the preferred approach, as blunt spreading maneuvers carry a higher risk of inadvertent urethral disruption.

INTRAOPERATIVE CONSIDERATIONS

Placement of an AUS can be performed under general or spinal anesthesia. In absence of patient allergy, preoperative intravenous antibiotics typically consist of vancomycin and gentamicin, with dosing determined by age, weight, and renal function. Based on our preferred approach, described below, patients are positioned in low lithotomy. After adequate anesthesia has been obtained and the genital region has been shaved, we perform a 10-minute scrub with chlorhexidine impregnated sponges, dry with sterile towels, and then prepare the area with 2% chlorhexidine gluconate/isopropyl alcohol applicators (ChloraPrep; BD, Franklin Lakes, NJ, USA). Data demonstrate that rates of surgical site infections at 30 days in clean-contaminated cases are decreased with the use of chlorhexidine-alcohol versus povidone-iodine.[23] Furthermore, a study focusing on eradication of bacterial skin flora in genitourinary prosthetic surgery found chlorhexidine-alcohol to be superior to povidone-iodine based on positivity of post-preparation skin culture (8% vs 32%, respectively; $P = .0091$).[24]

We do not perform urethral or bladder irrigation as part of the preparatory process, but routinely irrigate the outside of the portion of the Foley catheter exiting the penis immediately after placement, since a portion has been in contact with the colonized urethra before withdrawing the inflated balloon back to the bladder neck. Adhesive iodine-impregnated drapes (Ioban; 3M Medical, Chelmsford, MA, USA) may be considered as part of the sterile draping process. After draping and Foley catheter placement, the perineum is approached first.

Although the AUS can be placed at the bladder neck in some patients (male and female), for this article, we are dealing only with bulbar urethral placement. Our preference is to access the urethra via a perineal incision, although some have advocated for a penoscrotal/transscrotal approach. A penoscrotal approach allows for the patient to be placed supine, and the operation may be performed entirely through the initial incision, similar to a penile prosthesis. Proponents argue that downward retraction of the scrotum, possibly with a weighted vaginal speculum, allows adequate access to a segment of bulbar urethra of reasonable caliber. Critics, especially those that perform reoperative surgery for patients initially managed this way, argue that cuffs placed in this manner are uniformly around a distal urethral segment of unacceptably small caliber. When these techniques have been compared, the penoscrotal/transscrotal approach demonstrated significantly lower rates of dryness for initial cuffs (28.0% vs 56.7%, $P = .03$) and elevated instances of subsequent tandem cuffs to further improve continence (17.9% vs 3.1%, $P = .06$).[25] A follow-up, multicenter evaluation revealed similar findings. The dry rate for single-cuff AUS was 27.4% in the penoscrotal group compared with 44.1% in the perineal group ($P = .04$). Subsequent tandem cuff was performed to improve continence in 11.3% of penoscrotal cases versus 5.4% of perineal cases.[26] With more distal cuff placement, the length of the proximal urethral column of urine increases. It is unknown whether this translates into urinary urgency.

Exposure is facilitated by a self-retaining retractor (Lone Star; CooperSurgical Inc, Trumbull, CT, USA) with accompanying hooks. The bulbospongiosus ("bulbocavernosus" in older texts) muscle is sharply divided in the midline to expose the bulbar urethra. Care is taken to avoid sharp/tense retraction of this muscle to allow preservation for subsequent closure. Some surgeons omit division of the muscle on the ventral aspect and incorporate it within the AUS cuff.[27] We find this unconventional approach problematic, as the nature of the muscle fibers would seem prone to atrophy, resulting in "dead space" between the cuff and urethra. A section of the proximal/mid-bulbar urethra is chosen, at a point distal to where the proximal aspects of the corporal bodies merge. Although the lateral aspects of the urethra may be liberated with some blunt dissection, dorsal division from the attachments to the corpora cavernosa is performed sharply, with great care to avoid inadvertent entry into the dorsal urethra, where surrounding spongiosal tissue is less robust. Blunt spreading maneuvers may tear into the urethra, especially in patients with prior urethral surgeries or a history of radiation, the latter of which has been shown to significantly increase risk of erosion.[28,29] Premature passage of a right-angle clamp behind the urethra may likewise result in undesired perforation. If suspected, pericatheter irrigation can be performed using a filled syringe attached to an angiocatheter. In this setting, traditional advice would be to abort AUS placement, although survey data suggest that some providers are comfortable performing urethral repair and proceeding with placement of a urologic prosthetic.[30] Entry into the ventral aspect of the corporal bodies can be simply reapproximated with absorbable suture, and perforating vessels should be cauterized for hemostasis. We perform antibiotic field irrigation (bacitracin/gentamicin) intermittently throughout the case.

Once an adequate space has been developed, the urethra is assessed with the flexible measuring device provided by the

manufacturer. The goal is to select a cuff size that will restore continence without resulting in obstruction. The most commonly selected sizes are 4.0 and 4.5 cm.[11] It is important for the surgeon to understand that the cuff size refers to the outer circumference and not the inner inflatable aspect of the cuff. Thus, if the measurement appears to be between 2 available cuff sizes, it would seem wise to select the larger size to avoid postoperative retention and/or urethral compromise. Doing so should not reduce the ability for coaptation, as the cuff should fill to the desired pressure based on the properties of the PRB. Reports from authors who advocate choosing a size below what is typically measured may explain their not insignificant rate of erosion.[11] In the setting of transcorporal placement, we routinely choose a cuff size at least 0.5 cm larger than the measured circumference to avoid postoperative retention.

In January 2010, the 3.5-cm cuff was introduced, which features a 3-pillow design, with notches between these segments. Although some providers are apt to consider using this version, we have abandoned it in our practice, and multiple reports show that it affords a significantly increased risk of erosion.[28,29] We fully acknowledge that some patients may have a very small-caliber urethra, even at the proximal extent. This is especially true in patients who have undergone prior AUS removal. This has prompted some to apply commercially available xenograft for urethral bulking.[31] Porcine small intestinal mucosa, however, can result in an inflammatory response and is expected to be reabsorbed over time. In a small series of 8 patients managed with this approach, Trost and Elliott[32] noted that all patients developed urinary retention and received suprapubic catheters. At a median follow-up of 12.4 months, 62% had recurrent incontinence. Although we do not support urethral bulking between an AUS cuff and the urethra, we have used a strip of allograft to prevent the cuff from migrating distally when the degree of urethral mobilization is in excess of that required. In this setting, a strip of allograft is sutured to the midline of the ventral tunica albuginea of the corpora cavernosa distal to the planned cuff site. The graft is then brought around the urethra, and the ends are sutured to each other ventrally to recreate an attachment similar to that provided by the preexisting septal attachments.

Other approaches to the reduced-caliber urethra, assuming one has already approached the more robust proximal segment, have included tandem cuff placement and transcorporal cuff placement. Tandem cuff placement involves violation of an additional segment of urethra and has been shown to offer no improvement in pad usage yet increases complications, which often involves erosion at the distal cuff site.[33] Cadaveric studies show no improvement in leak point pressure with the second cuff.[34] In theory, the urethral segment between the 2 cuffs may also be at risk for stricture due to ischemia, and has been associated with spontaneous rupture.[8,35] Originators of the transcorporal technique subsequently abandoned the tandem cuff procedure, and we agree that it has no role in practice.[36] It is very rare that we would consider a primary transcorporal AUS, although this would be commonplace in our practice if the patient had undergone prior urethroplasty.

After cuff placement, bladder drainage is confirmed via the catheter, and a counterincision is made to allow placement of the PRB and pump. This is typically an oblique incision according to Langer's lines and made over the area of the right or left pubic tubercle, although the manufacturer also describes a lower midline approach.[7] The tubing connected to the cuff is tunneled subcutaneously with a passer to exit the upper incision. Dissection is carried down to the preperitoneal space, and the PRB is placed and filled accordingly.[11] Should the bladder be inadvertently punctured at this time, it should be repaired if the defect is large or allowed to heal with a sufficient period of catheter drainage. The cuff can be left in place and the other components placed at a subsequent surgical date. We prefer to fill the PRB with 24 mL of sterile saline, although some surgeons elect to use a mixture of contrast and sterile water to allow future assessment, if needed, via plain film radiography. The manufacturer provides a list of tested contrast solutions and the dilution instructions.[7]

Next, using the access afforded from the upper incision site, blunt dissection is performed to create a dependent position within the inferolateral scrotum, deep enough to avoid subsequent ascent toward the penopubic junction. This can be facilitated by a nasal speculum, ring forceps, or Mayo scissors. We try to limit overly aggressive sweeping maneuvers using gloved fingers. Before placing the pump, this area can be visually inspected for hemostasis, with cautery used as needed to avoid subsequent hematoma. Next, the pump is placed and should remain in position without the need for clamping the often thin scrotal skin around the tubing with something similar to a Babcock clamp (risk for skin disruption). Although some providers advise patients to manually pull down on their pump in the early postoperative period to avoid ascent, we believe this is ill-advised. It increases the risk of inadvertent activation, and many patients travel a considerable distance for care such that prompt presentation to an appropriate center for deactivation may be problematic.

At this point, excess tubing is trimmed, and the components are connected using the accessory kit. The Foley is removed, and flexible cystoscopy is performed with direct inspection of the urethra during cycling. Once urethral integrity is confirmed (unexpected violation with cuff exposure should prompt removal), assessment is made of the level of coaptation. If it appears largely insufficient, or if the extrinsic compression is excessive, the cuff should be changed to a more appropriate size at this time before leaving the operating room. If a minor decrease in compression is desired, Peterson and Webster[11] described an approach of excising up to 2 mm from inside the tab used to secure the cuff. As the authors noted, this is an unapproved technique that may result in cuff herniation or malfunction, and we also worry about delayed tab disruption resulting in uncoupling.

Once the device is noted to cycle appropriately, it is left deactivated. The surgical sites are irrigated and closed in multiple

layers of absorbable suture, and a topical skin adhesive can be considered over the final layer of closure. Once a dimple has been verified still within the pump (signifying deactivation), we place a 12-French silicone Foley catheter that is maintained until the following morning. Although some providers may discharge the patient from the recovery room without a catheter, we observe for a 23-hour stay, which is still considered outpatient.[11] Patients are discharged with prescriptions for antibiotics and analgesics. We typically provide 14 days of trimethoprim/sulfamethoxazole (800/160 mg), given reasonable coverage against methicillin-resistant *Staphylococcus aureus*, 30 tablets of acetaminophen/codeine (300/30 mg), and stool softeners. In our anecdotal experience, ~40% of our patients do not use the provided analgesic, and we have not been asked to provide a refill of this prescription in AUS patients, likely owing to preoperative counseling. Patients are evaluated at 3 weeks for a simple surgical site inspection, and again at 6 weeks for their activation visit. Providers should allow ample time for activation visits to ensure patient understanding of device use, which is often facilitated by the keychain model of the pump typically provided to patients. Well-trained midlevel providers can be extremely valuable in this setting. Patients may also be provided with a medical alert bracelet, alerting future providers to their indwelling AUS.

POSTOPERATIVE TROUBLESHOOTING

Although most patients will do well after surgery, some challenges may arise. After surgery, some patients may develop urinary retention despite a deactivated cuff. In the early postoperative period, this may be due to temporary bladder dysfunction, often a by-product of anesthesia-related effects, potentially compounded by use of narcotic analgesics. After ensuring that the cuff remains deactivated with an obvious dimple in the pump, it is reasonable to consider a small-caliber (≤12 French) urethral catheter for a short length of time (≤72 hours in our practice). We avoid having patients perform intermittent self-catheterization in this setting. If retention persists beyond this point, one must consider urethral obstruction from a cuff that is too compressive, even in the deactivated state, or possibly from some transient edema. Thus, the options would include cuff revision or placement of a suprapubic catheter. We often perform the latter and find that nearly all cases resolve without the need for cuff revision or persistent catheter drainage beyond 1 month.

At time of activation, if too little fluid was left within the deactivated pump, it may be challenging to reactivate. In this situation, the sides of the upper portion of the pump can be squeezed toward the midline, often allowing enough additional fluid to enter the pump to facilitate activation. Should the pump be noted to ascend to an uncomfortable position after a patient begins use, they can attempt to gently manipulate the device toward a more dependent position, often after a warm bath. However, if this problem persists, it may necessitate surgical revision. Similarly, if a patient has symptomatic herniation/migration of the PRB, relocation with suture reinforcement is advised.

Persistent SUI unchanged from baseline would suggest some form of surgical error, provided urge incontinence/bladder dysfunction has been ruled out. Although we have not seen this in our own cases, we have managed several cases of a phenomenon we have termed the *ghost urethra*. In these cases, prior AUS placement (always by low-volume implanters) has been performed around a segment of bulbospongiosus muscle (Figure 1). This highlights the value of proper training, as well as intraoperative cystoscopy.

Although superficial skin infections at the incision site may be effectively managed with antibiotics in many cases, deep tissue infections involving the device require removal. Some cases may present in a subtle fashion, perhaps with pump fixation to the overlying skin. Unlike penile prostheses, there is not sufficient data to support a salvage procedure with the AUS, likely because many cases of infection involve urethral erosion. In the setting of pump erosion through the skin, even in the absence of gross purulence, traditional teaching (and what seems to be the most prudent approach) has been to assume that the entire device is compromised and should be removed. However, we are aware of cases that have been successfully managed with single component removal and delayed replacement.

Instances of urethral erosion rarely present early in the postoperative period. If so, they may be due to unrecognized injury at

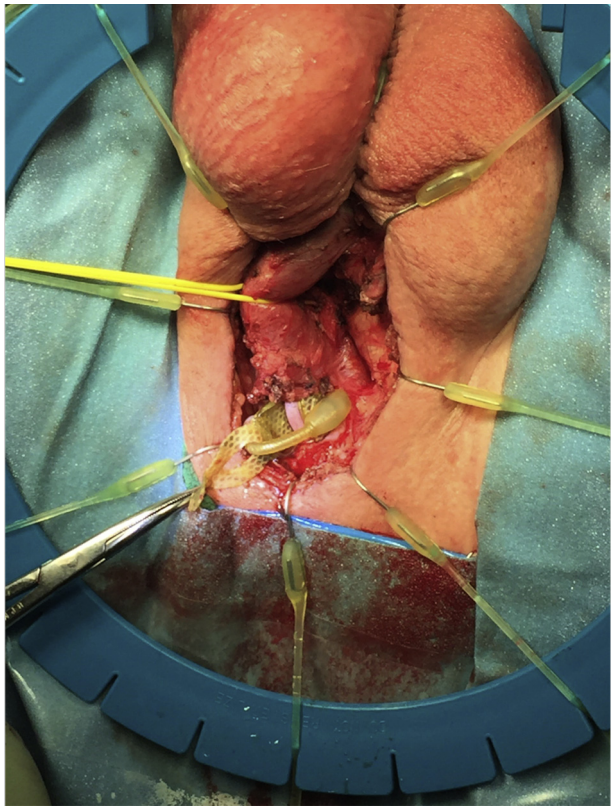

Figure 1. The ghost urethra. In this case, the previous surgeon placed the cuff through the bulbospongiosus muscle without violating the urethral lumen.

the time of surgery, rather than delayed tissue necrosis. This phenomenon may present as recurrent incontinence, usually with some degree of hematuria (microscopic or gross), or as an obvious tissue infection. Unlike instances of fluid loss, pump function appears normal. Although erosion should uniformly prompt device removal, management of the urethra is variable. Small defects may heal over a catheter without formal repair at explantation. Larger defects, however, require greater consideration. Allowing to simply heal over a catheter will often result in prolonged periods of catheterization, and potentially fistulization if bladder spasms consistently contribute to pericatheter extravasation. Even if these cases fully heal, the result often involves a urethral stricture, which appears to significantly reduce the chances of receiving a future AUS.[37] The same is seen with simple suture closure (urethrorrhaphy, rather than a true urethroplasty) over the catheter at time of AUS removal, though this appears preferable to simply healing over the catheter.[38] Our preference is to divide the urethra at the point of significant erosion, debride the edges, and mobilize to allow a tension-free primary anastomosis, similar to that described elsewhere.[38] Anecdotally, we've also performed substitution urethroplasty at time of AUS removal in a small subset of patients without gross infection and have observed no postoperative complications or stricture formation that would preclude a subsequent AUS.

Some patients may require future instrumentation for urethral and/or bladder pathology. For patients with recurrence of problematic BNC after AUS, we favor laser incision of the fibrosis, performed using a semirigid ureteroscope passed through a deactivated cuff. Should a patient develop a urothelial malignancy requiring transurethral resection (eg, bladder tumor), our preferred approach is to approach the cuff through a perineal incision and uncouple without dividing the tab. Transurethral management can be performed with standard instrumentation, followed by recoupling of the cuff and perineal closure. Others have noted that they are comfortable passing a 24-French sheath through a deactivated device.[27]

OUTCOMES

Although the majority of patients will do well after surgery, postoperative complications are possible and are commonly minor. Linder et al[39] retrospectively reviewed 100 primary AUS implantations for post-prostatectomy SUI to assess complications (Clavien-Dindo I–IV) within 6 weeks of surgery. The rate of any complication was 35%, most commonly involving urinary retention (31%). Other complications included device infection (2%), urethral erosion (2%), and cellulitis (1%). Patient comorbidities, prior pelvic radiation, prior urethral sling, or transcorporal cuff placement were not found to be different among those with or without perioperative complications. Of note, patients who had postoperative urinary retention were more likely to require revision surgery (76% vs 89%, $P = .04$), and had a higher rate of device infection/erosion ($P = .05$). Explantation was typically performed within 2 months after the initial operation.

Regarding long-term success, a prospective assessment of 40 consecutive AUS cases with a mean follow-up of 53.4 months noted a reduction of pad usage from 4.0 to 0.62 per day ($P < .001$).[40] Men also noted a significant decrease in incontinence impact, as measured by the visual analog scale (5.0−1.4, $P < .001$). The surgical revision rate was 20%.

A retrospective single-institution review of 1,802 cases with median follow-up of 4.1 years reported AUS survival of 90% at 1 year.[3] However, this decreased to 57% at 10 years and 41% at 15 years. In this series, 60% of cases involved primary implants, and no patient received a 3.5-cm urethral cuff. On univariate analysis, prior pelvic radiation (hazard ratio 1.34, $P = .02$) and urethral cuff size ≥5.0 cm (hazard ratio 2.91, $P < .0001$) were associated with receipt of revision surgery. However, on multivariate analysis, no specific factors were independently associated with undergoing a second operation. Of the 31.2% (n = 338) of men undergoing a second surgery, the most common reasons involved device malfunction (n = 131), urethral atrophy (n = 89), device infection or erosion (n = 89), and pump malposition or tubing complications (n = 29). Infection or erosion occurred sooner after device implantation than device malfunction or urethral atrophy, with median times of 2, 4.5, and 4.7 years, respectively ($P = .003$).

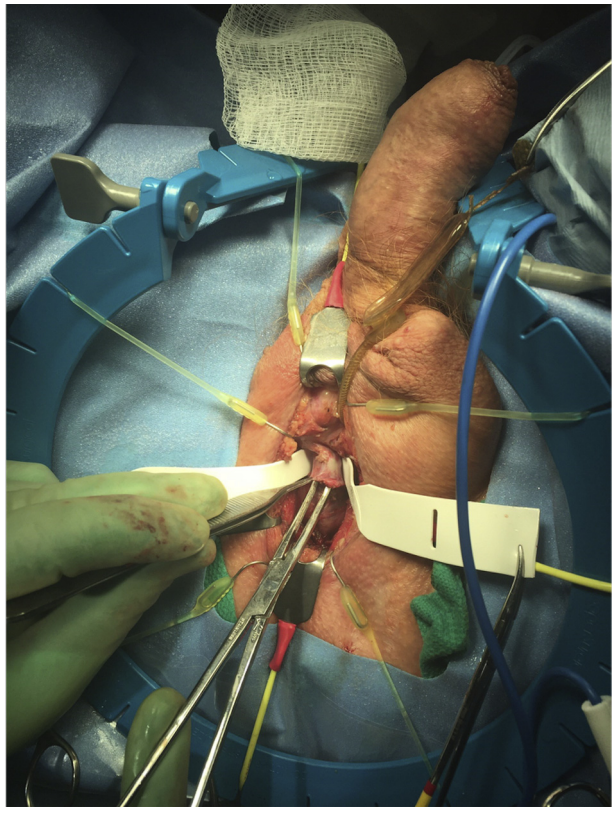

Figure 2. Elevation of the subcuff capsule in preparation for capsulotomy.

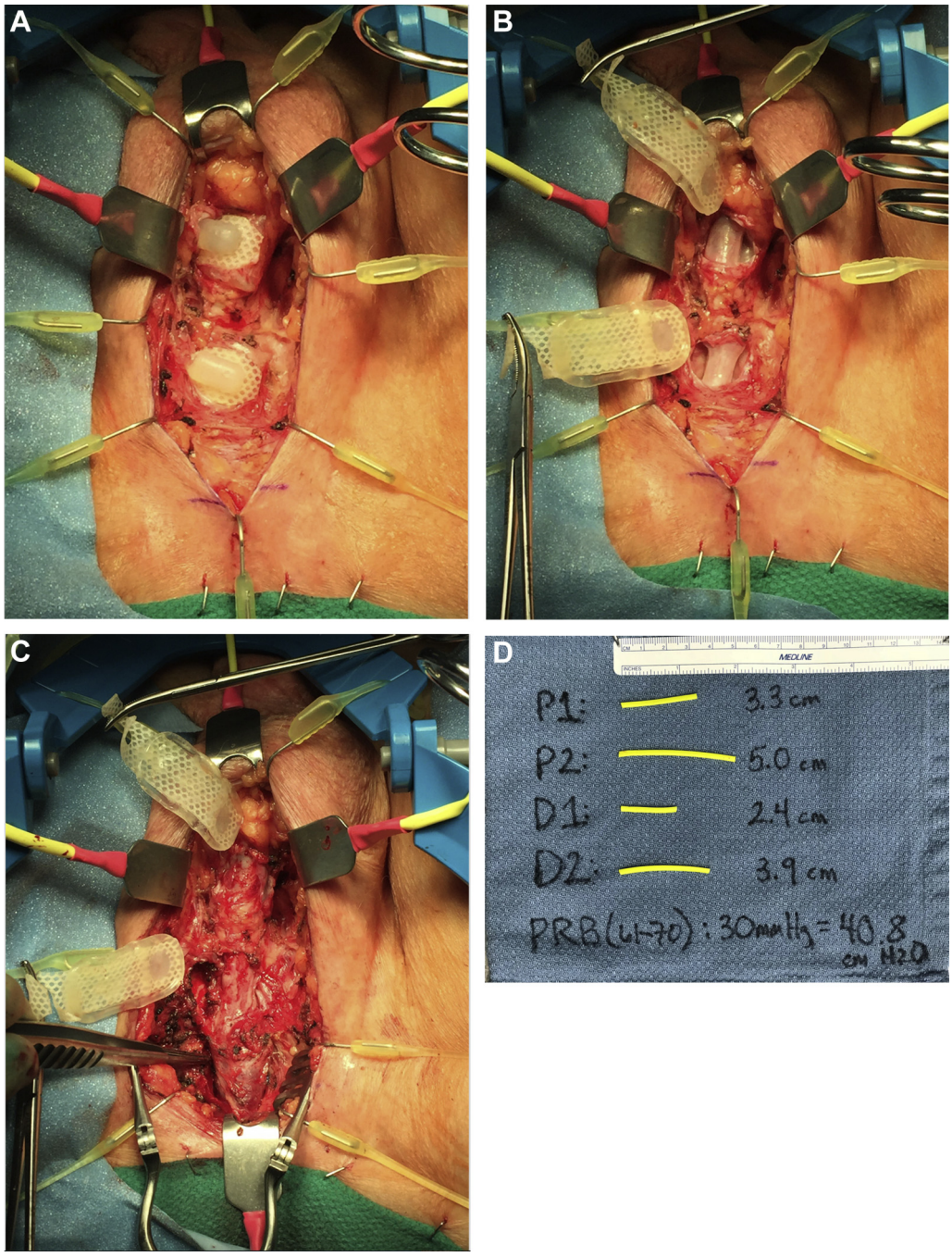

Figure 3. A, Tandem cuffs in a patient with recurrent SUI. B, Restrictive urethral encapsulation noted at both prior cuff sites. C, Urethral recovery after capsulotomy. D, Vessel loops were used to determine circumference of the urethra before (1) and after (2) capsulotomy at the previous proximal (P) and distal (D) cuff sites. Interrogation of the 61—70 cm of H_2O PRB revealed an internal pressure of 40.8 cm of H_2O.

APPROACHES TO LOSS OF EFFICACY

Although definitions of success after AUS placement may vary, the use of 0—1 pad per day is commonly applied. Thus, repeat surgery may not be best described as being for "recurrent incontinence," as many patients may have minor degrees of incontinence after surgery. However, the degree of continence may lessen over time, prompting some patients to request additional intervention in an attempt to recreate the initial degree of improvement. Patients should be evaluated to rule out infection, urge-related symptoms, and overflow incontinence, which would be managed as previously mentioned. Cases of fluid loss may be obvious to the surgeon when cycling the device, as the pump lacks the typical fullness and the sound of air within the system may be obvious. Imaging may be considered in less obvious cases, possibly involving sonography or axial imaging. If dilute contrast had been used, rather than saline, conventional

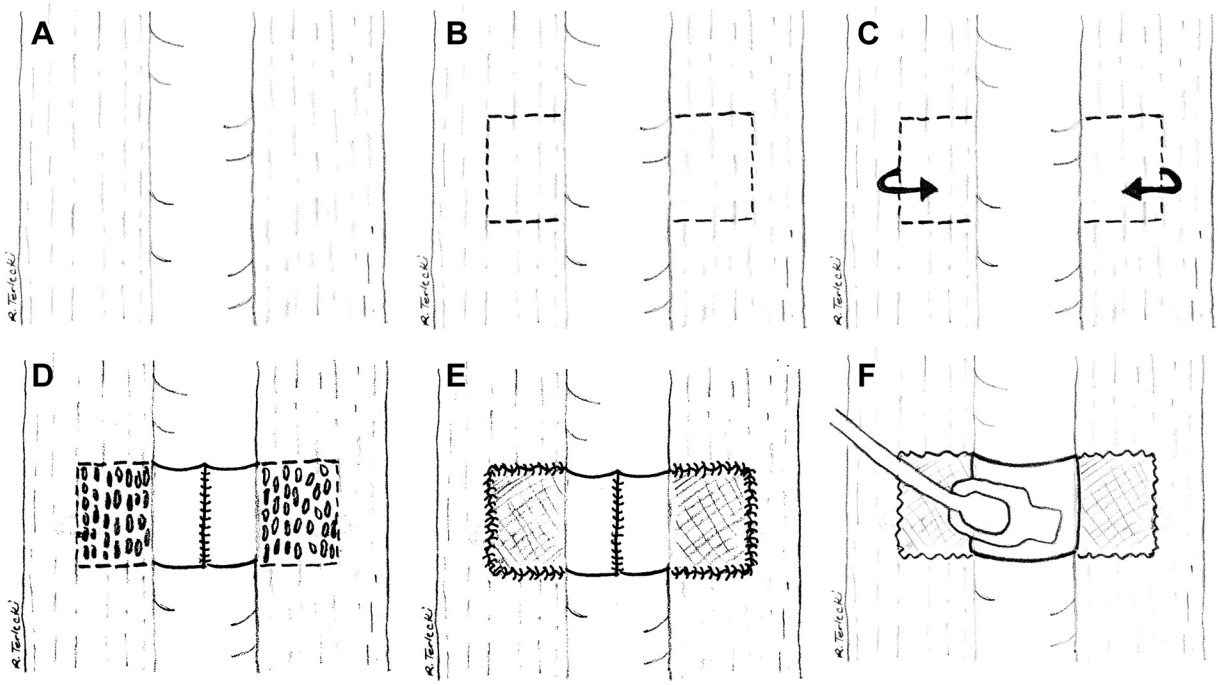

Figure 4. A, Gull-wing transcorporal technique. The distal bulbar urethra in the center of the drawing has been exposed along with the flanking corpora cavernosa. B, Rectangular flaps are outlined on the ventral surface of the corpora cavernosa (depicted via the dotted lines) adjacent to the urethral segment chosen for cuff placement. C, The gull-wing tunical flaps are incised with electrocautery, raised off the underlying cavernosal tissue, and brought ventrally around the urethra. D, After suturing the flaps together ventrally, the size of the defect exposing the cavernosal tissue is measured. E, A segment of commercially prepared graft material is cut to size and sewn into place, covering the defect. This is depicted with the shaded, rectangular areas on either side of the urethra. F, The AUS cuff is placed around the reinforced urethra.

radiography would be an option. In the absence of fluid loss, office cystoscopy with cycling of device should be considered to assess coaptation. If the system appears to coapt well, UDS may be considered. With loss of fluid, the development of increased SUI is often without hematuria and more abrupt than that seen with erosion.

Fluid Loss

In the setting of fluid loss, revision surgery is indicated. Approaches differ as to removing only the offending component or replacing the entire device, with some considerations based on arbitrary opinions regarding the elapsed time since the original operation.[11] In a series of 19 patients undergoing 20 operations for fluid loss identified by loss of contrast on plain film radiography, Selph et al[41] evaluated intraoperative use of an ohmmeter to localize the site of disruption. Success was noted in 90% of cases, with most leaks located at the level of the PRB (n = 13), followed by the cuff (n = 4). No patients had fluid loss from the pump. Although a proportion of these patients required repeat surgery at a median of 17 months, none did so because of a failure to identify the leak at prior surgery.

In 2016, Linder et al[42] reported on 125 cases of mechanical failure, with a median time to failure of 4.6 years. Most failures were attributed to the cuff (46.1%), followed by the PRB (22.6%). No specific length of time from initial surgery could be identified whereby replacement of only failed components or complete removal/replacement afforded significantly better device survival. However, the authors noted a trend toward improved 3-year device survival after replacement of the entire device (76% vs 60%, $P = .11$).

It is our practice to replace the entire system in the setting of fluid loss. The concern is that the system may now be contaminated with bodily fluids or tissue and that irrigation/aspiration cannot reliably confirm a "clean" system. We believe that this lessens the chance of a tertiary operation, which can cause significant frustration for patient and physician alike. Our experience is similar to that reported by Selph et al[41] in that all leaks identified at our center have been at the level of either the cuff or the PRB. In regard to attributing failure to the cuff, as noted in the discussion of the series by Linder et al,[42] this may be problematic if the device has not been assessed for material fatigue at the level of the PRB, or if subcuff urethral encapsulation was equated with cuff failure.

Non-Mechanical Failure

Instances of non-mechanical failure have traditionally been attributed to atrophy of the urethra. This assumption was based on the waist-like appearance of the urethra after uncoupling an existing device. However, we have shown that this does not represent true atrophy.[43] Rather, this is the product of restrictive

encapsulation that is reversible in real time at revision surgery. This capsule can be carefully dissected free from the urethra ventrally (Figure 2). Capsulotomy has been noted to allow recovery of urethral caliber, and we have described and demonstrated this technique previously.[44] However, we have also noted evidence of material fatigue at the level of the PRB, as the pressure profile appears to degrade over time.[43] These findings have implications for technique selection at time of revision surgery. Restoring a previously mobilized segment of urethra for cuff placement avoids the need for further dissection and the inherent further disruption of collateral circulation (especially important in patients with multiple prior cuff locations; Figure 3). It may also limit consideration of downsizing to a 3.5-cm cuff, which we find problematic, or the application of transcorporal placement, which has implications for the man that may either have or subsequently considers a penile prosthesis. Additionally, if capsulotomy were performed without division of the tab used to secure the cuff, the existing cuff could potentially be salvaged, although replacing the PRB for one with an intact pressure range would seem logical. Replacing the PRB alone may be problematic. The degree of urethral recovery with capsulotomy attests to the restrictive nature of the capsule. Thus, the blood supply surrounding the urethral segment below the capsule is likely compromised to some extent, which could be further aggravated by increased external pressure from a new PRB, potentially raising the risk for ischemic necrosis/erosion.

TRANSCORPORAL GULL-WING DOOR TECHNIQUE

The initial description of the transcorporal technique provides dorsal reinforcement of the urethra and narrows the caliber of the corporal bodies when reapproximated. We have developed a variation of this technique. Instead of simple longitudinal corporotomies, we raise rectangular shaped flaps from the ventral corpora flanking the urethral segment to be included within the AUS cuff. These "gull-wing doors" are brought around each side of the urethra and sutured to each other ventrally. The measuring tape is then used to elevate the urethra and included corporal segment. The rectangular-shaped defect of the ventral corpora is then measured, and an appropriately sized segment of xenograft (eg, bovine pericardium) or allograft (eg, cadaveric dermis) is sutured over the defect (Figure 4). We believe this approach provides additional urethral protection on the lateral and ventral aspects and preserves the caliber of the corpora, as well as provides a protective layer of separation from the AUS if a future penile implant were to be considered.

CONCLUSION

The AUS remains a valuable treatment option for surgical correction of male SUI. Successful outcomes can be achieved through appropriate patient selection and an understanding of the nuances of optimal surgical technique. Awareness of potential downstream issues and strategies for effective troubleshooting can maintain efficacy and patient satisfaction. For patients interested in reoperation for non-mechanical failure, familiarity with existing approaches is essential.

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Conflict of interest: Ryan P. Terlicki is a consultant with grant support from Boston Scientific. Jyoti D. Chouhan has no conflict of interest to declare.

Funding: None.

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