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INVITED REVIEW

Operational Andrology

Management of urethral atrophy after implantation of artificial urinary sphincter: what are the weaknesses?

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The use of artificial urinary sphincter (AUS) for the treatment of stress urinary incontinence has become more prevalent, especially in the “prostate-specific antigen (PSA)-era”, when more patients are treated for localized prostate cancer. The first widely accepted device was the AMS 800, but since then, other devices have also entered the market. While efficacy has increased with improvements in technology and technique, and patient satisfaction is high, AUS implantation still has inherent risks and complications of any implant surgery, in addition to the unique challenges of urethral complications that may be associated with the cuff. Furthermore, the unique nature of the AUS, with a control pump, reservoir, balloon cuff, and connecting tubing, means that mechanical complications can also arise from these individual parts. This article aims to present and summarize the current literature on the management of complications of AUS, especially urethral atrophy. We conducted a literature search on PubMed from January 1990 to December 2018 on AUS complications and their management. We review the various potential complications and their management. AUS complications are either mechanical or nonmechanical complications. Mechanical complications usually involve malfunction of the AUS. Nonmechanical complications include infection, urethral atrophy, cuff erosion, and stricture. Challenges exist especially in the management of urethral atrophy, with both tandem implants, transcorporeal cuffs, and cuff downsizing all postulated as potential remedies. Although complications from AUS implants are not common, knowledge of the management of these issues are crucial to ensure care for patients with these implants. Further studies are needed to further evaluate these techniques.

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INTRODUCTION

Significant stress urinary incontinence (SUI) is a source of psychological stress for many men. For patients with significant SUI, the placement of an artificial urinary sphincter (AUS) can greatly improve leakage rates, and overall quality of life, and remains the treatment of choice for moderate-to-severe SUI.¹

Particularly, while most commonly performed after radical prostatectomy, the use of AUS for significant SUI has also been reported after transurethral resection of prostate (TURP), cystoprostatectomy with neobladders, and in patients with neurogenic bladders. Importantly, the success of AUS implantation is consistent across most etiologies of SUI.^{2,3}

The AUS itself is a robust device; however, the risk of reoperation can still be as high as 25%–34%.^{4–6} Although the complication and reoperation rates have improved from historical data, clinicians still need an armamentarium of techniques to salvage AUS complications.⁷ In general, reasons for revision can be usually divided into mechanical and nonmechanical failures. Mechanical failures are due to defects or failure of the AUS itself and can be remedied with replacement of the device with good results. However, challenges remain with nonmechanical failures. The most common reasons for nonmechanical revisions are urethral atrophy and urethral erosion. The aim of this

review is to analyze the data regarding urethral atrophy, and the various techniques that have been used to address this aspect of nonmechanical failure, while continuing strive for good continence rates for patients.

AUS COMPLICATIONS

Mechanical complications

The most common AUS device currently on the market is the AMS 800 (Boston Scientific, MA, USA) device, although there are alternative devices available, such as the Flow-Secure® (Sphinx Medical, Bellshill, North Lanarkshire, United Kingdom), Periurethral Constrictor (Silimed, Rio de Janeiro, Brazil), and ZSI 375 (ZEPHYR Surgical Implants, Geneva, Switzerland) as shown in **Figure 1**.⁸ The currently available AUS implants are complex devices and combine several components to achieve the desired continence result, and the overall mechanical failure rate is 6.2% (2.0%–13.8%).⁶ These complications have been reported to occur from as early as 11–68.1 months postinsertion. The AMS 800, which is the most studied device, consists of a urethral cuff, pressure-regulating balloon (PRB), and control pump, which are all connected with tubing. While all components are susceptible to failure, the urethral cuff is the most common component to fail.⁹ While their durability is robust, certain patterns in the failure of the device itself have been observed. For the AMS 800, the use of the 3.5-cm cuff has been shown

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Figure 1: (a) AMS 800 (Boston Scientific, Marlborough, MA, USA), image reproduced with permission from Boston Scientific. (b) ZSI 375 (ZEPHYR Surgical Implants, Geneva, Switzerland).⁸ (c) FlowSecure (Sphinx Medical, Bellshill, North Lanarkshire, United Kingdom).⁸ (d) Periurethral Constrictor (Silimed, Rio de Janeiro, Brazil).⁸

to be associated with a higher mechanical failure rate when compared to the 4-cm cuff (hazard ratio [HR]: 7.313, $P < 0.0001$). Loh-Doyle *et al.*⁹ found in a retrospective study consisting of 993 individual cases that the urethral cuff was the most common component to fail. Subgroup analysis of this population found that the 3.5-cm cuff was at higher risk of failure on Cox regression modeling, and the incidence of cuff failure was distributed evenly over the 5-year follow-up of patients, leading the authors to postulate that this could be inherent to the cuff itself. Analysis of the explanted cuffs revealed that leaks tended to form in the creases of the 3.5-cm cuff when inflated, which is a unique trait of the smaller cuff. The introduction of the narrow backing cuff also coincided with a drop in the mechanical failure rate of the AUS.^{9,10}

Nonmechanical complications

Urethral erosion

Urethral erosion has shown to occur in up to 8.5% (3.3%–27.8%)⁶ of implants. Although cuff erosions are commonly reported in the literature when discussing AUS, there are little data on the timing and etiology of urethral erosions.

Urethral erosions seem to occur more frequently within the first 2 years of implantation, with subsequent decreasing incidence over time, and there are three main hypotheses for the mechanism of cuff erosion. For patients who experience urethral cuff erosion within 1 year, it is hypothesized that urethral injury or shallow dissection at the time of implantation may account for early erosion. For patients that present with later erosions, a consideration would be poor urethral tissues, which can be contributed by comorbidities, such as previous radiation or diabetes. The poor urethral tissue undergoes atrophy or necrosis, and this eventually results in erosion of the cuff. The final mechanism would be inappropriate or traumatic catheterization, especially by health-care providers that may not be aware of the AUS.¹¹

Management of urethral erosion is usually immediate removal of the AUS and subsequent urinary catheter placement. A case report reviewed the management of two cases with urethral erosion that were treated nonsurgically. In these two cases, the implant remained functional with no infection or loss of continence and decision to avoid explantation was refusal by the patients and should not be considered a

standard of care.¹² Subsequent reimplantation of AUS can be considered if the patient is still keen for intervention.

Common sequelae of cuff erosion are urethral strictures. The rates of between 8.3% and 32%^{13,14} have been quoted for patients who have had AUS cuff erosions. Several retrospective trials have described urethroplasty postexplantation and subsequent AUS reimplantation; however, up to 36% of patients had subsequent cuff complications, including early erosion and pump migration.¹³ For urethral strictures postcomplete AUS cuff erosion, management seems to follow that of traumatic urethral injuries, with dense, full-thickness scar formation. In these patients, delayed anastomotic urethroplasty may have success rates of up to 86%.¹⁴

Following cuff explantation, there is debate regarding explantation of the PRB that is located in the deep pelvis. A retrospective analysis of retained PRBs after the removal of infected or eroded cuffs suggested that up to 75% of patients can be managed conservatively, with the median time to PRB removal due to infection being 4 months.¹⁵

Urethral atrophy

SUI recurrence during follow-up of a functioning AUS is typically presumed to be due to urethral atrophy. The common presumed pathophysiology underlying urethral atrophy is urethral tissue hypoxia, which is secondary to long-standing pressure from the cuff on the urethral wall. A systematic review published in 2012 reported the mean pooled incidence of urethral atrophy as 7.9%.⁶ To date, this is the largest systematic review of long-term outcomes following AUS insertion in patients with nonneurogenic SUI. Only three studies gathered were prospective trials. The main indicator of success was continence, which was defined as no pad or 1 pad per day. However, current knowledge regarding urethral atrophy is still limited and further studies are needed to define urethral atrophy and assess the rate of urethral atrophy.

A recent prospective trial hypothesized that the entity of urethral atrophy may not be clinically significant.¹⁶ There is currently no standardized definition for urethral atrophy and is usually diagnosed intraoperatively from the characteristic waisted appearance of the urethra when the cuff is removed. Fifty consecutive patients underwent exploration and reimplantation for malfunctioning AUS. In 19 patients, no obvious cause was found in the device; nonetheless, when the explanted implants were challenged with manometry, it was found that there was loss of pressure in all instances. Replacement of the entire explanted AUS after capsulotomy with an identical cuff size and PRB was successful for the patients, in which no obvious abnormality was found (defined as totally dry or “socially dry,” *i.e.*, no more than 1 pad per day) in 85.7% of cases. However, this is a small study, with no histological results or control arm.

MANAGEMENT OF URETHRAL ATROPHY

In general, four main methods have been described when managing urethral atrophy in patients who have recurrent SUI despite a functioning AUS. They involve cuff downsizing, the placement of a second cuff or “tandem cuff placement,” cuff repositioning or transcorporal cuff placement, and changing PRBs to higher pressure ranges.

The aim of all these maneuvers is still to achieve continence for patients by reestablishing coaptation of the urethra by the AUS.

Cuff downsizing

Cuff downsizing involves removing the existing cuff and replacing it with a smaller sized cuff within the established false capsule. Early retrospective studies showed that severe leakage episodes decreased

and patient satisfaction increased after urethral cuffs were downsized.¹⁷ Many advocate downsizing cuffs to 4- or 3.5-cm cuffs, with good results. However, there are two main problems with cuff downsizing. As the pathophysiology of urethral atrophy is proposed to be secondary to pressure necrosis and hypoxia of urethral tissues, the use of smaller cuff sizes will likely lead to worsening atrophy or possibly erosion. Brant *et al.*¹⁸ recently reported that the use of a 3.5-cm cuff is a predictor of cuff erosion. While these were considered novel findings, this study was done shortly after the 3.5-cm cuff became commercially available. The authors postulate that the higher incidence of erosion may not be an inherent flaw of the device, but rather selection bias, as smaller cuffs may be sized for smaller urethras that are compromised and incapable of supporting an AUS. Conversely, Loh-Doyle *et al.*⁹ showed that the 3.5-cm cuff was an independent risk factor for component failure, even after its initial commercial introduction. Therefore, it is difficult to attribute the negative results simply to its new market availability. Patients must be counseled accordingly and weigh the benefits against the additional risk erosion that comes with cuff downsizing.

Transcorporal cuff placement or cuff repositioning

Transcorporal cuff placement or cuff repositioning has also been proposed as a salvage treatment for failed AUS due to urethral atrophy. The underlying concept of transcorporal AUS placement is to increase the healthy tissue bulk between the cuff and the urethral body. By placing the urethral cuff through the corpora cavernosa, this configures the tunica albuginea between the cuff and the urethra, while simultaneously avoiding further urethral dissection. The use of transcorporal AUS has previously been described as an effective salvage method for AUS that requires revision from either urethral atrophy or erosion, and its use has even been investigated as a primary intervention with no prior urethral surgery (Figure 2).^{19,20}

The use of transcorporal AUS has also been investigated in patients that may potentially have poorer urethral tissues, such as patients with previous radiation. A retrospective analysis of 44 patients showed that the social continence rate was 69.7%; however, overall complications were up to 45.9%.²¹ Subgroup analysis showed that patients with previous radiation had less AUS complications than those with previous urethral surgery.

The largest prospective trial included 23 patients that underwent transcorporal cuff placement after urethral atrophy or erosion or a previous AUS or male sling.²² Seventy-six percent of patients were found to be dry or socially dry, with 1 or fewer pads daily, with high patient satisfaction. In another study, continence rate at 45 months, defined as 0–1 pad daily, was 80%, with a reoperation rate of 37.5%.²³ Good erectile function has also been observed postsurgery, with those patients who were potent and able to maintain their sexual function. However, many of these patients start out with existing

erectile dysfunction, and due to small numbers in all published data, it is difficult to ascertain whether transcorporal cuff placement would really impact the sexual function.

Proximal urethral cuff repositioning has also been described in the treatment of urethral atrophy. This involves removal of the old cuff from the false capsule with subsequent mobilization of urethra proximal to the previous sphincter site.²⁴ This is based on the assumption that previous cuff location was likely suboptimal, and should be at the thickest part of the bulbar urethra, which is usually more proximal, thick, and robust. By mobilizing the urethra proximal to the existing pseudocapsule, this allows visualization of the most proximal aspect of the bulbar urethra, allowing proper replacement of the cuff. In six patients, five patients attained social continence (defined as none or 1 pad per day) with repositioning of the urethral cuff and no patient required revision at median 1-year follow-up.

Tandem cuff placement

Tandem cuff placement involves implantation of a second cuff, usually distal to the existing cuff, on the background of recurrent SUI post-AUS insertion. The concept behind tandem cuff placement is that the initial cuff provides little to no coaptation. A second cuff placed distally allows urethral compression and reestablishes continence.

The use of tandem cuff placement in the role of severe incontinence has also been investigated both as a primary intervention and as salvage treatment of failed AUS.²⁵ As a primary treatment, tandem cuff placement has not shown to be superior in dry rate and overall incontinence, yet is associated with additional complications that require surgical revision (55% of tandem cuff patients as opposed to 28% of single cuff patients). Complications included urethral stricture, mechanical failure, erosion, and rectourethral fistula. The authors hypothesize that ischemia due to the tandem cuffs may have contributed to at least 7 of the 12 double-cuff patients that underwent revision. Thus, tandem cuff placement as an index treatment for SUI should not be considered.

However, tandem cuff placement has been shown to improve incontinence rates for failed AUS. Usually, the existing bulbar urethral cuff is left *in situ* and a second distal cuff is placed transcorporally.^{26,27} However, both cuffs can also be placed transcorporally after explantation of the original bulbar urethral cuff. This technique is usually reserved for the most difficult salvage cases, especially those that have experienced previous infection or erosion. Continence rates posttandem cuff placement range from 56% to 69% with high patient satisfaction. Reoperation rate for tandem cuff placement ranges from 16% to 22%.

When compared to cuff downsizing, tandem cuff placement has been shown to be equivalent to single-cuff downsizing when treating urethral atrophy in device survival rates.²⁸ Median time to primary failure was 6.13 years (single cuff) versus 4.92 years (tandem cuff) ($P = 0.53$), with similar demographic groups. Subgroup analysis of the tandem cuff group revealed that those patients who underwent transcorporal cuff placement experienced a shorter 3-year device survival rate (44% vs 80%, $P = 0.0016$) when compared to their nontranscorporal approach cohort. However, Linder *et al.*²⁸ were not able to ascertain functional outcomes as it was a retrospective study. Significantly, there are no large prospective studies that compare cuff downsizing to tandem cuff placement in the treatment of urethral atrophy.

Replacement of PRBs

Although more difficult to revise, replacement of the PRB has been described in the management of recurrent SUI after AUS implantation.

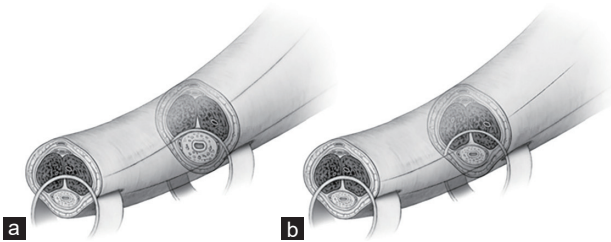


Figure 2: (a) Single transcorporal cuff on distal bulbar urethra placed in tandem with existing periurethral cuff on proximal bulbar urethra. (b) Two transcorporal cuffs placed on the proximal and distal bulbar urethra. (Images reproduced with permission from Dr. Daniel Elliott, Mayo Clinic, MN, USA).

This technique is usually used when there is recurrent incontinence in the absence of urethral erosion or obvious mechanical failure of any of the AUS components.

The rationale behind this technique is that the higher pressures in the PRB will help urethral coaptation and the reestablishment of continence. It also has the further benefit of leaving working components of the AUS (cuff and pump) undisturbed in their existing locations, hopefully reducing the chance of erosions or migration. A retrospective study comparing PRB replacement to cuff replacement found that reintervention rates following PRB revision compared to cuff revision were similar (44.8% vs 46.7%).²⁹ However, due to the difficulty of isolated PRB replacement, the authors concede that this technique has become less favorable compared to wholesale change of the device.

CONCLUSION

AUS continues to be the gold standard in the treatment of moderate-to-severe nonneurogenic SUI. As the complication rate continues to decrease with surgeon experience, counseling for reoperation for AUS still remains a pillar of patient awareness, no matter the etiology of the revision. Amidst the data available, there are several salvage techniques that are well documented when attempting to treat AUS complications. However, more prospective trials are needed to define urethral atrophy and assess the risk factors of future AUS complications. Determining the best salvage treatment with robust randomized controlled trials presents an even greater obstacle for clinicians in the future due to the small number of patients.

AUTHOR CONTRIBUTIONS

NHH performed the literature review and drafted the manuscript. RBWT conceived the study and provided guidance on the manuscript. Both authors read and approved the final manuscript.

COMPETING INTERESTS

Both authors declared no competing interests.

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REFERENCES

- Linder BJ, Rivera ME, Ziegelmann MJ, Elliott DS. Long-term outcomes following artificial urinary sphincter placement: an analysis of 1082 cases at Mayo Clinic. *Urology* 2015; 86: 602–7.
- Miller AR, Linder BJ, Rangel LJ, Yang DY, Elliott DS. The impact of incontinence etiology on artificial urinary sphincter outcomes. *Investig Clin Urol* 2017; 58: 241–6.
- Scott KA, Tonzi M, Nikolavsky D. Use of artificial urinary sphincter and slings to manage neurogenic bladder following spinal cord injury – is it safe? *Curr Bladder Dysfunct Rep* 2017; 12: 311–20.
- Raj GV, Peterson AC, Toh KL, Webster GD. Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J Urol* 2005; 4: 1242–5.
- Radomski SB, Ruzhynsky V, Wallis CJ, Herschorn S. Complications and interventions in patients with an artificial urinary sphincter: long-term results. *J Urol* 2018; 200: 1093–8.
- Kasyan GR, Cornu JN, Drake MJ, Petrolekas A, Van der Aa F. The artificial urinary sphincter after a quarter of a century: a critical systematic review of its use in male non-neurogenic incontinence. *Eur Urol* 2012; 63: 681–9.
- Serag H, Bang S, Zaki Y. Artificial urinary sphincters for treating postprostatectomy incontinence: a contemporary experience from the UK. *Res Rep Urol* 2018; 10: 63–8.
- Vakalopoulos I, Kampantais S, Laskaridis L, Chachopoulos V, Koptsis M, et al. New

- artificial urinary sphincter devices in the treatment of male iatrogenic incontinence. *Adv Urol* 2012; 2012: 439372.
- Loh-Doyle JC, Ginsberg DA, Hartman N, Boyd SD, Nazemi A, et al. Mechanical failure rates of artificial urinary sphincter components: is the 3.5-cm urethral cuff at higher risk? *NeuroUrol Urodyn* 2018; 38: 187–92.
- Elliott DS, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. *J Urol* 1998; 159: 1206–8.
- Agarwal DK, Linder BJ, Elliott DS. Artificial urinary sphincter urethral erosions: temporal patterns, management, and incidence of preventable erosions. *Indian J Urol* 2017; 33: 26–9.
- Singla N, Singla AK. Review of single-surgeon 10-year experience with artificial urinary sphincter with report of sterile cuff erosion managed nonsurgically. *Urology* 2015; 85: 252–6.
- Keihani S, Chandrapal JC, Peterson AC, Broghammer JA, Chertack N, et al. Outcomes of urethroplasty to treat urethral strictures arising from artificial urinary sphincter erosions and rates of subsequent device replacement. *Urology* 2017; 107: 239–45.
- Gross MS, Broghammer JA, Kaufman MR, Milam DF, Brant WO, et al. Urethral stricture outcomes after artificial urinary sphincter cuff erosion: results from a multicenter retrospective analysis. *Urology* 2017; 104: 198–203.
- Rozanski AT, Viers BR, Shakir NA, Pagliara TJ, Scott JM, et al. Is removal of the pressure-regulating balloon necessary after artificial urinary sphincter cuff erosion? *Urology* 2018; 113: 225–9.
- Bugeja S, Ivaz SL, Frost A, Andrich DE, Mundy AR. Urethral atrophy after implantation of an artificial urinary sphincter: fact or fiction? *BJU Int* 2016; 117: 669–76.
- Saffarian A, Walsh K, Walsh IK, Stone AR. Urethral atrophy after artificial urinary sphincter placement: is cuff downsizing effective? *J Urol* 2003; 169: 567–9.
- Brant WO, Erickson BA, Elliott SP, Powell C, Alsika N, et al. Risk factors for erosion of artificial urinary sphincters: a multicenter prospective study. *Urology* 2014; 84: 934–8.
- Guralnick ML, Miller E, Toh KL, Webster GD. Transcorporal artificial urinary sphincter cuff placement in cases requiring revision for erosion and urethral atrophy. *J Urol* 2002; 167: 2075–8.
- Aaronson DS, Elliott SP, McAninch JW. Transcorporal artificial urinary sphincter placement for incontinence in high-risk patients after treatment of prostate cancer. *Urology* 2008; 72: 825–7.
- Le Long EL, Rebibo JD, Nouhaud FX, Grise P. Transcorporal artificial urinary sphincter in radiated and non-radiated compromised urethra. assessment with a minimum 2 year follow-up. *Int Braz J Urol* 2016; 42: 494–500.
- Wiedemann L, Cornu JN, Haab E, Peyrat L, Beley S, et al. Transcorporal artificial urinary sphincter implantation as a salvage surgical procedure for challenging cases of male stress urinary incontinence: surgical technique and functional outcomes in a contemporary series. *BJU Int* 2013; 112: 1163–8.
- Lee D, Zafirakis H, Shapiro A, Westney OL. Intermediate outcomes after transcorporal placement of an artificial urinary sphincter. *Int J Urol* 2012; 19: 861–6.
- Vapnek M, Stone R. Proximal artificial sphincter cuff repositioning for urethral atrophy incontinence. *Urology* 1995; 45: 653–6.
- O'Connor RC, Lyon MB, Guralnick ML, Bales GT. Long-term follow-up of single versus double cuff artificial urinary sphincter insertion for the treatment of severe postprostatectomy stress urinary incontinence. *Urology* 2008; 71: 90–3.
- Magera JS, Elliott DS. Tandem transcorporal artificial urinary sphincter cuff salvage technique: surgical description and results. *J Urol* 2007; 177: 1015–20.
- Dimarco DS, Elliott DS. Tandem cuff artificial urinary sphincter as a salvage procedure following failed primary sphincter placement for the treatment of post-prostatectomy incontinence. *J Urol* 2003; 170: 1252–4.
- Linder BJ, Viers BR, Ziegelmann MJ, Rivera ME, Elliott DS. Artificial urinary sphincter revision for urethral atrophy: comparing single cuff downsizing and tandem cuff placement. *Int Braz J Urol* 2017; 43: 264–70.
- Wang R, McGuire EJ, He C, Faerber GJ, Latini JM. Long-term outcomes after primary failures of artificial urinary sphincter implantation. *Urology* 2012; 79: 922–8.

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