Review Article

Surgical strategies in artificial urinary sphincter revision surgery: troubleshooting the complications

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Abstract: Post-prostatectomy urinary incontinence (PPUI) is an important issue in the urological practice and imposes a negative effect on quality of life (QoL). Despite recent technological advances, PPUI remains a common complication and the artificial urinary sphincter (AUS) is regarded as the most effective long-term surgical treatment for moderate-to-severe stress urinary incontinence. Success rates for AUS as defined by a continence status of zero to one pad per day range from 59% to 90%. One potential downside of the AUS is the need for periodic revisions in a number of patients. Revision and explantation rates due to mechanical failure, urethral atrophy, infection and erosion vary considerably among studies with reports of 8–45% and 7–17%, respectively. These complications can be classified into different categories, including recurrent or refractory incontinence, erosion and/or infection, and other complications. This review article aims to describe the main AUS-related complications and their management strategies. Diagnostic work-up strategies are explored to facilitate timely identification and management of these complications. Additionally, emerging technologies and future directions in AUS development are discussed, highlighting potential advancements to mitigate complications and enhance device performance. This review consolidates current knowledge and provides insights for clinicians to manage the complexities associated with AUS therapy effectively.

Keywords: Post-prostatectomy; urinary incontinence; artificial urinary sphincter (AUS)

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Introduction

Post-prostatectomy urinary incontinence (PPUI) is an important issue in the urological practice and imposes a negative effect on quality of life (QoL). Carbonara *et al.*, in a meta-analysis, observed that urinary incontinence rates 12 months postoperatively were significantly lower after robotic radical prostatectomy (RARP) in comparison to laparoscopic radical prostatectomy (1).

Porpiglia *et al.* have reported urinary continence rates 12 months postoperatively of 95% and 83.3% in RARP versus laparoscopic radical prostatectomy group, respectively (2). The artificial urinary sphincter (AUS) is recognized as the most successful long-term surgical treatment for moderate-to-severe stress urine incontinence because, despite recent technological advancements PPUI remains a prevalent consequence. According to a continence

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status of 0 to 1 pad each day, defined like "social continence", success rates for AUS range from 59% to 90% (3). The requirement for routine revisions in a few patients is one potential drawback of the AUS.

Studies have reported revision and explantation rates of 8–45% and 7–17%, respectively, due to mechanical failure, urethral atrophy, infection, and erosion often associated with bladder dysfunction (4). These complications can be classified into different categories, including recurrent or refractory incontinence, erosion and/or infection, and other adverse events. From centers with fewer than 50 or more than 100 cases, comparable erosion/infection rates have been reported (5). Adherence to strict patient selection and safe surgical fundamentals are critical to afford clinical outcomes and minimize complications. Despite all the precautions taken, there remains a group of patients who are still at a higher risk of infection-erosion due to adverse status that alters the anatomy of the perineal area, reduces the host defense mechanisms, and enables the establishment of the infection-erosion complex. On the other hand, as experience with AUS has grown and the total number of cases performed at high volume centers (>20 cases in a year) has increased, the overall surgical revision rate has decreased (6).

Linder *et al.* studied 1,802 male patients that underwent AUS placement, 60% were primary implantations, with median follow-up of 4.1 years. Overall, 338 of 1,082 patients (31.2%) required additional surgery, including 89 for device infection and/or erosion, 131 for device malfunction, 89 for urethral atrophy, and 29 for problems related to the pump's location or the tubing. On multivariable analysis, there were no patient-related risk factors that were shown to be independently linked to a higher risk of secondary surgery. 90% at 1 year, 74% at 5 years, 57% at 10 years, and 41% at 15 years (7) were secondary surgery-free survival rates.

Materials and methods

PubMed, Embase, Lilacs (via BVS) and manual search were the sources of scientific information consulted in this study. Mesh terms used included: (Artificial Urinary Sphincter OR Artificial Urinary Sphincters OR Artificial Genitourinary Sphincter OR Artificial Genitourinary Sphincters OR Artificial sphincter OR AMS 800 OR AMS800); and manual search—reference within references, revisions and guidelines.

A deep dive on AUS-related complications

Recurrent incontinence after AUS implantation may be brought on by (I) altered bladder function, (II) urethral atrophy, or (III) mechanical issues with the device. These factors might coexist (3).

Bladder dysfunction

According to postoperative patient symptoms and the necessity for anticholinergic medication, Lai and Boone (8) reported that up to 23% of men who undergo AUS for PPUI can develop *de novo* overactive bladder (OAB) postoperatively.

Patients with neurogenic lower urinary tract dysfunction, particularly children, and individuals who have received radiation therapy, have altered bladder function (underactive or OAB) providing a greater risk of post-operative complications (9). Detrusor overactivity, a decline in bladder compliance, and the emergence of a high-pressure system are just a few of these alterations that can lead to incontinence, hydronephrosis, and ultimately renal failure.

UI after transurethral resection of the prostate (TURP) represents a large challenge, especially given findings that AUS complication rates are higher than in the general RP patients. Patients undergoing TURP may be at a higher risk of infection given baseline voiding dysfunction, history of indwelling catheters, higher post-void residuals, more previous urethral procedures, preexisting detrusor overactivity and older age (5).

Even patients with "unfavorable" urodynamic variables (OAB, underactive bladder, low complacence and low capacity), however, may exhibit positive outcomes with AUS insertion in the setting of PPUI (8,9).

Atrophy of the urethra

The cuff site may have urethral atrophy because of persistent mechanical compression of the periurethral and urethral tissues, with consent hypoxia. Between 3% and 9.3% of urethral atrophy cases result in revision (10,11). However, a study from a very experienced center argues that urethral atrophy does not occur, after reviewing 50 consecutive patients with recurrent incontinence (12). In 31 patients, a specific cause for malfunction of the AUS device was noted. In the other 19 patients, where no specific cause was found and 14 underwent device replacement (same size

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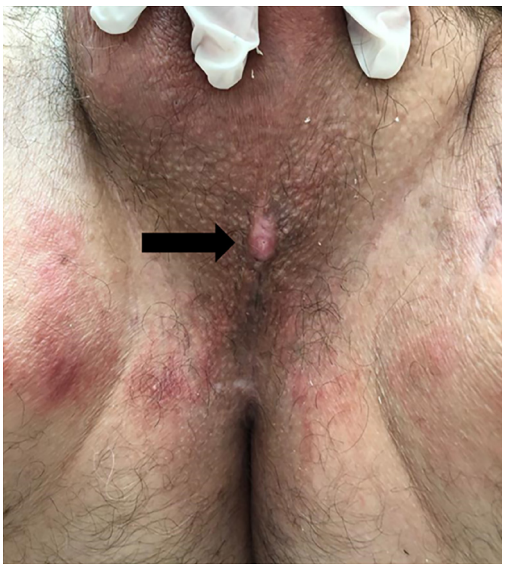

Figure 1 Incipient infection: perineal fistula (black arrow) and scrotal hyperemia.

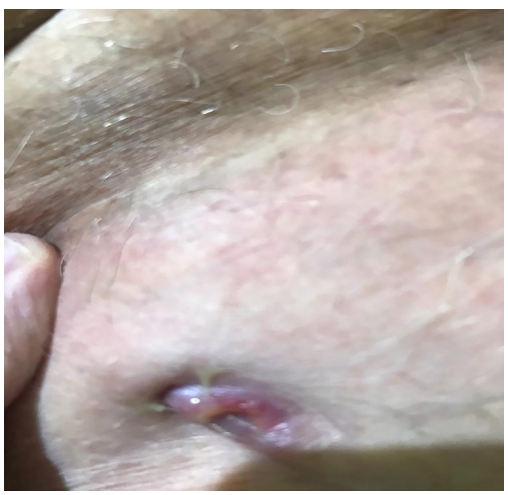

Figure 2 Perineal erosion.

cuff and pressure regulating balloon). Twelve out 14 patients were successfully treated without any cuff downsizing. The authors hypothesized that mechanical failure of the cuff or balloon could be the primary cause. Radiation therapy and advanced age were regarded as important risk factors for erosion in previous studies (3).

Mechanical failure

This includes the tubes being disconnected or kinked, air bubbles or organic waste impairing the pump's performance, one of the components becoming perforated and allowing fluid to leak from the system (13). "Kink-free" tubing has essentially done away with this last problem. With the longest follow-up, the incidence of these problems ranges from 0% to 52.5% (14). Following the pump failure (6 times in 4 patients), the cuff (22 cuff failures in 18 patients, most of them happening in the first 2 to 3 years after implantation) appeared to be the most susceptible component of the system in this later analysis. Blockage is a rare occurrence that only happened once in 61 individuals who were followed for 10 to 15 years (14). The fatigue of the material over the years with loss of pressure in the balloon must be considered, and it is good practice to exchange all its components in the event of a revision.

Infection and/or erosion

Two serious issues that nearly always require prosthesis removal are erosion and infection (*Figures 1*,*2*). In a review of 4,729 patients with up to 20 years of follow-up, diabetes, presence of radiotherapy, and absence of prior radical prostatectomy were identified as independent risk factors for infection (15).

These problems can occur anywhere from 0% and 24.6% of the time (3). The longest follow-up (10–15 years) has been associated with the highest incidence, as would be expected (16). According to Lai and colleagues from Baylor, erosion happened more frequently 19.8 months after surgery than during the perioperative period (17). Erosion risk is heightened if the cuff implantation site has previously undergone surgery. Delaying the cuff's activation, however, may lower this. Urinary catheterization and urethral endoscopic interventions with an active sphincter in place are additional risk factors. This aspect is critical, and patients with AUS must realize that if a catheter is to be inserted, they must first ask their doctor to have the AUS deactivated by a urologist. It is important that the patient knows that urethral catheterization should not be performed without deactivating the device and informs this to the emergency care or surgery team. A good strategy is

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to wear bracelets containing this information.

Erosion of the tubes may rarely occur, mainly in the scrotal or inguinal-scrotal area. This erosion may be related to infection of the system or very superficial passage of the tubes in the scrotum.

Unusual complications and 3.5 cuff considerations

The literature has documented a few strange and infrequent complications, including the intravesical migration of the reservoir with secondary stone formation in the bladder and the development of a massive urethral diverticulum at the site of a previously removed cuff due to erosion and urinary extravasation (18,19).

There is still a discussion regarding the use of 3.5 cuff. There are studies suggesting a higher risk of mechanical failure. But the main question is the increased risk of urethral erosion, especially in irradiated patients, with authors in favor and against this idea (20-22). If the idea is to avoid its use, a more proximal urethral location with a larger caliber can be sought. Another trick, in reoperations is incise the capsule urethral, to obtain a larger urethral caliber.

Diagnostic work-up

A difficult issue for the urologist is the diagnostic assessment of recurrent incontinence following AUS insertion, even though several strategies have been proposed to guide and standardize diagnosis (3).

A thorough clinical history and physical examination should rule out infection at the scrotal pump or cuff location. Compressing the pump with difficulty signals kinked tubes, fluid loss, or an obstruction in the system. The inability of the pump to properly refill after just one or two pumps may indicate a loss of fluid from the system (3). If the system is filled with a radiopaque solution, plain X-rays of the abdomen or pelvis might reveal fluid loss. In contrast, the pressure-regulating balloon's sonography may reveal volume decrease. After the initial implantation, when the reservoir is filled with contrast, one should get a baseline plain film for further comparisons because radiographic imaging of the balloon does not reveal changes until at least 50% of its volume has been lost (20). Urodynamics can show alterations in bladder function after the implantation of the AUS as previously mentioned. A urethral diverticulum may eventually be seen by cystourethrography where a cuff erosion has previously occurred. Any urethral erosion caused by the cuff will be revealed through endoscopy. Video-urodynamic is an exam that combines urodynamic exam and radiographic imaging, therefore if viable it represents the optimal method to diagnose AUS complications. Cystoscopy is very useful to evaluate trabeculations and bladder capacity, which can indirectly influence detrusor function, but mainly to evaluate urethral cuff coaptation and erosion. A proposed algorithm to assess patients with recurrent urinary incontinence following AUS implantation is presented in *Figure 3* (3,8,21).

Troubleshooting the complications

As mentioned above, there are three main types of problems that are directly linked to the existence of an artificial sphincter: *de novo* OAB (which is normally treated as OAB), urethral atrophy and/or mechanical failure, and infection/erosion.

Atrophy of the urethra

Prior descriptions of several therapeutic alternatives for treating this issue included decreasing the cuff diameter, adding more fluid to the device, or switching the balloon reservoir for one that produces a higher pressure (22). The most typical strategy is cuff down-size (3), and nocturnal cuff deactivation of urethral atrophy has been suggested (11).

An option is to use a transcorporal cuff, which is placed on the dorsal aspect of the urethra inside the corporal tunica albuginea or transalbugineal implantation technique preserving the integrity of the corpora cavernosa (23,24).

Double-cuff (tandem cuff) AMS 800 implantation has also been described as a primary procedure for individuals who are extremely incontinent (25) or as a salvage procedure after a failed single cuff (26,27). With the insertion of a second urethral cuff, positioned 1.5–2.0 cm distal to the first cuff, Dimarco *et al.* demonstrated outstanding outcomes (26). The longer-term continence of the 28 men who received double cuff placement was not different from that of the 28 men who underwent single cuff placement, according to O'Connor *et al.*'s experience with them (27). The rate of further surgery owing to problems was also higher in those who had the double cuff installation.

Mechanical failure

The AMS 800 AUS is subject to long-term failure, like any other mechanical device. The defective component

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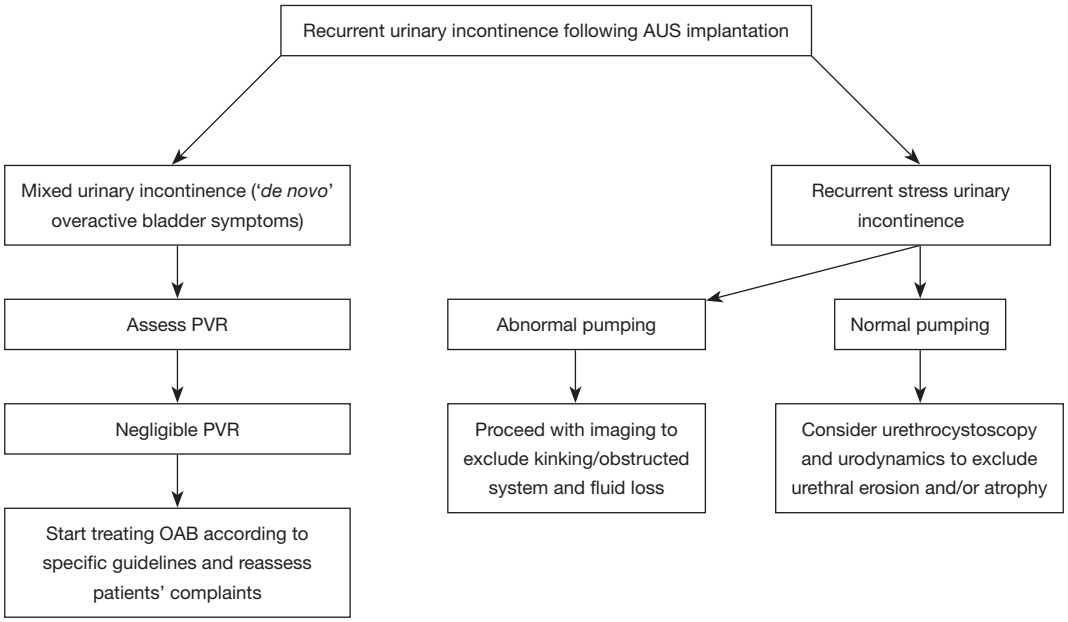

Figure 3 Algorithm for managing incontinence after artificial urinary sphincter placement. AUS, artificial urinary sphincter; PVR, post-void residual; OAB, overactive bladder.

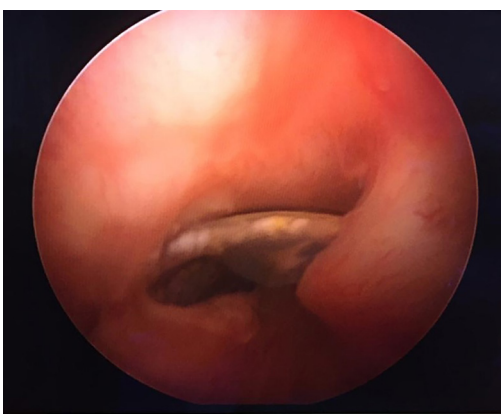

Figure 4 Urethroscopy demonstrating cuff erosion.

is surgically replaced as part of the treatment, and then the system is reconnected. There is a tendency for better outcomes if all components are replaced as opposed to just one, according to a recent Mayo Clinic study that looked back at outcomes following the repair of mechanical failures (7). In cases of suspected fluid loss as a cause of AUS malfunction, an ohmmeter can identify the site of fluid loss during component revision surgery, allowing the exchange of only the component with fluid loss (28). However, there is a natural fatigue of the sphincter material, and just be considered in devices implanted less than three years ago, and analyzing the risk of new problems in the other components in the future (27).

Infection

Removal of the entire device and the proper drugs are necessary for overt infection. After that, a second system can be implanted with comparable success (25). With an overall success rate of 87%, quick reimplantation (five days) of a new AUS after the removal of an infected but undamaged prosthesis has also been described as a viable approach, although being controversial (29). For high-risk patients, AMS released the InhibiZone-coated AUS (rifampin and minocycline hydrochloride coating) in 2007.

Erosion

In cases of urethral erosion, the cuff must be removed (3) (*Figures 4,5*). The amount of time from AUS implantation is the major factor in determining whether to remove the entire device or only the cuff (30,31). Erosion in the immediate postoperative period (less than 6 weeks) is probably the result of an undiagnosed urethral injury, and it should be managed by removing the cuff and preserving

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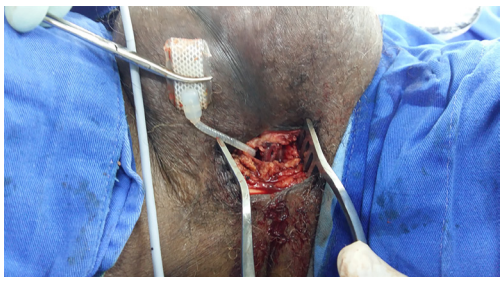

Figure 5 Cuff removal after urethral erosion.

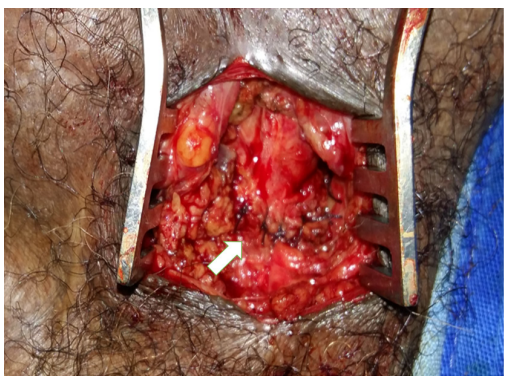

Figure 6 Primary urethral repair following cuff removal. The white arrow shows the final appearance of the urethroplasty and closed capsule after cuff removal.

the remaining AUS sections (in the absence of infection symptoms). Years after the procedure, erosions could lead to the removal of the entire device. Remove the entire system if in doubt.

Concerning concomitant urethral repair, controversial options have been previously reported. In patients with AUS cuff erosion treated with and without synchronous urethral repair, Rozanski *et al.* compared stricture outcomes (32) (*Figure 5*). In this retrospective case-series, two patient cohorts (in situ urethroplasty *vs.* Foley catheter only) were contrasted; 13 of the 26 documented cases of AUS cuff degradation received *in situ* urethroplasty, whereas 13 did not. With a mean follow-up of 24 months (range 8 to 69), patients were on average 73 years old (range 61 to 83). When compared to patients who received only Foley catheter treatment (11 of 13), the rate of urethral stricture formation after AUS explantation was considerably lower in patients treated with *in situ* urethroplasty (5 of 13, 38%) (P=0.047). When compared to patients with cuff erosion who only had Foley catheter treatment, patients treated with *in situ* urethroplasty had a significantly higher rate of subsequently requiring secondary AUS implantation [54% (7 of 13) *vs.* 15% (2 of 13), P=0.04].

To compare the intraoperative management strategies for AUS cuff erosion, including the insertion of a Foley catheter, urethral anastomosis (AU), and mobilization with primary urethral anastomosis (PUA) (*Figure 6*), Chertack *et al.* retrospectively evaluated the medical records of patients treated for AUS cuff erosion from 2005 to 2015 (33). AUS cuff erosion was treated in 75 patients, whose ages ranged from 72 to 83. Foley insertion, 8 abbreviated urethroplasty (AU), and 15 PUA were performed on 52 patients. Thirteen months were on average followed (0–106 months). The PUA group experienced severe erosions more frequently than Foley or AU [100% *vs.* 37% (P<0.001), 100% *vs.* 38% (P<0.001), respectively]. Foley treatment for severe erosions increased the likelihood that strictures would form (38% *vs.* 5%, P=0.009). In terms of the likelihood of reimplantation, there was no difference between PUA and Foley or AU [63% *vs.* 69% (P=0.748), 63% *vs.* 33% (P=0.438), respectively). The authors concluded that due to the increased risk of urethral problems, using a Foley catheter alone may not be the best course of treatment for severe or simultaneous cuff erosions. Such strategy imposes a higher risk of subsequent stricture formation after erosion. Patients presenting cuff erosions need a longer-term follow-up, including urethrocystoscopy, to provide a timely diagnosis of urethral strictures and potential urethroplasty subsequently.

A replacement cuff should be positioned far from the erosion location when it is installed. A double-cuff system that has one of its cuffs eroded into the urethra can be successfully converted into a single-cuff system by removing the eroded cuff. However, there is still a need for further studies to prove that this strategy is appropriate, especially in erosions that occur late, in which complete removal of the device is the most frequently used approach.

Emerging technologies and future directions

Studies are currently being conducted by Boston Scientific on a Bluetooth-activated version of the AMS 800 device (34). In addition to the convenience of a phone-controlled sphincter, this would also expand the potential patient population to those with limited dexterity or poor pinch strength, for whom the AMS 800 is not an option. In addition, competitors are currently pursuing trials of alternative devices to challenge the AMS 800™, with

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electromechanical devices consists of an adjustable urethral cuff adjusted by incontinence severity (35).

The addition of newer technologies will enhance the outcomes of these devices. The addition of newer concept surface treatment to further reduce infection and erosion risk is also a promise on the development horizon.

Conclusions

In conclusion, despite its status as the most effective long-term surgical treatment for moderate-to-severe stress urinary incontinence, the AUS is associated with significant challenges related to inherent complications such as mechanical failure, urethral atrophy, infection, and erosion. These issues require surgical revisions and can negatively impact the QoL of patients undergoing retreatment. As urological practice continues to advance, ongoing research and technological innovations are crucial to improving outcomes, minimizing complications, and enhancing patient satisfaction with AUS therapy. Efforts in refining surgical techniques, optimizing patient selection, and vigilant postoperative management will be pivotal in addressing these challenges and maximizing the benefits of AUS for individuals suffering from PPUI.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All clinical procedures described in this study were performed in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patients for the publication of this article and accompanying images.

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