Rev. Roum. Sci. Techn.– Électrotechn. et Énerg.
Vol. **71**, *1*, pp. 169–172, Bucarest, 2026

PRACTICAL ASPECTS OF THE ARTIFICIAL URINARY SPHINCTER IN MEN

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Keywords: Artificial urinary sphincter; Intrinsic sphincteric deficiency; Urinary incontinence; Post-prostatectomy incontinence.

The artificial urinary sphincter (AUS) remains the gold standard in moderate to severe urinary incontinence after prostatic surgery. Building on the authors' significant personal experience in the field, we aim to review the current indications, limitations, and challenges associated with the implantation of an AUS. We present different surgical approaches and pre- and postoperative considerations.

1. INTRODUCTION

The most effective treatment for male patients with urethral dysfunction or sphincter-related urinary incontinence whose bladder function is normal in terms of compliance and contractility is the artificial urinary sphincter (AUS). The European Association of Urology (EAU) and the International Continence Society (ICS) both offer recommendations about the use of artificial sphincters for incontinence following prostatectomy surgery or in other situations where conservative treatment is not effective [1].

Starting from our own experience with the AUS, we aim to summarize the everyday challenges that urologists encounter when offering this device to patients.

2. MAIN INDICATIONS FOR THE AUS

An analysis of the indications to implant an artificial urinary sphincter was performed by the authors and published in a previous paper named “The artificial urinary sphincter for the treatment of intrinsic sphincteric deficiency urinary incontinence”.

The most recent evolution on the market of artificial urinary sphincters changes the classic reservoir with an “active” one, which promises to be able to instantly react to any increase in abdominal pressure by increasing the pressure in the occlusive cuff. ([1], Fig. 2). The process is purely mechanical; no electronics are required [2]. The main advantage is that the pressure inside the cuff is kept low, significantly reducing the risk for urethral erosion. When the patient coughs or exercises any other kind of effort, the reservoir reacts, increasing the pressure inside the cuff, only for the duration of the effort. Then, the pressure comes back to baseline. Thus, the risky high pressure inside the cuff only lasts for seconds, instead of being permanent [3].

The device's relatively simple mechanics promise durability, as any revision, repair, or replacement means another surgical intervention for the patient, with all the discomfort that entails. This aspect is extremely important, since the case of human implants requires a deep understanding of what a warranty means. The producer covers the device for failures and malfunctions, but the “customer” must undergo a surgical procedure to benefit from the warranty.

3. THE ARTIFICIAL URINARY SPHINCTER

The two main competitors on the AUS market are the AMS 800 Urinary Control System (Boston Scientific, Marlborough, MA, USA) and Rigicon Conti Classic (Rigicon, NY, USA). There are other manufacturers offering similar devices, but neither of them is able to offer any significant improvement in terms of efficacy or safety [4]. Any AUS will include an occlusive cuff (the sphincter itself), the reservoir which holds the fluid, and the pump needed to use the device ([1], Fig. 3).

Urinary continence is achieved mechanically by modern devices. It consists of three primary parts: a reservoir for the fluid, a pump, and an inflatable, adjustable urethral cuff. Saline may be moved between components thanks to the tube system connecting the three pieces. The bulbar urethra in males and the bladder neck in women and children are the usual locations for the cuff placement. To provide simple access to the deactivation button, the pump is positioned just above the surface in the major labia or scrotum. When the cuff is inflated (default state of the device) it mimics the natural sphincter offering urinary continence. The saline or contrast medium is pushed from the cuff into the reservoir via a unidirectional valve after the pump has been pressed. Voiding is possible whenever the patient is comfortable, thanks to the deflated cuff. By using the deactivation button, the patient or the doctor can maintain the cuff deflated to promote healing following surgery, prevent damage during catheterization, or perform transurethral surgery [5, 6].

The ContiReflex® (Rigicon, New York, USA) is the newest device on the market. It boasts a novel, proprietary pressure-regulating balloon design that can detect changes in intra-abdominal pressure and instantaneously adjust the pressure inside the cuff. Given that the pressure inside the cuff remains low except for brief intervals when intra-abdominal pressure rises, and the sphincter reacts, the manufacturer claims that this adaptivity will result in improved continence and a decreased risk of erosion [7].

4. PREOPERATIVE ASSESSMENT

An important step towards the procedure should be the physical exam, the medical history of the patient, and some additional diagnostic procedures. Urinalysis and urine cultures confirm that the urine is sterile. The entire urinary tract is assessed by imaging, ideally with contrast medium to

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DOI: 10.59277/RRST-EE.2026.1.27

evaluate function. Finally, the (video)urodynamic exam and urethrocystoscopy should confirm the sphincter deficiency, offer information regarding the detrusor activity, and identify any anatomic, tissular, or vascular anomalies that could lead to complications. When important vesicoureteral reflux, bladder neck, or urethral strictures are diagnosed, they should be resolved preferably prior to surgery. At the end of the investigation protocol, the diagnosis of stress urinary incontinence due to intrinsic sphincteric deficiency should be clear; there is no correct indication for the implantation of the AUS.

In some cases, urodynamics will identify an overactive detrusor as well, which further aggravates the symptoms of the patient. While this is not a contraindication for the implant, it is recommended to treat detrusor overactivity before the surgery and assess the results of the treatment. There is enough evidence in the literature to state that detrusor overactivity becomes more serious after the sphincter is implanted, and it will also be harder to treat [5].

Patients who underwent radical prostatectomy are advised to postpone the implantation of the artificial sphincter for about 6 months, considered an acceptable time frame to regain continence. Moreover, for these patients, the possibility of needing adjuvant radiation therapy should be taken into consideration. The decision is usually taken early after surgery, so time frames don't overlap, but the urologist must consider the higher risks for adverse events and the urinary continence deterioration that may arise after radiation. Previous radiotherapy, however, is not associated with a higher risk of revision or removal of the implant. Recent data suggest that the implantation of an AUS should not be unnecessarily postponed, as it only keeps the patient unhappy. Early implantation is advocated if no other treatments are being done [8,9]. Niranjan et al. and colleagues followed up 77 patients undergoing AUS implantation for SUI after RP, including 29 irradiated patients. After a mean period of 21.2 months, they concluded that in both irradiated and non-irradiated patients, the rate of social continence (0–1 pads/day) was 87% (86.2 *vs.* 87.5%). Infection (3.4 *vs.* 0%), erosion (3.4 *vs.* 2.0%), and revision surgery (10.3 *vs.* 12.5%) rates also did not differ substantially between the groups. Given that co-existing urethral stricture disease is more common in patients with prior irradiation, the complexity of treatment may be increased; however, these patients are still able to achieve a level of social continence comparable to that of non-irradiated patients, with no apparent increase in complication rates. Urethrocystoscopy is indicated before surgery to evaluate the status of the urethra, bladder neck, and urethral anastomosis if prostatectomy was performed [8]. Urethral atrophy may develop after this treatment, rendering the device less effective, and the patient should be informed upfront about this potential risk. Since this is not an erosion, replacing the cuff with a smaller one restores continence, and both the explantation and insertion of the new cuff are usually done during the same procedure.

This treatment should not be offered to individuals with chronic or untreatable urinary tract infection, bladder outlet obstruction that cannot be treated, urethral stricture, or urethral diverticulum at the implantation area, bladder neck sclerosis, or individuals whose urethra cannot easily accommodate a 14 Ch catheter after healed urethral surgery.

A very important aspect is the performance status of the patient (ECOG). Values of 0 and 1 are ideal and any other value should lead to reevaluation of the strategy for treating incontinence.

5. SURGICAL TECHNIQUE

Prophylactic antibiotics should be administered up to 60 minutes before incisions are made (Grade of recommendation A, ICS). The American Urological Association advises on the use of Aminoglycoside, 1st or 2nd generation Cephalosporin, or Vancomycin, noting that the risk of prolonged antibiotic courses and of the use of vancomycin is higher than the risk of short-course first-generation cephalosporins [10, 11].

Hair removal, careful skin preparation, and sterile urine confirmed by urinary testing lower the risk of perioperative infection and complications. Chlorhexidine-alcohol solutions are preferred to povidone-iodine (Grade of recommendation A, ICS), with additional care to its flammable characteristics. If iodine is to be used, a pre-operatively 5-day hygiene routine with 4% chlorhexidine on the abdominal and perineal skin can be recommended. Most authors recommend that hair removal be done in the operating room, considering that if this maneuver is done at home or in the treatment room, the risk of infection increases because of the small lesions of the skin, which are inevitable. In a prospective cohort study, Magera *et al.* compared 50 men who utilized their regular hygiene (soap and water) with 50 men who underwent preoperative topical antimicrobial scrubs with 4% chlorhexidine to the abdominal site and perineal site prior to AUS implantation. A 4-fold decrease in preoperative perineal colonization rate and a general decrease in positive surgery site cultures were the results of preoperative topical antimicrobial scrub [12].

The patient can be placed either in lithotomy or in the supine position. There has also been described a supine position with slight abduction of the legs. A 14 Ch Folley catheter is used for continuous bladder emptying and to better visualize the urethra. The incision is classically done at the perineal level, with good exposure of the urethra and comfortable dissection of the deeper tissues. The transscrotal incision could be used in individuals or when serious scarring and fibrosis are expected in the perineal area (Grade of recommendation D, ICS).

Careful, sharp dissection ensures urethral integrity (Fig. 3). Because of more difficult access to the posterior side of the urethra, special attention should be given to its dissection from the corpora cavernosa. In case of accidental injury, absorbable sutures should be used; large defects require that the catheter stay in place and the procedure be abandoned. Most authors consider that a lesion of the urethra is more serious than an injury of the corpora.

Once the bulbar urethra has been exposed, the length of the cuff can be assessed. The manufacturer provides a device, referred to as a sizer, which measures the outer circumference of the urethra after dissection. It usually is 4.0…4.5 cm, but it should be carefully assessed during the procedure and reassessed in case of revision or replacement surgery [13]. The standard technique involves placing the cuff periurethrally (Fig. 4), but variations include transcorporeal implantation in men with urethral damage and who no longer wish to maintain erectile function (Grade of recommendation D, ICS). One paper in the literature

suggests that the cuff might be placed around the prostate, in patients with incontinence after TURP [13].

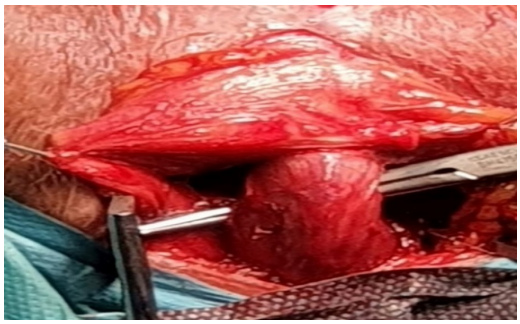

Fig. 3 – Dissection and exposure of the urethra.

The reservoir should be placed intra-abdominally through an inguinal second incision, in the retro-pubic space; newer techniques recommend the space between the abdominal muscles and the transversalis fascia. It should be filled with sterile saline or contrast medium. The pump is superficially placed in the scrotum to be accessible for maneuvering.

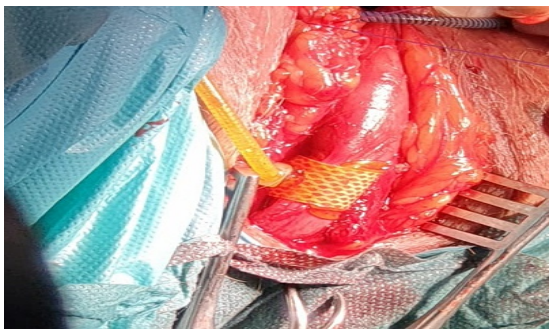

Fig. 4 – Occlusive cuff placed around the urethra**.**

Another technique for implantation has been described that involves a single penoscrotal incision. Its advantages are a shorter operating time (an average of 35 minutes) and a lower risk of infection while achieving continence rates like the perineal approach [14]. Jamaer *et. al*. conducted a retrospective review that included 40 patients with an AUS inserted via a penoscrotal incision. They concluded that AUS implantation via a single penoscrotal approach has several benefits and is not inferior to the perineal technique. While the results for continence are identical for both methods, the operating time is shorter, and there is only one incision required, both of which lower the risk of infections [15]. Nonetheless, some studies suggest the penoscrotal approach is an independent risk factor for increased short-term explanation rates [16]. By the end of the intervention, careful testing of the device should be carried out, as this is the last time the surgeon can correct any dysfunctionalities without performing another surgery.

6. **POSTOPERATIVE CONSIDERATIONS**

After a successful surgery, the device should be deactivated for 4-6 weeks. During this time, the urethra should be healing with no external pressure from the cuff. The patients are advised to avoid strenuous activity, horseback riding, motorcycle riding, constipation, sexual intercourse, or any other activity that increases intra-abdominal pressure.

Analgesics should be prescribed for pain, and ice packs should be applied to the labia or scrotum to prevent hematomas and painful edema. There is no consensus regarding antibiotic treatment after the procedure. Studies show that antimicrobial prophylaxis should be started 60 minutes prior to surgery and discontinued within 24 hours after the end of the surgery [17].

The urinary catheter should be removed as early as 24 hours after surgery. Casey *et. al.* evaluated 200 patients who underwent an AUS implantation. 44 patients had prolonged urethral catheterization (> 48 h)-of these men, erosions occurred in 17 (39%, p <.001). They concluded that catheterization for more than 48 hours after the procedure is an independent risk factor for cuff erosion [18]. If spontaneous micturition is delayed, the patient should use clean intermittent self-catheterization to void the bladder. If catheterization is needed for longer periods, a suprapubic catheter could be considered. Once the edema reduces, spontaneous voiding and incontinence will return until the device is activated. If this does not happen, the cuff size was probably too small, and revision surgery should be considered.

After 6 weeks, the device can be activated. The patient should prove a good understanding of device use and dexterity. The surgeon should provide a leaflet with the deactivation technique in case catheterization is needed, and the patient is not able to do it himself or is unconscious, to prevent urethral trauma. The long-term recommendation of using small urethral catheters (<14 Ch) for short periods decreases the risk of cuff erosion, urethral trauma, and device damage.

7. **COMPLICATIONS**

Intraoperative complications depend on the surgical approach and are a common risk to any surgical procedure. Due to its high risk of infection, rectal perforations must be sutured and the procedure abandoned. In men, cuff repositioning might be considered. Small, accessible urethral injuries can be sutured with 4.0–5.0 absorbable sutures, and the cuff can be repositioned; extensive injury requires suture, continuous urinary drainage, and deferral of surgery until healing. Urinary bladder perforation is resolved with a 2-layer suture and repositioning of the reservoir on the opposite side. Bladder neck perforation requires 3-0 or 4-0 resorbable sutures, but the device can only be activated in 3 months.

Scrotal hematomas are minor complications, but uncomfortable for the patient. They usually resolve on their own, using only topically applied ice. Large hematomas may require drainage. Any hematoma comes with the risk for infection so antibiotic treatment should be considered.

Due to periurethral edema, early urinary retention may require clean intermittent catheterization. Small catheters should be used, and the cuff must always be deflated. In case of prolonged need for catheterization, suprapubic catheters should be considered.

The most dangerous outcome is infection since it may necessitate the removal of the device. Methicillin-resistant S. aureus, Staphylococcus aureus, and Staphylococcus epidermidis are the typical bacteria involved [19]. These gram-negative organisms should be targeted by specific antibiotics. The device can be changed three months after the infection has been treated.

It has been estimated that the mechanical failure rate is 5.6 – 29%. To find the location of the mechanical failure and replace the problematic part, the system might be filled with

contrast medium. If a revision surgery is planned for a device that is more than three years old, it is recommended to replace the entire device.

Up to 37% of mechanical sphincter implantations require revision at some point in their lifespan. Tissue atrophy, infection, cuff erosion, mechanical problems, or an increase in incontinence are the key warning signs [19].

8. **CONCLUSIONS**

There are very few treatment options available for men with post-prostatectomy incontinence. The gold standard therapy is the AUS, and it is also one of the few alternatives that has shown long-term efficacy.

The first step towards patient satisfaction comes from a comprehensive discussion regarding all complications that may appear prior to surgery.

The surgical approach and the surgeon's experience play a crucial role in postoperative success rates. Candidates for AUS implantation should be referred to high-volume centers to obtain the best results.

CREDIT AUTORSHIP CONTRIBUTION STATEMENT

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Received on 2 October 2024

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