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THE ARTIFICIAL URINARY SPHINCTER FOR THE TREATMENT OF URINARY INCONTINENCE

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The artificial urinary sphincter (AUS) imposed itself as the most effective treatment for urinary incontinence after surgery of the prostate. Along with the technological development and improvement of the device over time, more indications have emerged, most of which are not yet considered mainstream but provide an alternative in the armamentarium of the modern urologist. The artificial urinary sphincter was first introduced in 1974 and has undergone significant evolution since then, with several manufacturers currently active in this market. This treatment is effective and safe, although some potential complications may still occur and need to be understood and accepted by the patient. Considering that there is no other therapeutic option comparable in terms of efficacy, the artificial urinary sphincter deserves its place as the gold standard treatment for post-prostatectomy incontinence in males. We conclude that the AUS brought significant improvement in the health-related quality of life for most men with incontinence after prostatic surgery; however, there is still a need for further development of the device, as the complication rate remains high, despite a noticeable improvement over the decades.

1. INTRODUCTION

Urinary incontinence, regardless of the causes or mechanisms behind it, has a tremendous negative impact on the patient, although the condition itself is not life-threatening or otherwise dangerous.

The artificial urinary sphincter (AUS) is the gold standard treatment for male patients with urinary incontinence due to sphincter or urethral dysfunction, and whose bladder function is normal in terms of compliance and contractility. Both The International Continence Society (ICS) and The European Association of Urology (EAU) advise recommending the artificial sphincter in post-prostatectomy surgery incontinence or, in other cases, when the conservative treatment fails [1].

Our paper aims to review the devices available on the market, the clinical evidence behind them, and the potential complications and limits of this technique. We conducted a narrative review, including the brochures of the manufacturers, intending to obtain a current state-of-the-art perspective on the status of this treatment.

2. MATERIALS AND METHODS

In this narrative review, we conducted a PubMed, EMBASE, and MEDLINE search from the beginning of 2002 until the end of March 2023 using the following search terms: “artificial urinary sphincter” AND “urinary incontinence” AND “intrinsic sphincter deficiency”. The title and abstract were the subject of the literature search. We also looked for any other pertinent sources in the reference section of each of the papers we gathered. We only considered articles written in English and with a full text available. The documents found in the first step were then thoroughly assessed, including the manuscript and appendices. Papers that did not meet the inclusion criteria or were not primarily analyzing the AUS were excluded. Additionally removed were duplicates, publications lacking original data, incomplete studies, and papers with ambiguous results. The description of the research selection procedure and the total number of entries located in each database are summarized in Figure 1.

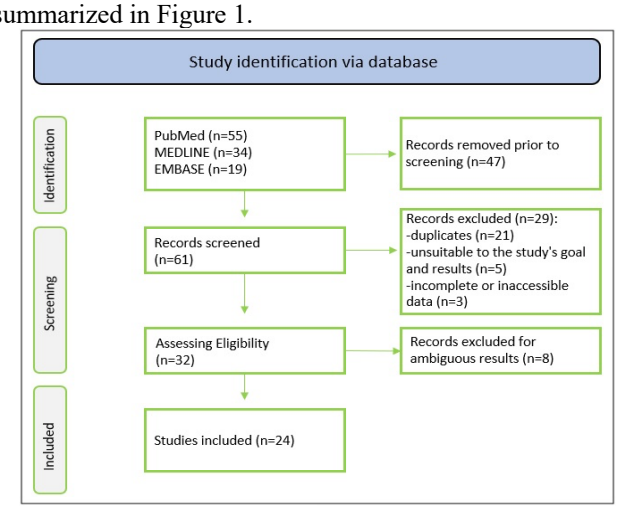

Fig. 1 – A visual representation of the selection procedure for studies.

3. MAIN INDICATIONS

The AUS is theoretically indicated in all cases of stress urinary incontinence, especially if intrinsic sphincteric deficiency is confirmed as the underlying mechanism. The last decades brought significant overall experience with the use of this type of implant, so the primary indication was “refined” to post-prostatectomy incontinence in males. While this emerged as the only indication accepted by regulatory authorities, there is still some use for the AUS in patients with incontinent neurogenic bladders, females with urethral hypermobility and intrinsic sphincteric deficiency, or even children. In cases of coexisting dysfunctions, such as detrusor overactivity, the urologist should ensure that these are manageable and should be treated before the patient undergoes the intervention. Detrusor overactivity is not a contraindication but treating it after the procedure might prove challenging. Patients may continue to have persistent overactive bladder symptoms despite a marked improvement in continence. Even in patients with pure stress incontinence, up to 23% of them will develop *de novo* overactive bladder following AUS implantation. A possible predictor identified

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was a bladder capacity of 200 cc or less [1].

Table 1

Studies assessing the correlation between preoperative urodynamic and AUS implantation outcomes

Study	Study Population	Outcome
Thiel et al., 2007 [2].	86 patients with AUS placed for radical prostatectomy (RP) incontinence	No clinical or urodynamic characteristic that would rule out the implantation of an AUS for post-RP incontinence was discovered.
Trigo et al., 2008 [3].	40 patients with AUS placed for RP incontinence	Preoperative findings like detrusor hyperactivity (DH), impaired detrusor contraction (IDC), low Valsalva leak point pressure, bladder outlet obstruction (BOO), and mild RBC were not associated with worse surgical outcomes.

As Table 1 shows, clinical and urodynamic findings such as detrusor overactivity, low pressure at first voiding sensation, decreased bladder compliance, low bladder capacity, detrusor hyperactivity, impaired detrusor contraction, low Valsalva leak point pressure, or bladder outlet obstruction are not associated with worse surgical outcomes after implantation of the artificial urinary sphincter [2,3].

4. **PATIENT SELECTION**

Most of the candidates are men who underwent radical prostatectomy and experience moderate to severe urinary incontinence. In some cases, urinary incontinence develops as an unfortunate outcome after transurethral resection of the prostate (TURP) for bladder outlet obstruction (BOO). A rather trim, but expanding category is that of female patients, who usually have a history of pelvic surgery (such as radical hysterectomy, procedures for treating incontinence, or surgery aiming directly at the bladder neck or the urethra), or who develop urethral sphincter deficiency due to aging and low levels of estrogen.

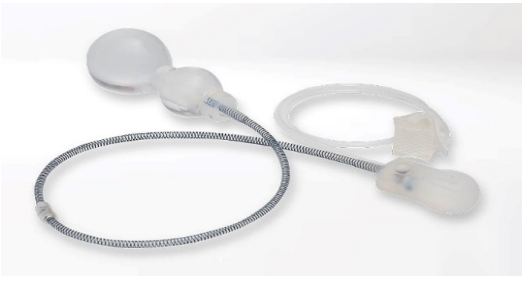

Fig. 2 – Modern Artificial Urinary Sphincter with three components – occlusive cuff, pump, and pressure regulating balloon.

While the American Food and Drug Administration disapproves of the implantation of the artificial urinary sphincter in women, it is used off-label and accounted for 1% of the total annual sphincter implantations in 2005 [4]. The pediatric population is an expanding indication for the implantation of an AUS, with specific limits, challenges, and debates. This includes the need for smaller devices, the requirement to change the device as the patient grows in age and size, and also the patient's ability to understand the voiding sensations and the proper way to use the sphincter (Fig. 2).

5. **THE DEVICE**

The market for artificial urinary sphincters has been developing since 1972, when the first sphincter, like the current ones, appeared. Today, it is dominated by the AMS 800 Urinary Control System (Boston Scientific, Marlborough, MA, USA) and the Rigicon Conti Classic (Rigicon, NY, USA), which have been used to treat several hundred thousand patients to date, according to the manufacturers. There are other manufacturers active on this market, offering similar devices.

The first theoretical model of the AUS was developed by Foley in 1947, although the technological development and conditions of the time were insufficient to produce and implant the device.

The first device used in humans was developed by the American Medical Systems company (AMS) in 1972 and consisted of four parts: a cuff, a reservoir, and two pumps. One pump was used to inflate the device, while the other was used to deflate it. The primary limitations of this device were frequent mechanical failures and the gradual loss of pressure within the tubing over time.

Two years later, in 1974, AMS introduced an improved device, featuring a pressure-regulating balloon that allowed for the automatic closure of the sphincter after approximately one minute, rendering the second pump unnecessary. This principle remains the norm for most devices available on the market today.

The next major leap in the development of the actual device occurred in 1982 with the introduction of the deactivation button, which reduced the rate of urethral erosion and provided additional safety for the patient during transurethral catheterization. All components were made of silicone, and the cuff was redesigned to reduce the risk of erosion.

The contemporary device achieves urinary continence through mechanical means. It consists of three main components – an inflatable, customizable urethral cuff, a pump, and a pressure-balloon reservoir. All three parts are linked through a system that allows saline to be displaced between components (Fig. 3). The customizable elements include the reservoir, which can exert pressures ranging from 51 to 80 cm H2O, and the occlusive cuff size, with lengths ranging from 3.5 cm to 11 cm. The cuff is usually placed on the bulbar urethra in men and at the bladder neck in women and children. Still, occasionally, the bladder neck site is also chosen for young men and men who perform frequent catheterizations. The pump is placed superficially in the scrotum or the major labia so that it can ensure easy access to the deactivation button. The default state occurs when the cuff is inflated, mimicking a natural sphincter around the urethra and thereby achieving urinary continence. Once activated by squeezing the pump, the saline or contrast medium is being displaced from the cuff through a unidirectional valve directly into the reservoir. The deflated cuff allows the patient to void at their convenience. Over the next few minutes, the liquid is slowly returned to the cuff

through the pressure-regulating balloon, and continence is restored. The deactivation button enables the physician or patient to keep the cuff deflated for healing after surgery or to prevent injury during catheterization or transurethral surgery.

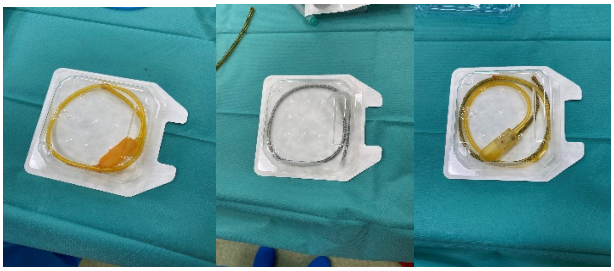

Fig. 3 – The main components of the AUS: occlusive cuff, pump with deactivation button, and pressure-regulating balloon.

A newer feature of the AMS implant is InhibiZone®, a combination of antibiotics designed to reduce the risk of infection. The main components of the device are coated with rifampicin and minocycline to minimize the risk of perioperative infection. The treatment is slowly released and is active against the most common germs associated with infection. There is conflicting data in the literature, with some authors advocating for the use of InhibiZone based on a significant series of patients in which peri- and postoperative infection rates were reduced by a statistically significant percentage. Some studies show no significant impact on infection or explantation rates compared to devices without InhibiZone [5,6].

Rigicon offers a distinct approach, featuring a hydrophilic coating on all components, tubing, and connectors. This allows surgeons to select their antibiotic mix and submerge the implant in that solution just before insertion. There is no solid data in the literature to support their approach, as this concept is relatively new. The slippery surface of this implant facilitates easier surgical insertion, as stated in the manufacturer's brochure [7–10].

The newest device on the market is the ContiReflex® (Rigicon, New York, USA) which features a proprietary new design of the pressure regulating balloon which promises to sense changes in the intraabdominal pressure and instantly modify the pressure inside the cuff (Fig. 4). Because of this adaptivity, the manufacturer promises better continence and lower erosion risk, given that the pressure inside the cuff stays low except for short periods when intraabdominal pressure increases and the sphincter reacts [7,11,12,13].

Table 2.

Studies assessing InhibiZone® antibiotic coating for AMS 800®.

Study	Study Population	Outcomes
Hüsch et al., 2017 [5]	305 patients with AMS 800® device 47 patients with InhibiZone® 258 without InhibiZone®	Neither the infection rate (p=0.534) nor the explantation rate (p=0.214) were significantly impacted by the InhibiZone® covering. Estimated infection-free survival did not significantly differ across groups (p=0.265).
de Cógáin et al., 2013 [6]	426 patients with AMS 800® device 213 patients with InhibiZone® 213 without InhibiZone®	With the antibiotic coated device, infection occurred in 2 of 50 patients (5%) and in 3 of 38 patients (6%) with the uncoated device (p=0.42). The artificial urinary sphincters' InhibiZone® covering had no effect on the rate of infection.

Fig. 4 – The proprietary novel reservoir by Rigicon.

6. **RESULTS**

A follow-up with a median duration of 15 years showed that out of 57 patients who received the artificial sphincter for stress urinary incontinence after prostate surgery, 43.8% still had their initial device implanted. Survival rates of the device without explanation were 87%, 87%, 80%, and 80% at 5, 10, 15, and 20 years. Survival rates of the device without revision were 59%, 28%, 15%, and 5% at 5, 10, 15, and 20 years. Explanation occurred in 9 cases – 7 because of erosion and two because of infection. At the end of the follow-up, 77.2% of the patients were continent [14-19].

An extensive retrospective study conducted in 16 centers in Europe and the USA assessed the efficacy and safety of artificial urinary sphincter implantation in 892 men with stress urinary incontinence after prostate surgery. At a mean follow-up of 32 months, the dry rate was 58%, while the revision rate was 30.7% [20].

The analysis of medical records from 155 patients who underwent artificial sphincter surgery, with a median follow-up of 45.1 months, revealed rates of 63.2% total continence and 84.5% social continence (defined as using ≤1 pad per day) at the last follow-up. Social continence at previous follow-up was higher in patients without reoperation (92.1%) than in patients who underwent revision of the implant (62.5%). The 5-year survival rate of the device without reoperation was 67%. Reoperation rate was 26.4% [21].

A study that followed 84 patients for a mean time of 39 months showed that 38.5% of patients were dehydrated, 42.2% were socially continent (using one pad per day), and 19.3% required two or more pads per day. The rates of revision, infection, and erosion were 13.25%, 2.4%, and 1.2%, respectively [22].

While a significant amount of data is available nowadays, the results are not fully comparable for several reasons. First, several devices are available on the market, and this induces differences in the results. Second, the definition of success ranges from complete continence to mild social continence, so again, we are not looking at comparable data. Third, some studies originate from highly specialized centers, while less experienced surgeons conduct others. The most crucial bias remains the difference between the patients included in the conditions, which led to incontinence, adjuvant treatments, and other factors.

Table 3

Studies assessing AUS implantation.

Study	Study Population	Follow-Up	Outcomes
Léon et al., 2015 [19]	57 patients	15 years	25 patients (43.8%) still had their primary AUS. The AUS was explanted in 9 patients- erosion (7) and infection (2). Survival rates, without AUS explantation, were 87%, 87% and 80% at 5, 10 and 15 years.
Tutolo et al., 2018 [20]	892 patients	mean 32 months	Overall dry rate was 58%. Surgical revision rate was 30,6%. Complications were reported in 248 patients(27,8%)- 60 (6,7%) erosion, 38 (4,2%) infection, 32 (3,5%) urethral atrophy and 118 (13,2%) mechanical failure.
Suh et al., 2017 [21]	155 patients	mean 45.1 months	98 patients (63,2%) achieved total continence. 131 patients (84,5%) achieved social continence (1pad/day). The rate of reoperation of AUS was 26,4%. Non-mechanical failure was a dominant etiology for reoperation (70,7%).
Serag et al., 2018 [22]	84 patients	mean 39 months	32 patients (38,5%) declared total continence. 35 patients (42,2%) achieved social continence (1pad/day). Reoperation rate was 13,25% (11 patients) including 9 mechanical failures (10,8%).

As with most surgical techniques, it is tough to perform prospective, randomized trials. There is no active comparator for the AUS; the devices are in a process of continuous evolution, and the indication for this treatment still seems to be variable between medical centers and countries. The 2019 European Association of Urology Guidelines mention a relatively low level of evidence regarding the effectiveness of the AUS for treating stress incontinence in men, associating it with a weak recommendation level. The current guidelines (2023), based on the most recent evidence available, have shifted to the strongest recommendation level, supported by an outstanding level of evidence [3]. This aligns with ongoing research in the field and the increasing number of patients who receive this treatment annually.

7. COMPLICATIONS

Short-term complications include intraoperative complications, hematoma, urinary retention, infection, and short-term explantation. Long-term complications are typically caused by mechanical failure, tissue atrophy, or cuff erosion.

Infection is the most serious complication because it can lead to device removal. The germs usually involved are Staphylococcus aureus, Staphylococcus epidermidis, and Methicillin-resistant S. aureus [23]. Antibiotics should target these germs as well as gram-negative organisms; three months after the infection has been treated, the device can be replaced. Infection is usually linked to cuff erosion. Infection rates vary between 0.47 and 7% as reported in Drogo K. literature review of AUS implantation [24].

Table 4

Studies assessing complications in primary AUS implantation patients vs. patients with revision/secondary implantation.

Study	Study Population	Outcomes
Lai et al., 2012 [29]	169 primary AUS implantation 37 revision cases 21 secondary reimplantation cases	Future erosion rates were four times greater in secondary artificial urinary sphincter reimplant cases (e.g., following explantation due to urethral erosion or infection) than in primary cases (p = 0.02, 14.3% vs. 3.6%, RR = 4.02). Revision cases of artificial urinary sphincters did not result in worse postoperative continence results, greater rates of complications (including recurrent urethral erosion), or reoperation rates compared to primary implantation.
Linder et al., 2013 [30]	497 primary AUS implantation 138 revision cases 69 secondary reimplantation cases	Reimplantation after erosion or infection resulted in a higher rate of patients needing recurrent explantation than primary implantation patients. (13 of 69 or 19% vs. 32 of 497 or 6.4%, p 0.001).
Raj et al., 2005 [31]	554 patients with AUS implantation 435 only primary AUS implantation 119 patients (21,4%) underwent secondary procedures	79,4% of primary AUS implantation showed a 5-year durability. Patients who underwent revision surgery had a 5-year durability rate of 88%. In the 119 patients who underwent secondary AUS implantation, 31 (25.2%) experienced mechanical failure, and 88 (73.9%) non-mechanical failures (urethral subcuff atrophy was the most common - 63 cases).

Erosion may arise due to repeated catheterizations without proper deflation of the cuff or due to cuff compression over the urethra. Erosion presents with pain, bloody discharge, and recurrent incontinence. In most cases, erosion involves the ventral and lateral sides of the urethra, but cases of complete circumferential erosion and rupture of the urethra are also seen. Cuff removal is needed, and replacement is advised only after the urethral injury has healed. Tissue atrophy should be considered when addressing insidious new urinary incontinence, characterized by expected inflation and deflation, but with a smaller reservoir diameter and an increase in the number of pump cycles required for cuff deflation, provided that mechanical defects of the device have been ruled out. It is confirmed via cystoscopy and urodynamics, specifically through leak point pressure measurements. Urethral atrophy rates are 9.6-11.4%, while cuff erosion rates are 3.8-10%. Revision is required to either increase the pressure in the reservoir, downsize the cuff, reposition the cuff transcorporally, or place a second, distal tandem cuff. However, tandem cuff placement is associated with a higher postoperative infection rate [25] and increased rates of complications requiring additional surgery [26]. Other studies report higher rates of complete continence for tandem cuffs compared with single cuff placement, with similar complication rates. Transcorporal cuff placement approach during revision lowers the risk of dissection injury, improves rates of continence, and has not been linked to a

higher risk of infection or erosion. However, there is a potential risk of erectile function deterioration from corporal body dissection; however, erectile function can be maintained. A recent study proposes the use of a flap of tunica albuginea, inserted between the cuff and the urethra, as a method aiming to reduce the risk of erosion further [27,28].

The mechanical failure rate has been estimated at 5.6-29%. Filling the system with contrast medium helps detect the mechanical failure site, allowing for the replacement of the faulty component. For devices older than 3 years, it is recommended to replace the entire device if a revision surgery is planned.

Revision is necessary for up to 37% of artificial sphincter implantations during their lives [24]. The main indications are tissue atrophy, infection, cuff erosion, mechanical issues, or worsening incontinence. Compared to virgin cases, studies show no difference in complication rates, reoperation rates, or postoperative continence outcomes. The only exception is the erosion rate, where a fourfold rate of future erosion was reported after revision for artificial sphincter explanation due to erosion or infection [29,30,31].

In an extensive, multi-center retrospective study involving 1,632 male patients who underwent initial implantation of an AUS, Sidney B. and colleagues concluded that the 10-year revision or removal rate is estimated at 34%, and the reimplantation rate at 27%. The general perception is that, in any case, device removal represents a drama for the patient, who underwent several surgeries, hoping for a positive outcome, and now finds himself in a similar or worse condition. This may also lead to legal actions against the medical team and increased stress for an in-depth discussion with the patient, as well as documentation of all aspects involved [32].

8. **CONCLUSIONS**

Stress urinary incontinence is a serious medical condition that has a significant impact on the patient's health-related quality of life and self-esteem. While, from a medical perspective, incontinence does not pose significant risks, from a social perspective, it has a more substantial impact than most other conditions.

In men with post-prostatectomy incontinence, the treatment options are minimal, with the AUS being the gold standard therapy and one of the very few options that have proven effective in the long run.

Although used to treat SUI in women and children, there is not enough evidence to support the AUS for such indications.

The evolution over the last few decades has brought significant improvements to the mechanical device, lowering the rates of infections, erosions, and failures in the latest generation of sphincters. Nevertheless, there is still room for improvement, as the overall complication rate remains significant and the device's life expectancy remains suboptimal.

A comprehensive review of the literature confirms that the results obtained in high-volume centers are significantly better, which may become a future recommendation to refer such patients to highly experienced surgeons.

CREDIT AUTORSHIP CONTRIBUTION STATEMENT

Cristian Persu: Conceptualization, methodology, supervision.
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Irina Ciofu: Original draft preparation, review.
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Alexandru Ciudin: formal analysis, data curation.
Bogdan Mastalier: data curation, proofreading.
Victor Cauni: project administrator, supervision.

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