The Artificial Urinary Sphincter for the Treatment of Post Prostatectomy Urinary Incontinence in Male Patients

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ABSTRACT

Post prostatectomy urinary incontinence is a bothersome condition, marked by severe leakage in most cases, with poor response to most treatments. Our paper aims to review the history, current indications and future perspectives of the artificial urinary sphincter (AUS), a device which imposed itself as the gold standard therapy for post prostatectomy urinary incontinence.
We describe the AMS 800, the Rigicon ContiClassic and the newer Rigicon ContiReflex devices, with data from the international literature and practice guidelines, underlining pros and cons of each sphincter.
Our paper concludes that there is a significant improvement in the field of AUS and that future projects are promising in terms of better efficacy and safety.

Key-words: artificial urinary sphincter, intrinsic sphincteric deficiency, prostatectomy, urinary incontinence

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INTRODUCTION

Urinary incontinence (UI) is described as an involuntary loss of urine and is known to affect up to 32% of men with LUTS, with a prevalence ranging from 11% in men aged 60 to 64 years to 31% in men over 85 years. Urinary incontinence can be further divided into three types: stress urinary incontinence (SUI), urgent urinary incontinence (UUI), and mixed urinary incontinence (MUI) [1,2].

Stress urinary incontinence is further defined as urine loss that occurs with activity, effort, or generally when there is greater abdominal pressure (e.g. sneezing, coughing). These symptoms are suggestive for sphincter deficiency that occurs mainly after a radical prostatectomy or benign prostatic obstruction surgery. Other causes that may lead to SUI are neurogenic condition, pelvic surgery or even pelvic trauma [2,3].

The internal urethral sphincter (IUS) and the external urethral sphincter (EUS) are two anatomically distinct units that regulate male continence [4]. Men without IUS can still maintain urinary continence, while complaining of retrograde ejaculation, making the EUS the primary predictor of male continence. Male UI can be caused by detrusor overactivity, pelvic nerve injury, and support mechanism damage. Advanced age, inactivity, urinary tract infections (UTIs), diabetes, cognitive impairment, and neurological disease are the primary risk factors for male UI [5,6].

The artificial urinary sphincter (AUS) is currently the only mechanical device that accurately mimics the function of a biological urinary sphincter. Since its initial release in 1973, the hydraulically controlled AMS 800™ (American Medical Systems, Minnetonka, MN, USA) device has been used for close to 50 years and has helped many men and women suffering from serious stress urinary incontinence regain their quality of life [7,8].

The Pro-ACT device (Uromedica) [9], Zephyr ZSI 375 (Mayor Group) [10], and Rigicon ContiClassic or ContiReflex (Rigicon Inc., NY, USA) [11] are devices that promise to overcome some of the limitations of the AMS 800 device by having a simpler design with fewer components, easier device preparation, and an adjustable urethral compression component or pressure-regulating balloon (PRB) [12]. Newer and novel AUS-like devices have shown early promising results. There are currently few studies available on the mechanical reliability, safety, and long-term clinical effectiveness of these AUS-like devices [13].

The purpose of this article is to review current data on the use of artificial urinary sphincters for patients with stress urinary incontinence secondary to prostatic surgery and to list the key features of the most recent devices.

History of the Artificial Urinary Sphincter

According to the Edwin Smith Papyrus, the first time urinary incontinence was mentioned was in 1500 B.C. in the context of spinal cord damage: "*If though examines a man having a dislocation in a vertebra of his neck, shouldst thou find him unconscious of his two arms and his two legs on account of it, while his phallus is erected on account of it and urine drops from his member without his knowing it.*" [14,15].

Going further to a 1947 publication, Frederic Foley was the first to describe an outwardly worn artificial urinary sphincter as a treatment for urinary incontinence, but he was ahead of his time and his current technology didn't allow him to build it [16].

It wasn't until 1972 when F. Brantley Scott came up with the first artificial urinary sphincter and first published it in 1973 [17,18]. Over the following 9 years, he reached several significant device advancement benchmarks, eventually creating the AMS 800 we are familiar with today [18].

Two pumps were included in the initial AUS, also known as AMS 721 (Fig. 1A), one for each hemiscrotum or labium major. The cuff was filled by one pump, then drained by another. The patient continued to pump until they were empty. Since cuff erosion was practically unavoidable, it was taken off the market in 1976 [18].

In 1979, the AMS 791 (for men-Fig.1B) and AMS 792 (for women-Fig.1D) debuted with the first pressure regulating balloon (PRB), which gradually filled the cuff after it had emptied to void. Within 30 days of starting to use the device, one third of patients had cuff erosion. B.Scott first proposed the idea of primary deactivation to give the urethra a break for 6–8 weeks so that the capsule development could start. Unfortunately, these patients needed a second visit to the hospital for activation [18,19].

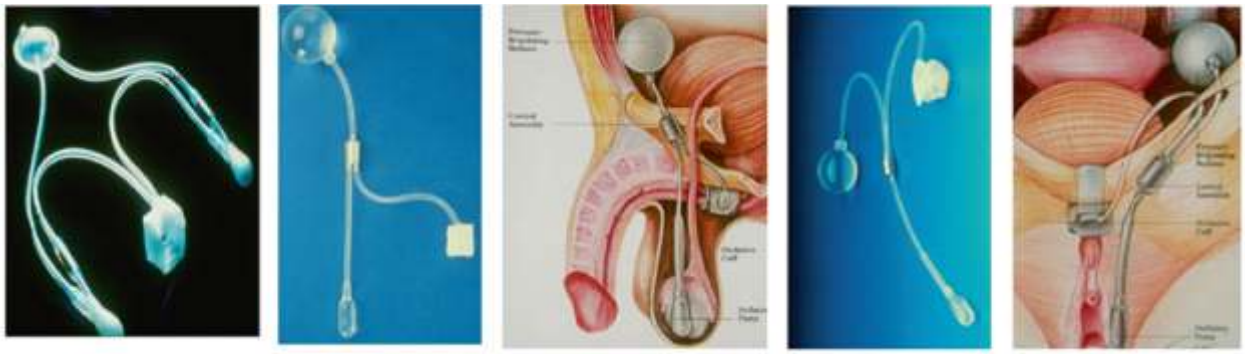


Figure 1. Early artificial urinary sphincters (image source Internet, creative commons license)

The AMS 800 (Fig.2) with cuff, PRB, and pump with deactivation button was introduced in 1982. The improved cuff did not require four ties to secure it because it had a tab and button closing. Almost 40 years later, the device is basically the same, with the exception of the addition of 4.0 and 3.5 cm cuffs and the coating of the cuff and pump with an infection-retardant material. Midway through the 1980s, it became clear that both patients and their doctors had trouble using the deactivation switch. A device called the AMS 830, which had no internal parts and was operated by a magnet placed on the scrotum, was put to the test. Prior to marketing, the business gave up on the project [18,20].



Figure 2. AMS 800 Artificial Urinary Sphincter – cuff, pump and reservoir

Surgical treatment for SUI

Since it was introduced 50 years ago, the artificial urinary sphincter, specifically the AMS 800, has been the "gold standard" for treating males with moderate to severe stress urinary incontinence [18]. Although many other surgical treatments are in use (e.g. nonadjustable sling, adjustable sling), AUS is the only one to achieve a level of evidence of 1B, and a strong recommendation to use in EAU Guidelines [3].

AUS was implanted by Scott and the original AUS implanters through two incisions. In order to dissect and expose the urethra and wrap a silicone cuff circumferentially around it, the patient was put in high lithotomy and a perineal incision was made. The PRB was then positioned in the Retzius area after making an incision in the right lower quadrant of the abdomen. Into the abdominal incision, the cuff's cabling was tunneled. The connections were made in the abdominal incision after the transversalis fascia was closed, and the pump then tunneled retrogradely into a subdartos pouch that was formed in the upper scrotum. Today, the surgical insertion process is largely unaltered [18].

According to evidence from Chen Y-C systematic review, the number of daily pads was significantly reduced (-3.75) and the total cure rate was 56% for AUS. The range for the social continence rate (from 0 to 1 pad everyday) is between 55% and 77% [21].

Studies that followed up their participants for more than 15 years found a 77% continence rate and a 90% rate of subjective satisfaction [22]. Experienced surgeons, larger surgical volumes, and intact bladder compliance are indicators of good outcomes [3,23].

Even though instances have been documented that occurred much later, infection and erosion typically occur within the first two years of implant placement. A combined study found that 8.5% of male non-neurogenic patients who received an AUS implant experienced erosion and infection. The cuff and pump of the AMS800 device are coated with rifampicin and minocycline, but the pressure-regulating balloon and its tubing are not. The effectiveness of a partly coated device in avoiding erosion and infection is unclear [24]. A cohort study conducted by Tanja Hüsch discovered that for AUS, previous pelvic irradiation ($p = 0.002$) and urethral stricture ($p = 0.011$) were separate predictors for urethral erosion. Furthermore, poor wound healing was also independently predicted by diabetes mellitus ($p = 0.002$) [25]

A well-known late side effect of AUS implantation is urethral atrophy, which is usually assumed when SUI recurrence occurs during follow-up with a working AUS. The primary pathophysiologic process is believed to be hypoxia of urethral tissue [24,26]. Van der Aa F et al. SR reported 7.9% (1.9-28.6%) cases of urethral atrophy occurred 3-23 months of follow-up [24].

An AUS might experience mechanical failure in one of the mechanical parts, in the tubing, or in one of the connectors. Mechanical failure rates ranged from 2.0% to 13.8%, and they were recorded between 11 months and 68.1 months after insertion according to Van der Aa F et al. SR [24]. The mechanical failure of the AUS is primarily a result of fluid loss from the device, such as a connector site leak, cuff tear, or tubing leak. Mechanical failure could also be caused by a faulty control pump and a blockage in the flow caused by detritus, an airlock, blood, or crystallized material [8,27].

AMS 800™

Since it was first launched in 1982, the AMS 800™ (American Medical Systems, Minnetonka, MN, USA) device has been used for more than 40 years and continues to improve the quality of life for many men and women who suffer from severe stress urinary incontinence. It has three parts: an inflatable cuff, a pressure-regulating balloon (PRB), and a control pump (Figure 2). The PRB performs two tasks: it controls pressure and also works as a fluid reservoir. The "resistor" in the pump enables the fluid from the PRB to travel down the pressure gradient to the urinary cuff and progressively closes the urethral lumen when the AUS is in its active (closed) state. Urine is kept in the bladder and is not lost thanks to the inflated sleeve. The PRB receives fluid from the control pump when the control pump is manually compressed. The control pump will then automatically expand again, drawing fluid from the sphincter cuff so that the urinary sleeve will deflate and the patient will be able to urinate as a result. The locking mechanism that was added to the control pump's side enables the AUS device to remain open (deactivated), providing opportunities for delayed postoperative AUS activation and nocturnal AUS deactivation [8].

The amount of pressure in the reservoir and the diameter of the balloon wall decides the degree of cuff occlusion. The latter comes in five different sizes, and thanks to the AUS pressure-volume relationship, pressure inside the device can be kept within a predetermined range by filling a chosen reservoir with between 16 and 24 ml of fluid. To suit urethral and bladder neck dimensions, cuff lengths range from 4 to 11 cm, but all are 2 cm wide. A 4 cm cuff and a 61-70 cm H_2O balloon reservoir are the two most frequently used parts of an AUS device that is positioned around the bulbar urethra to address post-prostatectomy incontinence [28].
The patient must have the manual skills and mental capacity necessary to cycle the sphincter prior to surgery, and there must be no lower abdominal, genital, or perineal skin lesions that could serve as a septic focus. InhibiZone™ (IZ), an antibiotic coating for the AMS 800 that contains rifampicin and minocycline, was launched in 2008. The antibiotic mixture has been shown to be effective for penile implants and other indwelling devices both in vitro and in vivo. Tanja Hüsch and colleagues made a multicenter cohort study that aimed to retrospectively analyze 305 patients with an AMS

800 and conclude if IZ was effective. Neither the infection rate (p = 0.534) nor the explantation rate (p = 0.214) were significantly impacted by the InhibiZone® covering [29].

ContiClassic™

ContiClassic™ is one of the newest AUS made by Rigicon. (Figure 3). Although it's similar to the classic AMS 800, having 3 components: an inflatable cuff, a PRB, and a control unit working almost the same, it comes with several advantages that allows in theory better results. First of all, it offers a better individual fit for every patient since its PRB comes in different ranges of pressure, from 40 cm H_2O up to 89 cm H_2O and the inflatable cuff offers a variety of sizes that allows the surgeon to choose the most appropriate size for each patient: ranging from 3.5 cm up to 13 cm. Another advantage of the ContiClassic consists of a hydrophilic coating that covers all its components surfaces unlike AMS 800 which has only a partial hydrophilic coating. Another facility that comes in ease of the procedure is represented by its connectors which doesn't require an additional assembly tool [11].
Due to its novelty, ContiClassic hasn't been included so far in any international publication and its long-term effectiveness as long with its complications remain to be established.



Figure 3. Rigicon ContiClassic™ (image source: Internet, creative commons license)

ContiReflex™

ContiReflex it's the newest AUS entering the fray of replacing AMS 800 as gold Standard treatment for SUI. Coming as an enhancement for ContiClassic, the ContiReflex keeps the same advantages such as the customization for its inflatable cuff, the hydrophilic coating that covers all its components surfaces bur brings an innovation regarding its PRB.

Due to the Reflex's two reservoirs, the patient is better protected from stress incontinence as the occlusive pressure on the urethra changes automatically in reaction to the patient's sudden increase in abdominal pressure. This effectively means that the utmost pressure that the pressure regulating balloon (PRB) labels as its limit no longer applies to cuff occlusion pressure. Additionally, because of the two-reservoir design, the balloon's resting pressure can be lower than with competing devices because leakage safety is no longer dependent on the PRB's labeled pressure. Lower PRB resting pressure is thought to increase urethral viability and lessen the need for repeat surgeries. In simple terms, if the intraabdominal pressure will rise above 70 cm H_2O, the pressure in the cuff will increase accordingly, offering in theory both a better protection in time of the urethra and a better dry-rate for the patient (Figure 4) [30].



Figure 4. Rigicon ContiReflex™

CLINICAL DATA

In a multicenter, retrospective study conducted by Manuela Tutolo and colleagues in 16 centers across Europe and USA which followed 892 primary AUS implantations for a mean follow-up of 32 months. The overall dry rate was 58% and the surgical revision rate was 30.7%. Furthermore 6.7% of the patients suffered from erosion, 4.2% encountered infections, 3.5% were diagnosed with urethral atrophy and mechanical failure was observed in 13.2%. The outcomes of this research demonstrated that AUS is a successful option for treating SUI following prostate surgery [31].

Laercio A Silva and colleagues reviewed a study with 45 patients that suffered from SUI or total UI. The participants were divided in an AUS-group and Macroplastique injection group and had been followed up for 6 to 120 months. Overall, the AUS-treated men had a higher likelihood of being dry (18/20, 82%) than the injectable-treated men (11/23, 46%) in the study. The expenses were higher and there were more serious complications in the group receiving AUS. AUS implantation was complicated in 5/22 (23%) of the men: one man had to have the implant removed due to infection, another man had to have the cuS replaced, one man had to have the pump replaced due to mechanical failure, one man had migration to the intraperitoneal area, and one man had scrotal erosion. Despite the favorable outcome for the implantation of an AUS in the group of patients with severe incontinence, the small sample size should be taken into consideration when interpreting this finding [32].

To evaluate the ZSI375 artificial urinary sphincter's effectiveness and safety Alexander Kretschmer and colleagues reviewed a multinational case series which included 13 male patients with SUI that benefit from a ZSI375 AUS. During the median follow-up of 13.5 months 30.8% devices were extracted due to defects, 15.4% complicated with infection, urethral erosion occurred in 7.7% of patients. Social continence was achieved in 15.4 % of the participants [27].

CONCLUSIONS

The standard of care for males with post prostatectomy stress urinary incontinence remains the implantation of an artificial urinary sphincter. Although it was first presented 50 years ago, with the longest track records for effectiveness and safety, the AMS 800-AUS continues to be the gold standard of care for social continence. While other AUS-like devices are intended to solve the current AMS 800 limitations, they come with their own set of problems. Rigicon ContiReflex represents the latest innovation in AUS devices, but further studies need to evaluate its effectiveness and safety over time.

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