DOI: 10.4081/aiua.2024.12661

ORIGINAL PAPER

Single-component artificial urinary sphincter: Outcomes from one centre in Portugal

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Summary ***Purpose: Radical prostate cancer treatment is the predominant cause of iatrogenic stress urinary incontinence (SUI) in men, significantly impacting their quality of life (QoL). This prospective single-center study in Portugal aimed to evaluate the outcomes of men with moderate-to-severe SUI treated with a single-component artificial urinary sphincter (AUS).***

Materials and methods: Male patients with iatrogenic moderate-to-severe SUI, determined by a 24-hour pad weight test, were included. The single-component device comprises a cuff linked to a pump unit through a kink-resistant tube. The implantation involved perineal incision for cuff placement and an inguinal incision for pump and tank positioning within the scrotum. Complications, pad usage, perioperative complications (Clavien-Dindo classification), and quality of life assessment using the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) questionnaire were documented.

Results: Between May 2021 and March 2023, 20 consecutive single-component AUS insertions were conducted at a Portuguese urology department. Follow-up concluded in July 2023, with a mean follow-up duration of 15 months (range: 5-27). Four patients experienced complications necessitating device revision or removal (erosion = 2, infection = 1, mechanical failure = 1). Social continence (0/1 pad/day) was achieved in 70% (14/20 patients), while 30% (6/20 patients) experienced incontinence. Perioperatively, one patient was classified as grade 2, while the remaining were grade 0/1 in the Clavien-Dindo classification. The mean ICIQ-SF score reduction was 10.5 points.

Conclusions: The single-component AUS shows promising efficacy in managing moderate-to-severe male SUI, offering a good success rate, acceptable complications, improved QoL, and a straightforward surgical procedure.

KEY WORDS: *Artificial urinary sphincter; Zephyr Surgical Implants 375; Male stress urinary incontinence; Radical prostatectomy; Quality of life.*

Submitted 13 May 2024; Accepted 6 June 2024

INTRODUCTION

The prevalence of *urinary incontinence* (UI) in men can reach up to 39% and tends to rise with advancing age (1). The primary cause of *stress urinary incontinence* (SUI) among adult men is commonly attributed to iatrogenic impairment of the external urethral sphincter, predominantly resulting from radical prostate cancer treatment (2). Irrespective of its underlying causes, SUI significantly diminishes the quality of life for those who experience it (3-9). The primary approach for managing male SUI involves pelvic floor muscle training, biofeedback, and electrical stimulation. If these conservative methods prove ineffective, surgical interventions are the only available alternative (1-16).

In 1973, the *artificial urinary sphincter* (AUS) was initially developed to address male moderate-to-severe SUI, eventually establishing itself as the preferred treatment for this pathology (17-19). However, the process of inserting an AUS remains intricate and carries the potential for complications such as erosion, infection, and mechanical failure.

Introduced in 1983, the last version of *American Medical Systems* (AMS) 800 device stands as the gold standard of AUS and continues to be utilized to this day (4, 5, 9, 12). While it has demonstrated favorable long-term outcomes, it is important to note that the preparation and execution of the procedure remain intricate, carrying a potential risk of complications. In instances of postoperative urethral atrophy, it is not feasible to readjust the cuff, and once activated, there are no available options to modify the pressure of the device (4, 5, 9, 13-16, 20).

The success of the procedure relies heavily on the meticulous preparation of the sphincter, proper connection of its components, and the surgeon's expertise, considering the lengthy learning curve. The majority of AUS insertions are performed by surgeons who only conduct a few procedures (between 1 and 3) per year. Less than 10% of AUS insertions in the USA are carried out by surgeons who have completed at least 100 procedures, which indicates a lower level of experience (21). As a result, the likelihood of requiring additional surgery increases from 13% to 24% (22).

The purpose of designing *Zephyr Surgical Implants* (ZSI) 375 is to simplify the process of inserting the AUS. The first implantation of ZSI 375 took place in March 2009, making it a relatively recent innovation (23). The cuff is adaptable and placed around the urethra, already connected beforehand. Additionally, ZSI 375 eliminates the need for an abdominal reservoir, leading to reduced operating time and avoiding the requirement for abdominal

incision and dissection in previously scarred retroperitoneum. By increasing the pressure, it enhances the patient's continence (10, 24).
We conducted an analysis of the outcomes of the AUS ZSI 375 implantation for stress urinary incontinence in 20 male patients, and its influence on the individual's *quality of life* (QoL).

Materials and methods

Patients

The study employed a prospective, non-randomized design and was conducted at a single urological department in Portugal. Between May 2021 and March 2023, 20 consecutive placements of the AUS ZSI 375 were performed in male patients presenting iatrogenic moderate to severe SUI as determined by the 24-hour pad weight test. The procedures were carried out by two experienced surgeons. Prior to surgery, the pre-operative protocol encompassed patient history assessment, physical examination, urinalysis, cystoscopy to rule out stenosis, a 24-hour pad weight test, and urodynamics to exclude overactive bladder. All patients had previously undergone pelvic floor muscle training. In preparation for the surgical procedures, all patients completed the *International Consultation on Incontinence Questionnaire-Short Form* (ICIQ-SF questionnaire).
The study was approved by the Ethical Committee of our center.
All study participants provided written informed consent.

ZSI 375 Device

The ZSI 375 is a single-component device made up of a cuff linked to a pump unit through a kink-resistant tube. The adaptable cuff is designed in a curved shape to prevent creasing. It is positioned around the urethra, while the pump unit, which includes a pressure-regulating tank and pump, is situated within the scrotum, specifically in the subdartos pouch. It has no abdominal reservoir. Once activated, the hydraulic circuit's pressure can be adjusted up or down to enhance the patient's continence (25). The improved hydraulic system of the ZSI 375 PF (pre-filled) has been in use since March 2015, and it is anticipated that the reduced operating time will lead to decreased infection and mechanical failure rates (25).

Surgical procedure

The implantation surgical procedure was carried out under general anesthesia with the patient in the lithotomy position. The surgical technique consists in a perineal incision for cuff placement and an inguinal incision for pump and tank placement in the scrotum. A 14 Fr Foley urethral catheter is placed for guidance and was removed by routine in the day after surgery. The device was activated six weeks later.

Follow-up after implantation

The scheduled appointments occurred at intervals of 1, 3, and 6 months following device activation, with subsequent annual appointments. Patients documented their daily pad usage in a 7-day diary prior to each visit. The follow-up process was concluded in July 2023. Total continence was defined as the absence of any pad usage, while social continence was characterized by the use of 1 pad per day. Incontinence was ascribed to individuals who required > 1 pad per day. Success was defined as achieving social continence, which encompassed the range of pad usage from 0 to 1 per day. Perioperative complications were classified using the Clavien-Dindo classification system. The quality of life was evaluated by means of the ICIQ-SF questionnaire, administered both before the surgical procedure and during the follow-up period subsequent to device activation. Additionally, a subjective assessment of patient satisfaction was documented.

Results

Patient characteristics

A total of 20 patients had the ZSI 375 device implanted, with a mean (range) follow-up of 15 (5-27) months. The averaged (range) patient age was 71.5 (62-80) years old. The indications were incontinence following radical prostatectomy (RP, n = 11), RP and radiotherapy (n = 8) and transurethral resection of prostate (TURP, n = 1). Five (25%) patients with a 24h pad weight test between 200-400g and 15 (75%) > 400g. The mean (range) ICIQ-SF score before surgery was 20,8 (17-21) points. The mean (range) operative time was 69 (35-100) minutes, and the mean hospital stay was 1 day with catheter removal on the same day. The device was activated six weeks later by routine.

Complications

Complications leading to a revision or permanent device removal arose in 4 patients: 2 erosions of the urethra with device explantation, 1 infection and 1 mechanical failure both with device re-implantation. Perioperatively, one patient was classified as grade 2, while the remaining were classified as grade 0 or 1 in the Clavien-Dindo classification (Table 1).

Pressure adjustment

In 5 (25%) patients, there was a need for device pressure adjustment under radiographic control, in an outpatient setting, to improve continence.

Efficacy

Three (15%) patients achieved total continence (0 pads per day), 11 (55%) social continence (1 pad per day), and

Table 1.
The aetiology of the incontinence and complications.

Aetiology of incontinence	Infections n (%)	Urethral erosions n (%)	Mechanical complications n (%)
RP (11 patients)	0	1 (9.1)	1 (9.1)
RP+RT (8 patients)	1 (12.5)	1 (12.5)	0
TURP (1 patients)	0	0	0
Total (20 patients)	1 (5)	2 (10)	1 (5)

RP: radical prostatectomy; RT: radiotherapy; TURP: transurethral resection of prostate.

Table 2.
The efficacy after the implantation of the ZSI 375.

	Total continence - 0 pads per day (%)	Social Continence - 1 pad per day (%)	Incontinence - > 1 pad per day (%)
Moderate SUI (5 patients) 200-400g - 24h Pad weight test	1 (20)	3 (60)	1 (20)
Severe SUI (15 patients) > 400g - 24h Pad weight test	2 (13.3)	8 (53.3)	5 (33.3)
Total (20 patients)	3 (15)	11 (55)	6 (30)
Overall success	14 (70)		

6 (30%) experienced incontinence (> 1 pad per day), resulting in an overall success rate of 70% (total and social continence). The mean (range) ICIQ-SF score after surgery was 10,5 (0-18) points with a mean reduction of 10,3 points in a scale from 0-21. The grade of satisfaction with the device was 75% (Table 2).

Discussion

In this study, we present our short-term experience with 20 patients who received the ZSI 375 AUS. Over a median follow-up period of 15 months, the overall success rate, encompassing total and social continence, reached 70%. While the AUS AMS 800 currently stands as the gold standard therapy for moderate to severe SUI in men, concerns regarding its complexity, time-consuming nature, inability to adjust device pressure, and the challenge of cuff readjustment in cases of postsurgical urethral atrophy have arisen (4).

The ZSI 375 device represents a relatively recent addition to this field. Our study highlighted the simplicity of the surgical procedure, even during the early stages of the learning curve, with notably short surgical times. One significant advantage of this device lies in its capacity to adjust internal pressures using the in situ trans-scrotal applicator within an office outpatient setting, offering the potential for improved outcomes post-surgery. Enhanced management of pressure escalation following activation is expected to reduce the incidence of urethral erosion (25). In our study, this procedure was necessary for five patients. Regrettably, as of the conclusion date, it has not been possible to assess post-adjustment outcomes.

The most frequent complication observed was urethral erosion, which affected 2 (10%) of the patients, a rate comparable to that of AMS 800 (11, 16, 24, 26, 27). Notably, one of these two patients had undergone previous radiotherapy, a well-recognized adverse factor for sphincter insertion (28). The second patient was catheterized in primary healthcare following a suspected episode of urinary retention, indicating a potential iatrogenic cause.

Mechanical failure necessitating device re-implantation occurred in 1 (5%) patient during the early stages of the study, likely attributed to the surgeons' relative inexperience with implanting this new device. This rate is also in line with that reported for the AMS 800 (12, 24, 27). Our overall complication rate aligns with that of other reported series involving ZSI 375 implantations (10, 23-25, 29, 30). Assessment of QoL using the ICIQ-SF questionnaire revealed a significant improvement, and a high level of patient satisfaction with the device was noted, possibly attributable to its simplicity.

Finally, this study has limitations, including a short follow-up duration and a small patient cohort. Some patients with prior AMS 800 AUS procedures underwent surgery, and the study was conducted during the early stages of the surgical learning curve. Additionally, utilizing the weight pad test after device activation may offer a more accurate measure for assessing real improvements in incontinence.

Conclusions

In this short-term follow-up study, the ZSI 375 AUS demonstrated effectiveness in the management of moderate to severe male SUI, exhibiting a commendable success rate while maintaining a low incidence of complications. The QoL was evaluated using the ICIQ-SF questionnaire, revealing a significant improvement. Notably, the surgical procedure proved to be straightforward with a brief learning curve. In conclusion, the ZSI 375 AUS emerges as a promising treatment option for moderate to severe SUI in male patients.

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Conflict of interest: The authors declare no potential conflict of interest.