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A Novel Artificial Urinary Sphincter (VICTO®) for the Management of Postprostatectomy Urinary Incontinence: Description of the Surgical Technique and Preliminary Results from a Multicenter Series

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Keywords
Artificial urinary sphincter · Incontinence · Urinary incontinence · Postprostatectomy urinary incontinence · Stress urinary incontinence

Abstract
Aims: The objective of the study was to analyze short-term outcomes and safety profile of the newly designed artificial urinary sphincters (AUSs) VICTO® and VICTOplus®. ***Methods:*** Data from the implant of VICTO® or VICTOplus® AUSs on a series of consecutive male patients with stress urinary incontinence (SUI) following radical prostatectomy (RP) were retrospectively collected in 3 tertiary referral centers between May 2017 and December 2019. Patients were affected by moderate-severe genuine SUI (200–400 or >400 g urine leakage in 24-h pad test) refractory to conservative treatment. Outcomes were evaluated through the 24-h pad test and the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF). Follow-up was scheduled after 3, 6, and 12 months and then when clinically needed. Nonparametric tests were applied in subgroup analyses. ***Results:*** Seventeen patients were enrolled: 8 were implanted with the VICTO® device and 9 with VICTOplus®. The median age at surgery was 69 (interquartile range (IQR) 60–75) years. The median follow-up was 15 (IQR 12–18) months. At 12 months, the dry rate was 76.4% and the social continence rate was 94%. The postoperative complication rate was 17.6%. All complications were classified as Clavien-Dindo I. No difference in terms of outcomes was observed between the VICTO® and the VICTOplus® subgroups. ***Conclusions:*** Preliminary outcomes of the VICTO® and VICTOplus® implantation are satisfactory. These devices may represent a safe and realistic solution for patients with moderate-severe SUI following RP.

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Introduction

Stress urinary incontinence (SUI) is one of the most common adverse effects following radical prostatectomy (RP) [1]. During the early postoperative course, conservative and medical treatments are employed [2]. In treatment refractory situations, surgical procedures may be considered to attempt to restore the patient to his baseline level of function [3]. SUI may be surgically addressed; a variety of continence devices have been developed [4–6]. Artificial urinary sphincter (AUS) is considered the gold standard [7], although there are several drawbacks (cost, incidence of postoperative complications, and surgical revision rates). A limitation of AUS is also the inability to adjust the device without formal surgical revision, as the pressure exerted upon the urethral tissues by the cuff is relatively fixed [7]. In 2015, under the International Continence Society auspices, an expert panel attempted to reach a consensus on diverse aspects of the AUS. Among the different issues, they debated the features of an "ideal" AUS [7]. Research and development are guided to designing the ideal AUS, with features including the following:

- Easy manipulation of the pump and deactivation of the system
- Ability to simply adjust the occlusive cuff pressure in postoperative settings
- Possibility to alter the occlusive cuff pressure in real-time manner
- Simple and robust design to eliminate mechanical failure
- Ability for straightforward minimally invasive implantation
- Cost-effectiveness
- Inert material with minimal or no risk of infection

The current AMS 800 (AMS; Boston Scientific, Marlborough, MA, USA) was released in 1983. Since then, only minor innovations occurred through the years. In 2006, a new AUS-class (FlowSecure®; Sphinx Medical, Bellshill, UK) was introduced into the market [8]. Despite the initial enthusiasm and reasonable continence rates, this newly designed AUS was subsequently abandoned due to the high incidence of mechanical failures and needs for revision [9]. The VICTO® AUS (Promedon, Austria) [10] is the most recent AUS introduced in the European market. The basic principles of this new device followed the same of the FlowSecure® and included a self-sealing port allowing for in-office pressure adjustment, a simple preassembled system. The second model (VICTOplus®) also comprised a stress relief mechanism providing low resting occlusion pressure, with conditional increased urethral occlusive pressure (only for version VICTOplus®) during higher intra--abdominal pressures. The aforementioned characteristics, more than simply improving the continence outcomes, are hoped to reduce the risk of urethral atrophy and erosion, by reducing the degree of constant pressure upon the urethral tissues. Moreover, the device can be modulated in postoperative settings according to continence outcomes and is pre-assembled, allowing for a simple and efficient implantation as well possibly reducing the incidence of mechanical failure. The scientific literature currently lacks reported outcomes for this device. We aim to report the safety and the efficacy of this novel adjustable AUS for the treatment of postprostatectomy SUI on a preliminary series of patients.

Materials and Methods

VICTO Adjustable AUS Technical Features

VICTO® (Victo®; Promedon, Austria) is a preconnected adjustable device consisting of an occluding urethral cuff, a pressure regulating balloon, and a self-sealing port for pressure adjustment. In a subsequent model (VICTOplus®), an additional stress relief balloon transmits transient intra-abdominal pressure changes to the occluding cuff. The principal innovative features of VICTO® include a self-sealing port in the pump assembly for postoperative in situ pressure adjustment and a stress relief mechanism providing low resting occlusion pressure and conditional occlusion of the urethra. Furthermore, it is composed by one-piece assembly to facilitate implantation simplicity and minimize mechanical failure. In the present study, the choice of the implanted device (either VICTO® or VICTOplus®) was related to the surgeon's preference.

Study Setting and Patients

From May 2017 to December 2019, a consecutive series of male patients underwent the implantation of VICTO® or VICTOplus® for the management of treatment refractory SUI secondary to RP in 3 tertiary referral centers. All patients had a history of organ-confined or locally advanced prostate cancer and had undergone RP. All patients underwent a preoperative assessment consisting of detailed physical examination, video-urodynamic study, and flexible urethro-cystoscopy. The following inclusion criteria were applied:

- RP with subsequent treatment refractory SUI, classified as moderate (24-h pad weight 200–400 g) to severe SUI (>400 g)
- Minimum 12 month duration following RP
- Early postoperative rehabilitation program consisting in pelvic floor muscle training
- Biochemical oncological control (PSA <0.2 ng/mL)

The exclusion criteria were defined as follows:

- Low bladder capacity (cystometric capacity <500 mL) and compliance ($C \leq 40$ mL/cm H_2O), uncontrolled detrusor overactivity (determine at video-urodynamic study) [11]
- Unstable urethro-vesical anastomotic contracture
- Follow-up shorter than 12 months

All patients were counselled about the possible advantages and the drawbacks of the implant of a novel prosthetic device. After a thorough discussion, patients could choose either the well-known AMS 800 or the new VICTO® or VICTOplus® devices.

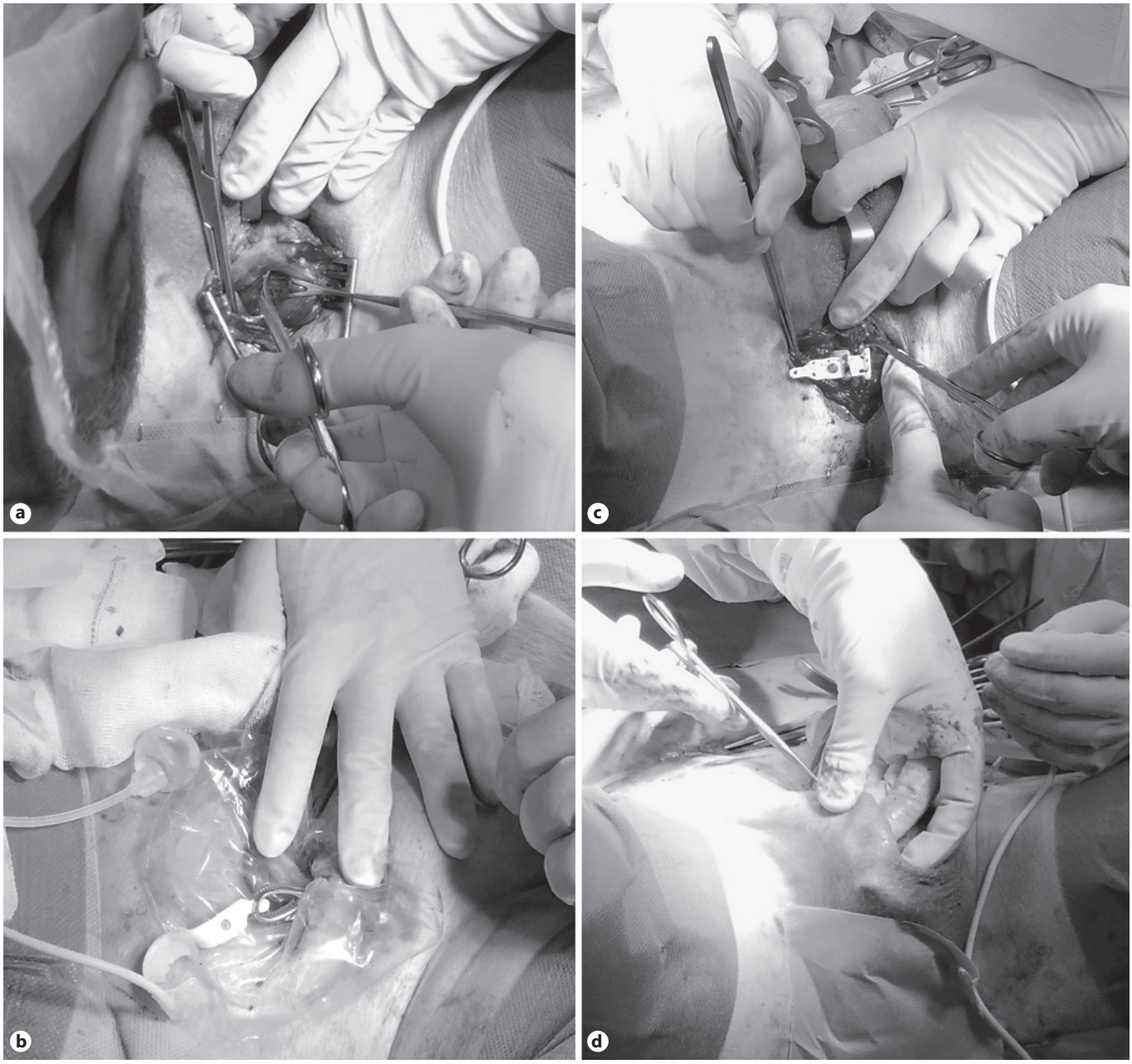

Fig. 1. Key points of the surgical technique. **a** Bulbar urethra is elevated from the underlying corpora cavernosa. **b** Urethral circumference is measured to guide the choice of the cuff diameter. **c** A cuff with appropriate size is positioned around the urethra. **d** The pump is placed in a scrotal superficial dartos pouch.

Outcome Measures

Descriptive features and surgical outcomes were retrospectively extrapolated from clinical records. Complications (both intraoperative and postoperative) were recorded, including bleeding, hematoma formation, mechanical failure, device infection/urethral cuff erosion, and device-related pain. Perioperative data included the operative time and the duration of hospital stay. Functional outcomes were evaluated 3, 6, and 12 months postoperatively and then when clinically needed. These included a 24-h pad weight and count, the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) questionnaire [12], and dry/social continence rate (additionally assessed during the last available follow-up).

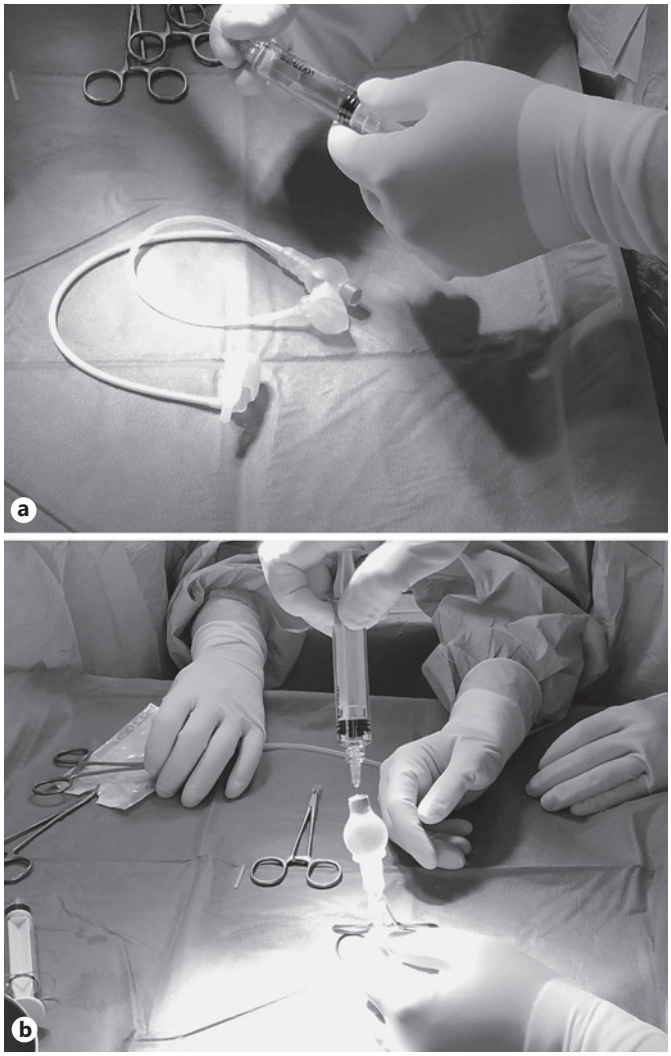

Fig. 2. Phases of AUS preparation. **a** The prosthesis is prepared for the implantation. **b** Saline solution is used to fill the prosthesis (13cc for VICTO® and 20cc for VICTOplus®).

Statistical Analysis

The normality of the variables' distribution was tested by the Kolmogorov-Smirnov test. Categorical variables were described using the frequency and percentage, and continuous variables were described using the median and interquartile range (IQR). Kruskal-Wallis and χ^2 tests were applied in subgroup analysis. Statistical analysis was conducted with Stata 12® (StataCorp., College Station, TX, USA).

Surgical Technique

Surgery was carried out under general anesthesia, with the patient in the lithotomy position. A 16 Fr indwelling urethral catheter was placed. Two surgical incisions were performed: perineal and iliac fossa. Dissection of the superficial perineal fascia was performed. The corpora spongiosum and urethra were progressively isolated. The bulbospongiosus muscle was divided in the midline. The bulbar urethra was then carefully elevated from the underlying corpora cavernosa (shown in Fig. 1a), and its circumference was measured to guide the choice of the cuff diameter (shown in Fig. 1b). The iliac incision was performed at the level of the anterior superior iliac crest, in order to gain access to the extraperitoneal space, which was bluntly dissected to provide a space for the pressure-regulating balloon. The regulating balloon was placed in the submuscular area. In the case of a VICTOplus® implantation, the peritoneum was opened, with the stress relief balloon placed inside. The AUS was prepared (shown in Fig. 2a) and filled with saline solution (shown in Fig. 2b), 13 cm^3 for VICTO® and 20 cm^3 for VICTOplus®. A disposable trocar was passed in a subcutaneous tunnel from the perineal to the abdominal incision in order to deliver the occluding cuff into the perineal wound. The cuff with appropriate size was then positioned around the urethra (shown in Fig. 1c). The pump was placed in a scrotal superficial dartos pouch (shown in Fig. 1d). At the end of the implantation, the device was left deactivated [13].

Device Pressurization

After 6 weeks, patients were evaluated in the outpatient clinic. The device was pressurized via the self-sealing scrotal port following skin disinfection. Under sterile conditions, 4 mL of saline solution was injected into the port percutaneously through a 25 G Huber needle. An additional refill was considered at 3 and 6 months interval to optimize the continence rate.

Results

Descriptive features of the current series are summarized in Table 1. Seventeen patients were enrolled in the present study. Eight patients underwent the implantation of a VICTO®, whereas 9 underwent VICTO plus® placement. The subgroups yielded statistically comparable results for all the analyzed variables. The median age was 69 years (IQR 60–75 years). The median follow-up was 15 months (IQR 12–18 months). All patients had previously undergone RP (2 laparoscopic and 15 robotic-assisted laparoscopic). The median time between the RP and AUS implantation was 15 (IQR 12–20) months. Adjuvant or salvage radiotherapy was required in 76.4% of cases. All patients were in complete remission from cancer disease with undetectable PSAs at the time of the implantation. Twelve months after RP, patients with moderate or severe SUI were then offered video-urodynamic studies as well as urethro-cystoscopy, which confirmed SUI with patent urethro-vesical anastomosis in all cases. Patients were subsequently offered AUS implantation. The device was activated in all cases 6 weeks postoperatively. Surgical outcomes are summarized in Table 2. No major intraoperative complications occurred. A minor postoperative complication was detected in 17.6% of cases (a transient

Table 1. Preoperative features of patients undergoing VICTO® AUS

Variable	Total	Model		*p* value
		VICTO	VICTOplus	
Patients, *n* (%)	17 (100)	8 (47)	9 (53)	
Age (IQR), years	69 (60–75)	73 (72–75)	69 (60–74)	>0.05
Follow-up (IQR), months	15 (12–18)	13 (12–14)	16 (14–19)	>0.05
Time RP-AUS (IQR), months	15 (12–20)	13 (12–18)	16 (14–20)	>0.05
Hypertension, *n* (%)	9 (52.9)	4 (50)	5 (55.5)	>0.05
Active smoker, *n* (%)	5 (29.4)	2 (25)	3 (33.3)	>0.05
Radiotherapy, *n* (%)	13 (76.4)	6 (75)	7 (77.7)	>0.05
Previous prosthetic surgical treatments for SUI, *n* (%)	4 (23.5)	2 (25)	2 (22.2)	>0.05

IQR, interquartile range; RP, radical prostatectomy; AUS, artificial urinary sphincter; SUI, stress urinary incontinence.

Table 2. Surgical outcomes of VICTO® AUS

Variable	Total	Model		*p* value
		VICTO	VICTOplus	
Patients, *n* (%)	17 (100)	8 (47)	9 (53)	
Operative time (IQR), min	105 (74–120)	90 (74–110)	112 (92–120)	**0.03**
Hospital stay (IQR), days	3 (2–3)	3 (1–3)	3 (2–3)	>0.05
AUS cuff measure (IQR), cm	4 (4–5)	4 (4.5–5)	4 (4–5)	>0.05
Postoperative AUS refill (IQR), *n*	1 (0–2)	1 (0–1)	1 (0–2)	>0.05
Intraoperative complication, *n* (%)	0 (0)	0 (0)	0 (0)	>0.05
Postoperative complication, *n* (%)	3 (17.6)	1 (12.5)	2 (22.2)	>0.05

IQR, interquartile range; AUS, artificial urinary sphincter. Figure in bold indicates statistical significance at $p < 0.05$.

hematuria in a single case and a transient fever in the remainder). All complications recorded appeared in early settings and were classified as Clavien-Dindo grade I, requiring supportive measures only. After a median follow-up of 15 months, all devices were still in place and well-functioning. No chronic device-related pain was reported, no late complications occurred, and, to date, none of the devices have been explanted. A median number of 1 (0–2) adjustment refills of the device with a median of 2 cm^3 (1–3) of saline solution was required in postoperative settings to adjust the cuff pressure. Functional outcomes are summarized in Table 3. We experienced a notable reduction of the median 24-h pad weights, pad counts, and ICIQ-UI SF values. At 12 months, 76.4% of patients were dry and 94% reached social continence. At the last follow-up, functional results were persistent, and, to date, any device loss of function was reported. Overall, no differences were detected in the subgroup analysis, apart from the operative time which resulted in favor of the VICTO® over VICTOplus®.

Discussion

Historically, the AUS has been widely accepted as the gold standard treatment for moderate to severe non-neurogenic male SUI [14]. Nonetheless, the quality of scientific evidences supporting the use of this device is low, characterized by heterogenous data, low quality study, and lack of validated outcomes [15]. Additionally, comparative studies of the AUS versus other surgical devices are rare [16, 17]. A recent propensity score-matched analysis showed better results for the AUS than for the fixed sling for moderate SUI. The expected continence rate

Table 3. Functional outcomes of VICTO® AUS

Variable	Total	Model		*p* value
		VICTO	VICTOplus	
Patients, *n* (%)	17 (100)	8 (47)	9 (53)	
Preoperative 24-h pad test (IQR), g	500 (300–650)	480 (300–600)	500 (300–650)	>0.05
3-month postoperative 24-h pad test (IQR), g	200 (50–300)	220 (60–300)	190 (50–260)	>0.05
6-month postoperative 24-h pad test (IQR), g	0 (0–180)	0 (0–150)	0 (0–180)	>0.05
12-month postoperative 24-h pad test (IQR), g	0 (0–60)	0 (0–65)	0 (0–60)	>0.05
Preoperative 24-h pad count (IQR), *n*	4 (3–6)	4 (3–5)	4 (3–6)	>0.05
3-month 24-h pad count (IQR), *n*	1 (0–2)	1 (0–2)	1 (0–2)	>0.05
6-month 24-h pad count (IQR), *n*	0 (0–1)	0 (0–1)	0 (0–1)	>0.05
12-month 24-h pad count (IQR), *n*	0 (0–1)	0 (0–1)	0 (0–1)	>0.05
Preoperative ICIQ-UI SF (IQR), *n*	19 (17–21)	19 (17–21)	19 (17–21)	>0.05
3-month ICIQ-UI SF (IQR), *n*	10 (6–14)	8 (6–12)	10 (7–14)	>0.05
6-month ICIQ-UI SF (IQR), *n*	0 (0–10)	0 (0–10)	0 (0–10)	>0.05
12-month ICIQ-UI SF (IQR), *n*	0 (0–5)	0 (0–5)	0 (0–5)	>0.05
Dry rate, *n* (%)	13 (76.4)	6 (75)	7 (77.7)	>0.05
Social continence rate, *n* (%)	16 (94.1)	8 (100)	8 (88.8)	>0.05

IQR, interquartile range; ICIQ-UI SF, Incontinence Questionnaire-Urinary Incontinence Short Form; AUS, artificial urinary sphincter.

achievable from AUS implantation ranges from 4 to 86% [7, 14, 15]. The AUS has also demonstrated significant rates of postoperative complications [18]. A recent systematic review highlighted that infection or erosion occurred in 8.5% of cases (3.3–27.8%), mechanical failure in 6.2% of cases (2.0–13.8%), and urethral atrophy in 7.9% (1.9–28.6%). The reoperation rate was 26.0% (14.8–44.8%) [7, 14, 15, 18]. Therefore, although reasonably effective, it appears that the AUS is still far from the ideal continence device. It is widely accepted that the risk of complications after AUS implantation may be even higher in patients with prior pelvic radiotherapy or urethral stricture surgery. The mechanism sustaining these complications is thought to fix high pressure of the occlusion cuff on the urethra [19, 20]. Our results, despite the high rate of patients who have undergone previous radiation therapy (76.4%), highlighted the effectiveness and the reliability of this new device. We found a 76.4% dry rate and 94.1% of social continence rate. The good continence outcomes and the progressive improvement of continence until 12 months are related to the possibility to pressurize the device after implantation as needed. This aspect could represent a relevant improvement compared to the previously available AUSs. The incidence of postoperative complications was minimal when compared to alternative AUS device implantation [18, 20, 21]. However, the relatively limited duration of follow-up remains an important weakness of this study, particularly when examining the risks of urethral erosion, atrophy, and mechanical failure [20]. That said, this early evidence is encouraging, suggesting the noninferiority of conditional occlusion versus continuous occlusion on continence outcome, while promising a possible better safety profile in the long term. The role and objective improvement of the stress relief mechanism on cuff occlusion provided by VICTOplus® still have yet to be rigorously studied. Within the limits of this small study, any difference regarding continence outcomes and complications was demonstrated over the standard VICTO®. The current study also looked at men (23.5%) who underwent a secondary implant following initial device failure or complication; we confirm that at least in the short term, AUS efficacy is maintained in such cases.

In conclusion, according to the current evidences, the VICTO® family may present some relevant innovations that could improve the handling and reduce the complications while maintaining good clinical results. Considering the limitation of limited follow-up, this study highlights some of the advantages of this new device including early reliability, effectiveness, and absence of short-term

complications. We acknowledge importantly, however, that the current study contains several limitations such as a small number of patients enrolled in the series, the retrospective nature of the study, the lack of randomization between study groups (VICTO®/VICTOplus®), and the relatively short follow-up. Larger prospective series, ideally with randomization, and long-term follow-up are strongly advocated to clarify the possible advantages described in the present article.

Conclusions

Despite the low number of cases in our series, the preliminary outcomes of the VICTO®/VICTO plus® seem to be satisfactory. This newly designed AUS may represent a safe and realistic solution for patients with moderate to severe SUI following RP.

Statement of Ethics

The present study was conducted in full compliance with the World Medical Association Declaration of Helsinki. Due to the retrospective nature of the study, there was no need of approval from the internal Institutional Review Board.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

All authors provided substantial contribution to the realization of the present article.

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