Original Article

A new adjustable artificial urinary sphincter for male stress urinary incontinence (Victo™): preliminary clinical results

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Background: Artificial urinary sphinkter (AUS) are still the gold standard for treatment of male stress urinary incontinence with good clinical outcomes and high patient's reported satisfaction rate. However, more than half of the patients with an AUS will require additional procedures, most likely revisions. To introduce a novel adjustable AUS for treatment of male stress urinary incontinence and perform a preliminary clinical investigation to determine the safety and efficacy of the device.

Methods: Men with urodynamically proven SUI following radical prostatectomy (RP), transurethral resection of prostate (TURP) and pelvic injuries were implanted with the Victo-AUS. Patients with three or more previous incontinence surgeries were excluded from the series. Patients were monitored over a mean follow up of 29 months (range, 13.7–47.9 months). The device was tested for efficacy by using objective measurements of urinary leakage and continence. We used validated questionnaires at baseline and clinical follow-ups. The key outcomes were overall improvement, patients reported satisfaction and complication rate.

Results: A total of 88 patients between December 2016 and December 2019 have been enrolled in this trial. Improvement was defined as a reduction in pad usage per day (p/d) over 50% compared to baseline. In total, 70 (88%) patients were reported to be improved. Treatment success according to the definition of 0–1 p/d was accomplished in 56 (70%) patients. Urethral erosion, infection or mechanical failure occurred in 4 (5%), 4 (5%) and 1 (1.3%) patient respectively. Explantation of the device was mandatory in 6 patients due to erosion, infection or mechanical failure.

Conclusions: In this series, a continence rate of 70% was achieved with an acceptable complication-rate. These results together with a high satisfaction rate demonstrate effectiveness and safety of the Victo system in mid-term follow-up for the treatment of male SUI.

Keywords: Male stress urinary incontinence (male SUI); post-prostatectomy incontinence (PPI); surgical treatment; artificial urinary sphincter (AUS); quality of life

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Introduction

The hydraulically controlled artificial urinary sphincters (AUS) have been used in the treatment for persistent post-prostatectomy incontinence (PPI) for nearly 50 years and are still the gold standard for treatment of male stress urinary incontinence (SUI) (1). The first implantable prosthetic urinary sphincter was introduced in 1973 by

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Scott *et al.* (2) and has been evolved into the currents AMS-800 (Boston Scientific, Marlborough, MA, USA).

To date, the AMS-800 is still the device with the largest level of evidence in the literature and many retrospective studies with long follow-up have reported good clinical outcomes and high patient's reported satisfaction rate (3,4). However, more than half of the patients with an AUS will require additional procedures, most likely revisions (5). Depending on study population and follow-ups, revision rates have been reported up to 30%, increasing with time after implantation (3,6,7). The reasons for revisions are mainly difficulties involving cuff and urethra; the erosion/infection and atrophy rate is in average 8.5% and 7.9% in the literature (3,6-8).

A recent long-term evaluation of AMS 800 reported 26% atrophies, as well as 25% infections and erosions in a median follow-up of 5.4 years (3). The current AMS-800 is available in three predetermined pressure ranges (9). The required urethral compression pressure to remain dry can vary from case to case, so adapting the system pressure to each patient's individual situation may potentially reduce some of the complications regarding cuff and urethra such as erosion and atrophy.

To address these problems, we used a new one-piece artificial sphincter, Victo adjustable AUS (Promedon, Cordoba, Argentina), in men with SUI. The device is pre-connected and consists typical components of an AUS such as a urethral cuff (UC), a pressure regulating balloon (PRB) and a control pump, however it has a few innovative features (*Figure 1*). All above is the self-sealing port in the pump for *in situ* pressure adjustments in addition, the device is also available as Victo$^+$ with an additional stress relief balloon (SRB), which is positioned between the cuff and the pump. In case of sudden, short-term increase of abdominal pressure such as coughing, additional fluid is provided by the SRB to the cuff in order to increase temporarily the compression (*Figure 2*). This mode of action allows increased temporary cuff pressure while at the same time the baseline system pressure remains low.

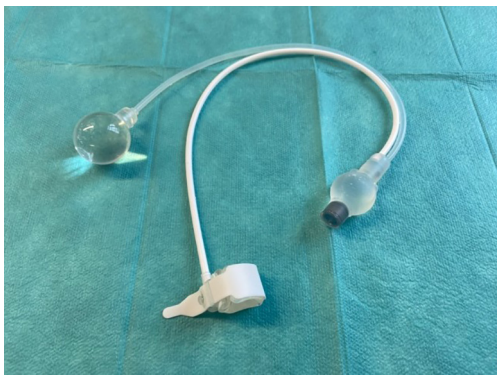

Figure 1 Victo adjustable artificial urinary sphincter.

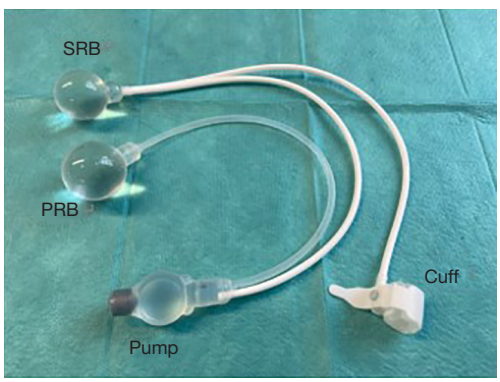

Figure 2 Victo$^+$ with additional SRB. SRB, stress relief balloon; PRB, pressure regulating balloon.

The design features include:

- ❖ Both Victo configurations are provided pre-connected;
- ❖ Victo and Victo$^+$ come with a pump with a self-sealing port for *in situ* pressure adjustments (*Figure 3*);
- ❖ Victo$^+$ with an additional SRB offers the lowest effective occlusive pressure and provides increasing system pressure when needed (in stress situation such as sneezing or coughing);
- ❖ The cuff tubing runs parallel to the urethra, thereby avoiding possible oblique forces increasing the risk for erosion;
- ❖ Adjustments can be done at any time after implantation.

The system pressure is adjustable in the range

Highlight box

Key findings

- We introduce a novel adjustable artificial urinary sphincter and report about functional results and quality of life after device implantation.

What is known and what is new?

- Preliminary clinical results of Victo system.

What is the implication, and what should change now?

- The functional results together with a high satisfaction rate demonstrate effectiveness and safety of the Victo system in mid-term follow-up for the treatment of male stress urinary incontinence.

Figure 3 Pump with self-sealing port for *in situ* pressure adjustments.

0–100 cmH_2O and can be altered by injection or removal of fluid (Aqua ad injectabilia). Adjustment can be done through the self-sealing port any time after implantation (*Figure 3*).

The Victo artificial sphincter was first implanted in December 2016 and has been used in Europe and Latin America. However, to date there are only small cohort studies on efficacy and safety of the device (10).

The current trial aims to evaluate the efficacy and safety of Victo and Victo$^+$ for the treatment of male SUI.

Although there is still a lack of definition for outcome measurement in surgical treatment of male SUI, the most appropriates are the number of utilized pads per day (11). However, the patients global impression of improvement (PGI-I) appears to be an appropriate tool for outcome success as well (12) and has been included as secondary endpoint in this trial.

Methods

Clinical investigation method

The current trial is a monocentric cohort trial. Data collection of baseline characteristics, perioperative course as well as follow-up visits have been collected retrospectively.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Local Ethics Committee under the ethics number GS4–EK–4/6152019 and informed consent was taken from all individual participants. Furthermore, the trial has been registered in the German registry for clinical trials (DRKS) with the number DRKS00018990.

The data has been collected and evaluated retrospectively in one high volume center.

Investigational device and methods

Study population

This investigation was conducted in a retrospective, non-randomized format. Patient selection and evaluation prior to surgical therapy were performed according to recommendation of International Continence Society (ICS) (13).

All men had previously failed rehabilitation by conservative management and presented sufficient dexterity and cognitive function to operate the device. Preoperative evaluation was performed focusing on the characterization of incontinence, its severity and progression over time as well as pad usage per day (p/d), furthermore physical examination and cysto-urethroscopy were performed in all cases.

During December 2016 and December 2019, the new AUS was indicated in 88 men (mean age 70.9 years; range, 29–88 years) with SUI. Of these men, 76 (86.4%) were incontinent after radical prostatectomy (RP), 8 (9.1%) after transurethral resection of the prostate (TURP) and 4 (4.5%) after pelvic injuries. All patients had previously failed rehabilitation by pelvic floor training. We included the data of patients with history of pelvic radiotherapy as well as patients with two or less previous surgical treatment for incontinence or stricture. Eight patients with three more than three previous incontinence surgeries were excluded in this cohort.

The pre-implantation evaluation included patient's medical history, evaluation of urinary incontinence (UI) episodes, the p/d and clinical examination (*Table 1*). Cystoscopy was performed pre-operatively in all cases to evaluate the urethra and bladder neck in order to diagnose potential strictures, we do not routinely perform urodynamic studies before AUS implantation. In this cohort none of the patients had a history of neurological bladder conditions. Victo$^+$ was indicated only in patients, who were not able to interrupt the stream. The SRB transmits intra-abdominal pressure changes and increases temporarily the compression.

The Victo system is available as a one-piece, pre-

Table 1 Baseline characteristics

Characteristics	Victo, n=45	Victo$^+$, n=35	In total, n=80
Age (years), mean (median)	71.3 (72.3)	70.3 (72.4)	71 (72.5)
Origins of incontinence			
RP	40 (88.9)	29 (82.9)	69 (86.3)
TURP	2 (4.4)	5 (14.3)	7 (8.8)
Pelvic injuries	3 (6.7)	1 (2.9)	4 (5.0)
Diabetes mellitus	6 (13.3)	9 (25.7)	15 (18.8)
History of pelvic irradiation	18 (40.0)	14 (40.0)	32 (40.0)
History of surgical treatment of SUI	10 (22.2)	5 (14.3)	15 (18.8)
History of treatment of bladder neck pathologies	4 (8.9)	8 (22.9)	13 (15.0)
Androgen deprivation	4 (8.9)	3 (8.6)	7 (8.8)

Data are presented as n (%) unless otherwise stated. RP, radical prostatectomy; TURP, transurethral resection of prostate; SUI, stress urinary incontinence.

connected, not prefilled device. Before implantation the new AUS was placed into a sterile tray and filled with isotonic contrast medium. The device was filled with 13 mL in case of Victo and 20 mL in case of Victo$^+$ via the self-sealing port in the base of the pump using a non-coring needle.

The implantation was performed under general or spinal anesthesia in the lithotomy position with two incisions.

In term of surgical technique for AUS placement, we used a perineal approach, so the first step was the perineal incision, preparation of the urethra and measuring the circumference. After choosing the right cuff size, the pre-connected device was filled by an experienced nurse or by the assistance to save operation time. In the meantime, the procedure was proceeded by a lower abdominal incision and PRB was placed intra-peritoneally. We tend to place the PRB intra-peritoneally to avoid potential capsule formation that might influence the system pressure. When Victo$^+$ was indicated, the SRB was positioned extra-peritoneally at the same body site.

The transfer of the pre-connected cuff to the perineal incision was performed using a camera bag and a straight packer. Finally, the pump was placed in the scrotum by blunt dissection and the wounds were closed. We have already published the implantation technique in 2018 at *Central European Journal of Urology* (14).

Device activation and adjustments

The time needed for scrotal swelling and hematomas to subside vary greatly from person to person, but the AUS activation can be done approximately 4–6 weeks after insertion.

The activation procedure was carried out via the self-sealing port under aseptic conditions. The base of the pump was palpated to identify the port, which was pierced with a 23-G short needle. To activate the AUS, 4 mL of sterile Aqua were injected, irrespective of which AUS configuration (Victo or Victo$^+$) were implanted. If necessary, additional fluid was added to optimize continence at a later appointment.

Assessment of postoperative continence

Patient follow-up assessments after implantation was at day 1 and 2 (during the hospitalization), at AUS activation and at follow-up visits at 3, 6, 12 months after the procedure and then annually after.

The assessment included clinical examination, urinalysis, uroflowmetry, bladder and lower abdomen sonography, as well as the continence situation at each follow-up via patient reported number of pads used in 24 hours. In addition, all patients were requested to fulfill a diary including pad per day usage and their physical activity on that day. Each patient was evaluated individually on whether there was a need for adjustment or not. Adjustments depended on the severity on urinary leakage, 1 mL rarely 2 mL were added to the system to optimize the continence.

Statistical analysis

Descriptive data was presented as appropriate by either

Table 2 Adverse events at clinical follow-up

Adverse events	Victo, n=45	Victo⁺, n=35	In total, n=80	P value
Hematoma and scrotal swelling	11 (24.4)	9 (25.7)	20 (25.0)	0.898
Transient perineal or scrotal pain	8 (17.8)	5 (14.3)	13 (16.3)	0.444
Impaired wound healing	–	–	–	
Infection of the device	3 (6.7)	1 (2.9)	4 (5.0)	0.429
Urethral erosion	3 (6.7)	1 (2.9)	4 (5.0)	0.429
Pump repositioning	3 (6.7)	1 (2.9)	4 (5.0)	0.429
Mechanical failure	–	1 (2.9)	1 (1.3)	

Data are presented as n (%).

median [min, max] or mean ± standard deviation (SD). Categorical variables were presented using numbers and frequencies.

Chi-square test was used to compare categorical variables. Differences between groups were tested Mann-Whitney-U-test, Fischer exact test, or log rank tests as appropriate. A significance level of 5% was determined. Infection and explantation rates were correlated with diabetes mellitus, history of pelvic irradiation and history of urethral stricture disease to identify risk factors for failure.

Social continence was defined as the need of zero to one pad in 24 hours, and improvement as ≥50% reduction in pads compared with the baseline. Otherwise, they were defined as 'not improved'.

Results

The study site is a reference center for the treatment of male SUI. Patients which have underwent Victo or Victo⁺ implantation for the treatment of SUI from December 2016 to December 2019 and correspond to the inclusion criteria were enrolled in this trial.

In total 45 and 35 patients underwent implantation of Victo and Victo⁺ respectively. The procedures were performed by two surgeons. The baseline characteristics are described in *Table 1*.

Concomitant procedures during the implantation included onabotulinum toxin-A injections (n=8), explantation of the prior medical device for male SUI (n=5), surgical treatment of urethral stricture by either urethrotomia interna (n=2) or Turner-Warwick procedure (n=7).

The Implantation and recovery were uneventful. Only one patient with Victo required intervention because of postoperative hematoma. The mean time of postoperative catheterization was 1.1 (±0.28) days.

The mean clinical follow-up time was 32.2 (±9.3) and 26.5 (±9.9) months for Victo+ and Victo respectively. Postoperative adverse events are presented in *Table 2*. Early postoperative adverse events to report included: hematoma and postoperative scrotal swelling, which occurred in 20 patients (25.0%) and were treated with non-invasive local procedures as cooling and decongestive drugs; transient perineal and/or scrotal pain, which occurred in 13 patients (16.3%) was conservatively managed with use of NSAIDs (none required device removal).

No case of postoperative urinary retention was reported. Dislocation of the pump occurred in five patients. The pump was located in the upper part of the scrotum, pump repositioning was performed in four patients as mentioned before, in one case of Victo⁺ the device handling was still feasible, and no surgical revision was necessary.

In the other case, the pump was successfully relocated.

In total, there were four cases of infections reported. One postoperative hematoma and wound infection occurred, in this case surgical treatment was required, however the device was not infected and an explantation was not necessary. One case of pump infection was documented in the Victo group, which occurred after adjustment with sterile saline, the device was removed because an infection of the whole device was suspected. The remaining infections were accompanied by urethral erosion and consecutively infection and explantation of the device.

Infection correlated significantly with explantation of the device (P<0.001). No other risk factor was identified correlating with explantation of the device.

In four cases urethral erosion was identified, which caused explantation of the device. Two of the erosions occurred concomitant with infection of the device after

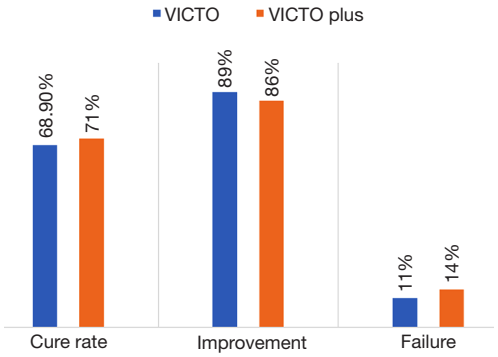

Figure 4 Treatment success at clinical follow-up.

traumatic catheterization as explained in the prior passages. There were no cases of urethral atrophy reported in this analysis.

Functional results

The activation was performed after a mean of 39 days from operation date with 4 mL saline solution as described before. One case of injury during the adjustment was reported.

By the mean follow-up of 29 months (median 28), the reduction of number of pads in comparison between baseline and follow-up was significant in both groups (P<0.001).

There were 40 (88.9%) and 30 (85.7%) of patients either cured (socially dry or total continent; 0–1 p/d) or improved by definition in the Victo and Victo$^+$ group respectively. Furthermore, treatment success according to the definition of 0–1 p/d was accomplished in 68.9% and 71.4% in the Victo and Victo$^+$ group respectively (*Figure 4*). There was no correlation between success and the device group (P=0.696).

A median of 1.7 adjustments (IQR 2) were required to obtain this result. There were only one patient's data missing regarding patient's global impression of improvement.

In univariate analysis, no risk factor correlated with success, neither by pad definition (0–1 p/d) nor patients' global impression of improvement.

Discussion

The aim of the current trial was the evaluation of safety and efficacy of a new adjustable artificial sphincter system.

According to EAU guidelines, the AUS is still the treatment of choice for persistent moderate to severe male SUI, however there is no generally accepted objective definition of neither incontinence severity nor outcome success after surgical treatment of male SUI (1,15). The most common classification in clinical practice is the Stamey's classification. Stamey scores relates the activity that caused the incontinence from 0 to 3, with grade 0 indicating that the patient is dry and grade 3 indicates continuous incontinence irrespective to position or activity. In the current study, most of patients presented with moderate to severe stress incontinence (Stamey score 2 or 3). However, it should be recognized that the majority of literature did not classify baseline incontinence severity at all (7,16) and furthermore, success rates differ significantly depending on the utilized definition as well (12).

The vast majority of evidence of AUS exist from AMS 800 (Boston Scientific, Malborough, MA, USA) which will be utilized as reference in the discussion (6).

Regarding baseline characteristics such as age, body-mass-index (BMI), diabetes mellitus, history of urethral stricture disease, results from this trial are in line with literature in a heterogenous non-selected patient population (7,16,17). However, considering history of pelvic irradiation and history of surgical treatment of male SUI, the incidence was 40% and 18.8%, which is at and even above the upper limit in comparison to literature. The incidence of prior pelvic radiotherapy in patients receiving an AUS is described between 10.3–30.2% in some large cohort trials (3,7,17,18).

There is evidence in the literature that pelvic irradiation is related to adverse events after artificial sphincter. A recent study of AUS after RP reported that patients with previous radiotherapy were more likely to require a second operation (18). Bates *et al.* identified in a meta-analysis increased revision rates and higher risk for persistence of urinary incontinence in patients with a history of pelvic irradiation (19). The current knowledge on the impact of pelvic irradiation on the AUS outcome, should be considered when analyzing the results in the current trial. As this fact can have a considerable impact not only on the increased risk for repeated surgeries and explantation but also for increased risk of persistent incontinence, thus, decreased treatment success.

Furthermore, previous surgical treatment of SUI was 18.8% in this investigation, which is comparable as reported in the literature between 17% and 26.5% (3,8,20).

Outcome success was defined in this trial using zero to one pad per day. Additionally, PGI-I was utilized. Depending on the definition of success, overall treatment

success was 88% according PGI-I and 70% according to pad usage.

Overall success rates, defined by 0–1 p/d, are described between 20% to 89% in literature (21,22). These differences might be arising from the lack of objective of severity grading and outcome success. Deruyver *et al.* described in their analysis of long-term functional outcomes of AUS implantation in men for the treatment of SUI an overall social continence rate of 60% after 5 years (23). A recent large cohort study reported cure rates after 1–2 years of 47% and patients' global impression of improvement of 87% (3,8).

Despite the above average number of patients with risk factors for failure in this cohort, the results of the current trial are consistent with the evidence in literature and confirm the effectiveness of Victo system for treatment of male SUI.

The most common complication after artificial sphincter placements are erosion, mechanical failure, urethral atrophy, dislocation and subsequently explantation (6). The overall infection rate was 5% and overall erosion rate was 5% in this trial which are consistent with literature. Bates *et al.* reported in a meta-analysis of 15 studies surgical revision rates from 5% to 40% and the most common cause of explantation were infection or erosion (52.8%) (19).

Dislocation and mechanical failure occurred in 5% and 1.3% in this trail which are consistent with literature. The combined mechanical failure and dislocation rates are reports in literature between 3.6–44% (7,17,21). Any of these complications generally require surgical revision.

Urinary retention is frequently not reported in literature but is the most common complication in the postoperative curve after AUS implantation (21,24).

Overall explantation rate in the current trail was 7.5% (n=6). The reason for explantation were either infection, combined with erosion or leakage of the device or device malfunction. In a multicenter cohort trial and heterogenic patient population, explantation rate was reported up to 21.5% after a mean of 14 months (17). The five years device survival is reported between 59–79% (7,22,25). It needs to be mentioned, that AUS implantation is associate with an increased risk of secondary surgeries and/or explantation in general (3,6,8,21,26). Furthermore, this risk is increased in particular by risk factors such as a history of radiation therapy or prior surgical therapy for SUI (27,28). It should be considered that the current patient population presented above average, with regard to the risk factors for failure and development of complication as discussed above. Concluding, that the explantation rates are consistent with literature even considering the increased risk for failure of the current population.

We acknowledge several limitations of the current trial. The current data were retrospectively collected; Furthermore, the patient population is heterogenous and the number of patients limit the subgroup analysis. In particular, the patient population was at increased risk for failure due to increased number of patients with recognized risk factors such as radiation therapy and prior surgical treatment of SUI. Nevertheless, the data represents clinical daily practice and current results support comparability in effectiveness and adverse event in comparison to AUS in literature so far.

Conclusions

The current results support the effectiveness and safety of Victo and Victo$^+$ for the treatment of male SUI. The success rates as well as complications were comparable to evidence for AUS in literature.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Local Ethics Committee under the ethics number GS4–EK–4/6152019 and informed consent was taken from all individual participants. Furthermore, the trial has been registered in the German registry for clinical trials (DRKS) with the number DRKS00018990.

References

1. Burkhard FC, Bosch JLHR, Cruz F, et al. Urinary Incontinence in Adults EAU Guidelines on 2019. Available online: https://d56bochluxqnz.cloudfront.net/media/EAU-Guidelines-on-Urinary-Incontinence-2019.pdf
2. Scott FB, Bradley WE, Timm GW. Treatment of urinary incontinence by implantable prosthetic sphincter. Urology 1973;1:252-9.
3. Tutolo M, Cornu JN, Bauer RM, et al. Efficacy and safety of artificial urinary sphincter (AUS): Results of a large multi-institutional cohort of patients with mid-term follow-up. Neurourol Urodyn 2019;38:710-8.
4. Kretschmer A, Nitti V. Surgical Treatment of Male Postprostatectomy Incontinence: Current Concepts. Eur Urol Focus 2017;3:364-76.
5. Wang R, McGuire EJ, He C, et al. Long-term outcomes after primary failures of artificial urinary sphincter implantation. Urology 2012;79:922-8.
6. Van der Aa F, Drake MJ, Kasyan GR, et al. The artificial urinary sphincter after a quarter of a century: a critical systematic review of its use in male non-neurogenic incontinence. Eur Urol 2013;63:681-9.
7. Linder BJ, Rivera ME, Ziegelmann MJ, et al. Long-term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic. Urology 2015;86:602-7.
8. Boswell TC, Elliott DS, Rangel LJ, et al. Long-term device survival and quality of life outcomes following artificial urinary sphincter placement. Transl Androl Urol 2020;9:56-61.
9. Ratan HL, Summerton DJ, Wilson SK, et al. Development and Current Status of the AMS 800 Artificial Urinary Sphincter. Available online: https://www.imop.gr/sites/default/files/pdf-2.pdf
10. Giammò A, Falcone M, Blecher G, et al. 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. Urol Int 2021;105:414-20.
11. Kielb S, Dunn RL, Rashid MG, et al. Assessment of early continence recovery after radical prostatectomy: patient reported symptoms and impairment. J Urol 2001;166:958-61.
12. Linder BJ, Rangel LJ, Elliott DS. Evaluating Success Rates After Artificial Urinary Sphincter Placement: A Comparison of Clinical Definitions. Urology 2018;113:220-4.
13. Biardeau X, Aharony S; , et al. Artificial Urinary Sphincter: Report of the 2015 Consensus Conference. Neurourol Urodyn 2016;35 Suppl 2:S8-24.
14. Weibl P, Hoelzel R, Rutkowski M, et al. VICTO and VICTO-plus - novel alternative for the mangement of postprostatectomy incontinence. Early perioperative and postoperative experience. Cent European J Urol 2018;71:248-9.
15. Bauer RM, Gozzi C, Hübner W, et al. Contemporary management of postprostatectomy incontinence. Eur Urol 2011;59:985-96.
16. Sacco E, Prayer-Galetti T, Pinto F, et al. Urinary incontinence after radical prostatectomy: incidence by definition, risk factors and temporal trend in a large series with a long-term follow-up. BJU Int 2006;97:1234-41.
17. Hüsch T, Kretschmer A, Thomsen F, et al. Risk Factors for Failure of Male Slings and Artificial Urinary Sphincters:

Results from a Large Middle European Cohort Study. Urol Int 2017;99:14-21.
18. Dosanjh A, Baldwin S, Mytton J, et al. A national study of artificial urinary sphincter and male sling implantation after radical prostatectomy in England. BJU Int 2020;125:467-75.
19. Bates AS, Martin RM, Terry TR. Complications following artificial urinary sphincter placement after radical prostatectomy and radiotherapy: a meta-analysis. BJU Int 2015;116:623-33.
20. Grabbert M, Bauer RM, Hüsch T, et al. Patient Selection in Surgical Centers of Expertise in the Treatment of Patients with Moderate to Severe Male Urinary Stress Incontinence. Urol Int 2020;104:902-7.
21. Crivellaro S, Morlacco A, Bodo G, et al. Systematic review of surgical treatment of post radical prostatectomy stress urinary incontinence. Neurourol Urodyn 2016;35:875-81.
22. Léon P, Chartier-Kastler E, Rouprêt M, et al. Long-term functional outcomes after artificial urinary sphincter implantation in men with stress urinary incontinence. BJU Int 2015;115:951-7.
23. Deruyver Y, Schillebeeckx C, Beels E, et al. Long-term outcomes and patient satisfaction after artificial urinary sphincter implantation. World J Urol 2022;40:497-503.
24. Linder BJ, Piotrowski JT, Ziegelmann MJ, et al. Perioperative Complications following Artificial Urinary Sphincter Placement. J Urol 2015;194:716-20.
25. Lai HH, Hsu EI, Teh BS, et al. 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. J Urol 2007;177:1021-5.
26. Trost L, Elliott DS. Male stress urinary incontinence: a review of surgical treatment options and outcomes. Adv Urol 2012;2012:287489.
27. Lai HH. Incontinence: what is the learning curve for artificial urinary sphincter surgery? Nat Rev Urol 2011;8:475-6.
28. Linder BJ, Viers BR, Ziegelmann MJ, et al. Artificial Urinary Sphincter Mechanical Failures-Is it Better to Replace the Entire Device or Just the Malfunctioning Component? J Urol 2016;195:1523-8.

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