uro

MDPI

Review

Urinary Artificial Sphincter in Male Stress Urinary Incontinence: Where Are We Today? A Narrative Review

Anna Ricapito [1,2,*], Matteo Rubino [1,2], Pasquale Annese [2], Vito Mancini [2], Ugo Falagario [2], Luigi Cormio [2], Giuseppe Carrieri [2], Gian Maria Busetto [2] and Carlo Bettocchi [1,2]

[1] Andrology Unit, Department of Urology and Organ Transplantation, University of Foggia, 71122 Foggia, Italy; matteo_rubino.544106@unifg.it (M.R.); carlo.bettocchi@unifg.it (C.B.)
[2] Department of Urology and Organ Transplantation, University of Foggia, 71122 Foggia, Italy; linoannese@libero.it (P.A.); vito.mancini@unifg.it (V.M.); ugofalgario@gmail.com (U.F.); luigi.cormio@unifg.it (L.C.); giuseppe.carrieri@unifg.it (G.C.); gianmaria.busetto@unifg.it (G.M.B.)
* Correspondence: annaricapito96@gmail.com

Abstract: Introduction: Urinary incontinence is a prevalent condition, especially in elderly men, with stress urinary incontinence (SUI) being a common cause after radical prostatectomy. The artificial urinary sphincter (AUS), particularly the AMS 800™ device, has been the gold-standard treatment for moderate-severe male SUI for decades. Despite some technical advancements and alternative devices like ZSI-375, Victo, and BR-SL-AS 904 being introduced, there is limited literature comparing their effectiveness to the AMS 800™. Methods: This literature review compares the AMS 800™ to the newer technologies in the management of SUI. We reviewed the current literature on urinary sphincter implant in male stress incontinence, including AMS 800™, ZSI-375, Victo, and BR-SL-AS 904. Findings: The AMS 800™ is a sophisticated system consisting of an inflatable cuff, a pressure-regulating balloon, and a control pump. Studies show continence rates ranging from 61% to 100% with AMS 800™ implants, with low infection rates and significant improvement in patients' quality of life. The ZSI-375 sphincter is a unique single-piece cuff without an abdominal reservoir, simplifying implantation. Preliminary data show a social continence rate of 73% at six months, with lower complication rates than the AMS 800™. The VICTO® device offers adjustable pressure and a stress relief mechanism, providing conditional occlusion of the urethra. Early studies report a satisfaction rate of up to 94.2% and a complication rate of 17.6%. BR-SL-AS 904 is a newly proposed urinary sphincter, but due to the limited number of cases and a single study, its efficacy and complication rates remain uncertain. Conclusions: Overall, AMS 800™ remains the gold-standard treatment for SUI after radical prostatectomy. Alternative devices like ZSI-375 and VICTO® show promising results, but longer studies and more data are needed to establish their effectiveness and safety compared with the AMS 800™. Further research and ongoing monitoring are essential to address mechanical issues associated with AUS implants.

Keywords: artificial urinary sphincter; male stress incontinence; review

Citation: Ricapito, A.; Rubino, M.; Annese, P.; Mancini, V.; Falagario, U.; Cormio, L.; Carrieri, G.; Busetto, G.M.; Bettocchi, C. Urinary Artificial Sphincter in Male Stress Urinary Incontinence: Where Are We Today? A Narrative Review. *Uro* **2023**, *3*, 229–238. https://doi.org/10.3390/uro3030023

Academic Editor: Pawel Miotla

Received: 2 August 2023
Revised: 20 August 2023
Accepted: 24 August 2023
Published: 6 September 2023

1. Introduction

Urinary incontinence, a prevalent condition affecting a significant proportion of the male population, has been a subject of extensive research and medical attention. With a reported prevalence ranging from 11% in men aged between 60 and 64 years old to a staggering 31% in men aged ≥85 years old, it presents a considerable healthcare burden and warrants a comprehensive investigation into its management and treatment options [1].

Stress urinary incontinence (SUI), a specific type of urinary incontinence characterized by urine loss during instances of increased abdominal pressure, is a particularly distressing condition for affected individuals. Although SUI is relatively less common in men, accounting for less than 10% of cases, it can be significantly debilitating and severely impact the

quality of life. Radical prostatectomy, benign prostatic obstruction, and pelvic surgery are some of the common causes leading to SUI in men [1].

Since 1972, the artificial urinary sphincter (AUS) has been recognized as the gold-standard treatment for moderate to severe male SUI. The device's introduction revolutionized the management of this condition, providing patients with improved bladder control and enhanced quality of life. Over the years, numerous technical advancements have contributed to refining AUS devices both from a surgical and functional perspective. Among them, the AMS 800™ (AMS, Minnetonka, MN, USA) device has stood out as the most successful and widely used solution, making its debut in 1972 [1,2].

The remarkable success and well-established efficacy of the AMS 800™ have been attributed to its stable design and materials, which have remained relatively unchanged over the years. This consistency in performance and safety has solidified its status as the go-to option for surgeons and patients alike [3].

However, the ever-evolving field of medical technology has not rested, leading to the emergence of a few innovative alternatives that have been deemed promising as potential replacements for the gold standard. Devices such as the Zephyr 375 urinary sphincter, Victo, BR-SL-AS 904, and Conti® have captured the attention of researchers and clinicians due to their potential to match or even surpass the efficacy of the AMS 800™. Despite their potential, the limited availability of scientific literature and data has hindered a robust comparison and evaluation of their effectiveness [4–6].

In light of these advancements and the need to comprehensively assess the current landscape of surgical management for SUI, we undertook a meticulous literature review. Our objective was to delve into the wealth of available evidence, comparing the tried-and-true AMS 800™ device with the latest technologies that have recently entered the market. By doing so, we aimed to shed light on the most effective and cutting-edge solutions available for the surgical management of SUI in men.

Through this comprehensive analysis, we hope to provide valuable insights to healthcare practitioners, researchers, and patients alike, aiding in the informed decision-making process for selecting the most suitable treatment option for individuals struggling with stress urinary incontinence. Ultimately, our efforts seek to improve patient outcomes, enhance their quality of life, and advance the field of urology by harnessing the potential of novel and innovative technologies while acknowledging the enduring efficacy and safety of the gold-standard AMS 800™ device.

When conducting this review, we hypothesized that, though AMS 800™ is considered as the gold standard, new artificial urinary sphincters have been validated in practice nowadays.

2. Methods

Our narrative review collected its sources through Medline search and by cross-referencing citations in the articles evaluated. We also reviewed EAU and AUA guidelines. The search involved combining the keywords "artificial urinary sphincter", "AMS 800™", "ZSI-375", "VICTO®", "BR-SL-AS 904" and "Conti®". We assessed the risk of bias of the different studies included, using the Newcastle Ottawa Scale (Table 1).

3. AMS 800™

AMS 800™ is a sophisticated system comprising three key components: an inflatable cuff, a pressure-regulating balloon, and a control pump. Cuff sizes range from 3.5 to 11 cm, with increments of 0.5 cm up to 8.0 cm, and then 1 cm increments for larger cuffs from 9 to 11 cm. To cater to different needs, the pressure-regulating balloon offers five preset pressures, ranging from 41 to 90 cm H_2O.

During the surgical procedure, the surgeon chooses the appropriate cuff size and reservoir pressure. Once implanted, the AUS operates through a smart cycling mechanism, which involves squeezing and releasing the control pump. Each squeeze pushes the pump's

contents into the reservoir while an equivalent amount of fluid is shifted from the cuff to the pump. This process continues until the cuff is emptied, ensuring controlled pressure.

The ingenious one-way valve prevents any backward flow of fluid, enhancing the device's efficiency and reliability. To allow sufficient time for voiding, the cuff remains open due to a refill-delay resistor. Around 2 minutes after the initial cycle, the cuff begins to refill slowly.

For added convenience, the pump is equipped with a deactivation button on its proximal side. When necessary, this button can lock the cuff in the open position before refilling. However, it is essential to leave a small amount of fluid in the pump to ensure easy reactivation later.

To reactivate the device, one only needs to squeeze the pump, disengaging the deactivation button. However, if the device was deactivated without any fluid in the pump, reactivation might be challenging due to insufficient pressure. In such cases, squeezing the sides of the pump's proximal aspect together overrides the deactivation, enabling the pump to gradually fill up, eventually reaching the required pressure for activation [7].

According to a recent systematic review considering seven studies, continence rates after AMS 800™ implant range from 61% to 100% in literature with concomitant improved patients' satisfaction rates [8].

Among the most recent published studies, the outcomes of 435 primary AUS implants with 119 cases involving AUS revisions were compared, reporting a 90% success rate in using 0–1 pad per day in the first group against the 82% in the latter [9].

In another noteworthy study spanning 13 years, Lai et al. shared their findings after performing AUS implantations on 218 patients with an average daily pad usage of 5.3. Following the surgery, the postoperative pad use dropped significantly to an average of 1.1 pads per day, even in patients with a history of radiation therapy [10].

Furthermore, a study involving 124 patients with a median follow-up of 6.8 years utilized validated questionnaires to evaluate the results. The data showed that 27% of the patients achieved total continence, meaning they reported not using any pads at all. Additionally, 52% of the participants attained social continence, using just one pad per day [11].

Moreover, a recent systematic review compared AMS 800™ with slings in five studies with a total of 509 patients. The findings showed a significantly higher success rate for AUS and comparable complication rate, thus stating the effectiveness and safety of this gold standard device [12].

From a complication standpoint, AMS 800™ infection rates do not differ significantly in literature, ranging from 0.5% to 10.6% [7]. A feature helping to improve the incidence of this feared complication is the introduction of InhibiZone Surface Treatment (American Medical Systems), a combination of rifampin and minocycline hydrochloride to both the pump and the cuff. An intriguing retrospective study examined 426 patients who underwent AMS™ 800 implantation. Half of them received the implant without the antibiotic coating, while the other half received the InhibiZone-coated implant. Surprisingly, the infection rate did not show significant differences between the two cohorts, providing an interesting perspective on the effectiveness of this feature [13].

Erosion represents a complication when considering prosthetic devices with a range between 5 and 10% [14].

Mechanical dysfunction is a significant concern in patients with AUS implants, as indicated by various studies. For instance, Linder et al. conducted a series of 1082 primary AUS implantations and found that 31.2% of patients (338 individuals) required secondary surgery. The reasons for secondary surgery included device infection and/or erosion (89 surgeries), device malfunction (131 surgeries), urethral atrophy (89 surgeries), and pump malposition or tubing complications (29 surgeries) [15].

Table 1. Newcastle Ottawa Scale for assessment of risk of bias.

Scheme 11	Selection			Comparability		Outcome		Total Score
	Representativeness of the Cohort	Ascertainment of Intervention	Demonstration That Outcome of Interest Was Not Present at Start of Study	Comparability of Cohorts on the Basis of the Design or Analysis	Assessment of Outcome	Was Follow-Up Long Enough for Outcomes to Occur	Adequacy of Follow Up of Cohorts	
Raj et al. [9] (2005)	*	*	*	*	*	*	*	7
Lai et al. [10] (2007)	*	*	*	*	*	*	*	7
Kim et al. [11] (2008)	*	*	*	*	*	*	*	7
De Cogain et al. [13] (2013)	*	*	*	*	*	*	*	7
Linder et al. [15] (2015)	*	*	*	*	*	*	*	7
Staerman et al. [16] (2013)	-	*	*	*	*	-	*	5
Ostrowski et al. [4] (2018)	*	*	*	*	*	*	-	6
Ostrowski et al. [17] (2019)	*	*	*	*	-	*	*	6
Ostrowski et al. [18] (2020)	*	*	*	*	*	*	*	7
Giammò et al. [5] (2021)	-	*	*	*	*	*	*	6
Lima et al. [6] (2018)	-	*	*	*	*	*	-	5

In terms of device survival rates, Linder et al. reported that the AUS had a survival rate of 90% at 1 year, 74% at 5 years, 57% at 10 years, and 41% at 15 years [15]. Other studies have utilized Kaplan–Meier reporting to assess mechanical failure. In one series involving 530 men, the 5-year Kaplan–Meier freedom from reoperation was 79.4% after primary implantation and 88% for revisions. Similarly, another study with 124 patients showed a 10-year Kaplan–Meier freedom from mechanical failure of 64%, with a median follow-up of 6.8 years [9,11].

4. ZSI-375

The ZSI-375 sphincter (Zephyr Surgical Implants, Geneva, Switzerland) offers a unique single-piece cuff design intended to encircle the urethra, accompanied by a pre-connected pump and pressure-regulating tank situated within the scrotum. Notably, unlike other devices, the ZSI-375 does not require an abdominal reservoir, which can significantly reduce operating time and eliminate the need for reservoir positioning maneuvers during implantation. This innovation represents a significant advantage in terms of surgical efficiency and patient comfort.

The initial introduction of the ZSI-375 sphincter in March 2009 paved the way for its utilization in medical practice across both Europe and Latin America, further establishing its potential as a viable alternative to traditional treatments for stress urinary incontinence (SUI) in men [8].

An important study conducted by Staerman et al. in 2013 provided valuable insights into the efficacy and safety of the ZSI-375 sphincter. The investigation involved 36 patients who received ZSI-375 implants, with a follow-up period of 15.4 months. Remarkably, complications leading to the removal of the sphincter occurred in only four patients, mainly attributed to issues of erosion and infection. Notably, the social continence rate at six months of follow-up was reported to be 73%, indicating a relatively low complication rate, especially compared with other studies with longer follow-up periods [16].

Further studies conducted by Ostrowski et al. added to the growing body of evidence supporting the effectiveness and safety of the ZSI-375 sphincter. In the first study, outcomes were assessed four years after implantation in 50 patients at a Polish center. Of these patients, 12 experienced complications, primarily related to urethral erosion and mechanical failure, leading to revision or removal of the device. Notably, urethral erosion was the sole

reason for permanent sphincter removal, while the cases of mechanical failure underwent successful re-implantation. Importantly, no infections were reported in this study [4].

In a subsequent prospective study, also conducted by Ostrowski et al., 86 male patients underwent ZSI-375 implants at two selected centers. The patients demonstrated a satisfaction rate of up to 94.2%, further reinforcing the potential patient benefits of this innovative treatment option. The study reported a complication rate of only 17.5%, primarily attributed to issues of urethral erosion and mechanical failure. It is noteworthy that the ZSI-375 exhibited a lower rate of complications and infections compared with the well-established AMS 800 device, underscoring its potential as a promising alternative [17].

The only multicenter study available, with a total of 109 patients undergoing ZSI-375 implants across 10 European centers, evaluated the effectiveness and safety of the device over an extensive follow-up period of 43 months. The study demonstrated a successful implantation rate of 92.66%, further confirming the device's efficacy in managing SUI in men. Importantly, only 8% of patients experienced urethral cuff erosion, leading to the permanent removal of the ZSI-375, while 2.75% reported mechanical complications, with no reported infections [18].

While the ZSI-375 sphincter shows great promise, further research and long-term follow-up studies are necessary to establish its long-term effectiveness, safety, and potential advantages compared with other existing devices. Nevertheless, the accumulating evidence from multiple studies underscores its potential as a viable and efficient treatment option for stress urinary incontinence in men. As technology continues to advance, the ZSI-375 represents a valuable addition to the array of treatments available to improve the quality of life for patients struggling with SUI. Continued research and innovation in this field are critical to address the diverse needs of patients and enhance the management of this common urological condition.

5. VICTO

The VICTO® device (Promedon, Austria) represents a notable advancement in the field of adjustable implantable devices for managing stress urinary incontinence (SUI). Comprising an occluding urethral cuff, a pressure-regulating balloon, and a self-sealing port for pressure adjustment, the VICTO® device offers a comprehensive and innovative solution for patients struggling with SUI.

Notably, the VICTOplus® model, an enhanced version of the VICTO® device, includes an additional stress relief balloon that effectively transmits transient intra-abdominal pressure changes to the occluding cuff. This feature is designed to optimize the device's performance, providing low resting occlusion pressure and conditional occlusion of the urethra, further enhancing its efficacy in controlling urinary flow and improving continence.

One of the principle innovative features of the VICTO® device lies in its self-sealing port integrated into the pump assembly. This unique aspect facilitates postoperative in situ pressure adjustment, allowing healthcare professionals to tailor the device's pressure settings to individual patient needs and optimize treatment outcomes. Such adjustability is crucial in achieving the desired continence level and ensuring patient satisfaction after surgery.

Moreover, the stress relief mechanism incorporated into the VICTOplus® model serves as a remarkable addition to its functionality. By effectively responding to transient intra-abdominal pressure changes, this feature further minimizes the risk of accidental leakage, providing patients with a more reliable and comfortable experience.

A significant advantage of both the Victo® and VICTOplus® devices is their one-piece assembly design, simplifying the implantation procedure and reducing the potential for mechanical failure.

In a retrospective analysis conducted by Giammò et al., both the Victo® and VICTOplus® devices were implanted in a cohort of 17 patients, with a follow-up period of 15 months. The study revealed the efficacy of these devices at one year after surgery, with an impressive

social continence rate of 94%. This outcome highlights the potential of the VICTO® devices to significantly improve the quality of life for patients dealing with SUI.

From a safety standpoint, the study reported a total of 17.6% Clavien Dindo I complications observed in the cohort, with no significant difference between the two devices. These complications are typically minor and manageable, further underscoring the safety profile of the VICTO® devices.

While the retrospective analysis provided promising results, it is essential to recognize the need for further research and long-term follow-up studies to validate and establish the VICTO® devices' long-term effectiveness and safety. As with any medical device, continued monitoring and evaluation are crucial to identify potential issues and optimize patient outcomes [5].

6. BR-SL-AS 904

BR-SL-AS 904 has been proposed for the first and only time by a Brazilian group headed by Lima in a prospective non-randomized trial including 15 patients in 2018.

Unlike conventional devices, the BR-SL-AS 904 presents a distinctive combination of a pumping system and an activating valve. The pumping mechanism plays a pivotal role in controlling the flow of fluid between the urethral cuff and the peritoneal reservoir, facilitating urination through cuff deflation for approximately three minutes. In the resting mode, urinary continence is ensured by the inflated urethral cuff, offering a more dynamic and adaptive solution to managing SUI.

The reported surgical technique for implanting the BR-SL-AS 904 involved both perineal and inguinal incisions. The perineal incision was utilized to locate and position the cuff, while the inguinal incision was utilized for the reservoir. The pump was placed in the scrotal sac, further highlighting the device's versatility in accommodating different anatomical variations and ensuring optimal placement for effective functioning.

Notably, the device was activated after a 30-day waiting period, during which the patient's postoperative recovery was monitored. Following the activation, a precise volume of 15 mL of distilled water was infused into the system through the activation valve, effectively initiating the device's functionality and enabling the dynamic control of urinary continence.

In a mean follow-up period of 192.7 months, a general improvement in the patients' quality of life was observed after the BR-SL-AS 904 device implant. The objective assessment revealed lower scores of involuntary urinary losses, indicating the device's effectiveness in achieving better continence control and enhancing patient satisfaction [6].

However, it is crucial to note that the long-term follow-up period revealed some instances of malfunctioning due to mechanical problems in four patients. These complications were effectively managed through the removal of the sphincter, highlighting the need for ongoing monitoring and evaluation of device performance to identify and address potential issues in a timely manner.

While the initial findings from this prospective trial are promising, the limited number of patients and the relatively short follow-up period warrant further research to establish the device's long-term efficacy and safety. Additionally, conducting randomized controlled trials with larger patient cohorts would provide more robust evidence and enhance the generalizability of the results.

7. Conti®

Conti® Artificial Urinary Sphincter (Rigicon, Inc., Ronkonkoma, NY, USA) was recently launched globally in two different models: ContiClassic® and ContiReflex®. This AUS consists of three pieces: a pump, an adjustable cuff and a reservoir, featuring the HydroShield™, a hydrophilic coating on all external surfaces, including the pressure regulating balloon. The improvement made in the ContiReflex® mainly concerns the pressure regulating balloon: the so-called "smart Reflex Balloon" has the feature to sense intra-abdominal pressure changes, modifying the occlusive cuff pressure in real time [19]. The

absence of literature about this new device does not allow a proper analysis and comparison and studies are needed to better evaluate its promising characteristics.

8. Discussion

SUI is a devastating complication for men undergoing major pelvic surgery, especially radical prostatectomy, or with benign prostatic obstruction. Although not life-threatening, SUI can be a major cause of anxiety, depression, and psychosocial disturbance that may significantly impact a patient's quality of life [20,21], in addition to also burdening the various health systems from an economic point of view. Of the various AUS used to date in the treatment of this pathology, in patients with surgical indications for their positioning, the AMS 800™ remains the gold standard for the treatment of SUI.

To date, the major indication for placement of these devices is SUI after radical prostatectomy, in cases where rehabilitation and medical therapy fail. The preoperative evaluation of the degree of urinary incontinence by means of tests such as the pad test, urodynamic examination and cystoscopy is fundamental, not before 12 months from the surgery, the latter performed above all to evaluate that the urethra is patent (especially in patients who have also received radiotherapy treatment) and there is no tumor pathology of the lower urinary tract. A large amount of data regarding efficiency, complications and patient satisfaction has been published regarding the AMS 800™. Overall continence rates after AMS 800™ placement range from 61 to 100%. Linder et al. recently published the largest reported cohort of AUS implants. They reviewed data from 1983 to 2011 identifying 1802 AMS 800™ procedures, of which 1082 (60%) were primary implantations that defined their study cohort. The median follow-up was 4.1 years. At last follow-up there were only 466 live patients of which 148 (32%) responded to a written correspondence regarding satisfaction and continence, 88 of 148 (59%) patients reported social continence (0–1 pad/day) and 94% patients (139 of 148) reported they would "definitely" (116) or "probably" (23) recommend AUS placement to a family member or friend [15].

The most important complications reported in the various series associated with the placement of this device are infections, ranging from about 1 to 10% in contemporary series, despite the recent introduction of InhibiZone Surface Treatment, which has not demonstrated changes in outcomes associated with its use but only an increase in costs. Management includes device removal and extensive irrigation followed by AUS replacement after 3 months or more; erosions, ranging from about 5 to 10% in contemporary series, usually occurring in the weeks or months immediately following surgery and usually due to accidental secondary injury caused during mobilization of the urethra; the mechanical dysfunction and revisions are a complication well-explained by Linder et al. that in their series of 1082 primary implantations of AMS 800™ reported 338 patients (31.2%) who underwent secondary surgery. This included 89 surgeries for device infection and/or erosion, 131 for device malfunction, 89 for urethral atrophy, and 29 for pump malposition or tubing complications. In addition, they reported an AUS device survival rate of 90% at 1 year, 74% at 5 years, 57% at 10 years, and 41% at 15 years. In case of revision for urethral atrophy, although resizing the diameter of the cuff is a good choice, it is often necessary to change its position, perhaps after another cystoscopy which highlights which tract of the urethra is most suitable for housing the new cuff.

The ZSI-375 sphincter has the advantage of not having an abdominal reservoir and this limits the surgical maneuvers and all the complications associated with them; the other advantage is that of being able to regulate the pressure of the cuff in case of urethral atrophy. Staerman et al. presented preliminary results in 36 patients with 73% of them achieving social continence at 6 months. Compared with AMS 800™ fewer studies have been conducted on the satisfaction rate and on the follow-up also linked to possible complications, especially of an infectious type. The two types of complications most described, related to the use of this device are urethral erosion and mechanical failure ranging from about 10 to 18% in contemporary series.

The VICTO® (Promedon, Austria) device has the advantage to be able to adjust the pressure of the port present in the pump even in the postoperative period and with a simple outpatient maneuver, in addition to the fact that it has an easy implantation method and creates less pressure on the urethra. Obviously, the main disadvantage is that it cannot be used in patients with severe SUI, as, precisely because of the technical characteristics of the product, it is deficient in the occlusive mechanism compared with AMS 800™; therefore, particular attention must be paid to the indication. The most important study on this device is that of Giammò et al. in which it was demonstrated a continence rate of 94% and a complication rate of 17.6% in a 15-month follow-up of 17 patients that were implanted Victo® and VICTOplus® devices without significative differences [5].

BR-SL-AS 904 has been proposed for the first and only time by a Brazilian group in a prospective non-randomized trial including 15 patients in 2018. Precisely because of the small number of cases and the presence of a single study in this regard, it is difficult to express judgments regarding both the functional results and the complication rates. Longer studies are needed to understand its efficacy (Table 2).

Table 2. Summary of outcomes and complications of the devices according to the literature.

	Total Number of Patients	Mean Follow-Up (Months)	Social Continence Rate (%)	Complication Rate, n (%)	Infections (n)	Erosions (n)	Mechanical Dysfunctions (n)
Raj et al. [9] (2005)	554	50–68	90%	21.5	/	21	31
Lai et al. [10] (2007)	218	36.5	/	44 (27.1%)	12	13	13
Kim et al. [11] (2008)	124	72	52	46 (37%)	7	10	29
De Cogain et al. [13] (2013)	213 vs. 213	4	/	38 (18%) vs. 50 (23%)	7 vs. 7	/	/
Linder et al. [15] (2015)	1082	48	59	338 (31.2)	89	89	131
Staerman et al. [16] (2013)	36	15.4	73	4 (11%)	3	1	/
Ostrowski et al. [4] (2018)	50	21.4	58	12 (24%)	0	9	3
Ostrowski et al. [17] (2019)	86	21	69.8	15 (17.5%)	0	4	11
Ostrowski et al. [18] (2020)	109	43	65.14	12 (11%)	0	9	3
Giammò et al. [5] (2021)	17	15	94	17.6	/	/	/
Lima et al. [6] (2018)	15	192.71	/	/	/	/	/

The absence of literature about the Conti® Artificial Urinary Sphincter (Rigicon, Inc., Ronkonkoma, NY, USA) impairs a proper analysis of the device with no continence or complication rates available.

However, our narrative review is not without limitations. The lack of randomized control trials affects the findings of our work, which includes mainly cohort studies. Moreover, a meta-analysis would have provided a more granular analysis and comparison of the different devices.

9. Conclusions

In conclusion, the management of stress urinary incontinence (SUI) in men after radical prostatectomy continues to revolve around the widely recognized and time-tested AMS 800™, which stands as the gold-standard treatment in this domain. Its long-standing success and well-established efficacy have solidified its position as the go-to option for urologists and patients alike. However, it is essential to acknowledge that the medical landscape is constantly evolving, with new technologies and alternative devices emerging as potential contenders.

Author Contributions: Conceptualization, A.R. and M.R.; methodology, A.R.; software, A.R.; validation, U.F., V.M. and C.B.; formal analysis, A.R.; investigation, M.R.; resources, M.R.; data curation, A.R., M.R. and U.F.; writing—original draft preparation, A.R. and M.R.; writing—review and editing, P.A., V.M. and C.B.; visualization, G.M.B. and C.B.; supervision, L.C., G.C. and C.B.; project administration, C.B. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: Data available in a publicly accessible repository. The data presented in this study are openly available in PubMed.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Gacci, M.; Sakalis, V.I.; Karavitakis, M.; Cornu, J.-N.; Gratzke, C.; Herrmann, T.R.; Kyriazis, I.; Malde, S.; Mamoulakis, C.; Rieken, M.; et al. European Association of Urology Guidelines on Male Urinary Incontinence. *Eur. Urol.* **2022**, *82*, 387–398. [CrossRef] [PubMed]
2. Scott, F.B.; Bradley, W.E.; Timm, G.W. Treatment of urinary incontinence by an implantable prosthetic urinary sphincter. *J. Urol.* **1974**, *112*, 75–80. [CrossRef]
3. Light, J.K.; Reynolds, J.C. Impact of the new cuff design on reliability of the AS800 artificial urinary sphincter. *J. Urol.* **1992**, *147*, 609–611. [CrossRef] [PubMed]
4. Ostrowski, I.; Ciechan, J.; Sledz, E.; Dys, W.; Golabek, T.; Chłosta, P.L. Four-year follow-up on a Zephyr Surgical Implants 375 artificial urinary sphincter for male urinary incontinence from one urological centre in Poland. *Cent. Eur. J. Urol.* **2018**, *71*, 320–325. [CrossRef]
5. Giammò, A.; Falcone, M.; Blecher, G.; Ammirati, E.; Geretto, P.; Manassero, A.; Bottero, D.; Lorusso, V.; Signorello, D.; Gontero, P.; 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*, 414–420. [CrossRef] [PubMed]
6. Lima, S.V.C.; De Barros, E.G.C.; Vilar, F.D.O.; Pinto, F.C.M.; Barros, T.D.P.; Truzzi, J.C.; De Toledo, L.G.M.; Kanasiro, F.; Amaro, J.L. Artificial sphincter "BR-SL-AS 904" in the treatment of urinary incontinence after radical prostatectomy: Efficacy, practicality and safety in a prospective and multicenter study. *Int. Braz. J. Urol.* **2018**, *44*, 1215–1223. [CrossRef] [PubMed]
7. James, M.H.; McCammon, K.A. Artificial urinary sphincter for post-prostatectomy incontinence: A review. *Int. J. Urol.* **2014**, *21*, 536–543. [CrossRef] [PubMed]
8. Van der Aa, F.; Drake, M.J.; Kasyan, G.R.; Petrolekas, A.; Cornu, J.N. 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*, 681–689. [CrossRef] [PubMed]
9. Raj, G.V.; Peterson, A.C.; Toh, K.L.; Webster, G.D. Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J. Urol.* **2005**, *173*, 1242–1245. [CrossRef] [PubMed]
10. Lai, H.H.; Hsu, E.I.; Teh, B.S.; Butler, E.B.; Boone, T.B. 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. *J. Urol.* **2007**, *177*, 1021–1025. [CrossRef] [PubMed]
11. Kim, S.P.; Sarmast, Z.; Daignault, S.; Faerber, G.J.; McGuire, E.J.; Latini, J.M. Long-term durability and functional outcomes among patients with artificial urinary sphincters: A 10-year retrospective review from the University of Michigan. *J. Urol.* **2008**, *179*, 1912–1916. [CrossRef]
12. Lin, L.; Sun, W.; Guo, X.; Zhou, L. Artificial Urinary Sphincter Is Better Than Slings for Moderate Male Stress Urinary Incontinence With Acceptable Complication Rate: A Systematic Review and Meta-Analysis. *Front. Surg.* **2022**, *9*, 841555. [CrossRef]
13. de Cógáin, M.R.; Elliott, D.S. The impact of an antibiotic coating on the artificial urinary sphincter infection rate. *J. Urol.* **2013**, *190*, 113–117. [CrossRef]
14. Suarez, O.A.; McCammon, K.A. The Artificial Urinary Sphincter in the Management of Incontinence. *Urology* **2016**, *92*, 14–19. [CrossRef]
15. Linder, B.J.; Rivera, M.E.; Ziegelmann, M.J.; Elliott, D.S. Long-term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic. *Urology* **2015**, *86*, 602–607. [CrossRef] [PubMed]
16. Staerman, F.; G-Llorens, C.; Leon, P.; Leclerc, Y. ZSI 375 artificial urinary sphincter for male urinary incontinence: A preliminary study. *BJU Int.* **2013**, *111*, E202–E206. [CrossRef] [PubMed]
17. Ostrowski, I.; Śledź, E.; Wilamowski, J.; Józefczak, M.; Dyś, W.; Ciechan, J.; Drewa, T.; Chłosta, P.L. Patients' quality of life after implantation of ZSI 375 artificial urinary sphincter due to stress urinary incontinence. *Cent. Eur. J. Urol.* **2020**, *73*, 178–186. [CrossRef]
18. Ostrowski, I.; Golabek, T.; Ciechan, J.; Śledź, E.; Przydacz, M.; Dyś, W.; Blewniewski, M.; Von Heyden, B.; Pottek, T.; Neugart, F.; et al. Preliminary outcomes of the European multicentre experience with the ZSI 375 artificial urinary sphincter for treatment of stress urinary incontinence in men. *Cent. Eur. J. Urol.* **2019**, *72*, 263–269. [CrossRef]

19. Rigicon, I. ContiReflex® Enhanced Artificial Urinary Sphincter. Available online: https://files.rigicon.com/Rigicon-ContiReflex-Artificial-Urinary-Sphincter.pdf (accessed on 25 June 2023).
20. Zhang, A.Y.; Fu, A.Z. Cost-effectiveness of a behavioral intervention for persistent urinary incontinence in prostate cancer patients. *Psychooncology* **2016**, *25*, 421–427. [CrossRef] [PubMed]
21. Kwak, Y.; Kwon, H.; Kim, Y. Health-related quality of life and mental health in older women with urinary incontinence. *Aging Ment. Health* **2016**, *20*, 719–726. [CrossRef]