Submitted: 05 March, 2025 Accepted: 19 May, 2025 Published: 30 July, 2025 DOI:10.22514/jomh.2025.091

REVIEW

JOMH Journal of Men's Health

# The inflatable penile prosthesis—the ultimate treatment for severe erectile dysfunction

Cristian Persu[1], Remus Nicolae Cartas[1,*], Irina Ciofu[1,*], Alexandru Ciudin[2], Victor Mihail Cauni[3]

[1]Department of Urology, "Carol Davila" University of Medicine and Pharmacy, 020021 Bucharest, Romania
[2]Urology Department, Hospital Universitari de Mollet, 08100 Barcelona, Spain
[3]Department of Urology, Colentina Clinical Hospital, 020125 Bucharest, Romania

***Correspondence**
Irina.ciofu@drd.umfcd.ro
(Irina Ciofu);
remus-nicolae.cartas@rez.umfcd.ro
(Remus Nicolae Cartas)

**Abstract**

Erectile dysfunction (ED) is a long-standing condition that benefits from modern treatments. For those seeking medical attention for ED, it brings a significant negative impact on health-related quality of life and self-esteem. The penile prosthesis represents the last option in the therapeutic hierarchy for this condition, and the last decades have seen major improvements in both mechanics, durability and safety of this implant. Herein, this review highlights the most commonly used penile prosthetic devices, the surgical techniques involved, and the current evidence supporting their safety and effectiveness. Data from the literature consistently supports the inflatable penile prosthesis as the ultimate treatment for ED, despite its irreversible nature, arising from the destruction of the natural tissue involved in erection. We conclude that the penile prosthesis should be offered as the last alternative treatment, only for regaining erectile function but not for the enlargement of the penis.

**Keywords**

Penile prosthesis; Erectile dysfunction; Penile implant

## 1. Introduction

The penile prosthesis (PP) represents a modern treatment option for an old condition: erectile dysfunction (ED). Although the concept behind the PP was first described over 70 years ago, recent technological improvements have made the penile implant an effective and reliable surgical treatment for ED. The European Association of Urology recommends the use of a penile prosthesis if other treatments fail or based on patient preference (strength rating: strong). This marks a significant paradigm shift, since older guidelines only mentioned the PP as a third-line therapy, indicated when conventional treatments failed. In contrast, the contemporary approach allows the patient to opt for a PP as the first- or second-line treatment as well [1]. In patients who understand and accept the risks of complications and the limits of the device, the inflatable penile prosthesis is a definitive treatment, providing improved quality of life and high satisfaction rates for both the patient and his partner [2].

This review aims to summarize the current available devices, the clinical data supporting their use, and the technique's potential drawbacks and limitations. To acquire a modern perspective of the present state of penile prosthesis treatment, we conducted a narrative review, beginning with our own clinical experience.

## 2. Materials and methods

A literature review was performed using PubMed, EMBASE and MEDLINE databases from January 2000 to April 2023. The following search terms were used: "erectile dysfunction" AND "penile prosthesis" OR "penile implant". The title and abstract were initially screened to identify relevant articles. Only articles written in the English language and with a full text available were taken into consideration. The manuscripts and appendices of the articles selected during the initial screening were thoroughly analyzed. Additionally, the reference section of each article was also reviewed for any pertinent sources. Studies were excluded if they did not meet the inclusion criteria or were deemed irrelevant. Duplicates, publications lacking original data, incomplete studies and papers with unclear results were also excluded. Fig. 1 provides a visual overview of the article selection process and the total number of entries found in each database.

## 3. Results

### 3.1 Main indications and patient selection

Typical candidates for penile prosthesis implantation include patients with ED after radical prostatectomy, severe diabetes mellitus or metabolic syndrome, and neurological conditions. The criteria for selecting the patient who might benefit from the implant are complex. Importantly, the patient with ED must be seeking medical treatment; the diagnosis itself does not necessarily lead to medical recommendations. The use

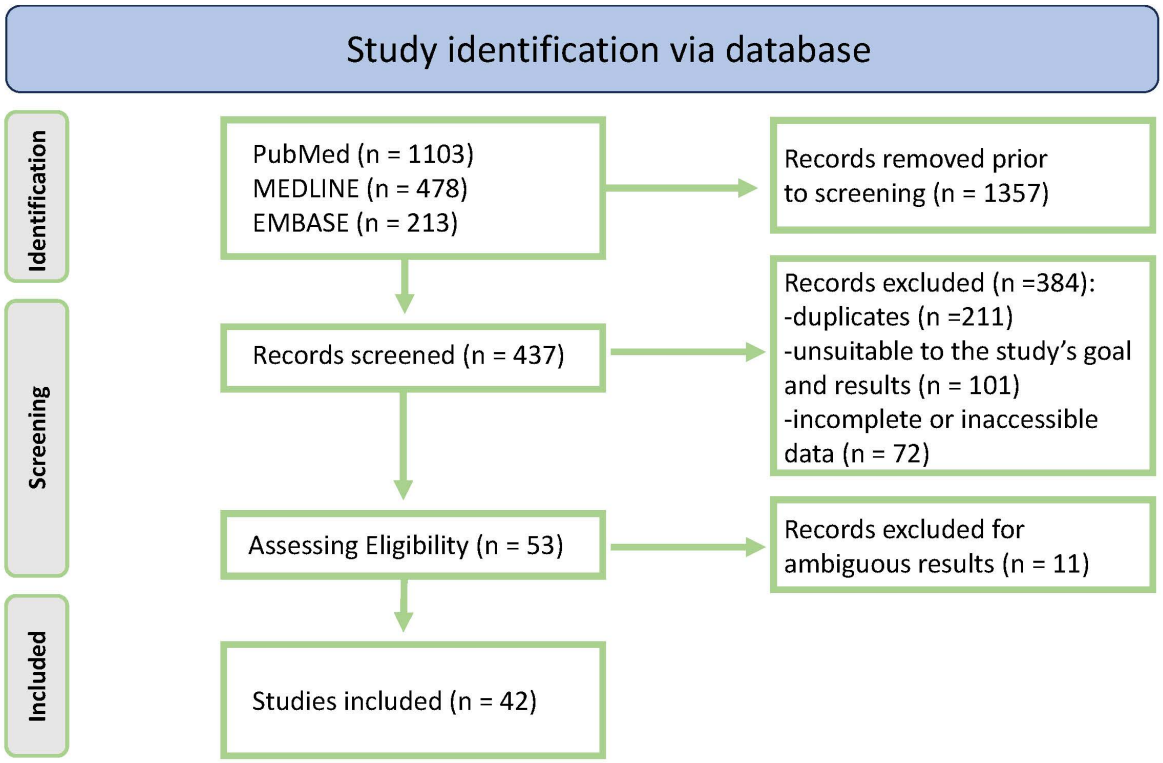


**FIGURE 1. A graphic illustration of the study selection process.**

of phosphodiesterase-5 inhibitors (PDE5i) is usually recommended as an effective therapy for ED. If a patient does not experience a satisfactory response from one agent, guidelines suggest trialing alternative PDE5 inhibitors before escalating to more invasive treatments. Patients who are unwilling to rely on medications, have contraindications to PDE5i, or have failed conservative therapy are considered candidates for PP implantation [1].

Patients undergoing female-to-male gender reassignment surgery represent a rather new indication for PP implantation. To achieve the necessary rigidity for sexual penetration, a PP might be the best option. In a large retrospective, single-center study, Falcone *et al.* [3] assessed the outcomes in 247 PP implantations after total phallic reconstruction secondary to gender dysphoria. After a mean follow-up of 20 months, 88% of patients were satisfied with the result, and the 5-year device survival was 78%. However, patients must be informed that there is a substantial risk of complications and that they might require numerous adjustments throughout their lives [3].

In the preoperative setting, the surgeon must assess the patient's compliance and expectations to enhance postoperative satisfaction. It is advised to take extra care when deciding which side the pump will be placed; this should be by the patient's preference, which is typically based on their dominant hand. When obtaining informed consent, the urologist must highlight risks such as mechanical failure, possible adverse events, including severe infection and the potential short lifespan of these implants.

Patients' comorbidities may influence the surgical outcome; therefore, a full medical history should be assessed before surgery. In a recent comprehensive study, Daniar *et al.* [4] and colleagues reviewed 130 systematic reviews and peer-reviewed studies to assess evidence associated with inflatable penile prosthesis implantation and to provide clinical recommendations on behalf of the European Society for Sexual Medicine (ESSM). In accordance with the Oxford criteria for levels of evidence and grades, they made some suggestions: patients with diabetes mellitus should have optimal glycemic control and achieve normal hemoglobin A1c (HbA1c) levels prior to penile implant surgery (level 2; grade B). Smoking may increase the likelihood that a patient having a PP implantation will need revision surgery, therefore, patients should be encouraged to quit smoking prior to the surgery (level 3; grade C). Peripheral vascular disease and hypertension may be linked to a higher risk of revision surgery (level 3; grade C). Spinal cord injury patients can receive PP if bladder emptying is possible and long-term indwelling catheters are avoided. Inflatable PPs are recommended for these patients (level 3; grade C). The satisfaction levels of patients getting a PP are not affected by age. When appropriate, patients of any age should be referred to PP implantation (level 3; grade C). PP implantation surgery is recommended for patients with ED regardless of HIV infection status (level 3; grade C). PP implantation is feasible for patients with Peyronie's disease; however, it should only be performed in the stable phase of the disease, and patients non-responding to medical treatment for ED (level 3; grade B) [4].

ED often has a profound negative effect on partner intimacy and overall quality of life. Treatment improves not only patient satisfaction but also partner sexual well-being [5]. In a study by Vakalopoulos *et al.* [6], 69 patients were evaluated for pre- and postoperative erectile function, and both patient and partner satisfaction were assessed using the International Index of Erectile Function Questionnaire (IIEF-5) and the Erectile

Dysfunction Inventory of Treatment Satisfaction (EDITS). Regression analysis revealed a direct linear correlation between partner satisfaction and overall treatment success [6]. This underlines the importance of involving both the patient and the partner in the preoperative discussion to manage expectations realistically.

A particular category of patients is represented by those who have simultaneous urinary incontinence (UI) and ED. (*e.g.*, after radical prostatectomy). The opportunity of a simultaneous implantation of both an inflatable penile prosthesis (IPP) and an artificial urinary sphincter (AUS) should be discussed with those patients, discussing all the complications that might arise. A recent retrospective study by Patel *et al*. [7] that analyzed 11,531 patients who underwent AUS surgery, PP surgery, or both (n = 161) concluded that there is a higher possibility of undergoing revision surgery for the PP in patients with dual treatment at 1 year (Odds Ratio (OR): 2.08; 95% Confidence Interval (CI): 1.32–3.27; $p < 0.01$) and at 3 years (OR: 2.60; 95% CI: 1.69–3.99; $p < 0.01$) follow-up. Revision surgery rates remained the same for AUS in the compared groups [7]. Similarly, Pyrgidis *et al*. [8] reviewed 18 studies, including a total of 16,517 patients, on the synchronous surgical management of ED and stress UI. Comparing synchronous implantation of PP and AUS versus asynchronous surgery, no statistically significant differences were observed in the reoperation rates (OR: 0.98, 95% CI: 0.52–1.84, $I^2$: 0%). However, combined surgeries (PP and AUS) versus implantation of only a PP or an AUS led to a higher reoperation rate in the combined group (OR: 2.02, 95% CI: 1.29–3.16, $I^2$: 36% and OR: 1.7, 95% CI: 1.25–2.32, $I^2$: 0% respectively). They concluded that in patients with severe ED and stress urinary incontinence, synchronous penile prosthesis and AUS implantation appear safe and efficacious [8].

## 3.2 The devices

The history of penile implants spans almost 70 years, with a constant evolution both in concept and mechanics. The first known penile implant was used in 1952 and consisted of an acrylic cylinder with constant volume. The prototype of inflatable devices was presented in 1973. The main reason for failure in the early days was the poor mechanical quality of the implant and the high rate of rejection.

Several penile implants are available on the market. One of the market leaders is the three-piece inflatable penile prosthesis developed by Boston Scientific® (Massachusetts, USA), the AMS 700®. With over half a million products implanted, this device proved to be a durable, effective and safe permanent treatment for erectile dysfunction. There are three variations of the basic device to accommodate different needs: Controlled Expansion® (CX), with girth-expanding cylinders; the Length and Girth Expansion® (LGX), shown in Fig. 2 and Controlled

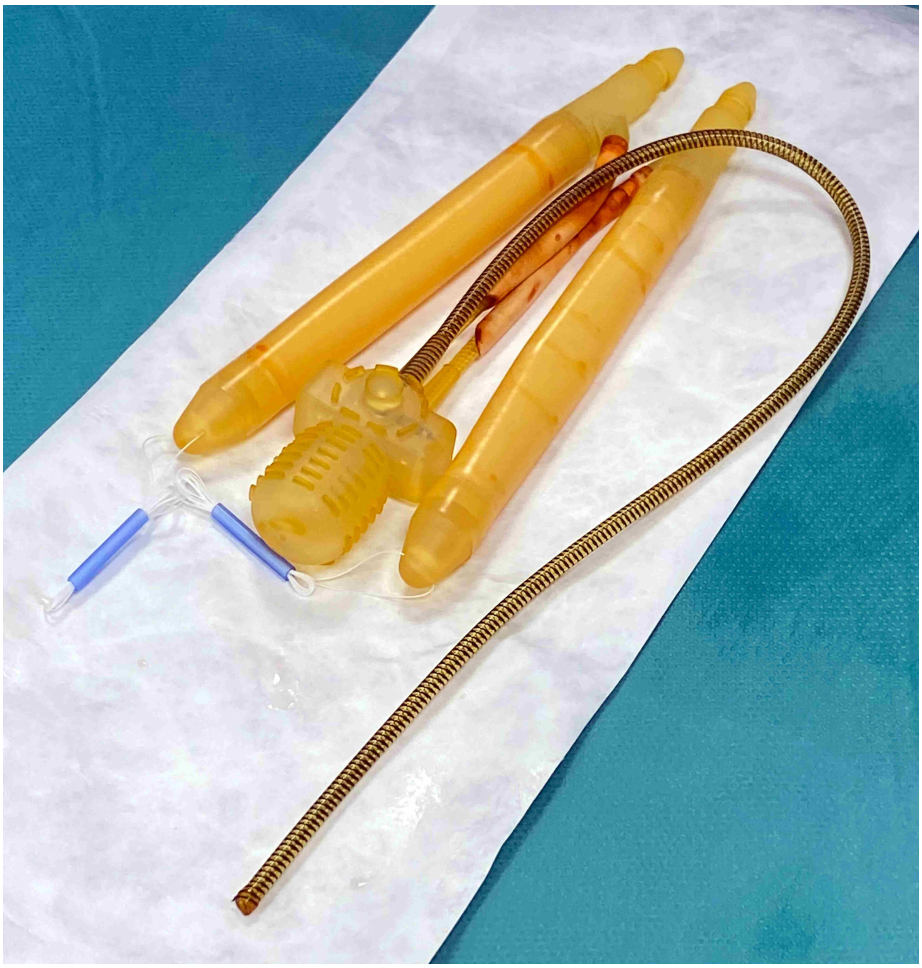

**FIGURE 2. Inflatable penile prosthesis, which increases both in length and girth.**

Expansion Restricted® (CXR), with shorter cylinders, developed for the oriental market or patients with corporal fibrosis or scarred tissues.

The AMS 700® consists of 3 main components: two cylinders, a pump and a reservoir. The cylinders are made of durable silicone, with 3 layers of fabric to minimize mechanical failure, and a Parylene coating on both the inside and outside to provide wear protection. The size of the prosthesis is customizable during surgery. For the LGX model, the length of the cylinders can be 12, 15, 18 or 21 cm, respectively, while the diameter ranges from 12 to 18 mm. There are also multiple, stackable rear-tip extenders of various sizes. The spherical reservoir accommodates 65 mL or 100 mL, depending on the size of the implant. The pump is connected to both the reservoir and the cylinders with color-coded tubes. It consists of the pump bulb, a deflation button, and an internal lock-out valve to prevent auto-inflation of the penile cylinders under high pressures inside the reservoir. The tubing is made of silicone and is kink-resistant.

The hydraulic system is filled with sterile saline, which is displaced between components. The user squeezes the pump multiple times to transfer fluid from the reservoir into the cylinders, thereby simulating a natural erection. When the deflation button is pressed for 2–4 seconds, the fluid returns to the reservoir and the cylinders deflate. Additional squeezing of the penile shaft helps achieve a natural flaccid appearance.

A notable feature of the AMS 700® implant is the InhibiZone® technology, which involves an antibiotic coating applied during the manufacturing process. The formulation of minocycline hydrochloride and rifampicin is effective against the most common germs linked to prostheses infection, leading to a decline in the infection rate of up to 82.4% at 60 days after surgery and 57.8% after 180 days [9]. Even among diabetic patients, who have higher infection rates than the non-diabetic population (8.4% *vs.* 4%) [10], the antibiotic coating was linked to a significant decrease in infection-related revision rate [11]. A study analyzing bacterial growth on non-infected devices removed during revision surgery reported fewer positive cultures on antibiotic-coated devices compared to native prostheses [12]. Additional studies evaluating the efficacy of antibiotic-coated devices are presented in Table 1 (Ref. [11–15]).

Even in non-coated devices, the tubing material exhibits a bactericidal effect, which is more effective against Gram-positive bacteria (S. aureus and S. epidermidis) than Gram-negative bacteria. This effect can be enhanced by immersing the device in ampicillin or ciprofloxacin solutions before surgery [13].

Another device with a long history on the market is the Coloplast Titan® Penile Implant (Fig. 3). While the design is similar to the AMS 700®, there are a few distinct features of the Titan. First, the implant is made of Bioflex®, a proprietary, medical-grade polyurethane that promises increased durability, rigidity, and flexibility compared to silicone-only devices, and enhanced axial rigidity and resistance to kinking. Additionally, the device has a hydrophilic coating made with polyvinylpyrrolidone (PVP), which allows for the intraoperative absorption of antibiotics, thereby reducing infection risk. The reported mechanical reliability rate exceeds 90% at 5 years. From a surgical perspective, the technique is similar to that used for other inflatable prostheses. Patient satisfaction, as reported in the literature, is comparable to that of other devices, including high rates of return to sexual activity. Complication rates and the type of complications encountered are also similar to those reported with other devices [2].

A newer competitor on the market is Rigicon (New York, USA), offering similar devices, with the flagship being called the Infla10 AX, providing expansion both in length and girth. The main difference lies in its approach to infection prevention. While Rigicon devices do not feature the antibiotic coating used by AMS devices, they include a hydrophilic outer layer, allowing the surgeon to submerge the implant into any antibiotic solution just before insertion. This hydrophilic layer also extends to the connectors, marking another difference from the AMS devices. According to the manufacturer, this layer promotes a faster insertion of the device because it becomes slippery once submerged in the antibiotic solution [8]. A brief comparison between the three competitors is shown in Table 2.

Alternatively, the industry offers semi-rigid implants, which have a constant volume while the shape can be manually adjusted to simulate natural erections (Fig. 4). The main drawback of these models is that they maintain the same volume all the time, which might be uncomfortable or undesirable for the patient. The most important advantages are their significantly lower price and long-term durability, since there are no mechanical components that could fail. At present, there is not enough data in the literature to support any conclusion regarding semi-rigid implants. All these aspects need to be discussed in detail with the patient before choosing between an inflatable or semi-rigid implant, given the permanent, irreversible nature of this treatment. It is generally accepted that a semi-rigid implant can be replaced with an inflatable one or vice versa, if required by the patient or considered more appropriate by the physician.

## 3.3 Surgical technique

Preoperative surgical site preparation is essential for reducing the risk of infection during surgery, especially in implanted patients. In a prospective, randomized, controlled study involving 100 patients, Yeung *et al.* [16] compared chlorhexidine-alcohol and povidone-iodine for genitourinary prosthetic surgery. Postoperative cultures were positive in 8% of patients in the chlorhexidine-alcohol group versus 32% in the povidone-iodine group ($p = 0.0091$). They concluded that chlorhexidine-alcohol appears to be the superior agent for skin preparation in genitourinary prosthetic procedures, though care must be taken due to its flammable properties [16]. Due to a claim that scrotal rugae are more vulnerable to cuts by clippers than ordinary skin, the Sexual Medicine Society of North America advises surgeons to choose the appropriate type of razors for hair removal before penile prosthesis surgery. It is recommended to perform the hair removal in the operating room rather than on the ward, which is considered as being less sterile [17].

Sterile urine, confirmed by preoperative urinary testing, is required before proceeding with surgery. Antibiotics for prevention should be given up to 60 minutes before mak-

**TABLE 1. Studies assessing antibiotic coating for PP implantation surgery.**

| Study | Study Population | Outcomes |
|---|---|---|
| Mulchahy *et al*. [11], 2011 | 6071 diabetic men with minocycline and rifampin (M/R) coated PP, 624 diabetic men with non-impregnated PP | 1.47% of M/R-impregnated implants experienced initial revisions due to infection, compared to 4.17% of non-impregnated implants. At 7 years, M/R-impregnated implants had a significantly lower rate of revisions due to infection (1.62% *vs.* 4.24%; log-rank $p < 0.0001$) than non-impregnated implants. |
| Ciftci *et al*. [12], 2016 | Swab cultures were obtained at first revision from all components: 31 devices with antibiotic coating, 40 devices without antibiotic coating | Devices coated with antibiotics and those not coated had culture positivity rates of 13% and 35%, respectively ($p = 0.00254$). Antibiotic-coated prostheses have much fewer positive cultures than non-coated devices. |
| Lipsky *et al*. [14], 2019 | 14,969 patients with primary IPP implantation from 1996 to 2014 | During the study period, there were 343 patients (2.3%) who needed surgery due to an infection, of which: 4.2% (217/5200) in the pre-antibiotic-coated IPP era, 1.5% (126/8209) in the antibiotic-coated-IPP era ($p < 0.001$). When antibiotic-coated IPPs were introduced, both diabetes and non-diabetic patients' infection-free survival rates improved ($p < 0.001$). |
| Mandava *et al*. [15], 2012 | 5214 IPP without an infection retardant coating, 4696 coated IPP of which:<br>- minocycline/rifampin (n = 3158)<br>- rifampin/gentamycin (n = 181)<br>- vancomycin/gentamycin (n = 181)<br>- hydrophilic coating only (n = 1176) | The infection rate for noncoated *vs.* coated prostheses was 2.32% *vs.* 0.89% ($p < 0.01$), including 0.63%, 0.55%, 4.42% and 1.11% for minocycline/rifampin, rifampin/gentamycin, vancomycin/gentamycin, and hydrophilic coatings, respectively. |

*PP: penile prosthesis; IPP: inflatable penile prosthesis.*

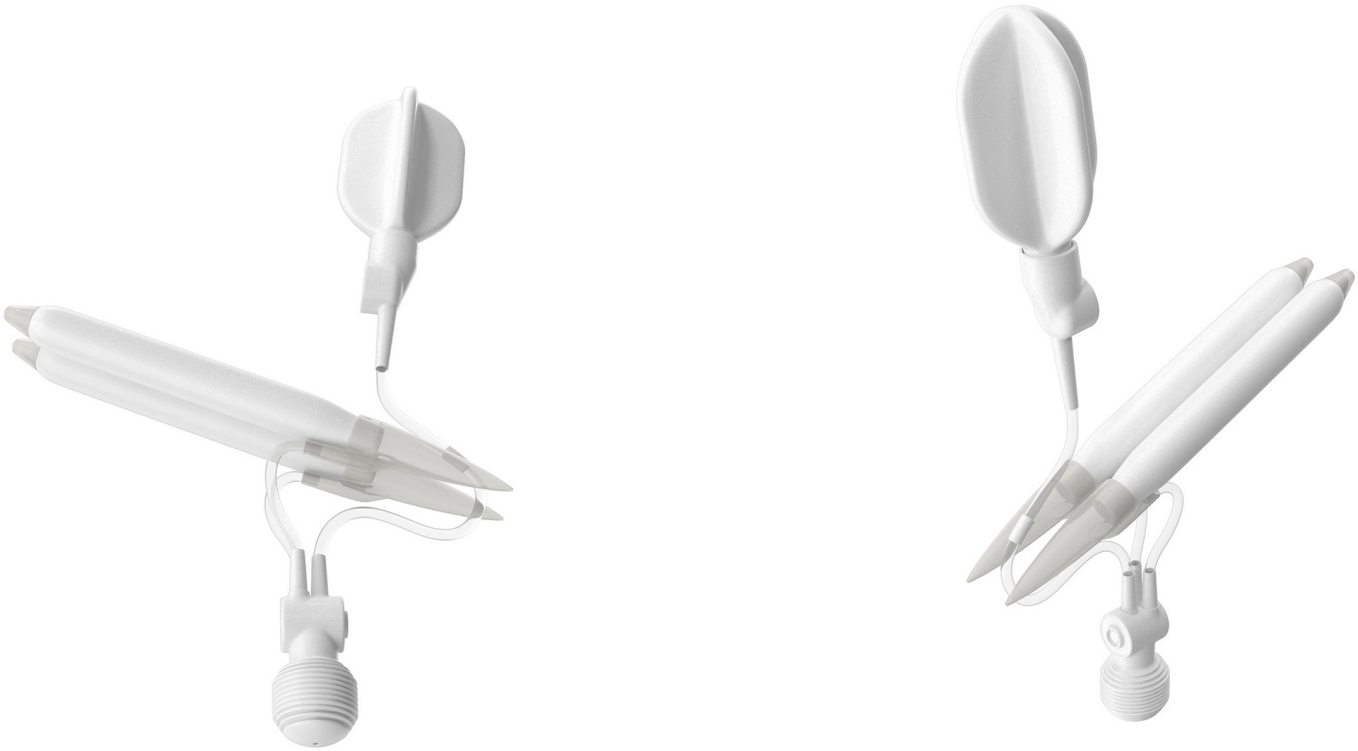

**FIGURE 3. Coloplast titan inflatable penile prosthesis.**

**TABLE 2. Comparison of the three main inflatable penile implant competitors on the market.**

| Device | Coloplast Titan | AMS 700 | Rigicon Infla10 |
|---|---|---|---|
| Manufacturer | Coloplast (Denmark/USA) | Boston Scientific (USA) | Rigicon (USA/Turkey) |
| Material | Bioflex (polyurethane) | Silicone | Silicone |
| Cylinder Expansion | Girth only | Girth (CX), Girth + Length (LGX) | Girth only (Standard and XL) |
| Antibiotic Coating | Hydrophilic (custom ABX) | InhibiZone (rifampicyn + minocycline) | Hydrophilic (custom ABX) |
| Pump | Durable, firm | Ergonomic, easier inflation | Ergonomic, anti-rollback deflate valve |
| Deflation Mechanism | Manual + lock | One-touch deflation | Quick-release valve |
| Reservoir | Standard or ectopic | Standard or ectopic | Standard or ectopic |
| FDA Approval | Yes | Yes | Yes |
| Axial Rigidity | High | Moderate to high | Moderate to high |
| Durability (5 yr) | >90% | ~85–90% | Limited data |
| Infection Rate | ~1–3% | ~1–2% | <3% (estimated) |
| Device Longevity | >10–15 years | Up to 20 years | <5 years |
| Ease of Use | More force to inflate | Easier pump | Easier pump |
| Post-op Satisfaction | 85–95% | 85–90% | Emerging data |

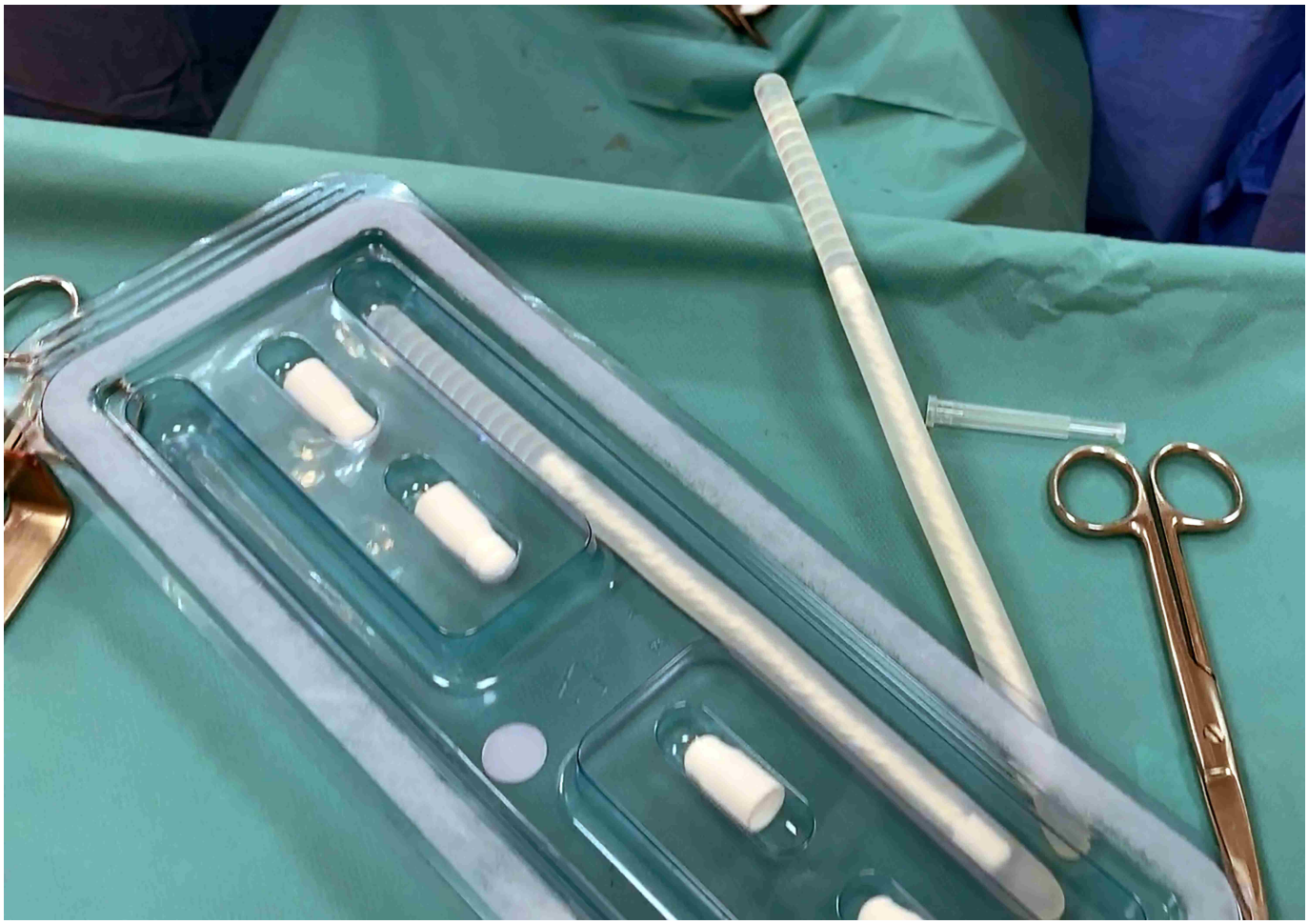

**FIGURE 4. Semirigid penile prosthesis.**

ing incisions. Aminoglycoside, first or second-generation cephalosporins, or vancomycin are all recommended by the American Urological Association, with the suggestion that antimicrobial prophylaxis should be discontinued 24 hours after penile prosthesis surgery [18, 19]. In a recent multicenter, retrospective study, Barham *et al.* [20] evaluated a total of 4161 patients who underwent primary IPP placement regarding the regimen of antibiotic prophylaxis. Of these, 2411 received vancomycin plus gentamicin alone, and 1750 received other regimens. For standard *vs.* nonstandard prophylaxis, the infection rate was similar between groups, at 1% *vs.* 1.2%. In a multivariable analysis, vancomycin plus gentamicin (Hazard Ratio (HR): 2.7, 95% CI: 1.4 to 5.4, $p = 0.004$) and diabetes (HR: 1.9, 95% CI: 1.03 to 3.4, $p = 0.04$) were significantly associated with a higher risk of infection. Antifungals (HR: 0.08, 95% CI: 0.03 to 0.19, $p < 0.001$) were associated with a lower risk of infection. The authors concluded that vancomycin plus gentamicin alone may increase the risk of infection compared to nonstandard regimens, and that adjunctive antifungal use may offer protective benefits [20]. Prospective studies are required to clarify effective practices in antimicrobial prophylaxis for PP implantation surgery.

The surgical approach is decided by the surgeon, who can opt for the penoscrotal or the infrapubic approach. Both approaches are safe and effective, and no difference has been reported in infection rates. However, the penoscrotal approach remains popular worldwide [21].

The penoscrotal incision should allow for clean dissection of Dartos and Buck's fascia, provide adequate exposure of the tunica albuginea, and enable safe incision of the corpora cavernosa without urethral injury. The Foley catheter decompresses the bladder and helps to better identify and protect the urethra. Bilateral tracts through the corporal bodies should be created for the cylinders using dilators of up to 12 mm distally and 11 mm proximally. With the help of the Furlow insertion tool, the cylinder size is determined by adding the proximal and distal lengths. The main instruments used for insertion are pictured in Figs. 5,6. Rear tip extenders can be used to fit the patient's anatomy (Fig. 7). There is a clear consensus that inserting an implant longer than the internal length of the corpora is not recommended, as it does not result in increased penis length and significantly raises the risk of erosion. After preparing the cylinders and the reservoir with saline, the cylinders can be inserted; using the Furlow insertion tool (Fig. 8) and the Keith needle, the traction suture at the tip of the cylinders is guided through the glans. The cylinders are fitted in by gently pushing them distally and with slight traction from the tip sutures (Fig. 9). Proximally, the ends of the cylinders should sit firmly against the crus and must not be twisted.

The reservoir is placed in the prevesical space, reached by blunt dissection in the transversalis fascia through the inguinal ring. Then, the reservoir can be filled with the appropriate amount of saline.

For the pump, the scrotum is bluntly dissected to form a pocket that will be easily accessible to the patient. The location of the pump should be previously discussed with the patient and should consider the dominant hand or other options of the patient.

After the corporotomy is closed with sutures, an inflate/deflate test is performed to assess device function. If no adjustments are required, the sutures from the glans can be removed, and the connection of all the components can be finalized. A final complete inflation and deflation test is then conducted to confirm proper device function. The penoscrotal incision is closed with sutures, the surgical site is dressed, and the penis is secured in an elevated position by taping it to the abdomen (Figs. 10,11).

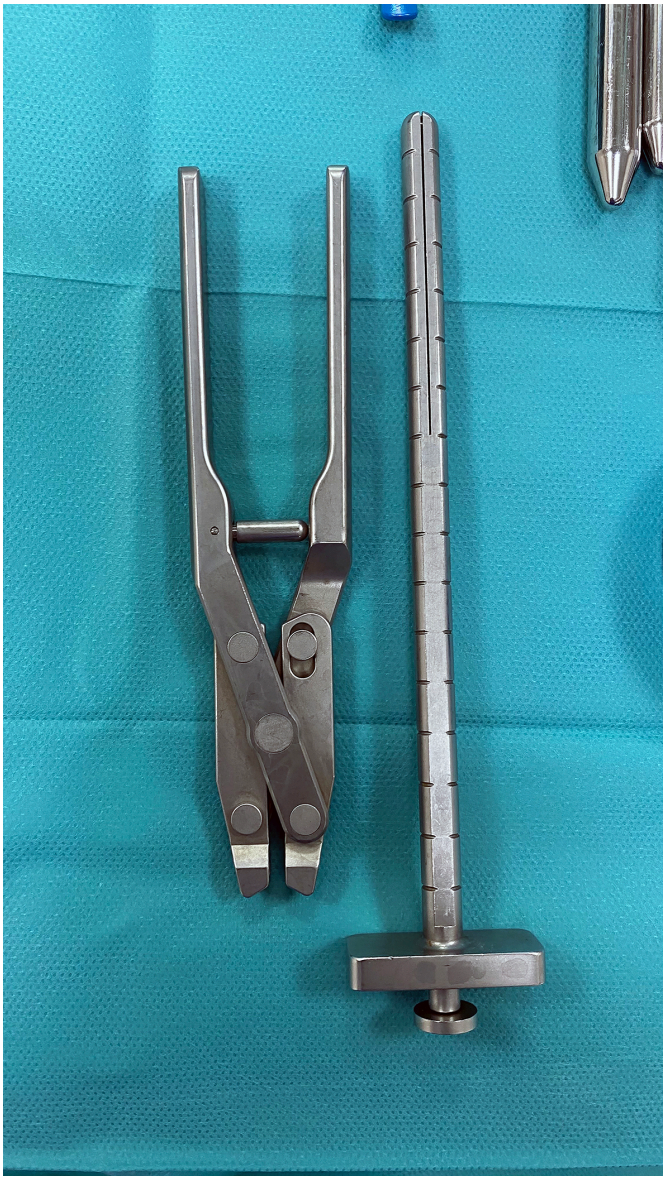

**FIGURE 5. Quick connect tool and Furlow insertion device.**

Some authors recommend leaving the device inflated to about 60–80% in the immediate postoperative setting or even for the next 6 weeks. Then, a protocol of daily maximum inflation shows benefits in keeping the device operational [22]. Some studies suggest that by performing these daily inflations, penile lengthening is more likely to be acquired. The position of the pump in the scrotum should be assessed and corrected daily by the patient after swelling from surgery has subsided [22].

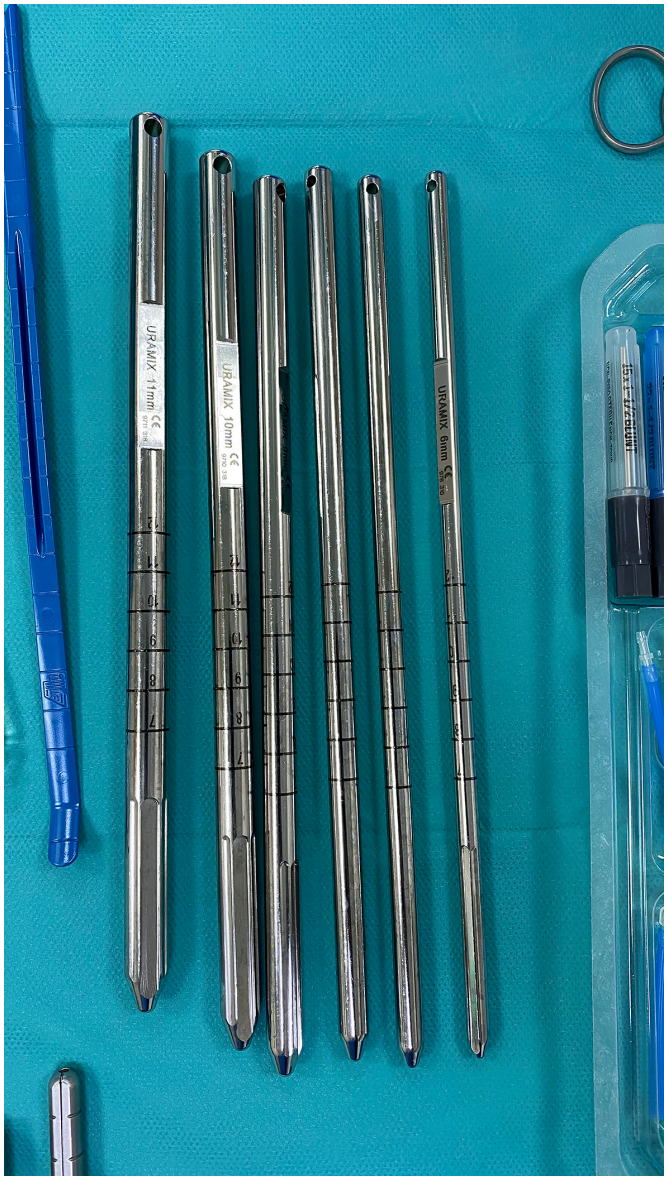


**FIGURE 6. Tool kit for cavernotomy.**

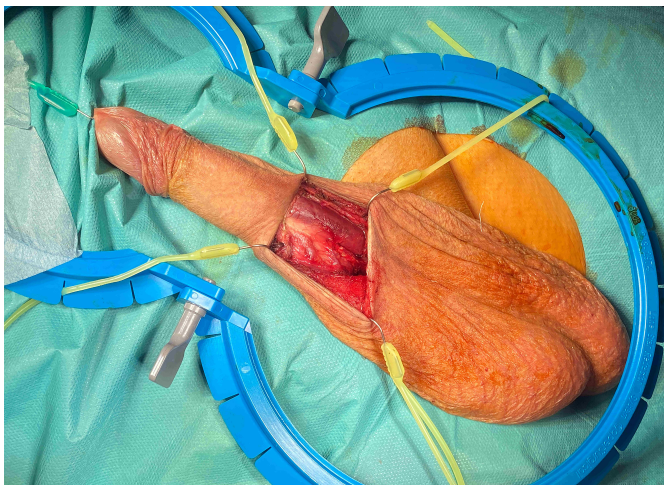

**FIGURE 7. Penoscrotal incision and exposure of the corpora cavernosa and urethra.**

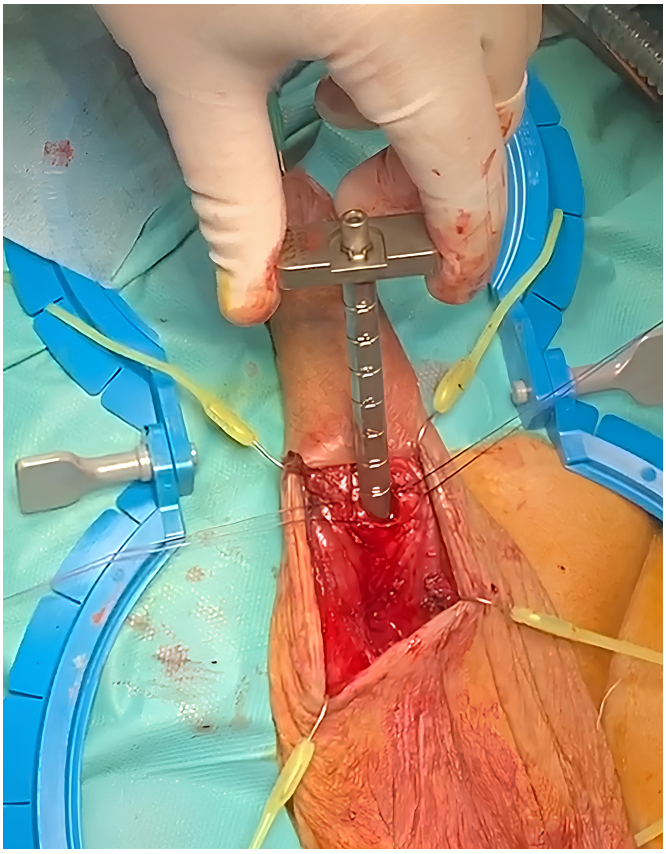

**FIGURE 8. Measurement of the internal length of the corpora.**

## 3.4 Intraoperative complications

During dilation of the corporal bodies, inadvertent crossover through the septal wall to the contralateral side may occur. If suspected during surgery, a distal crossover can be confirmed by placing dilators simultaneously inside both corporal bodies and detecting the sound of metal-on-metal contact. In such cases, a new dilation plane should be created by repositioning the dilators more laterally. If not technically possible, a hemi-corporotomy at the suspected crossover site may be performed to facilitate proper dilation and cylinder placement. For proximal crossovers, either due to fibrosis or technical errors, a similar technique can be used with good results. If not discovered during surgery, the patient may later present with pain, shortening or asymmetry of the penis during inflation, or de novo angulation of the penis. Management in such cases involves revision surgery, using similar maneuvers, although it may be complicated by the development of a fibrous capsule around the device [23].

Urethral injury and distal perforation should be suspected if blood is observed from the urethra or if irregular fluid from the corporal bodies leaks around the catheter. It is usually due to an aggressive dilation technique or too large cylinders and can occur at the initial dissection site or at the distal end, where the tunica albuginea is the thinnest. For distal urethral injuries, the urethra should be allowed to heal for 3 months before reoperating. Minor injuries do not require suturing and can be managed with catheterization for up to 7 days. Larger defects can be closed with two-layer sutures. In both instances, the

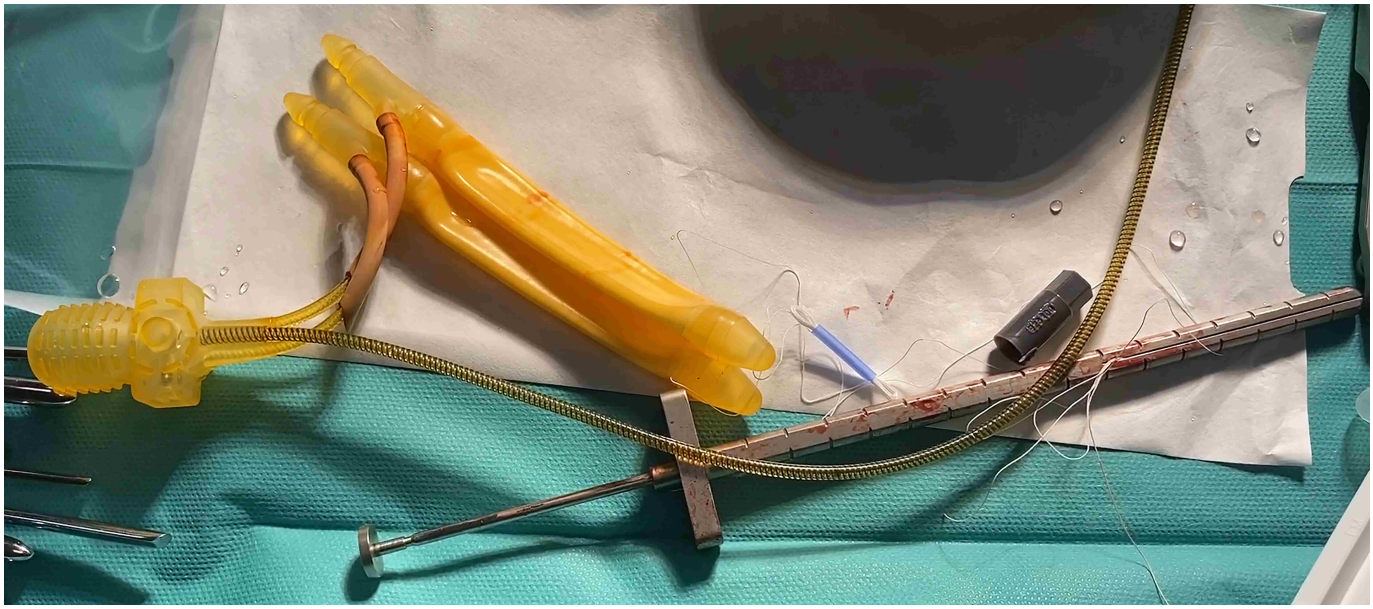

**FIGURE 9. Final preparation of the implant.**

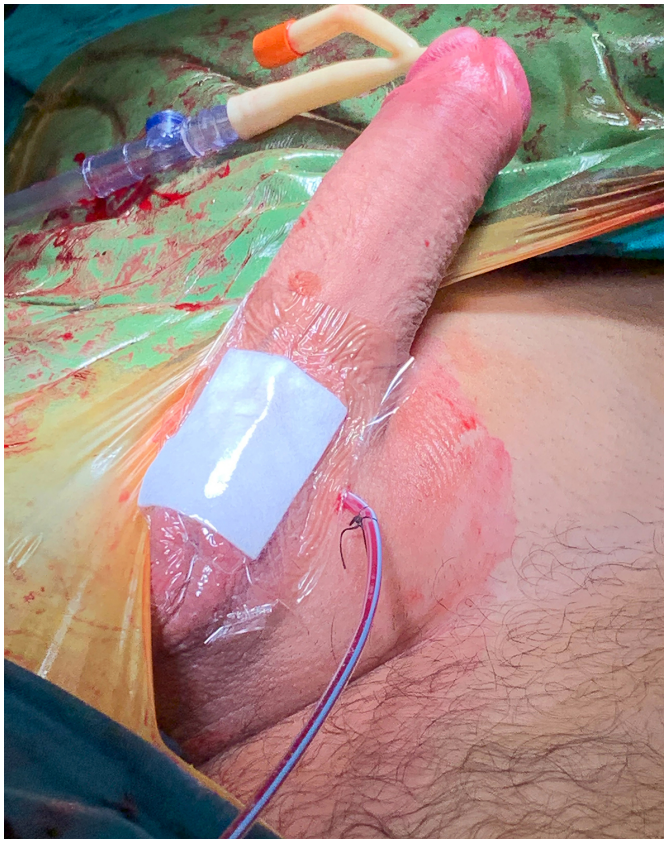

**FIGURE 10. Final aspect.**

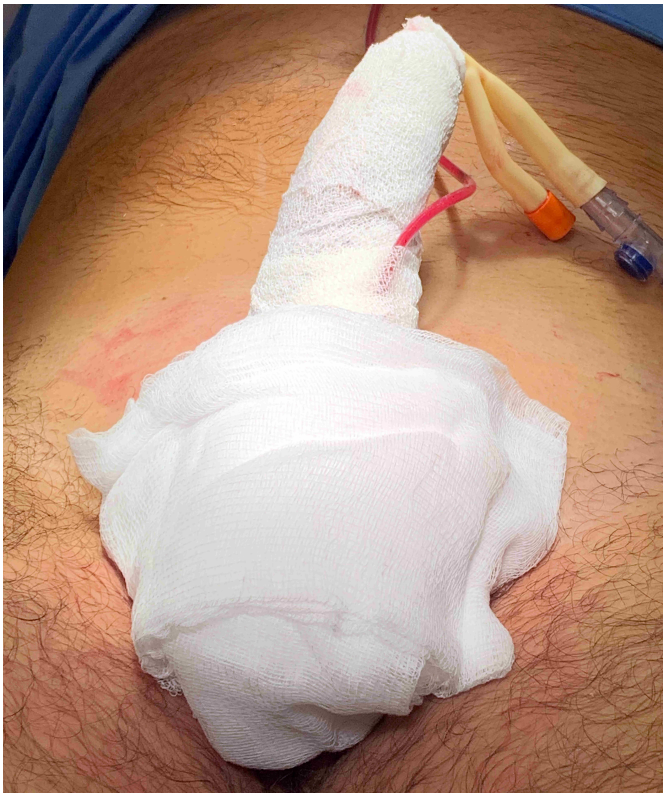

**FIGURE 11. Compressive dressing at the end of the procedure.**

contralateral cylinder can be left inside the uninjured corpora. If the injury is not close to the cylinder tips, the urethra can be sutured with a two-layer technique, and the surgeon will attempt to continue with the device insertion [24].

Several strategies exist for managing proximal corporal perforation. A traditional technique involves perineal dissection to assess and repair the corporotomy with direct suturing. Another technique uses a windsock repair with a non-absorbable mesh, which maybe later replaced because of infectious complications by a "plug and patch" technique that uses absorbable material. More recently, a technique was described in which a non-resorbable suture is placed at the site of the corporotomy and passed through the tunica albuginea and the rear tip extender, preventing the proximal tip of the cylinder from migrating. In these cases, the prosthesis should not be activated for six weeks to allow for adequate healing [25].

### 3.5 Follow-up

Frydman *et al*. [26] conducted a single-center study evaluating long-term outcomes following penile prosthesis (PP) implantation. A total of 130 patients who underwent the implantation surgery were assessed for a mean of 6.3 years. Surgical revision was needed in 32 patients (24.6%), including 20 cases (15.4%) where the prosthesis was removed. Global PP survival rate was 84.6%, and a history of previous PP placement was identified as a significant risk factor for device removal ($p$ = 0.02) [26]. In a similar single-center study, Bellaiche *et al*. [27] evaluated 150 patients for a mean follow-up of 76.12 months. They reported the PP survival rate of 69.7% at 5 years and 58.5% at 10 years (95% CI, 50.0–66.9). Their findings suggest that long-term prosthesis survival may be significantly influenced by the implant type and final prosthesis length [27]. Wilson *et al*. [28] analyzed 2,384 patients who underwent primary PP implantation. They reported an estimated 10-year revision-free survival rate of 68.5% and a 15-year rate of 59.7% [28]. Finally, Miller *et al*. [29] conducted a systematic review and meta-analysis of 12 studies encompassing over 20,000 patients with a minimum follow-up of 5 years. The analysis found that PP survival rates ranged from 93.3% at 1 year to 52.9% at 20 years, highlighting the progressive decline in device longevity over time and a summary is presented in Table 3 (Ref. [26–29]).

Long-term device survival does not necessarily equate to patient satisfaction. Further longitudinal studies assessing satisfaction in both patients and their partners are needed to provide a more comprehensive evaluation of therapeutic success. Additionally, the differences between the several available devices might influence the results. One of the most significant sources of bias remains the heterogeneity in the underlying causes of ED among the patient populations studied.

### 3.6 Postoperative complications

Hematomas occur in approximately 1–5% of patients and, while often painful and uncomfortable, are generally not dangerous. The scrotum is the most common site of development. These cases usually do not require revision surgery, rarely lead to device failure, and can be treated conservatively [30]. Prevention measures include the use of the “mummy wrap” dressing technique and partial inflation of the cylinders. Delayed hematomas (more than 5 days after surgery) are rare, with an estimated incidence of 0.5%. Management includes hematoma evacuation, oral antibiotics, and antibiotic irrigation. Patients are advised to avoid strenuous activity for at least 3 weeks and to withhold anticoagulants for at least 5 days, if possible, as prophylactic measures [31].

In a prospective study, Wang *et al*. [32] concluded that IPPs may result in a short erect penis length compared to that obtained with intracavernosal injections. The mechanism of shortening is not well understood but could be due to incorrect measurements during surgery and implantation of an inappropriate size of the prosthesis, or it could be related to the absence of glans tumescence, which contributes to the perception of length loss [32]. However, a study involving 56 patients with inflatable penile prostheses, in which 40 (72%) reported a subjective decrease in penile length, showed the absence of actual measurable penile length changes [33]. A more recent study comparing penile length after intracavernosal injections and after inflatable penile prosthesis insertion showed a significant increase in both length and circumference associated with prosthesis placement compared to preoperative injections [34]. Regardless of the mechanism, the loss of penile length can greatly affect the patient’s satisfaction rate with the prosthesis. Concomitant surgical intervention can be used to improve the patient’s perception of penis length and thus, his

**TABLE 3. Studies assessing long-term results of PP implantation surgery.**

| Study | Study Population | Follow-up | Outcomes |
|---|---|---|---|
| Frydman *et al*. [26], 2021 | 130 patients with PP implantation surgery | Mean 6.3 yr | Global PP survival rate was 84.6%. 32 patients (24.6%) required surgical revision. 6 non-life-threatening events occurred during surgery (4.6%), including 2 that resulted in non-placement of a PP (1.5%). 91 patients (80.5%) who still had their PP after the follow-up period expressed satisfaction |
| Bellaiche *et al*. [27], 2021 | 150 patients with PP implantation surgery | 76.12 mon | 61 patients (40.7%) required surgical removal of the device. Survival rate at 5 years was 69.7% and 58.5% at years (95% CI, 50.0–66.9). Survival rate of the PP was influenced by:<br>- type of prosthesis (other *vs.* Coloplast TITAN®, HR 1.89, 95% CI, 1.03–3.45)<br>- prosthesis final length (20–29 cm *vs.* 12–17 cm, HR 0.27, 95% CI, 0.09–0.77) |
| Wilson *et al*. [28], 2007 | 2384 patients with primarily PP implantation surgery | 10–15 yr | The 10-year revision-free survival rate for all reasons was 68.5% and 59.7% for 15 years, respectively. Freedom from mechanical breakage at 10 years was 19.4% and 71.2% for 15 years |
| Miller *et al*. [29], 2022 | 12 retrospective studies with 20,161 patients with PP implant | at least 5 yr | At one year, PP device survival was 93.3%; at three years, 91.0%; at five years, 87.2%; at ten years, 76.8%; at fifteen years, 63.7%; and at twenty years, 52.9%. In a subgroup analysis, 5-year device survival rates across newer and older studies were 90.6% *vs.* 82.1% ($p$ = 0.01) |

*PP: penile prosthesis; CI: Confidence Interval; HR: Hazard Ratio.*

satisfaction with the procedure. The ventral phalloplasty used by Miranda *et al*. [35] in a study was associated with the perception of increased penile length in 83.7% of the patients. Additional procedures, such as suspensory ligament release, suprapubic lipectomy, and augmentation corporoplasty, can be used during the implantation surgery or as part of a strategy to recover the perceptual length after the penile prosthesis insertion [36].

Impending erosion is another recognized complication, with a reported incidence ranging between 1–6% [37]. The device can erode laterally, medially, involving the urethra or into the glans. Contributing factors include infection, cylinder oversizing, perforation while dilating, or microperforations associated with the vigorous use of small dilators. Patients performing frequent clean intermittent catheterization are at increased risk of urethral erosion due to repetitive trauma. If both erosion and infection are present, explantation of the device is necessary. If not, the same device can be used. A distal incision allows the surgeon to dilate a new, more medial tract for the cylinder while performing corporoplasty using the fibrous tissue developed around the device. Patch grafts can be used as well. For medial erosion, a similar procedure is used, dilating a new, lateral tract and reinforcing the medial wall towards the urethra with surrounding tissue or allografts [38].

Infection is the most serious complication, usually requiring explanation of the device. Infection rates vary greatly in the literature. In a study following 7666 patients, Mirheydar *et al*. [39] concluded that the 5-year and 10-year reoperation rates with removal or replacement of the prostheses were 11.2% and 15.7%, respectively, with infection accounting for 27% of those reoperations. In another study with 2263 patients, Grewal *et al*. [40] found a 3.6% reoperation rate due to infection. Chung *et al*. [41], with a mean follow-up of 76 months, reported an infection rate of just 0.8% after 955 implantations. To reduce infection risk, several strategies have been proposed. These include minimizing skin-to-device contact and utilizing a “no-touch” surgical technique, and selecting antibiotic-coated devices. One large study found an infection rate of 5.3% with non-coated devices, which decreased to 2% with antibiotic-coated prostheses. The infection rate dropped to 0.46% in the group of patients where the “no touch” technique was also used [42]. A mummy wrap dressing technique has also been shown to reduce infection by improving hemostasis and minimizing hematoma formation [43]. A comprehensive review by Baird *et al*. [44] outlines a multitude of factors contributing to prosthesis-related infection.

Infection is usually followed by device explantation, as eradicating pathogens from genitourinary implants proves challenging. Particularly, bacteria rapidly form a biofilm that coats the device within 48 hours [45], making it harder for antibiotics to reach the organisms. Biofilms significantly reduce antibiotic efficacy, promote resistance and allow bacteria to spread easily across the tubing, meaning the entire implant is typically compromised. As a result, swab cultures may often show no growth, despite ongoing infection.

Clinical signs and symptoms of infection include persistent pain, tethering of the pump to the scrotum, erosion of different parts of the device to the exterior, open wounds and pus drainage. The InhibiZone® treatment decreased the rate of infection with coagulase-negative Staphylococci introduced on the surgical site during the procedure, which presented with local, mild infection signs. Fewer infections are present today, but with a more toxic presentation, due to more virulent pathogens such as Methicillin-Resistant Staphylococcus Aureus (MRSA) and Enterobacter aerogenes.

Revision surgery may be necessary when an infection is suspected. This generally involves complete device removal, extensive local irrigation, and the administration of systemic antibiotics. After the infection has been eradicated, a new device is implanted. However, inflammation causes scarring and fibrosis, leading to penile length reduction of up to 3.7 cm [46].

In 1991, Mulcahy introduced a salvage technique that permits immediate reimplantation during the same procedure. This strategy aims to preserve penile length and avoid difficult delayed reimplantation. The protocol involves irrigating the wound with seven antiseptic solutions, changing surgical attire and instruments, and then placing a new device. Patients are prescribed oral antibiotics for one month postoperatively. Using this approach, 82% of patients remained infection-free at follow-up [47]. A subsequent study evaluating antiseptic solutions for irrigation found that diluted povidone-iodine may be particularly effective in both preventing and treating infections during salvage procedures [48].

Since both inflatable and semirigid implants have several pros and cons, we tried to summarize them in Table 4, including most aspects of the decision-making process.

## 4. Conclusions

Erectile dysfunction, although not a life-threatening medical condition, represents a significant psychosocial issue both for the patient and his sexual partner. It has a profound impact on health-related quality of life, emotional well-being, and self-esteem. Despite this, many patients do not seek medical attention, and treatment should be reserved for those who are motivated to regain their erectile function.

In recent decades, there has been a notable evolution in both therapeutic options and clinical attitudes toward erectile dysfunction. Today, the treatment armamentarium includes reassurance, psychotherapy, medications, life-style changes and external devices, all of which have proven efficacy and play a critical role in a personalized, stepwise approach. When conservative measures fail, penile prosthesis implantation remains the final therapeutic option. This procedure has demonstrated long-term safety, efficacy and high patient acceptance, particularly in those who are strongly motivated to restore erectile function.

It is important to emphasize that penile prosthesis surgery is irreversible, and this aspect should be clearly and extensively discussed with the patient and documented in the medical files. While some degree of penile length preservation or enhancement may be achieved, this procedure should not be marketed as a method to increase penile length or girth. Instead, it must be positioned as a functional intervention aimed solely at restoring erectile capacity.

**TABLE 4. Comparison of the main features of inflatable *vs.* semirigid prostheses.**

| Device type | Inflatable (IPP) | Semirigid (SPP) |
|---|---|---|
| Mechanism | Hydraulic, inflatable | Bendable rods |
| Erection Control | On-demand, more natural | Constant semi-rigid |
| Concealment | Better (deflatable) | Poor (permanently rigid) |
| Satisfaction | 85–95% | 70–85% |
| Surgical Complexity | High | Low |
| Post-op Recovery | 4–6 weeks | 2–3 weeks |
| Infection Risk | 1–3% | 1–2% |
| Cost | High | Lower |
| Ideal For | Younger, active men | Elderly, limited dexterity |

*PP: penile prosthesis.*

## AVAILABILITY OF DATA AND MATERIALS

The data are contained within this article.

## AUTHOR CONTRIBUTIONS

CP, AC and VMC—Conceptualization; validation. RNC and CP—methodology. IC and AC—software. IC and CP—formal analysis. CP, AC and IC—investigation. VMC—resources. IC and RNC—data curation. RNC—Writing-original draft preparation. IC and VMC—Writing-review and editing. AC—visualization. CP—supervision. CP and VMC—project administration. All authors have read and agreed to the published version of the manuscript.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical review and approval were waived for this study by the "Carol Davila" University of Medicine and Pharmacy due to the retrospective nature of our literature review. All the patients treated in our clinic signed an informed consent form, including the agreement for the data obtained to be used for research purposes and publication without personal data.

## ACKNOWLEDGMENT

The authors acknowledge the support given by the medical nurses, residents and all the medical personnel involved in the treatment of this particular population of patients.

## FUNDING

This research received no external funding.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## REFERENCES

[1] Salonia A, Bettocchi C, Capogrosso P, Carvalho J, Corona G, Hatzichristodoulou G, *et al*. EAU guidelines on sexual and reproductive health. EAU Guidelines. EAU Annual Congress Milan: Milan. 2023.

[2] Jorissen C, De Bruyna H, Baten E, Van Renterghem K. Clinical outcome: patient and partner satisfaction after penile implant surgery. Current Urology. 2019; 13: 94–100.

[3] Falcone M, Garaffa G, Gillo A, Dente D, Christopher AN, Ralph DJ. Outcomes of inflatable penile prosthesis insertion in 247 patients completing female to male gender reassignment surgery. BJU International. 2018; 121: 139–144.

[4] Osmonov D, Christopher AN, Blecher GA, Falcone M, Soave A, Dahlem R, *et al*. Clinical recommendations from the European society for sexual medicine exploring partner expectations, satisfaction in male and phalloplasty cohorts, the impact of penile length, girth and implant type, reservoir placement, and the influence of comorbidities and social circumstances. The Journal of Sexual Medicine. 2020; 17: 210–237.

[5] Wilson SK, Chung E, Langford B, Schlesinger R, Koca O, Simsek A, *et al*. First safety outcomes for rigicon conticlassic® artificial urinary sphincter. International Journal of Impotence Research. 2024; 36: 829–832.

[6] Vakalopoulos I, Kampantais S, Ioannidis S, Laskaridis L, Dimopoulos P, Toutziaris C, *et al.* High patient satisfaction after inflatable penile prostheses implantation correlates with female partner satisfaction. The Journal of Sexual Medicine. 2013; 10: 2774–2781.

[7] Patel N, Golan R, Halpern JA, Sun T, Asafu-Adjei AD, Chughtai B, *et al*. A contemporary analysis of dual inflatable penile prosthesis and artificial urinary sphincter outcomes. Journal of Urology. 2019; 201: 141–146.

[8] Pyrgidis N, Barham DW, Hammad M, Sokolakis I, Hatzichristodoulou G, Lentz AC, *et al*. Synchronous surgical management of erectile dysfunction and stress urinary incontinence: a systematic review and meta-analysis of reoperation rates. Sexual Medicine Reviews. 2022; 10: 782–790.

[9] Carson CC III. Efficacy of antibiotic impregnation of inflatable penile prostheses in decreasing infection in original implants. Journal of Urology. 2004; 171: 1611–1614.

[10] Wilson SK, Carson CC, Cleves MA, Delk JR 2nd. Quantifying risk of penile prosthesis infection with elevated glycosylated hemoglobin. Journal of Urology. 1998; 159: 1537–1539; discussion 1539–1540.

[11] Mulcahy JJ, Carson CC III. Long-term infection rates in diabetic patients implanted with antibiotic-impregnated versus nonimpregnated inflatable penile prostheses: 7-year outcomes. European Urology. 2011; 60: 167–172.

[12] Ciftci S, Nemut T, Culha MM, Yilmaz H, Ustuner M, Yavuz Y, *et al.* Non-infected penile prosthesis cultures during revision surgery; comparison between antibiotic coated and non-coated devices. International Brazilian Journal of Urology. 2016; 42: 1183–1189.

[13] Chanyi RM, Alzubaidi R, Leung EJY, Wilcox HB, Brock GB, Burton JP. Inflatable penile prostheses implantation: does antibiotic exposure matter? Sexual Medicine. 2018; 6: 248–254.

[14] Lipsky MJ, Onyeji I, Golan R, Munarriz R, Kashanian JA, Stember DS,

*et al*. Diabetes is a risk factor for inflatable penile prosthesis infection: analysis of a large statewide database. Sexual Medicine. 2019; 7: 35–40.

[15] Mandava SH, Serefoglu EC, Freier MT, Wilson SK, Hellstrom WJ. Infection retardant coated inflatable penile prostheses decrease the incidence of infection: a systematic review and meta-analysis. Journal of Urology. 2012; 188: 1855–1860.

[16] Yeung LL, Grewal S, Bullock A, Lai HH, Brandes SB. A comparison of chlorhexidine-alcohol versus povidone-iodine for eliminating skin flora before genitourinary prosthetic surgery: a randomized controlled trial. Journal of Urology. 2013; 189: 136–140.

[17] Levine LA, Becher EF, Bella AJ, Brant WO, Kohler TS, Martinez-Salamanca JI, *et al*. Penile prosthesis surgery: current recommendations from the international consultation on sexual medicine. The Journal of Sexual Medicine. 2016; 13: 489–518.

[18] AUA. Urologic Procedures and Antimicrobial Prophylaxis (2019). 2019. Available at: https://www.auanet.org/guidelines/urologic-procedures-and-antimicrobial-prophylaxis-(2019) (Accessed: 19 March 2021).

[19] Wosnitzer MS, Greenfield JM. Antibiotic patterns with inflatable penile prosthesis insertion. The Journal of Sexual Medicine. 2011; 8: 1521–1528.

[20] Barham DW, Pyrgidis N, Gross MS, Hammad M, Swerdloff D, Miller J, *et al*. AUA-recommended antibiotic prophylaxis for primary penile implantation results in a higher, not lower, risk for postoperative infection: a multicenter analysis. Journal of Urology. 2023; 209: 399–409.

[21] Palmisano F, Boeri L, Cristini C, Antonini G, Spinelli MG, Franco G, *et al*. Comparison of infrapubic vs penoscrotal approaches for 3-piece inflatable penile prosthesis placement: do we have a winner? Sexual Medicine Reviews. 2018; 6: 631–639.

[22] Wallen JJ, Madiraju SK, Wang R, Henry GD. Implementation of length expanding inflatable penile prosthesis is not sufficient to prevent postsurgical penile shortening. Asian Journal of Andrology. 2019; 21: 98–100.

[23] Karpman E. Management of distal & proximal penile prosthesis crossover. The Journal of Sexual Medicine. 2016; 13: 1008–1012.

[24] Yang DY, Kohler TS. Damage control considerations during IPP surgery. Current Urology Reports. 2019; 20: 10.

[25] Pearlman AM, Terlecki RP. Proximal corporal perforation during penile prosthesis surgery: prevention, recognition, and review of historical and novel management strategies. The Journal of Sexual Medicine. 2018; 15: 1055–1060.

[26] Frydman V, Pinar U, Abdessater M, Akakpo W, Grande P, Audouin M, *et al*. Long-term outcomes after penile prosthesis placement for the management of erectile dysfunction: a single-centre experience. Basic and Clinical Andrology. 2021; 31: 4.

[27] Bellaiche J, Gonzalez Serrano A, Larre S. Survival and associated factors with long-term survival of penile prosthesis. Progrès en Urologie. 2021; 31: 374–380. (In French)

[28] Wilson SK, Delk JR, Salem EA, Cleves MA. Long-term survival of inflatable penile prostheses: single surgical group experience with 2,384 first-time implants spanning two decades. The Journal of Sexual Medicine. 2007; 4: 1074–1079.

[29] Miller LE, Khera M, Bhattacharyya S, Patel M, Nitschelm K, Burnett AL. Long-term survival rates of inflatable penile prostheses: systematic review and meta-analysis. Urology. 2022; 166: 6–10.

[30] O'Rourke TK Jr, Erbella A, Zhang Y, Wosnitzer MS. Prevention, identification, and management of post-operative penile implant complications of infection, hematoma, and device malfunction. Translational Andrology and Urology. 2017; 6: S832–S848.

[31] Garber BB, Bickell M. Delayed postoperative hematoma formation after inflatable penile prosthesis implantation. The Journal of Sexual Medicine. 2015; 12: 265–269.

[32] Wang R, Howard GE, Hoang A, Yuan JH, Lin HC, Dai YT. Prospective and long-term evaluation of erect penile length obtained with inflatable penile prosthesis to that induced by intracavernosal injection. Asian Journal of Andrology. 2009; 11: 411–415.

[33] Deveci S, Martin D, Parker M, Mulhall JP. Penile length alterations following penile prosthesis surgery. European Urology. 2007; 51: 1128–1131.

[34] Xie D, Nicholas M, Gheiler V, Perito D, Siano L, Kislinger I, *et al*. A prospective evaluation of penile measures and glans penis sensory changes after penile prosthetic surgery. Translational Andrology and Urology. 2017; 6: 529–533.

[35] Miranda-Sousa A, Keating M, Moreira S, Baker M, Carrion R. Concomitant ventral phalloplasty during penile implant surgery: a novel procedure that optimizes patient satisfaction and their perception of phallic length after penile implant surgery. The Journal of Sexual Medicine. 2007; 4: 1494–1499.

[36] Lee KC, Brock GB. Strategies for maintaining penile size following penile implant. Translational Andrology and Urology. 2013; 2: 67–73.

[37] Narang GL, Figler BD, Coward RM. Preoperative counseling and expectation management for inflatable penile prosthesis implantation. Translational Andrology and Urology. 2017; 6: S869–S880.

[38] Henry GD, Laborde E. A review of surgical techniques for impending distal erosion and intraoperative penile implant complications: part 2 of a three-part review series on penile prosthetic surgery. The Journal of Sexual Medicine. 2012; 9: 927–936.

[39] Mirheydar H, Zhou T, Chang DC, Hsieh TC. Reoperation rates for penile prosthetic surgery. The Journal of Sexual Medicine. 2016; 13: 129–133.

[40] Grewal S, Vetter J, Brandes SB, Strope SA. A population-based analysis of contemporary rates of reoperation for penile prosthesis procedures. Urology. 2014; 84: 112–116.

[41] Chung E, Van CT, Wilson I, Cartmill RA. Penile prosthesis implantation for the treatment for male erectile dysfunction: clinical outcomes and lessons learnt after 955 procedures. World Journal of Urology. 2013; 31: 591–595.

[42] Eid JF, Wilson SK, Cleves M, Salem EA. Coated implants and "no touch" surgical technique decreases risk of infection in inflatable penile prosthesis implantation to 0.46%. Urology. 2012; 79: 1310–1315.

[43] Henry GD. The Henry Mummy Wrap™ and the Henry Finger Sweep™ surgical techniques. The Journal of Sexual Medicine. 2009; 6: 619–622.

[44] Baird BA, Parikh K, Broderick G. Penile implant infection factors: a contemporary narrative review of literature. Translational Andrology and Urology. 2021; 10: 3873–3884.

[45] Wilson SK, Costerton JW. Biofilm and penile prosthesis infections in the era of the coated implants: a review. The Journal of Sexual Medicine. 2012; 9: 44–53.

[46] Lopategui DM, Balise RR, Bouzoubaa LA, Wilson SK, Kava BR. The impact of immediate salvage surgery on corporeal length preservation in patients presenting with penile implant infections. The Journal of Urology. 2018; 200: 171–177.

[47] Mulcahy JJ. Long term experience with salvage of infected penile implants. The Journal of Urology. 2000; 163: 481–482.

[48] Pan S, Rodriguez D, Thirumavalavan N, Gross MS, Eid JF, Mulcahy J, *et al*. The use of antiseptic solutions in the prevention and management of penile prosthesis infections: a review of the cytotoxic and microbiological effects of common irrigation solutions. The Journal of Sexual Medicine. 2019; 16: 781–790.

**How to cite this article:** Cristian Persu, Remus Nicolae Cartas, Irina Ciofu, Alexandru Ciudin, Victor Mihail Cauni. The inflatable penile prosthesis—the ultimate treatment for severe erectile dysfunction. Journal of Men's Health. 2025; 21(7): 1-13. doi: 10.22514/jomh.2025.091.