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Review

Penile Implants: A Lesson from the First 50 Years

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Abstract: This year marks the fiftieth anniversary of the first implant of an inflatable penile prosthesis (IPP). The authors of this paper want to celebrate the event with a narrative review of the current literature. The main scopes are antibiotic prophylaxis, patient satisfaction, and future developments. The implant of the first IPP in 1973, performed by Branteley Scott was a turning point in the history of penile prosthesis, revolutionizing the treatment of erectile dysfunction (ED). Since then, the idea of an inflatable device has not changed much. However, the innovations in design, materials, surgical techniques, and perioperative management led to a more natural, durable, and reliable device featuring fewer complications and greater patient satisfaction. Currently, IPP is associated with high patient satisfaction and excellent long-term outcomes, remaining the gold standard for men with refractory ED. Several strategies are under investigation to improve the technology of penile prosthesis, and we expect in the next future the introduction of new devices that are easier to activate, discreet, comfortable when deflated, and durable in time, mimicking a more physiological erection.

Keywords: penile implants; inflatable penile prosthesis; patient satisfaction; review

Citation: Giordano, A.; Capece, M.; D'Alterio, C.; di Giovanni, A.; Zimarra, A.; Napolitano, L.; Marino, C.; La Rocca, R.; Creta, M.; Cai, T.; et al. Penile Implants: A Lesson from the First 50 Years. *Uro* **2023**, *3*, 1–9. https://doi.org/10.3390/uro3010001

Academic Editor: Bartosz Małkiewicz

Received: 17 November 2022
Revised: 13 December 2022
Accepted: 15 December 2022
Published: 27 December 2022

1. Introduction

Erectile dysfunction (ED) has plagued a million men over centuries. Before penile prosthesis marketing, herbs, aphrodisiacs, and ointments were used to treat ED [1]. In the first half of the 1900s, the first attempts to restore erectile function were reported. In those years, the first prototypes of penile implants were introduced [2]. In 1973, the first inflatable penile prosthesis (IPP) was implanted by Brantley Scott, revolutionizing the treatment of the ED [3]. When the oral phosphodiesterase type 5 inhibitors (PDE5i) were marketed, it was thought that the era of the penile prosthesis was over. However, despite the efficacy of these new drugs, some patients suffering from ED were not responsive to medical treatment. Thus penile prosthetic surgery remains the main approach for refractory ED and for men who prefer a permanent solution [4].

Indeed, the demand for prosthetic surgery is increasing, and every year the number of implanted prostheses grows. However, during the SARS-CoV-2 pandemic, surgical procedures dropped significantly. The implantation of such a device is elective and should be deferred until it can be performed safely [5].

The objective of this paper is to review published literature of the last 50 years about penile prostheses. We focused particularly on antibiotic prophylaxis, patient satisfaction, and future developments.

We examined the penile prosthesis evolution, highlighting the improvement of the materials, the device coatings, and the mechanical design elements over the last 50 years.

2. The Advent of Penile Prosthesis Implants

The first examples of the penile implant were reported in the first half of the 20th century. Several approaches were tested to restore erectile function, such as rib cartilage,

acrylic and silicone implants, and polyethylene rods [6–10]. These devices frequently caused infections, significant penile pain, crus perforation, and partner pain during sexual intercourse [2].

The turning point of penile prosthesis history was the annual meeting of the AUA in 1973. The University of Miami and Baylor University groups presented their initial experiences with penile prosthesis implantation. Small and Carrion, from the University of Miami, shared their experience with a new type of paired sponge-filled silicone prostheses [11,12]. Brantley Scott, from Baylor University, shared the results of the first IPP [13], whose development started in 1969 while his team focused on bladder physiology and neurophysiology research. The intuition came from the hydraulic technology of the artificial urinary sphincter. A fluid was transferred into expandable cylinders placed inside the corpora cavernosa to restore a rigid erection.

The original device consisted of a round reservoir and two expandable single-layer silicone cylinders with two separate pumps. After the successful cadaveric trial in Baylor's Methodist Hospital, Scott's IPP was marketed through American Medical System (AMS). However, fewer than 15 devices were implanted from February 1973 to August 1974.

On the other hand, the prototype proposed by Small and Carrion consisted of two semi-rigid cylinders composed of a medical-grade silicone exterior with a silicone sponge interior. This semi-rigid prosthesis was either rigid to permit sexual intercourse or flexible enough to become comfortable during the day [11].

Since then, urologists have become interested in treating ED surgically.

The semi-rigid penile prosthesis was updated in the following years.

The first truly malleable penile prosthesis was introduced in 1980 by Jonas and Jacobi. This device was made of silicone wrapped around a metal core that provided the implant "memory" [14].

3. Penile Prosthesis: From 1973 to Current

Over the 50-year history of the device, penile prostheses have evolved to be easier to use. All components of 3-pieces IPPs have been updated to meet specific needs. (Summary in Tables 1 and 2).

Table 1. The updates of penile prosthesis introduced by AMS.

Year	Device	Manufacturer	Innovation
1973	First IPP introduced	AMS	Two single-layer cylinders with both a pump for inflation as well as another for deflation.
1974	-	AMS	A single inflation/deflation mechanism was introduced.
1983	700	AMS	Single layer-cylinders. Single pump.
1987	700-CX	AMS	Three-ply design
1990	700-CXR 700-CXM	AMS	Designed for corporal fibrosis
1990	700-Ultrex	AMS	Bidirectional polypropylene fabric layer
1993	700-Ultrex Plus	AMS	Improved cylinders that limited lengthening to 25%
2001	Inhibizone-coated model	AMS	These cylinders, covered with an antibiotic solution resulted in a decreased infection rate.
2004	Tactile Pump	AMS	It was able to release more fluid per squeeze.
2006	Momentary squeeze	AMS	To press the button just once, without holding it, was enough to deflate the cylinders.
2010	Conceal reservoir	AMS	It optimized submuscular placement.

Table 2. The updates of penile prosthesis introduced by Mentor/Coloplast.

Year	Device	Manufacturer	Innovation
1983	Mentor-IPP	MENTOR/COLOPLAST	Three piece-implant
1989	Mentor-I-Alpha	MENTOR/COLOPLAST	Preconnected-closed system
1992	Enhanced-Mentor-I-Alpha	MENTOR/COLOPLAST	Reinforced tubing
2000	Reservoir-lockout valve	MENTOR/COLOPLAST	It prevented the autoinflation
2002	Titan-IPP	MENTOR/COLOPLAST	Hydrophilic coating
2008	One touch pump	MENTOR/COLOPLAST	It made the deflation easier
2012	Zero-degree tubing	MENTOR/COLOPLAST	It facilitated intracorporal cylinder placement
2012	Soft cylinder tips	MENTOR/COLOPLAST	They decreased palpability when the device was inflated.

Nowadays, the main manufacturers are Boston Scientific and Coloplast.

The prototype introduced by Scott and marketed by AMS was then modified to avoid cylinder aneurysm [15].

In 1983 AMS released the series 700. It featured three-layer cylinders and a singinflation and deflation instead of the single-layer and two separated pumps.

In the same year, Mentor company, acquired later by Coloplast, released its own implant. It was made of silicone and Bioflex, a supple yet durable biopolymer material.

In 1987 AMS updated the series 700 with the CX model. Three years later, the narrower 700 CXM and 700CXR were marketed for smaller penis or penile fibrosis as a minor corporal dilation was required. In these models, the previous Polytetrafluoroethylene (PTFE) coating was replaced by a multilayer design of woven silicone to reduce friction and resistance to inflation [16].

In the same year, AMS released the 700 Ultrex model, the ancestor of the AMS 700 LGX. The main innovation was the expansion of the device in both length and girth during inflation. Despite the appealing feature of this model, this implant was not indicated in patients affected by Peyronie's disease due to unfavorable mechanical properties compared to AMS CX/CXR [16].

The 700 Ultrex Plus, released by AMS in 1993, showed better resistance and fewer complications than the original 700 Ultrex [17].

In 2001 AMS introduced the InhibiZone® technology. The cylinders were coated by the manufacturer with antibiotics that were slowly released after the operation.

This new technology decreased infection rate compared to the uncoated models [18].

With the same purpose, in 2002, Coloplast introduced the Titan IPP featuring the HydroVantage® (Figure 1). This hydrophilic coating could hold whichever antibiotics were used for the soak solution and prevent bacterial attachment [19].

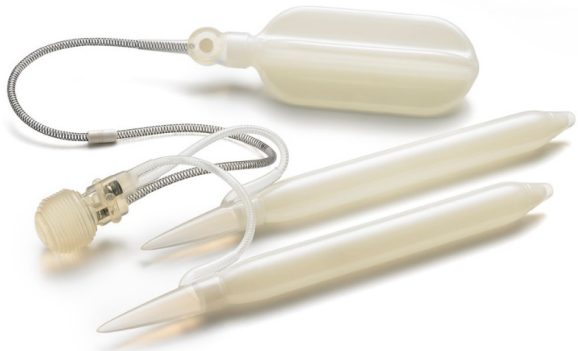

Figure 1. The Coloplast inflatable penile prosthesis Titan with One Touch Release pump and cloverleaf reservoir. Courtesy of Coloplast, www.us.coloplast.com (accessed on 16 November 2022).

Both InhibiZone® and HydroVantage® are still mainstays of the two manufacturers.

The effort to build an increasingly efficient and reliable device led to the pump and reservoir innovation. In 2004 AMS introduced the Tactile Pump, which is easier to grab and can transfer more fluid per squeeze. Shortly after, the Momentary Squeeze was presented. Thanks to this innovation, the patients could press the button just once to deflate the cylinders without holding them.

In 2010 AMS released the Conceal reservoir: its flattened shape optimized the submuscular placement compared to the spherical one.

On the other hand, Coloplast 2000 provided a lock-out valve for the reservoir to decrease the risk of auto-inflation (Figure 2). The lock-out mechanism contains a "poppet" valve that does not allow fluid to exit when pressure is applied to the reservoir.

Figure 2. Coloplast cloverleaf reservoir with the lock-out valve is available in 75 and 125 mL sizes. Courtesy of Coloplast, www.us.coloplast.com (accessed on 16 November 2022).

In 2008 the One Touch Release pump was introduced with the same intent as AMS' Momentary Squeeze [20].

In 2012 Coloplast introduced the zero-degree junctions to facilitate intra-corporal placement.

In recent years, two new manufacturers entered the market of penile implants: Zephyr and Rigicon.

Rigicon markets three types of IPP: the Infla10X, Infla10AX, and Infla10NB. They feature a novel fourth layer to increase integrity and prevent a malfunction from erosion. The Infla10X and Infla10AX offer only girth and both length and girth expansion, respectively, while the Infla10NB is designed for fibrotic narrow corpora cavernosa [21].

Zephyr has marketed penile prostheses since 2012. Different devices are currently available: the 3-piece inflatable ZSI 475 (Figure 3), the malleable ZSI100, and the soft ZSI100 CF penile implant. The latter consists of two flexible silicone cylinders featuring a hydrophilic coating in polyvinylpyrrolidone (PVP). It was designed to maintain the space in the corpora cavernosa in case of penile prosthesis removal due to infection.

Zephyr is the only manufacturer to market both malleable and inflatable prostheses specifically designed for phalloplasty: ZSI100FtM and ZSI475FtM, respectively. The latter comprises a single inflatable cylinder connected to a reservoir, a manual pump, and realistic shapeable glans. Both prostheses feature a fixation plate to anchor the device to the pubic bone and guarantee a more anatomic angle of erection [22].

Figure 3. The ZSI475 for cis male implantation. Courtesy of Zephyr Surgical Implants, www.zephyr-surgical-implants.webflow.io (accessed on 16 November 2022).

4. Outcomes of Penile Prosthesis

4.1. Infection Rate and Antibiotic Prophylaxis

Infection is the most significant complication following penile prosthesis implantation leading to postoperative morbidity, increasing health care costs, and psychological stress for the patient. Over 80% of post-surgical infections are caused by gram-positive bacteria such as Staphylococcus epidermidis, with the remaining usually caused by gram-negative bacteria such as Escherichia coli, Serratia, and Proteus mirabilis. More recently, infection sources have shifted to a larger proportion of gram-negative bacteria and fungi [23]. Prosthetic materials attract bacterial seeding during the time of surgery both through direct inoculation and hematogenous or lymphatic spread [24]. Once colonized, bacteria initiate the formation of a glycocalyx biofilm, a multi-layered bacterial microenvironment that prevents antibiotics from getting inside and that often determines the need for device explant.

Several cautions have been adopted to decrease the risk of infection: treating urinary or other site infections before surgery, preoperative night cleaning, preoperative washing with an antiseptic solution, intraoperative antimicrobial washing, and preventing unnecessary traffic into the operation room and "no-touch" technique [25].

Even manufacturing companies have spent significant resources revising their devices to minimize infection rates.

Antibiotic and hydrophilic coatings of prostheses have been developed to reduce the risk of infection. InhibiZone® is a coating combination of rifampin and minocycline developed by AMS that was proven to reduce explant surgery due to infection. Similarly, Coloplast's HydroVantage® coating adsorbs whichever antibiotic and/or antifungals and slowly elutes it after the implantation. Surgeons tested various combinations of dips for hydrophilic implants to minimize infection rate. Several in vitro studies have shown the combination of rifampin and gentamicin as highly effective [26]. While rifampin and gentamicin appear to be the most widely used and studied combination for the antibiotic soak solution, a study by Wilson et al. examined various antibiotic dips, not including the combination of rifampin with gentamicin. The combination trimethoprim/sulfamethoxazole was the most effective, with broad-spectrum properties and low-cost [27].

The antibiotic administration to the patient before and after the surgery is equally important. According to AUA Guidelines, a combination of an aminoglycoside with a first- or second-generation cephalosporin or vancomycin (i.e., gentamicin-vancomycin) is recommended. At the same time, EAU guidelines suggest the administration of second-

or third-generation cephalosporin or a penicillin agent with anti-penicillinase efficacy (i.e., Ampicillin-Sulbactam) [28].

However, the most effective antibiotic choice varies according to geographical areas and the related bacterial resistance.

The penile prosthesis infection rate decreased in the last 50 years from 8–11% in 1980 to the current rate of 0.3–2.7% due to the introduction of new materials and periprocedural care. Currently, penile prosthesis is a reliable and low infection rate device implanted in men. There are no lower infection rates reported in the literature for other commonly implanted prosthetic devices such as knee prostheses, prosthetic heart valves, total hip arthroplasty, and breast implants that show infection rates of 0.74–2.39%, 0.98–4.4%, 0.4–2%, and 2.9%, respectively [29–31].

4.2. Patients Satisfaction and Reliability

Besides functional and surgical outcomes, patient satisfaction was a frequent research subject. Patient satisfaction rates are generally very high, in most cases above 80%. The differences observed are mainly related to the brand of penile prosthesis and the device implanted, inflatable or malleable. Several studies on patient satisfaction with malleable prostheses were conducted: the general satisfaction rates in retrospective surveys range from 69% to 86.6% [32–35].

When the implant of a two-piece IPP (Ambicor®) is indicated, the general patient satisfaction rate is high and varies from 80–96.4% across the studies [36–39].

A huge body of evidence about three pieces of a penile prosthesis is reported in the literature. In the early series [40,41], lower satisfaction rates were reported. In more recent studies, satisfaction rates range from 86% to 98.1% [42–46].

Most patients are very satisfied after a penile implant as these devices are durable and reliable for a long time. In a large prospective study by Wilson et al., data about prosthesis survival were collected. Four different models were implanted in 2384 virgin patients, and a 15 years survival estimate was available for AMS 700 CX and Mentor Alpha I. This work is a milestone in the literature about penile prostheses as it provides long-term survival rates of inflatable penile prostheses manufactured by both AMS and Mentor/Coloplast. The overall survival of the devices was 60% at 15 years. However, thanks to technical improvement, mechanical survival improved: at 10 years, the survival rate of Mentor Alpha I was 65.1% and 88.7% before and post-enhancement, respectively. The same trend was observed for the AMS 700CX in a shorter time of 3 years; before and after introducing Parylene coating, the mechanical survival was 88.4% and 97.9%, respectively. Compared to other devices such as elbow, breast, tricuspid, and intra-ocular prosthesis, the IPP remains one of the most reliable and revision-free device [46].

Despite the high satisfaction rate reported in the literature, a perfect tool to evaluate penile satisfaction in patients with a penile implant does not exist [47].

Indeed most of the studies used suboptimal or non-validated questionnaires.

5. Future of Penile Prostheses and Conclusions

The main scope of research and development about penile prosthesis is to realize new devices that are easier to activate, discreet and comfortable when deflated, and mimic a physiological erection. Several innovative prototypes have been proposed recently, like touchless prostheses, electronic penile implants, and injectable semi-rigid penile prostheses. They failed for a lack of funding, and probably none of those devices will make it to the marketplace [48–51].

We think research and investors should focus on cosmetic and aesthetic enhancement. Indeed, the main reasons for patient dissatisfaction are the subjective loss of penile length and glans' flaccidity. So several adjuvant surgical techniques have been described to improve aesthetic outcomes after penile implantation, but with the introduction of new devices, these surgeries could be avoided. [52,53].

In conclusions, different strategies to make prostheses more "user-friendly" and less invasive are under investigation. Still, we would like to underline that many innovations are likely to be launched in the near future since no brand would reveal a novel technology without a precise market plan.

Author Contributions: Conceptualization: T.C., A.P. and M.C. (Marco Capece); Methodology: A.G. and C.D. Investigation: A.d.G.; Writing—Original Draft: A.d.G., C.D., C.M. and A.Z.; Writing—Review & Editing: A.G., A.d.G. and L.N.; Visualization: M.C. (Massimiliano Creta); Supervision: M.C. (Marco Capece) and R.L.R.; Project Administration: T.C. and A.P. 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: Not applicable.

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

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