Penile Implants

Subjects: Andrology
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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.

penile implants | inflatable penile prosthesis | erectile dysfunction

1. 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 [1][2][3][4][5]. These devices frequently caused infections, significant penile pain, crus perforation, and partner pain during sexual intercourse [6].

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 [7][8]. Brantley Scott, from Baylor University, shared the results of the first IPP [9], 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 [7].

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” [10].

2. Penile Prosthesis

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 [11].

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 [12].

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 [12].

The 700 Ultrex Plus, released by AMS in 1993, showed better resistance and fewer complications than the original 700 Ultrex [13].

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 [14].

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 [15].

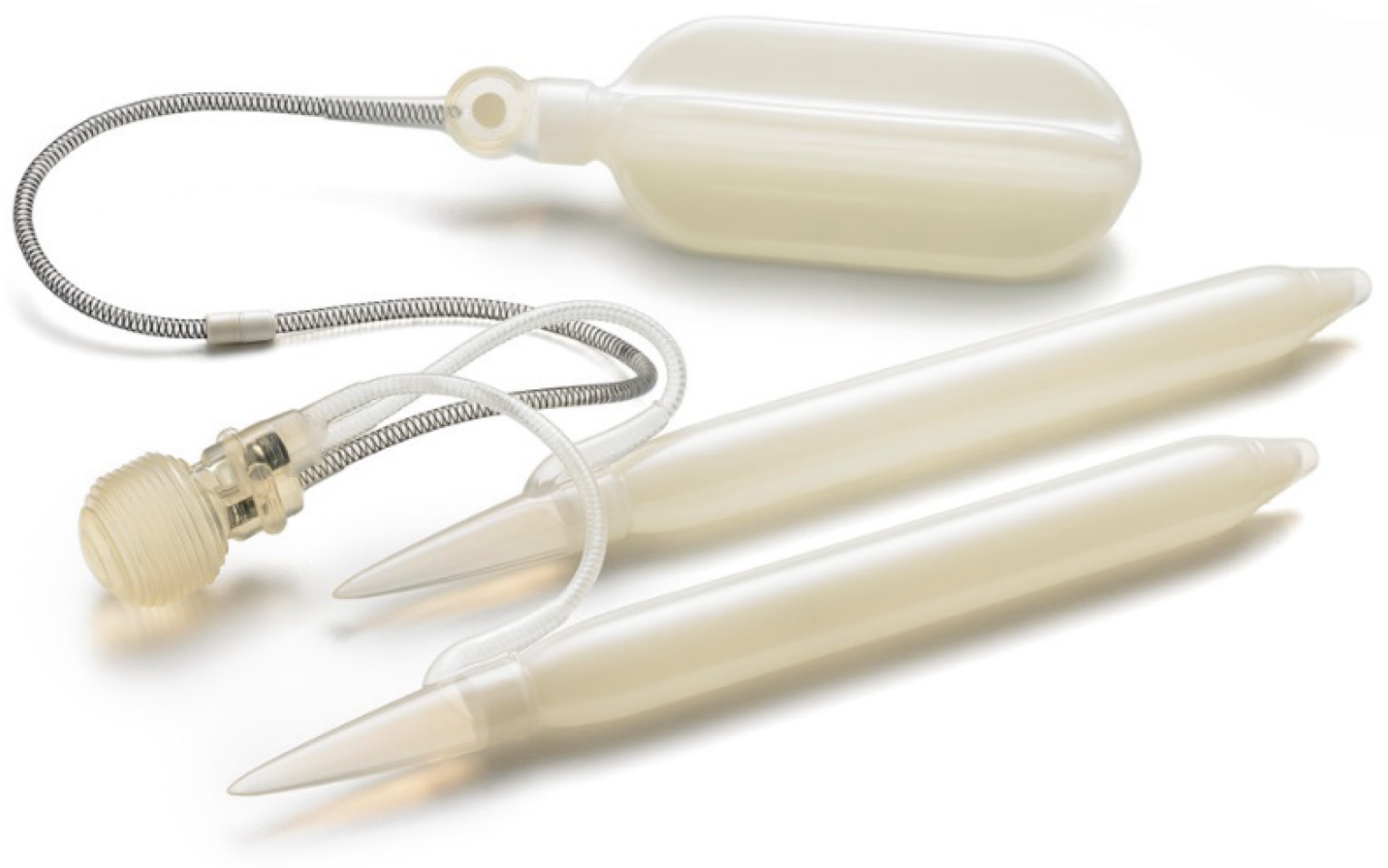


Figure 1. The Coloplast inflatable penile prosthesis Titan with One Touch Release pump and cloverleaf reservoir. Courtesy of Coloplast, www.us.coloplast.com (accessed on 16 November 2022).

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 [16].

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 [17].

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.



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

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 [18]

2.1. 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 [19]. Prosthetic materials attract bacterial seeding during the time of surgery both through direct inoculation and hematogenous or lymphatic spread [20]. 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 [21].

Antibiotic and hydrophilic coatings of prostheses have been developed to reduce the risk of infection. The antibiotic administration to the patient before and after the surgery is equally important.

2.2. 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% [22][23][24][25].

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 [26][27][28][29].

References

1. BOGORAS N Uber die volle plastische wiederherstellung eines zum Koitus fahigen Penis (Peni plastica totalis). Cent. Chir. 1936, 22, 1271–1276.
2. Frumkin, A.P. Reconstruction of the male genitalia. Am Rev Sov. Med 1944, 2, 1944–1945.
3. Bergman, R.T.; Howard, A.H.; Barnes, R.W. Plastic reconstruction of the penis. J. Urol. 1948, 59, 1174–1186.
4. LOEFFLER, R.A.; SAYEGH, E.S. Perforated acrylic implants in management of organic impotence. J. Urol. 1960, 84, 559–561.
5. Lash, H. Silicone implant for impotence. J. Urol. 1968, 100, 709–710.
6. Carrion, H.; Martinez, D.; Parker, J.; Hakky, T.; Bickell, M.; Boyle, A.; Weigand, L.; Carrion, R. A History of the Penile Implant to 1974. Sex. Med. Rev. 2016, 4, 285–293.
7. Small, M.P.; Carrion, H.M.; Gordon, J.A. Small-Carrion penile prosthesis. New implant for management of impotence. Urology 1975, 5, 479–486.
8. Small, M.P. Small-Carrion penile prosthesis: A report on 160 cases and review of the literature. J. Urol. 1978, 119, 365–368.
9. Brantley Scott, F.; Bradley, W.E.; Timm, G.W. Management of erectile impotence. Use of implantable inflatable prosthesis. Urology 1973, 2, 80–82.

10. Jonas, U.; Jacobi, G.H. Silicone-silver penile prosthesis: Description, operative approach and results. J. Urol. 1980, 123, 865–867.
11. Sadeghi-Nejad, H. Penile prosthesis surgery: A review of prosthetic devices and associated complications. J. Sex. Med. 2007, 4, 296–309.
12. Rodriguez, K.M.; Pastuszak, A.W. A history of penile implants. Transl. Androl. Urol. 2017, 6, S851–S857.
13. Milbank, A.J.; Montague, D.K.; Angermeier, K.W.; Lakin, M.M.; Worley, S.E. Mechanical failure of the American Medical Systems Ultrex inflatable penile prosthesis: Before and after 1993 structural modification. J. Urol. 2002, 167, 2502–2506.
14. Carson, C.C. Efficacy of antibiotic impregnation of inflatable penile prostheses in decreasing infection in original implants. J. Urol. 2004, 171, 1611–1614.
15. Wolter, C.E.; Hellstrom, W.J.G. The hydrophilic-coated inflatable penile prosthesis: 1-year experience. J. Sex. Med. 2004, 1, 221–224.
16. Hakky, T.; Lentz, A.; Sadeghi-Nejad, H.; Khera, M. The Evolution of the Inflatable Penile Prosthesis Reservoir and Surgical Placement. J. Sex. Med. 2015, 12, 464–467.
17. Infla10® NB Inflatable Penile Prosthesis. Designed for Compromised Anatomies. Available online: https://www.rigicon.com/infla10-nb/ (accessed on 27 October 2022).
18. ZSI 475 FTM. Available online: https://zephyr-surgical-implants.webflow.io/products/zsi-475-ftm/zsi-475-ftm (accessed on 27 October 2022).
19. Wein, A.J.; Kavoussi, L.R.; Partin, A.W. Surgery for erectile dysfunction. In Campbell-Walsh Urology; Elsevier: Amsterdam, The Netherlands, 2015; pp. 709–721.
20. Carson, C.C.; Robertson, C.N. Late hematogenous infection of penile prostheses. J. Urol. 1988, 139, 50–52.
21. Burnett, A.L.; Nehra, A.; Breau, R.H.; Culkin, D.J.; Faraday, M.M.; Hakim, L.S.; Heidelbaugh, J.; Khera, M.; McVary, K.T.; Miner, M.M.; et al. Erectile Dysfunction: AUA Guideline. J. Urol. 2018, 200, 633–641.
22. Chiang, H.S.; Wu, C.C.; Wen, T.C. 10 years of experience with penile prosthesis implantation in Taiwanese patients. J. Urol. 2000, 163, 476–480.
23. Salama, N. Satisfaction with the malleable penile prosthesis among couples from the Middle East--is it different from that reported elsewhere? Int. J. Impot. Res. 2004, 16, 175–180.
24. Minervini, A.; Ralph, D.J.; Pryor, J.P. Outcome of penile prosthesis implantation for treating erectile dysfunction: Experience with 504 procedures. BJU Int. 2006, 97, 129–133.

25. Falcone, M.; Rolle, L.; Ceruti, C.; Timpano, M.; Sedigh, O.; Preto, M.; Gonella, A.; Frea, B. Prospective analysis of the surgical outcomes and patients' satisfaction rate after the AMS Spectra penile prosthesis implantation. Urology 2013, 82, 373–376.
26. Lux, M.; Reyes-Vallejo, L.; Morgentaler, A.; Levine, L.A. Outcomes and satisfaction rates for the redesigned 2-piece penile prosthesis. J. Urol. 2007, 177, 262–266.
27. Gentile, G.; Franceschelli, A.; Massenio, P.; Tuccio, A.; Cocci, A.; Divenuto, L.; Romagnoli, D.; Natali, A.; Vitarelli, A.; Cormio, L.; et al. Patient's satisfaction after 2-piece inflatable penile prosthesis implantation: An Italian multicentric study. Arch. Ital. di Urol. Androl. organo Uff. Soc. Ital. di Ecogr. Urol. e Nefrol. 2016, 88, 1–3.
28. Levine, L.A.; Estrada, C.R.; Morgentaler, A. Mechanical reliability and safety of, and patient satisfaction with the Ambicor inflatable penile prosthesis: Results of a 2 center study. J. Urol. 2001, 166, 932–937.
29. Natali, A.; Olianas, R.; Fisch, M. Penile implantation in Europe: Successes and complications with 253 implants in Italy and Germany. J. Sex. Med. 2008, 5, 1503–1512.

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