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INVITED REVIEW

Update on penile prosthesis

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The aim of this narrative review is to provide a comprehensive overview of penile prostheses (PPs) for the treatment of erectile dysfunction (ED), exploring their historical evolution, types, key advancements, clinical outcomes, and future directions. A comprehensive literature search of studies published in English was conducted between January 2000 and April 2024, using databases including PubMed, MEDLINE, Embase, and the Cochrane Library. Search terms included "penile prosthesis", "penile implants", "malleable penile implant", "inflatable penile prosthesis", "two-piece IPP", "three-piece IPP", and "penile implant advancements". The included studies focused on the development, effectiveness, and complications of penile prostheses. These studies are clinical trials, randomized controlled trials, observational studies, systematic reviews, and meta-analyses. Data were synthesized qualitatively and quantitatively. Penile prostheses have significantly evolved since their invention, with notable advancements in both malleable and inflatable models. Malleable prostheses, known for their simplicity and reliability, offer a semirigid state that is beneficial for patients with limited hand dexterity or those undergoing salvage procedures. Inflatable penile prostheses (IPPs), particularly the three-piece models, have seen substantial technological improvements, including enhanced mechanical reliability, reduced infection rates due to antibiotic coatings, and better patient satisfaction. Key innovations include the development of hydrophilic coatings, parylene microcoatings, and antibiotic-impregnated implants, which have collectively reduced complications. *Asian Journal of Andrology* (2025) **27**, 1–8; doi: 10.4103/aja2024100; published online: 09 May 2025

Keywords: erectile dysfunction; penile erection; penile implantation; penile prosthesis; prostheses; implants

INTRODUCTION

Penile prostheses (PPs) have transformed the management of erectile dysfunction (ED), providing renewed hope and restored functionality to countless individuals globally. The development of these devices began in 1936, when Nikolaj Bogoraz, a Russian surgeon, performed the first autologous penile implant using rib cartilage.¹ The advent of the inflatable penile prosthesis in the 1970s marked a turning point, with subsequent technological advancements continually enhancing their efficacy and safety.²

Penile prostheses are classified into two primary and three secondary primary categories based on their design and mechanism of action.

Inflatable penile prostheses (IPPs)

(i) Three-piece prostheses include inflatable cylinders, a pump placed in the scrotum, and a fluid reservoir. This design provides both rigidity and a natural flaccid state, offering high patient satisfaction and improving quality of life.³ (ii) Two-piece prostheses featured inflatable cylinders and a scrotal pump. These eliminate the need for an abdominal reservoir. They are less invasive, reliable, and user-friendly, though slightly less natural in function compared to three-piece systems.⁴

Malleable PPs

Malleable PPs are composed of semirigid rods and are mechanically simpler than IPPs, making them cost-effective and user-friendly. They are particularly beneficial for patients with limited manual dexterity or those requiring a salvage procedure. However, their permanent rigidity may cause discomfort in daily activities and less natural esthetics.⁵

This review explores the evolution, clinical outcomes, and future directions of PPs. A systematic literature search was conducted using PubMed, MEDLINE, Embase, and the Cochrane Library to identify relevant studies from January 2000 to April 2024. The full search string used was:(("penile prosthesis"[Title/Abstract] OR "penile implant"[Title/Abstract] OR "penile implants"[Title/Abstract]) AND ("update"[Title/Abstract] OR "dvancement"[Title/Abstract]] OR "dvancement"[Title/Abstract]] AND ("malleable"[Title/Abstract]] OR "semi-rigid"[Title/Abstract]] OR "two-piece"[Title/Abstract]] OR "2-piece"[Title/Abstract]] OR "inflatable"[Title/Abstract]]).

Studies were included if they met the following criteria: (1) published in English; (2) focused on the development, effectiveness, or complications of penile prostheses; (3) clinical trials, randomized controlled trials, observational studies, systematic reviews, or meta-analyses; and (4) provided data on either malleable or inflatable penile implants. Extracted data were analyzed qualitatively and quantitatively, synthesizing key findings into a narrative summary.

MALLEABLE PPS: HISTORY, CHARACTERISTICS, AND ADVANCEMENTS

Malleable PPs are among the earliest forms of surgical treatment for ED, providing a reliable solution with a simpler mechanical design

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compared to inflatable models. For recipients of malleable implants, the penis always stays in a semirigid condition. The user can manually position the prosthesis upward to engage in sexual activity. While often viewed as less advanced compared to the three-piece IPP, the malleable penile implant offers distinct advantages. It is more cost-effective and simpler to implant and has fewer mechanical issues. This type of prosthesis is particularly beneficial for patients with limited hand dexterity and those requiring a salvage procedure due to infection and as an emergency solution for acute ischemic priapism.⁶ Its reliability and ease of use make it a valuable option in specific clinical scenarios.

Till date, there are six commercially available types of malleable PP devices, each with its unique characteristics: the Coloplast Genesis PP (Coloplast, Minneapolis, MN, USA), the Boston Scientific Tactra prosthesis (Boston Scientific, former American Medical Systems [AMS], Marlborough, MA, USA), the Zephyr 100 FTM and ZSI 100 devices (Zephyr Surgical Implants, Geneva, Switzerland), the TUBE malleable prosthesis (Promedon, Córdoba, Argentina), the Rigi10 prosthesis (Rigicon Inc., Ronkonkoma, NY, USA), and the Shah prosthesis (Surgiwear, Shahjahanpur, Uttar Pradesh, India), as shown in **Table 1**.

The Coloplast Genesis, introduced in 2004, is a malleable PP consisting of a flexible silicone elastomer device. It features a hydrophilic and antibiotic coating, allowing surgeons to choose and customize antibiotics for preparation and release.⁷ The device includes a silver core but lacks internal springs, cables, or moving parts, enhancing mechanical reliability and preventing unintended spring back. Its distal shaft is rigid enough to avoid buckling during sexual activity. Early studies on Genesis prostheses reported excellent results in patients with both ED and Peyronie's disease.⁸ Habous *et al.*⁹ found a correlation between larger PP rod diameter and higher complication rates. Furthermore, when compared to the AMS (now owned by Boston Scientific) Spectra model, the Genesis device showed similar outcomes in terms of patient satisfaction.⁷

Introduced and developed by Boston Scientific in 2019, the Tactra[™] malleable penile prosthesis represents an advancement over the original Spectra device.¹⁰ This next-generation malleable implant features a dynamic core made of Nitinol (a nickel-titanium alloy), which is surrounded by a unique dual-layer silicone exterior to ensure both rigidity and durability. Like the Genesis device, the Tactra implant includes trimmable exterior etchings to optimize fit

according to corporal size. There is no published research concerning its effectiveness or complications. A clinical trial funded by Boston Scientific Corporation is underway, evaluating the quality of life of patients who undergo Tactra[™] malleable penile prosthesis insertion for moderate-to-severe ED.¹¹

The Zephyr ZSI malleable implant series is manufactured by Zephyr Surgical Implants, a European company.12 First introduced in 2020, the Zephyr ZSI 100 malleable implant features a NuSil silicone cylinder with an inner Nitinol cable for mechanical strength and a flexible distal section for comfort when flaccid. Its rods come in various lengths, and adjustable proximal and distal parts, but only in a single diameter size of 11 mm. Unlike other malleable implants, the Zephyr ZSI 100 femaleto-male (FTM) is uniquely designed for trans males, with an adjustable distal end and a broad, glans-shaped device that can be attached to the tip of the implant.13 The proximal end is composed of silicone and stainless steel, allowing it to be fixed to the pubic bone. Till now, the only one available study evaluated the use of ZSI 100 FTM.14 In this study, 25 patients underwent prosthesis implantation after free or pedicled flap phalloplasty, 13 of which managed to engage in penetrative sexual activity. The authors concluded that the ZSI 100 FTM prosthesis tends to have high complication rates initially during the learning curve. Despite being designed and created with the transgender community in mind, not all transgender patients will qualify for this prosthesis.14

The Rigi10[™] malleable prosthesis, introduced in 2019, features a proprietary HydroShield coating, that is, hydrophilic, facilitating easier implantation and selection of antibiotic elution.¹⁵ Similar to the Coloplast Genesis device, it is crafted from flexible silicone elastomer and possesses excellent shape memory to reduce springbacks. The Rigi10[™] prosthesis is offered in six diameters and two lengths. Additionally, SecureFit Extenders are available in size of 0.5 cm and 1.0 cm sizes for the rod's distal end. This device is also known for its 135° flexibility, offering a better and closer-to-reality flaccid state. A study conducted between 2019 and 2022, in order to ensure the safety of this device, concluded that it is a very safe malleable PP, with <1% of a total of 605 patients in need of reoperation due to complications.¹⁶

The TUBE, first introduced in 2006, is a malleable prosthesis made from a silicone elastomer that varies in hardness, being soft at the distal tip, medium in the middle, and hard at the proximal end to anchor into

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Brand	Company	Materials	Diameter	Length	Device bend flexibility
Genesis	Coloplast	Flexible silicone elastomer with a hydrophilic PVP coating	13 mm, 11 mm, and 9.5 mm	18–27 cm, 16–25 cm, and 14–23 cm	90°
Tactra	Boston Scientific	Dynamic Nitinol (nickel-titanium alloy) core encased by dual-layer silicone exterior	13 mm, 11 mm, and 9.5 mm	18–27 cm, 16–25 cm, and 14–23 cm	120°
Rigi10	Rigicon Inc	Flexible silicone elastomer with a HydroShield coating	9 mm, 10 mm, 11 mm, 12 mm, 13 mm, and 14 mm	23 cm, 23 cm, 25 cm, 25 cm, 25 cm, and 25 cm	135°
Zephyr ZSI 100	ZSI	NuSil silicone cylinder with an inner plate of Nitinol (nickel- titanium) cable and a flexible distal part	11 mm	12-25 cm	Unknown
TUBE malleable	Promedon	Flexible silicone elastomer with a soft distal part, medium hardness middle part, and high hardness proximal part with a silver core wire	9 mm, 10 mm, 11 mm, 12 mm, and 13 mm	20 cm, 22 cm, 24 cm, 26 cm, and 26 cm	Unknown
Shah malleable	Surgiwear	Flexible silicone elastomer consisting of four parts: a soft distal silicon tip, an anterior segment of very stiff silicon, a central 5 cm zone of soft silicon (provides flexible hinge), and a moderately firm posterior crural segment	9–13 mm	Sum	Unknown

PVP: polyvinylpyrrolidone; ZSI: Zephyr Surgical Implants



the corporal body. The functional length, which makes up the distal two-thirds of the device, includes a core of polytetrafluoroethylene (PTFE)-covered silver twisted wire. This design ensures axial rigidity while allowing the distal part to be bent up to 130°. The proximal third features multiple 5 mm circular markings for customizing the length. Additionally, two rear-tip extender caps are available in 2 sizes. Fathy *et al.*¹⁷ evaluated the reliability and safety of this device in 83 patients. No infection was reported, and 75% of the patients reported successful sexual intercourse and complications such as hypesthesia (0.8%) and retarded ejaculation (10%) resolved without any intervention within 6 months. Another study of 128 patients who underwent TUBE implantation showed a satisfaction rate of 78.5%, while 9.4% eventually underwent device removal due to infection or mechanical failure.¹⁸

In 1996, the Shah malleable prothesis was the first Indian malleable penile implant ever produced. Since then, it has undergone numerous model updates.¹⁹ Unlike the last five malleable models, the Indian malleable penile implant is primarily sold within the Indian market and is significantly cheaper than Western malleable prostheses. The current Shah device is made of a silicone elastomer and consists of four components that vary in stiffness. It comes in two versions: one with a hinge (flexible central zone facilitating easy bending for concealment) and the other without (no flexible part but adequate stiffness for successful sexual intercourse).²⁰ It is shown that Shah offers similar results, when compared to AMS 650, yielding high satisfaction according to the ED Inventory of Treatment Satisfaction (EDITS) questionnaire, even after 12 months postoperatively.²¹

TWO-PIECE INFLATABLE PROSTHESES

The Mentor GFS (girth, flaccidity, and simplicity) two-piece IPP was first introduced in 1988.²² This device features paired cylinders linked by tubing to a combined reservoir and pump unit, known as a "resipump", implanted in the scrotum. These cylinders can expand to a predetermined girth and are available in two different widths. Despite its innovative design, the device faced high complication rates, including mechanical reliability issues and infections. Consequently, a second-generation model, the Mark II, was introduced with fewer connection components to enhance reliability and reduce complications.²³

The Uniflate 1000, a two-piece inflatable penile prosthesis, was introduced by Surgitek Inc., in the 1980s. This device featured a self-sealing penetrable port on the bottom of the resipump and had cylinders composed of two layers: an outer silicone layer and an inner Dacron layer, creating two chambers in each cylinder, augmenting the girth of the cylinder. Despite its promising features, the Uniflate 1000 encountered several obstacles, failing to secure the USA Food and Drug Administration (FDA) approval.²⁴ Moreover, tubing fracture emerged as a persistent issue, contributing to mechanical failures.

In 1994, Boston Scientific introduced the AMS Ambicor prosthesis, featuring pre-filled and pre-connected components. The Ambicor IPP enhanced the pumping system of the Dynaflex one-piece prosthesis, thereby eliminating the need for a reservoir within the penile anatomy.²⁵ Instead, a separate scrotal pump inflated the cylinders to achieve an erection. During the activation process, the pump transferred a solution from small reservoirs situated at the base of each cylinder into the shafts of the cylinders, facilitating an erection.²⁶ Its corporal cylinders are parylene coated. Further improvements were made in 1998, including the reshaping of rear tip extenders (RTE) for more secure positioning and added protection for the tubing.²⁷ Although limited, most studies yielded favorable long-term results in terms of patient and partner satisfaction, whereas complication rates varied from 2% to 9.5%, with the most common being infection. Remarkably, this

two-piece IPP remains available on the market today, since it serves as a safe and popular alternative to patients with a neurological disorder, thick fingers, pelvic organ transplant, and limited use of fingers.²⁵ Furthermore, the Ambicor IPP achieves inflation of the cylinders after only 3–6 pumps, whereas rigidity is feasible after at least 10 pumps.

Due to its broad spectrum of indications, the Ambicor IPP length reaches up to 22 cm, whereas its maximum diameter reaches 15.5 mm. Furthermore, the newly designed RTEs provide an additional length of 0.5-3 cm.

Two-piece IPPs, with Ambicor being its main representative, still remain crucial for certain patients with ED. Since erection is feasible only after 3-6 pumps, compared to the 10-14 squeezes of the threepiece IPPs, two-piece IPPs meet the needs of elderly patients or patients with compromised hand strength.28 Bayrak et al.29 compared patient outcomes between the Ambicor and the malleable IPP, showing that patients in the Ambicor group experienced higher satisfaction, as well as their partners.²⁹ Additionally, two-piece IPPs are preferable for patients with retropubic scarring from surgeries like pelvic organ transplants, as they avoid the complications associated with placing an intra-abdominal reservoir.³⁰ For spinal cord injury patients, two-piece prostheses offer practical solutions for both urinary management and sexual satisfaction.²⁸ Two-piece IPPs are also valuable in constructing neophallus for FTM transgender patients while offering acceptable complication rates, such as infections, erosion, dysfunction, and malpositioning.31

MULTICOMPONENT (THREE-PIECE) INFLATABLE PROSTHESES

History of three-piece inflatable prostheses

By precisely imitating the natural states of penile flaccidity and erection, the first three-piece IPP, branded the "Fluid Transfer System 2", was developed in 1973 and represented a major breakthrough in the surgical treatment of ED.³² The creation of this groundbreaking gadget was a collaborative effort by Dr. F Brantley Scott, engineer Dr. Gerald Timm, and neurologist Dr. William Bradley. The system includes a pump in the scrotum that allows for the movement of fluid between cylinders within the body and a reservoir of fluid. The reservoir is usually placed either in the space of Retzius, which is in front of the bladder, or in the submuscular space below the rectus muscle. In addition, the system comprises tubing, connectors, RTE, and a range of protective coatings. During the last five decades, the three-piece IPP has undergone several improvements and versions, which are described in **Box 1**. Currently, Coloplast and AMS/Boston Scientific are the main producers of these devices in the USA, although many international companies make comparable items.³³

The USA market is primarily dominated by three-piece penile prosthesis, that holds a market share of more than 80%.⁴ The current review focuses on the technical and surgical improvements of the three-piece IPP. The first iterations, which were first launched in the early 1980s, consisted of the same fundamental elements seen in contemporary versions: two inflated cylinders placed within the body, a pump located in the scrotum, and a fluid reservoir situated in the abdomen. Technological progress made in the 1980s and 1990s greatly enhanced these devices, resulting in a decrease in complication rates from an initial rate of over 50% to only 13% following a 4-year follow-up.³⁴

The implantation of three-piece penile prosthesis may be carried out using either transscrotal or infrapubic methods, each offering unique advantages. The penoscrotal method reduces the likelihood of dorsal nerve damage, improves the ability to see the corpora cavernosa, and makes it easier to position the scrotal pump. On the other hand,



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Innovation 1500 Wooden splints utilized to facilitate urination Use of rib cartilage with tubular phalloplasty 1936 1952 Acrylic splints, extracavernosal implantation 1958 Intracavernosal polyethylene rods 1960 Intracavernosal acrylic rods 1964 Silicone penile implants: reduced infection 1973 Small-Carrion prosthesis: customized length, enhanced girth, more reliable, easier nlacement 1973 implantation Flexirod: soft hinge improved concealment 1977 1980 Jonas malleable prosthesis: silicone prosthesis with silver wires, first true malleable AMS 700: thick cylinders, PTFE sleeves 1983 Mentor 3-piece IPP; polyurethane (Bioflex): enhanced strength over silicone AMS 600M and 650: malleable devices, central wire core, trimmable silicone DuraPhase/OmniPhase: central cable, frequent mechanical malfunction 1983 1983 1985 1985 Hydroflex and Flexi-Flate: poor concealment, incomplete flaccidity AMS 700: kink-resistant tubing added 1986 AMS 700CX: 3-ply design with woven fabric layer; reduced cylinder aneurysms 1987 1987 Mentor IPP improvements: cylinder base reinforcement, pump modifications, 1989 1990 AMS 700CXM: narrow version AMS Ultrex: expanded girth/length Mentor Apha-1: reinforced tubing/pump, enhanced mechanical reliability 1000 1992 1993 AMS Ultrex cylinders strengthened: improved mechanical reliability AMS Ambicor: 2-piece prosthesis Mulcahy salvage technique Coloplast Acu-Form: malleable device 1004 1998 AMS 700; added parylene coating: improved mechanical reliability; pre-connected cylinders, color-coded tubing: facilitated implantation 2000 2000 Mentor: lockout valve 2001 AMS InhibiZone: antibiotic impregnation with minocycline/rifampin 2002 Mentor Titan: hydrophilic substance absorbs aqueous solutions, reduces bacterial 2002 Mentor Alpha-1 Narrow Base: narrow model 2004 2006 Coloplast Genesis malleable AMS Momentary Squeeze 2006 One-way valve reduced auto-inflation 2006 2006 Coloplast acquires mentor AMS LGX Coloplast One Touch Release 2008 Titan XL Cylinders (24 cm, 26 cm, and 28 cm) AMS Conceal: flat reservoir 2008 2010 No-touch technique: reduced infection 2011

- 2012 Coloplast 0° tubing, molded silicone contoured tip
- Titan Touch 3-piece IPP FDA approval for submuscular reservoir placement 2015
- ZSI 475 FTM: 3-piece IPP designed as transgender neophallus Coloplast 16 cm/18 cm Narrow Base 0° AMS 700 CX and 700 LGX optimized tubing length 2016
- 2017 2018
- Box 1: Timeline of innovations in penile prosthesis development. IPP: inflatable penile prosthesis; PTFE: polytetrafluoroethylene; AMS: American Medical Systems; ZSI: Zephyr Surgical Implants.

the infrapubic technique is linked to reduced device implantation durations and provides improved visibility for inserting the reservoir.35

Cylinders

The earliest three-piece IPPs were constructed from flexible materials such as silicone.36 The AMS 700 model, released in 1983, had PTFE sleeve coatings to reduce friction and prevent damage between silicone components. Further advancements in cylinder design included enhancements in prosthesis circumference, regulated capability for elongation, and improved RTEs that securely attach by snapping or screwing, effectively resolving problems such as cylinder detachment from the proximal corpora.36 The AMS 700 CX model, introduced in 1987, included a robust three-layer design consisting of a silicone foundation on the inside and a Dacron-Lycra weave on the outside. This structure effectively minimized strain on the corpora during the inflating process.

The Dacron-Lycra layer, which is comparable to the polyurethane layer found in the Coloplast Titan implant, is advised for patients with tunica albuginea deficiencies in order to avoid the development of aneurysms. In 2001, AMS upgraded its cylinders by applying a Parylene microcoating. This coating increased endurance and decreased friction, resulting in a higher 3-year revision-free survival rate of 87.4% compared to noncoated versions, which had a survival rate of 78.6%.37

In 1981, RTEs were implemented in IPP technology to enhance placement security and minimize cylinder wear, especially for penises of smaller to medium sizes.38 By 2006, the designs of RTE had undergone significant improvements, resulting in improved safety and more reliable positioning of cylinders. AMS provided snap-fit RTEs

ranging in size from 0.5 cm to 6 cm, while Coloplast supplied screwon RTEs ranging in size from 1 cm to 3 cm. A research conducted in 2018 aimed to assess the impact of RTEs on the stiffness of IPPs. Using an ex vivo model, the researchers measured the amount of downward bending of Coloplast Titan cylinders with a 4 cm RTE after a 200 g weight was inserted at the end of the inflated prosthesis. The findings revealed a positive link between longer RTE length and more pronounced downward deflection. These results indicate that improving the length of inflated structures by decreasing the size of RTEs may improve the overall dynamics of erectile rigidity. The use of RTE in prosthesis surgery had a substantial increase, rising from 6%-8% in 2000 to 93% in 2015.39

The design of cylinders has consistently advanced in order to more accurately imitate the natural erectile action while yet keeping a satisfactory flaccid condition. AMS launched the Ultrex cylinders in 1990, which allowed for increased girth expansion thanks to a fabric layer that could expand in both directions.⁴⁰ In 1993, this design underwent an upgrade using more durable materials, resulting in improved device dependability and increased patient satisfaction. In a research conducted in 2002, Milbank et al.⁴¹ conducted a comparison between the improved Ultrex and the original version. The results showed substantial improvements with the altered version. The upgraded Ultrex demonstrated superior 5-year survival rates (77.7% vs 64.7%), mechanical reliability (93.7% vs 70.7%), and cylinder durability (96.2% vs 77.7%) when compared to the original type. The Ultrex underwent a name change and became known as the Length Girth extension (LGX) model. This updated version had thinner proximal ends, making it simpler to insert, and allowing for extension in both girth and length.⁴² AMS and Coloplast have developed narrow cylinders, such as the AMS 700 CXM and CXR models and the Coloplast Titan narrow base models, to specifically cater to patients with smaller penises or significant corporal fibrosis. These models are particularly recommended for patients with corporal scarring and Peyronie's disease.

In 2017, Coloplast produced Narrow Base 0° (zero-degree) cylinders with the aim of reducing tube wear and enhancing anatomical alignment. In 2018, AMS adjusted the length of the tubing in their penoscrotal versions to prevent the need for RTEs and improve the location of the scrotal pump.⁴³ However, the primary reason for early IPP failure continues to be tube failure, often caused by sharp bends and friction against adjacent tubing. Additional research is required to address these concerns and enhance the longevity of IPPs.

In summary, the progress in three-piece IPP technology has greatly enhanced their dependability, functionality, and patient contentment, establishing them as a vital choice in the surgical treatment of ED.

Anti-infective coatings

Infections are a major issue in surgical procedures involving the insertion of a medical device. Potential consequences of penile prosthesis implantation include the need for device removal, reduction in penile length, the need for further surgical procedures, and the possibility of other issues.44 In the past, more than 80% of infections that occurred after surgery were caused by Gram-positive bacteria, namely Staphylococcus epidermidis. The remaining instances were usually attributed to Gram-negative bacteria, including Escherichia coli, Serratia, and Proteus mirabilis. In recent times, there has been a notable change and a surge in infections caused by Gram-negative bacteria and fungi, mostly attributed to the growing incidence of diabetes and other medical problems.

To address these infections, manufacturers have developed several innovations in prosthesis coatings.⁴⁰ In the year 2000, AMS implemented a Parylene coating on the CX device with the purpose of improving lubrication, decreasing friction, and minimizing silicone deterioration. In a study conducted by Salem et al.37 in 2009, a total of 775 patients were analyzed, including 596 who were undergoing the procedure for the first time and 179 patients who were undergoing a revision. The researchers found that the 3-year survival rate without the need for further revisions went from 78.6% to 87.4%. Additionally, the rate of avoiding mechanical breakage improved from 89.2% to 97.5%.37 In the same year, AMS introduced the InhibiZone[™] coating, which combines minocycline hydrochloride and rifampin.⁴⁰ This combination has shown significant efficacy against Staphylococcus, the predominant bacterium accountable for device infections. In a 2007 research conducted by Wilson et al.,45 it was shown that the use of an antibiotic washout resulted in a drop in infection rates from 3% to <1% for original implant insertions and from 10% to 2.45% in revision cases. In the same scope, a 2004 study reported similar outcomes, with a postoperative infection rate of 1.61%.46

Coloplast used the latest advancements and in 2002 implemented a hydrophilic covering for its devices. The Titan prosthesis is covered with polyvinylpyrrolidone (PVP), a hydrophilic polymer that reduces bacterial attachment and absorbs antibiotics, which are then released during immersion in the operating room. After 1 year, a total of 2839 implants were examined, with 2357 of them being coated Titan IPP implants and 482 being noncoated Alpha-1 prostheses. The infection rate for the coated implants was determined to be 1.06% (25 out of 2357), while the noncoated prostheses had an infection rate of 2.07% (10 out of 482).47 Staphylococcus species were the most common disease-causing organisms in both groups. They caused 9 out of 25 infections in the Titan group and 6 out of 10 infections in the noncoated group. In this regard, many researches have examined the effectiveness of different antibacterial solutions in preventing infections related to the Coloplast Titan implant. These studies have compared the outcomes with those of the AMS InhibiZone implant. A prominent research conducted by Wilson et al.48 investigated several antibiotic dips, intentionally excluding the rifampin and gentamicin combination. This research conducted a comparison of InhibiZone and Coloplast implants that were treated with various solutions, including trimethoprim with polymyxin B ophthalmic solution, trimethoprim with sulfamethoxazole infusion solution, bacitracin, rifampin with minocycline, and rifampin with trimethoprim-sulfamethoxazole. The findings demonstrated that InhibiZone had lower efficacy compared to all other combinations of antibiotics, with the exception of bacitracin, when assessing the zone of inhibition against Staphylococcus epidermidis, Staphylococcus lugdunensis, Staphylococcus aureus, Pseudomonas, and Enterococcus. Of all these combinations, trimethoprim/sulfamethoxazole was shown to be the most successful since it has a wide range of effectiveness and is cost-efficient. In addition, Lokeshwar et al.49 conducted a separate research to examine the impact of immersing implants in bupivacaine on the zone of inhibition against Staphylococcus epidermidis and Escherichia coli, which are two prevalent bacterial sources of device infections. This study included both AMS implants covered with InhibiZone and Coloplast implants soaked with rifampin and gentamicin. The in vitro results demonstrated that the antibacterial efficacy of the InhibiZone-coated AMS and the rifampin and gentamicin-soaked Coloplast implants were not diminished by the presence of bupivacaine. Applying a

combination of rifampin and gentamicin to the Coloplast Titan before implantation is commonly recommended as the most efficacious method.

Pump

Various modifications have been made to pump design in order to address the special mechanical and functional difficulties associated with IPPs. An important consideration is to provide haptic feedback, which allows patients to readily perceive and exert pressure on the pump in order to transfer fluid into the cylinders for use. Furthermore, it is essential to be able to identify and activate the release valve in order to revert to a relaxed condition.

During the early 2000s, the two prominent American corporations implemented changes by adding a one-touch release function, which enabled users to completely empty the cylinders with a single squeeze. This functionality was included in both the 2004 AMS Tactile and the 2008 Coloplast Classic versions.⁴⁰

In 2004, the Tactile pump was included in three-piece IPPs, representing a notable progress. This design improvement allowed a higher amount of fluid to be squeezed out with each push, enhanced the ease with which patients could use the scrotal pump, and simplified the process of deflating the device. A prospective, multicenter research was conducted with 30 patients to evaluate the use of the novel pump. The results showed that all participants (100%) were able to easily identify the pump, and 96.7% of them were able to deflate it without difficulty.⁵⁰ Additionally, the majority of patients (86.7%) were able to learn how to operate their devices within 3 min.

In 2006, the AMS Momentary Squeeze (MS) pump was introduced, which further improved this design. The MS mechanism allows for rapid deflation in a time frame of 2-4 s by just pressing the depressurization button once. The revamped pump has a lockout valve and a more compact pump body. The MS pump has a textured surface and a one-touch mechanism that enables deflation without the need of continually holding the pump. The lockout valve is specifically engineered to limit the potential for spontaneous inflation. Knoll et al.51 found that 96% of patients using the AMS 700 model with the MS were able to readily find the inflate bulb, and 94% were able to deflate the IPP with only one click of the release button. The MS Pump, despite its intended purpose of reducing autoinflation, would sometimes have lockouts, resulting in the inability to inflate or deflate and requiring replacement. The USA FDA enforced the inclusion of the "pull-stretch technique" in the product labeling in 2013 as a requirement to restore the operation of the system. Vitarelli et al.52 conducted research to assess the 10-year survival rates of the AMS 700 CX touch pump and the AMS 700 CX MS pump. The study found that the survival rate for the AMS 700 CX touch pump was 77.6%, while the survival rate for the AMS 700 CX MS pump was 82.5%.52 Additionally, 90.8% of patients were able to successfully use the device and engage in penetrative sexual intercourse.

Coloplast obtained certification for their One Touch Release (OTR) pump system in 2008. This invention featured "Touch Pads" on both sides of the pump, enabling deflation with one hand using tactile features. The OTR pump was made from a more robust silicone polymer and was also smaller than earlier versions, which improved its longevity and toughness. A multicenter research conducted in 2017 by Otero *et al.*⁵³ compared 197 patients who had AMS 700CX implants with 54 individuals who had Coloplast Titan One Touch Release implants. The research revealed that a mere 4% of individuals using the AMS 700CX had unhappiness with the deflation of their

prosthesis, whereas a much higher proportion of 24% of Coloplast Titan users reported feeling unsatisfied. A comprehensive review conducted by Atri *et al.*,⁵⁴ found no statistically significant disparity in patient satisfaction, as assessed by the EDITS score, between the AMS 700CX with MS pump and the Coloplast Titan with Touch pump.⁵⁴

Reservoir

The occurrence of autoinflation has been a common and problematic issue in the past with three-piece penile prostheses. Based on published statistics, this problem occurs in around 11% of patients, with approximately 2% necessitating surgical revision.⁵⁵ Autoinflation often occurs during the first period after surgery as a result of increased abdominal pressure causing the movement of fluid from the reservoir into the cylinders. If the problem persists for more than 6 months, it is generally regarded as permanent, and surgical intervention may be required. The cause of this problem is thought to be the development of a tissue capsule around the reservoir, which typically occurs within 3 months after the operation.

In 2000, Coloplast produced a textured reservoir to solve the problem of encapsulation and minimize autoinflation by increasing the surface area. In the same year, they improved the design of the reservoir by including a Lock-out Valve[™] with the purpose of avoiding automatic inflation.⁴⁰ This innovation successfully decreased the rate of autoinflation from 11% with the previous technology to 1.3% with the new design.⁵⁵ While most instances of autoinflation following IPP implantation are considered benign, severe cases may require a capsulotomy to release and correctly position the reservoir.⁵⁶ In contrast, Boston Scientific's AMS 700 features its lockout valve in the pump, rather than in the reservoir.

The detectability of the reservoir is a major issue for recipients of IPP, which is why the reservoir is often placed in the space of Retzius to ensure its concealment. Nevertheless, significant progress has been achieved in the development and implementation of reservoir design and placement methods. The AMS Conceal reservoir was introduced in 2010, designed with a low-profile form to provide improved fit and comfort when placed in the submuscular area. This design is compatible with all AMS 700 IPPs and may be obtained with or without the InhibiZone antimicrobial coating.⁴³ The USA FDA granted approval to the Coloplast Cloverleaf reservoir with a lockout valve for alternative reservoir placement (ARP) in April 2015.⁵⁷

Placing IPP reservoirs in the Space of Retzius, as traditionally done, might provide challenges after pelvic procedures like radical prostatectomy. This can increase the likelihood of damaging the bladder, blood vessels, or intestines. According to a poll conducted in 2013 by Karpman et al.,58 81% of skilled surgeons specializing in implant procedures considered that using robotic assistance for laparoscopic radical prostatectomy made the installation of implants more challenging. This suggests that using ARP for this procedure might be a desirable option.58 Hernández et al.59 conducted a study to evaluate the safety of AMS and Coloplast ARP in the sub-Scarpa and submuscular areas using either the inguinal canal or an abdominal incision, following the FDA's clearance in 2015 for submuscular reservoir insertion. This 5-year, multi-institutional study included 974 patients (612 with ARP) with a median follow-up of 20.4 months. Reservoir leakage, which happened in five individuals, was the most prevalent complication. Additional uncommon complications were tube torsion, muscular pain, and intraperitoneal reservoir implantation. In general, the rates of complications were comparable for ARP (2%) and space of Retzius (1.3%) installations, with no significant variations seen between initial and revision instances.

Latest three-piece IPP developments

Penile prostheses have historically been a major area of focus for innovation in the science of andrology. Boston Scientific has recently submitted many patent applications, suggesting possible improvements to the operation of its pumps. Patent application #14/863 965 describes a subamplifier specifically created to enhance the manual pressure applied to the pump.⁶⁰ Furthermore, patents #10 285 815, #9 522 065, #9 889 010, and #9 808 343 detail a mechanized pump system that utilizes an external controller to wirelessly provide the necessary energy for the operation of the pump mechanisms. These innovative ideas seek to reduce one of the primary drawbacks of three-piece systems, which is the need for manual inflation and deflation. This matter is especially relevant for males who have sensitivity in the scrotum, have atypical scrotal anatomy, or encounter difficulties in operating the pump to its maximum capacity.

Coloplast has sought patents for advancements in prosthesis insertion methods, such as application #9 980 722, which describes a locking needle specifically developed for the Furlow insertion tool. While the exact purpose of this innovation is not revealed, it is probable that its goal is to ease the insertion of a needle during implantation and minimize unintended harm to nearby tissues or the prosthetic device.

A novel design in the field of prosthetic devices utilizes a nickel-titanium alloy that undergoes a transition between a flaccid and rigid state in response to temperature changes.⁶¹ In order to reach the required temperature for activation, an external magnetic induction coil may be used to induce a rise in temperature, forcing the material to become straight and upright. When the device cools down, it returns to its bent (detumesced) and more pliable shape. The *in vitro* mechanical testing of this device revealed that it can withstand a maximum axial load of 2.6 kg while in an erect position. This performance surpasses that of inflated prostheses, which can only sustain up to 1.4 kg of axial force. However, it falls short compared to other malleable devices, which can withstand up to 6.5 kg of axial strain. The gadget demonstrated remarkable longevity, capable of switching between states several times without any visible structural damage.

The ZSI 475 is a recent addition to the field of three-piece penile prostheses, though it has yet to receive FDA approval.⁶⁰ The device features a unique three-layer construction consisting of silicone on the outer and inner layers and biocompatible polyester in the middle layer. This design enhances the implant's width, rigidity, and stability.

A study conducted between 2012 and 2016 involved 28 patients who received the ZSI 475 implant.⁶² The findings indicated a very high level of satisfaction, with an average rate of 93%, seen throughout a mean follow-up period of 35 months. Nevertheless, there were three documented complications: one patient encountered a scrotal hematoma, another need a total replacement owing to tubing breakage, and the third underwent a reoperation to alter the pump's placement.

Unlike Boston Scientific and Coloplast devices, the Zephyr 475 does not include a one-touch release mechanism or antibiotic coatings.⁶⁰ Despite these differences, the Zephyr 475 is often more affordable and retains a similar design with two cylinders, a pump, and a saline-filled reservoir. The study also found that 93% of the patients remained free from the need for revision at the last follow-up, mirroring the high satisfaction rate.

DISCUSSION

Technological advancements and a deeper understanding of patient needs have significantly improved penile prostheses' design, durability, and outcomes. Modern penile implants are reliable and effective

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solutions for men with moderate-to-severe ED, particularly when other treatments have failed.

Significant progress, such as the refinement of flexible and threepiece inflatable prostheses and the incorporation of antibiotic coatings, has notably reduced infection and mechanical failure rates. These innovations enhance implantation success and contribute to favorable long-term patient outcomes. Additionally, minimally invasive surgical techniques have shortened recovery times and lowered complication risks, increased accessibility, and reduced hesitancy among potential candidates.

While flexible prostheses do not entirely replicate the natural sensation of inflatable systems, they offer advantages in specific scenarios. Research indicates that flexible rods are associated with fewer technical failures and reduced reoperation rates compared to inflatable prostheses. Moreover, flexible prostheses are much more cost-effective, which is particularly important for patients without insurance coverage.63 The implantation process for malleable prostheses is quicker and requires less intraoperative preparation. They are particularly beneficial for patients with limited manual dexterity or those undergoing salvage procedures for infected prostheses or acute priapism.28 Furthermore, malleable rods can be later exchanged for IPPs in patients with infections or priapism, potentially leading to higher satisfaction rates with longer and wider cylinders.^{64,65} A systematic review of 17 studies evaluating patients with priapism undergoing PP implantation, highlighted the importance of PPs, especially in cases of medically refractory recurrent priapism or ischemic priapism lasting more than 36 h.66 Of interest, malleable implants may also be beneficial in patients with a buried penis, a condition where the functional length of the penis is very short, usually due to excess fat.67

One of the primary concerns regarding penile implant surgeries is the need for reoperation. A large-scale study involving 14 969 men who underwent penile implant surgery from 1995 to 2014, with a median follow-up period of 95 months, revealed an overall reoperation rate of 6.4%. Furthermore, implants inserted by surgeons with lower annual case volumes had a higher likelihood of needing reoperation due to infection but not due to noninfectious complications. When compared to patients treated by surgeons performing more than 31 cases annually, those treated by surgeons with lower case volumes at least 2 times more likely to require reoperation for inflatable penile prosthesis infection.68 Mahon et al.64 performed a systematic review of studies evaluating infectious adverse events after penile prosthesis insertion.⁶⁴ Ninety-one studies were included, covering 97 different scenarios. Rates of prosthetic infections varied widely, spanning from 0 to 24.6% across all studies. In particular, IPP exhibited a broader range of infection rates (0-24.6%) compared to malleable devices (0-9.1%). The most commonly reported infection rate for inflatable devices was 5% or lower. Another study evaluating patient parameters that could provoke penile implant infection, found that glycated hemoglobin levels >8.5%, Peyronie's disease, and high body mass index (BMI) may predict possible implant infection.69

Advances in device coatings and surgical methods have significantly lowered infection rates. Over the past two decades, the majority of firms have implemented many alterations to their implants with the objective of minimizing issues and improving both durability and usage. These improvements have been comprised into more recent versions of both flexible and expandable penile implants. Currently, penile implants provide long-lasting durability and contribute to an acceptable quality of life, even after a 20-year follow-up period. In addition, the use of antibiotic and hydrophilic-coated implants has substantially reduced infection rates, decreasing from 3%–5% in the early 2000s to 0.3%–2.7% by 2015. The use of "no-touch" procedures has resulted in a further reduction in infection rates to as low as 0.46%.

Penile implant technology has substantially enhanced patients' quality of life. Future research is likely to focus on improving device durability and integrating advanced technologies, such as remote controls and biofeedback systems. These innovations have the potential to further improve patient satisfaction and functionality.

CONCLUSION

The continuous advancements in penile prosthesis technology represent a significant leap in managing ED. Ongoing research, patient-centered approaches, and technical innovation ensure that penile prostheses remain a cornerstone of ED therapy, offering hope and improving the quality of life for men worldwide.

AUTHOR CONTRIBUTIONS

MI participated in study conceptualization and manuscript drafting. LG was responsible for literature review, data analysis, and critical revision of the manuscript. TS was responsible for data collection, methodology, and visualization. AA was responsible for study supervision, project administration, and critical review and editing. VRK participated in clinical expertise and manuscript review. All authors read and approved the final manuscript.

COMPETING INTERESTS

All authors declared no competing interests.

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