ARTICLE

Technological advances in penile implants: past, present, future

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Attempts to "cure" erectile dysfunction (ED) are as old as recorded history. The history of penile prosthetic devices dates back over 500 years, when a French military surgeon designed the first known wooden prosthesis to support micturition. There have since been a great many technological advancements in penile prosthetics. Penile implants for the improvement of sexual function date to the twentieth century. Like all human endeavors, penile prosthesis innovations have progressed via trial and error. This review aims to provide an overview of penile prostheses for the treatment of ED since their introduction in 1936. More specifically, we aim to highlight important advances in penile prosthesis development and discuss dead ends that were abandoned. Highlights include two-piece inflatables, three-piece inflatables, and malleable/semirigid, along with modifications and updates to each basic design that improved both insertion and usability. Dead ends include innovative ideas that were lost to history due to a variety of factors. We also look to the future and discuss expected advances, including remotely activated devices and prostheses designed for special populations, including transgender men.

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INTRODUCTION

Erectile dysfunction (ED) is a problem as old as humanity. Attempts to "cure" ED date back similarly far and are documented by many civilizations. The Old Testament, the poetry of Ovid, and ancient Hindu writings all contain references to male impotence. Designs preserved on ancient Greek cups depict ED, as do paintings in Egyptian tombs [1, 2]. Early attempts to cure ED are equally well documented; prayers, visits to and from religious/community leaders, and recipes for tinctures and potions all make an appearance [2].

True surgical success with the treatment of ED dates to the twentieth century, when injuries resulting from the World Wars inspired a wave of new breakthroughs. Penile prosthetic devices have since been innovated and improved by trial and error. The modern era of penile implants dates to 1973, with the introduction of the inflatable (IPP) and semirigid penile prostheses [3]. The debut of these devices resulted in an explosion of technological innovation and refinement that continues into the present day. Many dead ends in penile implant development have simultaneously occurred in the last five decades. In this review, we explore the most important advances in penile prosthesis placement as well as the ideas that were ultimately lost to history. Lastly, we look to the future for potential advancements in penile prosthetics.

PAST

The first known penile prosthetic dates to the sixteenth century, when a wooden pipe was crafted to facilitate micturition [3]. Designed by a French military surgeon, Ambroise Paré, this wooden prosthesis enabled men to urinate while standing. There is no documentation of its use for intercourse. War injuries further propelled the science of penile prostheses, with advancements during World War I in tubularized pedicle flaps designed for both urination and penetration [2].

The first known implantable penile prosthesis for ED dates to 1936, when Russian surgeon Nikolaj Bogoraz augmented harvested cartilage from ribs to create a rigid implant. Though rib implants were successfully documented to enable satisfactory sexual intercourse, this approach was limited by high rates of infection—with resultant disfigurement of the penis—and the propensity of cartilage to be reabsorbed by the body [4].

In the 1960s, Drs Lash and Pearman wrote on the use of single silicone rod implants, which were installed under the penile fascia. In a short time, the insertion process was revised to beneath the tunica albuginea to better mimic the appearance and feel of a native erection [5].

Effective penile implants were developed 50 years ago. In March 1973, Dr F. Brantley Scott of Baylor College of Medicine placed the first inflatable penile implant in Houston, Texas [6]. This device consisted of two cylindrical silicone tubes, one placed in each corpus cavernosum, and inflated with isotonic fluid to compress the spongy erectile tissue, expand the tunica albuginea, and provide a rigid erection. A release valve on the pump allowed almost all the fluid to return from the penis to a reservoir contained in the abdominal cavity, enabling flaccidity.

Almost simultaneously with the introduction of Dr Scott's inflatable implant, Drs Michael Small and Hernan Carrion placed soft silicone semirigid rods with a sponge-filled central cavity in the corporal bodies giving support to the erection and bendability to the penis for positioning [5].

Both inflatable and malleable implant types gained popularity over the decades to come. With time, the prevalence of implantation grew. In 1976, the Finney soft silicone Flexirod (Fig. 1) and in 1980, the Jonas malleable implant with a silver wire core (Fig. 2) were added to the

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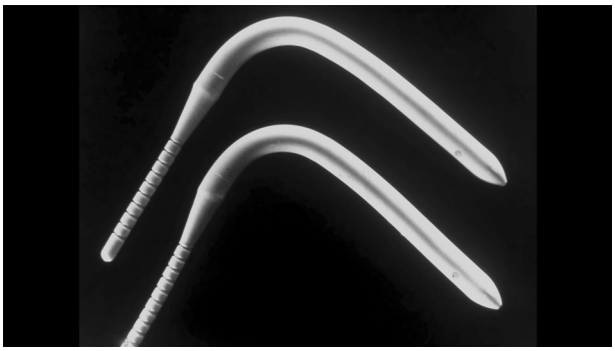

Fig. 1 Historic Malleable Implants. Finney Flexirod implant.

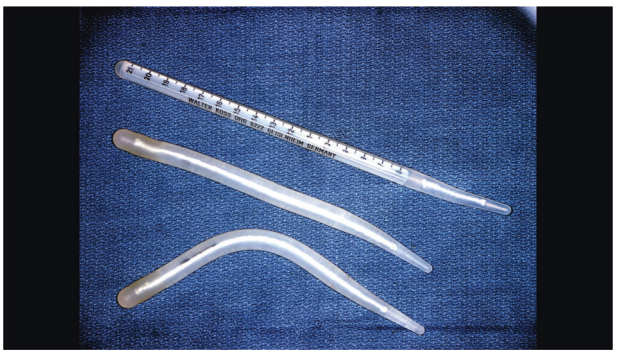

Fig. 2 Historic Malleable Implants. Jonas implant.

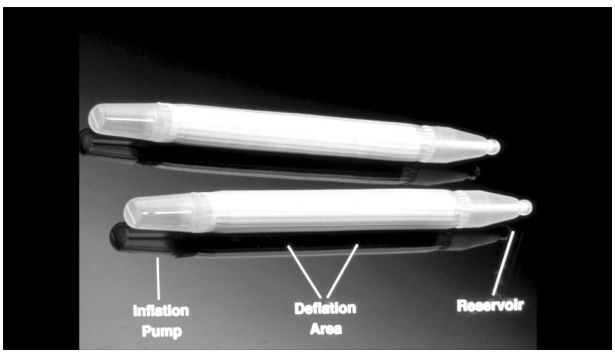

Fig. 3 Historic Self-contained Inflatable Implants. Dynaflex implant.

Fig. 4 Historic Self-contained Inflatable Implants. Flexiflate implant.

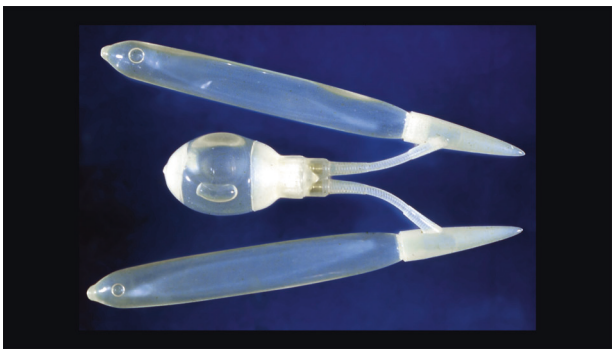

Fig. 5 Historic Two-piece Inflatable Implants. Mark-II implant.

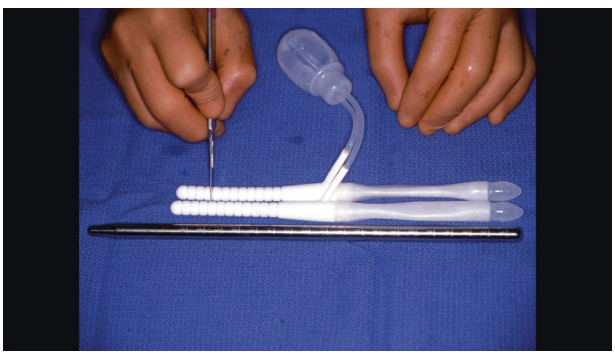

Fig. 6 Historic Two-piece Inflatable Implants. Uniflate 1000 implant.

prosthetic toolbox [7, 8]. Initially, the semirigid rods outsold the inflatables due to the simplicity of insertion and lower cost. However, with time, the market share of inflatables surpassed that of semirigid due to both the quality of the erection and the ability to achieve a truly flaccid state between uses. With practice, urologists gained experience in placing the three-piece inflatable implant, further contributing to their market share takeover.

In 1982, Mentor Corporation introduced the Alpha-1 three-piece inflatable device, which was structurally identical to Dr Scott's inflatable implant but with a reservoir and cylinders composed of Bioflex, a polyurethane material [9].

Throughout the 1980s, sales continued to increase annually. Vendors sought to attract both patients and implanting physicians by creating simpler devices. The abdominal reservoir was the particularly troublesome aspect of the 3-piece inflatable implant insertion, and as a result, new devices notably lacked such reservoirs. In the mid-1980s, the Hydroflex, its successor Dynaflex (Fig. 3), and Flexiflate (Fig. 4) implants were introduced [10–12]. These were termed "self-contained inflatables" because they had no parts outside the erectile chambers. The implants were both prefilled and packaged in a saline broth. Pumping the distal end of each cylinder transferred fluid from a small reservoir compartment to the power or central chamber for rigidity. A release mechanism allowed fluid to return to the reservoir chamber for relative flaccidity. The rigidity of the erection depended on the firmness of the device itself, with no expansion of the tunica albuginea. The flaccid state was suboptimal because a substantial amount of fluid remained stored in the base of the penis.

The 1980s saw the introduction of two new malleable rod implants, the Mentor Malleable with braided silver wire core, later named the Genesis, and the American Medical Systems AMS 600 and later model 650 with a stainless-steel core [13, 14].

At the same time, two-piece inflatable implants were introduced. Mentor Corporation marketed the Mark-II (Fig. 5) [15]. This device was composed of two silicone cylinders, one in each corporal body connected to a dual reservoir pump, termed the resipump, contained in the scrotum. Squeezing the resipump

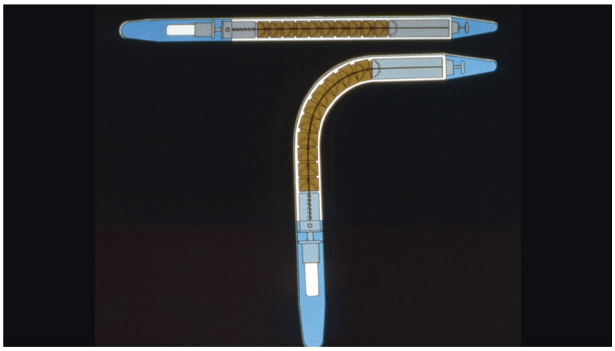

Fig. 7 Historic Self-contained Mechanical Implants. Omniphase implant.

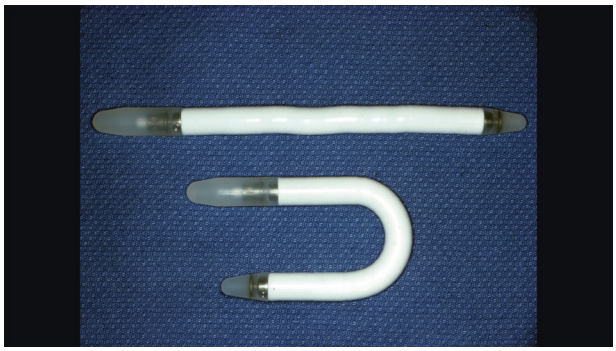

Fig. 8 Historic Self-contained Mechanical Implants. Duraphase implant.

transferred 15–20 cc of fluid from the pump to the cylinders. Squeezing the neck of the pump allowed fluid to return to the resipump. Surgitek Corporation simultaneously introduced the Uniflate 1000, a two-piece inflatable implant with two cylinders and a resipump (Fig. 6) [13]. The resipump volume of both implants could be adjusted transcutaneously, and each contained a similar maximum volume of fluid [13].

The Ambicor, a third two-piece inflatable prosthesis, was introduced in the early 1990s by American Medical Systems [16]. This device had two cylinders, a proximal reservoir chamber, and a small pump. Squeezing the pump pressurized the reservoir and transferred a small volume to the power chambers of the cylinders. Bending the cylinders downward from the horizontal position opened a valve to allow fluid to return to the reservoir chamber. Like the self-contained inflatables, these two-piece devices relied on the intrinsic rigidity of the cylinders for erectile support, did not expand the tunica albuginea, and left a substantial amount of fluid remaining in the penis in the flaccid state.

In the mid-1980s, Dr. Gerald Timm, an engineer who with Dr Scott designed the original 3-piece inflatable prosthesis, founded Dacomed Corporation. He designed a self-contained mechanical penile implant termed the Omniphase (Fig. 7) [17]. This cylinder consisted of a series of polysulfone segments that articulated in a ball and socket fashion and were held together by a central cable. A switch shortened or lengthened the cable by a fraction of a centimeter, and the segments came together or fell away from each other. The cylinders were easily bendable and gave support to the erection comparable to malleable implants, but the switching mechanism and location were at times confusing and the difference between the erect and resting states was unimpressive.

The Omniphase was soon succeeded by the Duraphase implant (Fig. 8) [18]. This device maintained the same polysulfone articulating segments, but the central cable was fixed at each end. One easily bent the device upward for erectile function and downward for concealment. The Duraphase and its successors, the Dura-II and the Spectra, became the semirigid rods of choice for many implanters. The Spectra was very costly to manufacture compared with the available malleable, the Coloplast Genesis. The maker of Spectra, Boston Scientific, therefore recently replaced it with the Tactra, a malleable rod implant with a central core composed of a cost-effective nickel–titanium alloy. By the early 2000s, both unitary inflatable implants, two of the three two-piece inflatable devices, all the soft silicone semirigid rod implants, and the Omniphase/Spectra lineage had been removed from the marketplace due to low sales volume.

TODAY

Today, inflatable prostheses account for the vast majority of the US implant market due to the exceptional rigidity and flaccidity of these devices [19]. There are two three-piece inflatable prostheses makers in competition today: AMS (now owned by Boston Scientific) and Coloplast (formerly Mentor). This rigidity is achieved by stretching the pseudo-capsule and the tunica albuginea surrounding the cylinders, much like an inner tube fills a bicycle tire. Other devices relied solely on the intrinsic rigidity afforded by the cylinders. Only one two-piece device remains on the market, the Ambicor, which has very limited application: specifically, when a hydraulic device is desired, but an abdominal reservoir is contraindicated. The malleable implants have also seen a continued reduction in market share and are now mainly used in patients with limited manual or mental dexterity, or as spacer rods following salvage procedures for penile implant infections, immediately following episodes of acute ischemic priapism, or those who do not have insurance coverage for another device [20].

Since the 1970s, penile prostheses for the treatment of ED have undergone an impressive array of modifications and technological advances. With time, surgical standardization of the approach has improved efficiency, outcomes, and reduced complications. Surgical tool advancements—from Furlow to Brooks to cavernotome dilators, blunt and sharp hooks for retraction, and the Keith needle—have simplified access and insertion [21]. Impressive advancements have also been made in infection control techniques and technologies, including Dr Eid's "no touch" insertion technique and two anti-bacterial mechanisms, InhibiZone from AMS (now part of Boston Scientific) in 2001 and Titan from Mentor (now Coloplast) in 2002 [22–24]. Together, these have substantially decreased infection rates and increased prostheses longevity.

FUTURE

As we look to the future, novel implant designs aim to address the needs of specific patient populations and provide answers to the problems vexing implanting physicians for the past 80 years. Identified areas of need include better protheses for use in gender-affirming surgeries, more easily activated designs for patients with limited manual dexterity, more comfortable alternatives to manual inflation, and less complicated designs with lower potential for malfunction.

Penile protheses used in gender-affirming surgeries for female-to-male patients are noted to have higher rates of infection, erosion, and complications than those in cisgender men [25, 26]. However, a notable lack of long-term studies focused on two- and three-piece IPPs exists in the literature. One device, the ZSI 100 FtM, is a malleable implant specifically designed for use in transgender men. It features a steel plate for fixation to the pubic periosteum, a feature aimed at meeting the need for a point of fixation specific to this patient population. A 2020 study examining outcomes found that 11/25 devices were explanted within six

months due to infection, protrusion, pubic pain, and "difficulty living with the device" [27]. There exists a clear need for advancement in this space.

Additional populations for special consideration include patients with diabetes, spinal cord injury and corporal fibrosis such as Peyronie's disease or a history of priapism. In these populations, there may be an increased risk of infection or erosion [28–31]. Among patients with diabetes, glycemic effects on immunity may lead to impaired healing, with some studies showing evidence that higher A1c is associated with higher risks of infection [28, 32]. Among patients with spinal cord injuries, impaired wound healing, altered blood supply, and urinary tract infections may increase the risk of infection; infections themselves could contribute to the risk of erosion [30]. For patients with corporal fibrosis, the technical challenges of device installation may lead to increased instrumentation with associated risks of infection, malfunction, and corporal perforation [33]. In all of these populations, considerations for easy use, durability, and ever-improving materials to reduce complication risk are imperative [34].

Other implantable devices aim to answer the need for less complicated designs that can be activated without a pump, which may prove uncomfortable or inaccessible in patients with limited dexterity. In 2018, Robles-Torres et al. described a prototype for a three-component inflatable that uses a hydraulic pump supported by an electronic microprocessor to activate the reservoir pump [35]. Rather than manually move saline, the electronic component which triggers the hydraulic pumps is activated by a mobile device. Though stalled in development, such a device pushes technology toward remote, rather than manual, filling. Shortly thereafter, Le et al. described an implantable device composed of temperature-activated nickel–titanium alloy [36]. It is activated with external magnetic induction over the course of 45 s. The magnetic induction creates heat that leads to conformation changes in the heat-sensitive polymers allowing for a rigid and flaccid temperature-dependent outcome. The device can withstand substantial buckling force with a minimal increase in cavernosa temperature. Questions of MRI compatibility and the potential impact of the described temperature remain, but the elimination of pumps and tubing represent a substantial simplification of existing options.

CONCLUSION

While there has been stepwise improvement in penile prosthesis over the last 50 years, the ideal device does not yet exist. Such a device would mimic a natural erection, be easy to use, free of malfunction, and without risk of erosion or infection. Limitations to devices include palpable components, an erection that does not mimic the feel of a natural erection, and the need for device manipulation to achieve an erection. New technologies will need to show an advantage over existing technologies. It is possible that the ideal device is not a device at all, and that future regenerative therapies such as stem cell therapy, gene therapy, and advanced pharmaceuticals that restore and/or enhance native erectile function will compete with penile prostheses. For now, however, penile prostheses are marvels of technological achievement with a long and storied history.

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AUTHOR CONTRIBUTIONS

MSG and JJM conceived of the presented ideas. MSG supervised the project with support from JJM. MH, EM, and JJM collaborated in drafting the manuscript. All authors provided critical feedback and finalized the manuscript.

COMPETING INTERESTS

MSG and JJM are consultants/speakers for Coloplast. JJM is a consultant/speaker for Boston Scientific. The other authors declare no competing interests.

ADDITIONAL INFORMATION

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