Current Urology Reports (2019) 20:17
https://doi.org/10.1007/s11934-019-0880-x

SURGERY (J SIMHAN, SECTION EDITOR)

Innovating Incrementally: Development of the Modern Inflatable Penile Prosthesis

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Abstract

Purpose of Review The inflatable penile prosthesis (IPP) was introduced in 1973. Since that time, the fundamental design of the IPP has not changed, but numerous improvements to the device, surgery, and peri-operative management have resulted in a modern IPP with excellent reliability, infection control, safety profile, and user experience.

Recent Findings We describe important modifications to the IPP and review available data assessing the impact of these changes. We also discuss possible changes to the IPP that would result in continued improvement.

Summary Since its introduction in 1973, changes to the penile prosthesis have resulted in significant improvements in reliability, infection control, safety, and user experience. Design changes are anticipated to continue, resulting in a better and more versatile penile prosthesis.

Keywords Penile implant · Penis prosthesis · Prosthesis · Penile · Prostheses and implants

Introduction

In 1973, Brantley Scott introduced the inflatable penile prosthesis (IPP) and founded American Medical Systems (AMS). Since that time, the fundamental design of the IPP has not changed, but numerous improvements to the device, surgery, and peri-operative management have addressed weaknesses as they were discovered (Fig. 1). This has resulted in a modern IPP that resembles the original device introduced by Scott but is superior in terms of reliability, infection control, safety, and user experience.

Reliability

Numerous product enhancements and design changes have improved device reliability considerably. The number of seams—a common point of failure—was reduced in the initial AMS reservoir to one in 1974 and then to zero with the introduction of the AMS 700 in 1983. Additional modifications incorporated into the AMS 700 included kink-resistant tubing, rear tip extenders, polytetrafluoroethylene (Goretex) sleeves over the input tubing, and elimination of the internal reinforcing rod. Also in 1983, Mentor released a competing IPP made of Bioflex, a polyurethane with excellent elasticity and tensile strength. In 1986, AMS introduced the AMS 700 CX, whose three-ply design with a middle layer of Dacron-Lycra allows controlled girth that is its hallmark. This design allows for controlled expansion and reinforcement of the inner silicone layer, reducing the likelihood of aneurysm and rupture. In 1989, Mentor introduced the Alpha I, which included nylon reinforced kink–resistant tubing and pre-connected cylinder tubing, which further simplified implantation and eliminated a potential source of failure. In 1990, AMS introduced the Ultrex IPP, which allowed for length in addition to girth expansion. In response to durability issues, AMS modified the Ultrex cylinder design in 1993 to limit length expansion and incorporate a stronger fabric weave. In 2000, AMS introduced parylene, a coating that reduces friction and cylinder rupture, as well as pre-connected cylinders. In 1992, Mentor modified the Alpha I by lengthening tubing and reinforcing tubing at the exit from the pump.

Not unexpectedly, reliability of the original device was poor [1, 2]. Leakage rates were as high as 70% in early models [3, 4]. Revision rates with the initial prostheses were around 61% at 3–11 years but decreased to 13% at 4 years after the

This article is part of the Topical Collection on *Surgery*

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Published online: 07 March 2019

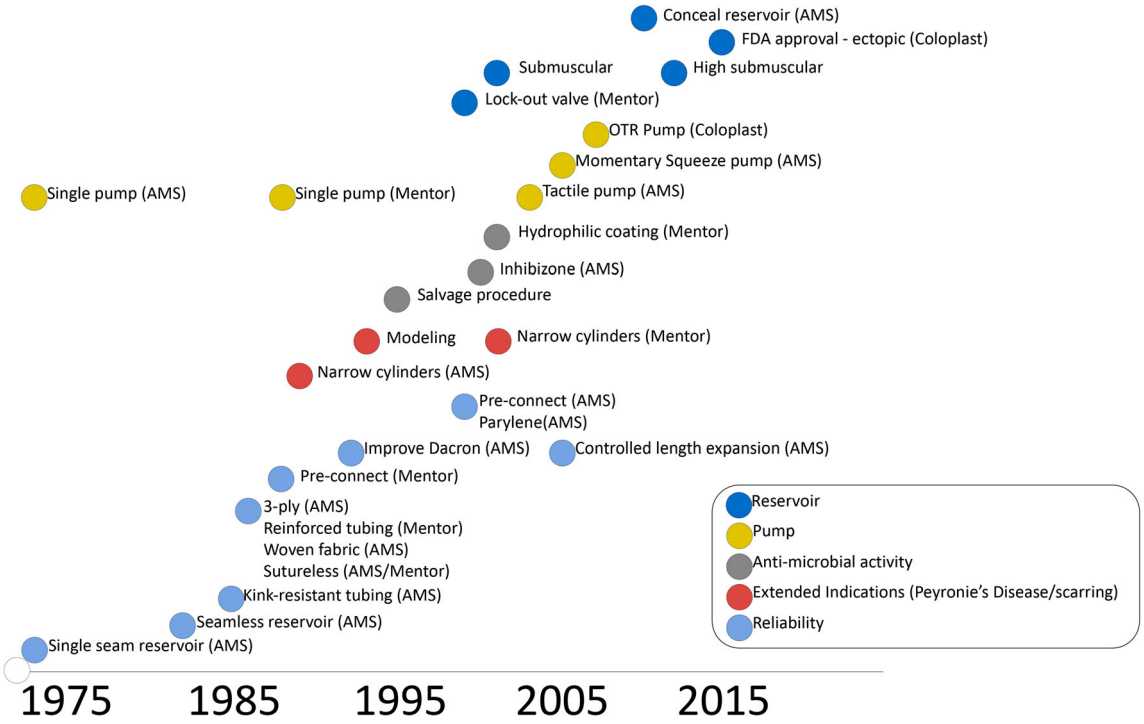

Fig. 1 Timeline showing significant innovations in IPP design and implant surgery. Innovations are categorized as addressing reliability, extended indications (Peyronie's disease/scarring), anti-microbial activity, pump, and reservoir. Initial design changes were focused on improving device reliability. Later efforts focused on easing implantation in those with Peyronie's disease/scarring and reducing risk and morbidity of infection. Recently, improvements have been made to the pump and reservoir

introduction of the AMS 700 in 1983 [3, 5]. Following the introduction in 1983 of controlled expansion cylinders with the AMS 700 CX, revision rates decreased further from 15 to 5% at 5 years [6]. Improvements to the Ultrex cylinder in 1993 resulted in 5-year mechanical failure-free survival rates of 94% compared to 71% prior [7, 8]. The addition of parylene increased the revision-free survival rates of the AMS CX from 88 to 94% at 8 years in one study [9] and from 80 to 92% at 3 years in another [10]. Modifications to the Mentor Alpha I, mainly reinforced tubing at the pump exit, improved device reliability significantly [11]. Similar long-term mechanical reliability has been reported with the Titan [12, 13], a model introduced by Mentor in 2002. Currently, mechanical survival rates are estimated at 97.6% (3 years), 86.2%–93.2% (5 years), 68.5%–85.0% (10 years), and 59.7%–79.2% (15 years) [14].

Extended Indications (Peyronie's disease and scarring)

The IPP has long had a role in the treatment of Peyronie's disease (PD), either because of co-existing erectile dysfunction (ED) or from ED resulting from treatment of Peyronie's disease. When the IPP was introduced, management of PD deformities such as narrowing and curvature often required complex reconstructive surgery. This changed in 1994 when Wilson popularized the concept of modeling—a technique for straightening the penis by bending over an inflated prosthesis. The use of Coloplast Titan was initially preferable because of premature cylinder wear and tearing of the outer layer [15] in the AMS CX after modeling, but the addition of a parylene coating to the AMS devices in 2000 seems to have resolved this issue. When modeling is not fully effective, proposed methods for treating residual curvature include incision with or without grafting and Yachia corporoplasty [16•]. Patients with narrow or scarred corpora cavernosa from priapism or prior infection/prosthesis removal can undergo placement with narrow cylinders—the AMS CXR, which was introduced in 1990, or the Titan NB, which was introduced in 2002.

In his 1994 publication, Wilson reports that modeling the penis over an inflated prosthesis for 90 seconds was effective in 92% of patients [17]. Long-term follow-up revealed that modeling predisposed the AMS devices to wear relative to the Titan [15], but the same authors report that the addition of parylene ameliorated this issue [10]. Recently, the AMS 700 CX and the Coloplast Titan were compared in patients undergoing modeling, and were equivalent in terms of straightening, satisfaction, and durability [18].

Anti-microbial Activity

Device modifications as well as changes in surgical technique have dramatically reduced the likelihood of and morbidity of infection after IPP implantation. For nearly two decades after the introduction of the IPP, standard treatment for an IPP infection was to remove the entire device, resulting in fibrosis, scarring, and shortening of the corporal bodies. Reimplantation would be difficult and sometimes impossible. In 1996, Mulcahy described a salvage procedure that would ultimately become the standard for treatment of infected IPPs. In 2000, AMS introduced InhibiZone (IZ), a method for impregnating minocycline and rifampin directly into the silicone. In 2002, Mentor coated the Titan with polyvinylpyrrolidone, a hydrophilic substance that permits absorption and subsequent diffusion of aqueous antibiotic solutions and potentially reduces bacterial adherence.

In 1996, Mulcahy and Brant reported their results after an IPP salvage procedure in 11 patients, 82% of whom were infection free at 9–42 months follow-up [19]. A greater infection-free rate of 93% was reported in 2016, when Gross et al. reported the results of a multi-institutional study using malleable prostheses for the salvage procedure. Published data strongly suggest that coated IPPs have a lower infection rate than non-coated IPPs [20]. In one study, patient information forms from AMS were used to determine 60- and 180-day infection rates, which were 1.59% and 1.61% for the controls and 0.28% and 0.68% for the InhibiZone group [21]. Another study using patient information forms from Mentor found that the infection rate for the coated Titan was 1.06%, compared to 2.07% for the non-coated Alpha-1 during the same time period [22]. In a single institution comparison of Coloplast devices soaked in vancomycin-gentamycin (VG), AMS devices with IZ, and Coloplast devices soaked in rifampin-gentamycin (RG), infection rates were 4.3%, 1.3%, and 0% [23]. Use of rifampin was found to be a significant predictor of freedom from infection, but manufacturer (Mentor/Coloplast vs AMS) was not.

Pump

The first change to the IPP pump occurred in 1974, just 1 year after the IPP was introduced, when AMS moved from a dual-pump to a single-pump design. No significant improvements in pump design occurred until 2004, when AMS introduced the Tactile Pump. This pump represented a fairly marginal improvement over the previous pump—incorporating ribs on the pump inflation bulb and pads on the deflation mechanism. In 2006, AMS introduced the Momentary Squeeze (MS) pump, which was a more dramatic improvement in pump design. The new smaller pump incorporated a lock-out valve and improved both inflation and deflation. Whereas the tactile pump required a two-finger squeeze for the duration of deflation, the MS pump incorporated a single button that achieved complete deflation after being depressed for a few seconds. In 2008, Coloplast released the One Touch Release (OTR) pump. Compared to the older Genesis pump, the major modification in the OTR pump was improved deflation. The pump was equipped with release pads, rather than bars, and only required one squeeze of these pads to initiate deflation. In 2013, Coloplast introduced the Titan Touch pump, which has a smaller profile than the OTR pump and also utilizes a one-touch deflation mechanism.

The AMS Tactile Pump was reported by patients to be easier to find, inflate, and deflate than the previous version, although surgeons reported no difference in terms of implantation [24]. In a survey, the AMS MS pump was noted by patients to be easy to locate/deflate and by most physicians to be easier to implant [25]. The Coloplast OTR pump was compared to the Coloplast Genesis and required fewer sessions for patient teaching [26]. The OTR pump has been noted to become stuck in the deflate position in 8% of patients; this can be overcome with very firm pressure and does not require surgery [27]. An even smaller profile, one-touch release pump was released in 2013, the Titan Touch.

Reservoir

Initially, reservoirs were placed retropubically—a capacious potential space deep to transversalis fascia under the pubic bone—in order to minimize risk of auto-inflation. This began to change in 2000 when Mentor added a lock-out valve to its reservoir, to reduce the risk of auto-inflation and aid reservoir placement in patients with a scarred retropubic space from previous surgery or radiation. The addition of the lockout valve coincided with the increasing popularity of transperitoneal robotic prostatectomy, which intraperitonealizes the retropubic space, and forced surgeons to consider other ("ectopic") locations for the reservoir. In 2002, Wilson reported his first experience with the Mentor reservoir and reported successfully placing the reservoir below the abdominal musculature in 8 patients [28]. In 2006, AMS introduced the Momentary Squeeze pump, which contained a lock-out valve, and in 2011 a Conceal reservoir with a flat profile designed for sub-muscular placement [29]. In 2015, the FDA approved the Coloplast Cloverleaf for ectopic placement.

Prior to the introduction of a lock-out valve, auto-inflation occurred in an estimated 11% of patients and required surgical revision in 2%; after introduction of the lock-out valve, auto-inflation occurred in 1% and no patients required surgery [28]. The major concerns with sub-muscular reservoir placement are palpability and herniation [30], which may occur less

frequently with high sub-muscular placement [31]. Using this technique, Morey reported a herniation rates of 2%—similar to their prior experience with retropubic placement—but notably deep pelvic complications were less common with high sub-muscular placement (1.9% vs 0.5%) [32••].

Looking Forward

Current IPPs—a result of decades of innovation by manufacturers and surgeons —are functional, reliable, and safe. While tempting to imagine dramatic design changes to the penile prosthesis, the several decade history of penile prosthesis implantation suggests that future changes will be subtle but numerous, ultimately resulting in devices much better than what we have today. Anticipated areas of further innovation include the following:

Durability While durability is excellent—and much better than in earlier devices—mechanical failures do still occur. Development can focus on reducing the likelihood of fluid leak by identifying and reinforcing points of failure and potentially transitioning away from a hydraulic device.

Extended Indications The current penile prostheses produced by Coloplast and AMS are not designed for implantation in a neophallus (e.g., radial forearm free flap)—a skin tube that originates near the pubis [33•]. Zephyr Surgical Implants (Switzerland) manufacturers an implant (not currently available in the USA) that is specifically designed for a neophallus. It consists of a single cylinder that can be anchored directly to the pubis. Similar models are anticipated to eventually become available in the USA. Dual-cylinder prostheses suitable for implantation in a patient after metoidioplasty, where the erectile bodies are narrower and shorter, would also be welcome and could potentially be used as a tissue expander to increase the size of the phallus.

Anti-microbial Activity While antibiotic coating has reduced the likelihood of a device infection, there are a number of limitations. For example, InhibiZone cannot be modified based on patient- or hospital-specific factors (e.g., allergies, cultures, local antibiotic resistance profiles), while the Coloplast approach of dipping in an antibiotic solution prior to implantation is cumbersome. Future models will likely include non-antibiotic anti-microbial mechanisms incorporated into the implant.

Pump/Patient Experience The pump is currently the main source of patient interaction with the device, and often a major source of patient frustration. As major durability issues have been addressed, usability has become more of a focus for manufacturers. As a result, the pumps are expected to either improve further (e.g., one-touch inflation, easier deflation) or be replaced with other mechanisms (thermal [34••], magnetic [35••], and electronically-activated [36] penile prostheses have been proposed). Other aspects of the patient experience (e.g., comfort, cost, simplified surgery, more physiologic erection) are additional areas for improvement.

Reservoir While great strides have been made in reservoir design and implantation techniques, the placement of the reservoir and need for connections adds time, complexity, and morbidity to the surgery. We expect this component to be ultimately eliminated from the penile prosthesis.

Compliance with Ethical Standards

Conflict of Interest Mark Ehlers, Benjamin McCormick, R. Matthew Coward, and Bradley D. Figler each declare no potential conflicts of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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