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Technological Advances in Penile Implant Surgery

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ABSTRACT

Background: During the last century, surgical management of erectile dysfunction has evolved from an experimental concept to a core treatment modality with widespread use among the men's health community. Over time, innovations in materials, mechanical design elements, device coatings, and surgical technique have provided patients with low-risk, reliable, and reproducible erectile function with high satisfaction rates.

Aim: To provide a foundation for future innovation by improving understanding of historical penile prosthetics and the rationale behind incremental technological improvements for the contemporary Men's Health physician.

Methods: Literature review was conducted to generate a comprehensive review of historical technological innovations in penile implant surgery. Companies with FDA approved penile prosthetics in use in the United States were contacted for information regarding technological innovations in the past and future devices in development. A separate literature review was performed to identify any significant future device design elements being tested, even in the ex vivo setting, which may have future clinical applications.

Outcomes: Technological innovations in penile implant surgery were described.

Results: Current options for the prosthetic surgeon include malleable penile prostheses (MPP), self-contained (2-piece) inflatable penile prostheses, and multicomponent (3-piece) inflatable penile prostheses. Current MPPs consist of a synthetic coated solid core which allow for manipulation of the penis for concealability while maintaining sufficient axial rigidity to achieve penetration when desired. Multi-component (3-Piece) IPPs currently include the Coloplast Titan and Boston Scientific/AMS 700 which consist of a fluid reservoir, intrascrotal pump, and intracavernosal cylinders. The devices have undergone numerous design updates to the cylinders, pump, reservoir, tubing, and external coatings to increase reliability and decrease short- and long-term complications.

Clinical Implications: Future innovations in penile prosthetic surgery seek to broaden the indications and applicability to the transgender community and improve both safety and functionality for patient and partner.

Strengths & Limitations: The review is limited primarily to penile prosthetics approved for current or historical clinical use in the United States and may not be representative of the global prosthetic environment. Additionally, the research and development of future innovations, particularly those provided by device manufacturers, is likely limited by non-disclosure to maintain a competitive advantage.

Conclusions: Penile prosthetic surgery will undoubtedly remain integral to the treatment of erectile dysfunction, and education regarding the current state of technological innovation will empower the prosthetic surgeon and biomedical engineering community to improve contemporary patient care and drive the development of the next generation of implantable penile prosthetics. **Barnard JT, Cakir OO, Ralph D, et al. Technological Advances in Penile Implant Surgery. J Sex Med 2021;xxx:xxx–xxx.**

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INTRODUCTION

Penile prosthetic surgery remains a critical tool in the urologic surgeon's armamentarium for the management of erectile dysfunction, Peyronie's disease, and in female-to-male gender reassignment operations. The first phalloplasty was described in 1936 by Nikolaj Bogoras using autologous human rib cartilage

within a tubularized abdominal flap, marking the beginning of penile implant surgery.[1] A decade later the first female to male gender reassignment operation was performed by Dr. Harold Gillies on a fellow physician, and his technique remained the standard for many years. Then, in 1952 Goodwin and Scott created the first artificial, acrylic penile prosthesis which was shortly followed by a silicone-based implant in 1964 by Lash et al. Although marking the transition to utilization of prosthetic material for erectile restoration, the early implant materials left significant opportunity for improvement with respect to surgical outcomes and functionality.[2] Finally, in 1973 Scott et al described the first inflatable penile prosthesis (IPP) which has remained the model for contemporary penile implant surgery, albeit with numerous iterations and improvements.[3] Advances in functional outcomes and patient satisfaction are an ongoing endeavor representing innovations in implant technology, perioperative management, and refinements in surgical technique. Herein, technological advances in implant surgery will be presented to increase surgeon awareness and understanding of contemporary devices and components, and to highlight the future opportunities for improvement.

MALLEABLE PENILE PROSTHETICS

The optimal malleable penile prosthesis includes an implantable cylinder of fixed length that can be manipulated to achieve penetration when desired while being concealable enough to remain socially and functionally acceptable while not in use. Ideal surgical candidates are those who lack the manual dexterity to operate a 3-piece device and in whom concealment is not of particular concern.[4] The first type of device described in 1975 was marketed as the semirigid rod prosthesis, and many iterations of this device were attempted by several manufacturers.[5] Just prior, in the 60s and early 70s Egyptian surgeon GE Beheri is credited as performing over 700 implants of polyurethane rods after corporal dilation. His technique was slow to be accepted in the urologic community due to his publications being in plastic surgery journals.[6] The eventual incorporation of this technique, combined with NASA innovation resulting in creation of high-grade silicone, culminated in significant improvements in semirigid devices (Figure 1). In the 1980s, Jonas and Jacobi created the concept of a silicone cylinder with a twisted wire core. In one study of 11 patients, there was 100% satisfaction at a mean of 21.7 months follow-up; one early extrusion and one UTI resulted in an 18% early complication rate.[7] In 2003, American Medical Systems (AMS, Minnetonka, MN) created a mechanical malleable prosthesis with segmented articulating polyethylene rods for improved range of motion while sustaining sufficient rigidity for intercourse, known as the Dura II.[4] This was followed in 2004 by the Coloplast (Humlebaek, Denmark) Genesis Malleable prosthesis which increased distal shaft column strength to prevent buckling, and comes in multiple diameters, and can be trimmed to customize the fit intraoperatively (Figure 2). In 2009 AMS developed the Spectra Concealable penile prosthesis which added alternating

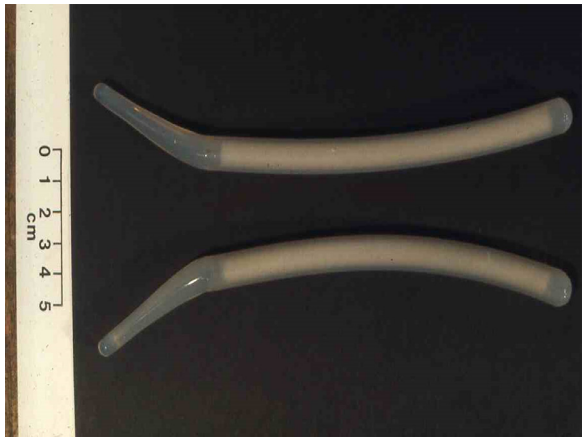

Figure 1. Early example of silicone rod penile prosthesis.

titanium and polyethylene segments for better concealment. The Spectra was designed with 3 different diameters (9.5, 12, and 14 mm) and 12, 16, and 20 cm lengths and could be customized with snap fit rear tip extenders (RTE). In 2019 AMS released the current iteration, the Tactra malleable penile prosthesis which is a dual layer silicone design constructed around a nitinol core which allows for improvement in durability (Figure 2). The Tactra also has more simplified customization as it comes in 3 diameters (9.5, 11, and 13 mm); each is trimmable in length from ~14 to 27 cm and comes with insertion fit RTE for a more streamlined design. Also in 2019, a third company, Rigicon, received FDA approval for implantation of its Rigi10 MPP which offers up to 135° bending angle. The distal and proximal ends of the synthetic coated, steel core, titanium tipped Rigi10 shaft are designed to maintain a rigid, natural feel while the increased bending angle of the midportion allows for easier implantation through a smaller corporotomy (Figure 2). The Rigicon MPP is offered with a hydrophilic external coating and comes in 2 lengths (23 and 25 cm) and 5 diameters (9−13 mm), and each includes 0.5 and 1 cm RTE for further customization intraoperatively.

SELF-CONTAINED (2-PIECE) INFLATABLE PENILE PROSTHETICS

In 1985, AMS developed a two piece "self-contained" inflatable penile prosthesis known as the Hydroflex which essentially consisted of 2 cylinders and a pump containing fluid with no reservoir. This first iteration was fraught with mechanical failure at nearly 20% for a mean follow-up of 14.5 months in one study of 32 patients from 1985 to 1995. Nonetheless it offered an opportunity for intercourse for men suffering with ED with a history of multiple abdominal procedures in whom traditional reservoir placement would be considered high risk. In 1988 Mentor (now Coloplast) developed a competing, but now defunct, self-contained prosthesis known as the Mentor GSF (later Mark II after tubing connectors were eliminated). In 1994 AMS developed the Ambicor which is a similar self-contained pair of cylinders

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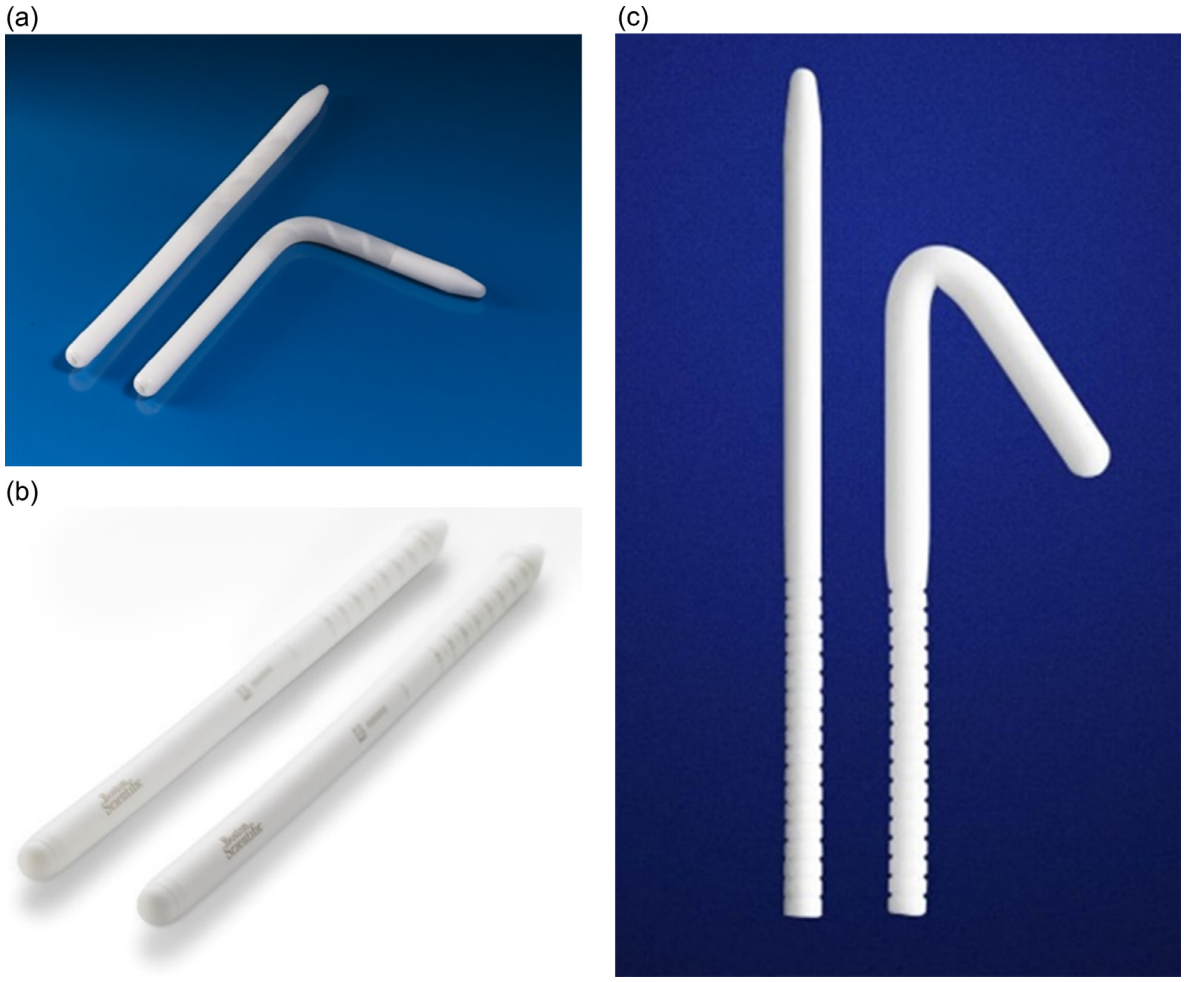

Figure 2. Coloplast Genesis (a), AMS Tactra (b), and Rigicon Rigi10 (c) Malleable Penile Prostheses.

Figure 3. AMS/Boston Scientific Ambicor 2-piece inflatable penile prosthesis.

with preconnected pump (Figure 3). A comparison of 142 patients who underwent either malleable penile prosthesis or Ambicor placement showed significantly greater overall satisfaction (90.1% vs 74.2% "Very Satisfied")[8] with the latter. Additionally, 93.1% said Ambicor "Fully Met Expectations" compared with 77.4% for malleable, and 79.5% of Ambicor patients used their device "Very Often" compared to 56.2% for malleable devices despite no differences in the cohorts with respect to age, BMI, smoking, comorbidities or device revision/replacement. The Ambicor prosthesis avoids the need for reservoir placement and associated complications, while improving patient satisfaction over the semirigid prostheses, and may be preferred in patients who have had multiple abdominal procedures or are averse to reservoir placement but have sufficient manual dexterity to operate the pump.

MULTICOMPONENT (3-PIECE) INFLATABLE PENILE PROSTHETICS

The first 3-piece inflatable IPP was made available in 1973 (known as the "Fluid Transfer System 2") and has since

revolutionized the surgical management of erectile dysfunction, offering the most functional similarity to both the flaccid and erect states of the penis.[3] The device consists of a pump mechanism that resides in the scrotum which transfers fluid between the intracorporal cylinders and the fluid reservoir which is typically in the space of Retzius anterior to the bladder or in the submuscular space beneath the rectus muscle. Other components include the tubing and connections between the devices, the addition of RTE, and various coatings applied to the devices themselves. There have been numerous iterations and improvements to all components of 3-piece IPPs over the nearly 50-year history of the device (Summary in Table 1). Currently two companies, Coloplast and AMS/Boston Scientific, manufacture the devices approved for use in the United States, and there are numerous international device companies as well (Figure 4).

Pump

Variations in pump design have been implemented to address the unique mechanical and functional challenges associated with IPPs. One important issue is tactile feedback allowing patients to feel and squeeze the pump to transfer fluid to the cylinders before use, and the ability to identify and depress the release valve to achieve a flaccid state is also of concern. Early device alterations included improvements to the internal reliability of the pump mechanism and making the release button higher profile for consistent identification by the patient (High pressure, Classic/Genesis Pumps). In the early 2000s, both major US companies made changes which included a one-touch release feature where a single squeeze would initiate complete drainage of the cylinders (2004 AMS Tactile and 2008 Coloplast Classic). The Tactile pump was shown to be preferred over its predecessor in 93.3% of patients preoperatively and patients reported it was easier to find (100%) and deflate (96.7%) postoperatively.[9] This design was further improved in 2006 and 2013 via the AMS Momentary Squeeze (MS) and Titan One Touch Release (OTR) pumps (Figure 5). The former added a ridged surface and one touch function, and the latter decreased the depression force and time to deflation, added a ridged surface and increased the surface area of the button. The AMS Momentary Squeeze pump also contains the lock-out valve of the device to reduce auto-inflation, while the Coloplast lockout valve is located on the reservoir as discussed below. The Momentary Squeeze version of the AMS 700 showed 96% of patients easily locating the inflation bulb and 94% deflating the IPP with a single push of the release button.[9] The current limitations to pump design include the need for manual inflation/

Table 1. Summary of IPP innovations

Year	Innovation
1936	Autologous Human Rib Cartilage
1952	Acrylic Prosthesis
1964	Silicone Based Rods
1973	First IPP: Fluid Transfer System 2
1975	Semi-rigid Rod Prosthesis
1980	Rear Tip Extenders
1983	AMS 700 IPP
1985	AMS Hydroflex (First 2-Piece Device) and Quick Connect tubing
1990	Narrow Cylinders (AMS 700 CXM)
1994	AMS Ambicor 2-Piece Device
1996	Pre-connected AMS 700 Devices
2000	Reservoir Lock-Out Valve to Prevent Autoinflation (Coloplast)
2001	Inhibizone and Parylene Coating (AMS)
2002	Narrow Cylinders (Coloplast) and Hydrophilic Coating (Coloplast)
2003	AMS Dura II Semirigid
2004	Coloplast Genesis Semirigid and AMS Tactile Pump
2006	AMS Momentary Squeeze Pump and LGX cylinders
2008	Coloplast One Touch Release Pump and Titan XL Cylinders
2009	AMS Spectra Semirigid Device
2010	AMS Conceal Low Profile Reservoir
2011	Coloplast Low Profile Reservoir
2012	Coloplast Zero Angle Cylinders
2013	Coloplast Titan IPP with Touch Pump
2016	Zephyr FtM Transgender Prosthesis (Europe)
2018	AMS 700 IPP with Penoscrotal Optimized Tubing Length
2019	AMS Tactra Semirigid and Rigicon Rigi10 Semirigid

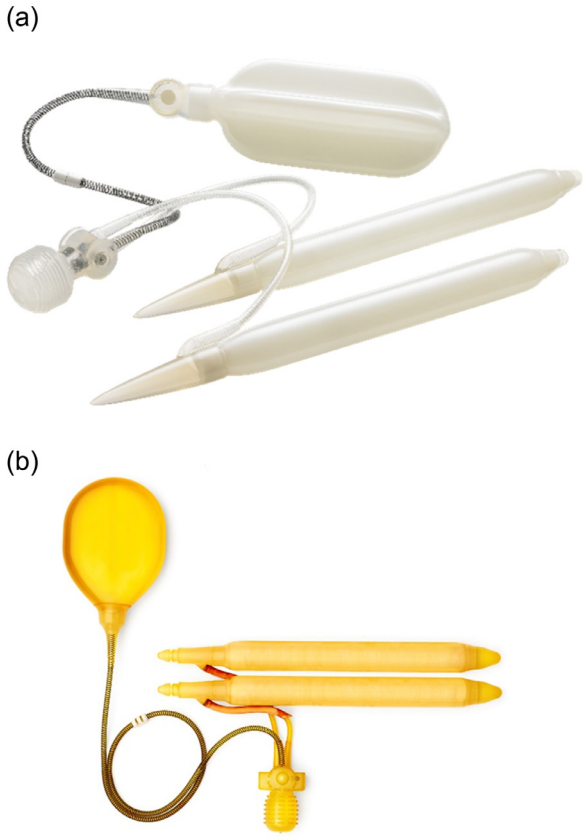

Figure 4. Current Coloplast Titan(a) and AMS 700 IPPs(b).

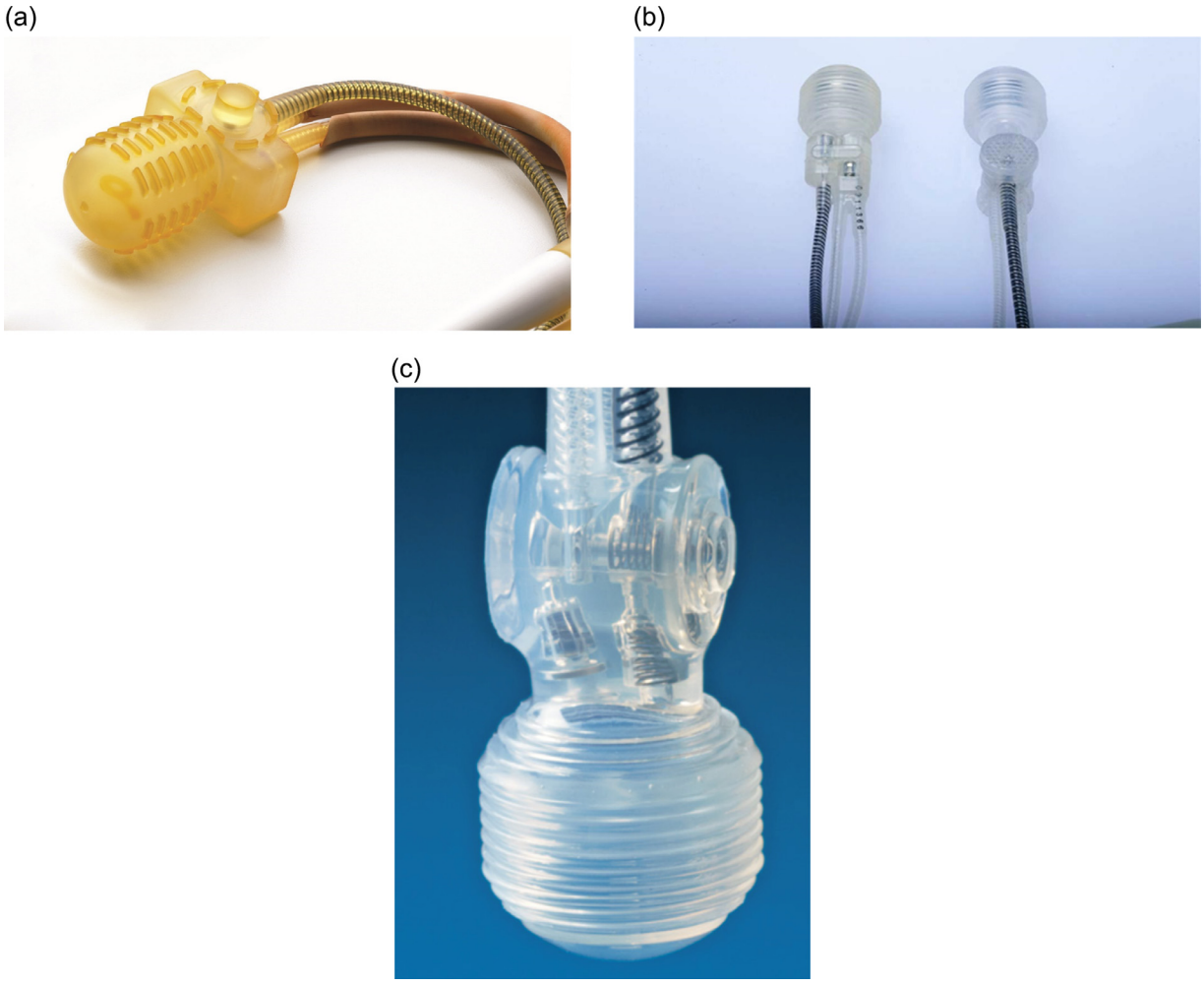

Figure 5. AMS/Boston Scientific Momentary Squeeze (a) and Coloplast Classic/Genesis (b, left), OTR (b, right) and One Touch (c) pumps.

deflation of the device and pump pseudo-malfunction or Stiction Syndrome where the valve components become "stuck" to the silicone components within, particularly after the device has not been used for a long period.[10] Both issues are similar and are addressed by firmly compressing the pump to relieve the obstruction and/or squeezing the cylinders firmly while depressing the release valve. One study of the Coloplast OTR pump revealed that the rate of pseudo-malfunction was 7.8% in a study of 550 patients and 5.3% had to be examined by a physician to apply pressure and release the valve disc into the "inflate" position.[11] AMS added description of the "pull-stretch technique" to product labeling in 2013 at direction of the Food and Drug Administration to address this issue.[9] In general, the AMS MS and Coloplast OTR are considered similar in patient satisfaction rates; however, one study did suggest patients with decreased key pinch strength may have difficulty using the Coloplast OTR pump when compared to the AMS MS as evidenced by patient reported preference.[12] Coloplast's current iteration of their one touch release pump is known as the Titan Touch pump (Figure 5).

Reservoir

Reservoir design and placement have also changed significantly over the lifetime of IPPs. The initial reservoirs were simple spherical devices that held approximately 40−125 cc of fluid to be distributed to the cylinders on-demand. Reservoir placement was in the space of Retzius through the medial floor of the inguinal canal at the level of the external inguinal ring. Early innovations in reservoir design included the development of "kink proof" reservoirs due to early mechanical failures attributable to sometimes sharp angles at the transition from reservoir to tubing, and the addition of textured coatings to prevent herniation. A major innovation was the addition of a reservoir lock out valve in 2000 by Coloplast, which decreased the risk of auto-inflation dramatically for their iteration of the IPP.[13] Wilson et al demonstrated that the rate was decreased from 11% to 1.3% with addition of the lockout valve to the Coloplast reservoir.[14] In 2010/2011, both device manufacturers developed low profile or cloverleaf style reservoirs intended to lie flatter when filled to less than full capacity. The current reservoirs are 65 cc and 100 cc for

AMS/Boston Scientific Conceal and 75 and 125 cc for Coloplast and are chosen based on cylinder length and reservoir location (Figure 6). In 2015, the submuscular or ectopic reservoir indication for Coloplast IPPs became widely accepted.[15] Despite being used previously by implanters, this designation allowed for more industry sponsored literature, teaching, and workshops to make this technique more familiar to even infrequent implanters. In this setting, typically a larger volume reservoir is placed and is filled to less than full capacity, so the reservoir lies flat just beneath the patient's rectus abdominus muscle either anterior (ATF) or posterior (PTF) to the transversalis fascia. The submuscular reservoir location is intended to avoid the catastrophic complications of placement into the space of Retzius (bowel, bladder, vascular injury) while minimizing what has been established as a slight increased risk of reservoir herniation and palpability.[16]

Cylinders

Cylinder design has undergone numerous iterations during the era of IPPs. Arguably the most critical portion of the device, the goal is to achieve reliable and durable replication of the corporal engorgement that occurs during natural tumescence while maintaining an acceptable flaccid state when not in use. Cylinder designs began with either silicone (AMS) or a polyurethane (Coloplast Bioflex) material[9]. For AMS devices, cylinder aneurysms proved problematic on early devices which led to the development of a Controlled Expansion (CX) cylinder which consisted of a 3-layer design consisting of silicone and a Dacron-Lycra woven blended fabric layer intended to reduce uneven cylinder expansion, dropping the aneurysm rate significantly.[17] Coloplast's proprietary Bioflex material consisted of polyurethane which is seven times stronger than silicone but remained biocompatible and reliable in a single ply cylinder design, now available from 11 to 28 cm.[18] To address issues with corporal fibrosis and smaller penis size, narrow cylinders were developed beginning in 1990.[9] AMS model 700 CXM and CXR cylinders allowed dilation to 9−11 mm rather than 14 mm standard diameter dilation. Additionally, this same year AMS developed a cylinder which allowed for length expansion of 20% and standard girth expansion, in contrast to girth only expansion. This lead ultimately to the development of LGX (Length-Girth Expansion) model AMS 700 device in 2006 which slightly decreased the proximal girth to allow easier placement while maintaining the distal length/girth dimensions. Early iterations allowed nearly 50% expansion which resulted in significant stress on the corpora and issues with rupture of the cylinders and mechanical failure.[19] The fiber strength was increased by 61% and the weave was changed to achieve the total elongation of only 20% with the goal of decreasing mechanical failure rates. A retrospective review of over 55,000 implants comparing LGX to CX revealed overall survival rates of 88.7% and 89.5%, respectively, which was not statistically significant.[20] For Coloplast devices, narrow cylinders were also introduced in 2002 to facilitate placement in smaller penises and in the case of significant corporal fibrosis. Titan XL cylinders were introduced in 2008 allowing for slight girth increase and in lengths up to 28 cm. Then, in 2012 Coloplast introduced Zero-degree cylinders which decreased the angle of departure of the tubing from 45° to 0° to decrease issues with input tubing wear due to improper corporotomy location, while also adding softer cylinder tips to decrease palpability when the device was inflated. After numerous iterations, the current selection of cylinders from both device manufacturers allows significant customization based on penis length and degree of corporal scarring while maintaining a high degree of reliability, rigidity, and longevity for IPPs.

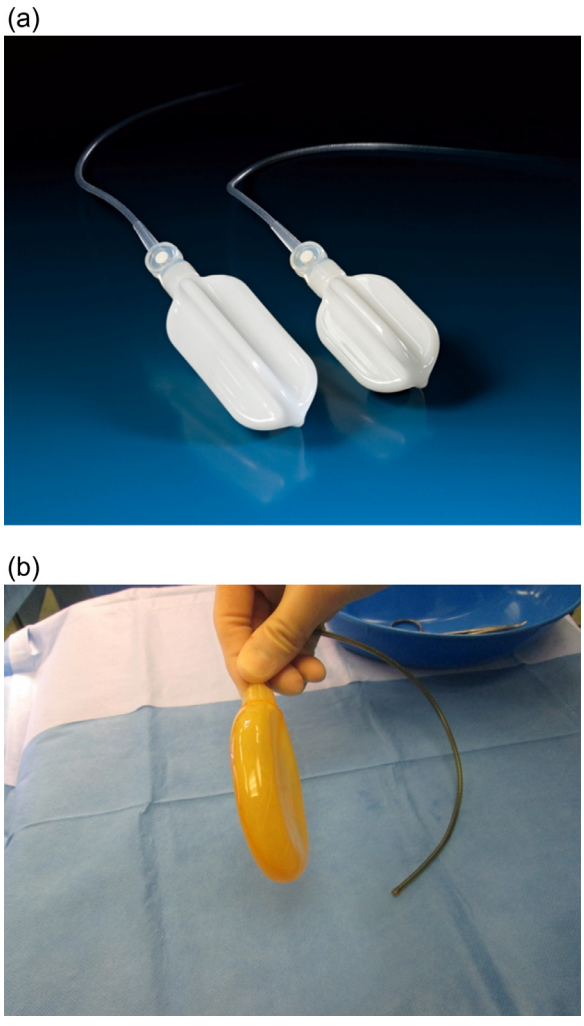

Figure 6. Coloplast Cloverleaf (a) and AMS/Boston Scientific Conceal (b) Reservoirs.

Tubing

Initially all components of the IPPs were connected to one another intraoperatively which added to operative time and complexity. Tubing innovations began in 1985 when the development of Quick Connect devices which allowed for more streamlined connections between the components. In 1996 the first "pre-connected" device was brought to market with the tubing from the cylinders to pump attached, allowing for placement

with only the final connection from the pump to reservoir performed intraoperatively. In 2012 Coloplast changed the angle of input tubing from 45° to 0° from the pump to the cylinders which facilitated a more parallel lie within the corpora and decreased input tubing wear.[9] The goal was to give more flexibility in location of corporotomies while minimizing RTE use and mechanical failures. In 2018, AMS similarly released a new version of the CX/LGX with tubing length optimized for penoscrotal implantation.

Rear Tip Extenders (RTE)

Corporotomy location was a more critical step with earlier devices, as improper placement could lead to increased input tubing wear and decrease device longevity. AMS devices have a tubing insertion approximately 3.5 cm from the proximal tip of the device while Coloplast are approximately 4.5 cm. Initially the tubing entered at approximately a 30-degree angle and was subject to significant shear stress and even kinking of the intracorporeal portion. In 1980, RTE were created to allow for more precise tailoring of the prosthesis size and also to ensure more accurate synchronicity of the proximal extent of the corporotomy to the location of tubing insertion into the cylinders. Twist-on (Coloplast) and Snap-Fit (AMS, 1998) RTEs were also introduced to facilitate more reliable removal of the RTEs when performing revision surgery or explantation. In 2013, Coloplast also introduced narrow RTE for narrow proximal corpora and an insert lock nut that further prevents RTEs being left behind after cylinder removal. Although RTEs allow increased flexibility with device sizing and corporotomy location, their use has been shown to affect the biomechanics of IPPs during intercourse and also limits the proportion of the device which is dynamic during induction of an erect state; therefore, some prosthetic surgeons advocate minimizing RTE use when possible. A lab study of Coloplast devices ex vivo showed increasing RTE length correlated with downward deflection which may manifest as diminished perceived device rigidity.[21]

Coatings

Design innovations in device coatings have been crucial in addressing several key issues including resistance to device colonization and infection as well as longevity concerns related to friction between components. In 2000 Boston Scientific/AMS developed Parylene coating which was added to the CX device in January 2001. Parylene was added to the nontissue contacting surfaces of the cylinders to increase lubricity, reduce friction and silicone wear. A study of 775 implants showed that 3 year revision free survival increased from 78.6% to 87.4% and freedom from mechanical breakage improved from 89.2% to 97.5%.[22] Additionally, in that same year, a minocycline HCL and rifampin coating (InhibiZone) was also added to the exterior of AMS implants imparting improved device infection rates. Wilson et al demonstrated in 2007 a reduction of observed infection rate from 3% to <1% in virgin IPP insertions and from 10% to 2.45% in revision cases when paired with antibiotic washout.[23] For Coloplast devices, a hydrophilic external coating was added in 2002 which is covalently bonded to all components of their devices. The coating increases lubricity, decreases bacterial adherence, and allows for absorption of any aqueous antibiotic solution the surgeon chooses into the external surface of the device.[24]

Improvements in Operative Techniques

While evolution of device components has certainly been a driving force in IPP innovation, changes in operative technique have also improved the safety and reliability of surgical implantation. Early approaches were highly variable with respect to surgical incisions and even placement of implant material either subcutaneously or between Buck's fascia and the tunica albuginea rather than within the corpora cavernosa.[6] A discussion of the merits and drawbacks of individual surgical approaches is outside of the context of this review; however, it is important to note that contemporary device manufacturers have separate products with optimized tubing lengths for both the infrapubic and penoscrotal approach to IPP placement. Select patients may also benefit from a subcoronal approach for concomitant correction of penile curvature through manual modeling with or without plication. Additionally, ectopic reservoir placement has become increasingly popular resulting in both structural changes to the reservoirs ("lie flat" designs) and changes in surgical technique (decreasing fill volumes) which reduces reservoir perceptibility in the ectopic setting.

FUTURE DEVELOPMENTS IN PENILE PROSTHETIC SURGERY

Patient satisfaction has been shown to be similar between device manufacturers Coloplast and AMS/Boston scientific, and overall satisfaction across studies is typically around 90%−95% for contemporary devices.[25] Invariably both Coloplast and AMS/Boston Scientific are continuing to develop new and improved pump, cylinder, and reservoir designs as well as improved procedural accessories. A potential "touchless" IPP has been reported in preclinical studies that removes the need for manual pumping and is controlled by an external remote that routes fluid from the reservoir to the cylinders and contains an implantable battery similar to a sacral neuromodulation device. Another current area of advancement is in transgender surgery applications of inflatable and malleable penile prosthesis. Internationally there are neophallus specific inflatable prostheses (eg, ZSI 475 FtM) which have been available in Europe since March 2016. An analysis of 20 patients showed 85.7% were able to have penetrative sexual intercourse and 92.8% were satisfied or very satisfied with the prosthesis; the overall revision rate was 19%.[26] Zephyr's 2021 model 475 FtM will have a removable glans option to make the implant further customizable to a patient's individual neophallus (Figure 7) Additionally, thermal activated prostheses consisting of an exoskeleton of temperature tuned nitinol and

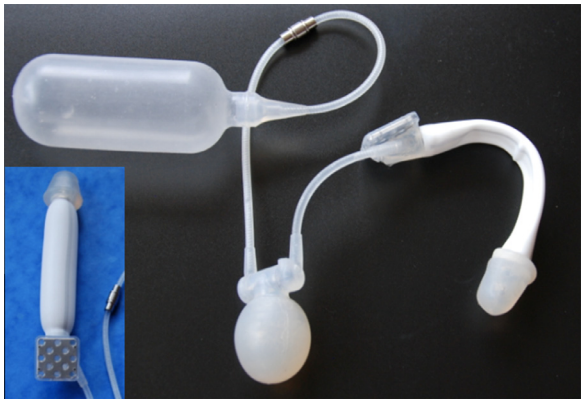

Figure 7. Zephyr Surgical Model 475 FtM neophallus specific implant with removable glans option available 2021. Inset photo showing plate for fixation to patient's bony pelvis for mechanical support. 168 × 115 mm.

Ni-TI alloy have been created and demonstrated similar mechanical parameters to IPPs in laboratory studies.[27] Induction of erection is achieved by using an external magnetic induction wand and has been tested in animal and cadaveric models with promising early results. Other ideas have included augmentation to normal erectile function such as the creation of vibrating penile implants to enhance partner satisfaction; however, the increased device complexity and widespread availability of external vibration devices may preclude such developments. Additionally, the implications are questionable as clitoral stimulation is usually most pleasurable to partners which further favors using external vibrators instead.[28] Penile prostheses have been a reliable option for men with ED for nearly 50 years and will undoubtedly remain a vital tool to urologic surgeons going forward. Further studies and innovations in device technology and surgical technique will increase patient and partner satisfaction by more reliably and accurately replicating normal erectile function.

CONCLUSIONS

Over the last 50 years, the IPP has solidified a central role in the surgical treatment of ED. Technological advancements in IPP design have been instrumental in improving patient safety, satisfaction, and device longevity. An understanding of the history of IPP design will drive future innovation to further improve ease of use, safety, reliability and also expand options for select patient populations such as the transgender community.

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STATEMENT OF AUTHORSHIP

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