SEXUAL MEDICINE REVIEWS REVIEW

New Advancements in Inflatable Penile Prosthesis

Brian F. Dinerman, MD,[1] Leon Telis, MD,[1] and Jean Francois Eid, MD[1,2]

ABSTRACT

Introduction: Inflatable penile prosthesis (IPP) technology is a mainstay in the treatment of erectile dysfunction refractory to medical management. Technological advancements in the design of 3-piece IPPs have been improved to optimize concealability and surgical placement since the 1980s. Recent advancements over the past 10 years include pump, reservoir, tubing, and cylinder updates.

Objectives: This review examines the latest updates in IPP technology, reviews recent relevant research, and is based on over 32 years of experience performing IPP surgery in addition to concurrent postoperative management.

Methods: A literature review was conducted for studies published over the last 10 years through March 2020 with an emphasis on technical updates of IPP, specifically the pump, reservoir, tubing, and cylinder, and their functional outcomes. Anti-infective coating and transgender innovations, in addition to postoperative management, are also reviewed.

Results: Technological advancements include a flat reservoir designed for improved discreteness and a prosthesis with optimized tubing length, a one-touch deflatable 3-piece system, narrow-base cylinders, a 0° angle design between the cylinders and tubing to aid in cylinder placement, a soft molding cylinder tip redesign that better mimics human anatomy, and a 3-piece IPP specifically designed for neophallus use. Furthermore, the Food and Drug Administration approved the submuscular reservoir placement.

Conclusion: Penile prosthesis has evolved over time to improve functional outcomes, ease of use, and minimize postoperative complications and pain. Penile prosthesis implantation continues to be a life-changing procedure for patients and it is imperative for surgeons to be up-to-date on the latest developments and research in order to provide the best functional outcomes for those they take care of. **Dinerman BF, Telis L, Eid JF. New Advancements in Inflatable Penile Prosthesis. Sex Med Rev 2020;XX:XXX–XXX.**

Key Words: Inflatable Penile Prosthesis; Erectile Dysfunction; Infection; Transgender; Review

INTRODUCTION

Over 18 million men in the United States suffer from erectile dysfunction (ED).[1] Inflatable penile prosthesis (IPP) technology is a mainstay in the treatment of ED refractory to medical management, and is under constant improvement by medical professionals and industry collaborations.[2] This review examines the latest updates in IPP technology, reviews recent relevant research, and is based on over 32 years of experience performing IPP surgery in addition to concurrent postoperative management. A 3-piece IPP is composed of a scrotal pump, dual intracorporeal inflatable cylinders, and a separate intra-abdominal fluid reservoir. These 3-piece IPPs will be the focus of this review as they provide the best rigidity and flaccidity in addition to holding the largest market share and having vast popularity in comparison to 2-piece IPP and malleable penile prosthesis.[3,4] IPP devices developed by the major manufacturers, American Medical Systems (AMS) (Minnetonka, MN, USA, a subsidiary of Boston Scientific), and Coloplast (Minneapolis, MN, USA), formerly Mentor, have been updated. Other manufacturers, including Zephyr Surgical Implants (ZSI) (Geneva, Switzerland) and Rigicon (Ronkonkoma, NY, USA), have also made changes in their products in the last decade. Innovations regarding transgender neophallus and anti-infective coating will also be discussed.

Received May 4, 2020. Accepted September 27, 2020.

[1]Department of Urology, Lenox Hill Hospital, Zucker School of Medicine at Hofstra/Northwell, New York, NY;

[2]Advanced Urological Care, PC, New York, NY

https://doi.org/10.1016/j.sxmr.2020.09.007

INFLATABLE PROSTHESIS MECHANICS INNOVATIONS

Technological advancements in the design of 3-piece IPPs have been continually improved to optimize concealability and surgical placement since the 1980s. Recent advancements over

the past 10 years include pump, reservoir, and cylinder updates. Specifically, a flat reservoir designed for improved discreteness and a prosthesis with optimized tubing length was developed by AMS in 2010 and 2018, respectively. Additionally, a one-touch deflatable 3-piece system and narrow-base cylinders introduced by Coloplast in 2013 and 2017, respectively, mark recent improvements that a urologist can employ. The company also introduced a 0° angle design between the cylinders and tubing to aid in cylinder placement as well as a soft molding cylinder tip redesign that better mimics human anatomy in 2012.[5] Furthermore, the Food and Drug Administration (FDA) approved submuscular reservoir placement in 2015. In the transgender space, Zephyr offers a 3-piece IPP specifically designed for neophallus use. Rigicon, whose 3-piece IPP is predominantly available in Europe, is currently being tested in clinical trials in the United States.

PUMP AND RESERVOIR INNOVATIONS

IPP pumps have evolved over time in order to improve manipulation of the device for comfort and ease of use with inflation and deflation. Masterson et al[6] recently evaluated patients' pinch strength relative to preference for IPP. 100 men were asked to squeeze a dynamometer and then asked to operate 3 separate IPP devices, the Coloplast Titan Classic, Coloplast Titan Touch, and AMS 700 with Momentary Squeeze (MS) pump, installed within identical rubber penis models. The Coloplast Titan Classic was the most favored pump based on ease of inflation. Ease of pump inflation is an important factor for consideration of the type of implant a patient will be most satisfied by.

It is only recently that manufacturers have realized the correlation between the ergonomics of the pump design and cylinder rigidity. The easier it is to hold and to secure the inflation bulb in the scrotum, the more the patient will be able to pressurize the cylinders. One of the reasons that patients preferred the Classic pump could well be that it is easier to grab. The stalk connecting the deflation footprint to the inflation bulb of the Touch pump was foreshortened when the One Touch Release pump was retired and replaced with the Touch pump. This made it more difficult for patients to secure the inflation bulb of the Touch pump. There was no space or stalk between the inflation bulb and the deflation footprint of the MS pump, which made it more difficult to firmly secure it.

Ease of deflation is another important issue encountered by men with IPP. Otero et al[7] evaluated patient and partner satisfaction after virgin IPP implant. In a multicenter study, 197 patients with AMS 700CX and 54 patients with Coloplast Titan One Touch Release implants were compared. While 4% of patients with the AMS 700CX implant were dissatisfied with deflation of the prosthesis, 24% of patients were dissatisfied ($P = .0031$) with the Coloplast Titan. The deflation nipple of the AMS MS pump, introduced in 2006, is approximately twice as tall as that of the Coloplast Titan Touch pump (Figure 1). This makes it potentially easier for the bearer to locate the deflation nipple and deflate the cylinders. Another study indicated that there was no significant difference in patient satisfaction as measured by Erectile Dysfunction Inventory of Treatment Satisfaction score in AMS 700CX with MS pump and Coloplast Titan with Touch pump.[8]

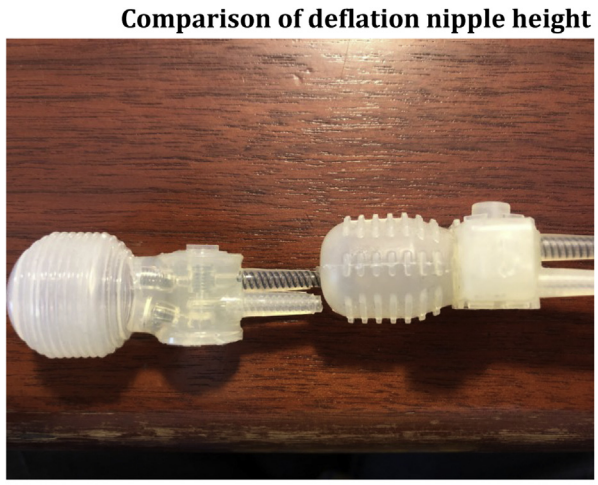

Figure 1. Comparison of deflation nipple height: Coloplast Titan Touch (left) and American Medical Systems Momentary Squeeze pump (right). Figure 1 is available in color online at www.jsm.jsexmed.org.

A frequent complaint that is expressed by patients regarding deflation is that there is no feedback when the deflation button is pressed, such as a "click." Patients do not know how hard to press or if they are pressing the correct location of the deflation footprint. AMS is in the final stages of a pump redesign with a much improved inflation bulb with ergonomic design and a deflation valve with tactile feedback.

Reservoir design and placement continues to evolve. The AMS Conceal reservoir was released in 2010 and has a low-profile shape designed to optimize fit in the submuscular space. As compared to the previous AMS spherical reservoir, the flattened shape aids in submuscular concealment in the lower abdominal wall and patient comfort. The reservoir is compatible with all AMS 700 IPPs and is available with or without the InhibiZone antibiotic coating. Coloplast's Cloverleaf reservoir with lockout valve was approved by the FDA in April 2015 for changes in labeling to incorporate alternative reservoir placement (ARP) of the device.

IPP reservoirs are traditionally placed in the space of Retzius, which can be compromised with prior pelvic surgery, ie, radical prostatectomy. Blind reservoir placement in such a patient may result in iatrogenic bladder, blood vessel, or bowel injury. According to a 2013 survey, 81% of experienced implant surgeons believed that robotic-assisted laparoscopic radical prostatectomy made reservoir placement in the space of Retzius more difficult. They concluded ARP would be beneficial.[9] In light of the FDA

approving submuscular reservoir placement in 2015, Hernandez et al[10] studied the safety of AMS and Coloplast ARP in the sub-Scarpa space (deep to Scarpa's fascia and superficial to abdominal wall musculature) and submuscular space (between the rectus sheath and transversalis fascia) via the inguinal canal or abdominal counter incision. In a 5-year multi-institutional study with median follow-up of 20.4 months and 974 patients (612 with ARP), the most common complication of ARP was reservoir leakage observed in 5 patients. Complications were comparable between the 2 groups (2% in the ARP group vs 1.3% in the space of Retzius group, $P = .44$). Other complications included tubing torsion, muscle discomfort, and intraperitoneal reservoir placement, although these complications were rare. Complication rates between primary and revision cases had no significant difference ($P = .72$).

CYLINDER AND TUBING INNOVATIONS

The AMS Length Girth Expansion (LGX), originally released as the AMS 700 Ultrex model in 1990, was launched in 2006 and permits expansion in both girth and length. Additional features include snap-on rear tip extenders (RTEs) and a smaller diameter at the proximal end for easier placement. Enemchukwu et al[11] compared the device survival rates of 55,133 AMS CX and LGX IPPs implants between 1997 and 2008. Their analysis demonstrated no significant difference in 7-year survival between the CX (88.7%) and LGX (89.5%, $P = .6811$) IPPs.

It is important to note that IPP cylinders are heterogeneous systems: partly inflatable and partly rigid. This raises the question of what amount of inflatable and rigid portion of the prosthesis is buried in the proximal crus and how it affects erectile rigidity. RTEs play a role in this relationship and are designed to increase the total cylinder length. A recent study sought to determine the effect of RTEs on erectile rigidity in IPP. In an ex vivo model, downward deflection measurements were noted for Coloplast Titan cylinders of 22 cm, 20 + 2 cm RTE, and 18 + 4 cm RTE after a 200 g weight was placed at the tip of the inflated prosthesis. Notably, as the length of RTE increased, an increased downward deflection was noted. These data suggest that maximizing inflatable length by minimizing RTEs improves overall erectile rigidity dynamics.[12]

In 2017, Coloplast introduced narrow base zero degree 16 and 18-cm cylinders (Table 1). These cylinders feature 0° angle input tubing at the proximal base of the cylinder and a silicone-molded distal tip, introduced in 2012. These features are devised to enable proper anatomic positioning and proximal placement of the prosthesis. The narrow base 20-cm cylinder was previously phased out.

In 2018, AMS optimized the tubing length of their 700CX and 700LGX penoscrotal models. The purpose of increasing the pre-connected tubing length was to avoid the use of RTEs. Additionally, the added tubing length was designed to improve the scrotal positioning of the pump by preventing it from riding high in the scrotum.

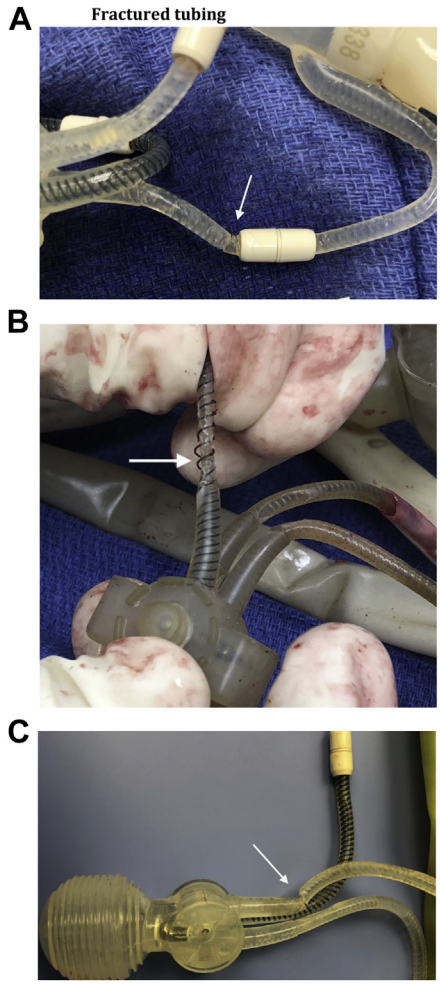

Figure 2. Fractured tubing at the junction with a connector (A) and at the tapered portion of the pump connection (B, C). Figure 2 is available in color online at www.jsm.jsexmed.org.

Currently, the main cause of early failure of the 3-piece IPP is tubing failure. The tubing connecting the cylinders to the pump is prone to early deterioration and fracture. Sharp bends of the tubing that are likely to occur at the point where the tubing inserts into the tapered portion of the pump connection or at the junction with a connector are the location of tubing fractures. In addition, rubbing of the tubing against one another results in weakening of the silicone and exposure of the polydioxanone suture filament and subsequent fluid leakage (Figure 2). Further research is warranted to investigate the failure rate of the kinked tubing leading to malfunction of IPP.

The length of the rigid portion of the IPP should be addressed as well. The proximal fixed portion of the cylinders measures 5 and 4.5 cm for the Coloplast and AMS cylinders, respectively (Figure 3). There is no reason why these lengths cannot be shortened. This would increase the inflatable portion of the cylinders and improve overall rigidity dynamics. As the pseudocapsule matures over time, it becomes looser around the fixed portion of the cylinders including the RTEs. As a result, the erect

Figure 3. Proximal cylinder: American Medical Systems (left) and Coloplast (right) cylinders. Sharp end of the right cylinder more likely to create a false passage or get caught into the cavernosal muscle tissue as it is inserted into the proximal aspect of the corpora. Figure 3 is available in color online at www.jsm.jsexmed.org.

penis becomes inferiorly buttressed to the pelvis and will wobble. This phenomenon is less likely to occur over the inflatable portions of the cylinders because these are maintained in the flaccid state most of the time.

ANTI-INFECTIVE COATING INNOVATIONS

Infection remains the most feared complication of penile prosthesis implantation, necessitating device explantation, potential penile shortening, further surgery, and other issues.[13] Traditionally, over 80% of post-surgical infections have been caused by gram-positive bacteria such as *Staphylococcus epidermidis*, with the remaining usually caused by gram-negative bacteria such *Escherichia coli*, *Serratia*, and *Proteus mirabilis*.[14] More recently, infection sources have shifted to a larger proportion of gram-negative bacteria and fungus, in part thought to be due to the increasing prevalence of diabetes and other medical comorbidities. Antibiotic and hydrophilic coatings of prosthesis were developed in order to reduce the risk of infection.[15] InhibiZone is a coating combination of rifampin and minocycline developed by AMS in 2000 that was proven to reduce revision surgery due to infection. Similarly, in 2004, Coloplast developed a hydrophilic coating to which antibiotics would adhere and elute from after implantation. With a changing landscape of infective organisms, new strategies in coatings are at the forefront of anti-infective innovation.

While there has not been a great deal of change recently in the type of coating of these implants, surgeons have studied various combinations of antibiotic dips for implants with coatings such as Coloplast's in order to optimize antibacterial properties and minimize infection. Several in vitro studies have shown the combination of rifampin and gentamicin as a highly effective dip. Dhabuwala et al[16] compared the infection rates of combinations of rifampin and gentamicin, vancomycin, and gentamicin, and the AMS InhibiZone. They found that both AMS with InhibiZone and Coloplast Titan with rifampin and gentamicin had lower infection rates as compared to a vancomycin and gentamicin-dipped Coloplast Titan.

While rifampin and gentamicin appears to be the most widely used and studied antibiotic dip combination, a study by Wilson et al[17] examined various antibiotic dips, not including the combination of rifampin with gentamicin. The group evaluated InhibiZone with Coloplast dipped in trimethoprim with polymyxin B ophthalmic solution, trimethoprim with sulfamethoxazole-infusion solution, bacitracin, rifampin with minocycline, or rifampin with trimethoprim−sulfamethoxazole. InhibiZone was found to be inferior to all antibiotic dip combinations except for bacitracin in regard to zone of inhibition when studied against *S. epidermidis*, *Staphylococcus lugdunensis*, *Staphylococcus aureus*, *Pseudomonas*, and *Enterococcus*. Of these combinations, trimethoprim/sulfamethoxazole was found to be the most effective, with broad-spectrum properties as well as low cost.

It is important to know the potential implications on the antibacterial effect of the various coatings of penile prosthesis. Lokeshwar et al[18] examined if bupivacaine soaking of implants altered the zone of inhibition against *S. epidermidis* and *E. coli*, 2 of the most common bacterial causes of device infection, on InhibiZone-coated AMS implants and antibiotic-soaked Coloplast implants. In their in vitro study, the addition of bupivacaine did not impede the antibacterial activity of InhibiZone-coated AMS or rifampin and gentamicin-soaked Coloplast implants.

Innovations in both antibiotic coatings promise improving postoperative infection outcomes in a changing microbiologic landscape. Developing new strategies for analgesic dips will help tackle pain control for patient comfort and help address the growing opioid epidemic. One of the problems with some of the clinical studies for InhibiZone and Coloplast dip is the fact that they relied on self-reporting of infections. In addition, the infection rate was compared to historical infection rates. Further, there have not been many studies documenting how long the antibiotic remains on the Coloplast implants and how fast it elutes from the implant. Finally, in our practice, we have not used antibiotic irrigation since 2006 and use saline irrigation instead. Our infection rate with the "no touch" technique has remained at 0.6% (23 patients out of 4,098 consecutive patients). This is to say that perhaps antibiotic-coated implants and antibiotic irrigation may not statistically significantly reduce infection rate and surgical technique may be equally, if not more, important.

TRANSGENDER

Treatment for gender dysphoria and the desire to live in the opposite gender requires hormonal, anatomical, and psychosocial changes. With increased acceptance and encouragement of transgender individuals, an emphasis is placed on the importance of their physical and emotional health, including the surgical management of gender reassignment.[19] Neophallus

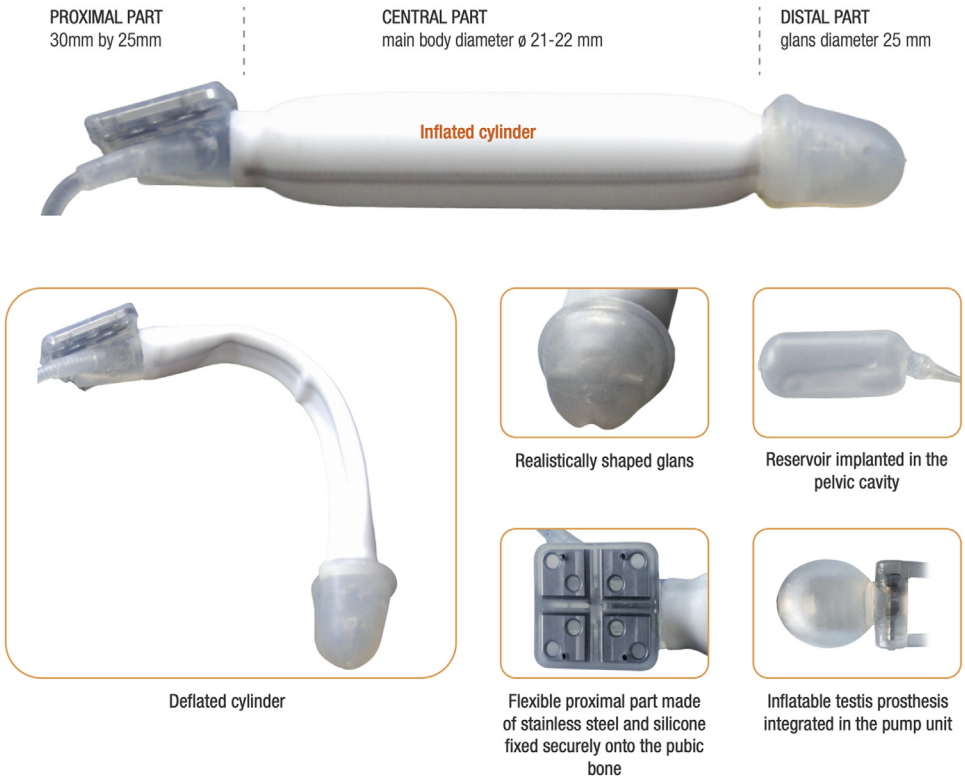

Figure 4. Zephyr ZSI 475 FTM inflatable penile implant. Used with permission from Zephyr Surgical Implants (ZSI). Figure 4 is available in color online at www.jsm.jsexmed.org.

creation is a complex, multistage process with several different surgical techniques potentially utilized. A number of different flaps can be used in the creation of a neophallus, with the most common being the free radial forearm flap phalloplasty.[20] Phalloplasty surgery offers a cosmetic phallus with the possibility of voiding in standing position. However, prosthesis implantation is generally required to achieve adequate penetrative erectile function. Prosthesis implantation in these patients requires a unique approach given the lack of corpora cavernosa. Several groups have described their technique and outcomes for penile prosthesis implantation in transgender men following phalloplasty. The time from phalloplasty creation to insertion of penile prosthesis is variable but is typically at least 1 year postoperatively, when patients have no urethral problems, and do not require secondary correction of their phalloplasty or scrotoplasty.

The technique for placement of penile prosthesis has varied and evolved but one common method has involved the use of a malleable implant with a Dacron graft to aid in fixation of the implant to the periosteum of the pubic bone. IPPs have also been used. van der Sluis et al[20] retrospectively assessed surgical outcomes of 45 implantations in 32 patients undergoing prosthesis placement. Of all the prostheses placed, 44% were eventually either surgically removed or replaced, most commonly due to infection (15.5%), and also for leakage, extrusion, dislocation, dysfunction, or pain.

Neuville et al[21] described early and late-onset complications following implant surgery in 95 patients undergoing insertion of an AMS Ambicor prosthesis with or without a vascular graft following phalloplasty. The majority of patients (93.7%) had no early-onset complications (within 1 month). Those with early-onset complications (4.2%) were related to infection. Late-onset complications were erosion (4.2%), infection (4.2%), dysfunction (10.5%), and malpositioning (12.6%).

Recently, a new prosthesis was developed by ZSI, known as the inflatable 3-piece ZSI 475 FTM, that was specifically designed for the neophallus (Figure 4).[22] Several design modifications were made to address the challenges of implant insertion in these scenarios, including a large base for pubic bone fixation, an anatomically accurate firm glans, and a testicle-shaped pump. Neuville et al[22] analyzed the surgical outcomes for this device in 20 patients and found a low significant complication rate, and high patient satisfaction rate as measured by International Index of Erectile Function score at 1 year follow-up.

Additionally, a malleable prosthesis was developed by ZSI, known as the ZSI 100 FTM (Figure 5), consisting of a single cylinder design and a 25-mm wide distal glans-shaped stopper. Recently, Pigot et al described preliminary experience and surgical outcomes of implantation of the ZSI 100 FTM malleable penile implant after phalloplasty in transgender men.[23] 25 patients who previously underwent phalloplasty were identified. Of these patients, 32% underwent device explanation for either infection,

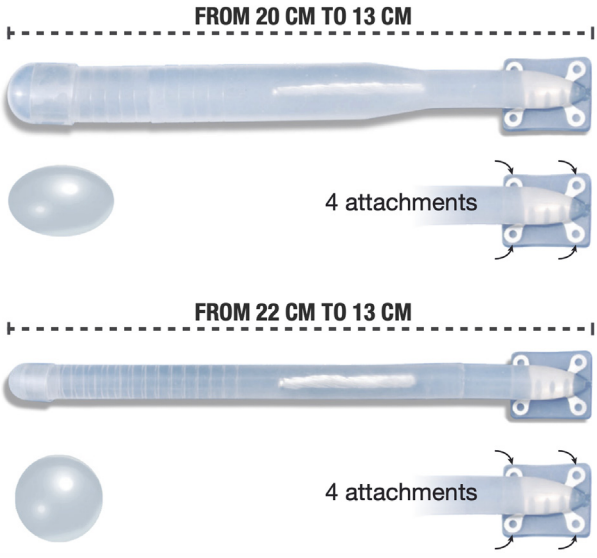

Figure 5. Zephyr ZSI 100 FTM malleable penile implant for phalloplasty. Used with permission from Zephyr Surgical Implants (ZSI). Figure 5 is available in color online at www.jsm.jsexmed.org.

protrusion, pain, or difficulty living with a malleable implant. 93% of patients in whom the device remained in place were able to engage in penetrative intercourse. While initial complication rates appear to be high with these devices in the transgender setting, further experience is needed to improve outcomes.

Revision or explanation surgery in transgender men undergoing penile prosthesis placement is fairly common. New techniques and devices specifically designed for the transgender male offer potential for more promising results in the future.

OPERATIVE ADVANCES

Delayed recognition of distal crossovers, impending lateral extrusion, and unidentified distal crossovers are complications of implant insertion. Antonini et al[24] described a distal corporal anchoring stitch technique to address the said complications. Dissection is carried out via Buck fascia and tunica albuginea where the distal affected cylinder is identified using a subcoronal incision at the site of the prosthesis crossover or extrusion. Once an appropriate intracorporeal channel is created, a 4-0 polydioxanone suture is threaded through the distal cylinder ring. Finally, the suture is passed through the glans and tied down via a cruciate incision at the glans. In the 53 patients who underwent the corrective technique, none developed infections, glandular hypoesthesia or pain, anesthesia, wound-healing defects, or altered sensation. 2 patients reported lateral herniation postoperatively.

The "no-touch" surgical technique was originally described for IPP implantation to treat ED in 2011.[25,26] The approach has also been used in orthopedic, cerebrospinal fluid shunt placement, and breast reconstruction/augmentation surgeries.[27] Briefly, the surgery begins traditionally, where the surgeon delivers the penis and scrotum through a small hole in an iodophor-impregnated drape. The incision is made in the penoscrotal raphe and is carried down through dartos and Buck's fascia. After the skin edges are retracted by 5 yellow hooks, all surgical instruments are removed from the surgical field as they are considered contaminated. A 3M #1012 drape is loosely placed over the penis and secured with its adhesive edges. A small incision is made in the drape and 4 additional yellow hooks are used to retract the drape while securing the opening of the drape to the skin edges. The remainder of the surgery is carried out through this opening, thus eliminating all direct and indirect contact between the implant, instruments, and gloves with the patient's skin—the source of contamination. Once the implant is in place and an overlying layer of tissue is closed, the drape is removed. Notably, the "no touch" enhancement adds on average 10 minutes to the procedure for a total average operating time of 1 hour and 15 minutes while demonstrating a decreased postoperative complication rate as seen in our experience.[27] We have had 23 infections since January 2006 out of 4,098 consecutive implants. Increased surgical time (greater than 2 hours), additional incisions, excessive manipulation and repositioning of device components, and anticoagulation with postoperative scrotal hematoma seem to be risk factors for our infections.

In relation to infection, special attention to the 2-piece Furlow inserter instrument should be recognized. Retained bacteria or blood products on the internal or external component even after sterilization is a cause of concern for infection. Yafi et al evaluated retained bacteria or markers of improper cleaning among these reusable instruments.[28] After sterilization, 83 Furlow devices with a median surgical age of 4 years over multiple centers were evaluated. At the time of surgery, unassembled devices (4.9%), external component discoloration (3.6%), internal component discoloration (2.4%), and positive swab cultures for *S. epidermidis* (2.4%) were identified. Data regarding infectious outcomes were unavailable at the time of publication; however, this study raises the question for the need of a disposable version of this instrument.

CONCLUSIONS

Penile prosthesis has evolved over time to improve functional outcomes, ease of use, and minimize postoperative complications and pain. Teaching patients how to inflate and deflate remains a challenging portion of the penile implant journey and has been facilitated by preoperatively providing models of the pump in order for patients to familiarize themselves with the different anatomical attributes of the inflation and deflation footprint of the devices. The rise in acceptance and practice of transgender surgery will continue to expand the role of penile prosthesis in patients undergoing female to male gender affirmation procedures. Penile prosthesis implantation continues to be a life-changing procedure for patients and it is imperative for surgeons to be up-to-date on the latest developments and research in order to provide the best functional outcomes for those they take care of.

Table 1. History of penile prosthesis

Date	Innovation
1500	Wooden splints utilized to facilitate urination
1936	Use of rib cartilage with tubular phalloplasty
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 placement
1973	IPP implantation
1977	Flexirod: soft hinge improved concealment
1980	Jonas malleable prosthesis: silicone prosthesis with silver wires, first true malleable device
1983	AMS 700: thick cylinders, PTFE sleeves
1983	Mentor 3-piece IPP; polyurethane (Bioflex): enhanced strength over silicone
1983	AMS 600M and 650: malleable devices, central wire core, trimmable silicone
1985	DuraPhase/OmniPhase: central cable, frequent mechanical malfunction
1985	Hydroflex and Flexi-Flate: poor concealment, incomplete flaccidity
1986	AMS 700: kink-resistant tubing added
1987	AMS 700CX: 3-ply design with woven fabric layer; reduced cylinder aneurysms
1987	Mentor IPP improvements: cylinder base reinforcement, pump modifications, nylon-reinforced tubing
1989	Mentor Alpha-1: connectorless IPP; reduced connector complications
1990	AMS 700CXM: narrow version
1990	AMS Ultrex: expanded girth/length
1992	Mentor Apha-1: reinforced tubing/pump, enhanced mechanical reliability
1993	AMS Ultrex cylinders strengthened: improved mechanical reliability
1994	AMS Ambicor: 2-piece prosthesis
1996	Mulcahy salvage technique
1998	Coloplast Acu-Form: malleable device
2000	AMS 700; added parylene coating: improved mechanical reliability; pre-connected cylinders, color-coded tubing: facilitated implantation
2000	Mentor: lockout valve
2001	AMS InhibiZone: antibiotic impregnation with minocycline/rifampin
2002	Mentor Titan: hydrophilic substance absorbs aqueous solutions, reduces bacterial adherence
2002	Mentor Alpha-1 Narrow Base: narrow model
2004	Coloplast Genesis malleable
2006	AMS Momentary Squeeze
2006	One-way valve: reduced auto-inflation
2006	Coloplast acquires Mentor
2006	AMS LGX
2008	Coloplast One Touch Release
2008	Titan XL Cylinders (24, 26, 28 cm)
2010	AMS Conceal: flat reservoir
2011	No-touch technique: reduced infection
2012	Coloplast 0° tubing, molded silicone contoured tip
2013	Titan Touch 3-piece IPP
2015	FDA approval for submuscular reservoir placement
2016	ZSI 475 FTM: 3-piece IPP designed as transgender neophallus
2017	Coloplast 16/18 cm Narrow Base 0°
2018	AMS 700CX and 700LGX optimized tubing length

AMS = American Medical Systems; FDA = Food and Drug Administration; IPP = inflatable penile prosthesis; PTFE = polytetrafluoroethylene.

Corresponding Author: J. Francois Eid, MD, Director, Advanced Urological Care, PC, 50 East 69th Street, New York, NY 10021, USA. Tel: +1 212 535 6690; Fax: +1 212 535 7025; E-mail: jfeid@urologicalcare.com

Conflict of Interest: J. Francois Eid has been associated with Coloplast, American Medical Systems, and Rigicon. The other authors report no conflicts of interest.

Funding: None.

STATEMENT OF AUTHORSHIP

Brian F. Dinerman, Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing - original draft, Writing - review and editing; Leon Telis, Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing - original draft, Writing - review and editing; J. Francois Eid, Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing - original draft, Writing - review and editing.

REFERENCES

1. Saigal CS, Wessells H, Pace J, al Set. Predictors and prevalence of erectile dysfunction in a racially diverse population. **Arch Int Med 2006;166:207-212.**
2. Burnett AL, Nehra A, Breau RH, et al. Erectile dysfunction: AUA Guideline. **J Urol 2018;200:633-641.**
3. Natali A, Olianas R, Fisch M. Penile implantation in Europe: successes and complications with 253 implants in Italy and Germany. **J Sex Med 2008;5:1503-1512.**
4. Mulcahy JJ. The development of modern penile implants. **Sex Med Rev 2016;4:177-189.**
5. Pastuszak AW, Lentz AC, Farooq A, et al. Technological improvements in three-piece inflatable penile prosthesis design over the past 40 Years. **J Sex Med 2015;12(Suppl 7):415-421.**

6. Masterson JM, Horodyski L, Patel R, et al. Impact of key pinch strength on patient preference for inflatable penile prosthesis: a prospective study comparing Coloplast and AMS models. **Int J Impot 2020;32:113-116.**
7. Otero JR, Cruz CR, Gomez BG, et al. Comparison of the patient and partner satisfaction with 700CX and Titan penile prostheses. **Asian J Androl 2017;19:321-325.**
8. Morgado A, Cavadas AS, Pacheco Figueiredo L, et al. Long-term patient-reported satisfaction with different inflatable penile prosthesis: comparison between AMS 700CX and Coloplast Titan. **Rev Int Androl 2018;16:112-118.**
9. Karpman E, Sadeghi-Nejad H, Henry G, et al. Current opinions on alternative reservoir placement for inflatable penile prosthesis among members of the Sexual Medicine Society of North America. **J Sex Med 2013;10:2115-2120.**
10. Hernandez JC, Trost L, Kohler T, et al. Emerging complications following alternative reservoir placement during inflatable penile prosthesis placement: a 5-year multi-institutional experience. **J Urol 2019;201:581-586.**
11. Enemchukwu EA, Kaufman MR, Whittam BM, et al. Comparative revision rates of inflatable penile prostheses using woven Dacron(R) fabric cylinders. **J Urol 2013;190:2189-2193.**
12. Thirumavalavan N, Cordon BH, Gross MS, et al. Rear tip extenders and penile prosthesis rigidity: a Laboratory study of Coloplast prostheses. **J Sex Med 2018;15:1030-1033.**
13. Gross MS, Phillips EA, Carrasquillo RJ, et al. Multicenter investigation of the Micro-organisms involved in penile prosthesis infection: an analysis of the Efficacy of the AUA and EAU Guidelines for penile prosthesis Prophylaxis. **J Sex Med 2017;14:455-463.**
14. Carson CC 3rd, Mulcahy JJ, Harsch MR. Long-term infection outcomes after original antibiotic impregnated inflatable penile prosthesis implants: up to 7.7 years of followup. **J Urol 2011;185:614-618.**
15. Serefoglu EC, Mandava SH, Gokce A, et al. Long-term revision rate due to infection in hydrophilic-coated inflatable penile prostheses: 11-year follow-up. **J Sex Med 2012;9:2182-2186.**
16. Dhabuwala C, Sheth S, Zamzow B. Infection rates of rifampin/gentamicin-coated Titan Coloplast penile implants. Comparison with Inhibizone-impregnated AMS penile implants. **J Sex Med 2011;8:315-320.**
17. Wilson SK, Salem EA, Costerton W. Anti-infection dip suggestions for the Coloplast Titan Inflatable Penile Prosthesis in the era of the infection retardant coated implant. **J Sex Med 2011;8:2647-2654.**
18. Lokeshwar SD, Horodyski L, Lahorewala SS, et al. The effect of bupivacaine on the Efficacy of antibiotic coating on penile implants in preventing infection. **Sex Med 2019;7:337-344.**
[19]. Telis L, Singer T, Berookhim BM. Fertility issues in transgender care. Transgender medicine: a Multidisciplinary approach. Switzerland: Springer; 2019. p. 197-212.
20. van der Sluis WB, Pigot GLS, Al-Tamimi M, et al. A retrospective Cohort study on surgical outcomes of penile prosthesis implantation surgery in transgender men after phalloplasty. **Urology 2019;132:195-201.**
21. Neuville P, Morel-Journel N, Maucourt-Boulch D, et al. Surgical outcomes of erectile implants after phalloplasty: Retrospective analysis of 95 procedures. **J Sex Med 2016;13:1758-1764.**
22. Neuville P, Morel-Journel N, Cabelguenne D, et al. First outcomes of the ZSI 475 FtM, a specific prosthesis designed for phalloplasty. **J Sex Med 2019;16:316-322.**
23. Pigot GLS, Sigurjónsson H, Ronkes B, et al. Surgical experience and outcomes of implantation of the ZSI 100 FtM malleable penile implant in transgender men after phalloplasty. **J Sex Med 2020;17:152-158.**
24. Antonini G, Busetto GM, Del Giudice F, et al. Distal corporal anchoring stitch: a technique to address distal corporal crossovers and impending lateral extrusions of a penile prosthesis. **J Sex Med 2017;14:767-773.**
25. Eid JF. No-touch technique. **J Sex Med 2011;8:5-8.**
26. Eid JF, Wilson SK, Cleves M, et al. Coated implants and "no touch" surgical technique decreases risk of infection in inflatable penile prosthesis implantation to 0.46%. **Urology 2012;79:1310-1315.**
27. Eid JF. Penile implant: review of a "No-touch" technique. **Sex Med Rev 2016;4:294-300.**
28. Yafi FA, Furr J, El-Khatib FM, et al. Prospective analysis of cultures from the Furlow insertion tool: a possible etiology for penile prosthesis infections [Epub ahead of print]. **Int J Impot 2020.**