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REVIEW

# Safety and Efficacy of Inflatable Penile Prostheses for the Treatment of Erectile Dysfunction: Evidence to Date

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**Abstract:** Erectile dysfunction (ED) is a common problem, and prevalence rates are expected to rise as life expectancy increases worldwide. In more severe cases of ED, penile prosthesis implantation has been an excellent option for patients. Over the past few decades, significant design improvements have been made to the penile prosthesis and modifications to surgical technique to improve clinical outcomes. The purpose of this review is to summarize the safety and efficacy of FDA-approved penile implants in the US market. Design modifications have greatly improved the safety and reliability of the implant. Development of improved surgical techniques has decreased intraoperative injuries and reservoir-related complications. With its high overall satisfaction rates and low risk of complications, the inflatable penile prosthesis remains an excellent option for patients with erectile dysfunction.

**Keywords:** inflatable penile prosthesis, erectile dysfunction, prosthesis complications, prosthesis satisfaction

## Introduction

Erectile dysfunction is a common disorder with roughly half of men between the ages of 40 to 70 experiencing some degree of erectile dysfunction.[1] Prevalence of ED increases with age, diabetes, hypertension, cardiovascular disease, smoking status along with many other factors.[1,2] Current treatment of ED commonly involves the use of oral phosphodiesterase type 5 inhibitors (PDE5i) as first-line therapy. In more severe cases of ED that are refractory to oral regimens, patients may require intracavernosal injections (ICI) of vasodilators. Patients who do not respond well to ICI or who do not desire to pursue ICI may be offered a penile prosthesis to create an artificial erection. Although implantable penile prostheses have gone through significant iterations over the past century, the principal characteristics of the device have not changed over the years – a penile prosthesis should produce an artificial erection that would mimic a natural erection in terms of rigidity and not interfere with sensation, ejaculation, spontaneity, orgasm, and urination.

Historically, the first documented penile prosthesis dates to the 16th century when Dr. Ambroise Pare inserted a wooden pipe following a traumatic penile amputation.[3] However, its intent was to facilitate urination rather than sexual activity. In 1936, Dr. Nikolaj Bogoraz utilized autologous rib cartilage to achieve an artificial erection.[4] Rib cartilage unfortunately was temporary as it was resorbed by the body over time. Drs. Goodwin and Scott reported the use of acrylic prostheses in 1952, which allowed for a more permanent solution.[5] In the 1960s, polyethylene and silicone rods were developed and experience showed that placing the prosthesis under the tunica albuginea created a more rigid erection that was less likely to erode than implants placed outside of the tunica albuginea.[6] In 1973, Dr. Scott developed the contemporary 3-piece inflatable penile prosthesis (IPP), with two inflatable silicone cylinders, a reservoir, and a pump that allowed the transfer of fluid from the reservoir to the cylinders to produce an artificial erection.[7] Over the years, significant design developments were made to improve durability, rigidity, safety, and the patient experience. This review will focus on FDA-approved devices in the United States and their safety and efficacy.

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# Safety

## Risk of Intraoperative Injuries

While penile prosthesis placement is generally safe and well tolerated, intraoperative complications can occur (Table 1).[8] Proximal or distal corporal perforations can occur typically at the time of dilation. A proximal corporal perforation can be addressed by placement of a sling through rear tip extenders to prevent implant migration.[9] A distal corporal perforation requires careful inspection of urethral injury. Urethral injury at the time of penile prosthesis placement is rare but historically was managed with abortion of the prosthesis procedure as an urethral injury would increase the risk of implant infection.[9] Small urethral injuries may heal without repair, and a catheter may be placed. Larger urethral injuries may require primary closure.[10] In a recent survey of surgeon practices, 55% of surgeons would abort the procedure after distal urethral injury, while 45% would continue the procedure with either unilateral or bilateral insertion of cylinders.[11] In the setting of distal corporal perforation with crossover but without urethral injury or extrusion, the trajectory of the tract can be altered and re-dilated. The cylinders can then be re-placed in the appropriate corporal tunnels.

Traditionally, the implant reservoir is placed in the space of Retzius through the floor of the external inguinal ring. Intraoperative reservoir complications are rare but can result in bladder, bowel, or vascular injury.[12] Furthermore, the reservoir may have been placed ectopically or could erode into the bladder/surrounding structures. Post-operatively, reservoir herniation and auto-inflation of the cylinders may occur.[12,13] In rare situations, the reservoir can cause compression of the external iliac vein resulting in venous compression syndrome. Patients with a history of pelvic surgery such as radical prostatectomy or cystectomy are at higher risk of reservoir complications due to the altered space of Retzius and increased pelvic scarring. Patients with previous pelvic radiation may also have poorer tissue quality and be more prone to complications such as erosions. In patients with a history of unilateral inguinal hernia repair or renal transplantation, the reservoir can be placed on the contralateral side to avoid the patients' previous surgeries.

In patients with a higher risk of reservoir complications, surgeons can elect to place a 2-piece implant or opt for an ectopic reservoir location. The 2-piece Ambicor prosthesis was designed to eliminate the need for an external reservoir by integrating the fluid reservoir into the proximal aspect of the pair of cylinders itself. Although data comparing the Ambicor prosthesis with 3-piece implants are limited, the existing literature shows high patient satisfaction rates.[14–16] Early studies of its reliability showed a 2.3% mechanical failure rate with a mean follow-up of 43 months.[14] Fluid leak at the proximal end of the cylinders was one of the most common reasons for mechanical failure before the device was redesigned in 1998.[17] Despite these revisions, cylinder aneurysms at the deflation flex point continue to be a cause of mechanical failure.[18] A systematic review of penile prosthesis found higher survival rates among malleable and 2-piece implants compared to 3-piece implants.[19] Although the Ambicor prosthesis eliminates the need to place a separate reservoir, it has a less natural deflated appearance compared to the 3-piece implant. Thus, the Ambicor 2-piece implant is a less popular choice and accounts for less than 5% of penile implants today.[17] However, the Ambicor prosthesis is still considered an excellent option for certain patients with a history of pelvic surgery or radiation.

Although the Ambicor prosthesis is a good option in patients with higher risk of reservoir complications, ectopic reservoir placement is another option that allows for a 3-piece IPP placement without the risks associated with space of Retzius placement. Most commonly, an ectopic reservoir is placed between transversalis fascia and transversus abdominis or rectus abdominis. In obese patients, the reservoir can even be placed anterior to the abdominal muscles with

**Table 1** Summary of Intra-Operative Complications

| Complication | Management |
|---|---|
| Proximal Corporal perforation | Support via rear tip extender sling[9] |
| Distal Corporal perforation/urethral injury | Abort vs unilateral/bilateral placement of cylinders[11] |
| Corporal crossover | Re-dilate corpora and re-direct cylinders |
| Bowel, bladder, vascular injury | Repair injured structure ± abort implant[12] |

good outcomes as the increased adipose tissues can hide the reservoir well.[12,20,21] The disadvantage of an ectopic reservoir placement is that the reservoir may be visible, and the patient may be able to feel the reservoir. A low profile reservoir design was introduced to decrease reservoir visibility in submuscular reservoir placements. Common complications related to ectopic reservoir placement include reservoir leakage, abdominal muscular pain, folding of the reservoir itself, and torsion of reservoir tubing resulting in blockage of fluid transport.[22] Overall reservoir-related complications requiring revision were similar between standard space of Retzius placement (1.3%) compared to ectopic placement (2.0%).[22] However, ectopic reservoir placement remains a reliable option and may be considered in patients with a history of pelvic surgeries. For surgeons who do not prefer ectopic reservoir placement, the Levine Jorgenson scissors technique allows for safe entry into the space of Retzius.[23] This technique involves the use of Jorgenson scissors, which are placed through an external inguinal ring just superior to the pubis. The curved tips of the Jorgenson scissors are pointed away from the bowel and bladder, allowing for controlled perforation through the transversalis fascia. Reservoir-related complication rates were similar between patients with a history of prior pelvic surgery vs the virgin pelvis group with this technique.

## Risk of Infection

Prosthetic infection is perhaps the most feared complication as this could lead to sepsis requiring explant of the prosthesis. Reported rates of post-operative infection can range between 0.5% and 5% depending on antibiotic regimen, implant, surgical technique and patient demographics.[24–27] Evolution of prosthesis design has also reduced the risk of infection with the impregnation of minocycline and rifampin directly onto the silicone of American Medical System (AMS) implants in 2000 and the coating of a hydrophilic substance that allows the absorption of antibiotic solutions onto the Titan implant in 2002.[28] A retrospective review by Carson in 2004 found reduced infection rates in virgin implant placements when using AMS 700 series implant coated with InhibiZone (0.68%) compared to those without antibiotic coating (1.61%) at 180 days follow-up.[26] Similarly, Wolter et al found that by coating the polyvinylpyrrolidone coated Titan prosthesis had lower rates of infection (1.06%) compared to the Alpha-1 non-coated prosthesis (2.07%) at 1 year follow-up.[29] Furthermore, Wilson et al found reduced infection rates when using InhibiZone implants not only in the virgin setting but also in implant revision, when a washout was also performed.[30] Wilson et al also noted that there were no post-operative infections in 223 patients without diabetes compared to one post-operative infection in 83 (1%) patients with diabetes. Infection rates were higher in the revision setting, where 4 post-operative infections were seen in 123 cases (3%). In one of the largest retrospective studies, Carson et al reported long-term data with up to 7.7 year follow-up of over 39,000 patients who underwent penile prosthesis placement.[31] They reported a 1.1% infection-related revision rate in antibiotic-coated implants compared to 2.5% revision rate in non-coated implants. Furthermore, the incorporation of the "no-touch" technique decreased infection rates to 0.46%.[24] Currently, there are no universally accepted guidelines for peri-operative IV antibiotics and intraoperative antibiotic irrigation/prosthesis coating regimens that would minimize infections. Thus, antibiotic regimens should be chosen by the surgeon based on hospital-specific antibiograms. Other precautions that can reduce infection rates include a ten-minute betadine scrub, limiting through traffic within the operating room, and frequent re-gloving throughout the operation.

Despite the numerous advancements in prosthesis antibiotic coating and protocols taken, prosthesis infections still occur. Patients with an infected implant may present with fever, persistent penile pain, erythema, and fluctuance.[32] Patients with signs of sepsis require immediate treatment with IV antibiotics and fluids. Infected implants must be either completely removed or replaced following extensive washout utilizing Mulcahy's salvage approach.[33] The Mulcahy salvage approach involves the initial removal of all implant parts, followed by aggressive wound irrigation with a series of kanamycin/bacitracin, hydrogen peroxide, betadine, vancomycin, and gentamicin. After washout and changing of gloves, a new penile prosthesis is replaced.

## Risk of Mechanical Malfunction

Mechanical failure of the implant typically involves leakage of saline from the system due to a crack or tear in the cylinders, tubing or reservoir. This results in malfunction of the penile prosthesis and inability to achieve an artificial erection. The risk of mechanical failure increases with time and usage. A study of 438 consecutive patients who received

the AMS 700 CX showed that 82 patients (20.6%) experienced mechanical failure with a median follow-up of 82 months.[34] Mechanical survival rates of the penile prosthesis were 97.6%, 93.2%, and 78.2% at 3, 5, and 10 years follow-up, respectively. Over the years, design improvements to penile prosthesis implants have further improved mechanical reliability. In 1992, the Mentor Alpha 1 prosthesis added pump reinforcement that improved 10 years mechanical survival to 88.6%.[35] And in 2001, AMS added a parylene coating to the cylinders that increased 3 years mechanical survival to 97.9%.[35] Another study showed an overall penile prosthesis survival rate of 90.8% and 85.0% at 5 and 10 years follow-up.[36] The most common cause of mechanical failure was fluid loss in 75% of cases. In addition to fluid loss from the implant system, other mechanical malfunctions involve tubing kinks, pump/valve cycling issues, and auto-inflation of the prosthesis. However, prosthesis design improvements have significantly reduced rates of mechanical aberrations.

In the setting of mechanical failure, revision surgery can be performed if the patient wishes to be sexually active (Table 2). If an obvious defect in the prosthesis can be identified and isolated, the affected component can be exchanged. The entire implant may also be removed and replaced, especially if the original device was implanted many years ago (typically after 3–7 years) and prone to additional mechanical failures.[37] As it may be challenging to remove the reservoir, the reservoir may be drained and retained.[38]

## Safety Considerations in Following Pelvic Surgery

Patients commonly experience erectile dysfunction following radical prostatectomy, cystectomy, abdominoperineal resection, and other pelvic surgeries. Despite advances in nerve-sparing radical prostatectomy, many patients still cannot achieve erections hard enough for sexual penetration postoperatively.[39] Similarly, significant neurovascular trauma can occur following radical cystectomy and many patients experience erectile dysfunction despite alternative nerve sparing approaches.[40,41] Due to potentially serious nerve injury, many patients may be refractory to oral PDE5i/ICI and may be candidates for penile prosthesis placement. As radical prostatectomy and cystectomy involve incising the peritoneum, the traditional space of Retzius may be obliterated. While some surgeons may prefer two-piece prosthesis placement in post-prostatectomy patients, retropubic placement of the reservoir was not associated with increased complications.[22] In a retrospective study, use of the Levine Jorgenson scissors technique allowed safe placement of the reservoir into the space of Retzius even in patients with prior radical prostatectomy and inguinal hernia repair.[23] This approach was designed to enter the space of Retzius with the curved tips of the scissors pointing away from the bladder, bowel, and vessels, thereby reducing the likelihood of injury to these structures. If attempts to access the space of Retzius with the Levine Jorgenson scissors approach are met with resistance, then ectopic reservoir placement is recommended. Reservoir-related complication rates were similar between patients with a history of prior pelvic surgery vs the virgin pelvis group.[12,23] In another study of 115 post-prostatectomy patients, a retropubic reservoir was successfully placed without any bladder or iliac vessel injury in any patients.[42] More than 90% of devices were free of mechanical failure at 5 years of follow-up. While two-piece penile prosthesis remains a good option for post-prostatectomy patients, three-piece implants with traditional or ectopic reservoir placements can also be safely placed.[39,43]

Similarly, in patients with ED following radical cystectomy, options for penile prosthesis include malleable, two-piece, and three-piece implants. Following radical cystectomy, significant scarring, translocation of bowel and the presence of urinary diversion or orthotopic bladder make reservoir placement in the traditional space unwise.

**Table 2** Summary of Post-Operative Complications

| Complication | Incidence | Management |
|---|---|---|
| Implant infection[24,31] | 0.5–1.1% | Salvage vs delayed reimplantation |
| Mechanical failure[34,36] | 15–20% at 10 years | Replace or revise implant |
| Reservoir erosion/herniation[12] | <1% | Replace or reposition reservoir |
| Autoinflation[13] | 2–3% | Capsulotomy or repositioning of reservoir |
| Hematoma[8] | 0.2–5% | Bedrest and compressive dressings, exploration is rarely required |

However, ectopic placement of the reservoir can be placed in the lateral retroperitoneum through a counter-incision or in the pre-peritoneal space.[44–46] In a retrospective review of 80 patients who had 3-piece implants placed following radical cystectomy, there were no instances of bowel, urinary diversion, or vascular injury with a lateral retroperitoneal reservoir placement.[44] Of these 80 patients, 3 patients required revision of pump location, and 2 patients required revision for mechanical failure with a mean follow-up of 54 months. No associations were found between infection (5%) and type of urinary diversion, radiation, chemotherapy, or presence of artificial urinary sphincter (AUS). In patients with a continent cutaneous diversion or ileal conduit, the reservoir is typically placed contralateral to the stoma in order to decrease the risk of injury to the urinary tract if revision became necessary.[46] In patients with orthotopic neobladders, reservoirs can be placed on either side depending on surgeon preference.

## Safety in Transgender Patients

In female-to-male gender-affirming surgeries with neophallus construction, the placement of a penile prosthesis represents a last step to providing functional ability to the neophallus.[47] Tactile and erogenous sensations develop in the neophallus within 4 to 6 months.[48] Unperceived chronic pressure on the neophallus can increase the risk of prosthesis extrusion. Thus, the development of tactile sensation is protective, and many patients and surgeons opt to wait at least a year before prosthesis implantation. In one study, the mean time between neophallus construction and prosthesis placement was 3.5 years.[49] The first reported prosthesis placement in a neophallus was described in 1978.[50] In the 1990s, a modified single-cylinder 2-piece Mentor GFS, then later the Ambicor prosthesis was utilized in the neophallus, which provided excellent axial rigidity and avoided a separate reservoir.[48] A polytetrafluoroethylene wind-sock was fashioned as a pseudo-tunic and secured to the pubis to prevent cylinder migration. A single cylinder was utilized due to the fact that the largest Ambicor cylinder provides excellent axial rigidity. Furthermore, placement of 2 cylinders would require additional dissection, increasing the risk of injuring the neophallic neurovascular supply and compromising penile sensation. Zuckerman et al reported outcomes of semirigid and 3 piece inflatable prostheses in patients with total phallic construction.[51] At 5.5-month follow-up, 5 implants (23%) were explanted due to infection or erosion. This is quite high compared to the complication rate in cis-males, likely due to the fact that the neophallus in trans-males does not have a corpora cavernosa for prosthesis placement. Furthermore, gender-affirming surgery typically involves multiple surgeries, which can compromise vascularization and subsequently tissue/wound healing abilities following prosthesis implantation. Hoebeke et al reported on the outcomes of 129 female to male neophallus prosthesis implants.[52] Fifty-three of the 129 patients (41%) required removal or revision of the prosthesis due to infection, erosion, or mechanical failure with a mean follow-up of 30 months. The Dynaflex (n = 9), AMS CX/CXM (n = 50), AMS CX with Inhibizone (n = 17), Ambicor (n = 47), and Coloplast Mentor (n = 6) prostheses were utilized. Total infection rate was 11.9%, which is much higher than non-antibiotic coated implants, and the total protrusion rate was 8.1%. Falcone et al reported on data from a single centre with a 2-stage implantation approach.[53] An extraperitoneal reservoir was initially placed with the glans sculpture. During the 2nd stage, a dacron envelope was fitted around the proximal and distal tips of the cylinder and anchored to the pubic bone to help prevent protrusion. The overall revision rate was 43% with mean follow-up of 20 months. However, 88% of patients were satisfied with the result and 77% of patients used their device for sexual intercourse. In summary, many experts consider the 3-piece IPP the highest quality option for implantation in the neophallus.[47] Despite high complication rates and the need for revision, patient satisfaction scores are consistently high.

## Safety of Prosthesis Implantation in the Ambulatory Setting

Traditionally, implantation of penile prosthesis was performed in a hospital setting with 23 hours of observation. However, between the late 1980s and the early 1990s, surgeons started to show that IPP implantation can be safely and effectively performed in an outpatient setting.[54–56] Mulhall and Bloom compared outcomes between inpatient and outpatient penile prosthesis surgery.[27] They found similar intra-operative blood loss, operative time, and complication rates between the two settings. Furthermore, they noted significant cost savings by performing the procedure in the outpatient setting. Due to similar complication rates and lower costs associated with outpatient penile implants, national trends have showed decreasing rates of hospital-based IPP surgeries.[57–60] Theses studies show that by 2010, more than

80% of IPP placements were performed in the ambulatory setting. Although there is no consensus, patients who have more comorbidities were more likely to be performed in the inpatient setting given their increased risk for post-operative complications.[59] Segal et al proposed a number of comorbidities that would exclude patients from having their prosthesis performed in an outpatient setting.[61] Patients with comorbidities that increased anesthetic risk such as history of difficult intubation, severe pulmonary disease, BMI>50, OSA, severe cardiac diseases, recent coronary stent placement, precluded them from having their surgery in an outpatient setting.

## Efficacy

An ideal penile prosthesis should mimic the biomechanics of a natural erection and be able to provide sufficient rigidity for penetrative sex. Furthermore, the ideal prosthesis should be cosmetically appealing and be easily concealable. Therefore, the scrotal pump and prosthesis tubing should not be physically visible, and there should not be any physical deformity of the cylinders. Placement of a penile prosthesis should also not affect penile skin sensation, orgasms, urination, or ejaculation. Design improvements over the years have significantly improved the reliability and biomimicry of the device. Introduction of the triple layered Dacron and Lycra layers in AMS models and the polyurethane material in the Coloplast prosthesis increased cylinder rigidity and decreased rates of cylinder aneurysms.[62] Improvements to pump design made inflating and deflating the implant easier for patients. Overall improvements in implant design have improved the reliability and efficacy of the IPP and improved overall patient satisfaction.

### Biomechanical Efficacy

A normal physiologic erection can be characterized by its axial and radial rigidity. Physiologic penile hemodynamic and structural analysis has shown that axial rigidity increases with increasing intracavernosal pressure.[63] Furthermore, the axial rigidity is dependent on the maximal cavernosal volume at relatively low intracavernosal pressures, tunical distensibility, penile geometry, and the penile diameter-to-length ratio.[63] Radial rigidity increases with intracavernosal pressures to a finite maximum value, determined mainly by tunical surface wall tension properties.[64] Studies have shown that axial rigidity is what determines the ability to perform penetrative sex and pelvic thrusting without buckling.[62] Goldstein et al reported that the average axial force necessary for vaginal penetration was 900 grams (or 8.8 Newtons of force).[63] Similar to a physiologic erection, the efficacy of an erection produced by an IPP also depends on its axial rigidity.[65] Ansari et al assessed the axial rigidity of IPPs in 100 patients via rigidometry.[65] They found that digital inflection rigidometer scores correlated with patient satisfaction. Digital inflection rigidometer scores were 710, 842, 872 in unsatisfied patients with the Ambicor, AMS CX700, and Coloplast Titan, respectively. Scovell et al compared the biomechanical properties of the AMS 700 LGX against the Coloplast Titan prosthesis.[66] They found that the AMS 700 LGX kinked at lower pressures (0.7–1.5 pound-force) compared to the Titan (1.7–2.2 pound-force) at 10, 15, 20 PSIs of fill pressure at both 18 and 22 cm length cylinders. Furthermore, they found less variability in kink pressure with lower implant fill pressures in the Titan implant, representing improved axial rigidity in real-world situations. In another study by Romo et al, the length and girth of the AMS LGX, CX, CXR and Coloplast Titan Touch were measured as they were filled.[67] At 22 cc of saline, the 18 cm length Titan touch had a girth of 17.8 mm compared to 15.6 mm for the AMS LGX and 16.5 mm for the CX. The AMS 700 LGX increased in length by 13 mm from baseline. The Titan and CXR both had higher rigidity and required more force to reach 50% compression. In another study by Wallen et al, the AMS LGX, CX and Coloplast Titan were compared with similar performance at maximum fill.[68] However, at less than maximal inflation, the LGX was unable to withstand the 900 grams (or 8.8 Newtons of force) of pressure shown necessary for penetrative sex. The Titan had slightly better radial rigidity than the LGX and CX. Bending stiffness via 3-point flexure testing showed greater rigidity in the AMS CX at shorter cylinder lengths and greater rigidity in the Titan at longer cylinder lengths.[68] The Titan also had better results in patients with Peyronie's disease (PD). The increased radial rigidity seen in the Titan is likely secondary to the increased tensile strength of the polyurethane material. A laboratory study by Thirumavalavan et al evaluated the effects of rear tip extenders (RTE) on prosthesis rigidity.[69] They found that the use of longer RTE resulted in more significant bending deflection. Furthermore, the pseudocapsule around the non-expanding RTE can dilate over time leading to a less stable erection.[70]

## Patient and Partner Satisfaction

In patients with ED refractory to conservative therapies, penile prosthesis is an excellent option, and long-term data have shown excellent patient satisfaction rates ranging from 75% to 100%.[71] The two most commonly utilized validated questionnaires to evaluate patient satisfaction after penile prosthesis surgery are the International Index of Erectile Function (IIEF) and the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS).[72] The IIEF includes 15 questions assessing erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. EDITS includes 11 questions and was developed to access patient and partner satisfaction after ED treatment. Both IIEF and EDITS were not designed to evaluate patient satisfaction following implantation of penile prosthesis. However, without a validated questionnaire dedicated specifically to the evaluation of satisfaction following penile prosthesis implant, many investigators have utilized IIEF and EDITS as a proxy. Others have proposed their own questionnaires for evaluation of satisfaction following penile prosthesis, but these questionnaires have not been validated.[73] Recently, Salter et al developed the Satisfaction Survery for Inflatable Penile Implant (SSIPI).[74] The 16-item SSIPI had internal consistency, test–retest reliability and convergent and discriminant validity. The SSIPI is the first English questionnaire that has been validated to assess patient satisfaction following penile prosthesis placement. This may allow for a more accurate assessment of patient and partner satisfaction following penile prosthesis implantation.

In a study evaluating patient satisfaction of the semirigid prosthesis, 86.4% of patients (n = 22) and 52.6% of partners were satisfied by the AMS Spectra.[75] IIEF scores improved from 28.5 preoperatively to 53.9 at 12 months follow-up. EDITS scores were 45.2 at 12 months follow-up. The authors concluded that the semirigid penile prosthesis had a high degree of patient satisfaction and was also cheaper than the inflatable counterpart. In another study comparing inflatable penile prosthesis to semirigid penile prosthesis, patient satisfaction scores utilizing EDITS were higher in the IPP group (78±11) compared to the semirigid group (57±8).[76] Similarly, partners of these patients were more satisfied with the IPP (72±10) compared to the semirigid prosthesis (49±7).

Evaluation of the two-piece IPP also showed high patient satisfaction scores. In a study of 131 men who underwent placement of a 2-piece Ambicor IPP, overall patient and partner satisfaction rates were 96.4% and 91.2%, respectively. Of the patients who completed the EDITS questionnaire, 90.6% of patients and 82.6% of partners were either very satisfied or satisfied overall with the implant. In a similar study of 101 patients who received an Ambicor 2-piece IPP and completed satisfaction questionnaires, the overall patient and partner satisfaction were 85% and 76%, respectively.[16] Of these patients, 84% stated that the implant provided good to excellent rigidity and 86% would recommend the prosthesis to a friend or undergo the same procedure again. However, in a comparison of axial rigidity between the various implants, the Ambicor prosthesis had lower axial rigidity compared to the 3-piece implants and thus also had lower patient satisfaction scores.[65]

The three-piece IPP is the most common penile implant due to its high overall satisfaction rates, high axial rigidity, and its natural cosmetic appearance. In a retrospective series of 80 patients who had placement of the AMS 700 CX and CXR, long-term follow-up showed high patient satisfaction.[77] Of these patients, 91% of patients were able to cycle the device and engage in penetrative sexual activity. Median postoperative IIEF-5 and EDITS scores were 21.5 and 73.1, respectively. Similar to the AMS implants, the Coloplast Titan has high patient satisfaction rates. Lindeborg et al reported an 85% and 72% overall satisfaction rate in patients and their partners, respectively.[78] In a comparison of satisfaction rates between the AMS CX700 and the Coloplast Titan, Otero et al showed high overall satisfaction in both groups. No patients (n = 248) were dissatisfied with either implant.[79] The authors did note that more patients were overall very satisfied with the CX700 (71%) compared to the Titan (44%, $p < 0.0001$). On the other hand, roughly 10% of patients required 6 or more months to be able to learn how to manage the prosthesis (compared to 0% in patients with the Titan OTR). More than 25% of patients with the Titan were either dissatisfied or very dissatisfied with the ease of deflating the prosthesis compared to 4% in the CX700. More than 90% of partners thought sexual intercourse was good or very good in both implant models. However, more partners would strongly recommend the surgery again in the CX700 (69%) compared to the Titan (56%). In another study comparing the CX700 with the Titan prosthesis, there was no difference in EDITS score with a mean follow-up time of 58 months (n = 55).[80]

## Conclusion

Over the past few decades, the penile prosthesis has evolved significantly. Design modifications have greatly improved its safety and reliability. Development of improved surgical techniques has decreased intraoperative injuries and reservoir-related complications. Development of antibiotic coated penile implants has significantly decreased infection rates. Despite advancements in implant design, mechanical failure can still occur over time and can require surgical revision. Both two-piece and three-piece inflatable penile prostheses have high overall patient and partner satisfaction rates. Each brand of IPP has its advantages and disadvantages and can produce excellent clinical outcomes in the appropriately selected patient. With its high overall satisfaction rates and efficacy and low associated complications, the inflatable penile prosthesis remains an excellent option for patients with erectile dysfunction. In the future, there will be further design improvements including other IPP models and electronic IPPs, which would allow for control of inflation/deflation remotely with a smartphone app.

## Disclosure

Dr Laurence A Levine is a consultant/instructor for Boston Scientific, outside the submitted work. The authors report no other conflicts of interest in this work.

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