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An update on the best approaches to prevent complications in penile prosthesis recipients

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Abstract: Placement of inflatable penile prosthesis is a procedure frequently performed for medication-refractory erectile dysfunction. Device implantation is not without risks, and as the frequency of device implantation increases, so do associated complications. The aim of this work is to review the most frequent operative complications associated with implantation of inflatable penile prostheses, and to review the best approaches to prevent these most common complications. Complications can broadly be categorized as infectious, noninfectious tissue-related, device-related, or related to patient and partner satisfaction. With understanding of these complications and ways to avoid them, as well as with appropriate patient selection and counseling, the inflatable penile prosthesis is an excellent option for the treatment of erectile dysfunction.

Keywords: inflatable penile prosthesis, prosthesis complications, prosthesis infection, salvage therapy

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Introduction

Erectile dysfunction has long been a source of psychological, social, and physical distress for men, with treatments for this condition reported as far back as the early eighth century.[1] The concept of the penile prosthesis was first implemented in 1936 by Nicoli Bogoras, fashioned out of rib cartilage and bone.[2] Since that time, the penile prosthesis has undergone multiple iterations with variations in synthetic materials and surgical placement technique, in an attempt to decrease infection and erosion/extrusion risk. Optimization of penile prosthesis, in this way, finally resulted in devices composed of silicone placed within the tunica albuginea.

The desire for a more physiologic prosthetic erection led to the development of the inflatable penile prosthesis (IPP), which was first designed by Scott in 1973.[3] The two companies, Boston Scientific (AMS) and Coloplast, have been at the forefront of developing and optimizing the IPP since that time. The IPP has been revised multiple times to minimize the risk of mechanical failure, including aneurysmal dilation of the cylinders, pump autoinflation, and device buckling, and to maximize ease of patient use, cosmetic outcome in terms of corporal expansion and lengthening the prosthetic erection, as well as patient and partner satisfaction. Additional models have been developed to minimize complications within specific clinical scenarios including revision surgery or corporal fibrosis due to prior priapism, infection, or previous implant.

The frequency of IPP placement is increasing. In the United States (USA), the number of patients with a penile prosthesis increased from 17,540 to 22,420 from 2000 to 2009.[4] The global market for penile implants in 2016 was valued at US$232,000,000 and is expected to reach US$270,000,000 with an annual growth rate of 2.1% by 2023.[5] With the increase in frequency of device implantation comes an increase in complications associated with the procedure. Complications associated with IPP placement can broadly be categorized as infectious, noninfectious organ/tissue-related damage, device malfunction, and patient/partner dissatisfaction. The aim of this article is to review these complications and to provide current recommendations for techniques to avoid them.

Complications: type and prevention

Infections

Infections associated with IPP placement are well documented and may be the most thought of complication associated with IPP surgery. Much of the literature surrounding IPP placement has focused on minimizing this complication over the years. Additionally, manufacturing companies have expended significant resources on revising their devices to minimize infection rates. This includes the use of a hydrophilic coating and antibiotic dip of rifampin and gentamicin with Coloplast products, and InhibiZone® with Boston Scientific (AMS) products. InhibiZone® is an antibiotic coating impregnated with rifampin and minocycline. Currently, infection rates for primary IPPs range from ~1% to 3% with modern devices.[6,7] Infection risk with revision surgery increases, but with widely variable reported rates ranging from 3% to 25%. This variability is likely influenced by surgical indication, patient variability, and study design.[8]

Infections of the surgical site are to be differentiated from infections of the device itself. Surgical site infections (SSIs) present rapidly after surgery, involve the skin only, and can be treated with antibiotics as any other SSI. The majority of postoperative prosthesis infections occur within the first 3 months of device implantation. Acute device infections typically occur within 6 weeks of device implantation and may be associated with Gram-negative rod organisms. Acute infections may present similarly to SSIs with erythema at the incision but may also have persistent or worsening postoperative pain, an elevated white blood cell count, or tethering of the scrotal pump and tubing to surrounding tissues. Chronic infections or infections occurring after 6 weeks are more commonly subclinical with patients presenting with chronic pain at device components or device extrusion. Typically these infections are associated with common skin flora (including *Staphylococcus aureus* or *epidermidis*) due to biofilm formation following bacterial contamination at the time of surgery.[9,10] Since device explantation is often required once infection develops, the best method for managing infection is prevention.

Prevention of infection is based on preoperative, intraoperative, and postoperative factors. As mentioned above, device manufacturers have developed mechanisms to decrease infection risk inherent to the devices. Further work is being done to determine if additional antibiotic irrigation may further reduce infection risk. A recent study by Chanyi and colleagues demonstrated an *in vitro* suppression of growth of several bacterial strains by soaking IPP tubing in additional antibiotic solutions.[11]

Preoperative consideration should be given to administration of antibiotics as well as to patient factors which may alter the infection risk. The American Urological Association (AUA) guidelines state that penile prosthesis surgery should not be performed in the presence of systemic, cutaneous, or urinary tract infection.[12] If preoperative infection is identified, a full therapeutic course of antibiotics should be administered prior to implantation[13] The AUA best practice statement on antimicrobial prophylaxis for urologic surgery (published in 2008 and amended in 2012) recommends administration of an aminoglycoside plus vancomycin or a first or second generation cephalosporin 1 hour before surgery.[13] However, a large multicenter study recently investigated the specific microorganisms involved in penile prosthesis infection, and found that microorganisms isolated were not covered by the antibiotics recommended in the AUA or European Association of Urology (EAU) guidelines in 14–38% of cases. *Candida* species were identified in 11% of positive cultures in this series, and this group found that the addition of fluconazole to vancomycin and piperacillin-tazobactam would allow for coverage of 100% of the infectious organisms identified.[14] The orthopedic literature suggests that preoperative screening for methicillin-resistant *S. aureus* (MRSA) may allow for targeted preoperative antibiotics and decreased infection risk in prosthetics surgery. If a patient is MRSA-negative, a cephalosporin is administered rather than vancomycin.[15] Preoperative MRSA decolonization may decrease the risk for surgical site infection.[16] It may be beneficial to review the institution's local biome to assist with choosing appropriate targeted preoperative antibiotics. Similarly, a urinalysis on the date of the procedure and cursory skin exam of the implant site, although without robust evidence, may be best practice to help limit infection risk.

Appropriate counseling should be provided to patients with increased risk for developing infection. Spinal cord patients have a 5–9% increased risk, possibly due to impaired wound healing, use of chronic catheterization, and chronic urinary tract colonization/infection.[10,17] Conflicting evidence exists as to whether diabetes and hemoglobin A1c

affects infection risk. While some of the earlier studies suggested an increased risk of infection with increasing A1c, a large review of the literature in 2016 by Christodoulidou and Pearce did not show a statistically significant increased infection rate.[18] Most recently, a large multi-institutional study demonstrated that an increasing A1c is associated with a stepwise increase in infection risk. Patients with A1c of 7.6–8.5% had an infection rate of 6.5%, and patients with A1c $>$ 8.5% had a 14.7% infection rate, compared with a 1.5% infection rate when A1c was $<$7.5%. This study determined that the statistically ideal A1c is 8.5%, but that a lower threshold of 7.5% should be considered when planning prosthesis implantation in diabetic patients.[19] Immunosuppression and chronic steroid use may also increase the risk for infection. While there is no contraindication to placing IPPs in these patients, the surgeon should be mindful of the increased risk of infection prior to proceeding with surgery.[20]

To prepare the surgical site for incision, the skin should be scrubbed with a chlorhexidine-alcohol solution, as this has been shown to be superior to a standard povidone-iodine scrub and paint in decreasing skin colonization prior to device implantation.[21] An IPP may be placed by either a penoscrotal or infrapubic approach. The penoscrotal approach remains the most common and there is currently no evidence to suggest that the surgical approach changes the infection risk.[22] The implant should be placed using a 'no touch' technique, in which the surgeon minimizes contact with the patient's skin. Traditionally the 'no touch' technique starts with making a penoscrotal incision, exposure is obtained, and the retractor placed. At this point, a sterile loose drape is placed, and gloves and instruments are changed. This technique in combination with antibiotic-coated implants has been shown to reduce the infection rate from 5% to 0.46%.[23] While the traditional 'no touch' technique does significantly reduce infection risk, this approach adds time and cost to the operation, and has been modified at most institutions. Most commonly, surgical instruments are cleaned intraoperatively with an antibiotic solution, the field is irrigated with antibiotics, gloves are changed, and an additional sterile drape is placed. This allows for shorter operative time with acceptably low infection rates of ~1.5%.[24]

If the patient does develop infection of the prosthesis requiring device explant, a salvage technique may be employed. This salvage technique was initially popularized by Mulcahy in the late 1990s. The original approach involves removal of the infected device, and irrigation of the implant cavities with a series of antiseptic solutions using hydrogen peroxide, betadine, and bacitracin irrigation, followed by placement of a new prosthesis to reduce the risk of corporal fibrosis and to allow for immediate device replacement for preservation of sexual function. Aggressive irrigation is aimed at removing bacterial biofilm. Mulcahy reported a long-term infection-free rate of 82% in his initial series.[25] The salvage technique has been shown to preserve corporeal length, with one recent study reporting a mean length reduction of 0.6 cm following salvage *versus* a mean of 3.7 cm length reduction with delayed reimplantation, and 81% salvage success rate.[26] The salvage technique should not be attempted in patients presenting with sepsis, poorly controlled diabetes, urethral erosion, or tissue necrosis.[27]

According the 2008 AUA best practice statement, antibiotic prophylaxis should generally be discontinued within 24 h postoperatively. However, the panel recognizes that consideration may be given for extended antibiotic course in cases of prosthesis implantation given the theoretical risk of biofilm formation, though this is not well supported in the literature.[13] Among experts in the field, duration of extended antibiotic course has ranged from 5 to 14 days, and consisted of various oral agents including quinolones, penicillins, and cephalosporins, with use of trimethoprim or doxycycline in areas with high prevalence of MRSA.[28]

Noninfectious postoperative tissue-related complications: urethral or corporal perforation, erosion, glans hypoesthesia or ischemia, hematoma

The risk of proximal or distal corporal perforation, or urethral perforation is increased in patients who have significant corporal fibrosis, as in cases of diabetes, prior intracavernosal injections, ischemic priapism, Peyronie's disease, or prior prosthesis removal without immediate salvage.[29] Progressive dilation with caverenotomes may be required in cases of significant fibrosis. While this may assist with dilation in these cases, there is also an associated risk of corporal perforation, though this may be attributed to the increased difficulty of the case rather than the cavernotomes themselves.[30] Placement of a smaller implant may be required to minimize the risk of perforation in cases of severe fibrosis. Intraoperative 'safety checks' should routinely be

performed during IPP placement. One group recommends proximal dilation with a single 13 mm Brooks dilator aimed laterally to follow the natural divergence of the corpora, to minimize the risk of perforation.[31] Proximal perforation can be ruled out by the 'field goal' test in which dilators are placed concurrently in the proximal corpora bilaterally after proximal dilation. A difference of >1 cm suggests a proximal perforation. This can be managed with a proximal suture sling to prevent proximal migration of the cylinder. Another described technique involves securing, when present as in the case of the AMS 700, the shod material of the cylinder tubing to the adjacent tunica albuginea.[31] However, with these techniques, the theoretical risk remains that the proximal end of the device may still be through the perforation resulting in device placement outside of the corpora.[31] Leaving the device deflated for 6 months allows this to heal in place.[29,32] Distal corporal perforation or crossover can be ruled out by placement of simultaneous distal dilators. Crossover should be considered when dilator contact is noted distally. This can be managed by re-dilating the perforated side with a dilator in the uninjured side, with placement of the cylinder while leaving the dilator in the contralateral cavity.[32] When a distal perforation or crossover is noted, careful inspection should be performed to rule out urethral perforation by irrigating the corpora. The corpora should tumesce without drainage of irrigation around the urethral catheter.

Urethral injury is rare (0.1–3%) and most commonly occurs in cases of significant corporal fibrosis.[33] Historically, if a urethral injury was noted during implantation, the case was aborted out of concern for device infection. This thinking has changed in more recent years. If a urethral injury is noted in an area easily amenable to primary repair (most commonly penoscrotal), then the injury may be closed in two layers and the surgery completed as planned. Urinary diversion *via* suprapubic tube, placed prior to reservoir placement, may be considered.[33] The most conservative option if the injury is more distal, or if the patient is high risk for erosion or other complications, is to repair the injury as above and to defer further device implantation until the injury is healed. However, some groups now advocate primary urethral repair with immediate prosthesis implantation if the injury involves the fossa navicularis, distal or mid-pendulous urethra, or the urethra near the corporotomies, as long as there is no evidence of infection, to minimize corporal fibrosis, penile shortening, and risk of a more difficult prosthetic surgery with increased risk for complications down the road.[34] Prolonged catheterization following repair is not needed.[35]

Postoperative cylinder erosion or extrusion without erosion is also possible. Erosion suggests protrusion of device components through the overlying skin or mucosa, and represents an infected system, which requires device explantation with or without salvage. Extrusion of the cylinders may occur in the absence of skin or mucosal perforation, and in this case a primary repair may be considered. Several techniques have been reported for repair of an extruded cylinder without explantation, including the creation of a new corporal plane with use of the cylinder capsule as a buttress with corporoplasty, use of a Gore-Tex™ windsock, or augmentation with grafts or flaps.[36] Erosion is most likely to occur with intraoperative urethral injury, and in spinal cord patients with rates of ~6%.[29] The highest rate of cylinder erosion in spinal cord patients appears to be related to device type, with lower risk associated with the inflatable prosthesis.[37]

Complications involving the glans are rare. Glans hypermobility, or 'SST deformity,' has been reported in up to 5% of patients and can be associated with anatomic variation.[29] However, this can also be due to technical issues associated with device placement, and can be prevented with appropriate cylinder sizing and positioning. This complication may correct spontaneously with healing, but occasionally requires surgical repair by anchoring the glans to the distal tunica albuginea.[35] Decreased glans sensation remains a theoretical risk with an infrapubic approach or surgical correction of glans hypermobility, but reported rates of this are low.[22,32] Glans ischemia is a rare complication associated with cardiovascular disease, poorly controlled diabetes, smoking, radiation, and prior prosthesis, and is thought to be related to disruption of glanular blood supply *via* the dorsal penile arteries and corpus spongiosum muscle. Risk of this complication can be minimized by avoiding subcoronal incisions, concomitant circumcision or penile degloving in high-risk patients.[29,38] If the patient presents with physical exam findings concerning for glans ischemia in the early postoperative period, immediate removal of the intracorporal components should be performed to prevent subsequent glans necrosis.[38]

Techniques have also been aimed at minimizing postoperative hematoma formation, as this may

increase the postoperative infection risk, patient discomfort and need for more frequent postoperative follow up. Evidence suggests that placing a closed-suction drain in the scrotum for 12–24 h is associated with decreased hematoma formation and scrotal swelling and is not associated with increased infection risk.[39] Partial cylinder inflation is commonly employed to help reduce bleeding risk, and a mummy-wrap compressive dressing can be applied to minimize hematoma formation without the discomfort associated with adhesive dressings.[40,41] The combination of a closed-suction drain and compressive dressing has been shown to reduce hematoma formation to 0.9%.[42]

Device malfunction

As previously discussed, the current IPP models developed by Boston Scientific (AMS) and Coloplast have gone through multiple revisions to minimize device malfunction and failure.[43] Information presented here is mostly of historical interest, as there is little that the urologic surgeon can do to prevent device malfunction as a postoperative complication, aside from avoiding intraoperative damage to the device and selecting the appropriate cylinder size.

Prior to development of the lock-out valve by the Mentor Corporation (now Coloplast) in 2000, device autoinflation was of concern. This was thought to be related to incomplete deflation of the cylinders with formation of a fibrous capsule around the reservoir preventing complete expansion, or to ectopic reservoir placement in the absence of a lock-out valve.[44] Wilson and colleagues described their initial experience with the lock-out valve in the Mentor Alpha-1 prosthesis in 2002. In this series, patients who underwent standard reservoir placement had an autoinflation rate of 11%, with 2% of patients requiring reoperation and capsulotomy.[45] Additionally, autoinflation of the AMS 700 was reported to be around 2–3% prior to the implementation of the lock-out valve.[44] However, the addition of the lock-out valve has led to autoinflation rates of less than 2%, and has allowed for the more frequent and successful placement of the reservoir in the ectopic location which is beneficial in patients with an obliterated space of Retzius, as is seen following prostatectomy.[46]

With the plethora of device options available for implantation, some interest is being paid to the biomechanics of the devices to further identify the optimal device for each patient. Wallen and colleagues recently performed a cadaveric comparison of the AMS CX, AMS 700 LGX, and Coloplast Titan. While this study only compared a single device in each group, some interesting conclusions were drawn. This group found that all implants withstood compression loads that would allow for penetration at maximum inflation pressure. Each device also supported greater maximum loads as rear tip extender length increased, which suggests that increasing length of rear tip extenders may improve a patient's ability to penetrate. In addition, the Titan showed higher rigidity in the face of horizontal force and three-point flexure testing. The two circumferentially-expanding IPPs showed greatest resistance.[47] While additional testing needs to be performed to further evaluate these subtle differences, this group's results suggest that biomechanical factors should possibly play a role when counseling patients on the specific devices.

Patient and partner satisfaction

Implantation of penile prostheses is complex, as it treats both medical and psychological manifestations of erectile dysfunction. Preoperative counseling and managing patient and partner expectations are crucial for prevention of the postoperative complication of dissatisfaction. Trost and colleagues[48] reviewed the urologic and cosmetic surgery literature, and determined surgical as well as patient personality characteristics associated with postoperative satisfaction. The mnemonic 'CURSED patient' (compulsive/obsessive, unrealistic, revision, surgeon shopping, entitled, denial, and psychiatric) has been suggested to describe personality characteristics which may predispose a patient to postoperative dissatisfaction. These criteria should guide the surgeon during preoperative patient selection and counseling. Preoperatively, the surgeon should define realistic surgical and psychological goals, should have the surgical skill required to achieve the defined goals, ensure the patient understands that specific outcomes can never be guaranteed, and ensure that the patient is medically fit to undergo surgery as well as mentally capable of enduring potential disappointments or complications.[48] The Sexual Medicine Society of North America has published an information form to assist with the informed consent process.[49] In addition to informed consent, the patient should receive appropriate education about the surgery and device to be implanted, as well as possible postoperative complications. Postoperatively, the

patient should receive appropriate pain management and feel a sense of easy access to medical attention with a supportive relationship with the surgeon and medical staff.

Studies have shown a linear correlation between the degree of satisfaction with the IPP for male patients and female partners.[50] Satisfaction has been shown to be higher with inflatable devices as compared with malleable devices.[36,50] Additional factors that have been shown to be predictive of patient dissatisfaction include presence of a major complication, perceived postoperative penile size, mechanical device failure or difficulty with device function, presence of Peyronie's disease, prior radical prostatectomy, body mass index > 30, and surgeon experience.[48,51–53] Some patients will have a sense of decreased penile length postoperatively. Studies have shown that there is no significant reduction in penile length following placement of a penile prosthesis.[54] It is therefore recommended that measurement of stretched flaccid penile length be obtained preoperatively for counseling and postoperative comparison to avoid this failed expectation.[36]

The importance of setting realistic postoperative expectations during preoperative counseling cannot be overemphasized. In addition to counseling about expected post-implantation penile length, patients and their partners should have a clear understanding of the risks of sensory change, anorgasmia, dissatisfaction with sexual activity in general, injury to the urethra, bowel, bladder, or scrotal contents, mechanical failure, infection, and that the cylinders only extend to the midglans (i.e. risks of glans flaccidity). While complications do occur, patient dissatisfaction and medico-legal complications may be lessened by the setting of realistic expectations and appropriate informed consent. The authors recommend using the counseling and informed consent tool developed by Kovac and colleagues.[55]

Time should also be spent preoperatively on instructing the patients and their partners on how to use the device of choice. The surgeon should have models of each device being offered, and the patient should feel comfortable cycling the device before surgery is performed. To facilitate the use of the scrotal pump, a subdartos pouch should be generated in the anterior inferior scrotum for intraoperative pump placement. While the patient is recovering postoperatively, he should be instructed to palpate the pump and gently pull the pump to the inferior scrotum daily to ensure the pump heals in a position that will allow for easy access once the device may be used. Some patients may find it difficult to use the device *in vivo*, despite adequate education and practice on the model in the clinic setting. Kramer and colleagues surveyed patients before and after surgery to compare preoperative expectations with postoperative satisfaction, including the perceived ability to inflate and deflate the device. They found that higher expectations and expected ease of device manipulation correlated with lower postoperative satisfaction, and suggested that patients be informed that while the device is generally easy to use, a learning curve should be expected.[56] While patient and partner satisfaction with penile prostheses can be high, a sufficient amount of time and resources should be expended preoperatively to minimize the risk of patient and partner dissatisfaction postoperatively.

Conclusion

The IPP is a highly utilized and successful option for management of erectile dysfunction and results in durable response and high patient satisfaction. The surgeon should understand the most common potential complications associated with device implantation, including infection, corporal and urethral perforation, erosion, glans injury, hematoma formation, device malfunction, and patient or partner dissatisfaction, as well as ways to minimize these complications. With appropriate preoperative preparation, patient selection and counseling, outcomes can be excellent.

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Conflict of interest statement

The authors declare that there is no conflict of interest.

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