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MALE AND FEMALE SURGICAL INTERVENTIONS (C CARSON AND M KHERA, SECTION EDITORS)

Penile Prosthesis Salvage: Review of Past and Current Practices

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Abstract

Purpose of Review This review highlights landmark studies and recent literature regarding penile implant salvage in the setting of infection. We discuss both the historically relevant treatments and newest trends in current practice.

Recent Findings The most recent studies indicate that most penile prosthesis infections can be managed with explantation and washout with immediate implantation of malleable prosthesis. This technique allows for prevention of corporal fibrosis and possible transition to future inflatable penile prosthesis.

Summary While prosthetic infection rates have declined over the years, a 1–3% risk still remains. Originally, prosthetic infections were treated by immediate explantation with consideration for re-implantation months later once the acute period for infection had been managed with broad spectrum antibiotics. However, a landmark study by Mulcahy in 1996 advocated for explantation, antibiotic-based washout, and immediate re-implantation. More recent studies have favored a malleable implant salvage technique (MIST) to preserve penile length. This technique includes explantation, washout, and immediate malleable prosthesis insertion. Further, some researchers are now examining use of temporary intracorporal antibiotic-infused calcium sulfate paste in the setting of implant salvage.

Keywords IPP · Implant infection · Salvage · Implant salvage · Malleable salvage

Introduction

Since its introduction in 1973, the inflatable penile prosthesis (IPP) has become the gold standard surgical treatment for erectile dysfunction (ED) [1]. While recent studies have demonstrated high patient and partner satisfaction, prosthetic infection remains a serious potential complication [2–4]. Even with recent advances in antibiotic prophylaxis, antiseptic device preparation, implantation technique, and device modification, IPP infection rates remain between 1 and 3% in experienced hands [5].

Specific risk factors such as diabetes mellitus were believed to contribute to infection rates; however, recent investigations suggest infection rates in diabetic patients do not differ significantly from the general implant population [6]. Despite an ongoing debate regarding risk factors, the mechanism of prosthetic infection is well characterized. Specifically, during infection, bacterial or fungal biofilm grows around the implant and forms a protective barrier, thus making antibiotic penetration more challenging [7] [8]. Due to poor penetration with antibiotics alone, IPP device infection typically mandates device explantation.

Despite explantation being widely regarded as definitive treatment for device infection, newer reports have emerged suggesting alternative treatment options that can avoid explantation under certain circumstances. For example, a study by Luján and colleagues presented two patients with penile prosthesis infections who were treated by excision of tissue surrounding the pump. The area was then irrigated using high pressure irrigation consisting of povidone-iodine, gentamicin, vancomycin, and hydrogen peroxide; closed in multiple layers; aspirated with drainage tube placement for 24 h; and started on postoperative IV antibiotics [9]. Another study by Habous and

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associates demonstrated patients presenting with localized, early penile infection could be successfully treated with oral antibiotics alone. Importantly, however, it should be noted that the majority of patients in this study had malleable implants [10].

The original management of IPP infection includes antibiotics, device explantation, and washout of reservoir location. Some surgeons also opted for intracorporal drain placement following device removal [11]. Reimplantation was then typically attempted several months later. This strategy unfortunately had many pitfalls, as prolonged postoperative periods without a device in situ may result in the development of recalcitrant fibrosis and scarring of the corporal bodies [12]. The fibrosis may then in turn lead to penile shortening, thus making subsequent insertion of a future IPP more challenging.

Methods

This review was conducted by searching PUBMED for pre-existing studies that address penile implant infection management strategies. Specifically, a PUBMED search was performed using the following keywords: "IPP," "implant infection," "salvage," "implant salvage," and "malleable salvage." Only reports published in English were assessed. Case series or trials prior to year 1992 were excluded.

Discussion

The management of IPP infection was greatly improved in 1996 after Mulcahy described a groundbreaking salvage implant protocol [13]. In this retrospective study, 11 patients with IPP infections underwent complete removal of hardware, followed by a seven-step antibiotic irrigation, with subsequent insertion of a new penile prosthesis. With a mean follow-up of 21 months, 10/11 patients remained infection free. It should be noted, however, that the study excluded patients with device extrusion, poorly controlled diabetes, and/or purulent infection. Mulcahy's technique was then further solidified when a second longer term analysis was reported in year 2000 in which 44/55 patients showed no signs of infection with an average follow-up of 35 months [14]. A study by Kaufman and colleagues described a similar washout with immediate re-implantation protocol in which 6/7 men were infection free on follow-up [15].

It should be noted that at our institution, we historically used the originally described standard Mulcahy washout, which consisted of vancomycin/bacitracin solution irrigation, followed by half strength hydrogen peroxide/half strength povidone-iodine solution, followed by vancomycin/gentamicin/half strength povidone-iodine/half strength hydrogen peroxide irrigation, followed by kanamycin/bacitracin irrigation. However, recent data demonstrating deleterious cytotoxic effects and poor antibiotic coverage associated with hydrogen peroxide irrigation solution has changed practice at our institution and many others. Studies also suggest that diluted povidone-iodine (0.35–5%) has reduced cytotoxic effects while also decreasing incidence of postoperative infectious complications [16].

While Mulcahy favored immediate re-implantation, other studies examined delaying insertion of the new prosthesis until after the infection had been drained with device explantation and a period given for intravenous antibiotics alone to take effect. For instance, Teloken and associates described a similar washout protocol but with re-implantation 72 h following explantation [17]. Similarly, Knoll conducted an investigation which compared immediate salvage to 3-day delayed re-implantation. On follow-up, 8/10 (80%) immediate patients and 22/31 (71%) delayed patients were infection free. The investigators concluded no significant difference between the two approaches and advocated for immediate salvage due to potential savings in healthcare cost [18].

While the previously mentioned reports provide sufficient evidence regarding the timing of salvage, it is important to note that these studies often excluded patients with purulent infections or device erosions. For these patients, surgeons often favor the use of malleable rods in the setting of immediate salvage. The malleable prosthesis can serve as transition to eventual IPP replacement or as definitive therapy.

The malleable implant salvage technique (MIST) offers many benefits to both the surgeon and patient. For one, the malleable procedure typically consists of shorter operative times compared to IPP insertion. The malleable rods are also beneficial as they maintain corporal patency, thus helping prevent fibrotic scarring and penile shortening [19]. Malleable placement is also particularly useful in patients with scrotal pump erosions or scrotal purulence. Even if an infection is isolated to the scrotum, flora can colonize the tubing and travel more proximally. It is therefore safest to avoid immediate scrotal pump placement in such patients and opt for malleable placement. At our institution, purulent IPP infections are typically replaced with malleable devices. However, purulent infections involving the urethra or presenting with concomitant cylinder erosion are not considered candidates for salvage therapy, which is supported by multiple prior investigations [20, 21•].

A study by Kohler and colleagues in 2009 was one of the first to examine MIST as an option for prosthetic infection. The study included 6 men who had an IPP removed due to suspected scrotal pump infection/erosion with all undergoing replacement with a malleable prosthesis. All 6 patients were infection free with mean follow-up of 2 years, with one patient undergoing elective explantation for delayed glandular erosion [20]. As a result of this pilot investigation, many have advocated for a malleable substitution as an excellent option for surgical correction of scrotal pump infection.

Another landmark assessment examining MIST was conducted by Gross and colleagues in 2016. In this study, 58 patients underwent a protocoled Mulcahy irrigation with

removal of the IPP and replacement with an antibiotic soaked malleable prosthesis. At time of most recent follow-up, 54/58 (93%) patients had no infection [22••]. The researchers therefore concluded that IPP infection can be safely treated with removal of the implant, washout, and replacement with a malleable prosthesis. It is also important to note that there was only a 7% failure rate with MIST in this largescale study compared to a historic 18% failure rate demonstrated in the original Mulcahy series [14].

The techniques described by Mulcahy, Kohler, Gross, and many others all importantly include a washout protocol and/or placement of an antibiotic soaked implant. Multiple researchers therefore agree that proper washout decreases penile prosthesis infection and is therefore advocated during salvage strategies [23, 24]. Although multiple preventative measures such as antibiotic coating, revision washout, and alcohol-based skin prep have decreased the rate of IPP infection, infection risk still remains, and microbiotic biofilm composition is highly dynamic over time [25–27]. In fact, recent studies suggest that even asymptomatic implants could be infected, given that up to 50–80% of IPPs removed for mechanical malfunction in three separate series were found to be colonized with bacteria [5, 28•, 29]. Unfortunately, even with antibiotic coating and other preventative measures, studies show that microorganisms not covered by EUA and AUA antibiotic prophylaxis guidelines have been identified in as high as 38% infected IPPs [21•]. Considering this information along with other data, some are calling for a new standard set of antibiotics guidelines for implanters [30]. Specifically, the alarming rates of anaerobic and Candida infections in the current literature have driven our institution to broaden our antibiotic coverage for all implant cases and additionally incorporate antifungal coverage in revision cases and in our diabetic or immunocompromised patients.

Despite ongoing debate regarding antibiotic prophylaxis and management, the benefits and success of MIST remain evident. For instance, a recent analysis from Peters and associates demonstrated that immediate salvage can be successful, even with purulent IPP infections in IDDM patients [31]. Other researchers continue to demonstrate that successful salvage surgery preserves penile length [32]. However, arguably the most important benefit to MIST is the potential for eventual conversion to IPP. While discussing MIST with a patient, the surgeon is able to offer the malleable as a bridge to three-piece IPP insertion. Considering the multi-institutional assessment of the MIST, 17 of 54 patients eventually underwent IPP replacement at an average of 6.7 months post-op [22••]. On the other hand, many MIST patients may not wish to undergo a second surgery and are able to opt for the malleable prosthesis alone as definitive management.

Despite the aforementioned evidence, studies of national trends in IPP infection suggest that salvage techniques such as MIST are not commonly used. Zargaroff and associates reviewed the Nationwide Inpatient Sample database from 2000 to 2009 and reported that 82.7% of infected IPPs were treated with explantation alone, while only 17.3% underwent immediate salvage [33]. This report suggests that salvage has been nationally underutilized even though it is now considered the gold standard by many high-volume implanters. However, given the emergence of recent literature suggesting the benefit of MIST strategy to manage salvage infection situations, it is unclear whether review of a more recent database may indicate more of an upward trend in immediate implantation.

Future Research

While there is now sufficient data to confirm the efficacy of MIST, some investigators are examining the possibility of using alternate methods as a means of temporarily filling the corpora following a proper washout protocol. For instance, there have been discussions regarding the use of intracorporal antibiotic casting, similar to the material used in orthopedic reconstruction surgery. Stimulan® (Biocomposites, Wilmington, UK) is an antibiotic-loaded (vancomycin and tobramycin) calcium sulfate bead material that forms a paste used to fill in dead space in a multitude of reconstructive orthopedic procedures [34]. In a recent prospective observational study of 755 Stimulan®-assisted arthroplasty patients, only 4.2% exhibited wound drainage on follow-up, demonstrating an effective and well-tolerated means of filling open intraoperative space [35].

The use of Stimulan® has also been examined for use as a corporal space filler. Carrion and associates described two cases in which calcium sulfate antibiotic paste was used in penile prosthesis salvage. For the first case, one patient presented with erosion of his right malleable cylinder. The rod was removed and the space was washed out with antibiotic solution. Calcium sulfate antibiotic paste was then injected to fill in the right corpus. After 2 weeks, the cast had hardened. After 4 weeks, the cast was reabsorbing. Successful re-implantation was then able to be performed at 6 months following the initial salvage procedure. The author noted that during the case, there was no evidence of penile fibrosis [36]. The second case described a patient who had undergone multiple penile surgeries, including insertion of malleable prosthesis after IPP infection. The latest case, which was the focus of the paper, was for malleable prosthesis revision secondary to pain. Significant scar tissue was seen intraoperatively. The corpora were then washed out bilaterally and calcium sulfate antibiotic mixture was used to make bilateral corporal casts. Due to poor follow-up, re-implantation did not occur until 15 weeks following the aforementioned procedure. At the time of re-implantation, the cast had already fully resorbed and significant fibrosis was seen. Only a unilateral malleable was safely placed and the patient reported satisfactory

intercourse during his 2-month follow-up appointment [36]. The authors therefore concluded that the calcium sulfate antibiotic mix paste option is best suited for high risk acutely septic patients, cylinder extrusions, patients with a history of multiple implant infections, or patients who are not candidates for immediate salvage [36]. It is important to explain to potential patients that the cast described only manifests temporary benefits and necessitates close patient follow-up. Due to the continued experimental nature of Stimulan®, we suggest incorporation of this technique in the implanter's armamentarium only in accordance with hospital regulations and policy.

Conclusions

IPP device infection is a relatively rare but serious complication of prosthesis insertion. Management of infected implants was revolutionized by the work of Mulcahy in 1996 with the creation of a protocol that called for explantation and washout followed by immediate IPP reinsertion. It is important to note that patients with purulent infections or device erosion were excluded from this study and many subsequent evaluations that perform salvage implantation. More recent studies have favored the use of the Mulcahy washout protocol with immediate re-implantation of a malleable device instead of IPP. This method is particularly useful for patients with purulent drainage or pump erosion. Emerging studies exist regarding the use of an intracorporal antibiotic cast to serve as a temporary placeholder for several weeks prior to permanent device implantation.

Compliance with Ethical Standards

Conflict of Interest Jay Simhan reports personal fees from Boston Scientific Corporation as a consultant, and Coloplast Corporation as a consultant, outside of submitted work. Ryan Barlotta and Christopher Foote each declare no potential conflicts of interest.

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

References

Papers of particular interest, published recently, have been highlighted as:
- • Of importance
- •• Of major importance

1. Scott FB, Bradley WE, Timm GW. Management of erectile impotence. Use of implantable inflatable prosthesis. Urol. 1973;2:80–2. https://doi.org/10.1016/0090-4295(73)90224-0.
2. Bernal RM, Henry GD. Contemporary patient satisfaction rates for three-piece inflatable penile prostheses. Adv Urol. 2012;2012:707321–5. https://doi.org/10.1155/2012/707321.
3. Brinkman MJ, Henry GD, Wilson SK, Delk JR, Denny GA, Young M, Cleves MA. A survey of patients with inflatable penile prostheses for satisfaction. J Urol 2005:174:253–257. Doi:https://doi.org/10.1097/01.ju.0000161608.21337.8d
4. Vakalopoulos I, Kampantais S, Ioannidis S, Laskaridis L, Dimopoulos P, Toutziaris C, et al. High patient satisfaction after inflatable penile prostheses implantation correlates with female partner satisfaction. J Sex Med. 2013;10:2774–81. https://doi.org/10.1111/jsm.12311.
5. Henry GD, Carson CC, Wilson SK, Wiygul J, Tornehi C, Cleves MA, et al. Revision washout decreases implant capsule tissue culture positivity: a multicenter study. J Urol. 2008;179:186–90. https://doi.org/10.1016/j.juro.2007.08.168.
6. Christodoulidou M, Pearce I. Infection of penile prostheses in patients with diabetes mellitus. Surg Infect. 2016;17:2–8. https://doi.org/10.1089/sur.2015.164.
7. Welliver RC Jr, Hanerhoff BL, Henry GD, Köhler TS. Significance of biofilm for the prosthetic surgeon. Curr Urol Rep. 2014;15:411. https://doi.org/10.1007/s11934-014-0411-8.
8. Wilson SK, Costerton JW. Biofilm and penile prosthesis infections in the era of coated implants: a review. J Sex Med. 2012;9:44–53. https://doi.org/10.1111/j.1743-6109.2011.02428.x.
9. Luján S, Rogel R, Broseta E, Boronat F. Local treatment of penile prosthesis infection as alternative to immediate salvage surgery. J Sex Med. 2016;4:255–8. https://doi.org/10.1016/j.esxm.2016.06.002.
10. Habous M, Farag M, Williamson B, Laban O, Mahmoud S, Abdelwahab, et al. Conservative therapy is an effective option in patients with localized infection after penile implant surgery. J Sex Med. 2016;13:972–6. https://doi.org/10.1016/j.jsxm.2016.04.064.
11. Maatman TJ, Montague DK. Intracorporeal drainage after removal of infected penile prostheses. Urol. 1984;23:184–5. https://doi.org/10.1016/0090-4295(84)90019-0.
12. Yafi FA, Sangkum P, McCaslin IR, Hellstrom WJ. Strategies for penile prosthesis placement in peyronie's disease and corporal fibrosis. Curr Urol Rep. 2015;16:21. https://doi.org/10.1007/s11934-015-0491-0.
13. Brant MD, Ludlow JK, Mulcahy JJ. The prosthesis salvage operation: immediate replacement of the infected penile prosthesis. J Urol. 1996;155:155–7. https://doi.org/10.1097/00005392-199601000-00059.
14. Mulcahy JJ. Long-term experience with salvage of infected penile implants. J Urol. 2000;163:481–2. https://doi.org/10.1016/S0022-5347(05)67906-2.
15. Kaufman JM, Kaufman JL, Borges FD. Immediate salvage procedure for infected penile prosthesis. J Urol. 1998;159:816–8. https://doi.org/10.1016/S0022-5347(01)63740-6.
16. Pan S, Rodriguez D, Thirumavalavan N, Gross MS, Eid JF, Mulcahy J, et al. The use of antiseptic solutions in the prevention and management of penile prosthesis infections: a review of the cytotoxic and microbiological effects of common irrigation solutions. J Sex Med. 2019;16:781–90. https://doi.org/10.1016/j.jsxm.2019.03.271.
17. Teloken C, Souto JC, Da Ros C, Thorel E, Souto CAV. Prosthetic penile infection: "rescue procedure" with rifamycin. J Urol. 1992;148:1905–6. https://doi.org/10.1016/S0022-5347(17)37067-2.
18. Knoll LD. Penile prosthetic infection: management by delayed and immediate salvage techniques. Urol. 1998;52:287–90.
19. Lao M, Graydon RJ, Bieniek JM. Salvage penile prosthetic surgery utilizing temporary malleable implants. Transl Androl Urol 2017:6:S806–12. Doi:https://doi.org/10.21037/tau.2017.05.12.

20. Köhler TS, Modder JK, Dupree JM, Bush NC, McVary KT. Malleable implant substitution for the management of penile prosthesis pump erosion: a pilot study. J Sex Med. 2009;6:1474–8. https://doi.org/10.1111/j.1743-6109.2009.01236.x.
21.• Gross MS, Phillips EA, Carrasquillo RJ, Thornton A, Greenfield JM, Levine LA, et al. Multicenter investigation of the microorganisms involved in penile prosthesis infection: an analysis of the efficacy of the AUA and EAU guidelines for penile prosthesis prophylaxis. J Sex Med. 2017;14:455–63. https://doi.org/10.1016/j.jsxm.2017.01.007 **Discusses the need for improved antibiotic guidelines regarding penile implantation.**
22.•• Gross MS, Phillips EA, Balen A, Eid JF, Yang C, Simon R, et al. The malleable implant salvage technique: infection outcomes after mulcahy salvage procedure and replacement of infected inflatable penile prosthesis with malleable prosthesis. J Urol. 2016;195:694–7. https://doi.org/10.1016/j.juro.2015.08.091 **Describes technique often accepted as best current practice for most implant salvage cases.**
23. Henry GD, Wilson SK. Updates in inflatable penile prostheses. Urol Clin North Am. 2007;34:535–47. https://doi.org/10.1016/j.ucl.2007.08.015.
24. Elmussareh M, Goddard JC, Summerton DJ, Terry TR. Minimising the risk of device infection in penile prosthetic surgery: a UK perspective. J Clin Urol. 2013;6:280–8. https://doi.org/10.1177/2051415813488367.
25. Bodin T, Bruyère F. Penile prosthesis: systematic review of infectious complications. Prog Urol. 2015;25:381–9. https://doi.org/10.1016/j.purol.2015.02.006.
26. Al Mohajer M, Darouiche RO. Infections associated with inflatable penile prostheses. Sex Med Rev. 2014;2:134–40. https://doi.org/10.1002/smrj.30.
27. Dawn LE, Henry GD, Tan GK, Wilson SK. Biofilm and infectious agents present at the time of penile prosthesis revision surgery: times are a changing. Sex Med Rev. 2017;5:236–43. https://doi.org/10.1016/j.sxmr.2017.01.002.
28.• Etcheverry-Giadrosich B, Torremadé-Barreda J, Pujol-Galarza L, Vigués-Julia F. Bacterial colonization of penile prosthesis after its withdrawal due to mechanical failure. Act Urol Esp 2017:41:652–655. Dhttps://doi.org/10.1016/j.acuro.2017.06.002.·**Demonstrates frequency of infection in penile implants, suggesting need for improved perioperative antibiotic regimen.**
29. Silverstein AD, Henry GD, Evans B, Pasmore M, Simmons CJ, Donatucci CF. Biofilm formation on clinically noninfected penile prostheses. J Urol. 2006;176:1008–11. https://doi.org/10.1016/j.juro.2006.04.034.
30. Wosnitzer MS, Greenfield JM. Antibiotic patterns with inflatable penile prosthesis insertion. J Sex Med. 2011;8:1521–8. https://doi.org/10.1111/j.1743-6109.2011.02207.x.
31. Peters CE, Carlos EC, Lentz AC. Purulent inflatable penile prostheses can be safely immediately salvaged in insulin-dependent diabetics. J Sex Med. 2018;15:1673–7. https://doi.org/10.1016/j.jsxm.2018.10.002.
32. Lopategui DM, Balise RR, Bouzoubaa LA, Wilson SK, Kava BR. The impact of immediate salvage surgery on corporeal length preservation in patients presenting with penile implant infections. J Urol. 2018;200:171–7. https://doi.org/10.1016/j.juro.2018.01.082.
33. Zargaroff S, Sharma V, Berhanu D, Pearl JA, Meeks JJ, Dupree JM, et al. National trends in the treatment of penile prosthesis infections by explantation alone vs. immediate salvage and reimplantation. J Sex Med. 2014;11:1078–85. https://doi.org/10.1111/jsm.12446.
34. McPherson E, Dipane M, Sherif S. Dissolvable antibiotic beads in treatment of periprosthetic joint infection and revision arthroplasty - the use of synthetic pure calcium sulfate (Stimulan®) impregnated with vancomycin & tobramycin. Recon Rev 2013:3. https://doi.org/10.15438/rr.v3i1.27.
35. Kallala R, Harris WE, Ibrahim M, Dipane M, McPherson E. Use of Stimulan absorbable calcium sulphate beads in revision lower limb arthroplasty: safety profile and complication rates. Bone Joint Res. 2018;7:570–9. https://doi.org/10.1302/2046-3758.710.BJR-2017-0319.R1.
36. Swords K, Martinez DR, Lockhart JL, Carrion R. A preliminary report on the usage of an intracorporal antibiotic cast with synthetic high purity CaSO4 for the treatment of infected penile implant. J Sex Med. 2013;10:1162–9. https://doi.org/10.1111/jsm.12060.