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Minimizing Penile Prosthesis Implant Infection: What Can We Learn From Orthopedic Surgery?

Selin Isguven

Thomas Jefferson University

Paul H. Chung

Thomas Jefferson University

Priscilla Machado

Thomas Jefferson University

Lauren J. Delaney

Thomas Jefferson University

Antonia Chen

Brigham & Women's Hospital

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Authors

Selin Isguven, Paul H. Chung, Priscilla Machado, Lauren J. Delaney, Antonia Chen, Flemming Forsberg, and Noreen J. Hickok

Introduction

Erectile dysfunction (ED) affects one out of two American men over the age of 50 and is linked to prevalent medical conditions such as cardiovascular disease and diabetes. Approximately one third of men with ED will fail conservative treatments and around 25,000 patients choose to undergo penile prosthesis (PP) implantation annually.¹ While infrequent, infection is a devastating complication occurring in approximately 3% of primary and up to 18% of revision surgeries.² The risk for infection exists peri-operatively and also endures long-term with approximately 500,000-750,000 patients at risk at this present time. Infections may be severe or subtle, presenting as chronic pain or implant migration. Unfortunately, the majority of these patients will require a combination of systemic antibiotic treatment and device removal. Such treatment results in significant economic burden to the health system and physical, psychological, and financial burden to the patient. Improved prevention strategies are needed to reduce PP infection (PPI).

Literature suggests that infection prevention strategies amongst urologists performing PP operations vary in many aspects, including the duration of skin preparation and multiple aspects of antibiotic administration.³ This may be due in part to the fact that 75% of PP surgeries are done by urologists who perform ≤ 4 surgeries/year, while the top 20 highest volume urologists perform 17% of the total volume.⁴ Based on surgical outcome studies, low operation volume may be associated with worse outcomes, and low volume physicians and hospitals can learn from those with greater experience⁵. These findings support the need for best practices recommendations for PP surgery. The aim of this review is to broaden the discussion of best practices by not only examining practices

in urology, but additionally to delve into the field of orthopaedic surgery to identify techniques and approaches that may be applied to PP surgery.

Biofilm Formation

Upon implantation, biomaterials, which are often inert, are rapidly coated by extracellular matrix molecules (ECM), and provoke a foreign body reaction that induces fibrous encapsulation and causes attenuation of immune surveillance—all conditions ideal for bacterial and fungal biofilm formation (Figure 1).⁶ These adherent bacteria become antibiotic tolerant and can progress to form biofilms (i.e., communities of adherent bacteria encased by a polysaccharide coating). Generally, biofilms progress through surface attachment, cell proliferation and, film maturation, to detachment and spread.⁷

During biofilm maturation, cells also undergo phenotypic changes, becoming less metabolically active and needing fewer nutrients—so called sessile bacteria. The biofilm matrix, largely consisting of polysaccharides and proteins, provides isolation and security from mechanical forces and the body's immune system, and the phenotypic changes make the organisms more drug resistant. For example, many commonly used antibiotics attack bacterial cell wall production or protein synthesis, functions that are critical for rapid growth, but less important in a more dormant phenotype. As a result, antibiotic concentrations more than 1000 times that needed to inhibit growth (minimum inhibitory concentration, MIC) of the unadhered (planktonic) bacteria may be needed to combat biofilms.⁷

Biofilms pose a particular challenge when considering the increased infection rates after revision surgeries of PPs. One theory suggests that an initial biofilm is formed after primary surgery, which remains clinically silent until disrupted during the revision surgery.² A study by Henry *et al.* revealed that 70% of the non-antibiotic coated PPs had culture positive bacteria at the time of revision surgery due to non-infectious causes, of which 90% were *Staphylococcus* species.⁸ Another study by Silverstein *et al.* found that implants contained evidence of biofilm formation in 8 out of 10 patients undergoing revisions due to non-infectious causes.⁹ The orthopaedic field has similar findings. Particularly, large numbers of shoulder implant surgeries appear to harbor bacteria without manifesting signs of infection. Efforts to decrease biofilm formation could therefore decrease the infection risk after revision surgery.^{10,11}

Perioperative Measures to Decrease Surgical Site Infection (SSI)

Appropriate patient selection and optimization of patient related factors are important aspects of reducing SSI that are recognized and will not be covered in depth in this article. While there are not universally accepted approaches to patient related factors for PP surgery, even from an international consultation on sexual medicine,⁵ the following can be considered to minimize infection risk based on the orthopaedic literature: temporarily stopping immunosuppressive drugs (e.g. anti-rheumatic drugs),¹² having the HbA1c level below 7.7%,¹³ having a body mass index of less than 40 kg/m², not being malnourished (can be assessed by having normal serum albumin and transferrin levels and total lymphocyte counts), and abstaining from alcohol consumption and smoking for at least a period of four to eight weeks¹². Perioperative measures are crucial in fighting

the risk of infection, since most PP infections result from perioperative contamination from skin flora. Late implant infection is thought to be in part due to hematogenous spread from a remote infection.⁶

Many surgical fields struggle with biofilm formation and SSI. Prosthetic joint infections (PJI), which arise after joint replacements, are another important problem, and treatment methods have been reviewed by orthopaedic surgeons and infectious disease specialists at the International Consensus Meetings (ICM) in 2014 and 2018.¹⁴ This collaboration serves as a model for the type of collective approach that may help to further improve prevention across surgical specialties. A summary of current perioperative measures in PP and orthopaedic surgeries is provided in Table 1.

Pre-Existing Infection Control

The American Urological Association (AUA) ED Guidelines recommend that PP surgery should not be conducted “in the presence of systemic, cutaneous, or urinary tract infection”.¹⁵ In the case of pre-existing infection, surgery should only be performed once a course of antibiotics has been completed and symptoms have subsided. These recommendations are shared within surgical fields, including orthopaedic surgery. If the patient has an active skin infection, the lesions should be treated before (elective) joint replacement surgery.¹⁶ Specifically, many SSIs originate from surgically-mobilized pathogens that are considered endogenous skin flora. Likewise, any potential source of transient bacteremia, such as dental procedures and symptomatic urinary tract infections, should be resolved before surgery.¹⁶ In a retrospective study of 2,349 surgeries, patients with remote skin infections were three times more likely to have a SSI (21% with skin

infection vs. 7% without). Another prospective observational study with 9,245 patients undergoing joint replacement identified urinary infection as an independent predisposing factor for PJI (odds ratio=5.45, p=0.04).¹⁷

Finally, being a methicillin-resistant *Staphylococcus aureus* (MRSA) carrier (i.e., colonized, but not actively infected) is a major risk for infection. In a retrospective cohort study of 9,863 surgical procedures, patients whose nares were colonized with MRSA were 9 times more likely to have a SSI due to MRSA.¹⁸ For orthopaedic surgeries, preoperative nasal screening is not common, but Rao *et al.* found *S. aureus* screening before total joint arthroplasty, followed by decolonization with mupirocin ointment to the nares twice daily and chlorhexidine baths once daily for 5 days prior to the operation decreased infection rates from 2.6% to 1.5%).¹⁹

Antibiotic Prophylaxis

The AUA Urologic Procedures and Antimicrobial Prophylaxis Best Practice Statements indicate antibiotic prophylaxis should be started 1-2 hours before surgery²⁰, cover skin flora, and last perioperatively (postoperative administration is not recommended unless there is evidence for infection).⁵ Orthopaedic recommendations are similar, but with additional suggestions about local antibiotics and special circumstances. Extended antibiotic prophylaxis in the absence of infectious symptoms is discouraged, due to increased risk of resistance. This is contrary to commonly performed postoperative antibiotic administration after PP surgery, despite lack of data to support its use. An exception may be made for patients at an increased risk of infection, for example those undergoing revision surgeries. However, a recent study demonstrated that rates of

explantation due to PPI did not significantly vary between patients without risk factors with no postoperative antibiotics, patients with risk factors with no antibiotics, and patients with risk factors who did receive antibiotics (0% vs 4% vs 5%, $p=0.13$).²¹

Prophylaxis with a first-generation cephalosporin is common for those undergoing orthopaedic surgical procedures; for MRSA colonized patients (as well as those with cephalosporin allergies), vancomycin or teicoplanin is given. Local supplementation with vancomycin powder is frequently used in spinal and cardiothoracic/vascular surgery. While there is data to claim that vancomycin powder decreases SSI in the spine, a meta-analysis found that its protective effect only occurred in the presence of spinal implants ($p=0.023$), and was not significant without an implant ($p=0.226$).²² The results remain controversial as a randomized, controlled trial did not find an effect, albeit, reaching significance is difficult given the low incidence of SSIs—a ubiquitous problem with implant infection research.²³ In addition, antibiotic-loaded calcium sulfate/phosphate carriers have not been proven to decrease the risk of SSI/PJI and all antimicrobial prophylaxis carries the concern that antimicrobial resistance may be fostered.²⁴

Surgical Site Preparation

It has long been known that preoperative antiseptic washes decrease skin microbial counts. Preoperative bathing or scrubbing by the patient is largely left to the internal protocols of surgical centers.¹ However, some recommend using a chlorhexidine-based soap twice daily for at least a week before surgery.²⁵ In orthopaedic surgery, it is recommended that patients start cleansing at home with chlorhexidine gluconate and the

ICM on PJI and Centers for Disease Control (CDC) support whole-body cleansing at least 24 hours pre-operatively.¹²

Immediately before surgery, chlorhexidine-alcohol was more effective than povidone-iodine in clearing the skin flora at the incision site during genitourinary prosthetic surgery; 8% of chlorhexidine-alcohol patients' cultures were positive, while 32% were positive for the povidone-iodine group ($p=0.0091$).²⁶ The choice of skin preparation agent does not appear to matter as long as isopropyl alcohol is included in the solution. This suggestion is based on, among others, the systematic review by Maiwald and Chan, which found that the chlorhexidine-alcohol combination was superior to aqueous competitors, but comparable to other combinations with alcohol.²⁷

For PP surgery, an ideal time to remove hair has not been defined; however, clipping or use of depilatory creams resulted in fewer SSIs than shaving.¹⁰ One timing recommendation for hair removal via clipping has been immediately before the operation. The orthopaedic surgery recommendations likewise state that hair removal at the site of incision is not necessary if it will not interfere with the operation. However, it is suggested when necessary that hair be removed with clippers or depilatory creams immediately before the surgery outside the operating room (OR).²⁸ A meta-analysis of hair removal for surgeries found that there were no differences in the number of SSIs between hair removal techniques and no hair removal, except shaving which resulted in higher SSIs than all other options, including no hair removal.²⁹

OR Environment

OR environment may have an effect on SSI risk, and orthopaedic surgeons have recommended strategies such as keeping the OR traffic and personnel to a minimum, which reduces SSI risks associated with high levels of airborne microorganisms in the OR. A Swedish study showed strong correlation ($r=0.74$, $p=0.001$) between total colony-forming units (CFU)/m³ and total traffic flow during orthopaedic trauma implant surgery.³⁰ Other factors are related to surgical technique, such as suggested replacement of suction tips every 60 minutes, similar to recommendations about gloves, as both acquire bacterial contamination over time. Possible causes of contamination include the large amount of air and fluids passing through the suction tip, direct contact with the patient's skin, or improper technique by operating team members. Importantly, despite the low overall infection rates, one study showed suction tip bacterial contamination in 54% of evaluated surgeries.³¹ The contamination was less frequent for procedures lasting less than one hour (9.1%) compared to longer procedures (66.7%), again highlighting the risk of longer operative times. These recommendations could be more widely adopted despite a lack of specific studies examining the OR environment in PP surgery.

Antibiotic-coated implants

A powerful way to mitigate PPIs is to modify the device to prevent biofilm formation and infection. Boston Scientific (formerly American Medical Systems) developed a rifampin and minocycline coated implant in 2001, while Coloplast (formerly Mentor) developed a hydrophilic coated implant (in 2002) that allowed for individualized antibiotic coating at the time of surgery. Both device modifications decreased PPIs in both primary and revision surgery.³² For example, Eid *et al.* found that both brands of coated implants

decreased the infection rate from 5.3% to 2%.³³ In 2013, a group of experts on PPs unanimously recommended the use of devices that carried antimicrobial surface modifications.¹ Antimicrobial orthopaedic implants have explored tethering, coating, and loading, with a few silver coated implants used clinically, and the rest showing promise in pre-clinical and *in vitro* studies.⁶

Surgical Technique

Infection risk does not appear to correlate with surgical approach of PP placement (e.g., penoscrotal or infrapubic),^{20,5} but a 'no touch' technique for the operation resulted in decreased infection rates with combinations of this technique and antibiotic-coated implants brought rates to as low as 0.46%.³³ Another group achieved an infection rate of 1.5% with a less time- and effort-intensive 'modified no touch' technique.^{34,20}

Comparable to the 'no touch' technique, scalpel replacement is recommended after the initial incision in orthopaedic surgeries. Similarly, it is recommended that surgeons change gloves after draping, before working with implants, and whenever gloves are visibly perforated, with some even recommending that gloves be changed at least once every 60 to 90 minutes. Ward *et al.* demonstrated the benefit of changing gloves; in a randomized trial, changing outer gloves (while double-gloving) 1 hour into an orthopaedic procedure significantly decreased contamination of the gloves (13% vs 23%, $p < 0.05$).³⁵ There are no current recommendations for or against changing the gown. Using a bacterial strike-through study, Ward *et al.* also found that paper gowns had less bacterial transmission than cloth ones in the laboratory setting (26/27 cloth gowns vs. 0/27 paper

gowns, $p < 0.001$), and recommended that disposable paper gowns be used for all surgeries, especially those using implants.³⁵

In terms of wound closure, use of certain materials or specific techniques does not seem to affect SSI rates. For example, the antibacterial-coated sutures that decrease the risk of SSI after colorectal surgery have not proven to be as effective in orthopaedic surgeries.³⁶ *In vitro* studies have suggested that barbed sutures in aseptic surgery and monofilament sutures in septic surgery may be preferable; however, these suggestions are based on bacterial presence and not on other properties such as mechanical strength, which also need to be considered.³⁷ Prophylactic vacuum-assisted incisional dressings are only recommended for patients who are at increased risk. Surgical suction drains do not appear to influence the risk of SSI in PP or orthopaedic surgeries.³⁸ Occlusive and/or silver-impregnated dressings are recommended for routine use instead of standard gauze. A meta-analysis shows that occlusive dressings are associated with lower rate of wound complications; for example, hydrofiber dressings were less likely to have wound complications, such as blister and erythema, than standard passive dressings (odds ratio=0.28).³⁹ Once the dressing is applied, wound coverage for a minimum of 48 hours is recommended unless there is substantial drainage, and the incision site should stay dry during this interval.³⁶ A Mummy-wrap has been suggested as a penile-scrotal compressive dressing to decrease swelling and promote healing 24-48 hours after PP surgery; however, no further concrete wound recommendations exist at this time.³⁴

Irrigation

Based on CDC and World Health Organization (WHO) guidelines, surgical site irrigation with dilute betadine has been considered optimal in orthopaedic surgery. Betadine contains povidone-iodine, which achieves antiseptics by becoming toxic to microorganisms through the release of free iodine.⁴⁰ However, while some studies have shown decreased incidence of PJI following betadine lavage, the effectiveness of this practice has recently been called into question.⁴¹ Additionally, WHO and the National Institute for Health and Care Excellence recommend against the inclusion of antibiotics within the lavage solution, as this may increase antibiotic resistance and has been shown to be less effective than povidone-iodine.⁴⁰ The pressure of the irrigation solution does not seem to influence infection rates, suggesting that low pressure lavage with povidone-iodine is a cost-effective means for irrigation in PP operations. However, implementation of irrigation in the primary PP operation protocol can be challenging as the technique must not disrupt the antibiotic coating layer found in most PPs. Irrigation may best be employed before placing the implant, or after an initial layer of tissue is closed over the device and prior to closing the skin.

Washout

Studies have shown that washout after the removal of the first PP (for non-infectious causes) decreases the risk of infection after revision.¹⁰ As stated before, revision surgeries have a much greater risk of infection compared to primary surgeries. Such infections are hypothesized to originate from the biofilm that occurs after the primary surgery. Washout may help remove any remaining bacteria in spaces around the PP

implant. While a washout is recommended, no data suggests which solution(s) may be best.^{10,11}

Treatments for Implant infection

Diagnosis

A standard protocol for evaluating PPI does not exist; however common approaches may include swab of draining fluid, needle aspiration of fluid, computed tomography or ultrasound imaging, serum testing (complete blood count/C-reactive protein/erythrocyte sedimentation rate), and wound/tissue/device culture in the OR. A multi-institutional study evaluating clinically infected PP explantations have reported device cultures showing no growth or non-specific growth in up to 33% of cases.⁴² In orthopaedic surgery, the use of intraoperative Gram stain is an unreliable test to diagnose PJI. Likewise, swab cultures have weak diagnostic accuracy. Intraoperative tissue cultures (3-5 samples) and synovial fluid, on the other hand, should be collected. A study dedicated to finding the number of cultures needed for pathogen identification found the optimal number of cultures needed for a positive result was 4 in joint replacement surgeries.⁴³

Antibiotic therapy

In the case of active infection, after surgical removal and replacement of a PP, it is recommended to use systemic antibiotics based on culture results from the infection site.¹ Similarly, in the case of PJI, the antimicrobial therapy should be determined based on the organisms present in the joint space. When choosing antimicrobials, biofilm formation should be taken into account, especially in debridement and implant retention (DAIR)

procedures. For both orthopaedic and urologic surgeries, future studies may reveal novel, more reliable methods of local antibiotic administration.

Salvage Surgery & Irrigation

The Mulcahy's salvage technique was introduced as a method to remove and replace an infected PP during the same setting to minimize the development of corporal fibrosis, loss of penile length, and challenging repeat surgery that may result with device removal alone.⁴⁴ A series of antiseptic solutions are used to aggressively irrigate the tissue bed to mechanically remove the biofilm followed by further washing with antimicrobials in the hopes of eradicating remaining bacteria; however, there is no agreement on which solutions should be utilized.¹

There are several classification systems for PJIs; the one proposed by Segawa et al. is based on the clinical presentation.⁴⁵ Type-I, II, III and IV infections are defined as clinically silent infections associated with positive cultures at revision surgery, early postoperative infections (within one month), (late) acute hematogenous infections, and late chronic and typically indolent infections, respectively.^{45,46} The management strategies for each type of infection are very involved and include: for Type-I infections, the revision includes DAIR with replacement of the modular components (i.e., polyethylene, liners), similar to one-stage reimplantation, followed by parenteral antibiotic course for 4-6 weeks, which may be extended to oral antibiotic therapy.⁴⁷ Type-II infections should undergo surgical debridement and component retention, followed by parenteral antibiotics for 4-6 weeks, which may again be followed by oral antibiotics. For Type-III infections, if the symptoms have been present <3 weeks, the implant is well fixed

and the patient is immunocompetent, the salvage strategy consists of debridement, component retention, and parenteral antibiotics. However, biofilms or microbes may still be present on the retained implant components, and taken together with patient comorbidities, literature on DAIR shows a variable success rate (20-100%).⁴⁸ Finally, for Type-IV infections, a one- or two-stage reimplantation strategy is recommended, with resection of the implant, debridement, and a 4-6 week parenteral antibiotic course. The two-stage reimplantation surgery involves using an antibiotic-eluting polymethylmethacrylate static or articulating spacer that occupies the implant space for six weeks or more, after which a new implant is placed.⁴⁶ Literature on this procedure suggests success rates as high as 80%, but warn of increased surgical time, cost, and morbidity.⁴⁷ Overall, most PJIs require a combination of surgical debridement and parenteral and/or oral antibiotic therapy with either retention or replacement of the implant.

Multidisciplinary Approach

Due to the complexity of PJI case management, it is recommended that those cases be referred to a tertiary care center.⁴⁹ Revision surgeries due to infection were found to have longer operative time with more complications than revision surgeries in a study of hip replacements ($p < 0.02$).⁵⁰ Other outcomes such as number of hospitalizations, outpatient visits, and hospital costs were higher for revisions due to infection ($p < 0.001$). At tertiary health centers, patients have access to multidisciplinary healthcare teams consisting of infectious disease specialists, pharmacists, and more. Such teams following well-established care protocols seem to yield the best results in management.⁴⁹ Referring

PPI cases to tertiary care centers may also be beneficial. The summary of treatment strategies in PP and orthopaedic surgeries can be found in Table 2.

Discussion

The field of PP surgery has seen considerable advancements over the last 20 years.^{2,10} For PPI in particular, there has been a multifaceted approach to preventing infection. While these measures have helped, PPI remains a clinically-significant problem. Part of the challenge may be due to the lack of an unified infection prevention protocol among urologists and the fact that the majority of PP are placed by surgeons who perform this surgery relatively infrequently.⁴ This is in contrast to fields like orthopaedic surgery, where surgeons perform implant surgeries at higher volumes and each surgeon tends to specialize in certain procedures (e.g. hip vs shoulder).¹¹

In the fight against implant infections, it is critical to remember that not all responsible organisms are equally susceptible to preventative measures. Recent advances, such as antibiotic-coated PPs and alcohol-based skin antiseptics, have had a substantial impact on decreasing the overall rate of infection with a particular effect on *Staphylococcal* species, which is historically the most common infection organism. However, this also means that the relative prevalence of other organisms such as fungi and Gram-negative bacteria such as *Escherichia coli* have increased, in cases of both overt infection and clinically uninfected biofilms. This changing profile of responsible organisms must be taken into consideration, while planning novel strategies of infection prevention and treatment, especially because these organisms result in sicker patient scenarios.²

In this review, we have highlighted several measures that can be applied to ED surgeries by urologists to decrease the risk for SSI based on the orthopaedic literature. We refer to Tables 1 and 2 for an overview of perioperative measures in ED surgery and orthopaedic surgery. In summary, urologists may benefit from additional measures including nasal screening for MRSA and treating positive cases preoperatively. Extended antibiotic prophylaxis without evidence of infection should be avoided. In the perioperative time period, the surgical site should be prepared with an alcohol-based solution and, if hair removal is required, shaving should be avoided. In the OR, traffic, number of personnel, and operation length should be kept to a minimum. Gloves and suction tips may be changed every hour as well as when contamination occurs. Irrigation should be applied carefully and not disrupt the antibiotic coating on implants, if present. After surgery is complete, occlusive dressings are recommended instead of standard gauze. In the event of a postoperative infection, tissue cultures with 3-5 samples may be required for an accurate diagnosis. A multidisciplinary healthcare team may be best equipped to treat patients with SSIs.

In conclusion, while the advent of antimicrobial-coated PPs as well as other preventative measures have considerably decreased the risk of PPIs, the remaining infections require a reevaluation of practice protocols and creative thinking to find appropriate solutions. The most practical, cost-effective and patient-friendly method of infection control is preventing infections or even the establishment of biofilms that carry the risk of future infections. As research continues to investigate even better antimicrobial coatings and antiseptic washing regimens, we hope that reviewing orthopaedic surgery practices can serve to strengthen the fight against PPIs.

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Figure 1: Schematic representation of biofilm development in penile implants. In the inset, scanning electron microscope image of *Staphylococcus aureus* biofilm on polylactic acid disc *in vitro*; biofilm forms in surface irregularities and propagates outward, as would be seen in the connection points between the reservoir and tubing

Table 1: Summary of perioperative infection control measures, in chronological order of consideration during the surgical timeline

Table 2: Summary of treatments for implant infection, in chronological order of consideration during the treatment and surgical timeline