Current approach to the treatment of penile implant infections

John J. Mulcahy

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Abstract: Modern penile implants, introduced to the market almost four decades ago, have provided a predictable and reliable treatment of erectile dysfunction (ED) despite the development of less-invasive therapies. Infection associated with the placement of these devices does occur, and with prophylactic measures and protocols the incidence has decreased fortunately. In the presence of an infection the implant and all foreign material should be removed. A salvage procedure, during which the wound is thoroughly washed with antiseptic solutions after device removal and placement of a new implant during the same procedure, has a high success rate and is becoming a popular approach. The alternative, device removal with return at a later date for placing a new implant, entails a more difficult corporal dilation, and the resulting erection is noticeably shorter. Patient and partner satisfaction with a penile implant is the highest among all of the treatments for ED.

Keywords: penile implants, infected prostheses, salvage procedures

Introduction

Penile implants, introduced almost four decades ago as the first effective treatment of erectile dysfunction (ED), have stood the test of time and over the years have seen continuous improvement. Less-invasive treatments such as pills, intracorporal injections, intraurethral pellets, and vacuum erection devices have followed, but none of these has been universally effective or acceptable to everyone. Implants still hold a definitive place in the treatment of ED, and, despite problems with reimbursement and other procedures and activities competing for the urologist's time, there have been modest annual gains in the number of devices placed. Over the years the mechanical reliability of the penile implant has improved, and we are now quoting repair rates in the range of 15% at 5 years and 30% at 10 years [Carson *et al.* 2000]. Perfecting surgical techniques and postoperative management has led to fewer adverse events. The penile implant gives a predictable and reliable erection at each encounter and is especially suitable for the patient who has excessive scarring and deformity of the erectile bodies or who has failed medical treatment of his ED or found it unacceptable.

Incidence

Infection associated with penile implant placement has fortunately been an unusual occurrence.

The organisms are thought to enter the open wound during the surgical procedure, and the use of frequent irrigation has minimized the incidence. Hematogenous seeding of infection from another site in the body has been reported [Carson and Robertson, 1988]. Infection rates vary from 0.6% [Montague, 1987] to 8.9% [Thomalla *et al.* 1987] for primary procedures but have in reality ranged between 1% and 3%. Jarow noted an incidence of 13.3% associated with implant repairs and an even higher incidence of 21.7% when penile reconstruction accompanied the repair [Jarow, 1996]. In secondary or tertiary implant surgeries the prolonged operating time, the presence of scar tissue, reduced blood flow, and the use of foreign material such as polytetrafluoroethylene (Gortex) may complicate the procedure and promote bacterial growth. Recently Henry and colleagues found a positive culture rate of 70% in cases of implant repair with no preoperative signs or symptoms of clinical infection [Henry *et al.* 2004]. The organisms were nonaggressive, frequently *Staphylococcus epidermidis*, were thought to have entered the wound at the first surgery, and survived in a protective biofilm. Patients with diabetes mellitus are prone to a variety of infections as high glucose levels in tissues nourish bacteria. Jarow's series [Jarow, 1996] found no difference in the incidence of implant infections among diabetic

Correspondence to:
John J. Mulcahy, MD, PhD, FACS
 314 Cliftworth Place,
 Madison, AL 35758, USA
johnmulc@gmail.com

patients when compared with a group without diabetes. However, Fallon and Ghanem reported a threefold greater infection rate in their diabetic population [Fallon and Ghanem, 1990]. Bishop and colleagues suggested that glycosylated hemoglobin levels, an indicator of diabetes control in the recent past, could be used as a predictor of infection associated with penile implant placement in this group [Bishop *et al.* 1992]. Wilson and associates in a larger series showed that glycosylated hemoglobin, glucose levels, and insulin dependence could not reliably predict the development of postoperative implant infection [Wilson *et al.* 1998]. Patients with spinal cord injury have an increase in the number of positive urine cultures, but according to Diokno and Sonda, penile implant infections were not more commonly seen in this group [Diokno and Sonda, 1981]. This was in contrast to data presented by Wilson and Delk [1995] who found a ninefold higher infection rate among spinal cord injury patients receiving an implant, and Dietzen and Lloyd [1992] whose spinal cord injury population showed a 30% implant infection rate. This group has diminished or absent sensation in the genital region, and the incidence of erosion of a penile implant, especially the semirigid rod type, is higher than in the neurologically intact population [Zermann *et al.* 2006]. Friction as the penis rubs against the undergarments, which would cause pain or discomfort if sensitivity were intact, results in excessive wearing of skin over the end of the implant cylinder leading to eventual erosion to the exterior. Renal transplant recipients can undergo placement of a penile implant without a greater chance of infection when compared with patients who are not immunosuppressed [Sidi *et al.* 1987]. The brand of implant, incision site, number of components, excessive body fat, or prior pelvic irradiation does not seem to affect the incidence of penile implant infection. The rate of implant infection does not seem to be greater if drains are placed at the conclusion of the procedure [Sadeghi-Nejad *et al.* 2005]. Some authors suggest that the performance of simultaneous circumcision and penile implant placement yields a higher infection rate [Fallon and Ghanem, 1990; Thomalla *et al.* 1987]. If placement of a penile implant and a minor genital procedure are to be performed during the same surgery, the implant should be placed first and all incisions related to that procedure closed. Then the circumcision, inguinal herniorrhaphy, etc. can be completed. This will ensure that the time the

wound is open for the implant procedure is not prolonged. If phimosis is present a circumcision should be performed at a prior surgery.

Perioperative preparation

Urinary tract infections should be eradicated before the surgery. The urinary tract is not entered during implant placement, but leakage of urine onto the operative field is a possibility. Patients with a neurogenic bladder are more prone to develop urinary tract infections, and it might be prudent to place these patients on prophylactic oral antibiotics for a few days prior to the surgery to minimize the chance of such an infection developing. Patients who have had a previous radical prostatectomy may have stress urine leakage. Placing a urethral catheter during the operation will reduce the chance of urine spillage and also provide guidance to the location of the corpus spongiosum during scrotal dissection. The patient is advised to bathe the genital area with a strong soap for 3 days prior to the procedure, and the surgical field is shaved after administering the anesthetic. This avoids any small nicks in the skin being colonized with bacteria. Skin lesions such as comedones should be eliminated before the prep lest their contents be expressed into the wound during penile and scrotal manipulation. A thorough skin prep is performed using a strong antiseptic solution. A recent study found the use of chlorhexidine–alcohol solution as a preoperative skin prep to be more effective than a povidone iodine prep for preventing surgical site infection [Darouiche *et al.* 2010]. The most common organism associated with penile implant infections is coagulase negative staphylococcus comprising 58% in a large series [Mulcahy, 2000a]. Other bacteria less commonly seen were *Pseudomonas aeruginosa*, *Serratia marcescens*, enterococcus, *Proteus mirabilis*, and methicillin-resistant *Staphylococcus aureus*. Fungal infections such as *Candida albicans* and anaerobic infections such as *Bacteroides fragilis* can rarely be seen in these circumstances. Recent American Urological Association guidelines have been published dealing with the use of prophylactic antibiotics in a number of genitourinary procedures [Wolf *et al.* 2008]. In prosthetic surgery their use is encouraged systemically starting 1 hour prior to the incision and continuing up to 24 hours postoperatively. This ensures good tissue levels at the time the wound is open. Beyond 24 hours the wound is sealed and further use of antibiotics is unnecessary. The recommended combination is

vancomycin or a third-generation cephalosporin and gentamicin. Vancomycin and the cephalosporins have good efficacy against staphylococcus bacteria, while gentamicin eradicates the Gram-negative rod organisms. These recommendations are based on general surgery literature using synthetic mesh for hernia repair and orthopedic literature reporting on artificial joint placement, as there is no series reported comparing the infection rate when penile implants were placed with prophylactic antibiotic coverage with a group where no antibiotics were used. Some infectious disease experts believe that the use of prophylactic antibiotics in the absence of infection can result in resistant organisms developing, may lead to allergies in some patients, and is unnecessarily costly. As most organisms are introduced into the wound from the skin at the time of surgery, a recent series compared the infection rate using a no-skin-touch technique with the standard insertion procedure by the same surgeon. In the former group a protective adhesive skin drape was applied, the incision made through the drape, and skin hooks immediately placed in the edges of the wound to give surgical exposure without touching the skin during the entire procedure. The infection rate in the no-skin-touch group (0.7%) was less than one third of that in the control group (2.2%) [Siegrist *et al.* 2008]. During the procedure, frequent forceful irrigations containing antibiotics such as bacitracin or rifampin and gentamicin are applied to the wound using an Asepto syringe to wash out any organisms which might have invaded the sterile field. The three-piece inflatable implants of American Medical Systems (AMS) are available with an antibiotic coating called Inhibizone. This is a combination of rifampin and minocycline selected because of the low incidence of allergies to these antibiotics and their efficacy against the bacteria commonly seen in implant infections. The infection rate was reduced by 58% in a series using these coated implants compared with a series of noncoated three-piece inflatable AMS implants [Carson, 2004]. A 7-year evaluation of the Inhibizone-impregnated AMS implant in over 36,000 patients showed a significantly lower infection rate (1.77%) compared with a control group of AMS implants not coated with Inhibizone (3.09%) [Carson *et al.* 2010]. An even greater difference in the infection rate was seen in a subset of over 6000 diabetic patients in that large series who received an Inhibizone-coated implant (2.16%) versus a group of diabetics receiving a non-Inhibizone-coated device (5.3%)

[Mulcahy *et al.* 2010]. The entire line of Coloplast Corporation penile implants has a hydrophilic outer layer of polyvinyl pyrrolidone which adsorbs water and any compounds in solution to the implant surface when it is submerged in that solution. When such an implant is placed in the body, the antibiotics are eluted into the tissues over 48 hours where they can neutralize any bacteria that may have invaded the wound. A significant reduction in the incidence of implant-associated infection was seen when a series of surgeries using the hydrophilic-coated Titan implants (1.06%) was compared with a group of nonhydrophilic-coated Alpha implants (2.07%) [Wolter and Hellstrom, 2004]. A more recent report comparing the infection rate in over 20,000 Titan implant cases (1.4%) was considerably lower than that seen with almost 9000 Alpha devices (4.0%) [Richardson *et al.* 2010]. The dipping solutions in this multicenter series varied. John and colleagues found that, by investigating the in-vitro antibacterial activity of various tested mixtures, the best solution for soaking the Titan implant prior to insertion was rifampin 10 mg/ml and gentamicin 1 mg/ml [John *et al.* 2008].

Signs and symptoms of infection

Signs and symptoms of a penile implant infection may be subtle or dramatic. Fishman and colleagues found that 56% of infections were manifest within 7 months of surgery, 36% between 7 and 12 months, and 2.6% after 5 years [Fishman *et al.* 1987]. Increasing pain at the surgical site or over prosthetic parts, fever, cellulitis, fluctuance around parts of the device, or purulent drainage from the wound, especially after pressing on implant parts, are signs that an infection is present. Prolonged fixation of the pump to the scrotal wall, especially progressive fixation, is a hallmark of infection. An exposed part of the device should be considered contaminated and the entire implant looked upon as infected, as organisms can migrate along tubing to any part of the prosthesis. A question which frequently arises is whether prolonged pain after implant placement represents infection. Pain gradually subsides over 3–6 weeks after surgery, but may be prolonged especially in patients with neuropathy associated with diabetes mellitus. A trial of oral antibiotics such as sulfisoxazole-trimethoprim DS twice a day for 1 month may prove helpful in making a decision. Quinolone antibiotics have been effective in the past, but the development of resistance by organisms to these agents has rendered them less effective.

If pain improves on the antibiotics and then recurs when the medication is discontinued, the presence of an infection is likely, and definitive treatment may be commenced. Fluctuance may represent a hematoma, seroma, or abscess. Prepping the skin over the fluid area with a chlorhexidine–alcohol solution and aspirating the fluid for culture, being careful not to puncture prosthetic parts with the needle, will confirm the diagnosis. An increasing white blood cell count and sedimentation rate suggests infection; when these two parameters are declining, infection is less likely.

Treatment of an infected implant

When infection surrounding an implant is certain, the entire device should be removed. Using oral or systemic antibiotics in an attempt to sterilize the area containing the prosthesis will be difficult or impossible. A sheath of scar tissue surrounds the prosthetic parts as a response to walling off a foreign body. The fibrous sheath has poor blood supply, thus limiting the inflammatory response to the organisms present. Many bacteria produce a biofilm which holds the bacteria together and provides a hiding place to which diffusion of antibiotics is difficult and where nutrients can be trapped to support bacterial growth. The biofilm, composed of a matrix of bacteria, can adhere to the foreign body. When the implant is removed the body's defense mechanisms will clear the infection. The standard procedure for treating a wound infection is to leave the cavity open to heal from the inside out by secondary intention with the help of wet to dry dressings. In the penis this is associated with considerable morbidity and scar formation in the corporal bodies. A successful alternative is to place irrigation drains such as # 7 Jackson–Pratt within the corporal bodies after removing the implant and any foreign material, close the corporotomies loosely around the drain tubing, and close the wound in the standard fashion [Kim *et al.* 1995; Maatman and Montague, 1984]. The wound is then irrigated every 8 hours through the drains with about 10 ml of antibiotic solution usually vancomycin and gentamicin. After 72 hours wound cultures obtained at the time of implant removal will verify that the appropriate antibiotics are being used for the specific infection present, and the drains can be removed. If culture reports dictate, different antibiotics may be substituted and continued for 3 more days. If the drains are not placed and the wound simply closed, an abscess cavity

may develop, which will eventually drain to the exterior. A new implant may be placed 2 months later or beyond. Using a vacuum erection device daily to stretch and straighten the penis after implant removal will minimize the shortening and ventral curvature which invariably results in this circumstance. Replacing implant cylinders in scarred and contracted corporal bodies is a challenge.

An alternative approach in dealing with an infected penile implant is to remove the device entirely, including any foreign material and suture, cleanse the wound with a series of antiseptic solutions, and place a new implant before closing the wound. This method of treatment is termed a 'salvage' or 'rescue' procedure and is gaining in popularity [Fishman *et al.* 1997; Brant *et al.* 1996]. The principles of salvage are to remove foreign material entirely lest any organisms which may be attached to any remnant material continue to be protected in the biofilm. Thorough cleansing and vigorous irrigation of the cavities which contained implant parts will eradicate the organisms. The wound is now assumed to be sterile and a new implant may be placed. In a large series of infected penile implants 101 patients were treated with a salvage procedure with a success rate of 84% [Mulcahy, 2000b]. The antiseptic solutions used were a vancomycin–gentamicin mixture in water, half-strength hydrogen peroxide, and half-strength povidone iodine. The wound was then pressure washed with a water pick using a vancomycin–gentamicin solution, and the initial solutions repeated in reverse order, so that the brown and foamy solutions were cleared out with the clear antibiotic solution. A red rubber catheter was passed to the extremities of the corporal bodies and other cavities containing implant parts to make sure that every part of the wound in contact with the infected device was washed vigorously. After the series of antiseptic washes the operating field was changed with fresh drapes and newly sterilized instruments before placing the new implant. Povidone iodine is 99% bactericidal, hydrogen peroxide will neutralize anaerobic bacteria, and the pressure washing loosens any biofilm still attached to the wound. The characteristics of the failed salvage procedures in the large series noted above [Mulcahy, 2000b] were the short incubation time, virulent organisms, and the presence of extensive cellulitis. If these features are present in a patient with an infected penile implant, a course of systemic antibiotics

such as vancomycin and gentamicin for 3 days prior to a salvage procedure should be considered. Resolution of the cellulitis would indicate that the infection in the tissues is being treated effectively. Once the tissue infection is under control, the cavity infection can be eradicated with the antiseptic washes. Henry and colleagues cultured organisms from the capsule surrounding the pump of clinically uninfected penile implants prior to an antiseptic washing of the wound and found infection in 43% of cases. Following the antiseptic washing they again cultured the pump capsule scar tissue in the same patients and the cultures were positive in 25% [Henry *et al.* 2008]. Using an oral antibiotic with good tissue penetration such as sulfisoxazole-trimethoprim for 1 month after a salvage procedure might be helpful in neutralizing those organisms remaining in the tissues. Relative contraindications to a salvage procedure would be situations where the patient is otherwise very ill, or the likelihood of clearing the infection is remote or nil. These would include the immunosuppressed patient, or patients with sepsis, ketoacidosis, necrosis of penile tissues, or bilateral erosion of cylinders into the fossa navicularis. When one cylinder has eroded into the urethra, the device can be removed, a salvage procedure performed, and a new cylinder placed on the side without the erosion. At a later date the second cylinder may be added.

Delayed salvage has yielded comparable results [Knoll, 1998]. The infected implant is removed, drains are placed and the wound is closed, antibiotic irrigations of the wound are instilled through the drains, and the patient is returned to surgery in 72 hours to place a new implant. This entails two trips to the operating room, the tissues at 72 hours are inflamed and the corporal cavities contracted, and closure of the wound over prosthetic tubing is difficult, especially in the thin patient. Hence, immediate salvage is the preferable approach. Partial salvage has been advocated, but the results are not as successful [Furlow and Goldwasser, 1987]. In this approach parts of the implant are left in place, while the apparently infected or exposed part is removed, the wound thoroughly irrigated, and the new part placed in a different location if possible. Organisms can migrate along tubing to apparently uninfected parts of the implant, and symptoms of infection may be manifest in the future as bacterial propagation occurs. Removal of an infected implant or a salvage procedure should be performed promptly when an

infection is evident. To leave an implant in place hoping the infection will clear with time or prolonged antibiotic use will result in edema and inflammation developing in the penile shaft. Necrosis of the glans penis and corporal bodies has been seen in the presence or absence of infection. This is usually a slowly progressive process resulting from diminished distal perfusion, not necessarily from the infection. Prompt removal of the implant helps take pressure off the ischemic tissues and hopefully leads to better blood flow to the area.

When the urologist encounters a case of an infected penile implant, he evaluates the situation for possible contraindications to a salvage procedure and discusses the pros and cons of both implant removal and salvage. The patient, guided by the urologist's advice, makes the decision. Most patients choose the salvage procedure, as they were so highly motivated to continue sexual activity to have chosen to undergo implant placement initially and wish to maintain erectile ability and preserve erection length. The efficacy of a salvage-type procedure has been demonstrated in other disciplines, where the preservation of prosthetic grafts is essential for life and limb. Bandyk and colleagues successfully replaced 15 infected aortic grafts with no recurrent graft infection [Bandyk *et al.* 1991]. Hip prostheses [Carlson *et al.* 1978] and prosthetic heart valves [Slaughter *et al.* 1973] have been salvaged with a success rate in the range of 90%. Recent evidence has shown that, when the cavity of a clinically uninfected penile implant is cultured during surgery to repair a mechanical defect, a positive culture is obtained 70% of the time [Henry *et al.* 2004]. A minisalvage procedure is recommended in such repairs, consisting of the antibiotic, hydrogen peroxide, and povidone iodine irrigations after removing all prosthetic parts and before placing a new implant. This has been found to reduce the infection rate in secondary implant procedures from 10% to 3% [Henry *et al.* 2005].

Summary

Penile implants have provided a very effective and gratifying solution to the problem of ED, when medical treatments have been ineffective or are unacceptable to the patient. Infection of an implant once required removal with subsequent shortening and curvature of the erection after difficult reinsertion into scarred corporal bodies. Many patients who originally chose the implant

did not return for replacement after removal for infection. Advances in infection prevention have reduced the incidence of this catastrophic occurrence, and salvage procedures have enabled patients to maintain erectile ability and have preserved erectile length.

Conflict of interest statement

None declared.

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