

## Infections Versus Penile Implants: The War on Bugs

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**Purpose:** Infection of an inflatable penile implant is the worst complication in prosthetic urology. This review summarizes the milestone advances that led to today's infection rates being the lowest ever, describes the current profile of the ever evolving bacteriology of device infections and suggests possible future research directions.

**Materials and Methods:** A comprehensive review of the relevant literature was performed and the data from that literature were summarized.

**Results:** Continual refinements in surgical technique and implant design combined with a greater understanding of bacterial virulence factors led to a dramatic decrease in inflatable penile prosthesis infections.

**Conclusions:** Great strides have been made in decreasing the risk of inflatable penile prosthesis infections. The bacteriology of those infections is ever changing. Our continued success hinges on remaining attuned to those changes and adapting current approaches to meet them.

**Key Words:** penile prosthesis, penile implantation, infection, prosthesis-related infections, biofilms

ERECTILE dysfunction is the inability of a man to achieve or maintain an erection sufficient for the successful completion of sexual intercourse. The National Institutes of Health estimate that 30 million men in the United States experience chronic erectile dysfunction.<sup>1</sup> Phosphodiesterase type 5 inhibitors are the usual first line treatment for erectile dysfunction. Patients whose conditions are unresponsive may choose from further pharmacological or mechanical options ranging from intra-urethral prostaglandin pellets and intracavernous injection of vasoactive agents to vacuum erection devices. Inflatable penile prostheses are the definitive therapy for erectile dysfunction that is unresponsive to those nonsurgical approaches.

Scott et al published the first experience with inflatable penile implants in 1973.<sup>2</sup> In the earliest days 30% of

patients experienced device failure within the first 2 years after placement. Mechanical malfunction limited the success of IPP for several decades. Design improvements through the years dramatically decreased the incidence of malfunctions. In a 2007 review the 10-year survival of the latest implants at the time was up to 88.6%.<sup>3</sup> Comparing that number to the revision rates reported for other common prosthetic surgeries, Wilson et al concluded that the "long-term, revision-free survival for the IPP is probably the highest of any medical device implanted in humans."<sup>3</sup> With healthy competition between the 2 implant makers (American Medical Systems and Coloplast) ensuring their commitment to continual product improvement, future long-term survival with these devices is predicted to be even better.<sup>3</sup> Infections were always

### Abbreviations and Acronyms

CNS = coagulase negative staphylococcus

IPP = inflatable penile prosthesis

IV = intravenous

OR = operating room

Accepted for publication May 30, 2012.

Nothing to disclose.

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**Editor's Note:** This article is the first of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 2004 and 2005.

the most disastrous complication of implants, but in the early years the sheer frequency of mechanical failures overshadowed their impact. Achieving these major milestones in device reliability gradually shifted the spotlight onto infections as the most significant problem for patients with inflatable penile prostheses.

## METHODS

A MEDLINE®/PubMed® literature search was done in April 2012 for English language articles from 1995 forward using the key words penile implant infection, penile prosthesis infection, biofilm and infection retardant coating. After eliminating case series with fewer than 3 patients, 23 articles were analyzed and summarized. All references were reviewed and used to provide background narrative where appropriate.

## THE HORRORS OF IMPLANT INFECTION

Implant infections are the most catastrophic complication in prosthetic urology. Full-blown penile prosthesis infections do not respond to IV antibiotics alone. (We now know this is due to the ability of bacteria to produce and hide in biofilm.) The previous standard treatment called for immediate removal of the entire device followed by a lengthy course of IV and oral antibiotics with attempted reimplantation 3 to 6 months later. During that waiting period the spaces once occupied by spongy vascular tissue (and more recently by the device) become filled with dense scar tissue, which must be painstakingly cored out of those fibrotic corporal bodies to make room for the replacement device. Such procedures are exceedingly difficult and fraught with complications. In addition, reimplants have much higher infection rates than virgin implants. All told, the success rate of this approach is only 50% in expert hands. Even when the procedure is successful, delayed reimplant penile length is up to 2 inches shorter than after the first procedure. Thus, patient satisfaction rates are abysmal compared to the stellar ones routinely reported with uninfected primary implants.

In addition, IPP infections take as great a toll on doctors. The several hour, harrowing surgical experience can easily make a surgeon lose his/her enthusiasm for prosthetic urology. The fallout from an implant infection does not stop there. Additional surgeries and hospitalizations increase the potential risk of deep vein thrombosis and other complications in patients. Lengthy recovery prevents rapid return to employment, further burdening patients and society. The cost of treating an infected IPP has been estimated to be more than 6 times the cost of the original placement.<sup>4</sup>

## INFECTION SOURCES

Scott believed that implant infections came from organisms shed by the operating room team and from airborne contamination, and operated only through the ports of a laminar flow protective bubble he developed. More recent studies show that virtually every implant infection comes not from airborne contamination or delayed hematogenous spread but from direct contact with skin flora at surgery. It is believed that every implant becomes colonized with bacteria to some degree during the procedure no matter how compulsive the surgeon's technique. However, bacterial colonization of surgical implants does not necessarily indicate infection. In fact, most colonized implants do not become infected.<sup>5</sup> The body's defenses and preoperative antibiotics are usually enough to prevent these infections.

In the hands of experienced implanters only 4% of patients without risk factors became infected. The rate increases for patients with proven risk factors such as being on prednisone (20%), undergoing revision surgery (10%), or having spinal cord injuries (9%) or diabetes (8%).<sup>6</sup>

Upon formal study many of the factors once thought to influence the risk of implant infection were actually found not to. These include choice of surgical approach (scrotal vs infrapubic), history of radiation therapy, obesity, immunosuppression in transplant cases, hepatitis or HIV, concomitant circumcision and degree of control of diabetes.<sup>7</sup>

## PRESENTATIONS

The bacteria contaminating the wound at surgery come from the surgeon, the OR team and from the patient himself. Before the current era of retardant coated IPPs, the opportunistic skin organisms coagulase negative staphylococcus accounted for 75% of infections (most often *S. epidermidis* but also *S. lugdunensis*). Less often (25%), the more aggressive combatants such as *Escherichia coli*, *Enterococcus*, *S. aureus*, *Serratia* and *Pseudomonas* were responsible.<sup>8</sup>

The timing and symptoms of the infection suggest the identity of the infecting organism. More virulent infections tend to become clinically manifest within 6 weeks of implantation with obvious systemic symptoms (fever, chills, malaise) increasing penoscrotal pain accompanied by swelling and erythema, and purulent wound drainage with eventual device extrusion. Gram-negative bacteria can act synergistically with anaerobic bacteria like *Bacteroides* to cause penile gangrene. Infections with mycobacteria, *Neisseria gonorrhoeae* and fungi have also been reported. However, infections caused by CNS tend to manifest beyond 6 weeks (on average at 6 months after implantation) with a more subclinical, local

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