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An Outcomes Analysis of over 200 Revision Surgeries for Penile Prosthesis Implantation: A Multicenter Study

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ABSTRACT

Introduction. Inflatable penile prosthesis (IPP) implantation is a well-established treatment for medically refractory erectile dysfunction, with long-term reliability. Overall survival is 96% at 5 years and 60% at 15 years for primary (virgin) implantation.

Aim. The aim of this study was to explore factors associated with success and complications of IPP revision surgery in a multicenter study.

Main Outcome Measures. Reasons for revision including mechanical issues, patient dissatisfaction, corporal deformity, and supersonic transport (SST) deformity were recorded.

Methods. At four institutions, 214 clinically uninfected IPP revisions were performed between November 2000 and November 2007. Data were incomplete for 28 cases (14%). Failure-free survival was estimated using Kaplan–Meier's Meier product limit method.

Results. The majority of revisions were secondary to mechanical failure (N = 109; 65%) and combined erosion or infection (N = 17 + 15 = 32; 19%). Sixteen percent (N = 26) were carried out on functional uninfected prostheses secondary to patient dissatisfaction (N = 9), SST deformity (N = 10), scrotal hematoma (N = 2), or upsize revision because of corporal fibrosis (N = 5). Average age at revision was 66 years. Mean follow-up time was 55.7 months. In this study, 12 individuals required a secondary revision procedure or suffered a complication. Despite prior reports of high infection rates with revision surgery, only 5.7% of clinically uninfected and noneroded prostheses were complicated by infection or impending extrusion/erosion, following a revision washout protocol. Overall, 93% of cases were successfully revised, providing functioning IPPs.

Conclusions. For this study population, component exchange followed by revision washout showed a low incidence of infection and subsequent mechanical failure. **Henry GD, Donatucci CF, Conners W, Greenfield JM, Carson CC, Wilson SK, Delk J, Lentz AC, Cleves MA, Jennermann CJ, and Kramer AC. An outcomes analysis of over 200 revision surgeries for penile prosthesis implantation: A multicenter study. J Sex Med 2012;9:309–315.**

Key Words. Penis; Implants; Impotence; Surgery

Introduction

Implantation of inflatable penile prosthesis (IPP) is a well-established treatment for medically refractory erectile dysfunction, with proven long-term reliability. Long-term follow-up data have shown 96% survival at 5 years and 60% survival at 15 years for primary (virgin) implantation [1]. In addition, IPP as a therapeutic modality has been shown to have the highest degree of patient

satisfaction in the treatment of erectile dysfunction [2,3]. Nevertheless, device failure and patient dissatisfaction do occur, requiring surgical repair or replacement [4–7]. The most common cause of mechanical failure is fluid leak from the device [8]. Less commonly, there may be other problems with the IPP, including supersonic transport (SST) deformity, aneurismal dilation of the cylinders, impending lateral extrusion, and desire for upsizing the cylinder [8].

Revision surgery for IPPs is a well-established and largely successful treatment for devices that have become infected or eroded, experienced mechanical failure, or simply have not met with patient satisfaction. There is little known regarding the natural history and survival of revision implantations, especially for mechanical failures, in comparison with primary implants. Prior studies have indicated the risk of infection and failure for replacement of penile prosthesis is significantly greater than for primary cases [8–11]. With regard to primary penile implantation, factors such as diabetes, immunosuppression, and spinal cord injury have been associated with an increased risk of infection and erosion [10]. We sought to evaluate the impact of these comorbidities upon success of revision surgery. We postulated that devices simply repaired, rather than replaced entirely, would be at increased relative risk for both infection/erosion and mechanical failure [12]. In the same vein, we also postulated that a complete prosthesis exchange accompanied by a revision washout procedure, as previously described, may also bear an impact upon outcome by decreasing the risk of infection/erosion [8]. Moreover, our original published study on biofilms in IPPs showed revision cases with positive swab cultures had significantly lower survival time for mechanical failure than those with negative swab cultures [13]. This begs the question: Does revision washout improve mechanical survival rates of revision/replacement IPPs relative to those without the washout procedure? That study also demonstrated that all bacteria isolates cultured, including the most common bacteria found at the time of infection, *Staphylococcus* species, were sensitive to the antibiotic coating of many American Medical Systems (AMS, Minneapolis, MN, USA) IPPs—InhibiZone—a combination of minocycline and rifampin [13].

Few data are currently published in the literature regarding the natural history of revised IPPs. To further investigate outcomes for revised/replaced IPPs, we evaluated survival data, as well as the risk for specific causal failures of these devices over time. There are also minimal published data regarding the type of infections that occur in revised IPPs and whether or not success decreases with increased number of prior revision procedures. We aim to review the factors associated with success and complications of revision penile prosthesis surgery.

Materials and Methods

This was a retrospective evaluation of prospectively followed patients undergoing revision IPP surgery utilizing a pooled dataset from four locations: Shreveport, LA; Van Buren, AR; University of North Carolina—Chapel Hill, NC; and Duke University Medical Center—Durham, NC. This dataset included 214 consecutively followed patients who underwent revision of their IPP between November 2000 and November 2007. For each discrete outcome measure being evaluated, if data were missing from a case, it was not included in the analysis. One of the centers closed during follow-up; consequently, time to prosthesis failure was censored at the date the center closed. The indication for revision varied significantly among this cohort: infection/erosion, mechanical failure of all types, technical surgical issue, and patient dissatisfaction. Institutional review board approval was obtained for the study and all patients provided informed consent before surgery.

Only the 195 patients undergoing revisions for clinically uninfected reasons were included in the analysis of this study. Patients undergoing revision for infection, erosion, or did not have a functioning penile prosthesis at the end of the case were not included in the study. The study involved patients of varied identified ancestry/ethnic origins, including one Arabian, 151 Caucasian, 22 African American, and three Hispanic men.

Patients in this study had a variety of initial and replaced penile prostheses. The known prostheses used were AMS 700 CX models (N = 108) (American Medical Systems, Minnetonka, MN, USA), with a smaller number being Coloplast/Mentor IPPs (Minneapolis, MN, USA), divided nearly evenly between Titan (N = 17) and Alpha-1 (N = 14) cylinders. Rarely utilized penile prosthesis in this study included AMS Ambicor prosthesis (N = 1), Hydroflex IPP (N = 1), and malleable rods (N = 1). This study was not powered to evaluate for significant differences between these groups, and as such, no attempt was made to evaluate the relative reliability of any particular device or manufacturer.

It is also notable that there were minor variations in the method of washout technique employed in this study in terms of the exact antiseptic solutions