

## ORIGINAL RESEARCH—SURGERY

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

Gerard D. Henry, MD,\* Craig F. Donatucci, MD,<sup>†</sup> William Conners, MD,<sup>†</sup> Jason M. Greenfield, MD,<sup>‡</sup> Culley C. Carson, MD,<sup>§</sup> Steven K. Wilson, MD,<sup>¶</sup> John Delk, MD,<sup>¶</sup> Aaron C. Lentz, MD,<sup>§</sup> Mario A. Cleves, PhD,\*\* Caroline J. Jennermann, MS,\* and Andrew C. Kramer, MD<sup>††</sup>

\*Regional Urology, Shreveport, LA, USA; <sup>†</sup>Division of Urology, Department of Surgery, Duke University, Durham, NC, USA; <sup>‡</sup>Department of Urology, Columbia University Medical Center, New York, NY, USA; <sup>§</sup>Department of Urology, University of North Carolina, Chapel Hill, NC, USA; <sup>¶</sup>Institute for Urologic Excellence, Indio, CA, USA; \*\*Department of Biostatistics, University of Arkansas for Medical Sciences, Little Rock, AR, USA; <sup>††</sup>University of Maryland School of Medicine, Baltimore, MD, USA

DOI: 10.1111/j.1743-6109.2011.02524.x

### 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

that were employed. Forty-three of the patients did not undergo a revision washout, while 152 received a revision washout. The washout procedure employed by the surgeons in this study varied slightly but only with regard to which dilute antiseptic solution was utilized. The washout protocol that was universally done was complete device explant, followed by antiseptic lavage of all implant spaces, and subsequent placement of a new device [8]. This is a modification of the original Mulcahy procedure [14]. The washout procedure has evolved, as the mechanical cleansing of lavage combined with entire device explant was felt to be paramount to and simpler than the chemical sterilization of multiple antibiotic solutions.

Nonparametric revision-free duration curves were calculated using the Kaplan–Meier product limit method [15]. Patients were separated into two groups for analysis: group 1—those that underwent revision washout and group 2—those that did not undergo revision washout. There was no significant demographic difference between the two groups. Separate curves were estimated for patients with and without bacterial presence on swab culture and the two curves were compared using the log-rank test. Data management and analysis were performed using Stata version 11 (Stata Corporation, College Station, TX, USA) [15,16].

## Results

The reason for initial revision was unknown for 28 (14%) of the 195 cases being evaluated. Of the remaining 167 revisions, the majority was revised secondary to mechanical failure ( $N = 109$ ; 65%) or combined impending extrusion/erosion or infection ( $N = 17 + 15 = 32$ ; 19%). Sixteen percent ( $N = 26$ ) of the revision surgeries were carried out on functional and uninfected prosthesis secondary to patient dissatisfaction ( $N = 9$ ), SST deformity ( $N = 10$ ), scrotal hematoma ( $N = 2$ ), and upsize revision because of corporal fibrosis at time of initial IPP placement ( $N = 5$ ). The average patient age at time of revision was 66 years. There was no indication of effect of demographic factors, including age, as having an effect upon success with IPP revision surgery.

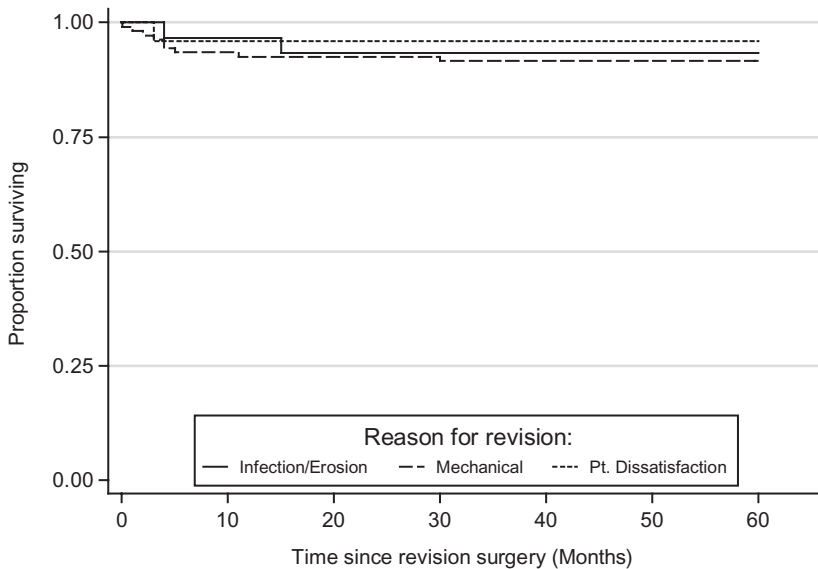
Overall, 5.7% of revised prostheses were complicated with infection or impending extrusion/erosion. If the device was revised but not replaced, infection/impending erosion developed in 9.1% of cases, as compared with 5% when the entire device was replaced. Most importantly, there was a significant impact of revision washout, 4% of cases

which incorporated wash out developed infection or impending extrusion/erosion, as compared with 25% of cases in which a washout procedure was not performed. Overall, 93% of all the patients were successfully revised and left with a functional IPP. Ninety-four percent of individuals with functional satisfactory IPPs at the end of the study period had a washout as part of their revision surgery, as compared with only 80% of those who did not receive a revision washout.

There was no significant effect of the presence of diabetes between groups of patients with surviving IPPs and those who developed an infection following revision surgery (23% and 25%, respectively; Fisher's exact test  $P = 0.5077$ ). In this study, we found 12 individuals required a secondary revision procedure or suffered a complication. Specifically, following revision surgery, there were nine cases of infection or impending extrusion/erosion (specifically three of these presented with erosion). There were two cases of mechanical failure: one each of aneurysmal dilation of the cylinder and autoinflation. Additionally, there was one case of iatrogenic bladder laceration from a repeat procedure. Presented in Figure 1 are the Kaplan–Meier estimated survival curves by original reason for revision. Mean follow-up time was 55.7 months. Time to failure of the revised prosthesis was independent of the reason for revision (log-rank test  $P = 0.7892$ ).

When overall device survival was examined, there was significantly greater survival when a washout procedure was performed (Figure 2). Mean follow-up time for patients who did not undergo a revision washout was 42.8 months (range of 4–60 months) and for those who did receive a revision washout was 56.6 months (range of 1–60 months). Total time at risk for all patients inclusive was 8,917 months. Kaplan–Meier estimated a 5-year survival was 94% when a washout procedure was employed and 60% if no washout was done (log-rank test  $P = 0.0002$ ). Infection-free survival also differed when a washout procedure was employed (Figure 3). Kaplan–Meier estimated a 5-year infection-free survival was 96% when a washout procedure was employed and 69% if no washout was done (log-rank test  $P = 0.0006$ ).

Even with regard to mechanical failure, there is a trend toward a significant difference based on the performance of a washout procedure (Figure 4). Kaplan–Meier estimated a 5-year mechanical failure-free survival was 99% when a washout procedure was employed and 89% if no washout was done (log-rank test  $P = 0.0606$ ).

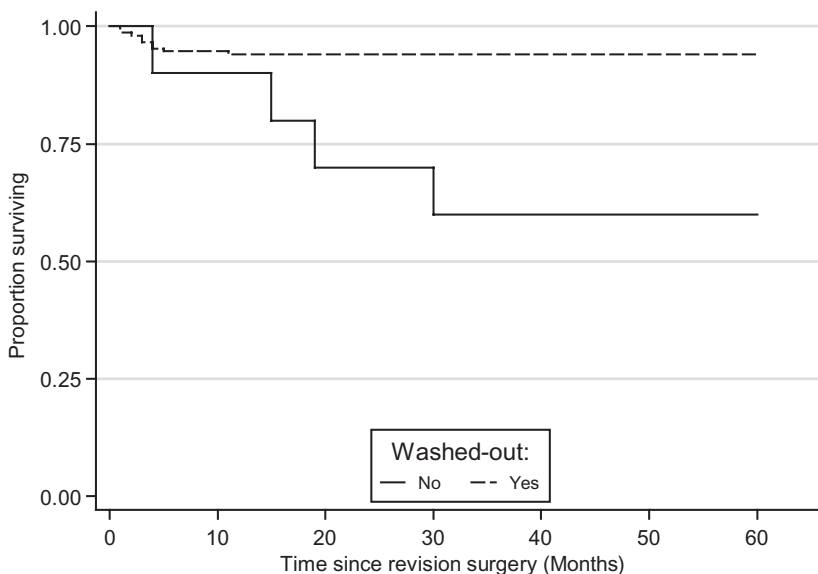


**Figure 1** Kaplan–Meier survival curves by original reason for revision. Log-rank test for equality of survivor functions  $P = 0.7402$ .

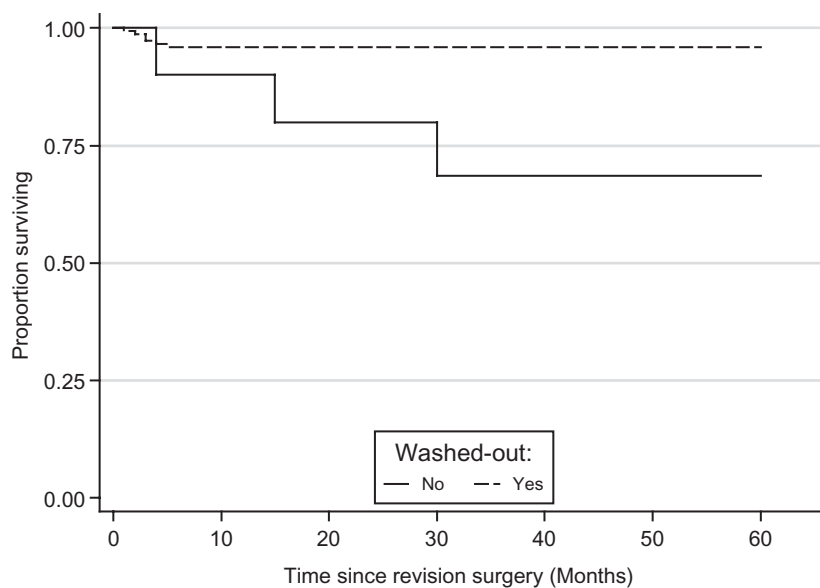
**Discussion**

This study demonstrated some surprising differences with regard to prognostic outcome factors not previously evaluated. Multiple studies indicate an increased risk of infection when repeat operations (revisions) are performed on genitourinary prostheses [8,10,12]. The incidence of primary implantation of an IPP was traditionally 2–4% prior to infection retardant coating and lowered to about 1% with infection-retardant coatings on the IPP [9,11,17]. The traditional infection rate for revision surgery was 8–12% [18,19]. The increased incidence of infection associated with

reoperation was postulated to be caused by decreased host resistance factors, impaired antibiotic penetration of the area because of the capsule surrounding the components, and decreased wound healing related to scar formation. It appears that the vast majority of clinically uninfected penile prostheses have organisms growing in the implant space at the time of reoperation [12,13]. Bacterial biofilm has been detected on devices and quantified using confocal scanning laser microscopy. The degree of biofilm formation on the IPPs studied suggests that most, if not all, patients have bacterial contamination of their implants with most experts in the field of biofilms



**Figure 2** Overall device survival curve comparing those revisions that were washed out vs. those that had no revision washout. Log-rank test for equality of survivor functions  $P = 0.0002$ .

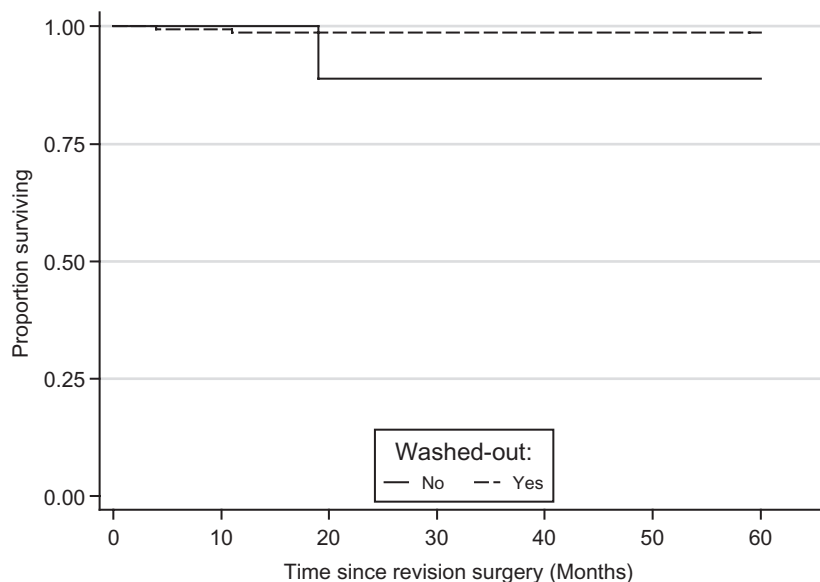


**Figure 3** Device survival curves for infection/erosion/impending erosion comparing those revisions that were washed out vs. those that had no revision washout. Log-rank test for equality of survivor functions  $P = 0.0006$ .

proposing that most likely all implants have bacterial contamination [20]. Something about revision surgery may stimulate the bacteria to become clinically active and symptomatic to the patient, resulting in a higher revision infection rate, as compared with primary implant infection rates. Recent studies show that removing the entire prosthesis and washing out the implant space with an irrigation protocol, coupled with complete replacement of the original prosthesis with an antibiotic-coated IPP, appears to reduce the infection rate of clinically uninfected IPPs undergoing revision surgery [8,21,22]. Simply replacing a

defective prosthesis with an antibiotic-coated IPP *without* the revision washout did not alter revision infection rates [8]. Tissue cultures of the capsule surrounding the implant before and after revision washout showed a decrease in culture positivity and reduced number of multiple isolates after the washout [12].

Prior studies have shown that diabetics having revision surgery without the revision washout had infection rates as high as 18% [18,19]. This study did not find the presence of diabetes to be a significant factor. The authors acknowledge that intuitively, diabetes should affect outcomes, and



**Figure 4** Device survival curves for mechanical failure comparing those revisions that were washed out vs. those that had no revision washout. Log-rank test for equality of survivor functions  $P = 0.0606$ .



perhaps a study with larger number of patients and/or longer follow-up might show a difference in outcomes.

One of the most powerful findings in this study was that a washout procedure appears to be quite helpful in decreasing infection, and perhaps, overall failure. The mechanical irrigation of all implant spaces with dilute antiseptic solution followed by entire device replacement appears to be highly efficacious. Indeed, this is consistent with an earlier study by Montague et al. demonstrating that one irrigating solution done with mechanical washout was as good as the four solution protocol, and revision surgery done in this manner does not carry an increased risk of infection [20]. With long follow-up, our study group showed a significant effect of washout. Four percent of cases in which washout was incorporated developed this dreaded complication, as compared with 25% of cases in which a washout procedure was not performed. Overall, 5.7% of revised prostheses were complicated with infection or impending extrusion/erosion. If the device is revised but not replaced, this complication developed in 9.1% of cases, as compared with 5% when the entire device was replaced. Leaving old components behind may increase the bacterial biofilm load that is known to be on IPPs at the time of revision surgery and possibly increase the infection/erosions/impending extrusion with long-term follow-up [12,13,21,23].

The inclusion of a revision washout procedure appears to have a significant beneficial effect on overall device survival. An impressive estimate, 94% of individuals having a functional IPP at the end of 5 years had a washout as part of their revision surgery, as compared with only 60% of those who did not receive a revision washout. These results, along with a recent article showing a decrease in infection rates in clinically uninfected revision IPP cases for those patients who had a revision washout, suggest replacement of IPP and revision washout maybe considered standard of care at some point in the future [24].

The findings have a tough question to answer: Why would revision washout affect mechanical failure rates? While the finding was not significant, there is a trend toward a significant difference based on the performance of a washout procedure with Kaplan–Meier estimated 5-year mechanical failure-free survival at 99% when a washout procedure was employed and 89% if no washout was done (log-rank test  $P = 0.0606$ ). This finding was surprising to us, similar to how our original biofilm article showed those revision cases with positive

swab cultures had significantly lower survival time for mechanical failure than those with negative swab cultures [13]. Once again we do not have a good reason for the finding. It has been postulated that bacterial biofilm may thicken and harden over the years, causing the tubing to become more friable. Therefore, the documented reduction in bacterial biofilm load associated with revision washout maybe leads to less tubing breakage in those patients undergoing a revision washout [12]. Despite the risks of implant surgery, this procedure affords patients the ability to enjoy very high satisfaction rates, comparable or better than all other forms of therapy in existence today [2].

One limitation to this study was that many patients were retrospectively identified, but followed prospectively. Another limitation is that all the surgeons in the study are experienced high-volume prosthetic urologists and results may not be generalized to all general urologists and while all patients were instructed to scrub preoperatively, and given preoperative and postoperative antibiotics, there was no uniform strategies used between the centers. Moreover, variations in the method of washout technique used at each center may have affected the results and the fact that the group who did not receive a revision washout was smaller than the group of patients who did get a revision washout (43 vs. 152). Lastly, another limitation is that there is no real comparable study in the literature with a large volume of data and/or number of patients undergoing revision IPP surgery.

## Conclusions

Revision surgery of IPPs has acceptably low incidences of infection and mechanical failure. Findings from this study support the idea that revision washout and component exchange is important in lowering infection and possibly mechanical failure rates following revision surgery.

**Corresponding Author:** Gerard D. Henry, MD, Regional Urology, 255 Bert-Kouns Industrial Loop, Shreveport, LA 71106, USA. Tel: (318) 683-0411; Fax: (318) 683-0743; E-mail: GDHenry@hotmail.com

*Conflict of Interest:* There was no funding for this study.

## Statement of Authorship

### Category I

#### (a) Conception and Design

Gerard D. Henry; Craig F. Donatucci; Culley C. Carson; Steven K. Wilson; Andrew C. Kramer

**(b) Acquisition of Data**

Gerard D. Henry; Craig F. Donatucci; Culley C. Carson; Steven K. Wilson; Andrew C. Kramer

**(c) Analysis and Interpretation of Data**

Gerard D. Henry; Mario A. Cleves

**Category 2****(a) Drafting the Article**

Gerard D. Henry; Andrew Kramer

**(b) Revising It for Intellectual Content**

Gerard D. Henry; Andrew Kramer

**Category 3****(a) Final Approval of the Completed Article**

Gerard D. Henry; Andrew Kramer

**References**

- 1 Wilson SK, Delk JR, Salem EA, Cleves MA. Long-term survival of inflatable penile prostheses: Single surgical group experience with 2,384 first-time implants spanning two decades. *J Sex Med* 2007;4:1074-9.
- 2 Rajpurkar A, Dhabuwala CB. Comparison of satisfaction rates and erectile function in patients treated with sildenafil, intracavernous prostaglandin E1 and penile implant surgery for erectile dysfunction in urology practice. *J Urol* 2003;170:159-63.
- 3 Govier FE, Gibbons RP, Correa RJ, Pritchett TR, Kramer-Levien D. Mechanical reliability, surgical complications, and patient and partner satisfaction of the modern three-piece inflatable penile prosthesis. *Urology* 1998;52:282-6.
- 4 Montorsi F, Rigatti P, Carmignani G, Corbu C, Campo B, Ordesi G, Breda G, Silvestre P, Giammusso B, Morgia G, Graziottin A. AMS three-piece inflatable implants for erectile dysfunction: A long-term multi-institutional study in 200 consecutive patients. *Eur Urol* 2000;37:50-5.
- 5 Tiefer L, Moss S, Melman A. Follow-up of patients and partners experiencing penile prosthesis malfunction and corrective surgery. *J Sex Marital Ther* 1991;17:113-28.
- 6 Kava BR, Yang Y, Soloway CT. Efficacy and patient satisfaction associated with penile prosthesis revision surgery. *J Sex Med* 2007;4:509-18.
- 7 Henry GD, Kansal NS, Callaway M, Grigsby T, Henderson J, Noble J, Palmer T, Cleves MA, Ludlow JK, Simmons CJ, Mook TM. Centers of excellence concept and penile prostheses: An outcome analysis. *J Urol* 2009;181:1264-8.
- 8 Henry GD, Wilson SK, Delk JR II, Carson CC, Wiygul J, Tornehl C, Cleves MA, Silverstein A, Donatucci CF. Revision washout decreases penile prosthesis infection in revision surgery: A multicenter study. *J Urol* 2005;173:89-92.
- 9 Carson CC. Efficacy of antibiotic impregnation of inflatable penile prostheses in decreasing infection in original implants. *J Urol* 2004;171:1611-4.
- 10 Carson CC. Infections in genitourinary prostheses. *Urol Clin North Am* 1988;16:139-47.
- 11 Wolter CE, Hellstrom WJ. The hydrophilic-coated inflatable penile prosthesis: 1-year experience. *J Sex Med* 2004;1:221.
- 12 Henry GD, Carson CC, Wilson SK, Wiygul J, Tornehl C, Cleves MA, Simmons CJ, Donatucci CF. Revision washout decreases implant capsule tissue culture positivity: A multicenter study. *J Urol* 2008;179:186-90.
- 13 Wilson SK, Delk JR II, Carson CC, Silverstein A, Cleves MA, Donatucci CF. Penile prosthesis cultures during revision surgery: A multicenter study. *J Urol* 2004;172:153-6.
- 14 Mulcahy J. Long-term experience with salvage of infected penile implants. *J Urol* 2000;163:481-2.
- 15 Lee E. Statistical methods for survival data analysis. 2nd edition. New York: Wiley; 1992:67-78, 109-12.
- 16 Cleves MA, Gould WW, Gutierrez RG. An introduction to survival analysis using STATA. College Station, Texas: Stata Press; 2002:51-69, 93-102, 113-5.
- 17 Wilson SK, Zumbé J, Henry GD, Salem EA, Delk JR, Cleves MA. Infection reduction using antibiotic coated inflatable penile prosthesis. *Urology* 2007;70:337-40.
- 18 Wilson SK, Delk JR II. Inflatable penile implant infection: Predisposing factors and treatment suggestions. *J Urol* 1995;153:659-61.
- 19 Brant MD, Ludlow JK, Mulcahy JJ. The prosthesis salvage operation: Immediate replacement of the infected penile prosthesis. *J Urol* 1996;155:155.
- 20 Montague DK, Angermeier KW, Lakin MM. Penile prosthesis infections. *Int J Impot Res* 2001;13:326-8.
- 21 Silverstein AD, Henry GD, Evans B, Pasmore M, Simmons CJ, Donatucci CF. Biofilm formation on clinically non-infected penile prostheses. *J Urol* 2006;176:1008-11.
- 22 Kava BR, Kanagarajah P, Ayyathurai R. Contemporary revision penile prosthesis surgery is not associated with a high risk of implant colonization or infection: A single surgeon series. *J Sex Med* 2011;8:1540-6.
- 23 Hsi RS, Hotaling JM, Spencer ES, Bollyky PL, Walsh TJ. Isolated infection of a decommissioned penile prosthesis reservoir with *Actinomyces neuii*. *J Sex Med* 2011;8:923-6.
- 24 Abouassaly R, Angermeier KW, Montague DK. Risk of infection with an antibiotic coated penile prosthesis at device replacement for mechanical failure. *J Urol* 2006;176:2471-3.