CLINICAL ARTICLE SUMMARY

Long-Term Revision Rate due to Infection in Hydrophilic-Coated Inflatable Penile Prostheses: 11-Year Follow-Up

Ege Can Serefoglu, MD
Sree Harsha Mandava, MD
Ahmet Gokce, MD
Jyoti D. Chouhan, MS
Steven K. Wilson, MD, FACS, FRCS
Wayne J.G. Hellstrom, MD, FACS

The Journal of Sexual Medicine
2012;9:2182-2186.

ABSTRACT

Introduction: Penile implant surgery continues to be an important option for men with erectile dysfunction. Advancements in technology of implants have contributed to improved survival from mechanical breakdown. Prosthesis infection remains a serious adverse event. For the last 8 years, the Titan® implant (Coloplast Corporation, Minneapolis, MN, USA) has been available with an infection-retardant polyvinylpyrrolidone coating.

Aim: To compare the infection rates between coated three-piece inflatable penile prostheses (IPPs) with the previous non-coated model.

Main Outcome Measures: Infection-related revisions reported in the physician-generated, manufacturer-tabulated patient information forms (PIFs).

Methods: PIFs reported into the voluntary, post-market registry of Coloplast Corporation from July 14, 2000 to September 30, 2011 were retrospectively reviewed. Infection-related revisions entered into the product evaluation database for coated and non-coated IPPs were compared. Data were analyzed using Pearson's chi-squared test.

Results: The database included 36,391 PIFs related to primary IPP implantation. At 11 years of follow-up, 4.6% (7,031) of non-coated IPPs were removed or replaced due to infections, whereas 1.4% (29,360) of hydrophilic-coated implants reported replacements due to device infections. The hydrophilic coating of the IPP components makes the device slippery and prevents bacterial attachment. The hydrophilic coating allows rapid absorption of antibiotics in an aqueous solution and allows these water-soluble antibiotics to elute off the device into the implant spaces. Unfortunately, information pertaining to what agents were used in the studies patients was not tabulated. The rate of revision due to device infection was reduced 69.56% in patients with hydrophilic-coated IPPs ($P < 0.001$).

Conclusion: To the best of our knowledge, this is the longest post-marketing registry report related to IPP infections. At 8 years of follow-up, the hydrophilic-coated IPPs demonstrated a significant reduction in revision rates due to infection when compared with the 11-year follow-up of non-coated implants. Since there was no information or uniformity of antibiotics used in the soaking solution, it is uncertain which antibiotic selection provided the best results. In vitro testing against known infectious agents may further benefit IPP patients by reducing the prosthesis infection rate.

Coloplast

COLOPLAST KEY TAKEAWAYS

- The introduction of hydrophilic coating on the Coloplast Titan implant provides a significant benefit in reducing the revision rates related to postoperative infections.
- To our knowledge, this is the longest outcome analysis with 8-11 years of follow-up and provides statistical evidence of the infection reducing capabilities of using hydrophilic coating in IPPs.
- In this study of 36,400 implants, the rate of infection with hydrophilic-coated IPPs was significantly lower then non-coated devices (1.4% vs. 4.6%, P <0.001).
- As they were not part of current PIF, other variables that could not be included in this analysis include the surgeon's skill level which was found to be a risk factor for post-IPP infection, the type of prophylactic antibiotic used, surgical site painting, and differences in surgical technique.

BRIEF STATEMENT

Indications: The Titan® and Titan Touch Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are considered to be candidates for implantation of a penile prosthesis.

Contraindications: The Titan, and Titan Touch Inflatable Penile Prosthesis is contraindicated in patients who have one or more of the following: Patients with an active infection present anywhere in the body, especially urinary tract or genital infection. Patients with a documented sensitivity to silicone. Patients with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder. Patients unwilling to undergo any further surgery for device revision.

Warnings: Implantation of the device may make latent natural erections, as well as other interventional treatment options, impossible. Men with diabetes or spinal cord injuries, as well as immunocompromised patients, may have an increased risk of infection associated with a prothesis.
Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition, leading to infection and loss of tissue. Implantation of a penile prosthesis may result in penile shortening, curvature or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical.

Precautions: Surgeons implanting penile prostheses should be familiar with the currently available techniques for measuring the patient, determining implant size, and performing the surgery. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or make it impossible. A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits. The prosthesis should not be implanted in patients who lack the manual dexterity or strength necessary to operate the device. The device may be used in the presence of Peyronie's Disease. If the manual modeling technique is to be utilize, see the Surgical Protocol for more information.

Potential Complications: Scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention, fever, migration, patient dissatisfaction, site infection, deflation, hematoma/seroma, wound leakage, bleeding, delayed wound healing, phimosis, sensory loss, cylinder aneurysm, fibrous capsule formation, over/under inflation, erosion scrotal erythema, genital change, wound infection, and inguinal hernia.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings and precautions refer to the product's Instructions for Use.
Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Ostomy Care / Continence Care / Wound & Skin Care / Interventional Urology

Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476
www.coloplast.us

PM-06010 02.22