Clinical Article Summary

Clinical Outcome: Patient and Partner Satisfaction after Penile Implant Surgery

Cedric Jorissen
Helene De Bruyn
Evert Baten
Koenraad Van Renterghem

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Abstract

Background: Erectile dysfunction (ED) is a common disorder, which affects at least 50% of males aged 50–70 years. According to EAU Guidelines on male sexual dysfunction, implantation of an inflatable penile prosthesis (IPP) is a valid, third-line therapeutic option for treatment of ED.

Objective: We conducted a retrospective single centre study to analyze mechanical reliability, complication rate, patient satisfaction and quality of life after penile prosthesis implantation.

Materials and Methods: A total of 126 electronic patient files after primary implantation of an IPP during a 5-year period were investigated. A structured telephone interview concerning patient and partner satisfaction was conducted at least 1 year after implant surgery.

Results: We found that 15 patients (11.9%) had revision surgery for various reasons. Mechanical failure occurred in 7.14% of the patients and was the main reason for revision surgery. Other major complications and complaints were loss of penile length (18.53%), postoperative pain (11.9%) and altered sensation (8.73%). No patients required explantation for infection, and 1 patient (0.79%) underwent revision surgery for an imminent erosion. One year or more after surgery, the patient and partner satisfaction rates, were 83.2 and 85.4%, respectively. We observed very high patient and partner satisfaction rates for the implantation of an IPP, with improvement of the general quality of life. These rates are negatively influenced by the occurrence of postoperative complications and complaints such as postoperative penile length shortening, pain and floppy glans syndrome. Most patients regain sexual function 6 weeks after surgery with no or minimal effect on the orgasm.

Conclusion: The implantation of a 3-piece IPP has proven an effective, third-line treatment for patients with ED.

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Coloplast Key Takeaways

- The satisfaction rate of patients with the Coloplast Titan was 91.1% while the patient satisfaction rate for the AMS LGX was 80.4%. However, this difference was not significant.
- Of the nine mechanical failures, seven (77.8%) occurred with an AMS prosthesis.
- Seventy-six out of 93 (85.4%) partners were happy with their partner's inflatable penile prosthesis.
- Quality of Life (QoL) ratings were evaluated on a subjective scale ranging from zero to five. Before the implantation of an IPP, patients averaged a score of two out of five. One year or more following surgery, this score improved to three out of five, a 30% improvement.

Titan & Titan Touch Inflatable Penile Prosthesis Brief Statement

Indications: The Titan Inflatable Penile Prosthesis is indicated for male patients with erectile dysfunction who are considered to be candidates for implantation of a penile prosthesis.

Contraindications: The Titan Inflatable Penile Prosthesis is contraindicated in patients who have one or more of the following conditions: Patients with an active infection present anywhere in the body, especially urinary tract or genital infection. Patients with a documented hypersensitivity or allergic reaction to silicone or polyurethane. 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: The Titan device should only be implanted by physicians experienced in the surgical procedures involving implantation of a penile prosthesis. Physicians should advise prospective patients, prior to surgery, of the warnings, precautions and potential complications associated with the use of this product, which may include the following: Potential for resurgery (Note: device is not a lifetime implant). Implantation makes latent natural erections, as well as other interventional treatment options, impossible. Implantation may result in penile shortening, curvature or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical. Diabetic, as well as immunocompromised patients, may have an increased risk of infection which could result in permanent damage to tissue/organs. Vigorous exercise and manual massage could lead to device damage. Certain stresses and pressures (straddle seating, obesity, etc.) could lead to involuntary inflation or deflation.

Precautions: Patients with spinal cord injury may have an increased risk of infection. This device may be used to treat ED in the presence of Peyronie's disease. A thorough preoperative consultation should include a discussion between the patient and physician of available treatment options and their risks and benefits. Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: Ability and willingness of the patient to follow instructions. Associated psychological status (e.g. psychogenic erectile dysfunction, inappropriate attitude or motivation). Health conditions which hamper sexual activity, such as severe angina, may prevent successful use of this device. Manual dexterity problems.

Potential Complications: Adverse events are known to occur with penile prostheses procedures and implants; some may require revision surgery or removal of the implant. Adverse events following penile prostheses implantation may be de novo, persistent, worsening, transient, or permanent.

Adverse events may include but are not limited to: Acquired phimosis, Adhesion(s), Bladder storage symptoms, Capsular contracture, Deformity, Delayed/Impaired/Abnormal wound healing, Discomfort, Erosion/Extrusion, Fistula, Foreign body reaction, Hematoma/Seroma, Hemorrhage/Bleeding, Hernia, Hypersensitivity/Allergic reaction, Induration, Infection (local or systemic), Inflammation (including, but not limited to edema, erythema, redness, swelling), Male Dyspareunia, Necrosis, Obstruction/Occlusion, Pain, Perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bowel, bone, bladder, urethra, ureters), Scar tissue, Sexual dysfunction, Tactile disorders, e.g., hypoesthesia, numbness, Urinary incontinence symptoms, Urinary tract infection, Voiding symptoms.

The occurrence of these events may require one or more subsequent surgeries which may or may not always fully correct the complication.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events 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 law (USA) restricts this device to sale by or on the order of a physician.

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