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Penile Prosthesis Surgery: Current Recommendations From the International Consultation on Sexual Medicine

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ABSTRACT

Introduction: Penile prosthesis implantation has emerged as a definitive treatment to restore sexual function to the motivated man with erectile dysfunction. Substantial improvements in the design of inflatable devices have been made since they first became available more than four decades ago.

Aim: To review the history of the penile prosthesis, the indications, preoperative evaluation, and patient and partner satisfaction. The current approaches to addressing intra- and postoperative complications, provide an understanding of prosthesis infection, and placement of these devices will be reviewed.

Methods: A committee of worldwide experts in this field was assembled during the 2015 International Consultation on Sexual Medicine (ICSM) and performed a systematic review of the peer-reviewed published medical literature pertaining to penile prosthesis. Particular attention was given to higher level trials when available. Recommendations are based upon the Oxford Criteria.

Main Outcome Measures: Unfortunately there is limited level 1 and 2 evidence, and where expert opinion was utilized, the decision was unanimous within the committee with a goal of presenting a clinically relevant guideline pertaining to penile prostheses.

Results: Penile prosthesis has undergone an evolution over the past 40 years resulting in a more effective and reliable treatment for advanced erectile dysfunction not responding to less invasive methods including oral treatment with PDE5 inhibitors, vacuum erection device, and intracorporal injection therapy. It should be considered an appropriate treatment option for the man who wishes to restore erectile function and who understands the potential risk of mechanical failure and infection, both of which are less common now as a result of improvements made in device design as well as surgical protocols adhered to in the operating room. Patients must be clearly informed of the risks associated with penile prosthesis including mechanical failure, infection, shortening of the penis, change in sensation and configuration of the penis, as well as injury to local structures. Intraoperative complications are unusual but do occur and can usually be addressed intraoperatively to allow placement of the device at the time of initial surgery. Postoperative complications may also be addressed when they occur but may require more advanced reconstructive surgical techniques. Men with Peyronie's disease, corporal fibrosis due to infection, trauma, prior prosthesis explantation, priapism, and men who have undergone construction of a neophallus may require additional advanced maneuvers to obtain optimum results with a penile prosthesis.

Conclusion: Penile prosthesis remains as an important, viable, and effective treatment for male erectile dysfunction that does not respond to other less invasive approaches or when these approaches are contraindicated or not acceptable to the patient. These devices provide the patient with the ability to engage in penetrative sexual activity without interfering with urination, ejaculation, sensation, or orgasm. Although mechanical failure can occur, the current devices are more reliable as a result of design modifications. Infection remains the most dreaded complication but since the introduction of antibiotic and hydrophilic coatings, infection is less common.

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Overall, patient and partner satisfaction appear to be reasonably high when a penile prosthesis is used to restore erectile function.

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INTRODUCTION

Prosthetic devices have been used to augment, replace, or restore penile function for more than 500 years. The primary goal of PP insertion is restoration of normal erectile function to allow penetrative sexual activity, and with the introduction of inflatable devices more than four decades ago, the use of PPs quickly became the gold standard therapy for medically refractory ED. Ongoing improvements have greatly improved all outcome measurements, with contemporary studies reporting consistently high satisfaction and lower complication rates. Currently, the role for PP in the management of ED is well established with several devices available to permit prosthesis insertion in virtually any clinical scenario. A large body of evidence has described techniques for enhancing device insertion, preventing infection, and managing intraoperative and postoperative complications, which are reviewed in this article.

NOTABLE DEVICE ALTERATIONS

Several device enhancements have directly resulted in improvements in mechanical reliability, intra- and postoperative complications, revision surgery, and overall satisfaction. An understanding of the history of noteworthy modifications is essential to interpret outcomes in the literature accurately, including the true rates of mechanical and overall device survival. A detailed discussion of this history is beyond the scope of this article and is presented in Table 1.[1–14]

The development of silicone was critical for the success of the penile implant. With the increased pliability of silicone, novel devices were technologically feasible, and in 1973, the IPP heralded a new era of penile implants. Silicone greatly decreased infection rates and offered a biocompatible, flexible, and resilient material that continues to be used in many contemporary devices.[1] The enhancements with inflatable devices improved the ability to achieve truly erect and flaccid states while optimizing concealment, decreasing erosion, and permitting urethral instrumentation when required.[2,15]

In 1983, a proprietary polyurethane, Bioflex, was used with the Mentor (now Coloplast; Minneapolis, MN, USA) three-piece IPP and provided significant improvements in penile cylinder strength. This decreased the rate of cylinder aneurysms and fractures and provided enhanced strength over silicone. To address the inherent limitations of silicone compared with Bioflex, American Medical Systems (AMS; Minnetonka, MN, USA) incorporated a woven fabric layer and three-ply system to devices in 1987, which helped provide additional strength and restrict expansion of the silicone, thus decreasing cylinder aneurysms.

One early challenge with placement of penile prostheses was frequent kinking of the device tubing. The later development of kink-resistant tubing (AMS, 1986) and nylon-reinforced tubing (Mentor, 1987) and the introduction of connector-less devices (Mentor, 1989) and pre-connected cylinders (AMS, 2000) served to decrease tubing-related complications. Parylene coating was introduced by AMS in 2000, which enhanced the mechanical strength of the devices. This improvement resulted in significant decreases in mechanical failure and related complications.[16] Although not directly related to improving mechanical reliability, the introduction of antibiotic impregnation (InhibiZone; AMS) and hydrophilic coatings (Titan; Coloplast) represent significant milestones in device manufacturing with resultant decreases in infection rates.

INDICATIONS FOR SURGERY

For men with ED alone, PPs are often considered third-line therapy after inadequate response or inability or refusal to use phosphodiesterase-5 inhibitors, intraurethral or intracavernosal injections, and vacuum erection devices. Men with combined ED and PD requiring surgical management could benefit from earlier placement of a PP, particularly in cases in which the patient is poorly responsive to phosphodiesterase-5 inhibitors.[16–19] The previously held notion that a PP is the last resort for treatment of ED should be reconsidered, because the PP could be the best option depending on the clinical scenario.

In addition to clinical indications, appropriate patient selection is an important aspect of PP surgery. Certain patient characteristics can place candidates at higher risk for postoperative dissatisfaction and should be taken into account when discussing placement of a PP.[20] Similarly, appropriate and thorough informed consent is an essential component of patient education, with postoperative satisfaction relating in part to established preoperative expectations.[21]

The operative decision to place a malleable, two-piece, or three-piece IPP is based on several factors, including patient