

Review Article

First implantation: preparation, setup and implantation for malleable penile prosthesis

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Abstract

Treatment for erectile dysfunction (ED) is becoming more common in Thailand. The spectrum of treatment varies from non-invasive techniques such as medication, to counseling for invasive treatment such as injection and finally to penile prosthesis implantation. As the demand for penile implant surgery increases it is increasingly crucial to ensure thorough preparation and patient care in order to minimize the risk of harmful complications, for example device infection. This review article aims to provide guidance on various aspects of the surgical process, including pre- and intra-operative patient preparation, essential equipment and supplies, and step-by-step surgical techniques. It also offers key pointers for post-operative care. This article may be valuable for those looking to start performing penile prosthesis surgery or for those seeking to improve their current practices. Literature was reviewed from PubMed and Google scholar databases. This article provides crucial information on patient selection, pre-operative counseling, surgical setup and technique, and post-operative care for malleable penile prosthesis implantation. A penile prosthesis is an excellent option for men with refractory ED as opposed to medical treatment or with contraindications to medical management. However, this operation is still relatively uncommon in Thailand. Malleable prostheses offer advantages including being cost-effective, having a low risk of malfunction, and being easier to implant in comparison to inflatable implants. This review aims to encourage, reassure, and convince new implanters to complete all spectrums of ED treatment.

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Introduction

Roughly one-third of patients with erectile dysfunction (ED) (30-35%) may not experience positive results from treatment with phosphodiesterase-5 inhibitors (PDE5i).¹ Challenges such as insufficient dosage, inappropriate dose adjustments, and titration may explain this lack of

response. Despite proper use of PDE5i, some ED patients may still not respond.² Aging, advanced cardiovascular issues, uncontrolled diabetes, metabolic syndrome, late-onset hypogonadism, and previous pelvic surgeries are known factors that can significantly decrease the effectiveness of PDE5i treatment for ED.³

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Penile prosthesis implantation is becoming an increasingly popular treatment option for men with refractory ED and is being performed internationally by urologists. However, this operation remains relatively rare in Thailand. A known issue in surgical training is that many trainee surgeons lack exposure to practical surgical training. Unfortunately, there is no simulation or cadaveric model available to supplement the training of residents, fellows, and low-volume penile prosthesis surgeons to enhance their procedural knowledge and confidence in penile prosthesis placement.

The malleable penile implant is often considered to result in lower levels of satisfaction compared to the three-piece inflatable penile prosthesis implant.⁴ However, it possesses unique benefits, including ease of use and being more cost effective, and is also associated with fewer mechanical complications than inflatable prostheses. A previous study showed that the malleable prosthesis can achieve excellent clinical outcomes in patients with both erectile dysfunction and Peyronie's disease.⁵ In a recent study, Habous et al.⁶ found that the size of the malleable penile implant (9.5 and 11 mm vs. 13 mm) does not significantly impact patient satisfaction (75.7% vs. 88.6%).

Additionally, a review of satisfaction rates for both the inflatable penile prosthesis (IPP) and malleable penile prosthesis (MPP) demonstrated that the average satisfaction rate for IPP and MPP were 86.2% and 75.1%, respectively.⁷ These findings can play crucial roles in decision-making for new implant surgeons and patients. This article provides details about patient selection and evaluation, pre-operative preparation, and also reviews different surgical techniques. The author hopes that this article will serve as a driving force to encourage, reassure, and convince new implanters.

Materials and Methods

Literature was reviewed using PubMed and Google Scholar databases. "Penile prosthesis", "Malleable penile prosthesis", "Surgical preparation penile prosthesis", "Surgical technique penile prosthesis" and "Complication penile prosthesis" were included in the search terms. Articles from well-known high-volume implanters, specifically Steven K Wilson, Tobias S Köhler, Paul Petit, Jean F Eid, and Daniar Qsmonov, and their references during 1980-2023 were selected for

extraction. The results are described in narrative fashion.

Results

Patient selection and evaluation

One of Dr. Wilson's favorite pieces of advice for novice implanters is, "NEVER IMPLANT A STRANGER." Implantation of a penile prosthesis is the most invasive and less frequently chosen option, but once these devices are placed, patients and their partners are generally satisfied with the resulting erections, as reported by Levine et al.⁸, with 96% of patients and 91% of partners expressing satisfaction. However, a negative outcome, or even a positive outcome with an unsatisfied patient, can have significant adverse physical and emotional effects on both the patient and the surgeon.

Before proceeding with penile prosthesis implantation, the implanter and the patient must consider various factors to determine whether the patient is a suitable candidate for an implant.

Dos for implant discussion

- Do document the failure or contraindication of treatment with Phosphodiesterase 5 inhibitors (PDE5i). Ensure that patients are aware of second-line treatments such as vacuum devices and intracavernous injections.

- Do ensure that patients fully comprehend the risks associated with infection. Primary procedures have infection rates ranging from 0.6% to 8.9%, with more complex procedures, such as excising Peyronie's plaques or implanting in severe corporal fibrosis, showing higher rates.^{9,10} Wilson and Delk¹¹ observed a staggering nine-fold increase in infection rates among spinal cord injury patients with implants. It is important for patients to recognize and act on any symptoms of infection, such as increasing pain at the surgical site or over prosthetic parts, fever, cellulitis, fluctuance around device components, and purulent drainage from the wound, particularly after pressing on implant parts. In cases of confirmed infection around an implant, removal of the entire device is necessary.

- Do discuss the issue of penile implant length. It is important to clarify that a penile implant will not make the penis longer. One major concern among patients who have undergone penile implants is the perceived decrease

in length compared to their natural erections when they were younger. According to a study by Devici¹², there were no significant differences in penile length after surgery when compared to preoperative measurements. However, it is essential for surgeons to effectively communicate with patients and manage their expectations. It should be emphasized that a prosthetic erection does not result in any engorgement or increase in glans size. Patients should also be informed that penile sensitivity, sexual desire, and ejaculatory function will not be affected by the surgery.^{13,14}

- Do inform patients about the choice of implant. Malleable devices are the easiest to implant, are cost-effective, simple to use, and require less technical skill and surgical knowledge for implantation. However, they may not be the best choice for patients with a short penis because the implant tends to cause the penis to stick out from the body's plane and may not provide sufficient length for bending the organ. In the long term, the implant can compress the erectile tissue in the corporal body and create a "finger in the glove" appearance. Three-piece inflatable devices are more realistic and result in high satisfaction rates, however they require patients to practice operating them and demand greater surgical skill for implantation. In 12 studies (20,161 patients; median age 57 years), survival of an IPP device was 93.3% at 1 year, 91.0% at 3 years, 87.2% at 5 years, 76.8% at 10 years, 63.7% at 15 years, and 52.9% at 20 years.¹⁵

Patient non-psychological factors

There are various factors that can affect the success of surgery, specifically the severity of any underlying condition, previous procedures having been performed on the surgical site, any co-morbidities (such as diabetes, cardiovascular or pulmonary diseases) and medication that may hinder healing. It is crucial to carefully consider these factors and assess the potential risks and benefits of undergoing surgery. However, patients with poorly controlled diabetes should not automatically be excluded from surgery for the rest of their lives. Instead, it may be more logical to have a discussion with the patient about the possibility of a higher risk of infection compared to someone without diabetes or with well-controlled diabetes, and then allow the patient make an informed decision. Habous et al.¹⁶ found that

in 902 patients (685 MPP, 217 IPP), the mean HbA1c level was 8.0%, with 81% of men having a HbA1c level of >6%. The overall infection rate was 8.9% (80/902). Using ROC analysis, they determined that an HbA1c threshold level of 8.5% predicted infection with a sensitivity of 80% and a specificity of 65%.

Preoperative preparation

The best practice statement of the American Urological Association recommends the use of two intravenous (IV) antibiotics before incision, specifically an aminoglycoside in combination with either a 1st or 2nd generation cephalosporin or vancomycin.¹⁷ The Center for Disease Control and Prevention (CDC) recommends that hair not be removed unless it will interfere with the operation, and if hair is to be removed it is done immediately before the operation with electric clippers rather than shaving.¹⁸ Chlorhexidine scrub solution needs to be used for preoperative skin preparation. Unlike iodophor-based preparations, chlorhexidine is not inactivated by blood or serum proteins, and it has been demonstrated that it has a greater residual activity than traditional povidone-iodine after a single application.¹⁹

Equipment and procedure setup

- Position: The patient is positioned supine in a modified "frog-legged" position.

- Skin Preparation: Prior to penile implant surgery, the skin is prepared by scrubbing with a Chlorhexidine solution for 5-10 minutes.²⁰ This step, performed by the surgeon or assistant, involves hand-scrubbing and donning sterile gown and gloves for optimal hygiene. The skin is prepped from the belly button to the upper thigh, with lateral areas extended to the flanks and thighs for thorough coverage.

- Hand scrub duration: Optimum hand scrub duration has been studied in orthopedic surgeons who carried out long duration hand scrub prior to total joint replacement surgery.²¹ In the case of arthroplasty procedures lasting less than 90 minutes surgical hand disinfection using Hibiscrub for a 5 min. hand-scrub was equally as effective as one of 10 min. Longer procedures (more than 90 min.) colony counts were significantly higher on subjects who had scrubbed for 10 min than on those who only scrubbed for 5 (p < 0.05). This data needs to inform the procedures

in penile prosthesis implantation as well.

- **Foley catheter:** To facilitate bladder emptying and assist in locating the urethra during the procedure, a Foley catheter is inserted after the surgical site is draped. Additionally, the incision is isolated from the surrounding skin using 3M Ioban.

- **Incision options:** Selecting the right incision for an implant is crucial. The three options, subcoronal, infrapubic, and penoscrotal, all have disadvantages and advantages.

Infrapubic incision: This technique results in less scrotal dissection/swelling but limits exposure in obese patients and increases the risk of dorsal nerve injury.

Subcoronal incision: Advantages are less discomfort postoperatively, and facilitates operation under local anesthesia. Disadvantages include limited exposure and intraoperative complications are difficult to correct (urethral injury, proximal perforation).

The penoscrotal approach: This offers optimal exposure for all patients, even those who are obese, it also poses a risk of scrotal manipulation resulting in discomfort and bruising. Despite this, the author's experience shows that this method is more convenient than others due to greater exposure and corporal length measurement, avoiding neurovascular injury and reducing intra operative complications. Penoscrotal incision is used in more than 80% of all placements of inflatable penile prostheses (IPPs) worldwide.²²

- **Incision preparation:** The penoscrotal skin is excised either vertically or transversely, and the overlying Dartos is dissected to expose the

corpora cavernosa with the urethra identified. To maintain the position of the penis cephalad, a Lone Star (Scott) retractor is used along with elastic stay hooks, which are loosely positioned at 5, 7, 11, and 1 o'clock, and tightly at 3 and 9 o'clock. (Fig. 1)

- **Absorbable Stay Sutures:** Absorbable stay sutures (Vicryl 3-0) are placed before the corporotomy. Corporotomies should be made as proximal as possible on the corpus cavernosa. However, corporotomies that are too proximal create an impossible angle for distal dilatation.

- **Corporal dilatation:** The procedure for corporal dilation commences with the use of Metzenbaum scissors to dilate the distal corpora cavernosa, with a lateral turning and angling motion (Fig. 2). A Brooks dilator, size 11 from Coloplast, Minneapolis, MN, USA, is then carefully passed through both distal and proximal regions, staying consistently lateral. The aim is to extend into the mid-glans distally and the lateral crux of the corpora proximally, until reaching the inferior pubic ramus. To protect the fossa navicularis during distal dilation, the surgeon should use their non-dominant hand to bend the glans contralaterally while dilating with their dominant hand. Each side is then sequentially dilated using Brooks dilators until the implant reaches the desired size (9.5, 11, and 13 mm).

- **Measurement Tests:** There are two tests to ensure accurate measurement. The "field goal test" involves placing two Brooks dilators proximally inside the corpora with comparisons being made regarding their depth and angle to check for

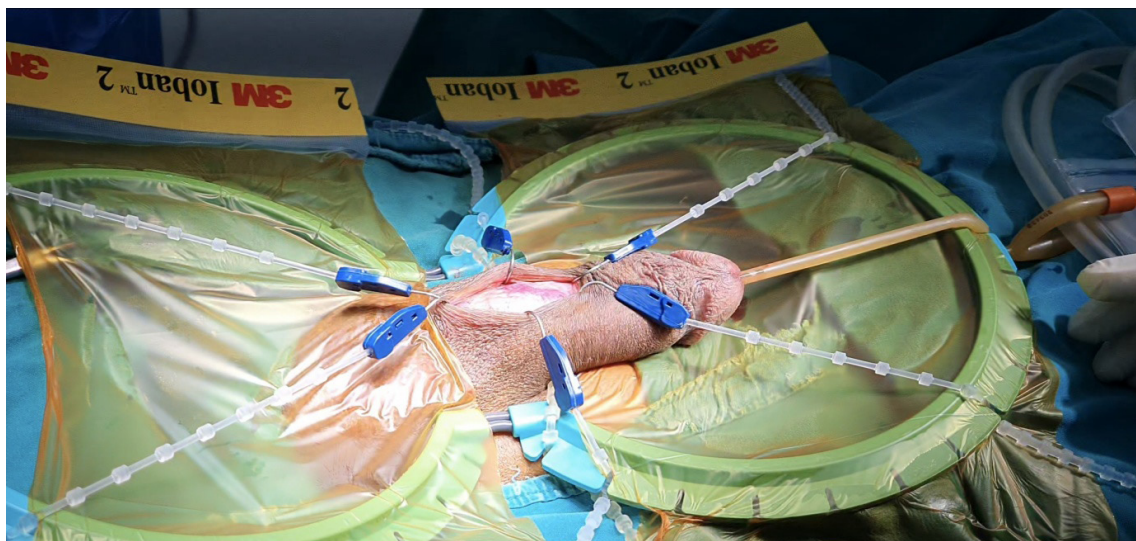


Figure 1. Penoscrotal incision. 6 Stay hooks with Lone star retractor.

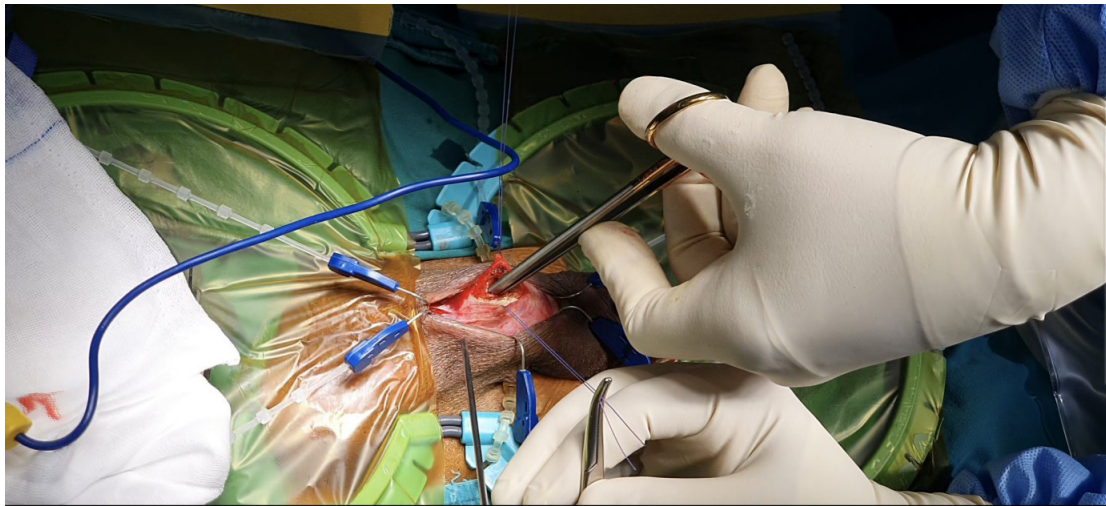


Figure 2. Corporal dilatation begins with distal corpora cavernosa dilation using Metzenbaum scissors turned and angled laterally.



Figure 3. Field Goal test.

crossover or perforation (Fig. 3). The “distal fluid challenge test” involves inserting a filled Asepto syringe into the corporotomy and injection from the syringe distally.

A failed test will result when fluid shoots out around the Foley catheter at the meatus, indicating a perforation into the urethra. If there is no false dilatation, corporal measurement needs to be performed with a Furlow dilator proximally and distally.

Implant preparation

The Coloplast Genesis® and Boston Scientific Tactra® are two comparable implant options. Both allow for the proximal end to be trimmed and end caps to be added in order to achieve the desired length. However, the Coloplast Genesis®

stands out by offering a hydrophilic coating, which enables rapid absorption of antibiotics into the implant when submerging it in an antibiotic solution.²³ To ensure proper infection prevention, an additional 1,000 ml of injectable saline mixed with 500 mg vancomycin and 80 mg gentamicin needs to be kept nearby and used for irrigation and instrumentation submersion throughout the procedure. It's worth noting that the effectiveness of this antibiotic irrigation technique has not yet been fully explored through a prospective, randomized trial.²⁴ Once the appropriate rod and rear tip extenders (RTE) have been selected, it's recommended to use the shortest RTE possible when placing the implants into the corporal body. Implants need to be placed into corporal bodies. The implant should be sized so that there

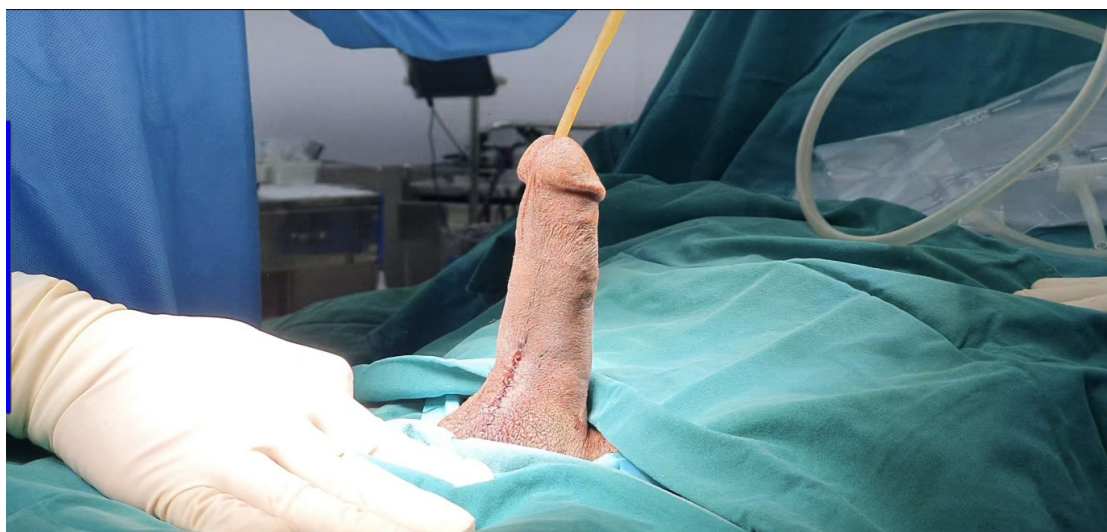


Figure 4. Implant fitted to corporal length. Incision closed.

is not excessive pressure on the glans of the penis which could lead to pain and give potential for erosion (Fig. 4).

To secure the closure of the corporotomy, the stay sutures on both sides need to be carefully tied in a horizontal mattress style. In the event that any part of the cylinder is visible, additional sutures are needed to fully close the corporotomy without disturbing the cylinders. The use of absorbable sutures allows for a multi-layered closure. Another advancement in penile lengthening techniques is ventral phalloplasty, where the penoscrotal web is removed during implantation.²⁵ The use of a drain after IPP implantation is a topic currently under debate and requires further investigation.²⁶ However, a study by Osmonov et al.²⁷ found that the placing of a scrotal drain for 72 hours following the surgery significantly reduces the rates of hematoma and infection compared to no drain placement.

Postoperative care

Köhler/Wilson's protocol

Patients are admitted for 24 hours for observation. On the morning after surgery the catheter and drain need to be removed. Recommended medication involves 10 days of a post operative antibiotic, and NSAIDs or opioids also given as required. Local wound dressing with normal saline solution needs to be carried out once daily with the wound being wrapped with sterile gauze. Showers or any submergence in water need to be avoided until the wound is completely healed. Patients are encouraged to place the penis in the upright position in underwear for 3 months to

allow the capsule to form around the implants, hence ensuring the implant erection is in the upward position. Patients need to be informed about indicators of infection, especially with regard to severe pain, discharge, swelling or fever.

Conclusion

Penile prosthesis surgery requires significant preparation on behalf of both surgeon and patient, comprising a series of steps that begin before the patient even arrives at the hospital and extending throughout the pre- and intra-operative stages. To ensure success, the surgeon must have access to the appropriate instruments, have a meticulously arranged aseptic operating room, skillfully execute the surgical technique and ensure appropriate post-operative care. These critical factors significantly impact the ease of the procedure and ultimately contribute to improved outcomes for the patient.

Conflict of Interest

The author declares no conflict of interest.

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