Original Article

Five-year overview of penile prosthesis implantation: general considerations from real-life practice

Dechapol Buranapitaksanti[1,5,6,7,8], Arnantkorn Chauvanasmith[2], Ussapol Tantarawongsa[3], Akanae Wongsawat[4]

[1]Navavej International Hospital, [2]Yanhee Hospital, [3]Police General Hospital, [4]Medpark Hospital, [5]Churarat 3 International Hospital, [6]Ladprao Hospital, [7]Piyavate Hospital, [8]Kasemrad Ramkamhaeng Hospital, Bangkok, Thailand

Keywords:
Penile prosthesis implantation, general consideration, real-life practice

Abstract

Objective: Penile prosthesis (PP) is the third-line therapy for erectile dysfunction in patients who do not respond to pharmacotherapy or who prefer a permanent solution to their problem. Even though the satisfaction rate is high, implantation is irreversible, and complications such as infection can lead to catastrophic outcomes. The objective of this study is to provide a 5-year (2018-2022) overview of patients who underwent penile prosthesis implantation, including techniques using both an inflatable penile prosthesis and semirigid prosthesis.

Materials and Methods: Aspects of the study include pre-surgical counseling, patient and device selection, operative technique, and special considerations in relation to implantation in complex cases, such as those involving corporal fibrosis, Peyronie's disease, or revision procedures.

Results: This 5-year overview demonstrates that the techniques remain effective and safe (0% infection rate) with a high satisfaction rate (84%) when compared to several prior studies. Better understanding and advancement in surgical techniques provide good outcomes; thus, implantation of a penile prosthesis is a good option for treatment of erectile dysfunction.

Conclusion: This 5-year review of PP implantation carried out in 35 patients by a single surgeon shows a very low complication rate after surgery with a high level of patient satisfaction. To maximize the potential for a good outcome, prior to surgery the physical status of patients should be evaluated and counseling is essential. In patients identified as being at a high risk, the implantation team should be prepared for complications using evidence-based data.

Insight Urol 2023;44(1):21-7. doi: 10.52786/isu.a.68

Corresponding author: Dechapol Buranapitaksanti
Address: Navavej International Hospital, Bangkok, Thailand
E-mail: buranadecha@gmail.com
Manuscript received: January 21, 2023
Revision received: May 16, 2023
Accepted after revision: June 2, 2023

Introduction

In 1973, Dr. F. Brantley Scott introduced the first Inflatable Penile Prosthesis (IPP).[1] Just a year later, in 1974, Dr. Michael Small and Dr. Hernan Carrion introduced their competitor device, a precursor to semirigid malleable devices. Since that date practices related to the PP have been developed with the use of materials and surgical techniques that have increased rigidity, durability, and patient satisfaction while decreasing postoperative complications. The introduction of Phosphodiesterase-5 inhibitors (PDE5-inh.) in 1998 changed the approach to treatment of erectile dysfunction. However, the American Urological Association (AUA) Guidelines showed that implantation of a penile prosthesis remained a promising solution for patients with erectile dysfunction (ED) in whom conventional medical therapies had failed.[2]

The objective of this article is to report on a 5-year overview of PP implantation that was either carried out or supervised by a single surgeon (DB) across many centers in Thailand. The article focuses on pre-operative considerations (patient selection, preparation, and counseling), intra-operative evidence-based decision-making in complex cases (such as Peyronie's disease, corporal fibrosis, and revision), and post-operative outcomes (complications and patient satisfaction).

Materials and Methods

This retrospective study included 35 ED patients who underwent implantation of a penile prosthesis, with ether an IPP and Semirigid malleable penile prosthesis from 2018 to 2022. The procedures took place across many centers, and were either performed or supervised by a single surgeon.

Patient selection

All patients were counseled, operated upon and followed up by implantation specialists (DB, AC, UT, AW). Data about sexual function, degree of ED, previous medical and surgical ED treatment, physical examination and current medical diseases was collected and analyzed for all patients. ED was defined as the inability to achieve and maintain an erection sufficient for satisfactory sexual performance.[3] If a patient had Peyronie's disease the degree of curvature and erectile function had been measured carefully prior to implantation. Revision surgery was carried out in cases of corporal fibrosis, which had occurred as a result of infected implantation or Priapism. The potential for a high complication rate (infection, erosion, deformity, perforation or urethral injury) needed to be discussed before proceeding.

16% of implanted patients were seeking revision for reasons outside of mechanical dysfunction or erosion.[4] This dissatisfaction was due to desire for "perfect" surgery. The identification of these patients is necessary to achieve the desired post-operative outcome and satisfaction. Pre operative counseling is a primary tool to identify the perception of the patients' expectation. IPP mainly restores physiological function (girth, sensation, ejaculation) but unrealistic expectations (increasing penile length and circumference) are at risk of post-operative dissatisfaction.[5]

Pre-operative preparation included medical clearance for patients with cardiovascular, endocrine, or other diseases. A diagnosis of ED is often a marker of underlying coronary artery disease.[6] This population was at high risk of cardiovascular events and needed to be carefully assessed. Patients with diabetes and a hemoglobin A1C greater than 8.5% have been shown to experience increased postoperative surgical site infections in association with PP.[7] Antiplatelet or anticoagulant therapy should be discontinued prior to the operation, or the operation postponed if patients were at high risk under EAU/AUA guidelines for patient selection.[8]

Device selection

The decision regarding device selection was made in consultation with the patient and surgeon, taking into account various factors such as the etiology of ED, penile length and anatomy, prior surgery, manual dexterity, spinal cord injuries, and prior device explant. All of these factors influenced the device recommendation. For instance, patients with limited manual dexterity and difficulty with device inflation/deflation were more suited to a semirigid implant. Patients with corporal fibrosis that limited the space in the corporal bodies were better suited to a narrow cylinder or a lower-diameter semi-rigid implant. In addition, the surgeon's preference and experience, device availability, and cost could also impact device selection.

Preoperative antibiotics prophylaxis

The most recent update from the American Urological Association guidelines advocates the use of an aminoglycoside plus cephalosporin or vancomycin as first-line prophylaxis.[9] Vancomycin 1 g plus Ceftriazone 2 g was administrated intravenously to all patients if no allergic history. Patients showered with Chlorhexidine solution on the day of surgery.

Technique

The technique for penile prosthesis implantation involves several steps. Firstly, the patient is prepared for surgery, and anesthesia is administered. The skin is then prepped, and a urethral catheter is inserted. The penis and scrotum are exposed using an Ioban® drape.

A penoscrotal incision is made, followed by corporotomies. Blunt tip scissors may be used to dilate the corporal bodies, and sequential Brooks' dilators are used to dilate down to the crus proximally and distally to the mid glans. The implant selected depends on the patient's anatomy and etiology of ED. In the case of IPP, an ectopic reservoir is placed via the external inguinal ring anterior to the transversalis fascia. The scrotal pump is placed by developing a subdartos plane.

Once all components are connected and in position, the skin is closed in two layers, and no drain is used. The operative time and blood loss are recorded, and the patient stays in the hospital for one night. The Foley catheter is removed before discharge, and antibiotics are switched to Amoxiklav 1 g twice daily for 2 weeks. Patients are instructed to avoid showering for a week, and at the one-week appointment, they are interviewed about postoperative pain, fever, urination, sensation, general appearance, and any other concerns. Sexual intercourse can start at 6 weeks after the operation. The satisfaction rate is assessed by a telephone interview after 6 weeks.

Results

Baseline characteristics

A total of 35 patients underwent penile prosthesis implantation between 2018-2022. 28 cases were implanted with semirigid implant Coloplast Genesis (Coloplast corp., Minneapolis, MN, USA) and 7 cases with IPP Coloplast Titan (Coloplast corp. Minneapolis, MN, USA).

The mean age was 59.5 (29-85) years. Causes of ED were vasculogenic (cardiovascular, diabetes) 27 (77.1%), neurogenic (spinal cord injury) 1 (2.8%), anatomical and structural disease (priapism and corporal fibrosis) 4 (11.4%), hypogonadism (post orchiectomy) 1 (2.8%) and Peyronie's disease 2 (5.7%).

Four patients had been undergoing revision surgery. Mean duration to initial malfunction was 2 (1-3) years. Two patients underwent revision with new IPP due to system malfunction (implanted by other centers), 1 patient underwent revision from a semi-rigid implant to IPP and 1 patient had revision from a semi-rigid implant to appropriate size and length. Four cases had corporal fibrosis (3 from untreated Priapism and 1 from infected prior implantation procedure) and 2 cases had Peyronie's disease (one with ED and one without ED). All ED patients were classified as severe ED, determined using the IIEF score (5-7) and were Phosphodiesterase-5 inhibitors (PDE-5inh.) non-responders, had contra-indications for PDE-5 inh. or could not tolerate side effects from PDE-5 inh. (Table 1).

Intra-operative events

Overall, the mean operative time was 77 minutes (ranging from 45 to 210 minutes) and the mean blood loss was 65 ml (ranging from 50 to 200 ml). A prolonged operative time of 3.5 hours and excess blood loss of 200 ml were observed in a patient with severe corporal fibrosis. During corporal dilatation in a patient with Peyronie's disease, one case of urethral injury was recorded. In this case a penoscrotal incision and corporotomy were extended to expose the perforated site, and a small perforation at the distal urethra was repaired with double layers of absorbable suture. Vigorous irrigation with NSS and Gentamicin diluted solution was performed before placing of the semi-rigid implants.

In another case, a cross-over was discovered intra-operatively, and the prosthesis had to be removed. A dilator was then placed in the correct corporal space, and the contralateral corporal body was re-dilated more laterally. The implant was then placed in the newly dilated tract while maintaining the dilator in the contralateral cavity to prevent error. Once the implant was in the proper position, the dilator was removed, and the second implant was placed in the other corpora.

Table 1. Patients who underwent penile prosthesis implantation (2018-2022)

Implant type	**Number of cases**
Semi-rigid implant	28
Inflatable implant	7
Mean age (years)	59.5
Age range (years)	29-85
Causes of erectile dysfunction	**Number of cases n (%)**
Vasculogenic (cardiovascular, diabetes mellitus)	22 (77.1)
Anatomical and structural diseases (priapism and corporal fibrosis)	4 (11.4)
Peyronie's disease	2 (5.7)
Hypogonadism (post-orchiectomy)	1 (2.8)
Neurogenic (spinal cord injury)	1 (2.8)
Severity of erectile dysfunction	**Number of cases**
IIEF score 5-7	35

Post-operative events

There were no immediate postoperative complications, such as bleeding, hematoma, or infection, and no blood transfusions were required. Urethral catheters were removed one day post-operatively, with the exception of the case of urethral injury when the catheter was removed after five days. Hospital stay was one day.

One late complication was reported, in which a patient experienced a pseudo-malfunction of the implanted device one year after IPP. The patient felt a "hard pump" and could not inflate/deflate the device. This was managed non-surgically by applying very firm pressure to the pump bulb to move the valve disc into the inflate position. Once this was accomplished, the device inflated and deflated normally.

Three patients experienced pain that persisted for more than two weeks after the operation. On physical examination, there was no sign of infection or inflammation. The pain was localized to some area of the penile shaft and scrotum and slightly decreased after treatment with NSAIDs and opioids but responded well to Gabapentin. They were pain-free after six weeks and could discontinue Gabapentin.

Twenty-five patients (20 with semirigid implants and 5 with IPP) completed questionnaires about their satisfaction with the devices. The questionnaire from the Modified Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) was used as a tool to assess satisfaction with the treatment: 1) Are you satisfied with the improvement in sexual life, sensation, orgasm; 2) Is it easy to conceal device when not used; 3) Would you advise friends to undergo the same procedure.

Twenty-one (84%) patients reported that the devices were easy to use, provided good rigidity for intercourse, and resulted in normal sensation and orgasm. One patient was not satisfied with the semirigid implant because it was not rigid enough and underwent revision to IPP. Three men with persistent pain after implantation reported lower levels of satisfaction and were reluctant to perform sexual intercourse after six weeks.

Discussion

Surgical implantation of a penile prosthesis may be considered in patients who do not respond to pharmacotherapy or who prefer a permanent solution to their problem.[10] This study aimed to evaluate the outcome of PP implantation and also share experiences about implantation in complex cases.

Our results confirmed reports from previous studies showing that PP implantation was an effective treatment option for men with ED with low risk of complications and had a high level of patient satisfaction (92-100%).[11,12] Although the PP implantation generally results in very high satisfaction rates, less-than-perfect outcomes and post-operative dissatisfaction can still occur. Pre-operative counseling to identify patients who are at risk of dissatisfaction is also important.[4,13] This is the only way to connect pre-operative

expectation and post-operative reality. This context also played role in the selection of the appropriate device.

Infection

The most serious complication of penile prosthesis implantation is infection. The risk of infection with modern IPP in a virgin implantation has ranged from less than 1% to up to 4%.[14,15] However, there were no infections recorded in this series. Growing evidence suggests that the risk of infection associated with penile prosthesis has decreased over time due to improvement in both devices and surgical expertise. Higher-risk populations for infection include patients undergoing revision surgery, those with impaired host defenses (immunosuppression, diabetes mellitus, spinal cord injury), or those with penile corporal fibrosis.[12]

Diabetes and immunosuppression

In this study, 77% of patients had diabetes, which were controlled with an HbA1c level below 8.5 prior to the operation in all cases. No surgical site infections (SSI) or acute infections were detected in this study. Traditionally, diabetics have been considered a high-risk patient group for infection-related complications. Habous et al.[7] found that Hb1Ac levels were significantly related to a higher incidence of infection and proposed a threshold of 8.5% to predict infection with 80% sensitivity and 65% specificity. A large meta-analysis which included 9,041 diabetic patients and 36,517 non-diabetics showed that diabetes mellitus increases the incidence of penile prosthesis infection with an odds ratio of 1.53 (95% CI 1.15–2.04; p = 0.004).[16] However, data from a recent meta-analysis data changed this opinion, showing similar infection rates between diabetics, poorly controlled diabetics, and non-diabetics.[17] The diabetic issue is still controversial, debatable, and lacks consensus.

One kidney-transplanted recipient underwent PP implantation while taking immunosuppressive drugs, including Mycophenolatemofetil (Cellcept®) 500 mg twice daily, Tacrolimus (Prograf®) 1 mg twice daily, and Prednisolone 5 mg once daily. At the 1-month follow-up, the patient was doing well with no sign of surgical site infection. Cuellar et al followed 46 organ-transplanted patients for 2 years after PP implantation. In this series, the incidence of infection was no different than that of patients without organ transplant.[18] Sun et al found no significant increase in the infection rate after a 30-month follow-up of transplant recipients.[19] Based on these limited data, it is reasonable to consider transplant recipients on immunosuppression therapy as potentially good candidates for a penile prosthesis.

Revision

Revision due to system malfunction was observed in four cases. Revision rates due to system failure vary between centers, with recorded failure rates ranging from 15% at 5 years to 30-40% at 10 years.[20] Infection rates following revision surgery have been reported to be as high as between 10.0% and 13.3%, compared to 0.46% to 2.00% in virgin cases.[21] Infectious complications remain a significant concern in IPP revision surgery, with the risk of specific device infection showing a strong correlation with an increased risk based on the number of prior IPPs.[22] In 1996, Mulcahy et al. described a new protocol for the immediate replacement of infected IPPs, which involved the complete removal of the device and serial wound washout, followed by re-implantation of a new IPP.[23] This protocol was strictly followed in this series. Not only is the high infection rate a concern in this population, but overall complication rates, including intra-operative events (perforation, adjacent organ injury), post-operative corporal deformity, erosion, and patient dissatisfaction, are also high. In our study, the revision procedure required longer operative time than naïve cases. All components were delivered and carefully inspected for causes of malfunction. The explanted space was vigorously washed out before implantation. There were no surgical site infections or acute infections in this series, but for this special group of patients, a long-term follow-up period is necessary.

Corporal fibrosis

Three patients had corporal fibrosis from untreated Priapism. Two had an unknown etiology and one had Sickle cell disease. One patient had severe fibrosis from infection prior to implantation. PP implantation in corporal fibrosis is a significant surgical challenge. Due to the limited number of series there is no standard approach for this condition. Corporal fibrosis carries a high

risk for infection due to prolonged operative time and extensive tissue trauma, perforation during dilatation, adjacent organ injury and failure of the implantat.[24] Buranapitaksanti used the "Double Corporotomy Incision Technique"[25] to avoid false dilatation by a combination of sharp and blunt dissection.

Rossello Cavernotomes (Coloplast Corporation, Humlebeck, Denmark), small sharp-raised dilators which are used to thin out scar tissue as the rods are pulled from corporal body were used. With this technique operative time and blood loss were reduced from 3.5 to 1.5 hours and 300 to 50 ml respectively in the first to the last case. All implants were successful with a semi-rigid implant being inserted without complication and a high level of satisfaction.

Peyronie's disease

Two patients with Peyronie's disease were implanted with semirigid implants. Penile prosthesis implantation is typically reserved for the treatment of Peyronie's disease in patients with ED, especially when they are non-responders to PDE5 inhibitors. The risk of complications such as infection and malformation is not increased in comparison to the general population.[26] Urethral injury was detected during the procedure in one patient, but implantation was not terminated. A urethral catheter was placed for 5 days, and there was no infection detected at the 2-week follow-up. Contemporary data suggest that termination and delayed implantation might not be necessary after injury.[27,28] One patient had an 80-degree dorsal curvature without ED. After a discussion about solutions for the deformity, such as plaque excision and grafting, plication, or shock wave therapy, he could not accept the consequences and risks of surgery, such as numbness, hourglass deformity, or shortening, and desired PP as a solution. After implantation with semirigid implants, the remaining curvature was less than 20 degrees, and both patients recorded a high level of satisfaction.

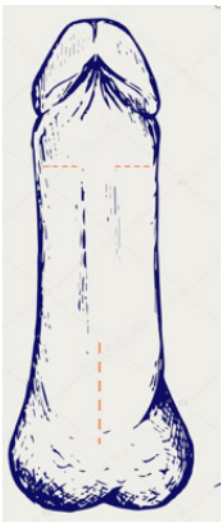


Figure 1. Double Corpototomy Incision Technique, Corporotomy performed along the red dotted lines.[25]

Conclusion

This 5-year review of PP implantation by a single surgeon shows a very low complication rate after surgery and a high level of patient satisfaction. Physical status of the patients needs to be evaluated before surgery and also all need to be counseled to ensure realistic, successful outcomes. In any high-risk group, implantation specialists should be prepared for complications using evidence-based data.

Conflict of Interest

The authors declare no conflict of interest.

References

1. Scott FB, Bradley WE, Timm GW. Management of erectile impotence. Use of implantable inflatable prosthesis. Urology 1973;2:80-2.
2. Burnett AL, Nehra A, Breau RH, Culkin DJ, Faraday MM. Erectile dysfunction: AUA Guideline. J Urol 2018;200:633-41.
3. Hatzimouratidis K, Giuliano F, Moncada I, Muneer A, Salonia A, Verze P. EAU Guidelines on Erectile Dysfunction, Premature Ejaculation, Penile Curvature and Priapism [Internet]. [cited 2022 December 12]. Available from: https://d56bochluxqnz.cloudfront.net/media/16-Male-Sexual-Dysfunction_2017_web.pdf
4. Gopal L. Narang, Bradley D. Preoperative counseling and expectation management for inflatable penile prosthesis implantation. Transl Androl Urol 2017;6:S869-80.
5. Henry GD, Donatucci CF, Conners W. An outcomes analysis of over 200 revision surgeries for penile prosthesis implantation: A multicenter study. J Sex Med 2012;9:309-15.
6. Jackson G, Boon N, Eardley I, Kirby M, Dean J, Hackett G, et al. Erectile dysfunction and coronary artery disease prediction: evidence-based guidance and consensus. Int J Clin Pract 2010;64:848-57.

7. Habous M, Tal R, Tealab A, Soliman T, Nassar M, Mekawi Z, et al. Defining a glycated haemoglobin (HbA1c) level that predicts increased risk of penile implant infection. BJU Int 2018;121:293-300.
8. Culkin DJ, Exaire EJ, Green D, Soloway MS, Gross AJ, Desai MR, et al. Anticoagulation and antiplatelet therapy in urological practice: ICUD/AUA review paper. J Urol 2014;192:1026-34.
9. Wolf JS, Bennett CJ, Dmochowski RR, Hollenbeck BK, Pearle MS, Schaeffer AJ. Urologic Surgery Antimicrobial Prophylaxis Best Practice Policy Panel. Best practice policy statement on urologic surgery antimicrobial prophylaxis. J Urol 2008;1794:1379-90.
10. Antonini G, Busetto GM, Berardinis ED, Givannone R, Vicini P, Giudice FD, et al. Minimally invasive infrapubic inflatable penile prosthesis implant for erectile dysfunction: Evaluation of efficacy, satisfaction profile and complications. Int J Impot Res 2016;28:4-8.
11. Salonia A, Burnett AL, Graefen M, Hatzimouratidis K, Montorsi F, Mulhall JP, et al. Prevention and management of postprostatectomy sexual dysfunctions part 2: recovery and preservation of erectile function, sexual desire, and orgasmic function. Eur Urol 2012;62:273-86.
12. Hellstrom WJG, Motague DK, Moncada I, Carson C, Minhas S, Faria G, et al. Implants, mechanical devices, and vascular surgery for erectile dysfunction. J Sex Med 2010;7:501-23.
13. Masterson TA, Palmer J, Dubin J, Ramasamy R. Medical pre-operative considerations for patients undergoing penile implantation. Transl Androl Urol 2017;6:S824-9.
14. Trost L, Wanzek P, Bailey G. A practical overview of considerations for penile prosthesis placement. Nat Rev Urol 2016;13:33-4.
15. Mandava SH, Serefoglu EC, Freier MT, Wilson SK, Hellstrom WJG. Infection retardant coated inflatable penile prostheses decrease the incidence of infection: A systematic review and meta-analysis. J Urol 2012;188:1855-60.
16. Gon LM, Campos CCC, Voris BRI, Passeri LA, Fregonesi A, Riccetto CLZ. A systematic review of penile prosthesis infection and meta-analysis of diabetes mellitus role. BMC Urol 2021;21:35.
17. Christodoulidou M, Pearce I. Infection of Penile Prostheses in Patients with Diabetes Mellitus. Surg Infect 2016;17:2-8.
18. Cuellar DC, Sklar GN. Penile prosthesis in the organ transplant recipient. Urology 2001;57:138-41.
19. Sun AY, Babbar P, Gill BC, Angermeier KW, Montague DK. Penile Prosthesis in Solid Organ Transplant Recipients-A Matched Cohort Study. Urology 2018;117:86-8.
20. Carson CC, Mulcahy JJ, Govier FE. Efficacy, safety and patient satisfaction outcomes of the AMS 700CX inflatable penile prosthesis: results of a long-term multicenter study. J Urol 2000;164:376-80.
21. Montgomery BD, Lomas DJ, Zeigelmann MJ, Trost LW. Infection risk of undergoing multiple penile prostheses: an analysis of referred patient surgical histories. Int J Impot Res 2018;30:147-52.
22. Brant MD, Ludlow JK, Mulcahy JJ. The prosthesis salvage operation: immediate replacement of the infected penile prosthesis. J Urol 1996;155:155-7.
23. Mulcahy JJ. Long-term experience with salvage of infected penile implants. J Urol 2000;163:481-2.
24. Krughoff K, Bearelly P, Apoj M, Munarriz NA, Thirumavalavan N, Pan S, et al. Multicenter surgical outcomes of penile prosthesis placement in patients with corporal fibrosis and review of the literature. Int J Impot Res 2022;34:86-92.
25. Buranapitaksanti D, Penile prosthesis in severe corporal fibrosis: a history of a difficult case using the double corporotomy incision technique. Insight Urol 2022;43:167-70.
26. Wilson SK, Delk II JR. A new treatment for Peyronie's disease: modeling the penis over an inflatable penile prosthesis. J Urol, 1994;152:1121-3.
27. Sexton SJ , Granieri MA, Lentz AC. Survey on the Contemporary Management of Intraoperative Urethral Injuries During Penile Prosthesis Implantation. J Sex Med 2018;15:576-81.
28. Robert B, Grimberg DC, Lentz AC. Management of Urethral Injury During Penile Prosthesis Surgery. Curr Sex Health Rep 2020;12:62-7.