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MASTERCLASS PAPER

Practical Considerations in Inflatable Penile Implant Surgery

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ABSTRACT

Background: Penile prosthesis implantation remains an effective solution for men with medical-refractory erectile dysfunction (ED) following radical pelvic surgery. Despite the distortion of pelvic anatomy, a penile implant can be performed with excellent clinical outcomes provided strict patient selection, proper preoperative workup and safe surgical principles are adhered to.

Aim: To provide practical recommendations on inflatable penile prosthesis (IPP) implantation in patients with medical-refractory ED, with an emphasis on patient selection and counselling, preoperative workup as well as surgical considerations to minimize intraoperative complications.

Methods: A Medline search on relevant English-only articles on penile prostheses and pelvic surgery was undertaken and the following terms were included in the search for articles of interest: "bladder cancer", "prostate cancer", "rectal cancer", "pelvic surgery" and "inflatable penile implant".

Outcomes: Clinical key recommendations on patient selection, preoperative workup and surgical principles.

Results: Patients should be made aware of the mechanics of IPP and the informed consent process should outline the benefits and disadvantages of IPP surgery, alternative treatment options, cost, potential prosthetic complications and patient's expectations on clinical outcomes. Specialised diagnostic test for workup for ED is often not necessary although preoperative workup should include screening for active infection and optimising pre-existing medical comorbidities. Precautionary measures should be carried out to minimise infective complication. Corporal dilation and reservoir placement can be challenging in this group, and surgeons may require knowledge of advanced reconstructive surgical techniques when dealing with specific cases such as coexisting Peyronie's disease and continence issue.

Clinical translation: Strict patient selection and counselling process coupled with safe surgical principles are important to achieve excellent linical outcomes and patient satisfaction rates.

Strengths and limitations: This masterclass paper provides an overview of the practical considerations for men who are undergoing IPP surgery following radical pelvic surgery. Limitations include the lack of highquality data and detailed surgical description on each surgical troubleshooting steps for various prosthetic-related complications.

Conclusion: The IPP implantation can be performed efficiently and safely in patients following radical pelvic surgery. **Chung E, Mulhall J, Practical Considerations in Inflatable Penile Implant Surgery. J Sex Med 2021;XX:XXX–XXX.**

Key Words: Radical pelvic surgery; Clinical outcomes; Surgical challenges; Inflatable penile prosthesis; Patient selection

INTRODUCTION

Presently, most data relating to erectile dysfunction (ED) and penile rehabilitation is derived from prostate cancer patients. Our recent understandings of the pathophysiology of ED in men following radical pelvic surgery especially in the radical prostatectomy (RP) men highlights that corporal oxygenation is critical to the earlier return of erectile function and preservation of penile size.[1–3] For men who do not regain spontaneous erection or develop medical-refractory ED especially in the setting of corporal fibrosis, penile prosthesis implant continues to play an important role.[1,3] Despite the introduction of various pro-erectile

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pharmacological agents in penile rehabilitation programs, penile prosthesis surgery offers sexual spontaneity and remains an effective, safe, and reliable definitive treatment for men with ED.[4–7]

The inflatable penile prosthesis (IPP) implantation is a more natural device than malleable prosthesis since it closely replicates a normal penile erectile function in terms of penile rigidity and flaccidity.[5,8] Over the last 4 decades, significant scientific advances in terms of device technology and surgical techniques have improved the mechanical reliability and durability of IPP.[5,9] Nonetheless, IPP surgery is not without risks and can carry additional cosmetic and psychosocial consequences in poorly selected and consented individuals. In the current climate of digital health information and consumer-driven access to better healthcare service, strict patient selection and counselling coupled with judicious adherence to safe surgical principles are paramount to ensure excellent clinical outcomes and patient satisfaction rate.[10–13] The following article provides a practical overview on patient selection and preparation for IPP surgery and offers strategic recommendations to address the technical challenges encountered in patients following radical pelvic surgery.

METHODS

A Medline search on relevant English-only articles on penile prostheses and pelvic surgery was undertaken and the following terms were included in the search for articles of interest: "bladder cancer", "prostate cancer", "rectal cancer", "pelvic surgery" and "inflatable penile implant". Given the lack of high quality randomized controlled trials in IPP surgery, specific emphasis is placed on review articles and published guidelines in this narrative review. A detailed surgical description related to the actual IPP surgery was not intended in this review nor was a detailed explanation of each surgical troubleshooting steps for various prosthetic-related complications.

The discussion on the factors for consideration IPP surgery was divided into a practical action-based set of recommendations, with an emphasis on patient selection and counselling, preoperative workup and various surgical challenges often faced by surgeons to minimize intraoperative complications in this group of patients who have undergone radical pelvic surgery. Discussion regarding IPP surgery in special populations such as in men who received adjuvant therapy, those with Peyronie's disease, or need to undergo concurrent continence surgery were included in this masterclass paper since specific considerations and technical skills are often involved in managing these special cases.

PATIENT SELECTION AND COUNSELLING

ED is a common complaint among men who underwent radical pelvic surgery despite the medical hype around robotic technology and refinements of innovative surgical techniques.[1,14] In addition to cavernous neurovascular injury, inadvertent damage to other relevant supporting structures like accessory blood supply and pelvic floor can contribute to the development of various forms of male sexual dysfunction.[4,15] Changes in psychosocial domains such as self-confidence and masculinity, relationship dynamics and economic burden may worsen underlying sexual dysfunction in these men.[1,4,15,16]

Published literature supports the use of a penile rehabilitation program to facilitate the earlier return of spontaneous erection and maintain penile health.[3,6,7] While traditionally a penile prosthesis is reserved as the last resort for men with medical refractory ED, it remains an effective treatment for men who achieve a suboptimal natural erection and wish for a more permanent solution. It is generally recommended that patients have tried at least one phosphodiesterase type 5 inhibitor medication and have given serious consideration to trying intracavernosal injections and/or vacuum erection device before proceeding to penile implant surgery.[5,11,17] Preoperative explanation of the mechanics of IPP is essential and patients must be fully informed that this procedure is irreversible where subsequent removal of the implant will not restore normal erectile capability.

The informed consent process should outline the advantages and disadvantages of IPP surgery, alternative treatment options, cost, and potential surgical complications. These complications can be divided into prosthetic-related such as infection and its consequences, mechanical failure, failure to regain lost preoperative length/girth, glans softness, device migration and erosion; as well as intraoperative complications including hemorrhage, injury to surrounding structures (urethra, bladder, bowel, or vessels) and postoperative issues such as hematoma, ecchymosis, deep vein thrombosis and anaesthesia-related problems.[10,18] The perioperative consent form provides legal documentation for the IPP surgery and is often unique to each institution although several organizations have published standardized surgical consent forms for penile prosthesis implantation [19,20] that can be adapted to suit the individual surgeon.

Preoperative patient counselling is essential to address any unrealistic expectations and provide honest open communication with patients to improve knowledge about their surgery and enhance postoperative satisfaction.[5;21]. Informed consent for some of the issues relating to IPP surgery such as loss of perceived length, lack of proper glans engorgement, as well as prosthetic unnaturalness as perceived by the partner should be discussed to minimize these dissatisfactions and future medicolegal consideration.[18,22] Relevant patient-related factors that increase the risk of prosthetic complications include uncontrolled diabetes mellitus or cardiovascular disease, presence of corporal fibrosis, poor personal hygiene with the presence of pathologic nasal and skin flora, the use of steroid or immunosuppressant drugs, history of radiation therapy and prolonged urinary catheterization.[23-25]

PREOPRATIVE PREPARATION

In contrast to the usual workup investigations for ED in the general population, men who develop ED following radical pelvic surgery often do not require further specialized testing.

Furthermore, the need for a mandatory penile color Duplex ultrasonography in every man with ED is often considered unnecessary as part of the diagnostic algorithm.[26] All men who have ED following radical pelvic surgery should receive a proper course of ED therapy before proceeding to IPP implantation.

However, pre-existing medical comorbidities will need to be optimised and may require additional consultations with relevant specialists. Diabetics are at higher risk of infection, and infectious diseases are more frequent and serious in patients with uncontrolled diabetes mellitus.[27,28] While there is no broad consensus on a specific cut-off for glycosylated haemoglobin (HbA1c) that translates directly to definitive penile periprosthetic infections, recent data suggest a level of >8.5% should be considered as cut-off to elicit postponement of the operation.[29–32] It is generally agreed that a high HbA1c carries higher infective risk, and that tight intraoperative glycaemic control may reduce infection risk[33–35].

Various medications can pose challenges at the time of penile prosthesis implantation. Newer hypoglycaemic agents such as sodium-glucose transport proteins-2 (SGLT2) inhibitors will need to be withheld to minimise postoperative diabetic ketoacidosis.[36] Antiplatelet agents and anti-coagulants will need to be ceased following consultation with a cardiologist or internal physician.[37] Patients at high risk of thromboembolism should be considered for a more aggressive perioperative management strategy with appropriate bridging therapy.[5,10]

All patients should have a negative urine culture and an absence of any active skin infection at the time of surgery.[5,10,13] Precautionary measures to minimize skin contaminants include a preoperative shower with antibacterial agents, intraoperative hair removal, perioperative skin scrub and skin prep with alcohol formulations, while full protective surgical attire, positive pressure airflow system and minimal theatre traffic have been shown to minimize organism flow within the operating room.[36–38] Meticulous intraoperative sterility care with multiple re-draping of the surgical field, judicious antibiotics irrigation, and minimizing device-skin contact or "no-touch" techniques have been utilized in the hopes of minimizing intraoperative skin flora (and atypical bacterial) contamination.[23,39] Current evidence supports the peri-operative administration of appropriate antibiotics at least 1 hour before incision, and the use of antibiotic-coated IPP devices.[5,23,36] While the American Urological Association Best Policy Statement recommends the use of two IV antibiotics before skin incision, specifically an aminoglycoside (or aztreonam) plus either a 1st or 2nd generation cephalosporin or vancomycin,[40] the choice of antibiotics use is highly dependent on the surgeon's preference, local institution prescribing guideline, and patient's concurrent medication use and allergy profile.

INTRAOPERATIVE CONSIDERATIONS

Incision

The three approaches for IPP surgery are penoscrotal (trans-scrotal), infra-pubic and sub-coronal incisions, and the decision on the chosen surgical method are likely dependent on various factors such as patient's specific anatomy, surgeon's preference and whether a concurrent penile reconstructive surgery is undertaken.[41] Each surgical approach has its advantages and disadvantages, with no clear advantage favoring one approach over another regarding patient satisfaction or implant infection rates.[42]

Corporal Fibrosis

The final common pathway to severe and permanent ED is corporal fibrosis. This fibrosis occurs after neural trauma, the greater the degree of nerve trauma, the more rapid and more complete the degree of fibrosis. This fibrosis is time-dependent and the longer a patient goes after surgery without erections, the greater the likelihood of corporal fibrosis developing. This is furthermore dependent also on patient age, baseline erectile function, the presence of comorbidities such as obstructive sleep apnoea and diabetes and some evidence exists to support the idea that pharmacologic penile rehabilitation may stall the development or reduce the magnitude of fibrosis.

Corporal fibrosis poses a substantial technical challenge to IPP surgery in terms of difficult corporal dilation increasing the risk of perforation of the urethra and crura.[43] Furthermore, inadequate corporal dilation may result in complications such as sizing errors, supersonic transport deformity and cylinder crossover. Various surgical techniques and instruments have been described in the literature[25,44–48] and these include but are not limited to an initial corporal dilation with Metzenbaum scissors, serial dilation with Hegar or Brooks dilators, and use of Dilametz inserts system (blunt and sharp dilators). There is an argument in favour of using the latter system which uses the single passage of a metal device to which an obturator is passed as opposed to serial dilation with dilators of increasing sizes.

While it is unusual to have such corporal fibrosis that requires more advanced manoeuvres, the use of cavernotomes (Carrion-Rossello, Minneapolis, MN, USA) or Uramix (Lansdowne, PA, USA) (ie double-bladed cavernotomes with linear blades) or multiple corporotomies with the excavation of fibrotic tissue from the tunica albuginea are valuable adjuncts.[49,50]

It is critical that the corporal dilation is performed in the dorsolateral direction to avoid direct urethral injury, and that adequate dilation to the distal tunica covering is necessary to ensure proper cylinder sizing. In cases of severe corporal fibrosis where corporal dilation is less than 12mm in size, a narrower implant can be selected such as the AMS 700 CXR or the Coloplast Titan narrow-based cylinder can be used.[5,43]

When placing a two-piece device (Ambicor, Boston Scientific), the corporal bodies should be sounded using a Hegar dilator or similar dilator to ensure that the corporal body is dilated enough as the Ambicor device does not deflate completely and is not lubricious.[51,52] This device comes in two widths (12.5 and 14mm) depending on the length of the cylinder chosen, and it is important to dilate to at least 1mm wider than the cylinder width (eg if a 12.5mm cylinder is being used, dilation/sounding should occur to at least 14mm).

Reservoir Considerations

The IPP reservoir is traditionally placed into the extraperitoneal space of Retzius (SOR) to avoid complications such as poor cosmesis (from reservoir outline), potential auto-inflation (from direct compression) and reservoir herniation. High-level experience is required for the placement of a reservoir in the SOR given the potential for the obliteration of this space after RP. A high submuscular ectopic reservoir location is a useful alternative. Likewise, in such patients, if the external ring is easily identified, a low submuscular placement (not into the SOR) is feasible.

For inexperienced implant surgeon, the traditional SOR approach with blinded reservoir placement is fraught with the potential risks of inadvertent organ injury (bladder and vascular). A separate hypogastric incision can be performed for direct placement of the reservoir.

High submuscular ectopic placement can provide an alternative approach but care should be taken to ensure that the reservoir is placed in the correct anatomical abdominal muscle layers namely between the transversus abdominis anteriorly and the transversalis fascia posteriorly; or more medially between the rectus abdominis muscle anteriorly and transversalis fascia posteriorly.[53–56] Suboptimal or incorrect ectopic reservoir placement will result in poor cosmesis and increase the risk of reservoir damage or herniation in the future.[53,57,58]

As further alternatives, the Ambicor device or even a malleable device can be utilized.[51,52,59] In patients who underwent cystoprostatectomy or pelvic extirpative surgery,[60–62] the pelvic anatomy is often distorted to the point combines with the displacement of bowel loops into the pelvis that a two-piece or three-piece device with a high ectopic location can be a safer option.

SPECIAL CASES

Patients Exposed to Adjuvant Therapies

It is worth mentioning that with an increasing number of RP patients being seen after multimodal therapy, including radiation therapy (RT) and androgen deprivation therapy (ADT), severe corporal fibrosis is becoming more commonly encountered in such patients at the time of implant surgery.[63,64]

The best time for penile implant placement following adjuvant or salvage radiation is unclear, although some studies suggest that RT can result in significant further corporal fibrosis and may increase implant surgery complications.[65–69] It is also clear that ADT (generally used in conjunction with RT in the patient requiring post-RP adjuvant therapy) worsens corporal fibrosis leading to permanent ED.[64, 68]

In triple therapy patients (RP, RT and ADT), the implant surgeon needs to be cognizant of the potential for severe corporal atrophy. In some men, the atrophy and corporal narrowing is such that a narrow-based device might be required. Furthermore, caution needs to be exercised when dilating proximally as the aforementioned atrophy can make proximal dilation challenging especially passing a dilator across the ischiopubic rami.

There is emerging data to suggest that modern chemotherapy regimens, particularly dose-dense regimens, is associated with a significant risk of neutropenia and wound-related complications.[70,71] Concern for the development of atypical bacterial or fungal infections in patients who are receiving chemotherapy is heightened in patients who have recently undergone placement of a prosthetic implant, although the data is inconclusive whether those who receive neoadjuvant, adjuvant or salvage chemotherapy had the highest rate of infectious complications.[71,72] However, the question of chemotherapy-related effects on implant complications may be attributed to other factors such as the adverse impact on cardio-metabolic comorbidities and changes in penile morphology. The role of an inflammatory state related to chemotherapy requires further exploration too. While there is no data on the suitable time frame between chemotherapy and subsequent risk of prosthetic infection, it is a common approach to delay penile prosthesis implant if the patient needs to undergo chemotherapy.[38,39,72] Discussion with the medical oncologist on the optimal timing of surgery will minimize immunosuppression and allow for proper recovery to take place.

PEYRONIES DISEASE

Recent data suggest that there is a link between RP and the development of Peyronie's disease (PD). Hence, it is reasonable to assume that the likelihood of putting an implant into men with severe corporal fibrosis combined with PD will increase.[25,45,73] Published literature shows no significant difference in terms of device survival and patient satisfaction rate between penile prostheses in men with PD.[74]

A manual penile remodelling of inflated cylinders by bending the inflated implant in the contralateral direction to the curvature can be performed but the tubing between the pump and the cylinders should be occluded with rubber-shod hemostats to protect the pump from high-pressure damage. For those with a residual curve greater than 30°, penile plication or plaque incision or excision with or without grafting can be performed.[45,75] For penile plication, the surgeon will need to pre-place plication sutures before inserting the cylinder to avoid accidental puncture to the implant components. A tunical defect greater than 2 cm following incision or excision of plaque will require a graft patch to decrease the risk of cicatrix contracture and herniation of the cylinders.[25,45]

Concurrent or Sequential Continence Surgery

There is an ongoing debate on whether IPP should be performed concurrently or in a sequential manner when the patient requires continence surgery, and if both procedures are taken place concurrently, should IPP be performed first before placement of the continence device.[25,75] For men who will receive the artificial urinary sphincter (AUS) at the time of IPP implantation, it is recommended that the AUS is usually placed first followed by a penile prosthesis in the event of urethral injury precluding both prostheses preparation and implantation. In

sequential device implantation, care is taken to avoid damaging the AUS cuff when subsequently placing the penile cylinders.[76] A review of previous operation record and the use of pre-operative imaging study will provide useful information and allow for surgical planning with regards to the placement of pump and reservoir on the contralateral (virgin) side.[69] Careful surgical dissection using cutting currents is advocated to avoid damage to any components of the first device. Similarly, it is recommended that the transobturator male sling is inserted first to avoid accidental damage of the proximal corporal cylinder during the transobturator puncture.[25,75,76]

Published literature shows that synchronous AUS or male sling and PPI surgery is often feasible and safe and as effective as the 2-stage procedure with potentially higher acceptance rate and cost-savings.[77–83] However, dual implantation in a single-stage procedure can be more challenging and may be associated with a higher likelihood of revision surgery.[5,77,82,83]

CONCLUSIONS

For motivated individuals, IPP remains one of the most effective treatment to restore sexual function in men especially following radical pelvic surgery. Penile prosthesis implantation should be discussed as part of the treatment algorithm for penile rehabilitation and the patient needs to understand that this is an irreversible surgical solution. Despite the scientific advances in penile prosthetic design and technology, it remains critical that strict patient selection and counselling process coupled with safe surgical principles are adhered to, to ensure excellent clinical outcomes and patient satisfaction rates. There is a need to establish a standardised surgical approach with key recommendations to minimise surgical complications and streamline penile prosthesis implantation care for men.

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STATEMENT OF AUTHORSHIP

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