

Inflatable penile prosthesis in the radical prostatectomy patient: a review [version 1; peer review: 2 approved]

Nelson Bennett ¹, I-shen Huang²

¹Department of Urology, Northwestern Memorial Hospital, Chicago, IL, 60611, USA ²Department of Urology, Taipei Veterans General Hospital, Taipei, Taiwan

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Abstract		Invited Reviewers

In the population of patients with prostate cancer, survivorship has come to the forefront of continuity-of-care. In addition to urinary control, erectile function is a significant issue after radical pelvic surgery. Penile prosthesis surgery remains an excellent option for restoring erectile function to those for whom more conservative measures have failed. This review article outlines the anatomical, surgical and post-operative consideration involved in the placement of a penile prosthesis in this special patient population.

Keywords

erectile dysfunction, penile prosthesis, prostate surgery

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1 Rafael E Carrion , University of South Florida, Tampa, USA				
2 Lawrence Jenkins (10), Ohio State University,				

Any reports and responses or comments on the article can be found at the end of the article.

Columbus, USA

Corresponding author: Nelson Bennett (nbennettjrmd@gmail.com)

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Erectile dysfunction (ED) rates after radical prostatectomy (RP)

Penile erection is the culmination of complex series of highly integrated phenomena involving the central nervous system, peripheral nervous system, endocrine system and the vascular system. These systems must be working in concert and at a high level in order for full erection to occur. ED may occur when there is an impairment or derangement to any of these systems. ED has been defined as the inability of a man to achieve or maintain an erection sufficient for satisfactory penetrative sexual intercourse¹.

Post-RP ED may be neurogenic, venogenic, arteriogenic or a combination of these etiologies. In all cases, injury of the cavernous nerves occurs during dissection of the prostate. The injury, whether caused by contact, traction, electro-cautery or transection, initiates a cascade of events that culminates in ED. Microscopically, cavernous nerve-fiber injury initiates Wallerian degeneration that will incapacitate the axon back to the cell body, typically at the level of the spinal cord. The lack of nervous input at the end-organ (cavernous muscle) is a major contributor to cavernosal tissue degeneration and atrophy^{2,3}. Venous leakage is another underlying mechanism responsible for ED after prostatectomy. Bilateral cavernosal nerve injury has been shown to induce cavernosal smooth muscle death which will lead to veno-occlusive dysfunction³. Chronic hypoxia, denervation, and activation of the TGF- β cascade are believed to initiate the apoptosis process, and increase the deposition of collagen-laden scar tissue^{4–7}.

The initiating factor in the development of arteriogenic ED as a result of radical pelvic surgery is transection of the accessory pudendal arteries. These arteries arise from the peri-prostatic vasculature and course toward the penis and providing a significant portion of the arterial inflow required for normal erectile function^{8,9}.

The incidence of post-prostatectomy ED has been reported to be between 29-88%¹⁰⁻¹⁶. This wide range of values can largely be attributed to failure to control various confounding factors including age, degree of nerve sparing, different definition of potency and preoperative ED. The CaPSURE study revealed that only 20% of patients returned to their preoperative baseline potency levels 1 year after RP¹². In the Prostate Cancer Outcome Study (PCOS), 59.9% of men self-reported having ED following RP¹⁴. Similar results were found by the Memorial Sloan-Kettering Cancer Center group^{17–19}. According to The Scandinavian Prostate Cancer Group, men who chose watchful waiting had a 45% incidence of ED. Those that selected RP as a treatment option experienced an incidence of ED at 80%²⁰.

Inflatable penile prosthesis (IPP) utilization after RP

Phosphodiesterase-5 inhibitors (PDE5Is) initially were the first-line treatment for ED secondary to RP. However, they are not uniformly effective. In a subset of patients who initially respond, the response deteriorates over time as progressive cavernosal tissue damage occurs and subsequent venous leak

develops^{18,21,22}. Penile implant surgery is a viable treatment option in patients in whom nonsurgical ED treatments are unsatisfactory or are associated with adverse effects²³. The utilization rate of penile implants after RP varies from 0.8 to 1.9%^{24,25}. These reported rates have been obtained from analysis of the Surveillance Epidemiology and End Results (SEER) cancer registry database. The higher rate of 1.9% in a study by Stephenson *et al.*²⁵ is probably due to a younger cohort, as 45% of subjects were younger than 65 years. There are numerous reasons that could be postulated for low utilization of penile implants. Firstly, prostate cancer treatment modalities have improved, thereby decreasing the incidence of ED that is unresponsive to nonsurgical intervention. Secondly, effective nonsurgical treatment modalities have been developed as alternatives to surgical treatment, predominantly PDE5Is. Meta-analysis of contemporary publications by Tal et al. revealed an overall erectile function recovery rate of 58% among men younger than 60 years after RP²⁶. The study acknowledged that the definitions of ED were different in each member study and some men used of PDE5i's for erectile rigidity²⁶. Nevertheless, Stanley et al. found that there was no significant change in total number of penile implant procedures over a 10-year period before and after the introduction of sildenafil citrate²⁷.

Surgical considerations Cylinder placement

Technique of dilation of fibrotic corpora. Corporal crossover and urethral perforation are more likely to occur during dilation of fibrotic corpora²⁸. After placing the stretched penis into anatomical position (urethral meatus pointing in a superior direction), a small dilating instrument is placed into the corporotomy and slowly advanced in a latero-superior direction until it reaches the mid-glans penis. Sequential dilation is needed until the cavernosa accepts a 11-12 Fr. dilator. The most important caveat to remember is to orient the dilating instrument in a latero-superior direction when advancing the dilator within the corporal space²⁸. This will prevent corporal crossover, as well as, provide a visual representation of the location of the dilator within the corpora. Tools used for dilation may include Metzenbaum scissors, Hagar dilators, Brooks dilators, Rossello cavernotomes. Mooreville cavernotomes, and the dialmezinsert dilator²⁹

Technique of corporal measurement. After corporotomy, PDS 2-0 stay sutures of are placed at the corporotomy edge. The sutures are used for traction, as well as, for closure of the corporotomy after insertion of the prosthesis. Historically, corporal dilation would then ensue with Brooks or Hegar dilators. After ensuring the corporal space was dilated to 14 mm, the corporal length was then measured and the prosthesis placed. In the contemporary setting, many implanters first measure the length of the corpora with the Furlow³⁰. This narrow device provides enough passive dilation to place an inflatable prosthesis, especially if the corpora are non-fibrotic. If the corpora are fibrotic, the implanter would then dilate the corpora to ensure smooth insertion of the prosthesis³¹. When dilating or measuring the corpora, it is imperative to direct any instrumentation laterally to avoid urethral injury or corporal crossover³².

To measure the length of the corpora, gently advance the cylindrical measuring device proximally within the corporal space. When the bottom of the corpora cavernosa is reached, a measurement is recorded. Next, the penis is placed and securely held in "anatomical" position. The measuring instrument is passed distally towards the glans penis while angling the instrument laterally. A distal measurement is recorded and added to the proximal measurement. There should be no more than a 1-cm discrepancy between the right and left corpora. A >1 cm difference suggests incomplete dilation, corporal crossover, crural perforation or urethral perforation.

Prevention and management of corporal crossover

Both proximal and distal corporal crossover can happen during dilation, measurement, or cylinder placement³³. In addition, the initial correct distal tunneling technique using laterally directed dilators will help avoid crossover²⁸. Side-by-side placement of the Brooks or Hagar dilators in each corpus to check for symmetry and proper positioning is the best way to check for proximal or distal crossover³⁴. If a crossover is detected, the dilator may simply be redirected with the contralateral dilator left in place to prevent repeat crossover²⁸.

Prevention and management of perforation

Proximal crural perforation is suspected when there is asymmetry of proximally positioned dilators or a significant length differential. Gentle dilation and corporal measurement can prevent this manageable complication. In the event of proximal perforation, management may take the form of direct repair of perforation, creation and placement of windsock using an "off-the-shelf" implantable graft, creation of a hammock using a rear-tip-extender, or anchoring of cylinder tubing to tunica^{35,36}. A simple 'U-type' suture will prevent proximal cylinder migration.

Distal corporal and urethral perforation requires termination of the procedure, especially if distal perforation occurs during dilation of the first side³⁷. If a second side is perforated after successful cylinder placement of the contralateral side, the single cylinder may be left on the non-perforated side³⁸. Urethral tear may be repaired or, if very small, left to heal over the catheter³⁹. Many surgeons will abandon the case during urethral injury in fear of prosthesis infection.

Reservoir placement

The reservoir is normally placed in space of Retzius. This is done to reduce the creation of inguinal floor weakness and to reduce the potential risk of visceral injury. After ensuring complete bladder drainage, the index finger is placed through the IPP incision and advanced to the medial aspect of the external inguinal ring. Using firm pressure, the finger is advanced in a posterior direction, piercing transversalis fascia. If finger pressure is inadequate, the fascia can be perforated with the tip of an instrument (scissors or clamp). This action will create a rent large enough to insinuate an index finger into the space of Retzius. Alternatively, a long-bladed nasal speculum is useful in expanding the retroperitoneal space. If the space of Retzius is obliterated due to previous pelvic surgery, ectopic placement of the reservoir should be considered^{40,41}. The reservoir may be placed in the deep to the abdominal musculature superior or posterior to transversalis fascia⁴². A Foerster or Debakey clamp may be used to advance the deflated reservoir to its ectopic position. Stember *et al* reported the outcomes of 2687 men who underwent ectopic reservoir placement⁴². In total, 83%, of men had reservoirs placed posterior to the transversalis fascia. The remainder had reservoirs placed in the anterior transversalis space. No injuries to the bowel or major blood vessels occurred with initial insertion of the reservoir, however two patients experienced bladder injury. Eight patients required reservoir revision secondary to herniation⁴².

Prevention and management of bladder and bowel perforation

The most serious intraoperative complications of penile prosthesis insertion occur during reservoir placement⁴³. Traditionally, the reservoir is placed blindly in a retrograde fashion into the space of Retzius through a penoscrotal incision. The serious potential complications include vascular injury, bowel perforation and bladder perforation⁴⁴.

Vascular injury (arterial or venous avulsion) may occur during overly aggressive finger or instrument dilation of the inguinal ring. In the event of brisk bleeding, tapenade with an index finger or sponge stick is advised⁴⁵. Direct access into the space of Retzius is then accomplished through an inguinal incision. Meticulous inspection of the pelvic sidewall will frequently localize the avulsed venous vessel. In the event of vascular injury of the major pelvic vessels, consultation from a vascular surgeon is recommended.

Bladder injury is a complication that should be recognized and managed immediately. Prior pelvic surgery or radiation may result in adherence or fixation to the pelvic sidewall. Bladder perforation can happen while piercing the transversalis fascia⁴⁶. Emptying the bladder prior to placing the reservoir can decrease the incidence of these injuries. Bladder injury is noted when gross blood is seen in the urine or the observation of urine emanating through the IPP incision³¹. The injury can be confirmed via flexible cystoscopy or by an on-table cystogram. In case of bladder injury due to scissors, the reservoir should be removed and placed on the contralateral side. The bladder should be drained for 7–10 days. Cystogram should be done prior to catheter removal.

The bowel may be damaged in a similar mechanism to bladder injury during reservoir placement³¹. Upon recognition bowel injury (succus entericus in the wound), a general surgeon should be consulted for repair and the prosthesis removed.

Satisfaction rates after penile prosthesis implantation

Serial reports regarding of penile prosthesis surgery outcomes demonstrate excellent long-term mechanical reliability of contemporary prosthesis models; satisfaction is superior when compared to PDE5Is and injections. Carson *et al.* performed a retrospective long-term multicenter study on 372 patients who underwent penile prosthesis implant and focused on the longevity, morbidity and patient satisfaction⁴⁷. More than 80% of patients were satisfied with the function of the device, the ease of inflation, and level of rigidity. Steege *et al.* reported that patient satisfaction with semi-rigid prostheses was higher than 90%, however, inflatable devices enjoy a slightly higher satisfaction⁴⁸. Holloway and Farah reported that the AMS 700 Ultrex prosthesis had a 86% patient and 76% partner satisfaction at a mean postoperative follow-up of 42 months⁴⁹. In a study by Rajpurkar *et al.*, the investigators demonstrated significantly enhanced erectile function and sexual satisfaction when compared to those receiving sildenafil and intracavernosal prostaglandin⁵⁰.

The psychosexual adaptation to penile implant may take up to 6 months. The patients experience a marked enhancement in erectile function with elevation of libido. Apprehension regarding the maintenance of an erection during intercourse is markedly assuaged. In addition to an upsurge in the regularity of sexual activity, a decrease in feeling of sadness, depression, anxiety and an improvement in sexual satisfaction has also been noted⁵¹.

Two major factors contributing to high level of satisfaction are rapid generation of erection and consistently excellent rigidity. Other factors, such as degree of postoperative pain and swelling, postoperative complications, ease of concealment, cosmetic outcome, device function, ease of use and partner acceptance, are critical in determining the patient satisfaction. Potential predictors of patient dissatisfaction with penile prosthesis include Peyronie's disease, a body mass index >30, or previous RP^{52} .

Predictors of requiring a penile prosthesis

The natural recovery time of erectile function may be up to 24 months after radical pelvic surgery; however, resultant penile rigidity may be maximized by early treatment with intracorporal injection therapy^{53–55}. Various different symptomatic treatments are available for patients who fail to regain a natural erection. Sildenafil becomes effective in the late recovery phase as the nerves recover from intraoperative injury⁵⁴. At 2 or more years from surgery, the recovery of natural function and improved response from other therapies is unlikely and implantation of penile prosthesis is warranted⁵⁴. A study by Tal et al. found that men who had surgery as an initial treatment (versus radiotherapy), were of a younger age, were of African/American/Hispanic race, were unmarried, and were living in a geographic region other than the North-east were more likely to utilize penile implants²⁵. Similarly, in a retrospective analysis of claims data from Medicare & Commercial databases of 3928 men undergoing penile prosthesis, Segal and Burnett elucidated the factors with the greatest predictive strength of penile prosthesis implantation, which included a diagnosis of prostate cancer, a diagnosis of diabetes mellitus and previous treatment with first-line ED therapy⁵⁶.

Conclusion

In the population of patients with prostate cancer, the concept of survivorship has become a central tenet of patient care. To that end, quality of sexual life, and especially erectile function has become a significant issue. Penile prosthesis surgery remains an excellent option for restoring erectile function to those who fail more conservative measures. IPP implantation enjoys high satisfaction rates for patients and their partners. Intraoperative complications can be distressing, but with prompt recognition, most of these complications can be navigated with excellent postoperative results.

Data availability

No data are associated with this article.

Competing interests

No competing interests were disclosed.

Grant information

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Lawrence Jenkins 🔟

Ohio State University, Columbus, OH, USA

Well put together manuscript reviewing the literature in penile prosthesis placement after radical prostatectomy. I commend the authors on their thorough summary. There are several points I would recommend clarified.

1. Page 2 paragraph 3 first sentence – "The initiating factor in the development..." This singular cause is debatable. There was a paper by Box et al.¹ that showed no difference with preservation of the APAs. I would recommend softening the tone.

2. Page 2 paragraph 4 – when discussing the potency rates I would recommend stating that those numbers include patients with and without the use of PDE5Is.

3. Page 2 – surgical considerations – 1st paragraph, last sentence – spell check – Dilamezinsert is the name listed in the Cooper Surgical catalog.

4. Page 3 – 3rd paragraph, prevention and management of perforation – Please clarify how the 'U-type' suture is used to prevent cylinder migration.

5. Page 3 satisfaction rates after penile prosthesis implantation, first sentence - Check grammar, "of" can be removed as the 4th word.

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Is the topic of the review discussed comprehensively in the context of the current literature? $\gamma_{\mbox{es}}$

Are all factual statements correct and adequately supported by citations? Partly

Is the review written in accessible language? Yes Are the conclusions drawn appropriate in the context of the current research literature? $\ensuremath{\mathsf{Yes}}$

Competing Interests: No competing interests were disclosed.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 27 June 2018

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Rafael E Carrion 🔟

Department of Urology, Morsani College of Medicine, University of South Florida, Tampa, FL, USA

The authors provide a review manuscript highlighting the role of a specific surgical modality in the realm of prostate cancer survivorship. They initially start by providing a concise review of ED after RP.

Under "Surgical Considerations," they begin to discuss specific steps of the penile implantation surgical process. I felt they provided a good review on the separate domains of penile implant surgery. However, I would avoid specific surgeon bias specific steps such as the first sentence under "Technique of corporal measurement," where the author's state, "After corporatomy, PDS 2-0 stay sutures..." This is NOT a surgical techniques manuscript, it is a review of the topic at hand.

Is the topic of the review discussed comprehensively in the context of the current literature? $\gamma_{\mbox{es}}$

Are all factual statements correct and adequately supported by citations? $\gamma_{\mbox{es}}$

Is the review written in accessible language?

Yes

Are the conclusions drawn appropriate in the context of the current research literature? Yes

Competing Interests: No competing interests were disclosed.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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