Current Urology Reports (2019) 20: 14
https://doi.org/10.1007/s11934-019-0876-6

SURGERY (J SIMHAN, SECTION EDITOR)

Optimizing Outcomes in the Virgin Penile Implant Patient

Charles Welliver[1]

Published online: 7 February 2019

Abstract
Purpose of Review Patient satisfaction with inflatable penile prosthesis (IPP) is an elective procedure that restores erectile function.
Recent Findings While the return of usable erections is almost always achieved with IPP, patients may still be unhappy with the procedure if the outcome has not met their expectations. Optimizing patient satisfaction and outcomes should incorporate considerations for pre-, intra-, and postoperative factors. Length optimization regimens and improved pain control options have dominated the recent literature.

Keywords Penile implant · Patient satisfaction

Introduction

Inflatable penile prosthesis (IPP) remains the gold standard for treatment of erectile dysfunction (ED) that is severe or recalcitrant to more conservative options. Ultimately, how the patient perceives their penile esthetics and erectile function with the implant will determine satisfaction. While improvements in the implanted device and new surgical techniques have improved outcomes, counseling (both pre- and postoperative) along with vigilant troubleshooting will help avoid the unhappy patient and improve satisfaction.

Preoperative Considerations

IPP surgery is a purely elective case focusing on quality of life. Despite the invasive nature of penile implantation, the procedure maintains the highest satisfaction rate among ED treatment. Overall satisfaction rates for penile injections, phosphodiesterase type 5 inhibitors (PDE5i), and penile implants in one study were 40%, 51%, and 93%, respectively [1]. Insertion of penile implants has also been associated with improvements in psychosexual well-being [2]. The penile implant occupies a unique position in ED treatment in that it is frequently used as a "last resort" treatment generally considered after other more conservative treatment options have failed. The procedure is essentially irreversible with the patient generally unable to return to more conservative treatments with failure.

For the above reasons, careful and accurate molding of patient expectations is crucial to patient (and provider) success. Patients with unrealistic expectations of functionality and particularly phallus size after implant will be disappointed even with the best result as it will not meet their preconceived notions. In some cases, potential patients will come to the clinic with already ingrained beliefs about the procedure and implant that they believe are true. Identifying and rectifying misconceptions are an important part of preoperative counseling.

In general, preprocedure counseling should focus on how the implant principally restores erection functionality. Many patients report shortening of the penis with the implant despite objective evidence of no changes in stretched penile length with the procedure [3] and indeed the procedure itself does not appear to change the penile length [4]. Many providers will measure the stretched penile length preoperatively and document this measurement in the chart for future reference. The stretched penile length can be measured in the supine or standing position. Most physicians will measure from the pubic symphysis to the corona of the glans.

As penile length is among the most common cause of dissatisfaction with penile implants [5–7], possible strategies to improve the postoperative esthetics and size have been

This article is part of the Topical Collection on *Surgery*

✉ Charles Welliver

[1] Albany, USA

proposed. While anatomic factors like a lack of glans engorgement can account for some of the differences in length [5], a lack of elastic distention of the capsule surrounding the cylinders may also play a role [8]. In efforts to optimize penile length with IPP, protocols have been developed both preoperatively and postoperatively. Vacuum erection device (VED) is a centerpiece of these protocols. In a paper looking at preoperative usage for 10 min daily for the 2 months before surgery, longer implants were able to be placed compared to historical controls [9].

While a minority, patients may still report dissatisfaction with penile implant. Additional factors beyond issues with phallus size after implant that lead to dissatisfaction include lack of glanular engorgement with erection, abnormal orgasmic/ejaculatory function, perioperative discomfort, partner satisfaction, and difficulties operating the device. Patients who are potentially at high risk for dissatisfaction with the device may fall under the mnemonic CURSED Patient (compulsive/obsessive, unrealistic expectations, revision surgery, surgeon shopping/seeking multiple surgical opinions, entitled, denial of prior erectile/sexual function, and psychiatric disorders). Patient factors that portend a happier patient included a willing partner, body mass index less than 30, absence of concomitant Peyronie's disease, and reasonable preoperative expectations [10••].

Intraoperative Considerations

GIRFT (or "get it right first time") is the British health system initiative to maximize quality care and patient outcomes. The program focuses on minimizing variation and mistakes and focusing on performing procedures correctly the first time to reduce later costs and complications of revision. The smart implanter is wise to keep GIRFT in mind intraoperatively. The need for a revision surgery, or having a major complication, is correlated with poor patient satisfaction [11•]. Any additional surgery increases the risk of infection and further complication with each additional procedure increasing infection risk [12].

Corporal Measurements and Device Length Selection

Intraoperative measurements of corporal length are generally taken from a fixed spot on the corpora (usually somewhere along the corporotomy) with the overall length broken down into proximal and distal measurements. Proper cylinder selection for the patient depends on a variety of factors including a blend of patient factors, device characteristics, and physician practices.

While the overall corporal length selects the implant size, consideration should be given to the relative lengths and length/size of the scrotum when deciding. Determining the ratio of inflatable cylinder size to any need for rear tip extenders (RTEs) will affect multiple aspects of patient satisfaction. As a rule, RTE use should be minimized as the inflatable portion of the device (fluid column) providers more rigidity. Boston Scientific (Marlborough, MA) implants are available in 12-, 15-, 18-, 21-, and 24-cm inflatable portions. Previously, there was a fixed tubing length independent of device length; however, they now offer longer tubing in the 24-cm devices. In general, when selecting a Boston Scientific implant, the inflatable portion is determined by subtracting 2 cm from the total length and then selecting the cylinder size that is shorter or equal to this calculated length. Whatever RTEs are needed to complement the inflatable portion and match the measured length are then used. The Coloplast (Humlebæk, Denmark) implants have tubing lengths that increase with cylinder length. When sizing these devices and determining RTE need, most implanters will use the proximal measurements in relation to 10. In the case where the proximal measurement minus 10 is negative, no RTEs are needed. In cases where the proximal measurement is longer than 10 cm, the number of RTEs generally recommended is the proximal measurement minus 10.

A potential pitfall in device size selection leading to patient dissatisfaction can occur in men with significantly longer proximal measurements (often seen in obese men). In these cases, the length of tubing protruding from the corporotomy may be insufficient. In cases where the proximal measurement is much longer than the distal measurement, additional RTEs than that calculated above may need to be added so that the pump may sit adequately dependent in the scrotum. In extreme cases, infrapubic implants with their longer tubing can even be placed via a penoscrotal approach.

Another potential pitfall may occur with either overly judicious RTE use or in men possessing a small scrotum. In either case, an excess of tubing protruding from the corporotomy may exist that will be difficult to conceal in the scrotum. While splicing in more connecters (and removing excess tubing) is a possibility, this is time-consuming and introduces even more foreign body.

Most implanters believe that the overall IPP length should be the same as the measured length. However, some surgeons do routinely undersize or oversize cylinders [13, 14]. While the merits of these practices are hotly debated among implanters, almost all agree that oversizing should not be done in men with Peyronie's disease or when corporal fibrosis is encountered during dilation.

Both anatomical variations and undersized cylinders may lead to a "floppy" or hypermobile glans. In the case where cylinders do not extend at least to the coronal sulcus, the implanter should consider careful re-dilation distally and/or re-measurement as the implant itself may be undersized. In cases with adequate cylinder extension but a still hypermobile glans, intraoperative repair may be considered. Originally

described by Ball [15], a more contemporary repair has been proposed that utilized two small dorsal incisions and a suture passed through the glans to tether it to the penile shaft [16]. While a possibility during the initial IPP placement, often the hypermobile glans will stabilize after deposition of scar tissue that will adhere the glans to the prosthesis. In cases where this does not improve in the months postoperatively, repair can then be advocated for unsatisfied patients.

What to Do with Unequal Measurements

Intraoperative troubleshooting and adjustment are an ongoing process throughout the case. A common precursor to a problem is dissimilar corporal length measurements. In one large analysis of over 63,000 implants, a greater than 1-cm discrepancy in corporal measurements was only seen in 2.7% of cases [17]. While this inconsistency is more acceptable in men with Peyronie's disease, the conscientious implanter should be careful to exclude other potential causes. Potential causes of a dissimilar measurement may include proximal perforation, distal perforation, and cylinder crossover.

Proximal tunical perforation may occur with an overly aggressive corporal dilation and in one study occurred in 4.5% of virgin prosthesis cases [18]. This may increase to 37% in patients with severely fibrotic corpora [19]. This error is generally recognized at the time of injury as the surgeon will feel a quick relief of the pressure against the dilator as the dilator travels through the tunica albuginea into the surrounding soft tissue of the perineum. The implanter should remember that the proximal corpora deviate laterally when dilating. In cases where a proximal perforation occurs, a butterfly perineal hematoma may be identified as the extravasated blood is captured in Colle's fascia. A "goal post" test should be performed with a dilator in each proximal corpus to assess depth and angle. If a perforation has occurred, this difference will generally be obvious. Repair of a proximal perforation was originally accomplished via a "windsock" type repair wherein Gore-Tex was used to create a pouch for the implant to sit in. However, with potentially increased infection rates [20, 21], this repair quickly fell out of favor with preference now being for the suture sling. The suture sling repair involves using a permanent suture passed through one side of the tunica, into the non-inflatable proximal portion of the implant and then through the other tunical edge. Implant cylinder is then placed into the corporal space and pulled distally via the suture protruding through the glans. The pre-placed permanent suture is then tied without slack so that the implant may no longer migrate proximally into the area of perforation [22].

Unlike proximal perforation, distal perforation may be complicated by a concomitant urethral injury. This injury occurs due to dilation that was not directed dorsally or laterally. If during irrigation of the corpora, fluid is seen effluxing from the meatus, urethral injury is essentially confirmed. Managing an intraoperative urethral injury can take on many forms. Classically, if the injury occurs on the dilation of the first corporal side, the case is aborted with prolonged catheter drainage and possible repair of the urethra and tunica. If the injury occurs on the second side of dilation, some will advocate leaving an implant cylinder on the dilated but uninjured side. However, in a recent survey of GURS and SMSNA members, 10.7% of those surveyed would plan to repair the urethra and still place the implant regardless of when the injury occurred during the case [23].

Cylinder crossover is characterized as a cylinder passing through the intercavernous septum onto the contralateral side. Perforation of the septum may occur in up to 25% of cases [24] and can be avoided by directing dilation dorsolaterally. An incomplete distal dilation should be excluded if cylinder crossover is suspected as the incompletely dilated side may be pushing the ipsilateral cylinder into the adequately dilated contralateral side. The implanter should place a large dilator into the side the device is herniating into and then ensure complete and correct dilation. Cylinder may then be placed with the initial dilator still in place to ensure the cylinder stays in its ipsilateral corpora; the initial dilator is then removed, and the other cylinder is placed. While a more involved repair, a subcoronal incision may be made over the affected cylinder delivering the crossed over (or even eroding) cylinder. A 4-0 PDS suture is then placed through the distal cylinder ring of the implant and then placed into a new intracorporeal channel with the PDS suture passed through the glans. The glans is incised, and the suture tied at the level of the tunica, burying it well into the glans after closure [25].

Reservoir Considerations

The Space of Retzius has been the traditional location for IPP reservoir placement. Access is generally gained by identifying the external inguinal ring and then perforating the transverse abdominal fascia to access the space. The implanter however should be careful to empty the urinary bladder before accessing the Space of Retzius. In a cadaveric study, distance from the inguinal ring to the bladder was significantly increased by decompressing the bladder (from 6.45 cm vs 2.61 cm). External iliac vein distance from the inguinal ring was found to be on average 36.4° lateral at a distance of 3.23 cm from the inguinal ring emphasizing the recommendation to stay medial when dissecting the space of Retzius to avoid vascular injury [26].

As radical prostatectomy has changed from the open to the robotic approach, new locations for the reservoir have become in vogue. As the peritoneal veil is not re-established after robotic prostatectomy, there is an increased risk of the reservoir causing bowel or vascular complication when placed into the space of Retzius after robotic prostatectomy.

Correspondingly, many implanters now prefer a location for the reservoir in the abdominal wall.

Placement of the reservoir into the abdominal wall position generally aims for the layer superficial to the transversalis fascia but below the abdominal wall muscles. Again, the external inguinal ring is identified as the first step. If approaching from a penoscrotal incision, a long clamp is then placed through the inguinal canal into the abdominal wall depositing the reservoir. If an infrapubic incision was utilized, the external ring may be accessed through the incision with a tonsil, nasal speculum, or clamp used to access the space for the reservoir.

Potential complications of the new submuscular placement are being identified. In a study looking at both artificial sphincter and penile implant reservoirs in a high submuscular location, approximately 20% of reservoirs were palpable either by the patient or surgeon. However, these generally did not cause bother and only 1.3% underwent revision due to bothersome palpability [27]. In a collection of almost 1000 cases from a multicenter group, abdominal wall placement required reservoir revision in 2% of cases compared to 1.3% in the space of Retzius group ($p = 0.44$). Three of the 612 patients required revision due to abdominal muscular pain [28].

While the area between the transversalis fascia and the abdominal wall musculature is frequently the goal location for the reservoir, a study in fresh cadavers found variable final locations of the reservoir. In 80% of cases, the reservoir was found anterior to the transversalis fascia. However, reservoirs were found also in intraperitoneal (5%), retroperitoneal (10%), and preperitoneal (5%) [29]. Very low BMI (less than 20) may be a risk factor for peritoneal location of reservoir [30].

Wound Closure

In the spirit of GIRFT, the device should be cycled before closure to ensure a satisfactory result. There is not a precise location in the scrotum where the pump should be placed, with some advocating for a more anterior location for easier patient access while others prefer a subtler, posterior location. Several layers should be closed over the pump to minimize a minor wound breakdown leading to exposed tubing. While seemingly a straightforward portion of the case, a few techniques should be considered to improve patient satisfaction.

Ventral phalloplasty (scrotoplasty) involves removal of excess skin at the penoscrotal junction to improve penile esthetics. In patients undergoing ventral phalloplasty, 84% of patients reported some degree of increase in penile length with concomitant device placement. This was in comparison to the group of patients undergoing IPP placement without phalloplasty who reported decrease in penile size in 84% of cases [31]. Care should be taken in patients with diabetes mellitus as this appears to increase risk of wound breakdown with ventral phalloplasty [32].

While controversial, use of a closed suction drain may reduce hematoma formation and postoperative pain and allow for earlier device cycling/use [33]. Drain use has not been shown to increase or decrease postprocedure infection, however, has been correlated with a low rate of hematoma formation [34].

Postoperative

Patient pain and discomfort dominate much of the periprocedural time period. A variety of techniques have been attempted including use of long-acting local anesthetic [35] and multi-modal anesthesia approaches.

Multi-modal anesthesia models look to use a variety of oral medications along with local anesthetic options to both control patient pain and limit narcotic use. Patients undergoing a multi-modal analgesia protocol at one institution reported lower visual analog pain scales and required fever narcotics (along with narcotic prescription refills) [36•].

The time frame over which patients become comfortable using the device will vary. In patients assessed by IIEF-6 erectile function scores after implant, scores improved over the first 12 months. Patient satisfaction with the implant also improved throughout the study period [37].

Strategies also exist to mitigate perceived penile length loss after surgery. Intraurethral alprostadil or PDE5i may help with glans engorgement [38]. In a protocol centering on daily inflation, patient penile length measurements and satisfaction was routinely queried. Of the patients assessed, 64% were satisfied with their penile length at 1 year. With 29% perceiving a length longer than before surgery and 45% saying length was the same as before surgery. Interestingly, authors also found that patients utilized more pumps to reach full inflation over the study period [39].

Conclusion

Optimizing patient satisfaction should take a multi-pronged approach with consideration of pre-, intra-, and postoperative factors. Careful preoperative counseling and setting realistic expectations are a cornerstone. Vigilant intraoperative troubleshooting and a motto of "get it right first time" will reduce the need for revisions. New and interesting postoperative pain control approaches will also help patients be more comfortable around the time of surgery and may allow for earlier device usage.

Compliance with Ethical Standards

Conflict of Interest Charles Welliver is a paid consultant for Coloplast.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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