

# Erectile Dysfunction: Surgical Management

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## Key Points

1. Various penile implants are available for patients. Thorough pre-operative counseling and appropriate patient selection are imperative.
2. There are intraoperative and postoperative complications that can occur with implantation of penile prosthesis and identifying patients at risk of developing these may help mitigate some of those risks.
3. Patients undergoing penile implantation with a history of Peyronie's disease warrant special considerations to execute curvature correction along with device placement.

## 1. Penile Implant Surgery

### 1.1 Indications

A **penile implant** (also known as penile prosthesis) is a device that is surgically implanted into the corpora cavernosa.<sup>1</sup> Penile implants are electively placed in patients who:

- (i) have failed non-surgical management of erectile dysfunction (ED)
- (ii) who are not candidates for non-surgical management or
- (iii) cannot tolerate non-surgical management<sup>1,2</sup>

Modern penile implants have been available for nearly 50 years and have undergone myriad refinements in device design and surgical technique. They are highly effective options for select men with ED.<sup>3</sup> Careful counseling and attention to surgical detail are essential for optimal patient outcomes.<sup>4</sup> The American Urological Association **Guideline for the Management of Erectile Dysfunction** can serve as a general framework for penile prosthesis patient selection and/or alternative ED therapies.<sup>5</sup>

### 1.2 Non-inflatable Implants (Malleable or Semi-rigid)

## See **Placement of malleable penile implant (semirigid): step-by-step surgical technique.**

This simple device utilizes two flexible rods, which are surgically inserted into each corporal body.<sup>6</sup> Current devices approved/cleared by the Food and Drug Administration (FDA) for use in the United States include the Boston Scientific Spectra® and Tactra®, Coloplast Genesis® and Rigicon Rigi10® implants. ( **Figure 1**) Malleable cylinders are rigid in the erect state but can be bent downward when not in use. The device allows for a functional erection for sexual activity, but there is no completely flaccid (soft) state with a malleable implant. Patient satisfaction is adequate with malleable devices although it may not reach the levels seen with inflatable devices.

In the US, these devices are most often placed in patients with manual dexterity difficulties (i.e. Parkinson's disease) or other significant health issues. These devices may also be most suitable for men whose primary need is penile rigidity for condom catheter use. Worldwide they are more common than inflatable devices due to cost. Given their comparably low rates of infection, they are also placed during revision surgery for infection or for treatment of priapism.<sup>8,9,10</sup> When placed in spinal cord injured patients, the surgeon and patient need to be aware of the potential for distal perforation due to the constant pressure on the glans and distal penile skin. Malleable devices come in fixed lengths that can be shortened or adjusted, and each brand has a variety of diameters.

The **following link** connects to a surgical video regarding malleable penile prosthesis insertion located in the Video Journal of Prosthetic Urology.



Figure 1a – Coloplast Genesis. 1b – Boston Scientific Spectra. 1c – Rigicon Rigi10.<sup>11,12</sup>

### 1.3 Two-Piece Inflatable Implant

There is currently only one two-piece device (Ambicor®, Boston Scientific, **Figure 2**) on the market. It consists of two inflatable cylinders and a scrotal pump.<sup>13</sup> The device allows for a fully rigid erection, however in the flaccid state the penis will have some tumescence as the device is pre-filled (given the absence of a reservoir). The fluid is located in the proximal (posterior) part of the cylinders when not fully inflated.<sup>14</sup> The pump mechanism transfers fluid from the proximal portion of the corporal cylinders to the distal (anterior) part of the device. Inflation is accomplished by squeezing the pump, while deflation is accomplished by bending the device cylinders in the mid-shaft to 90 degrees. This facilitates transfer of the fluid back to the proximal cylinder reservoir.<sup>14</sup> This device offers an excellent rigidity profile but concerns have been raised regarding sufficient rigidity for men with Peyronie's disease.<sup>15</sup>

The two-piece device is a reasonable option for patients who have bilateral inguinal herniorrhaphy (particularly with preperitoneal mesh), an obliterated space of Retzius (following radical prostatectomy), small bowel close to the inguinal ring (following radical cystectomy), or pelvic renal transplant (or need for such in the future).<sup>16</sup> Indications for a two-piece prosthesis are not necessarily contraindications for a three-piece device as the reservoir for the latter device can be placed in an abdominal wall location.<sup>17,18</sup> Nevertheless, two-piece devices remain an option due to this advantageous safety profile.<sup>19,20</sup> This device comes in standard sizes (2 cm increments 14-22 cm), which may be customized by addition of rear tip extenders (RTEs) proximally (1-3cm). With the advent of ectopic/alternative reservoir placement during three-piece inflatable penile implantation, fewer surgeons utilize two-piece penile implants in contemporary practice.

### AMS Ambicor® 2-piece IPP



Figure 2

## 1.4 Three-Piece Inflatable Implant

Three-piece penile implant devices currently approved/cleared for use in the United States by the FDA include Boston Scientific 700-CX®, 700-CXR®, (Figure 3) and LGX® implants and the Coloplast Titan® implant (narrow and standard base) (Figure 4).<sup>21,22</sup> Three-piece devices allow for both a flaccid and erect state that more closely resembles natural physiology. The three-piece inflatable implant cycles fluid from a reservoir into the penile cylinders via a scrotal pump to produce rigidity of the penis. Devices come in standard sizes (12-24 cm), which may be customized by the addition of RTEs. The reservoir is classically placed in the space of Retzius but for a variety of reasons may be placed in an alternative location. Alternative, sometimes called “ectopic,” locations include subcutaneous, subfascial and submuscular locations. Submuscular placement generally positions the reservoir between the peritoneum and transversalis fascia or superficial to transversalis fascia and deep to the rectus abdominus fascia.<sup>17,18</sup> Caucasians and men without spinal cord injury may be more likely to receive an inflatable penile prosthesis as opposed to a malleable implant.<sup>23</sup>



Figure 3 – AMS 700

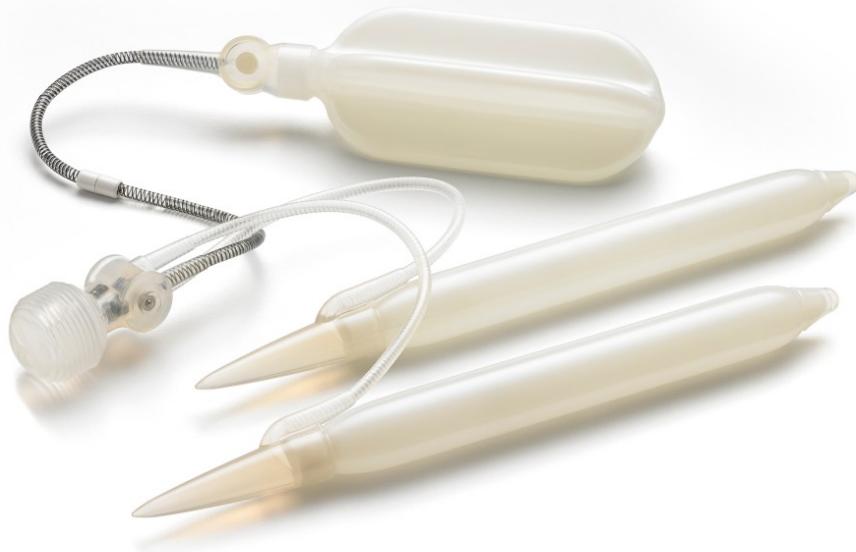


Figure 4 – Coloplast Titan

## 2. Pre-operative Counseling and Patient Selection

An in-depth discussion regarding the indications for penile implantation, pre-operative preparation, operative procedure, post-operative care and expectations of implant function and use is strongly recommended. This discussion should be directed towards men and their partners, with consideration of patient-specific and couple-specific factors. The informed consent process provides a framework for discussion of the complications that may occur intra- and/or post-operatively. Discussion should include: expectations of post-operative penile length, sensation, appearance, sexual function, mechanical life, post-operative pain, infection, injury during surgery, and erosion.<sup>24</sup>

Identifying patients at elevated risk for sub-optimal outcomes and dissatisfaction aids in expectation management. Trost *et al.* identified seven characteristics associated with higher rates of post-operative dissatisfaction.<sup>25</sup> These traits are represented in the mnemonic “CURSED Penis” which stands for: Compulsive, Unrealistic, Revision, Surgeon shopping, Entitled, Denial, and Psychiatric. See traits of these characteristics below in **Table 1**. Polysubstance abusers have also been found to have elevated risk of implant infection post-operatively.<sup>26</sup>

**Table 1**

Trait	Characteristic
Compulsive/Obsessive	<ul style="list-style-type: none"><li>• Penocentric and perfectionist</li><li>• May repeatedly obsess about minor or age-associated changes, and abnormalities pre- or post-op</li></ul>
Unrealistic	<ul style="list-style-type: none"><li>• Deny possibility of complications</li><li>• May have numerous, specific requests and are resistant to suggestions of a less than perfect outcome</li></ul>
Revision	<ul style="list-style-type: none"><li>• Increased risk complications/poor outcomes</li><li>• Seek surgery to placate underlying psychological problems</li></ul>
Surgeon-Shopping	<ul style="list-style-type: none"><li>• Numerous prior consultations</li><li>• May have experience in medical field</li></ul>
Entitled	<ul style="list-style-type: none"><li>• Overly demanding of time</li><li>• Disrespectful/patronizing, particularly to office staff</li><li>• Increased risk of litigious behavior</li><li>• Dominate conversations and are not good listeners</li></ul>
Denial	<ul style="list-style-type: none"><li>• Exaggerated memories of prior penile length, girth, function</li><li>• Frequently seen with Peyronie's disease</li></ul>
Psychiatric	<ul style="list-style-type: none"><li>• Psychotic disorders</li><li>• Mood disorders</li><li>• Personality disorders</li><li>• Body dysmorphic disorders</li></ul>
adapted from Trost et al. <sup>25</sup>	

Prior to the procedure, patients should be free of systemic, cutaneous, or urinary tract infection. There is evidence to recommend that patients be medically optimized. This includes medical management of their comorbidities as well as smoking cessation. Antibiotic coated devices should be utilized where available.<sup>27</sup> Pre-operative antibiotics should be administered to all patients;<sup>27</sup> local antibiograms should be consulted and consideration should be given to expanded coverage as organisms not covered by standard antibiotic regimens have been detected in up to 1/3rd of contemporary penile prosthetic infections.<sup>28</sup>

Patient satisfaction following IPP surgery has been reported to be as high as 90%.<sup>15</sup> However, one of the most common complaints is decreased penile length postoperatively. It is critical to counsel patients regarding real or perceived changes in penile length prior to implantation. Preoperative strategies to improve penile length with IPP include the use of penile traction therapy<sup>29</sup> and vacuum erection device (VED).<sup>30</sup> Levine and colleagues reported that 70% had postoperative measured erectile length gain, as much as 1.5 cm, compared with baseline pre-traction preoperative stretched penile length when patients utilized a penile traction device daily for 2–4 hours for up to 4 months. Furthermore, no patient had perceived length loss after surgery. However, this protocol requires excellent patient compliance. Canguyen and colleagues reported an increase in flaccid stretched penile length of  $0.8 \pm 0.38$  cm ( $p < 0.05$ ) in patients who utilized VED 10–15 minutes daily for at least 30 days preoperatively compared to control group. Several adjuvant procedures have been described and shown to safely increase perceived penile length with concomitant IPP surgery,<sup>31</sup> including ventral phalloplasty (a modified scrotoplasty used to remove penoscrotal webbing) and suprapubic fat pad excision. Postoperative penile rehabilitation programs have also been shown to improve penile length. These programs involve cyclic inflation of the IPP daily in a way that mimics physiologic skin stretch caused by nocturnal erections. The use of phosphodiesterase type 5 inhibitors in the postoperative period leads to increased glans engorgement and improved patient satisfaction.<sup>32</sup>

### **3. Surgical Considerations**

#### **3.1 Incisions**

Three incisions/surgical approaches can be used for penile implant placement:

- (i) **circumcising or sub-coronal**
- (ii) **scrotal (or penoscrotal)**
- (iii) **infrapubic**

Adequate exposure is possible with any of these surgical approaches; surgeon experience tends to mitigate disadvantages of any particular incision.

A circumcising or a sub-coronal circumcising incision can be used for the placement of non-inflatable and inflatable implants, but are more appropriately used in patients who have been circumcised or those desiring circumcision at the time of implantation. Others employ the subcoronal approach for

patients undergoing concomitant plaque incision with grafting or penile plication at the time of implantation. It has the advantage of being minimally invasive (using natural scars) and is well tolerated by patients. Disadvantages of this approach include the potential for cylinder migration, and dorsal penile nerve trauma during corporotomy placement. These disadvantages may be overcome by complete penile degloving and placing the corporotomies proximal and ventrolateral. There is a small but well-defined risk of distal preputial necrosis or chronic lymphedema with sub-coronal placement in circumcised men.<sup>33</sup> Care should be taken to minimize this risk by limiting peri-operative insults to the glanular blood supply (e.g. penile compression wrap, Foley catheter, or concomitant placement of anti-incontinence device). Patient factors which may further increase risk of glans necrosis include cardiovascular disease, diabetes mellitus, tobacco use, previous prosthesis explantation, and prior radiation therapy.<sup>33</sup>

The following [link](#) connects to a surgical video regarding subcoronal approach for inflatable penile prosthesis insertion located in the Video Journal of Prosthetic Urology (VJPU).

The scrotal (or penoscrotal) incision has the advantage of excellent exposure to the crura but only an indirect approach to the inguinal ring for reservoir placement. The potential for scrotal hematoma is higher with this approach, but it does facilitate easy scrotal pump placement. Ventral phalloplasty (scrotoplasty) may be performed using the same incision to improve aesthetics and concern about length loss.<sup>34</sup> Simultaneous scrotoplasty carries increased risks, particularly in patients with diabetes.<sup>35</sup>

The following [link](#) connects to a surgical video from VJPU describing the penoscrotal approach.

The infrapubic incision is often made transversely at the dorsal base of the penis and has the advantage of direct access to the inguinal ring. Placement of a scrotal pump may be more challenging with the infrapubic approach and there is possibly an underreported risk of damage to the dorsal neurovascular bundles which could lead to diminished penile sensation. Pump placement and distal corporal dilation in the setting of corporal fibrosis may be more difficult with this approach and is often reserved for higher volume experts.<sup>36</sup>

The following [link](#) connects to a surgical video demonstrating infrapubic inflatable penile prosthesis insertion located in the VJPU.

### **3.2 Corporal Incision and Dilation**

**Once the tunica albuginea has been exposed, longitudinal corporotomies are made in each corpus to expose the cavernosal smooth muscle.** The length of this incision should be the shortest length necessary for implant insertion. It is typical to place holding sutures on the edges of the corporotomy to help facilitate subsequent placement of the implant cylinders and to aid in subsequent corporotomy closure. Corporotomies need to be longer for non-inflatable and two-piece inflatable devices as these implants fold less easily during insertion.

**Corporal dilation follows corporotomy placement.** Dilation creates space for the cylinders within the corpora. Most implant surgeons sequentially dilate the corporal bodies using blunt tipped

instruments of increasing caliber (e.g. Hegar dilators, Brooks dilators). Pressure should be applied in a smooth, controlled fashion and should be aimed dorsally and slightly laterally to minimize risk of urethral perforation during distal dilation. Proximally, it is important to remember that the crura curve laterally along the ischiopubic ramus. Angling the dilation tool slightly laterally will reduce the risk of proximal crural perforation. In cases of severe corporal fibrosis it may be necessary to dissect using Metzenbaum scissors or more advanced dilators (Uramix® cavernotomes, Rosello cavernotomes). Dilation of fibrotic tissue should be done with caution due to increased risk of injury to the corpora and adjacent structures.

The following [link](#) connects to a surgical video regarding corporotomy placement and dilation.

### 3.3 Reservoir Space Creation

Also see [Body Donor Study of Ectopic and Traditional Reservoir Placement](#).

The reservoir placement of a three-piece inflatable penile prosthesis is a key step of the procedure and carries a risk of visceral or vascular injury. **The classic location for the reservoir is in the perivesical space, or the Space of Retzius (SOR)**. The SOR is an extraperitoneal space anterior to the bladder and deep to the pubic bone. Traditional reservoir placement is described well in the above video.<sup>37</sup> The bladder is nearly always drained at the onset of the procedure, or just prior to reservoir placement, to mitigate the likelihood of inadvertent bladder injury caused by reservoir placement. Trendelenberg position increases the distance between the inguinal ring and abdomino-pelvic viscera and allows decompression of the external iliac vessels, which can also help avoid injury during reservoir placement. The SOR may be accessed by piercing the transversalis fascia near the external inguinal ring or above the pubic bone and then developing a space with blunt dissection (using a finger, nasal speculum, or blunt tipped clamp). The surgeon should be cognizant of the often-close location of the iliac vessels and should direct dilation medially after entering the prevesical space.<sup>38</sup> The reservoir space may be created with a finger sweep, nasal speculum, scissors, Foerster clamp, or Pennington/Skylar clamp. The reservoir may then be placed in the developed space.

Prior pelvic surgery is associated with difficulty entering the SOR. Over the past decade, efforts have been made to minimize intraoperative complications associated with reservoir placement, especially in patients who have undergone prior pelvic surgery (such as robotic assisted laparoscopic radical prostatectomy) whose SOR may be scarred, predisposing them to visceral injury intraoperatively. The term “ectopic” placement has thus been born with the idea of placing the reservoir in an alternative location to the SOR thus obviating risk of damage to the abdominal viscera, bladder or iliac vessels.

Ectopic/alternative placement involves placement of a reservoir anywhere outside of the SOR. These options include the “submuscular” insertion between the peritoneum and abdominal wall musculature accessed via the external ring or counterincision. Lower profile reservoir development has increased the popularity of alternative reservoir placement. In 2011, Perito and Wilson reported alternative

placement of a reservoir through an infrapubic incision either posterior or anterior to the transversalis fascia. In this setting, a vicryl stitch may be used to close the reservoir space to decrease the risk of herniation.<sup>37</sup>

The high submuscular placement (HSM) of the reservoir 6-8cm above the external inguinal ring posterior to the belly of the rectus muscle has been utilized as an alternative location that not only minimizes reservoir herniation, but also maximizes patient satisfaction due to reduced palpability of the reservoir placed under more robust abdominal musculature.<sup>39</sup> Sub-external oblique reservoir placement through the external inguinal ring lateral to the spermatic cord has also been described with minimal reservoir palpability or reservoir associated complications. In obese patients, whose body habitus impedes access to the inguinal canal for HSM reservoir placement, intentional subcutaneous reservoir placement has been described successfully.<sup>40</sup>

The lateral retroperitoneum has also recently been investigated as a reservoir placement alternative to the SOR. This space is especially useful in thin patients with multiple prior abdominal and pelvic surgeries, or those with prior implants or urinary diversion. This space is accessed via a second counter incision just medial to the ASIS, where dissection is taken down through the internal and external obliques, where a space is developed deep to the transversalis fascia in the lateral retroperitoneum.

The following [link](#) demonstrates submuscular reservoir placement.

### 3.4 Cylinder Placement

**Proper placement of the cylinders of the penile implant is vital.** The anatomic extent of the corporal bodies extends from the ischio-pubic ramus proximally to the mid-glans distally. Measuring tools are used accurately measure the corpora proximally and distally. Once the measurements are recorded, the appropriate device can be prepared. Distal perforation can be investigated by infusing the corpora with irrigation, which will extrude from the urethra if perforated. Proximal perforation can be examined by placing dilators in each proximal corpus, which should result in an even “goal post” appearance.

Malleable and semi-rigid implants are typically inserted by placing the implant via the corporal incisions. Inflatable devices require a Furlow tool, a slotted plunger device that can place a Keith needle threaded to the distal implant through the distal corporal body and out of the glans. This allows the distal end of the device to reach the distal aspect of the penis. The proximal end of the implant can usually be seated at the ischio-pubic ramus using hand guidance although some specialized tools are available to help with proper seating. It is typical after placement to assess the device for appropriate placement. If placement is appropriate, the corporotomies can be closed.

The pump should be placed in the most dependent, midline, and posterior portion of the scrotum. Tubing length can be adjusted if needed. Connections to the other portions of the device should be made.

The following [link](#) connects to a surgical video regarding pump placement.

The wound should be copiously irrigated and closed in multiple layers. The debate on the merits of leaving a drain is ongoing and there are few data on whether this impacts subsequent complication rates.<sup>41</sup> Data suggests that infection rates are not increased with placement of a closed system suction drain.<sup>27,42</sup> Drains may either exit through the scrotum or groin.

There are a variety of adjunctive procedures to improve cosmesis and functional penile length. Examples include division of the suspensory ligament, resection of sub penile scrotal skin, circumferential incision and grafting, oversizing the corporal cylinders and augmentation of the glans.<sup>43</sup> A small randomized controlled trial suggested that a prior program of vacuum erection device application might lead to a small increase in penile length at the time of implantation.<sup>44</sup> A full review of these adjunctive maneuvers is beyond the scope of this summary but all additional procedures introduce additional elements of risk and should be utilized very selectively.

## 4. Complications

### 4.1 Infection

The most dreaded complication of penile prosthesis placement is infection. Historical rates of infection have been as high as 5% in first-time implants in experienced hands (see **Table 2**).<sup>45</sup> Use of infection retardant coatings has resulted in a 50% decline in penile prosthesis infections.<sup>46</sup> **Device innovations such as coating and adaptations in technique have led to device infection rates between 1-3% among high volume implanters in modern series.**<sup>47,48</sup> While the incidence of penile implant infections has declined in recent years, bacterial biofilms and pathogenic organisms (e.g. fungi, E Coli, Enterococcus, MRSA) are more frequently detected, indicating that infection in the modern era may be due to more aggressive microbes.<sup>49,50,51</sup>

**Table 2: IPP INFECTION RATES**

<b>Author</b>	<b>Year</b>	<b># infection related complications/# implants</b>	<b>Infection Rate (% of total)</b>
<b>Non-coated IPPs</b>			
Carson	2004	31/1,944	1
Drogin et al	2005	3/94	3.2
Garber	1998	6/360	2
Jarow	1996	2/556	1.8
Montague	1987	15/556	1
Montague et al	2001	7/285	2.9
Radomski and Herschorn	1992	2/107	1.9
Wilson and Delk	1995	24/823	3
Wislon et al	1998	15/333	4.5
Wolter and Hellstrom	2004	10/482	2.1
<b>Infection redundant coated IPPs</b>			
Abouassaly et al	2006	1/55	1.8
Carson	2004	15/2261	0.6
Dhabuwala et al	2011	1/77	1.2

Shaw and Garber	2011	1/100	1
Wilson et al	2007	1/83	1.2

**Device infections typically present within the first 8 weeks post-operatively with a non-healing incision, fever, pain, erythema, fixation of the scrotal pump to scrotal skin, pus drainage, and/or crepitus around the device pump or cylinders.** Risk factors for infection include tobacco use, immunosuppression, MRSA carrier status, history of spinal cord injury, diabetes, longer operative time, and procedures performed by low volume implanters.<sup>27,52</sup> Seasonal variation and humidity have also been found to have an association with implant infections.<sup>53</sup> Standard treatment is surgical with complete removal of all components of the infected device and extensive washout with a replacement of the implant at that time or at a later stage.<sup>54,55</sup> Broad-spectrum antibiotics should be administered and surgical drains are advocated by many authorities. Typical organisms leading to device infections are listed below (see **Table 3**).

**Table 3. Positive cultures identified at the time of device explantation<sup>56</sup>**

Cultured Organism	%, of total
<i>Escherichia coli</i>	18.3
Coagulase-negative <i>Staphylococcus</i> spp	15
<i>Candida</i> spp	11.1
Group B <i>Streptococcus</i> spp	10.5
MSSA	10.5
MRSA	9.2
<i>Enterococcus faecalis</i>	8
<i>Staphylococcus epidermidis</i>	7.2
<i>Klebsiella pneumoniae</i>	5.9
<i>Pseudomonas aeruginosa</i>	5.9
<i>Serratia</i> spp	2.6
<i>Staphylococcus haemolyticus</i>	2.6

Mulcahy and others have described a multistep salvage protocol based on corporal irrigation with antibiotic solution, hydrogen peroxide, and betadine. This approach may be used to washout the corpora in grossly infected cases with immediate salvage replacement of an inflatable implant.<sup>57-58</sup> More contemporary work done by Pan and colleagues have updated the original Mulcahy cocktail and have demonstrated the cytotoxic effects of hydrogen peroxide.<sup>59</sup> Thus, many implanters have now abandoned hydrogen peroxide from their corresponding washout regimen.

A reasonable strategy to help maintain penile length but further avoid scrotal manipulation at the time of salvage is to replace the infected implant with malleable cylinders with the intention (or option) of returning for inflatable device replacement after resolution of infection.<sup>60</sup> Observation with antibiotics and local treatment of the infected components without device replacement has been described but has not proceeded beyond small case series.<sup>61</sup> Failure to leave spacers of some type within the corporal bodies will invariably lead to significant corporal fibrosis and penile length loss.

Recurrent infection after salvage implant surgery was approximately 20%,<sup>62</sup> although this rate of failure in salvage procedures with malleable devices and washout has been found to be 7%.<sup>63</sup> These rates for successful salvage are highest at high volume centers with use of a washout.<sup>64</sup> Patients who present with signs of sepsis or those with tissue necrosis at the time of prosthesis infection are not candidates for salvage procedures and should undergo device removal without replacement.

**The following [link](#) from VJPU demonstrates explant of an infected penile prosthesis with washout and salvage with semirigid device.**

Patients undergoing revision procedures are at higher risk of infection, with estimated rates as high as 10.0% to 13.3% compared to 0.46% to 2.00% in virgin cases.<sup>27</sup> This is likely related to the increased duration of the procedure.

Recent literature has focused on fungal infections of IPPs as the microbial flora of implant infections has changed over time. Though they represent a small proportion of total inflatable implant infections (about 11%), they are the 3<sup>rd</sup> most common microbes responsible for infection. Furthermore, fungal infections are particularly relevant in overweight and diabetic patients. A recent multi-institutional study revealed that more than two thirds of fungal infections occur in diabetic patients and 85% occur in overweight or obese patients. These conclusions prompted the authors to suggest this patient population may benefit from additional antifungal prophylaxis in addition to the conventional antibiotic surgical prophylaxis.<sup>65</sup> Some practitioners utilizing implants with hydrophilic coating (e.g. Coloplast implants) have placed amphotericin in the implant antibiotic dip to combat colonization via fungal organisms rather than administer systemic antifungals.

Data regarding immunocompromised patients and infection remains mixed. It has been postulated that immunocompromised patients have increased rates of post-operative infection following IPP surgery, but recent work has shown no increased risk in patients with history of chronic steroid use, history of solid organ transplant, or other congenital or acquired immune deficiency.<sup>66</sup>

Multiple investigations have sought to elucidate the link between diabetes and IPP infections. Much

of this research has examined preoperative A1c or blood glucose measurements as surrogates for diabetes control. A recent systematic review of this literature concluded that these data do not support HgbA1c or preoperative blood glucose as predictors of penile prosthesis infection.<sup>67</sup>

## 4.2 Malfunction

**The risk of mechanical failure of an IPP is under 10% within the first 10 years of life following implantation (see Table 4).**<sup>48,68</sup> Common defects include shearing or fracture of one of the tubes coming off the pump (to the reservoir or cylinders) or leak in the tubing from the pump to the reservoir. It is unusual to have a reservoir defect. In men whose implant has never functioned after surgery, needle puncture of the device may have occurred intra-operatively.

Patients with a malfunctioning implant typically report that the pump no longer compresses or that compression does not produce tumescence. The sound of air movement within the device may be present. While the most common approach to device malfunction is to remove and replace the entire device some authorities recommend repair or replacement of only the malfunctioning component if the device is less than 2 years old.<sup>64</sup> The rate of infection in revision/replacement procedures is higher than in first-time implants.<sup>69</sup> The full Mulcahy irrigation protocol is not necessary in repairs and device replacement when the device is NOT grossly infected; however, most surgeons still proceed with washout with an antibiotic solution.<sup>70</sup> Pulsed irrigation without antibiotic can achieve similar results in the appropriately selected patient.

**Table 4. IPP Malfunction Rates**

<b>Author</b>	<b>Year</b>	<b># Malfunction related complications/# implants</b>	<b>Malfunction Rate (% of total)</b>
Chung et al	2012	8/138	6% (mean follow-up 60 mos)
Wilson et al	2007	488/2384 (entire series)	20.5% (120 mos actuarial data)
		686/2384 (entire series)	20.5% (120 mos actuarial data)
		(after 1992)	Mentor 11% (120 mos actuarial data)
		(after 2001)	AMS 2% (36 mos actuarial data)
Montague et al	2006	39/380	10.3% (median follow-up 91 mos)
			18.7% (120 mos actuarial data)
Deuk Choi et al	2001	20/273	7.3% (mean follow-up 49 mos)
Carson et al	2000	15/556	7% (mean follow-up 36 mos)
			12% (mean follow-up 60 mos)
Daitch et al	1997	10/111	9% (mean follow-up 47.2 mos)

Goldstein et al	1996	11/434	2.5% @ 22mos 8.0% @ 36 mos (actuarial)
Woodworth et al	1991	2.0/43	5% (mean follow-up 14 mos)
Knoll et al	1990	6.0/94	6.4% (mean follow-up 24 mos)

## 4.3 Urethral Perforation

Approximately 1-3% of penile implant procedures are complicated by urethral perforation.<sup>71</sup> Urethral perforation may occur while isolating the corpora to place the holding sutures in the penoscrotal approach but is more common during corporal dilatation, passage of the cylinders with the Furlow tool, or by Peyronie's curvature correction via modeling. If urethral injury is suspected, irrigation through the corporotomy should be performed to identify areas of injury. If a urethral injury is identified, traditionally the procedure should be aborted, the urethral injury repaired, and a urethral catheter left in place to allow the injury to heal.<sup>72</sup> An implant can later be placed safely, after at least 4-6 weeks to allow for healing. However, experienced implanters may choose to repair the urethral injury and complete implantation on a case-by-case basis.<sup>73</sup>

The following [link](#) from VJPU shows how a distal urethral injury may be repaired at the same time as penile prosthesis implantation.

If a corporal cylinder has already been placed on the side contralateral to the perforation it may be left in situ. Significant corporal fibrosis may be encountered during reoperation, and this has led more experienced implanters to primarily repair the proximal or distal urethral injury, divert the urine via suprapubic tube, and complete the implant.<sup>74</sup> Usually leaving one cylinder can maintain some erectile function and prevent the severe shortening that may occur with post-operative corporal fibrosis. This approach should only be considered for the appropriate patient who has no signs of complex urethral injury or presence of infection. Robust recommendations are not currently available, and the surgeon's intraoperative management should be based on clinical experience and judgement.

## 4.4 Crural Perforation

Unlike distal urethral perforations, **proximal perforations of the corporal crura during dilatation should not typically require termination of the procedure.** The surgeon can still proceed with the operation, but measures should be taken to contain the cylinder within the corporal space to avoid it migrating more proximally. Well-described techniques include windsock maneuvers or rear tip slings, both which involve securing a reartip or proximal implant component to a fixed point in the tunica albuginea.<sup>75,76</sup> Alternative/adjunctive options include securing the exit tubing by anchoring with a purse-string suture to keep this cylinder secured at the point of the corporotomy. Open repair of proximal perforation has been described via a perineal approach but is not typically advisable due the need for patient repositioning.

The following [link](#) shows how a proximal perforation can be corrected.

## 4.5 Vascular/Visceral Perforation

**Vascular, urinary bladder and (less commonly) bowel injury is a known potential complication of reservoir placement.**<sup>77,78</sup> Aborting the procedure and allowing several days to a week of catheter drainage is typically sufficient to manage bladder injuries and prevent extravasation of urine. However, direct repair of the bladder should be considered if severe injury is suspected or if the

patient has other risk factors for infectious complications. A bowel injury can occur in patients with prior cystectomy or other abdominopelvic surgery. If bowel or vascular injury occurs the procedure must be aborted, the abdomen immediately explored, and all injuries repaired. It is typically prudent to enlist the assistance of a general surgeon for this. Intraperitoneal placement or migration of the reservoir from the SOR is neither a complication nor a serious risk for subsequent morbidity.<sup>51</sup>

## 4.6 Device Erosion/Migration

Cylinders' tips protruding from the meatus in a delayed fashion may be due to infection or pressure necrosis of the urethra (most commonly seen with non-inflatable cylinders). This is more likely to occur in patients who are at higher risk of device infection (immunosuppression, diabetes, spinal cord injury, indwelling urethral catheter). Erosion of the scrotal pump through the skin is also generally associated with device infection. An erosion is technically also an infection due to device exposure, and similar care must be taken regarding device salvage.

If the implant cylinders extrude through the tunica in a delayed fashion without urethral perforation, the tips of the implant will be palpable ventrally or laterally in the glans. This may be associated with pain for the patient or his partner. If the device is extruded but not eroded, surgical revision may be undertaken to reroute the cylinders into an appropriate location via a corporal or glanular approach.<sup>79,80,81</sup> Distal corporoplasty can be performed by repositioning the cylinders and directly repairing the tunica albuginea, with or without a Goretex windsock. Since this repair can cause glans hypermobility, patients may also need glans fixation.

## 4.7 Device Crossover

**Cylinder crossover can occur during difficult dilation or subsequent cylinder placement, as the septum between the corpora is fenestrated.<sup>82</sup>** To avoid this, ensure the dilating device is palpable on the correct side of the glans during corporal dilation. If crossover is recognized intra-operatively by unequal corporal measurement, glans displacement or incomplete distal cylinder inflation, the device can be re-positioned after ensuring complete distal dilation without any consequence to the patient. Use of an anchoring stitch in the glans may assist in fixating the cylinder in the appropriate ipsilateral position.<sup>83</sup> If it is not appreciated during the procedure, patients usually present with an obvious kinking or twisting of the penis with the glans deflected to one side. In this case, the malpositioned cylinder should be moved to the correct corpora; the anchoring stitch method may assist with correction.

The following [link](#) from VJPU demonstrates cylinder crossover and its correction.

## 4.8 Post-operative Care

Management of post-operative pain has become more relevant in the era of the opioid epidemic. Pain management following IPP surgery has historically been challenging given the complex pathophysiology of male genital pain. **Recent innovations utilizing pre- and intra-operative analgesia have provided improvement in patient-reported pain outcomes.** Data supports the

utilization of aggressive local nerve blockade, with evidence that liposomal-bound local anesthetic is superior to classic administration.<sup>84</sup> In patients undergoing IPP surgery, multimodal analgesia (MMA), has been demonstrated to provide superior patient pain control and successfully decrease opioid usage compared to traditional opioid-based pain control.<sup>85</sup> These protocols typically include some combination of preoperative NSAID, gabapentin, Tylenol administration, intraoperative nerve block, and post-operative opioid limited analgesic regimen.<sup>86</sup>

## 5. Penile Prosthesis in the Setting of Peyronie's Disease

Surgical correction of Peyronie's Disease (PD) may be accomplished with IPP placement and represents **the best option for PD patients with comorbid moderate to severe ED**.<sup>87</sup> It is recommended to avoid non-inflatable implants in PD patients. PD patients present a greater challenge for the implant surgeon including more difficult corporal dilation due to plaque incursion into the cavernosal smooth muscle and residual deformity after implant placement and inflation.<sup>88</sup> IPP in the setting of PD has satisfaction rates generally lower than that of men without PD. It is postulated that much of this dissatisfaction is related to penile length/volume loss.

Care must be taken to avoid medial dilation of the corpora, which may result in cylinder crossover or urethral perforation. While placement of the implant itself may correct some mild deformities (i.e. 45 degrees or less) some PD patients will have significant residual deformity and adjuvant maneuvers will be required.<sup>89</sup> Most authorities recommend adjuvant straightening maneuvers when residual curvature after implant placement is greater than 30 degrees with inflation.

The simplest intervention for residual curvature correction is known as modeling (or molding).<sup>89</sup> With the device in the inflated state and the tubing from pump to cylinders clamped (to protect the pump from excessively high pressures and resultant damage), the penis is bent for a duration of 60-90 seconds in the direction opposite the plaque thus trying to stretch or fracture the plaque. This is repeated 2-3 times. This procedure has been reported as a simple and often successful option but it must be appreciated that this technique has a urethral perforation rate of 2-3%.<sup>89</sup> The optimal modeling technique with maintained glanular pressure reduces this risk.<sup>90</sup>

Alternatives include (in order of increasing complexity) tunical plication, plaque incision, or plaque excision with grafting.<sup>91</sup> All of these options carry some risk for damage to the implant. Experts recommend placement of plication sutures before seating of the implant in case plication should become necessary; if adequate curvature correction is obtained from implant placement alone these sutures may be removed with minimal risk.<sup>92</sup>

In the setting of plaque incision with a large defect requiring graft, a collagen fleece, or hemostatic patch may be used, which obviates the risk of cylinder puncture.<sup>93,94</sup> Recent multi-institutional studies have reported successful plaque incision and grafting using collagen fleece (Tachosil) in patients with severe preoperative curvature (>60 degrees). All patients reported erections sufficient for penetrative intercourse. Residual curvature was minimal, measuring <15 degrees in all cases.<sup>95</sup>

## 6. Penile Prosthesis in Female to Male Transgender Population

Penile implants have been successfully utilized in transgender men, though **special considerations must be made**. Modern convention suggests candidates be at least 1 year status post phalloplasty without urethral problems and have sensate neophallus to the extent that protective sensitivity is present.

There are several key challenges of penile prosthesis placement in the neophallus are attributable to unique anatomical differences between the neophallus and native penis. First, the neophallus lacks divergent corporal crura making it difficult to anchor the prosthesis leading to potential malposition. Second, the neophallus lacks the tunica albuginea which protects and anchors the implant distally coupled with potentially insensate reconstructed skin poses a significant risk for distal erosion of the implant.<sup>96,97</sup> The neophallus vascular supply and significant scarring associated with neophallus flaps compared to cis male anatomy also impedes the usual healing process and increases the risk of infection and erosion. Furthermore, the transgender male usually is of a younger age than the typical cis male patient who may use the device more, and possibly more aggressively leading to malfunction or malposition. Understanding these differences and incorporating novel techniques aim to improve functional outcomes and decrease morbidity.<sup>98</sup>

Recently published retrospective data has highlighted the high rate of explant and revision that accompanies this procedure, with up to 44% of implants ultimately requiring replacement or removal. An uneventful post-operative course was reported in only 31% of patients. It is imperative that patients be informed of these high rates of complications preoperatively.<sup>99</sup>

Several transgender-specific implants have been introduced that include features such as a large base for fixation to the pubic bone, a realistically shaped glans, and a pump shaped like a testicle. Pilot studies have demonstrated initial safety and efficacy, however long term data is lacking.<sup>100</sup> Ultimately, the experience with transgender implant surgery is evolving rapidly to increase patient satisfaction and outcomes overall.

## Additional Video Resources

[\*\*Video Journal of Prosthetic Urology \(VJPU\)\*\*](#)

[\*\*VJPU: Virgin Penoscrotal Inflatable Penile Implant\*\*](#)

[\*\*VJPU: Everything you want to know about IPP via subcoronal incision\*\*](#)

[\*\*VJPU: The Minimally Invasive Infrapubic Approach for placement of a 3 piece Inflatable Penile Prosthesis\*\*](#)

[\*\*VJPU: Simultaneous 3-Piece IPP at the Time of Robotic Prostatectomy: An “In Vivo” Characterization of Submuscular Reservoir Placement\*\*](#)

[\*\*VJPU: Infected Penile Prosthesis: Salvage & Washout with Replacement with Semi-rigid Device\*\*](#)

[\*\*VJPU: Urethral Injury During IPP: A New Repair\*\*](#)

## VJPU: Cylinder Crossover and Perforation

## ASVIDE: Corporotomy and measurement

## ASVIDE: Pump placement

## Videos

Placement of Malleable Penile Implant (Semi-Rigid)

Penile Prosthesis Implantation In Female To Male Transsexual

## Presentations

Erectile Dysfunction Surgical Management Presentation 1

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