

## Penile Prosthesis Surgery: Current Recommendations From the International Consultation on Sexual Medicine



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### ABSTRACT

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**Introduction:** Penile prosthesis implantation has emerged as a definitive treatment to restore sexual function to the motivated man with erectile dysfunction. Substantial improvements in the design of inflatable devices have been made since they first became available more than four decades ago.

**Aim:** To review the history of the penile prosthesis, the indications, preoperative evaluation, and patient and partner satisfaction. The current approaches to addressing intra- and postoperative complications, provide an understanding of prosthesis infection, and placement of these devices will be reviewed.

**Methods:** A committee of worldwide experts in this field was assembled during the 2015 International Consultation on Sexual Medicine (ICSM) and performed a systematic review of the peer-reviewed published medical literature pertaining to penile prosthesis. Particular attention was given to higher level trials when available. Recommendations are based upon the Oxford Criteria.

**Main Outcome Measures:** Unfortunately there is limited level 1 and 2 evidence, and where expert opinion was utilized, the decision was unanimous within the committee with a goal of presenting a clinically relevant guideline pertaining to penile prostheses.

**Results:** Penile prosthesis has undergone an evolution over the past 40 years resulting in a more effective and reliable treatment for advanced erectile dysfunction not responding to less invasive methods including oral treatment with PDE5 inhibitors, vacuum erection device, and intracorporeal injection therapy. It should be considered an appropriate treatment option for the man who wishes to restore erectile function and who understands the potential risk of mechanical failure and infection, both of which are less common now as a result of improvements made in device design as well as surgical protocols adhered to in the operating room. Patients must be clearly informed of the risks associated with penile prosthesis including mechanical failure, infection, shortening of the penis, change in sensation and configuration of the penis, as well as injury to local structures. Intraoperative complications are unusual but do occur and can usually be addressed intraoperatively to allow placement of the device at the time of initial surgery. Postoperative complications may also be addressed when they occur but may require more advanced reconstructive surgical techniques. Men with Peyronie's disease, corporal fibrosis due to infection, trauma, prior prosthesis explantation, priapism, and men who have undergone construction of a neophallus may require additional advanced maneuvers to obtain optimum results with a penile prosthesis.

**Conclusion:** Penile prosthesis remains as an important, viable, and effective treatment for male erectile dysfunction that does not respond to other less invasive approaches or when these approaches are contraindicated or not acceptable to the patient. These devices provide the patient with the ability to engage in penetrative sexual activity without interfering with urination, ejaculation, sensation, or orgasm. Although mechanical failure can occur, the current devices are more reliable as a result of design modifications. Infection remains the most dreaded complication but since the introduction of antibiotic and hydrophilic coatings, infection is less common.

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Overall, patient and partner satisfaction appear to be reasonably high when a penile prosthesis is used to restore erectile function.

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**Key Words:** Erectile Dysfunction; Penile Prosthesis; Surgical Indications; Corporal Fibrosis; Prosthesis Infection; Peyronie Disease

## INTRODUCTION

Prosthetic devices have been used to augment, replace, or restore penile function for more than 500 years. The primary goal of PP insertion is restoration of normal erectile function to allow penetrative sexual activity, and with the introduction of inflatable devices more than four decades ago, the use of PPs quickly became the gold standard therapy for medically refractory ED. Ongoing improvements have greatly improved all outcome measurements, with contemporary studies reporting consistently high satisfaction and lower complication rates. Currently, the role for PP in the management of ED is well established with several devices available to permit prosthesis insertion in virtually any clinical scenario. A large body of evidence has described techniques for enhancing device insertion, preventing infection, and managing intraoperative and postoperative complications, which are reviewed in this article.

## NOTABLE DEVICE ALTERATIONS

Several device enhancements have directly resulted in improvements in mechanical reliability, intra- and postoperative complications, revision surgery, and overall satisfaction. An understanding of the history of noteworthy modifications is essential to interpret outcomes in the literature accurately, including the true rates of mechanical and overall device survival. A detailed discussion of this history is beyond the scope of this article and is presented in Table 1.<sup>1–14</sup>

The development of silicone was critical for the success of the penile implant. With the increased pliability of silicone, novel devices were technologically feasible, and in 1973, the IPP heralded a new era of penile implants. Silicone greatly decreased infection rates and offered a biocompatible, flexible, and resilient material that continues to be used in many contemporary devices.<sup>1</sup> The enhancements with inflatable devices improved the ability to achieve truly erect and flaccid states while optimizing concealment, decreasing erosion, and permitting urethral instrumentation when required.<sup>2,15</sup>

In 1983, a proprietary polyurethane, Bioflex, was used with the Mentor (now Coloplast; Minneapolis, MN, USA) three-piece IPP and provided significant improvements in penile cylinder strength. This decreased the rate of cylinder aneurysms and fractures and provided enhanced strength over silicone. To

address the inherent limitations of silicone compared with Bioflex, American Medical Systems (AMS; Minnetonka, MN, USA) incorporated a woven fabric layer and three-ply system to devices in 1987, which helped provide additional strength and restrict expansion of the silicone, thus decreasing cylinder aneurysms.

One early challenge with placement of penile prostheses was frequent kinking of the device tubing. The later development of kink-resistant tubing (AMS, 1986) and nylon-reinforced tubing (Mentor, 1987) and the introduction of connector-less devices (Mentor, 1989) and pre-connected cylinders (AMS, 2000) served to decrease tubing-related complications. Parylene coating was introduced by AMS in 2000, which enhanced the mechanical strength of the devices. This improvement resulted in significant decreases in mechanical failure and related complications.<sup>16</sup> Although not directly related to improving mechanical reliability, the introduction of antibiotic impregnation (InhibiZone; AMS) and hydrophilic coatings (Titan; Coloplast) represent significant milestones in device manufacturing with resultant decreases in infection rates.

## INDICATIONS FOR SURGERY

For men with ED alone, PPs are often considered third-line therapy after inadequate response or inability or refusal to use phosphodiesterase-5 inhibitors, intraurethral or intracavernosal injections, and vacuum erection devices. Men with combined ED and PD requiring surgical management could benefit from earlier placement of a PP, particularly in cases in which the patient is poorly responsive to phosphodiesterase-5 inhibitors.<sup>16–19</sup> The previously held notion that a PP is the last resort for treatment of ED should be reconsidered, because the PP could be the best option depending on the clinical scenario.

In addition to clinical indications, appropriate patient selection is an important aspect of PP surgery. Certain patient characteristics can place candidates at higher risk for postoperative dissatisfaction and should be taken into account when discussing placement of a PP.<sup>20</sup> Similarly, appropriate and thorough informed consent is an essential component of patient education, with postoperative satisfaction relating in part to established preoperative expectations.<sup>21</sup>

The operative decision to place a malleable, two-piece, or three-piece IPP is based on several factors, including patient

## RECOMMENDATION STATEMENTS

1. Penile prosthesis (PP) implantation should be considered the optimal method of restoring erectile function in men with refractory organic erectile dysfunction (ED) after failure or rejection of other treatment options in motivated patients. Level of evidence 4, strength of recommendation C.
- 2a. Surgeons must perform careful medical and sexual histories and relevant physical examination before prosthesis implantation. Level of evidence 4, strength of recommendation C.
- 2b. The patient should be informed of alternative treatment options, appropriate expectations, and increased risks associated with diabetes, prior implantation, active smoking, and other comorbidities. Level of evidence 4, strength of recommendation C.
- 2c. The patient undergoing penile implantation should be informed preoperatively of specific potential areas of complication and/or dissatisfaction, including infection and its consequences, pain, decreased length and girth, injury to surrounding tissues, and mechanical failure. Level of evidence 4, strength of recommendation C.
- 3a. When using an inflatable prosthesis, and based on feasibility, surgeons should use antibiotic-impregnated or hydrophilic-coated devices. Level of evidence 3, strength of recommendation B.
- 3b. Malleable implants are recommended for patients with compromised manual dexterity but might be appropriate in other clinical scenarios. Level of evidence 4, strength of recommendation C.
- 4a. For penile implant surgery, no definitive recommendations can be made regarding preoperative site cleansing protocol and optimization of patient's hemoglobin A<sub>1c</sub>. Level of evidence 4, strength of recommendation C.
- 4b. Preoperative antibiotics with gram-positive and gram-negative coverage should be given with therapeutic antibiotic levels attained before making the surgical incision. Level of evidence 2, strength of recommendation B.
- 4c. Shaving vs clipping to remove scrotal hair is left to the surgeon's discretion with an objective to avoid traumatic skin disruptions. Level of evidence 4, strength of recommendation C.
- 4d. Whenever available, surgeons should use alcohol-based skin preparations in the operating room as the operative site scrub. Level of evidence 1, strength of recommendation A.
- 4e. Techniques to minimize skin and device contact can decrease inflatable PP (IPP) infection rates. Level of evidence 3, strength of recommendation C.
- 5a. Penoscrotal, infra-pubic, and sub-coronal are the three main approaches for inserting the PP. The method chosen is based on prosthesis type, the patient's specific anatomy, surgical history, and surgeon preference. Level of evidence 3, strength of recommendation C.
- 5b. Placement of IPP reservoir in an "ectopic" or submuscular location, with or without a counterincision, is a safe and feasible technique and represents a valid option in selected patients, especially with prior radical pelvic surgery. Level of evidence 3, strength of recommendation C.
6. The clinician should provide adequate postsurgical follow-up to maximize patient satisfaction, assess for complications, and assure appropriate device placement and function. Level of evidence 4, strength of recommendation C.
- 7a. Penile implant revision surgery should include the use of copious irrigation, preferably with antimicrobials. Level of evidence 3, strength of recommendation C.
- 7b. In stable patients with infected PPs, reasonable attempts should be made to remove all device components. During non-infected implant revision surgery, residual components can be safely retained in situ. Level of evidence 3, strength of recommendation C.
- 7c. For penile implant infection, surgeons should determine whether and when to attempt salvage. No recommendations can be made as to which salvage strategy to use (immediate reimplantation of IPP vs malleable or explant with delayed replacement) or length of postoperative antibiotic regimens. Level of evidence 3, strength of recommendation C.
- 7d. For the patient with post-explant IPP and corporal fibrosis, surgeons should be prepared to perform specialized maneuvers such as use of specialized cavernotomes, longer or additional corporotomy incisions, and/or corporal excavation. Level of evidence 4, strength of recommendation C.
8. Patients with priapism, when irreversible and protracted, can be offered early prosthesis implantation to preserve erectile function and penile size. Level of evidence 3, strength of recommendation C.
9. Patients with PP and attenuated corpora (impending erosion or extrusion) or aberrant cylinder placement should be managed with corporoplasty repositioning procedures. Level of evidence 4, strength of recommendation C.
10. When performing penile implantation in patients with Peyronie disease (PD) deformities and refractory ED, surgeons should perform adjunctive straightening maneuvers such as modeling, plication and corporoplasty, or grafting as indicated. Level of evidence 4, strength of recommendation C.

**Table 1.** Notable Milestones in Penile Prosthesis History

Date	Innovation
1500s	Wooden splints or wooden pipe used to facilitate urination
1936	Tubular phalloplasty with rib cartilage <sup>4,5</sup>
1952	Acrylic splints, extracavernosal implantation <sup>6</sup>
1958	Paired intracavernosal polyethylene rods <sup>7,8</sup>
1960	Intracavernosal acrylic rods <sup>9</sup>
1964	Silicone penile implants <sup>1</sup>
1973	Small-Carrion prosthesis with customizable length, enhanced girth, more reliable, easier placement <sup>10</sup>
1973	Introduction of inflatable penile prosthesis <sup>2</sup>
1977	Flexirod with soft hinge improved concealment <sup>11</sup>
1980	Jonas silicone prosthesis with silver wires; first true malleable device <sup>12</sup>
1983	AMS 700 with thick cylinders, PTFE sleeves, sutureless connector
1983	Mentor 3-piece IPP had polyurethane (Bioflex) that enhanced strength over silicone
1983	AMS 600M and 650 were malleable devices with a central wire core and trimmable silicone
1985–1986	Omniphase and Duraphase had a central cable and frequent mechanical malfunction <sup>13</sup> ; Hydroflex and Flexi-Flate had poor concealment and incomplete flaccidity
1986	Kink-resistant tubing added to AMS 700
1987	AMS 700 CX had a 3-ply design with woven fabric layer and decreased cylinder aneurysms
1987	Mentor IPP improvements of pump modifications, nylon-reinforced tubing, cylinder base reinforcement
1989	Mentor Alpha-1, a connector-less IPP, decreased connector complications
1990	AMS 700 CXM, a narrow version
1990	AMS Ultrex had expanded girth and length
1992	Mentor Alpha-1 had reinforced pump and tubing and enhanced mechanical reliability
1993	AMS Ultrex cylinders were strengthened and improved mechanical reliability
1994	AMS Ambicor, a 2-piece prosthesis
1996	Mulcahy salvage technique <sup>14</sup>
1998	Mentor Acu-Form malleable device with central wire cores
2000	AMS 700 had Parylene coating added, which improved mechanical reliability; pre-connected cylinders with color-coded tubing facilitated implantation
2000	Mentor had a lockout valve
2001	AMS InhibiZone was impregnated with antibiotics minocycline and rifampin
2002	Mentor Titan had hydrophilic coating that permitted absorption of aqueous antibiotic solutions and decreased bacterial adherence
2002	Mentor Alpha-1, narrow base model
2004	Coloplast Genesis malleable
2006	AMS Momentary Squeeze

(continued)

**Table 1.** Continued

Date	Innovation
2006	1-way valve decreased autoinflation
2006	Coloplast acquires Mentor
2007	AMS 700 LGX trademarked
2008	Coloplast one-touch release pump
2008	Titan XL cylinders (24, 26, 28 cm)
2009	AMS Spectra malleable
2011	Conceal Cloverleaf CL reservoirs
2011	No-touch technique decreased infection <sup>3</sup>
2012	Coloplast 0° tubing and molded silicone contoured tip

AMS = American Medical Systems; IPP = inflatable penile prosthesis; PTFE = polytetrafluoroethylene.

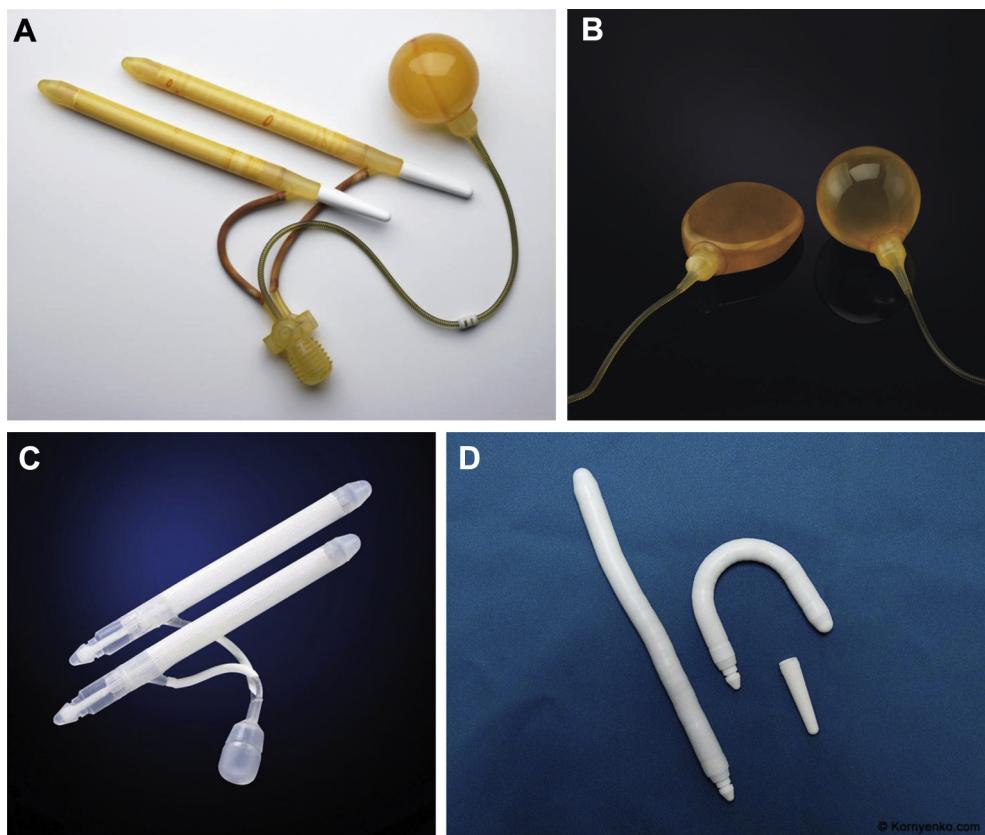
Modified with permission from Trost and Hellstrom.<sup>162</sup>

preference, surgeon experience, indication for procedure, manual dexterity, penile size, and mental function. Malleable devices require less manual dexterity by the patient and can be performed under local anesthesia. Given the nature of malleable devices, they are less prone to malfunction; however, they are permanently firm and have lower overall satisfaction compared with three-piece devices.<sup>22–24</sup> Two-piece IPPs do not require placement of a separate reservoir and therefore can be used in cases in which reservoir placement is problematic, such as after major pelvic surgery or renal transplantation. With the lack of a distinct reservoir, the two-piece devices do not permit complete deflation of the penile cylinders.<sup>25–27</sup>

The most common device implanted in penile surgery is the three-piece IPP. In a recent study, which aimed to evaluate the modern use of PP surgery, IPP placement accounted for 96.2% of procedures, whereas semirigid prosthesis placement represented 3.8% of procedures.<sup>28</sup> In another National Practice Pattern analysis, the overall proportion of IPP compared with malleable prosthesis increased from 2.3:1 in 2003 to 25:1 in 2012.<sup>29</sup> The same analysis concluded that although specialists and high-volume surgeons perform a disproportionate number of implants, low-volume surgeons (defined as implanting no more than four prostheses per year) perform most IPP implantations (75%) in the United States.

## CONTEMPORARY DEVICES AND SURGICAL CONSIDERATIONS

Currently, several PPs are available, with the most commonly placed manufactured by AMS and Coloplast. AMS manufactures three three-piece IPPs (AMS 700 CX, CXR, and LGX) and Coloplast has two currently available models (Titan and Titan NB). There are several distinctive differences among the various prostheses. For cylindrical strength, AMS uses a three-ply woven fiber technology with Parylene coating to limit the extent of expansion circumferentially (CX and CXR) and longitudinally (LGX), whereas Coloplast uses Bioflex as the base material for



**Figure 1.** Panel A depicts the AMS 700 CX inflatable penile prosthesis. Panel B shows the AMS Conceal (left) and Spherical (right) reservoirs. Panel C shows the AMS Ambicor two-piece inflatable device. Panel D shows the AMS Spectra malleable prosthesis. **Figure 1** is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

the cylinders that is more resilient to sheer forces than silicone. **Figures 1 and 2** show these devices ex vivo.

Differences in pumps also are noteworthy. The AMS three-piece pump includes a lockout mechanism, whereas the Coloplast three-piece system places the lockout valve in the reservoir. These companies provide low-profile reservoirs, which is particularly relevant for submuscular abdominal wall reservoir placement. With AMS, this is achieved through the Conceal reservoir, whereas with Coloplast, it is accomplished through under-inflation of the 125-mL (Cloverleaf) CL reservoir. AMS reservoirs include the 65- and 100-mL spherical and 100-mL Conceal, whereas Coloplast uses two reservoir sizes of CL, 75 and 125 mL (**Table 2**).

Recommended cavernosal dilation required for IPP cylinder placement is 12 mm for standard devices and 10 mm for smaller-diameter or narrow-base devices. The availability of smaller-diameter models permits easier placement in cases of significant corporal scarring or decreased tunic elasticity occasionally associated with PD.

## MECHANICAL RELIABILITY

Mechanical reliability of three-piece devices has been reported in several long-term series. In the largest single-surgeon report, Wilson et al<sup>16</sup> noted 5-, 10-, and 15-year mechanical survival rates of

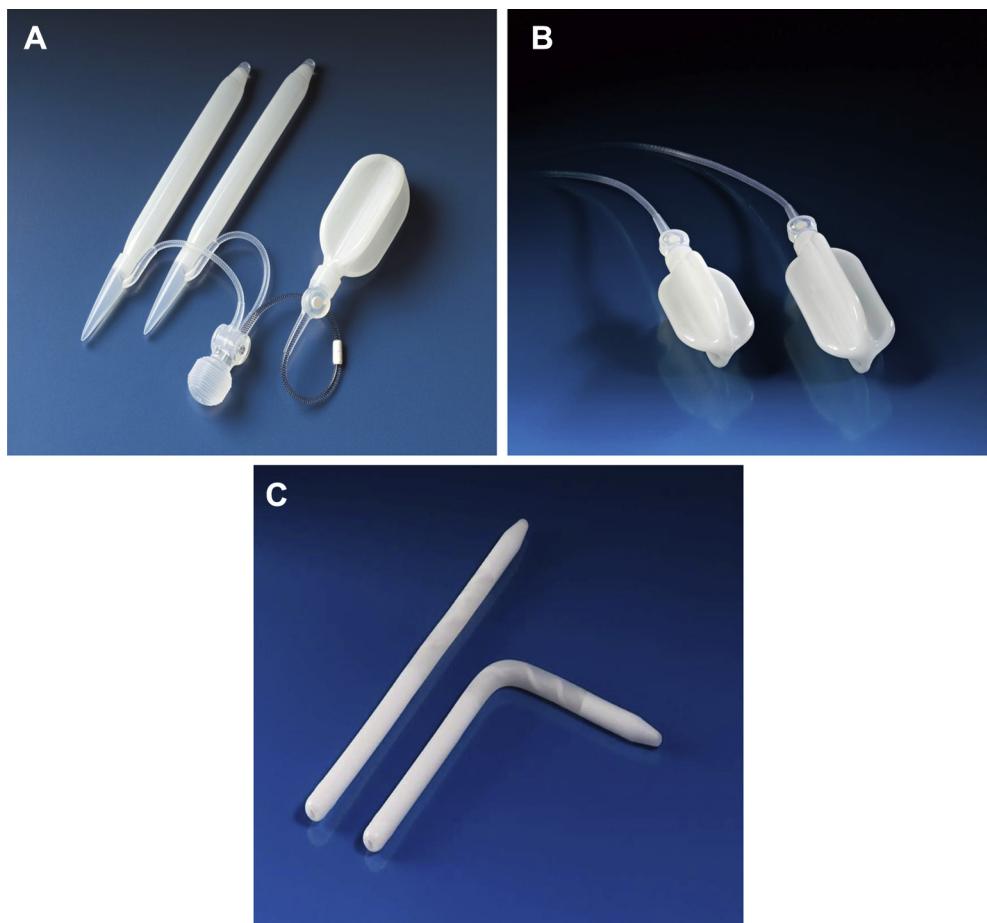
AMS 700 CX devices at 85%, 68%, and 57%, respectively. Ultrex devices were shown to have 74% and 62% 5- and 10-year mechanical survival, whereas a comparison of devices coated with Parylene vs non-coated showed significant improvements in 3-year rates at 92% vs 80%, respectively. Data from the same series on Mentor Alpha-1 and Alpha NB devices reported rates of 90%, 82%, and 76% at 5, 10, and 15 years for Alpha-1 and 94% at 5 years for the NB model. Significant improvements also were shown after device enhancements (10-year mechanical survival of 89% after enhancements vs 60% before enhancements).

Mechanical survival data on two-piece Ambicor devices are limited. Three studies evaluating outcomes of cases performed from 1990 to the present identified overall mechanical survival rates of 94% to 100% and estimated 4-year survival rates of 91%.<sup>25–27</sup>

Limited contemporary data also are available on malleable prostheses. Two series on the AMS 600 and Dura-II prostheses reported 100% mechanical survival, with follow-up ranging from 5.7 to 11.7 years<sup>24,30</sup> (**Tables 3–6**).<sup>16,22,24–27,30–48</sup>

## CONSENT ISSUES

It is imperative to obtain a proper informed consent before PP implantation.<sup>49</sup> The informed consent should clearly describe the advantages and disadvantages of the procedure, other



**Figure 2.** Panel A shows the Coloplast Titan three-piece inflatable penile prosthesis. Panel B shows the Coloplast Cloverleaf 75- and 125-mL reservoirs. Panel C shows the Coloplast Genesis malleable prosthesis. **Figure 2** is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

treatment options, limitations, and possible complications such as infection and its consequences, bleeding, pain, mechanical failure, penile shortening, change in sensation and shape, injury to local structures including the urethra, bladder, bowel, or vessels, and autoinflation. The legal informed consent format is unique to each institution and geographic area and follows local guidelines. A useful, downloadable example of this is available on the Sexual Medicine Society of North America Web site ([http://www.smsna.org/V1/images/SMSNAIPP\\_policy.pdf](http://www.smsna.org/V1/images/SMSNAIPP_policy.pdf)).

## PREOPERATIVE AND POSTOPERATIVE CARE

Most penile implants are placed in patients with an organic etiology to their ED and did not respond to, tolerate, or were unwilling to consider more conservative options.<sup>50</sup> Oral therapy often fails in men with severe ED because of diabetes mellitus, severe vascular disease, or after radical pelvic surgery. Men with PD-associated ED, with severe corporal fibrosis after priapism, are more likely to be considered for implantation of a PP. In the era before sildenafil, it was the norm to diagnose the precise etiology of a patient's ED. Comprehensive blood testing (including cholesterol, glucose, and hormone studies), vasoactive injection testing, color duplex Doppler ultrasound,

and nocturnal penile tumescence studies were routinely obtained.<sup>51</sup> This extensive evaluation process is considered unnecessary in the era of effective oral therapy. Most third-party payers have recognized that many of these diagnostic tests do not influence ultimate patient outcome and refuse to reimburse ancillary test expenses.

Diabetes mellitus is a known risk factor for severe ED and PP implantation.<sup>52</sup> Placement of a PP as any non-urgent surgical procedure should be avoided in men with uncontrolled diabetes, which is supported by a study showing an increased infection rate in men with uncontrolled diabetes.<sup>53</sup> Pain after placement of a PP is variable. Some scrotal ecchymosis and swelling is common, and if a scrotal hematoma forms, this usually resolves without operative intervention. Patients are instructed at discharge from the hospital to wear supportive underwear for the first month and direct their penis upward if possible.

Patients are taught how to operate their hydraulic devices approximately 4 to 6 weeks after surgery. Some surgeons prefer to begin cycling devices sooner, but in most patients, pain will be a limiting factor to early cycling. After patients are instructed in the operation of their device, they are advised to cycle regularly. When the cylinders are left semi-inflated for prolonged periods, a

**Table 2.** Characteristics of Currently Available Prostheses

	AMS	Coloplast
Malleable	Spectra Alternating titanium and polyethylene segments MRI conditional Lengths = 12, 16, 20 cm Diameters = 9.5, 12, 14 mm	Genesis Hydrophilic coating Lengths = 12, 14, 16, 18, 20, 22, 24 cm Diameters = 9.5, 11, 13 mm
2-piece IPP	Ambicor Parylene coating Reservoir contained in pump Lengths = 14, 16, 18, 20, 22 cm Diameters = 12.5, 14, 15.5 mm	
3-piece IPP	All devices Momentary Squeeze Parylene coating Inhibizone 700 CX Lengths = 12, 15, 18, 21, 24 cm Dilation $\geq$ 12 mm recommended 700 CXR Narrow base Lengths = 10, 12, 14, 16, 18 cm Dilation $\geq$ 10 mm recommended 700 LGX Lengths = 12, 15, 18, 21 cm Increases in girth and length Dilation $\geq$ 12 mm recommended	All devices Hydrophilic coating Bioflex material Titan NB Narrow base Lengths = 12, 14, 16, 18, 20, 22 cm Dilation $\geq$ 10 mm recommended Titan OTR Hydrophilic coating 0° tubing OTR Lengths = 12, 14, 16, 18, 20, 22, 24, 26, 28 cm Dilation $\geq$ 12 mm recommended
Reservoirs	Spherical 65 and 100 mL Conceal 100 mL Flat profile optimal for submuscular abdominal wall placement	Clover Leaf CL 75 and 125 mL Lockout valve incorporated

AMS = American Medical Systems; IPP = inflatable penile prosthesis; MRI = magnetic resonance imaging; OTR = one-touch release.

capsule forms over the reservoir in a less than full state, which can restrict its expansion and full deflation of the cylinders.

## PATIENT AND PARTNER SATISFACTION

Numerous studies have reported high satisfaction rates for patients and their partners after PP implantation for the treatment of ED. In a series of 185 patients from a group of European institutions, the investigators reported 98% patient and 96% partner satisfaction rates.<sup>31</sup> Some patients complain that their penis looks shorter after implantation, but frequently they compare their current with their previous appearance when they had a fully functional erection. This issue and unrealistic expectations and body changes such as weight gain and excess pubis fat can lead a frustrating perception. It is important that the physician discuss these issues with the patient and take a preoperative stretched flaccid penis length measurement for postoperative comparison. In a 2007 article from Memorial Sloan Kettering Hospital, where they prospectively measured stretched penile size before surgery

and up to 6 months postoperatively, they were unable to find a significant measured length loss despite a subjective penile length loss perceived by 72% of patients.<sup>32</sup>

Patients with PD and those after a radical prostatectomy often have a loss of penile length. These patients should understand this condition before they receive an implant and be reassured by the physician that the penile implant is not designed to restore their previous length. In addition to proper sizing techniques, there are some maneuvers that can be offered to patients at risk for shortening (ie, after radical prostatectomy, PD, after priapism, and after PP explantation), including the use of preoperative penile stretching with an external traction device.<sup>54</sup> A more aggressive approach is the simultaneous performance of a lengthening surgical procedure at the time of prosthesis implantation.<sup>55,56</sup> Patient satisfaction is a complex and multifactorial issue that can include the degree of postoperative pain and swelling, occurrence of postoperative complications, cosmetic outcome, device function, ease of use, and partner acceptance.

**Table 3.** Outcomes of AMS Three-piece Penile Prostheses

Study	Year (n)	Mean follow-up (mo)	Surgery ranges	Device(s)	Overall device survival	Mechanical survival	Comments
Chung et al <sup>36</sup>	2013 (88)	41	2006–2010	AMS 700 CX		91% at 5 y	Peyronie population; compared AMS and Coloplast devices; no statistical difference between Coloplast and AMS
Chung et al <sup>37</sup>	2013	76	1981–2010		91% at 5 y; 85% at 10 y		Ultrex most common cylinder placed (54%)
Song et al <sup>38</sup>	2013 (201)	>6 mo	2000–2011	AMS 700 CXM and CXR (80%); AMS 650 (20%)		98%	
Vitarelli et al <sup>39</sup>	2013 (80)		1997–2010	AMS 700 CX and CXR		78%–83% at 10 y (touch vs momentary squeeze pump)	
Enemchukwu et al <sup>40</sup>	2013 (55,013)		1997–2008	AMS 700 CX and LGX	88.7% at 7 y (Ultrex and LGX); 89.5% at 7 y (CX); results for Parylene coating		Retrospective database analysis looking at time to first revision; only useful to compare LGX with CX devices
Nehra et al <sup>41</sup>	2012 (11,064)	6.6 y	2001–2007	AMS	Revision 2.5% for impregnated vs 3.7% for non-impregnated		Patient information form data after revision surgery
Brinkman et al <sup>33</sup>	2012 (93)		1992–1998	AMS 700	84% at 3 y		Included AMS and Mentor; results are before Parylene coating; first time implants; no significant difference between AMS and Mentor
Thomas et al <sup>42</sup>	2011 (38)	101	1984–2007	AMS 700	53%; 82% at 50 mo		Significant increase in revisions after 72 mo
Kim et al <sup>43</sup>	2010 (438)	113	1991–2009	AMS 700 CX and CXM	95% at 3 y; 91% at 5 y; 76% at 10 y	79% at 82 mo; 98% at 3 y; 93% at 5 y; 78% at 10 y	Age, obesity, DM not associated with overall IPP survival
Deveci et al <sup>32</sup>	2007 (2,384)	NA	NA	AMS 700 CX (Parylene coated vs non-coated), Ultrex	700 CX: 77% at 5 y; 59% at 10 y; 48% at 15 y	700 CX: 85% at 5 y; 68% at 10 y; 57% at 15 y	

(continued)

Table 3. Continued

Study	Year (n)	Mean follow-up (mo)	Surgery ranges	Device(s)	Overall device survival	Mechanical survival	Comments
Dhar et al <sup>44</sup>	2006 (455)	Median = 92	1986–2004	AMS 700 CX and CXM	Coated: 94% at 1 y; 93% at 2 y; 92% at 3 y	Coated: 98% at 1, 2, 3 y	
Deuk Choi et al <sup>45</sup>	2001 (273)	49	1991–1999	AMS 700 CXM	Non-coated: 88% at 1 y; 85% at 2 y; 80% at 3 y	Non-coated: 95% at 1 y; 88% at 2 y; 88% at 3 y	
Montorsi et al <sup>51</sup>	2000 (200)	59		AMS 700 CX and CXM, Ultrex	Ultrex: 87% at 1 y; 63% at 5 y; 45% at 10 y	Ultrex: 97% at 1 y; 74% at 5 y; 62% at 10 y	Multiple institutions

AMS = American Medical Systems; DM = diabetes mellitus; IPP = inflatable penile prosthesis; NA = not available.  
Table modified with permission from Trost and Hellstrom.<sup>62</sup>

One large Italian study reported patient satisfaction rates of 97%, 81%, and 75% with the AMS 700 CX, AMS Ambicor, and AMS 600-650; partner satisfaction rates were 92%, 91%, and 75%, respectively.<sup>27</sup> A case series from China reported successful coitus in 97.6% of patients (41 of 42) after IPP placement.<sup>57</sup> Another study found that patients with PD, radical prostatectomy, or body mass index higher than 30 kg/m<sup>2</sup> have a statistically significant decrease in satisfaction compared with the general implant population.<sup>58</sup>

A 2005 study comparing Mentor and Coloplast Alpha prostheses with the AMS series found no difference in satisfaction rates between the two models when using a specialized follow-up questionnaire.<sup>59</sup> Although data are limited, comparisons between IPP and other forms of ED therapy generally show a higher satisfaction rate in men with ED who chose the prosthesis.<sup>34</sup> Setting proper patient expectations before PP surgery is important to achieve greater satisfaction.

## INFRA-PUBLIC VS PENOSCROTAL: RISK AND BENEFITS

Surgical implantation of penile prostheses can be carried out using different surgical approaches and incisions. Semirigid and malleable prostheses can be implanted through a distal sub-coronal penile approach. Multiple-component prosthesis placement can be placed through an infra-pubic or trans-scrotal approach. Advantages of the penoscrotal route include a potential lower risk of dorsal nerve injury, better corporeal exposure, and the ability to anchor the pump directly in the scrotum. In contrast, advantages of the infra-pubic approach include more rapid device placement and direct visualization during reservoir insertion.<sup>59</sup> Disadvantages can include difficulty with pump placement, limited corporeal exposure, and increased risk of damage to sensory nerves of the penis, particularly with revision cases.<sup>35,60</sup> In 2014 Trost et al<sup>61</sup> reported that, compared with the infra-pubic approach, the trans-scrotal approach achieved increased proximal dilation with a 1- to 2-cm longer prosthesis inserted. No clear advantage appears to exist with respect to patient satisfaction or infection rates between infra-pubic and scrotal incisions.<sup>52</sup>

## RESERVOIR PLACEMENT

Historically, the reservoir in the three-piece IPP design has been placed into the space of Retzius or extraperitoneal space by blind puncture through the transversalis fascia. This technique has been widely used for decades but has a recognized risk of troublesome complications.<sup>62</sup> The increasing popularity of robotic-assisted laparoscopic prostatectomy has added additional challenges to placing the reservoir in the space of Retzius because the space becomes obliterated with this technique.<sup>63</sup> To avoid complications, different maneuvers have been described for placing the reservoir into an “ectopic” location, superficial to the transversalis fascia. The new reservoir design—Cloverleaf for Coloplast and Conceal flat reservoir for AMS—are specially

**Table 4.** Outcomes of American Medical Systems Two-piece Penile Prostheses

Study	Year (n)	Mean follow-up (mo)	Surgery ranges	Device(s)	Overall device survival	Mechanical survival	Comments
Natali et al <sup>27</sup>	2008 (98)	29	1990–2004	Ambicor (and other devices)	89%	94%	
Lux et al <sup>26</sup>	2007 (146)	38	1999–2004	Ambicor	99% at 3 y; 91% at ≥4 y	100%	
Levine et al <sup>25</sup>	2001 (131)	43	1995–1999	Ambicor	92%	98%	

Table modified with permission from Trost and Hellstrom.<sup>162</sup>

designed for an “ectopic” placement. In 2011, Perito<sup>64</sup> and Perito and Wilson<sup>65</sup> popularized the ectopic reservoir placement (above the transversalis fascia and below the transversus abdominis muscle) through an infra-pubic approach.

## PP INFECTION CONSIDERATIONS

Infection remains one of the most devastating complications in prosthetic urology. Patients must be fully apprised of the consequences of penile implant infections. It has been documented that the cost of penile implant infection exceeds the original surgery by a factor of six.<sup>66</sup> Modern revision and salvage strategies have improved compared with historic penile implant reoperation outcomes.

Successful penile implantation involves balancing a methodical, systematic approach with safety checks vs operative speed and efficiency to help minimize the chance of infection. The patient’s best chance for a successful outcome lies with the first implant attempt, with each successive surgery carrying higher rates of infection and complications. With each subsequent surgery, penile shortening also can occur. Device explantation, pain, and penile shortening are key causes of dissatisfaction related to infection.

## PENILE IMPLANT INFECTIOUS FACTORS

Risk factors for penile implant infection can be divided into patient-related and surgical factors. Postulated patient-related factors include diabetes, degree of diabetic sugar control, presence and treatment of pathologic nasal flora, long-term steroid use, patient preoperative cleansing with antiseptics, smoking history, HIV status, history of radiation therapy, revision vs virgin implantation, spinal cord injury, obesity, concomitant circumcision, and prior renal transplantation. Table 7 presents a review of the current evidence regarding implant infection and patient factors.<sup>52,67–84</sup>

No studies specific to penile implantation exist that meet Oxford criteria level 1 evidence. Active smoking was found to carry an increased infection odds ratio of 1.79.<sup>67</sup> The same study supported smoking cessation at least 4 weeks before implantation to decrease infection risk by 2.3-fold. Level 1 data argue against

any benefit of patient preoperative site cleansing with alcohol-based preparations or other disinfectants.<sup>68,69</sup> However, an expert panel determined that surgeons’ personal preference should ultimately determine patient preoperative bathing and use of antiseptics.<sup>84</sup> One trial of artificial urinary sphincters showed fourfold decreased perineal colonization with the use of preoperative chlorhexidine for 5 days before surgery.<sup>85</sup> HIV status did not carry a statistically significant increased infection risk.<sup>70</sup>

The strongest literature specific to penile implantation (level 2) shows that revision surgery increases the risk of infection anywhere from two- to fivefold (historically and currently) above first-time cases. Most patient factors affecting penile implant infections reach only level 3 Oxford criteria. Diabetes can affect wound healing and susceptibility to infection. Several studies have reported increased infection risk for penile implants performed in patients with diabetes<sup>71</sup> and a non-statistically significant increased risk seen in other studies.<sup>72,73</sup> A manufacturer’s database of explants showed a significantly increased risk of infection in diabetics (n = 624) compared with normal controls (n = 6,071). Infection risk was 1.88% for diabetics vs 1.53% for non-diabetics for a relative infection rate increase of 23% ( $P = .0052$ ).<sup>71</sup> Use of a hemoglobin A<sub>1c</sub> cutoff point of 11.5 was found to confer greater infection risk in one study<sup>72</sup> but no increased risk in another.<sup>73</sup> Obesity, age, concomitant circumcision, history of renal transplantation, radiation, self-catheterization, or immunosuppression conferred no convincing evidence of increased infection risk.<sup>62,74–76,87</sup> Contrasting results showed a much higher risk of infection with steroid use.<sup>87</sup> In general, patients with spinal cord injury showed higher infection rates, especially when grouped with erosion.<sup>77</sup>

Surgical factors pertaining to risk of infection include hair-removal strategies, presence of device coatings on implants, use of surgical drains, minimization of device contact with skin, surgical approach, skin preparation type, surgeon experience, perioperative antibiotics, postoperative antibiotics, surgeon hand cleansing, and institutional processes to decrease infection. Table 8 presents a review of the current evidence regarding implant infection and surgical factors.<sup>3,87–102</sup>

Oxford level 1 and 2 evidence from the non-urologic literature has established the superiority of alcohol-based intraoperative scrub over iodine-based scrub.<sup>87–89</sup> Although these scrubs require

**Table 5.** Outcomes of Mentor (Coloplast) Three-piece Penile Prostheses

Study	Year (n)	Mean follow-up (mo)	Surgery ranges	Device(s)	Overall device survival	Mechanical survival	Comments
Chung et al <sup>36</sup>	2013 (50)	35	2006–2010	Titan		87% at 5 y	Peyronie population; compared AMS and Coloplast devices; no statistical difference between AMS and Coloplast
Brinkman et al <sup>33</sup>	2012 (1,205)		1992–1998	Mentor Alpha-1, Alpha NB	85% at 3 y for Alpha-1; 81% at 3 y for Alpha NB		Included AMS and Mentor; no significant difference between AMS and Mentor
Wilson et al <sup>16</sup>	2007 (2,384)	NA		Mentor Alpha-1, Alpha NB	Alpha-1: 80% at 5 y; 72% at 10 y; 64% at 15 y  Alpha NB: 90% at 1 y; 81% at 5 y	Alpha-1: 90% at 5 y; 82% at 10 y; 76% at 15 y  Alpha NB: 97% at 1 y; 94% at 5 y	
Rajpurkar and Dhabuwala <sup>34</sup>	2005 (65)	Median = 49	1995–2003	Mentor Alpha-1	68%; 63% at 5 y without revisions; 88% at 5 y without revisions	81%	32% required reoperation

AMS = American Medical Systems; NA = not available.

Table modified with permission from Trost and Hellstrom.<sup>162</sup>

**Table 6.** Outcomes of Malleable Penile Prostheses

Study	Year [n]	Mean follow-up (mo)	Surgery ranges	Device(s)	Overall device survival	Mechanical survival	Comments
Kim et al <sup>24</sup>	2008 (48)	11.7 y	1990–2004	AMS 600	83%	100%	Patients with spinal cord injury
Burns-Cox et al <sup>47</sup>	2007 (149)		1980–1995	Mentor Acufom, AMS 600, Jonas-Koss	95%		Includes discontinued Jonas-Koss
Montague and Nagermier <sup>25</sup>	2006 (393)	50 mo	1975–2000	Mentor Acu-Form (n = 256); Small-Carrion (n = 77); AMS 600-650 (n = 52); Finney (n = 4); Jonas (n = 4); other non-malleable devices	89%	99.5%	
Ferguson et al <sup>30</sup>	2003 (85)	68	1992–1996	AMS Durall	91%	100%	Compared primary with salvage IPPs, frequent vs infrequent implanters, malleable vs 3-piece IPPs
Lotan et al <sup>22</sup>	2003 (32)	NA	1988–1999	NA	87% at 10 y		
Chiang et al <sup>48</sup>	2000 (170)	35 mo	1985–1996	AMS 600, 650; Mentor Malleable + Acu-Form; other non-malleable devices	84%	88%	

AMS = American Medical Systems; IPP = inflatable penile prosthesis; NA = not available.  
Table modified with permission from Trost and Hellstrom.<sup>162</sup>

a 3-minute drying time after application, they are faster than the traditional 10-minute iodine-based scrub and have the added advantage of continued antibacterial activity for several hours when left undisturbed. Level 2 evidence shows equivalence between traditional surgeon hand scrub and hand rubbing with the use of alcohol-based lotion preparations.<sup>90</sup> Some centers always recommend traditional hand scrub for the first case of the day and in cases of gross hand contamination.<sup>84</sup> Comparable results have been found with 90 and 180 seconds of alcohol-based hand rubbing.<sup>103</sup>

For hair removal of sites other than the scrotum, level 1 evidence recommends surgical clippers (as opposed to razors) to decrease infection risk by 2.09-fold (confidence interval = 1.15–3.8).<sup>91</sup> No definitive recommendations support the superiority of day of hair removal (immediately preoperatively or 1 day before surgery) or location of removal (operating room vs preoperative holding area or home). However, a Sexual Medicine Society of North America position statement points out that the scrotal rugae are more susceptible to nicks and cuts from clippers, potentially opening up an alternate source of infection. Thus, the Sexual Medicine Society of North America posits that surgeons using the penoscrotal approach use whatever hair-removal strategy they prefer.

In 2001 and 2002, respectively, the two three-piece IPP producers in the United States introduced implant coatings capable of retarding infection. AMS uses an antibiotic mixture of rifampin and minocycline that is impregnated into the device during production. The AMS coating, called InhibiZone, elutes the antibiotics at implantation primarily during the first few days and tapers off in the ensuing weeks.<sup>104</sup> Based on data from infection prevention of central venous and urinary catheters, the InhibiZone coating has excellent activity against common skin organisms.<sup>105</sup> During production, the Coloplast device is coated with a hydrophilic substance called polyvinylpyrrolidone. This coating absorbs the first aqueous solution with which it comes in contact and allows the surgeon to tailor the antibiotic coating immediately before implantation. This coating is designed to decrease bacterial adhesion and elute the antibiotics. A meta-analysis of retrospective reviews showed a decrease from 2.32% to 0.89% with antibiotic coating.<sup>92</sup> A meta-analysis conducted on the available studies comparing non-coated with coated prostheses of these manufacturers confirmed a significant decrease in infection rates for all devices.<sup>106</sup> Also published was the finding that rifampin and gentamycin immersion conferred the greatest decrease in infection compared with the other tested combinations, including minocycline and rifampin or vancomycin and gentamycin.<sup>92</sup>

Level 2 data recommend preoperative antibiotics. The America Urological Association implant guidelines recommend an aminoglycoside with vancomycin or a first- or second-generation cephalexin for 24 hours.<sup>107</sup> Administration of these antibiotics must be initiated at least 1 hour before incision to ensure adequate tissue levels. Postoperative antibiotics lack evidence of any kind, with some experts recommending postoperative antibiotics such as

**Table 7.** Oxford Criteria for Patient Factors Postulated to Impact Implant Infection

Patient factor	Study outcome	Overall level of evidence (highest level)	Type of study and population studied	Study
Preoperative site cleansing with antiseptic	Meta-analysis of placebo-controlled randomized trials showed no statistical decrease in surgical site infection	1	Meta-analysis of randomized trials	Webster et al, <sup>68</sup> Chlebicki et al <sup>69</sup>
Smoking status	Smokers' increased risk of surgical site infection vs never smokers; cessation of smoking 4 wk before surgery decreased risk	1	Meta-analysis of cohort studies	Sorensen <sup>67</sup>
HIV status	Data from orthopedics implant data showed no significant increased infectious risk after sensitivity analysis	1	Meta-analysis of orthopedic cohort studies	Kigera et al <sup>70</sup>
Revision surgery	Markedly increased risk of infection seen in multiple studies	2	Retrospective reviews with good sample size and prospective cohort study; penile implant studies	Wilson and Delk, <sup>52</sup> Wilson et al, <sup>78</sup> Jarow <sup>79</sup>
<i>S. aureus</i> nasal carriage and treatment	Increased risk of SSI in orthopedic cases in which patient had positive nasal swab for <i>S. aureus</i> but often <i>S. aureus</i> isolates from the wound were a different strain than that from nasal culture; treatment of patients with nasal swabs positive for <i>S. aureus</i> decreased rate of infection from 7.7% to 3.4%	2	Multicenter prospective cohort study of surgical and orthopedic patients	Bode et al, <sup>80</sup> Berthelot et al <sup>81</sup>
Diabetes	Retrospective review of manufacturer's database of explants showed significantly increased risk of infection in diabetics ( $n = 624$ ) compared to normal controls ( $n = 6,071$ ; 1.88% vs 1.53% in non-diabetics); increased risk seen in some assessments and higher risk, but not reaching statistical significance, seen in other studies	3	Penile implant-specific meta-analysis and prospective trials	Mulcahy an Carson, <sup>71</sup> Bishop et al, <sup>72</sup> Wilson et al <sup>73</sup>
History of radiation therapy	No increased risk	3	Retrospective review of implant series	Wilson and Delk, <sup>52</sup> Dubocq et al <sup>75</sup>
Tight blood sugar control in diabetics	Insulin dependence or higher fasting sugar levels did not confer higher risk; patients with $\text{HgbA}_{1c} > 11.5$ at time of surgery showed increased risk	3	Prospective penile implant studies	Bishop et al, <sup>72</sup> Wilson et al <sup>73</sup>
Long-term steroid use and immunosuppression	No increased risk in 1 study (0 of 13) and 50% risk of in another (5 of 10)	3	Retrospective review of implant series	Wilson and Delk, <sup>52</sup> Sidi et al <sup>82</sup>
Spinal cord injury	6% risk of infection in patients with SCI; no infections in patients with SCI; multiple other studies showed increased risk but had no statistical analysis	3	Retrospective review of implant series	Wilson and Delk, <sup>52</sup> Diokno and Sonda, <sup>76</sup> Collins and Hackler, <sup>77</sup> Jarow, <sup>79</sup> Radomski and Herschorn <sup>83</sup>
Obesity	No increased risk	3	Retrospective review of implant series	Wilson and Delk <sup>52</sup>

(continued)

Table 7. Continued

Patient factor	Study outcome	Overall level of evidence (highest level)	Type of study and population studied	Study
Concomitant circumcision	No increased risk with circumcision at time of surgery; not performing circumcision at time of prosthesis placement was a risk for infection	3	Retrospective review of implant series	Wilson and Delk, <sup>52</sup> Thomella et al <sup>74</sup>
Prior renal transplantation	No increased risk	3	Retrospective review of implant series	Wilson and Delk, <sup>52</sup> Sidi et al <sup>82</sup>
Age ≥75 y	No significant difference in device survival or revision	4	Retrospective review of implant series	Chung et al <sup>86</sup>
Intermittent catheterization	No infections in patients who routinely performed catheterization with indwelling prosthesis	4	Retrospective Review of implant series	Diokno and Sonda <sup>76</sup>

HgbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; *S. aureus* = *Staphylococcus aureus*; SCI = spinal cord injury; SSI = surgical site infection.

trimethoprim-sulfamethoxazole for 10 to 14 days in virgin cases and up to 30 days in revision and salvage cases.<sup>84</sup> Other experts discourage postoperative antibiotics of any kind because no evidence exists that they decrease infection in the context of increased cost, problems with antimicrobial resistance, and potential drug allergy and side effects.

Recognizing that most infected implants are contaminated from the patient's skin, some surgeons have adapted a "no-touch" technique of operation in which the implant, instruments, and surgeon's hands are never in contact with the skin. After the retractor is in place and the initial incision is made, gloves and instruments are changed and the operation continues over a sterile drape. Level 3 evidence from a single-surgeon study compared with same-surgeon historical controls found that the combination of the no-touch technique with IPPs coated with infection retardant decreased their center's implant infection rate to 0.46%.<sup>3</sup> Further evidence supporting minimization of device or surgeon contact with the patient's skin is found in the results of a recent study in which the skin of patients undergoing penile implantation was swabbed immediately before and after being randomized to a standard povidone iodine or chlorhexidine prep stick. Cultures were positive in 79% of patients before preparation and a shocking 41% and 8% after preparation, respectively.<sup>108</sup>

Level 3 evidence shows improvement in infection rates for high-volume experienced surgeons<sup>93</sup> and for high-volume institutions that use surgical checklists and protocols.<sup>94,95</sup> The routine use of surgical drains<sup>96</sup> and infra-pubic vs scrotal approach have not yielded statically significant differences in infections.<sup>97</sup>

## BIOFILM

Biofilm can be defined as bacteria irreversibly adhered to a surface and enclosed in a self-made extracellular polysaccharide matrix.<sup>109</sup> In contrast to planktonic or free-floating bacteria in which antibiotics can kill the entire population, bacteria in biofilms can sustain a colony of residual bacteria (persister cells) despite aggressive antibiotic treatment. Bacteria in biofilm sometimes require up to 1,000 times the concentration of antibiotics to kill bacteria compared with their planktonic counterparts.<sup>104</sup> These mechanisms account for the inability of antibiotics to clear biofilm infections completely, demonstrating the need for complete removal of an infected device.

The list of biofilm-forming pathogens includes *Staphylococcal epidermidis*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Candida albicans*.<sup>109</sup> Biofilm can form within 16 hours of device placement<sup>110</sup> and infecting organisms are introduced through device contamination or transient bacteremia.<sup>111</sup> Although still under investigation, the formation of biofilms was summarized by Arciola<sup>111</sup> in 2010 as a four-step process of attachment: aggregation and accumulation in multiple cell layers, maturation, and detachment. During biofilm

**Table 8.** Oxford Criteria for Surgical Factors Postulated to Impact IPP Infection

Surgical factor	Study outcome	Overall level of evidence (highest level)	Type of study	Study
Operative site scrub in operating room	Patients randomized to conventional scrub of surgical site with povidone-iodine or chlorhexidine-alcohol scrub before urologic prosthetic implantation; chlorhexidine-alcohol was protective against deep and superficial wound infections in clean-contaminated cases vs povidone-iodine preparation	1	Mixed	Kava et al, <sup>87</sup> Darouiche et al, <sup>88</sup> Paocharoen et al <sup>89</sup>
Hair removal*	No statistically significant results based on insufficient power for hair removal; clipping is associated with fewer SSIs than shaving; no difference between hair removal the day before compared with day of surgery	1	Cochrane review of 14 trials	Tanner et al <sup>91</sup>
Surgeon hand cleansing	Trial of alcohol vs traditional hand scrubbing showed equivalence; 1.5 min of hand rubbing equivalent to 3 min	2	Prospective randomized	Parienti et al, <sup>90</sup> Tanner et al <sup>91</sup>
Antibiotic-impregnated implant	Meta-analysis of retrospective reviews showed decrease from 2.32% to 0.89% with antibiotic coating; small single-institute retrospective study showed decreased infection rates with rifampin- and minocycline HCl-coated prostheses	2	Meta-analysis of retrospective reviews	Mandava et al, <sup>92</sup> Abouassaly et al <sup>98</sup>
Antibiotic coating choice	Analysis showed that infection rates of minocycline and rifampin (0.63%) and rifampin and gentamicin (0.55%) were superior to vancomycin and gentamicin (4.42%)	2	Meta-analysis of retrospective reviews	Mandava et al <sup>92</sup>
Perioperative antibiotics around implantation	Significant decrease in implant infections; other studies trended toward decrease in implant infection; all studies showed significant decrease in wound infection	2	Prospective randomized vs placebo	Boxma et al, <sup>99</sup> Jensen and Kimose, <sup>100</sup> Yerdel et al <sup>101</sup>
“No touch” technique	Technique lowered infection rate from 2% to 0.45%	3	Cohort compared with same series of historical controls	Eid et al <sup>3</sup>
Surgeon experience	Comparison of single surgeon with multiple surgeons implanting IPPs; single-surgeon model showed improvements in multiple factors but minimal data for infection	3	Retrospective review	Henry et al <sup>93</sup>
Institutional process to decrease infection	Studies using comprehensive infection control program in institutional practices (limiting OR traffic, specific instrument handling practices, specially trained OR team, ventilation characteristics, etc.); checklist established for all IPP placements decreased infection rate	3	Varied	Stulberg et al, <sup>94</sup> Katz et al, <sup>95</sup> Graf et al <sup>102</sup>
Postoperative drain placement	Infection rates in patients with closed drainage did not differ from historical controls	3	Cohort compared with historical controls	Sadeghi-Nejad et al <sup>96</sup>
Surgical approach	Comparison of infra-pubic with penoscrotal approach; non-significant increase in rate of infection with infra-pubic approach	4	Retrospective review	Garber and Marcus <sup>97</sup>

IPP = inflatable penile prosthesis; OR = operating room; SSI = surgical site infection.

\*The Sexual Medicine Society of North America recommends that surgeons be permitted their choice of razors or clippers for preoperative preparation of the male genitalia.

detachment, the bacterial constituents once again can become planktonic and can initiate biofilm re-formation or acute infection elsewhere within the host. This property of reinfection demonstrates an additional threat posed by biofilms, because the bacteria are no longer necessarily localized and contained.

Polymorphonuclear neutrophils can recognize biofilms and phagocytose the bacteria within them, demonstrating that biofilms are not inherently resistant to all innate immune defenses.<sup>112</sup> However, despite an elicitation of an immune reaction, biofilms persist. This ineffective phagocytosis can prove harmful, because the inflammatory reaction created by polymorphonuclear neutrophils contributes to significant tissue destruction.<sup>111</sup> Not surprisingly, fewer bacteria are required to establish a biofilm infection on an indwelling foreign device than on a non-indwelling device.<sup>113</sup>

## REVISION SURGERY

Henry et al<sup>114</sup> cultured clinically uninfected implants removed for revision and found that 70% of implants were culture positive and 90% were positive for at least 1 of 10 staphylococcal species. In some cases, biofilms were visibly apparent on the surface of these implants. Citing the recurrence of the same bacteria isolates cultured at revision surgery of uninfected prostheses as those cultured from clinically infected implants seen by Brant et al,<sup>14</sup> Henry et al<sup>115</sup> postulated that the increased incidence of infection after revision could be due to disruption and activation of a pre-existing biofilm. They proposed that a revision washout of all existing implant capsule spaces could help decrease infection similar to how salvage rescue of an infected IPP helps in physically removing biofilm. A follow-up study investigated the combined use of a revision washout and an antibiotic-coated implant in revision surgery.<sup>115</sup> The two study groups received a coated implant at revision for noninfectious reasons, and groups were divided based on the performance of an antiseptic capsule lavage. In the control group, 11.6% of patients developed an infection within the 6- to 33-month observation period. In the group in which the washout was performed, only 2.9% of patients developed infection. Interestingly, they found no significant decrease in infection for revision operations when using antibiotic-coated implants unless capsule washout was performed.<sup>78</sup> All revision cases should undergo copious irrigation because infection rates decrease dramatically with this approach.<sup>84</sup> Unfortunately, there are no agreed-to evidence-based recommendations as to which antibiotic solutions should be used. Rifampin, Bacitracin, gentamycin, and amphotericin have been used most commonly.

The success of the washout procedure and complete device replacement in purportedly removing the biofilm has likely contributed to the decrease in post-revision infections. Infection rates have decreased to as low as 4% in revision surgeries and the 5-year infection-free survival for fully replaced and washed out implants are significantly higher than those not treated this way.<sup>116</sup>

## SALVAGE SURGERY

Before the era of coated implants, 75% of penile implant infections were local infections with coagulase-negative staphylococci. These patients presented late (>2 months) with symptoms and signs of a local infection, including pump stuck to skin, serous drainage from wound dehiscence, and scrotal pain. Although coated implants have dramatically decreased infections, most of those rare infections that occur with these devices do not manifest as only local involvement, but instead, are systemic and aggressive.<sup>87</sup> These patients are toxic and febrile with gross wound purulence. It appears that more infections in the era of the coated implant often preclude salvage procedures and necessitate removal of the entire device because the patient is too sick to risk removal and replacement of the device at one sitting.

When faced with the decision of whether to perform a penile implant salvage procedure, patients need to be involved in the decision process. For a suspected but non-definitive penile implant infection (such as persistent wound drainage after the procedure), a trial of long-term oral antibiotics is reasonable as long as the patient is willing to undergo close surveillance and understands that progression of infectious symptoms will necessitate surgery. Another strategy to determine whether a subclinical infection exists is to administer broad-spectrum intravenous antibiotics; immediate improvement in clinical symptoms confirms the diagnosis. Unfortunately, there is no test that can reliably identify a low-grade prosthetic infection. For severe sepsis or diabetic ketoacidosis, the entire infected implant device should be removed urgently. However, in the rare instance when removing the reservoir is difficult in the unstable patient, it can be left behind and removed later if local infection persists. Implant infections typically include an infection near the device with the formation of biofilm and a localized soft tissue infection resulting in erythema. Salvage procedures can fail because mechanical lavage cannot effectively treat the soft tissue infection. Patients with implant infections should be admitted to the hospital and given broad-spectrum antibiotics. Immediate wound culture of purulent drainage should be performed to

**Table 9.** Mulcahy Salvage Protocol

Remove all prosthetic parts and foreign materials
Irrigate wound and all compartments with 7 antiseptic solutions
Washes 1 and 7: kanamycin and bacitracin
Washes 2 and 6: half-strength hydrogen peroxide
Washes 3 and 5: half-strength povidone iodine
Wash 4: water pic pressure irrigation with vancomycin 1 g and gentamicin 80 mg in normal saline 5 L
Change gowns, gloves, drapes, and instruments
Implant new prosthesis
Primary wound closure without drains
Oral antibiotics as determined by culture for 1 mo

From Mulcahy.<sup>118</sup>

tailor antibiotic and washout medications. Because the device will be explanted regardless, fluctuance or an obvious fluid collection should be lanced to provide drainage with culture and provide pressure relief (which can prevent sepsis) without worry about exposing the device. Typically 2 to 3 days of broad-spectrum intravenous antibiotics will result in clinical improvement in wound erythema, fever curve, and clinical symptoms. At this point, device salvage has the highest chance of success. The decision to explant the device without salvage is always reasonable if the patient or physician is so inclined. However, future device implantation will be much more difficult because of dense corporal fibrosis and penile shortening.

Modern salvage protocols stress removal of all components of the device including the reservoir, vigorous mechanical lavage to remove biofilm, antimicrobial irrigation aimed at killing live bacteria, and use of postoperative oral antibiotics for 2 to 4 weeks.<sup>84</sup> Some clinicians leave short-term drains after washout because of the volume and possible tissue reaction from irrigation solutions. Many clinicians only substitute malleable rods. This technique carries the advantage of decreased operative time and difficulty and the theoretical advantage of less surface area of components (no reservoir and pump) to become reinfected. Success rates with replacing a malleable device have exceeded historical three-piece implant-exchange success rates.<sup>117</sup> Some patients will remain satisfied with the malleable device, whereas others will opt for reimplantation of a multicomponent device. Table 9 outlines the Mulcahy salvage protocol.<sup>118</sup>

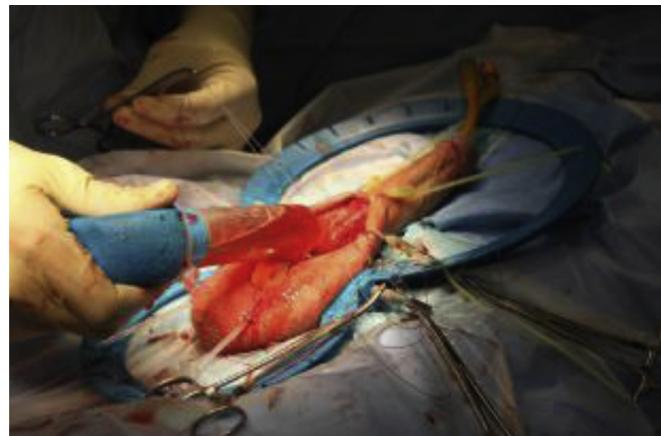
## INTRAOPERATIVE COMPLICATIONS AND TROUBLESHOOTING FOR PP SURGERY

As with any surgical procedure, complications during implantation of a PP can occur. In this section, the focus is primarily on intraoperative complications, including dilation difficulties, perforation and crossover, urethral injury, reservoir, pump, and tubing-related issues, and bladder, viscous, or vessel injuries.<sup>119</sup> It is expected that throughout the course of a prosthetic surgeon's career, intraoperative complications will occur, and preparedness will minimize operative morbidity and maximize patient outcomes.<sup>118</sup>

### Corporal Dilation

Corporal fibrosis can occur in men with ED after prolonged ischemic priapism, removal of an infected PP, secondary to diabetes, intracavernous injections, or trauma, and PD where involvement is not limited to the tunica albuginea.<sup>120–122</sup>

Penile fibrosis after priapism (usually distal) and infection (more proximal) is usually extensive and dense and poses a risk of perforation outside the corpora, resulting in cylinder extrusion, or into the urethra. Technically, dilation through severe fibrosis can result in one of three outcomes: placement of cylinders in standard fashion after successful dilation, limited dilation and placement of smaller-diameter penile cylinders, or



**Figure 3.** Distal fluid challenge test to identify the side of distal perforation. *Figure 3* is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

if primary closure of the tunica albuginea over the prosthesis is not possible, then the device can be covered by graft material.<sup>120–123</sup> Patients with extensive corporal fibrosis should be forewarned of increased risks associated with implantation into a scarred penis, especially in surgeries after removal of an infected implant where severe penile length loss might be unavoidable.<sup>122</sup> Further discussion is found in the section on Special Populations.

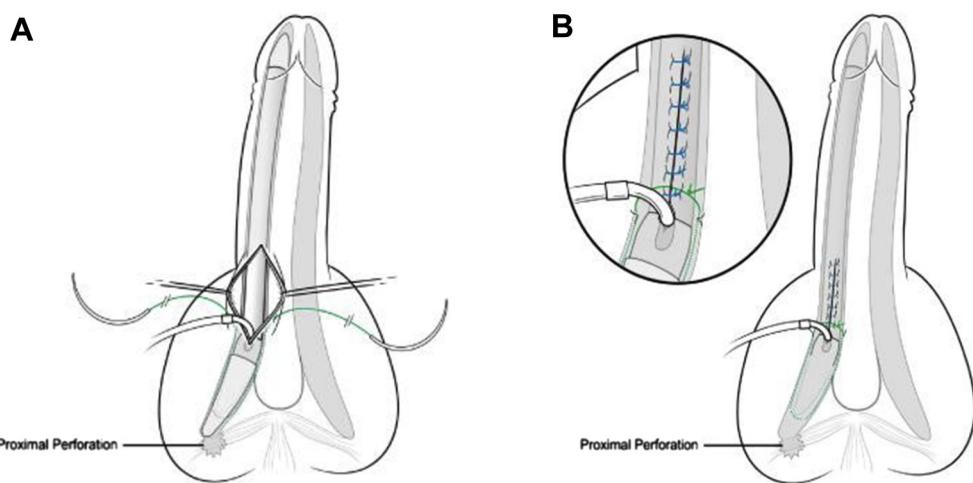
### Corporal Crossover

Cylinder crossover can occur during initial passage of the dilator or subsequent passage of the Furlow inserter or passage of the cylinder base proximally, which can occur owing to the fenestrated septum, corporal scar tissue, and dilation that deviates toward the midline. The primary goal is prevention, with dilators or scissors directed dorsolaterally toward the 2- and 10-o'clock positions.

Crossover is suspected when the corporal measurements are not equal, when there is difficulty inserting the second cylinder, when dilators placed simultaneously in each cavity are not symmetric (or there is contact between dilators), or when the erection looks lopsided or unusual on inflation.<sup>119,123</sup> A stepwise approach allows for rerouting of the cylinders into the appropriate corporal chamber. In most cases, a dilator tracking over the midline into the contralateral corpora cavernosa indicates the side that crosses over. After removal of the two cylinders and placement of a dilator in the common cavity, the opposite cavity is redilated laterally, and the IPP cylinder in the crossover side is placed with the stationary dilator maintained in place.

### Distal Perforation

While dilating the corpora cavernosa, distal perforation occasionally occurs and is often identified immediately as the dilator extrudes out of the meatus, fluid gushes out around the catheter upon irrigation of the corpora, or there is bleeding at the meatus. The "distal fluid challenge test" can be performed by placing a filled Asepto syringe into the corporotomy and then injecting



**Figure 4.** Panel A shows a suture through the rear-tip extender creating a sling. Panel B shows rear-tip sling suture emerging from the proximal corporotomy after positioning the proximal cylinder. Panel B are from Mulcahy,<sup>119</sup> used with permission. **Figure 4** is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

distally (Figure 3).<sup>17</sup> Perforation of the distal crus into the fossa navicularis can be repaired by creating a hypospadias and primary repair without placing of cylinders.<sup>1</sup> The safest course is to abort the implant portion of the case and return once the defect has sufficiently healed, which can take up to 6 months.<sup>119</sup> However, if the defect is unilateral and the contralateral side is confirmed intact, then the surgeon can consider proceeding with placement of just one cylinder, leaving the perforated side without placement of a cylinder temporarily or permanently.<sup>120–123</sup>

### Proximal Perforation

The management of proximal perforation has been simplified. Previously, the “windsock” repair was advocated. This has been replaced by two maneuvers, namely tightly closing the corporotomy at the exit point of the tubing through the tunica albuginea or using a rear-tip sling.”<sup>119,120,123</sup> As shown in Figures 4A and B, the suture or rear-tip sling obviates graft tissues because the windsock repair uses a non-absorbable suture such as polypropylene that is placed through the proximal end of the cylinder

or through the rear-tip extender and anchored to the tunica albuginea on each side of the corporotomy just distal to the input tubing exit site.<sup>119</sup> The corporotomy is closed and the suture sling is tied over the corporotomy closure. If perforation of the crus using narrow dilators is recognized by the sudden passage of the dilator into the soft tissue of the perineum, then it is often possible to use large scissors to establish the correct plane of dilation down to the attachment of the crus to the pelvic bone.<sup>120</sup> Using progressively larger dilators in this plane avoids further dilation of the false passage and the rear tip of the cylinder can be implanted within the crus as the small false passage seals over the tip.

## Urethral Injury

Urethral injury is an uncommon intraoperative complication, with estimated occurrence rates ranging from 0.1% to 3%, and occurring most often in conjunction with severe penile fibrosis.<sup>124</sup> If the urethral lumen is entered during the procedure at a site amenable to a two-layer closure, then this can be accomplished and the cylinder can be implanted after completion of the repair. This approach is technically most feasible for injuries that occur in the penoscrotal aspect of the urethra.<sup>119</sup> However, in most cases, it is reasonable to repair the defect and abort the implant procedure, especially for more distal injuries or in higher-risk patients such as those with diabetes, spinal cord injury, or requiring intermittent catheterization. Mulcahy<sup>119</sup> clarified that the urethral catheter does not need to be placed for an extended period (7–10 days) because the urinary stream will draw tissue fluid into it from the perforation site rather than allow urine to enter the corporal cavity by the Bernoulli principle. Anele et al<sup>124</sup> recently published a small series advocating for the use of a suprapubic tube in conjunction with primary repair, without altering standard implantation. It is recommended that the suprapubic tube be inserted before placing the reservoir to avoid injury to the reservoir in these cases. Nevertheless, it is reasonable to treat all urethral injuries using two layers of absorbable sutures, allowing for mucosa-to-mucosa apposition for the first layer, and deferring PP placement to a second procedure.<sup>120</sup>

## Pump, Tubing, and Retained Component Issues

Intraoperative complications of the tubing and the pump are infrequent.<sup>123</sup> Iatrogenic injury, most commonly a suture or sharp perforation, can occur to any component of the implant and necessitates replacement of the affected component. Many surgeons use the corporotomy sutures placed at the beginning of the case for closure in a mattress-stitch manner, instead of running a watertight stitch over the cylinders, to decrease the risk of inadvertent cylinder puncture.

Positioning of the scrotal pump varies according to implanter preference, and options include a sub-Dartos pouch, placement behind and between the testicles vs anteriorly in the scrotum, or more laterally, which can be used when implanting through an infra-pubic approach. The pump should be in a functional

position for the patient, and posterior tubing is preferable to prevent a “tail-pipe” penis or tubing that runs along the sides of the penis.<sup>119,123</sup> Recent concerns regarding pre-connected tubing that is too short and does not allow for dependent positioning of the pump reflects corporotomy positioning that is not proximal enough, because for every centimeter of more distal corporotomy, 2 cm of tubing is used (1 cm within the corpora and 1 cm “coming back” outside the corpora). Simply extending the corporotomy proximally will alleviate this in most cases. A less desirable maneuver is to add more rear-tip extenders. Tubing that is redundant also can be addressed at initial implantation by cutting tubing and making necessary reconnections or tacking the redundant tubing deeper in the scrotum to prevent coiling up onto the penis or anterior scrotal surface.

Levine and Hoeh<sup>62</sup> reviewed the ramifications of retained components and concluded that in non-infected revision surgeries, the risk of removing the reservoir outweighs retaining this component based on current medical literature. These studies show that retained reservoirs can lead to complications vs iatrogenic injury and technical difficulties inherent to a difficult extraction; it remains at the discretion of the surgeon as to whether the existing reservoir should be removed at the time of revision surgery for a non-infected device. However, the contrary is advised when a device is infected. All components must be removed in this scenario, and a second incision for reservoir removal might be needed unless the patient is unstable and reservoir removal is difficult.<sup>62,119,120</sup>

## Vessel and Viscous Injury

Pelvic vessel complications can be minimized by ensuring that an adequate space has been created anterior and lateral to the bladder such that there is no compression on the adjacent venous structures and by positioning the patient in Trendelenburg position when placing the reservoir.<sup>62,125</sup> If inadequate space is encountered, alternate reservoir placement outside space of Retzius should be considered. Should vascular injury occur, most commonly when struggling to remove a reservoir during a revision procedure, the vessel most commonly lacerated is a branch of the external iliac vein, such as the inferior epigastric, external superficial pudendal, or cremasteric vessels.<sup>62</sup> The iliac artery and vein are approximately 2.5 cm lateral to the pocket where the reservoir is placed and injury to either of these vessels can be catastrophic; if significant bleeding occurs during reservoir placement or retrieval, then pressure on the wound and extension of or creation of a secondary incision for adequate exposure are paramount, as is considering an intraoperative consultation with a vascular surgeon to repair the laceration.<sup>119</sup>

Bladder injury occurs most commonly from passage of the scissors through the transversalis fascia or, rarely, during reservoir overfilling “hydro-capsulotomy” for autoinflation revision surgery, although with lockout valves, the latter surgical intervention has almost been eliminated.<sup>126</sup> Immediate repair is warranted, and after two-layer bladder wall closure, contralateral

or ectopic placement of the reservoir can proceed in most cases.<sup>62</sup> If bowel contents are encountered, then the implant should be aborted and an intraoperative general surgery consult should be obtained immediately.<sup>119,126</sup> Reattempt at implant surgery occurs after complete recovery, and consideration of ectopic reservoir placement is recommended.

## SPECIAL POPULATIONS

### Prosthesis Implantation After Previous Explantation

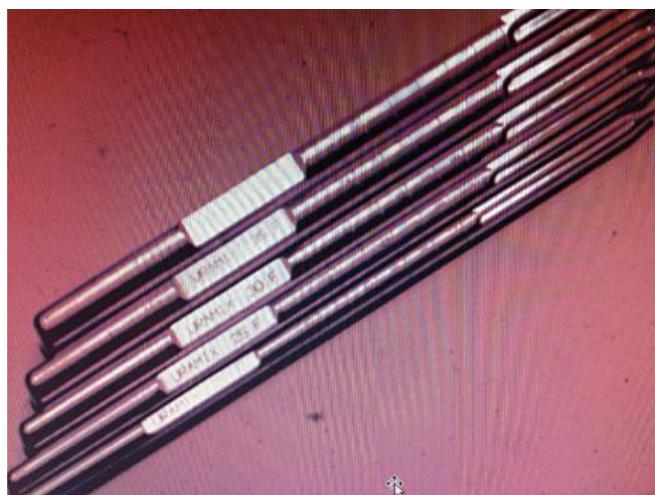
After examining an all-payer national database (Nationwide Inpatient Sample sponsored by the Agency for Healthcare Research and Quality) from 2000 through 2009, a 2014 study of national trends in the United States demonstrated that most patients (82.7%) with infected PPs underwent explantation rather than salvage (17.3%).<sup>126</sup>

After explantation, corporal fibrosis is typically encountered. A penoscrotal approach is recommended because this will allow more complete access to the corpora proximally and distally. Carbone et al<sup>127</sup> reported on 26 men with fibrosis, 18 of whom had a previous prosthesis explantation. Two patients required distal counterincisions and all patients had the tunica albuginea closed primarily. There was one infection requiring explantation and one explantation for cylinder crossover. The same group looked at an additional nine patients in whom the fibrotic corpora were removed by sharp dissection, from under the glans to "as far as possible in the crural area." A smaller device (AMS CXM) was placed in these cases, with primary closure of the tunic in all cases. No infections were reported, although one man required revision at 46 months from cylinder failure.<sup>127,128</sup>

Grafts also can be used to allow closure of the tunic, especially when smaller cylinders are not used. Synthetic grafts have demonstrated mixed results. Knoll et al<sup>129</sup> reported on 57 men receiving a polytetrafluoroethylene graft vs 20 men receiving



**Figure 5.** Carrion-Rosello cavernotome. From Mulcahy,<sup>119</sup> used with permission. **Figure 5** is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).



**Figure 6.** Uramix or Mooreville dilator. From Mulcahy,<sup>119</sup> used with permission. **Figure 6** is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

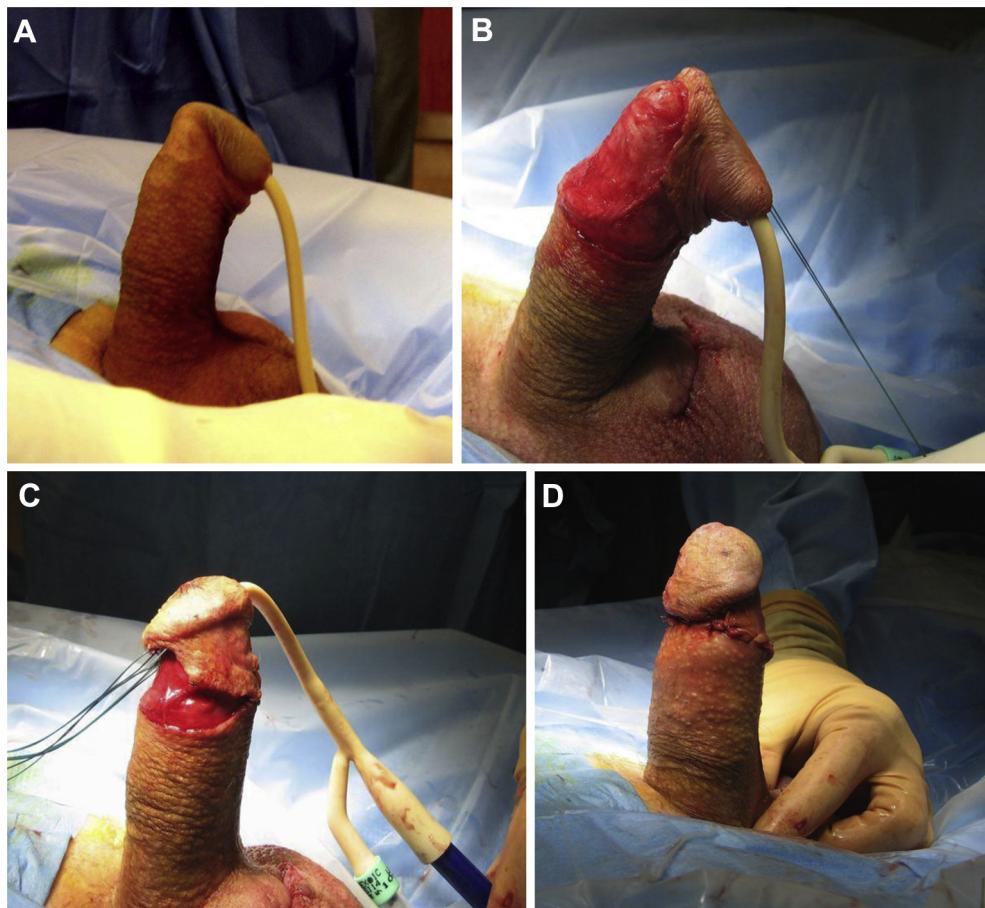
downsized cylinders to allow closure of the tunic. Infection occurred in 30% of the former group vs 5% in the latter group.

To achieve corporal space without sharp dissection of the corpora, a cavernotome can be used. Currently, two devices are commercially available. One is the Carrion-Rosello device, consisting of small rasps that are angled in a reverse direction so that they remove tissue when the device is pulled out, with a smooth surface on the side that faces the urethra to avoid injury. Its use was reported in 1995 in 32 men, with two cases of inadequate proximal dilation and two cases of infection<sup>130</sup> (Figure 5). Another device is the Uramix or Mooreville dilator, which has a recessed blade on one side. In 16 patients, there were five cases of proximal perforation and four cases of distal perforation<sup>131</sup> (Figure 6).

Because patients with corporal fibrosis have loss of size and elasticity of the penis, various techniques have been proposed to mitigate size loss. Vacuum erection devices can be used after explantation for intercourse. Of 11 patients who had had a previous implant explantation, 10 successfully used the vacuum erection device at home for intercourse.<sup>132</sup> One study used a traction device in four men after explantation before receiving a new IPP. These patients gained 1.5 to 3 cm in stretched penile length after daily traction for 2 to 3 hours for 3 to 4 months, with positive changes in length after IPP placement of 0 to 1.5 cm (compared with before traction).<sup>54</sup>

### Prosthesis Implantation After Priapism

Post-priapism implants are among the most challenging cases in prosthetic urology. Unlike after explantation, when there might be residual "normal" corporal tissues, the post-priapism corpora are often completely replaced with dense fibrosis especially in the distal corpora. Different techniques and instruments have been used to address the fibrosis, and surgeons have recognized that implants are far easier to place in the early



**Figure 7.** Panel A shows supersonic transport deformity with poor glans support. Panel B shows elevation of glans off the distal corpora tips. Panel C shows non-absorbable suture placed into the glans and secured to the dorsal tunica albuginea to retract the glans. Panel D shows the glans properly positioned over the corporal tips. *Figure 7* is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

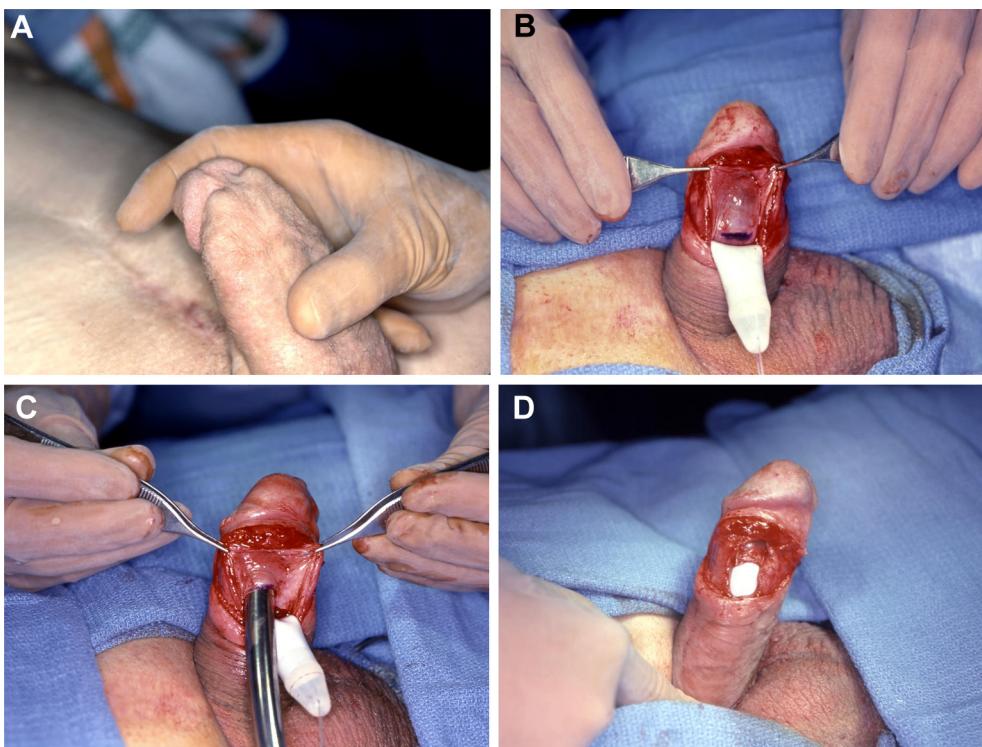
post-priapism period, when the tissue is more elastic and more conducive to dilation. One case report noted that corporal dilation for PP placement at the time of priapism was easy but virtually impossible 6 months later and the patient required sharp excision (excavation) of corporal tissue to allow placement of a narrow-based prosthesis.<sup>133</sup> Durazi and Jalal<sup>134</sup> reported on 17 patients receiving different implant types 6 to 18 months after the priapism episodes. All cases required some degree of sharp dissection of the fibrotic tissue, and an unreported number required some degree of excision of the tissue.

One of the first reports on early placement of a prosthesis for men with refractory ischemic priapism included a case report in which a two-piece inflatable Ambicor device (AMS) was placed after failure of two distal shunts in a patient with underlying ED.<sup>135</sup> One concern about early placement of a prosthesis is the risk of distal tip erosion when a distal shunt has been performed. A case series of 12 men reported on the use of malleable devices, with a non-absorbable suture being used to attach the device to the tunica albuginea at the site of the corporotomies.<sup>136</sup> They reported no infections or distal cylinder migration (mean follow-up = 15 months). A larger series reported on 50 men given

malleable (43 patients) or inflatable (7 patients) prostheses.<sup>137</sup> The choice of device was based on the amount of bruising and edema, with the thought that patients with minimal bruising and edema were at lower risk for infection and thus were better candidates for an inflatable device.

An additional rationale for early PP implantation is found in an important report in which 68 men with refractory priapism underwent early implantation (within 7 days) and 27 underwent implantation later (median = 5 months).<sup>138</sup> In the delayed group, there was a high rate of requiring additional corporotomies (80%) and downsized cylinders and a high revision rate (26%) for infection, erosion, or mechanical failure. These complications were not seen in the early implant group.

It would be useful to know which patients with ischemic priapism would be best served by proceeding directly to implantation. With progressive ischemia time, there is increased acidosis and hypoxia,<sup>139</sup> but blood gas determination is not good enough to predict unrecoverable ED. A promising modality could be magnetic resonance imaging. One study found that magnetic resonance imaging, when correlated to biopsy specimens of the corpora cavernosa, was 100% sensitive in predicting non-viable smooth



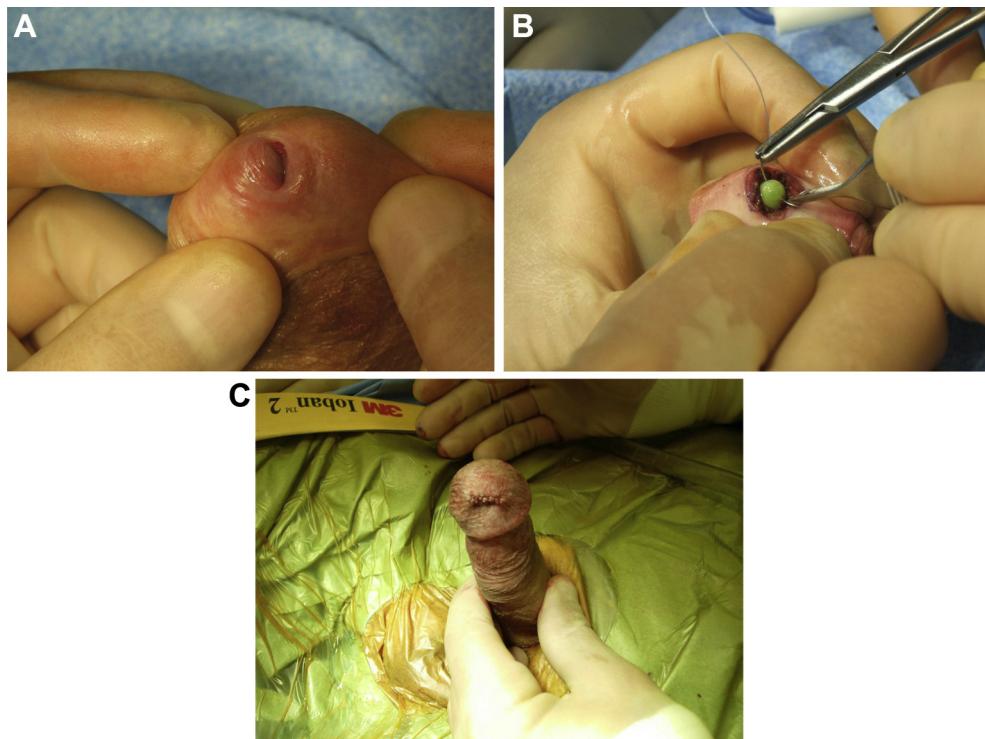
**Figure 8.** Panel A shows ventrodistal cylinder extrusion and malposition. Panel B shows ventrolateral corporotomy exposing the corporal space. Panel C shows dorsal transverse capsule incision allowing distal dilation. Panel D shows prosthesis cylinder in an improper position within the corpus cavernosum. **Figure 8** is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

muscle tissue.<sup>140</sup> When patients had magnetic resonance imaging alone, the findings predicted the clinical outcome in all 15 cases.

### Peyronie Disease

Different techniques have been proposed to straighten the phallus when placement of the prosthesis alone is not adequate; these include “modeling” (forceful bending of the penis in the direction opposite the curve), plications, plaque incisions or excisions with or without grafting, and internal corporotomies. A surgical algorithm was first proposed in 2000<sup>141</sup> and a more contemporary one was proposed in 2011.<sup>142</sup> Although a full discussion of the various methods of correcting PD deformities is beyond the scope of this section, the general consensus is that inflatable prostheses should be used in the context of stable disease when there is ED that is poorly responsive to medical therapy and there is compromised ability to achieve coitus owing to inadequate rigidity and deformity. For mild to moderate curves, the prosthesis alone might provide enough axial rigidity to correct the curvature, at least to functional straightness (generally defined as <20° curvature).<sup>143</sup> For more severe curvature, modeling should be added. Modeling consists of maximally inflating the device, applying shod clamps to the tubing to protect the pump, and forcibly bending the penis to the opposite direction for 30 to 90 seconds (usually a minimum of two rounds). If this is inadequate, then additional maneuvers such as plication or plaque incision (with or without grafting) can be added. There also have been reports of plaque incision performed intra-corporally using urethoscopes, knives, or

urethrotomies.<sup>144</sup> Modeling was first described by Wilson and Delk<sup>145</sup> in 1994 in 138 patients. Although there was no mention of the type or severity of curvature, they reported 86% had straight erections after modeling, although they noted a 3% distal urethral perforation rate. A series of 46 patients demonstrated that 39% had correction of the curvature with the device alone, and 61% were corrected by additional modeling.<sup>146</sup> In the 2000 algorithm by Levine and Dimitriou,<sup>141</sup> they proposed a stepwise approach consisting of prosthesis plus modeling, plaque incision, and then plaque incision plus grafting. Using this approach, they found that of 46 patients, 54% were corrected by modeling, 26% required plaque incision, and 20% required additional grafting. A larger series of 60 patients by Kadioglu et al<sup>147</sup> with a mean curvature of 47° noted that 35% were corrected by the device alone, 30% required modeling, 1.6% required plaque incision, and 33% required plaque incision and grafting. In another larger series by Levine et al<sup>148</sup> of 90 men with mean curvature of 55°, with a mean follow-up of 49 months, they reported success for curvature correction (defined as <20°), with seven mechanical failures, two surgeries for malposition of pump or reservoir, one infection, and two distal corporoplasty procedures for erosion through the tunica albuginea over a mean follow-up period of 4 years. In this study, 4% were corrected by the device alone, 79% with modeling, 4% with plaque incision, and 12% with plaque incision and grafting. They also noted that patients believed they achieved maximum straightness by 1.9 months (mean), and more than 80% believed that it occurred within 3 months. This emphasizes the need for



**Figure 9.** Panel A shows impending erosion through the meatus. Panel B shows trans-glanular incision exposing the cylinder tip with lateral fixation. Panel C shows two-layer closure over the cylinder tip. **Figure 9** is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

compliance with postoperative therapy such as aggressive cycling and gentle self-modeling of the device.

Chung et al<sup>149</sup> reported on 18 patients who had plication performed before IPP implantation for correction of curvature. In these cases, a scrotal incision was retracted distally to allow access to the more distal ventrolateral tunica albuginea. Using an artificial erection, plication was performed and the curvature was corrected before the incision was used to place the prosthesis. In this manner, the patient receives only one incision and does not require modeling. With a median preoperative curve of 39°, all patients ended up with less than 10° curvature and none required suture removal.

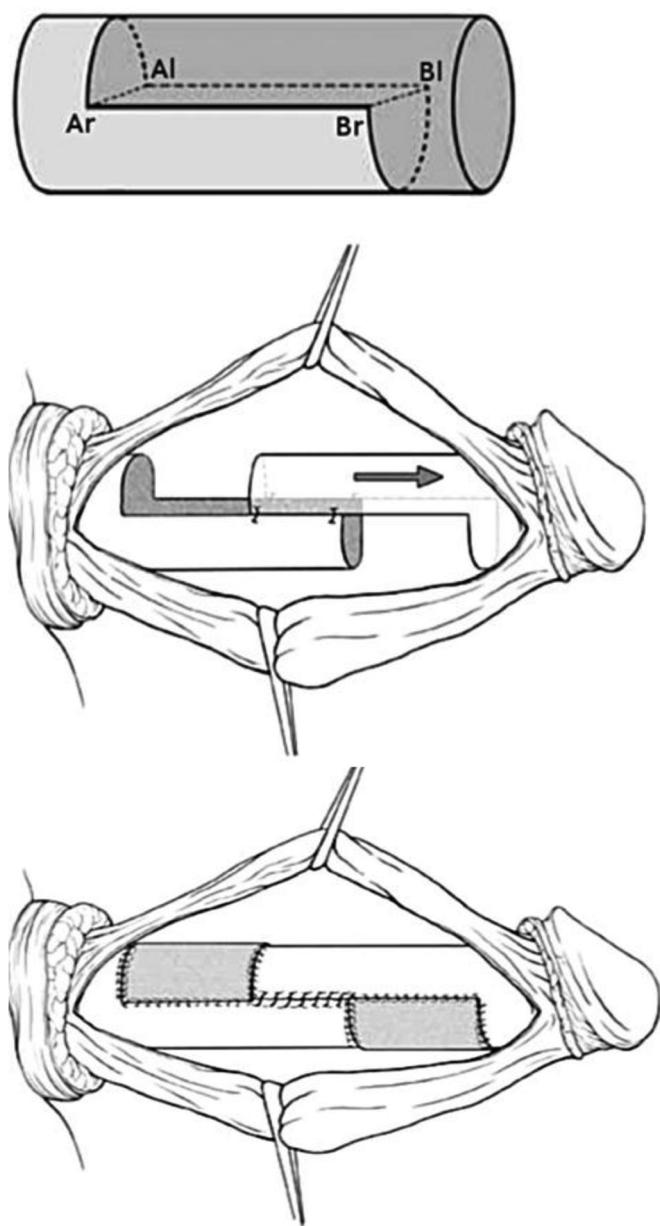
There is only one randomized study involving patients receiving an AMS 700 CX or Coloplast Titan device along with adjuvant maneuvers for penile straightening.<sup>36</sup> In this study, 138 patients with a mean curvature of 49° were randomized to receive one of the two devices, with 88 receiving the AMS device and 50 receiving the Coloplast device. Straightening was generally performed by modeling, but some patients (7%) had intracorporeal plaque incision and one patient had plaque incision and grafting. Mechanical survival was similar at 5-year estimates, with 91% survival in the AMS group and 87% in the Coloplast group. Only three devices were removed for infection, with no difference noted between the two manufacturers. Overall, there was a 79% satisfaction rate, with the most common reason for dissatisfaction being shortened penile length and no difference was noted between the two manufacturers.

### "Supersonic Transport" Deformity

The supersonic transport deformity is one in which the glans penis is not properly supported or positioned on top of the prosthesis and has a ventral "droop" resembling the nose of the Concorde jet (Figure 7). It can result from undersized cylinders at the time of prosthesis placement or from foreshortened corpora in which the bodies do not extend to the mid-glans. Mulhall and Kim<sup>150</sup> reported on a series of 10 patients who were treated through a dorsal sub-coronal incision through which the glans was partly separated from the corporal tips, the neurovascular bundle was mobilized, and then the glans was secured to the tunica albuginea by horizontal mattress sutures into a more appropriate location using a non-absorbable suture. There were no reported prosthetic injuries, no sensory deficits, and overall satisfaction in 90% of patients.

### Lateral and Medial Impending Erosions

Although commonly used, the term *impending erosion* is a misnomer. In these cases, there is erosion or severe attenuation of the tunica albuginea resulting in the tip of the prosthesis protruding under the skin (typically laterally or ventrally) or against the fossa navicularis (medially), without overt erosion of the overlying skin or mucosa. There are no established conventions, but often *erosion* describes a device that has come through the skin or mucosa, whereas *extrusion* describes one that has gone through underlying tissues but not the skin. Erosion, by definition, represents an infected system, whereas extrusion (which might become



**Figure 10.** Double dorsoventral sliding technique for length restoration. Used with permission from Rolle L, Ceruti C, Timpano M, et al. A new, innovative, lengthening surgical procedure for Peyronie's disease by penile prosthesis implantation with double dorsal-ventral patch graft: the "sliding technique". *J Sex Med* 2012;9:2389-95.

erosion) does not. Although there has been very recent controversy about how erosions (at least limited ones) can be treated, the conventional approach has been removal of all components. However, extrusions can be addressed through different techniques.

The most common repair of lateroventral extrusions was described by Mulcahy<sup>151</sup> in 1999. In this report, 14 patients (3 with bilateral extrusion) were treated through a distal, hemi-circumcision incision. The capsule over the prosthesis was

opened, and the device was retracted (if inflatable) or removed (if malleable). A transverse incision was made in the back wall of the capsule and a new plane was created and dilated to accommodate the device. In this way, the wall of the capsule is used as a buttress to give support and prevent future extrusion or erosion. In Mulcahy's series, 50% required granulopexy as described in the section on Supersonic Transport Deformity. For etiology, Mulcahy noted that four patients were found to have infection at the time of the surgery, and thus extrusion could be the result of a smoldering infection (Figure 8A–D).

Carson and Noh<sup>152</sup> reported on a larger retrospective series in which 18 men had Mulcahy's corporoplasty repair, whereas 10 were repaired with a Gore-Tex windsock. In the latter group, two had subsequent extrusion and another had infection necessitating device removal. No such complications were noted in the corporoplasty group. Carson<sup>153</sup> more recently described a variant of this approach, in which the new channel for the device was created in a more proximal location, through a penoscrotal approach. Other groups have described different augmentation materials such as tunica vaginalis flaps<sup>154</sup> and cadaveric pericardium.<sup>155</sup>

Medial extrusion has received less attention. Shaer<sup>156</sup> reported on three patients with total erosion through the urethra that was repaired by penile disassembly and grafting or primary repair. Another group reported on six patients (three with medial extrusion) who were repaired through a trans-glanular incision.<sup>157</sup> In this approach, the glans was manually repositioned and an incision was made through it, and the tip of the device was sutured into the prosthesis capsule, contralateral to the site of impending erosion using a soft, braided, non-absorbable suture. Then, the glans was closed in two layers using a long-lasting absorbable suture. There were no cases of sensory loss or urethral injury (Figure 9A–C).

### Penile Lengthening During Prosthesis Placement

One of the most common complaints in men receiving a PP is that there is subjective and objective loss of penile length owing to scarring, fibrosis, and general loss of elasticity from altered tissues qualities. Several groups have addressed this issue by developing techniques to restore some of the length that has been lost from the underlying disease process. One proposal has been to use physical therapy, in the form of a vacuum or traction device, before implantation to stretch the tissue as much as possible to implant a larger device. In one study of 10 men with medication-refractory ED and complaints of penile shortening after radical prostatectomy, priapism, or explantation, a protocol of external penile traction 2 to 4 hours daily for up to 4 months was used before IPP placement. In all these men, the stretched penile length before implantation was increased by at least 0.75 cm, and the median erect length after implantation was 0.9 cm longer than stretched length at original presentation.<sup>136</sup> This strategy also has been used in patients who already have an IPP to increase the size of the phallus during revision surgery. This

was reported as a case report<sup>158</sup>; the patient used a vacuum device twice a day for 10 minutes for a year and penile traction 8 hours a day for 8 months. With this extreme protocol, at the time of revision surgery, he gained 3 cm in device length and 4.4 cm in erect length.

Other groups have attempted to find new surgical techniques to lengthen the phallus at the time of implantation. A small series of three patients underwent a novel technique in which longitudinal incisions were made on either side of the tunica albuginea after the dorsal neurovascular bundle and the urethra were elevated.<sup>159</sup> These incisions were joined in an asymmetric fashion, in which the proximal side was incised dorsally and the distal side was incised ventrally. It is known as the *double dorsoventral sliding technique* (Figure 10). This setup allows the phallus to be distracted; the limiting feature is the length of the neurovascular bundle. In this case series, the patients gained 2.5 to 4 cm in length. A larger multicenter study of 20 patients with PD used the geometric principle popularized by Sansalone et al<sup>55</sup> to form a trapezoidal defect centered on the point of maximal curvature. In this group, the average length increase was 2.8 cm. However, a worrisome finding was a 20% rate of decreased glans sensitivity. Recently, Egydio and Kuetlas<sup>56</sup> described the sliding technique without grafting in 143 men (133 received a malleable device) in whom the mean length gain was 3.1 cm.

### Prosthesis Placement After Female-to-Male Transsexual Phalloplasty

Different techniques have been used to create a neophallus, most commonly in the context of female-to-male transsexual surgery. In these techniques, the free flap based on the radial artery remains the most popular. To achieve erection, a prosthesis can be placed once there is return of protective sensation, which appears to occur 9 to 12 months after neophallus construction. Of course, the anatomy of a neophallus is completely different from that of a native phallus, because it has no tunica albuginea, corpora cavernosa, or crus. Levine et al<sup>160</sup> reported on a series of four patients undergoing placement of a PP into a neophallus. They noted that inflatable devices were safest, because they allow for erection without constant pressure against the flap, and that two cylinders placed the urethra and vascular supply within the neophallus at risk. Therefore, they recommended using a modified inflatable two-piece Ambicor prosthesis with a single large-caliber cylinder. The largest contemporary series is a retrospective examination of 129 female-to-male patients treated over a 9-year period.<sup>161</sup> On average, there was a 2-year gap from the original phalloplasty to prosthesis placement. In keeping with the recommendations from the series of Levine et al, they placed one or two cylinders (depending on phallic girth) with fixation of a rear-tip extender to the pubic bone. Different devices were used, depending on the era in which the surgery was performed. Over time, they stopped offering two-cylinder surgery because of asymmetry between the two sides. Of the entire group, 41 required

replacement, 9 required a second revision, 5 required a third revision, and 1 required a forth incision. Rates were 12% for infection, 8% for erosion, 9% for prosthesis leak, and 15% for malposition. The study was neither powered nor structured to allow comparison between different devices.

### CONCLUSION

PP implantation remains one of the most appreciated and successful approaches to restore sexual function in virtually all situations and special populations.<sup>162</sup> Consideration for PP should be offered at initial consultation to the man with ED, although consideration for other less invasive treatments should be considered first. The previously held notion that a PP should be offered as a last resort should be reconsidered because it might be the best resort depending on the nature of the ED and the patient's goals. Clearly, for the highly motivated man who would like to restore sexual function but is not responding to or cannot tolerate oral or intraurethral medications, intracavernosal injection, or the vacuum constriction device, a PP is likely the best option. Informed consent for placement of a prosthesis is critical so that the patient understands the risks of mechanical failure, infection, pain, change in penile configuration including shortening and in sensation, and potential injury to local structures including the urethra, bladder, bowel, and vascular structures. The patient should understand that the PP is not designed to increase the length or size of the penis. Certainly, improvements in design and antibiotic and hydrophilic coating have improved mechanical reliability and decreased the infection rate with current devices. In addition, improved surgical technique for placement and addressing intraoperative and postoperative complications have yielded more successful postoperative outcomes even in the most difficult anatomic situations. There is a need to establish a standardized approach for pre- and postoperative systemic antibiotic coverage and local antiseptic measures during surgery. This will need to come from multicenter studies that have yet to be initiated. With all these advances, reported patient satisfaction rates for IPPs are high, providing an opportunity for the man with advanced ED to experience an erect penis without altering urination, sexual sensation, ejaculation, and orgasm.

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