Penile Prosthesis Surgery: A Review of Prosthetic Devices and Associated Complications

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ABSTRACT

Introduction. Although more invasive than some of the other currently available therapies, penile prosthesis surgery has the advantages of high patient satisfaction rates and avoidance of systemic adverse events in the vast majority of cases.

Aim. This article provides a review of the more widely used implants and some of the more frequently encountered complications of penile prosthesis surgery.

Methods. A retrospective review peer reviewed publications relevant to the field of penile prosthesis surgery.

Main Outcome Measures. Review of historical milestones and newer penile prostheses, as well as a review of prosthesis surgery complications.

Results. Improved designs and materials have resulted in decreased incidence of mechanical failures or infectious complications while simultaneously simplifying the operation of these devices.

Conclusions. Penile prosthesis surgery remains an excellent alternative for restoring erectile function to those in whom medical therapies such as phosphodiesterase inhibitors are contraindicated or who have failed more conservative measures. **Sadeghi-Nejad H. Penile prosthesis surgery: A review of prosthetic devices and associated complications. J Sex Med 2007;4:296–309.**

Key Words. Penile Prosthesis; Review; Complications

Introduction

Perhaps the most important milestone in penile prosthesis surgery is Scott et al.'s description in 1973 of intracavernosal, inflatable silicone cylinders [1]. Implantation of the inflatable device required more extensive surgery and entailed higher chances of mechanical failure, but the end result approximated the natural physiologic state better than all other available modalities [2]. At the same time that the Scott inflatable prosthesis was being developed, Dr. M.P. Small and his group developed the Small-Carrion device and published the results on the implantation of this prosthesis in 31 patients 2 years later. The authors described a much easier surgical implantation technique for the sponge-filled silicone prostheses through a perineal incision. Favorable results were obtained in 28 and were followed shortly by a more extensive report on 160 cases [3,4]. Independent reports by Finney [5] and Subrini and Couvelaire [6] addressed the "permanent erectile state" by proposing the concept of a "hinged" device with soft silicone in the middle of the implant.

The "Omniphase" prosthesis, first reported by Dr. Robert Krane in 1986, and its successor, the "Duraphase", combined the desirable properties of easy concealment, rigidity for intercourse, and a straightforward surgical technique. Unfortunately, they were phased out due to frequent cable failure and need for replacement [7,8].

The improved American Medical Systems (AMS) design in 1983 included a woven fabric layer between two silicone layers to alleviate the aneurysmal dilation problems of the previous silicone prostheses. This three-layer design limited

the ability for girth expansion, a problem that was addressed in 1987 by substituting polypropylene for the woven fabric in the new CX (controlled expansion) prosthesis.

Unitary hydraulic implants were ingenious in their design concept and combined the cosmetic advantages of inflatable multicomponent devices with the implantation ease of semirigid implants. These units have a nondistensible inner chamber that becomes rigid when filled with fluid. Unacceptably high rates of mechanical malfunction in both the Surgitek (Flexi-flate) and AMS (Hydroflex/Dynaflex) devices resulted in discontinuation of these prostheses [9].

"Bioflex" is a polyurethane material that has the advantage of resisting aneurysmal dilatation. First introduced in 1983, the Bioflex material used in the Coloplast (formerly Mentor) inflatable prostheses offered significantly higher durability than the existing silicone cylinders. Although the early models developed a high number of mechanical failures in the silicone tubing, additional reinforcement and modification in 1992 resulted in a 93% 5-year survival from revision for mechanical reasons in the enhanced Alpha-1 prosthesis [10,11].

Biofilm is an organized bacterial colony that grows on the surface of the implanted material and is typically resistant to systemic antibiotic therapy, because the bacterial metabolic rate is lowered due to low-oxygen tension conditions [12]. Newer strategies for lowering infections in the prosthesis recipient have therefore focused on altering the surface properties of the implant to affect the biofilm. Based on earlier work showing efficacy of antibiotic coating of central venous and bladder catheters, the Inhibizone™ antibiotic-coated device (AMS, Minnetonka, MN) was introduced in 2001 (Figure 1). The current AMS prostheses (not the rear-tip extenders) are coated with minocycline and rifampin to counter intraoperative device contamination; the antibiotics elute in the surrounding tissue space within 7 to 10 days [13]. Evaluation of the manufacturer's data bank on primary implants revealed that, after 180 days, the infection rate was 0.68% in the coated group vs. 1.61% in the uncoated prostheses [14].

Similarly, Coloplast A/S (Humlebaek, Denmark) has taken steps to reduce bacterial adherence. Both the inflatable Titan prosthesis (introduced to the American market in September 2002) and the malleable Genesis implant are coated with a hydrophilic layer that significantly enhances antibiotic coating of the device surface following immersion in an antibiotic solution. The prostheses

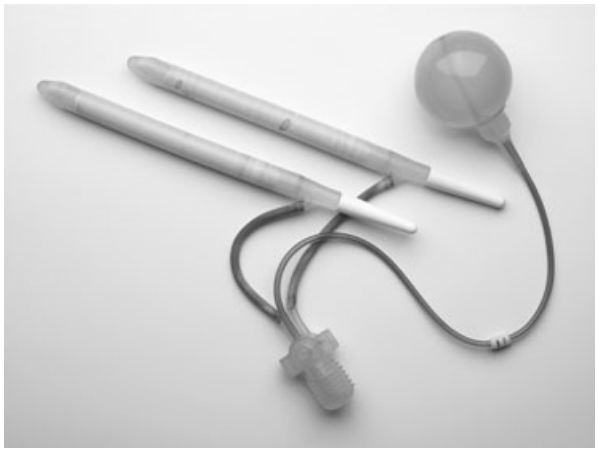

Figure 1 AMS 700 MS™ series cylinder with Inhibizone® antibiotic surface treatment. AMS = American Medical Systems.

are coated with polyvinylpyrrolidone (PVP), a hydrophilic substance that reduces bacterial adherence and absorbs and elutes the antibiotics which the device is immersed in intraoperatively. The operating surgeon has the ability to choose appropriate antibiotics for device immersion. Comparison of infection rates between the noncoated Alpha-1 inflatable penile prosthesis (IPP) and the coated Titan device demonstrated that the infection rate for the coated Titan IPP was 1.06% (25/2,357), as compared with 2.07% (10/482) for the noncoated device [15].

The latest development in device design involves improvements in pump design to facilitate inflatable prosthesis deflation [16]. The enhanced AMS 700 pump includes a deflation button that requires approximately 4 seconds of pressure application before the cylinder fluid will be drained back into the reservoir (Figure 2). The addition of "MS" (momentary squeeze) to the

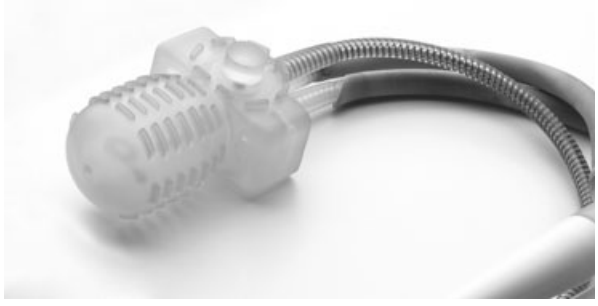

Figure 2 AMS 700 MS™ series enhanced pump with Inhibizone® antibiotic surface treatment. AMS = American Medical Systems.

Table 1 Important historical milestones in penile prosthesis surgery

1936	Prostheses using rib cartilage and bone
1960	Acrylic implants
1964	Silicone rubber suggested as implant material
1966	Intracavernosal polyethylene implants; midline dorsal penile approach
1973	Small Carrion: paired sponge-filled silicone implant; perineal approach
1973	Scott, Tim, and Bradley: inflatable intracavernosal prosthesis
1974	"Hinged device" with silicone in middle developed to overcome
1978	"Permanent erectile state" problem
1986	Omniphase; later followed by Duraphase
1983	AMS woven fabric design to avoid silicone aneurysm; limited expansion
1987	Polypropylene later replaced fabric in CX implant
1983	Mentor introduces the Bioflex (instead of silicone) inflatable device
1985	Unitary inflatable implants: AMS Hydroflex/Dynaflex and Surgitek Flexi-flate
1992	"Enhanced" Mentor inflatable prostheses addressed the silicone tubing problems of earlier models
2000	Mentor reservoir "lock-out valve" introduced to minimize autoinflation
2001	AMS Inhibizone® antibiotic-coated implants introduced to lower infections
2002	Mentor PVP-coated hydrophilic implants introduced to lower infections
2006	AMS enhanced pump & momentary squeeze; cylinder deflation 4-second press
2007	Coloplast Titan OTR pump scheduled for release

AMS = American Medical Systems; PVP = polyvinylpyrrolidone.

AMS nomenclature indicates the newly enhanced pump that is currently available in select models.

Future considerations include Coloplast's Titan® OTR, a one-touch release pump that is designed with accentuated deflation points and is scheduled for release in 2007. Clinical information about this product is not available at the time of this writing.

Table 1 is a summary of some of the important milestones in penile prosthesis surgery.

Semirigid/Rod Prostheses

These prostheses are constructed of two solid prostheses that are independently placed in each corpus cavernosum. They are ideal for patients in whom the cosmetic advantages of the inflatable devices are not as important as the ease of use and the lower chances of mechanical failure in semirigid implants. Pelvic organ transplant recipients may be well served by the semirigid devices (or a two-piece rather than a three-piece inflatable device). Cuellar and Sklar have stated that, as a general rule, three-piece prostheses should be avoided in this group because of a significantly higher incidence or reservoir complications in the retroperitoneal space [17].

The semirigid devices are typically made of pure silicone rubber (i.e., the Coloplast [formerly Mentor] and the AMS devices), which may be wrapped around a central coiled wire or have a core construction of articulating segments with metallic cables running through them (i.e., the Dura II device). The polytetrafluoroethylene-coated rings are interlocked and connected by a spring-loaded cable, which can lock the rings in a straight column when activated and unlock for a "relaxed" flaccid state.

The Dura II is a third-generation derivative of the Omniphase prosthesis discussed in the historical review that is currently marketed by the AMS Corporation. The Dura II is particularly well suited to those with poor manual dexterity because of its superb flexibility and ease of operation. Conversely, it is a relatively poor choice for those with a large-diameter penis or a very short penis, because the smallest device is 15 cm long [8].

The Genesis™ semirigid prosthesis is manufactured by Coloplast A/S (Figure 3). This is a PVP-coated prosthesis that has an outer helical wire surrounding a silver-wire core in the distal end. These implants are available in three diameters (9, 11, and 13 mm) with standard, 0.5-cm, and 1.0-cm tail caps, and may be trimmed using a standard #10 scalpel blade to various sizes (the caps are fitted onto the trimmed ends).

The AMS 600 was introduced in 1983 and had a twisted stainless steel wire surrounded by solid silicone. Despite excellent durability, the device had significant spring back and was redesigned as

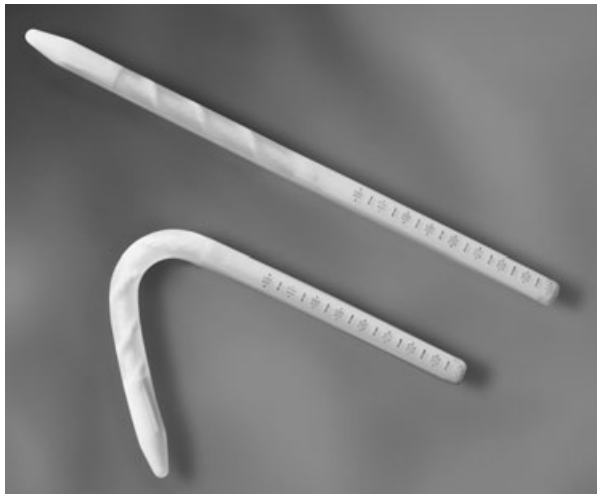

Figure 3 Coloplast genesis prosthesis.

the AMS 650. The improved prosthesis features finer strands in a spiral configuration in a polyester covering and is further encased in a solid silicone body [8]. This prosthesis has been marketed since 1996, and is available in 13- or 11-mm girths and 12-, 16-, or 20-cm lengths that are further adjustable with rear-tip extenders.

Semirigid prostheses may be placed through an infrapubic or penoscrotal incision as described below, with the caveat that the corporotomy incisions are slightly larger than those used for the inflatable cylinders. Excessive bending of the device during placement through a small corporotomy may damage the cylinders and cause poor rigidity [18]. Alternatively, the semirigid devices may be placed through a limited subcoronal incision [19]. Corporal and urethral complications encountered intraoperatively are similar to those described in more detail in the *Inflatable Prosthesis* section below. Other reported complications include infection, prolonged pain, mechanical failure, and erosion. The latter complication is more frequently encountered in the spinal cord injury patients compared with the general population (11% vs. 1%) [20].

Erosion of a malleable penile prosthesis into bladder has been reported in a patient with spinal cord injury and recurrent urinary tract infections [21].

Figure 4 AMS Ambicor® penile prosthesis. AMS = American Medical Systems.

Inflatable Prostheses

Unitary Self-Contained Cylinders

The Hydroflex prosthesis was introduced in 1985 (AMS) and later succeeded by the Dynaflex. These prostheses combined the easy implantability of the rod prostheses with the cosmetic advantages of inflatable devices [22,23]. Despite the elegant simplicity of design, inferior mechanical reliability and patient satisfaction, compared with the multicomponent devices, resulted in a gradual phasing out of the unitary devices. Wilson and Delk have stated that the combination of semirigidity and "ability to partially inflate acted as a tissue expander by compressing corporal tissue" [24]. Over time, this resulted in an inadequate size for a complete rigid erection.

Two- and Three-Piece Multicomponent Prostheses

In the United States, the multicomponent inflatable devices are made by the AMS and Coloplast corporations. Currently marketed devices in this category by the AMS are the AMS 700 series that include the CX ("controlled expansion"), CXR (smaller components than the CX; useful for implantation in fibrotic corpora), LGX (length and girth expansion), the AMS 700 Ultrex, and the Ambicor, which is a two-piece device with a combination scrotal pump/reservoir.

The Ambicor is currently the only marketed two-piece inflatable prosthesis in the United States. Although its small scrotal pump is unable to produce girth expansion, activating the pump transfers fluid from the proximal to the distal portion of the cylinders to obtain adequate rigidity (Figure 4). A two-center study of the mechanical reliability, safety, and patient satisfaction with the two-piece Ambicor penile prosthesis (AMS) from 1995 through 1999 evaluated 131 men who underwent implantation of this prosthesis at two medical centers, and revealed a 2.3% incidence of mechanical failure and high patient/partner satisfaction rates [25].

The AMS and Coloplast (formerly Mentor) three-piece prostheses share a similar general structural design: an intra-abdominal fluid reservoir to be placed in the perivesical space, a pair of cylinders for intracavernosal implantation, a scrotal pump for fluid transfer between the reservoir and the cylinders, and silicone tubing for connecting these components.

The Ultrex was introduced in 1990 and was designed to provide combined girth and length expansion [26]. LGX is the newest version of this

prosthesis. There was a higher incidence of cylinder failure with the Ultrex as compared with the same company's CX device, and the 5-year survival from mechanical revision was reported to be as low as 66% [27]. However, a recent report indicates that cylinder modification in 1993 appeared to have significantly decreased the propensity of cylinder failure of the premodification device [28]. Additional problems reported included buckling and accelerated wear of the Ultrex cylinders, due to limitations of length expansion after the natural process of capsule formation around the cylinders [24]. Montorsi et al. corroborated these findings and reported that, in the long-term evaluation of cylinders, the CX appears to be more mechanically reliable than the Ultrex [29]. The use of the AMS Ultrex is not recommended for penile straightening in scarred corporal bodies, because the development of adequate axial rigidity is restricted by the "lengthening" property of the cylinders [13]. A 10-year outcome review of patients receiving penile prostheses for Peyronie's disease revealed mechanical malfunction in 8 of 20 (40%) patients who received an Ultrex implant, as compared with 1 of 42 (2.3%) who received a CX 700 [30].

In 1990, the AMS Corporation introduced the AMS 700CXM with medium-controlled expansion cylinders, to provide an inflatable prosthesis with controlled expansion in girth and fitness for Asian men [31]. The newest version of this device, the CXR, is available with an antibiotic coating (Inhibizone) and the enhanced MS pump.

Coloplast inflatable products include the Titan and the "narrow-base" version of the same prosthesis. The latter is particularly well suited for difficult repeat implantations or postradiation surgery in fibrotic corpora. Both of the Coloplast three-piece prostheses are now hydrophilic coated and include the "lock-out valve" enhancement of the reservoir to inhibit undesired spontaneous autoinflation [32]. This feature is also helpful in preventing autoinflation when ectopic reservoir placement is considered (Figure 5).

Figure 5 Hydrophilic-coated Coloplast Titan™ three-piece prosthesis with reservoir lock-out valve to minimize autoinflation.

Indications

Penile prostheses are indicated for the treatment of organic erectile dysfunction (ED) due to a variety of causes. Most surgeons recommend a trial of less invasive modalities, including oral pharmacotherapy or intracavernosal injection, before moving onto prosthesis surgery. Even patients with severe penile curvature, shortening, and impaired penile rigidity due to fibrosis of the corpora cavernosa are candidates for three-piece inflatable penile implant surgery [33].

Pelvic organ transplant recipients with ED may be candidates for penile prosthesis surgery [34]. Cuellar and Sklar have reported that the complication rates are significantly higher in the transplant patients (22%) as compared with non-transplant patients (7.9%) receiving prostheses [17]. The difference is attributed mainly to higher reservoir complications in the transplant cohort, and it has been suggested that this group may therefore be better served with prostheses without a retroperitoneal reservoir [17].

Resolution of urinary management problems and successful treatment of ED has been reported in 90.3% and 82.6% of neurologically impaired patients with urinary drainage problems or ED, respectively [35]. Perforation rates are significantly higher for the semirigid, as compared with the self-contained inflatable, prostheses.

In prostate cancer therapy-related ED, penile prosthesis surgery has been reported as safe and efficacious after external beam radiation or radical retropubic prostatectomy [36]. Immediate sexual rehabilitation by simultaneous placement of a penile prosthesis in patients undergoing radical prostatectomy was described in 1997, with no apparent increase in morbidity [37]. However, the practice has not found widespread application, because many will regain spontaneous erections following nerve-sparing prostatectomy, and others will respond favorably to oral therapies such as phosphodiesterase type 5 inhibitors.

Compared with the general implant population, patient satisfaction rates may be somewhat lower in patients with Peyronie's disease undergoing

penile prosthesis surgery [38]. Penile modeling over an inflatable implant was originally proposed by Scott, but the available devices at the time lacked sufficient rigidity for the procedure. The concept was reintroduced by Wilson in 1994 and has since been accepted as an effective therapeutic option for the patient with simultaneous Peyronie's disease and ED [24,39–41]. The combination of prosthesis implantation and modeling can provide permanent straightening without an increase in revisions. Long-term follow-up of treatment for Peyronie's disease with penile modeling revealed that the Coloplast (formerly Mentor) Alpha-1 appeared less likely to fail mechanically than the AMS 700CX when followed more than 5 years. It has been suggested that modeling may predispose the AMS 700CX to earlier mechanical failure [39].

Levine and Dimitriou developed an algorithm for surgical management and placement of penile prostheses in patients with Peyronie's disease. The authors attempted manual modeling initially, followed by tunica incision for insufficient straightening. For tunical defects greater than 2 cm, polytetrafluoroethylene patch grafting was performed to prevent prosthesis cylinder herniation and recurrent deformity from cicatrix contraction. Full erectile capacity with a straight phallus was achieved in all patients [42].

Complications

A summary listing of some of the more common and important complications in penile prosthesis surgery is presented in Table 2. Moncada et al. have recently reviewed the different imaging techniques used for the diagnosis of complications of prosthetic surgery of the penis, including conventional radiology, use of sonography, the role of computerized tomography scan, and the magnetic resonance imaging (MRI) of the penile prosthesis. The authors found MRI to be the most valuable method for the diagnosis of penile prosthesis complications; among the cited advantages were avoidance of ionizing radiation and the ability to demonstrate penile anatomy in three orthogonal planes [54].

Mechanical Malfunction

Wilson et al. reported the results of a prospective study of 1,381 Coloplast (formerly Mentor) Alpha-1 penile prostheses implanted to treat impotence, and compared the mechanical reliability of the original and enhanced penile prosthesis. The 5-year survival rate increased from 75.3% for the original to 92.6% for the enhanced model. The failure rate of the enhanced model implants was about 0.8% per year during the first 3.5 years, and increased to approximately 3.1% per year thereafter [11]. In another publication, the same group reported that, in Peyronie's disease cases in whom modeling was used to straighten the penis after implantation, mechanical survival of the Coloplast (formerly Mentor) Alpha-1 was superior to that of the AMS 700CX, and concluded that modeling may predispose the AMS 700CX to earlier mechanical failure [39].

A long-term multicenter study of the AMS 700CX three-piece IPP reported mean device mechanical reliability plus or minus standard

Table 2 Summary of complications of penile prosthesis surgery

Complication	Incidence	Comment
Mechanical malfunction AMS	10.3%	Long-term data, AMS CX/CXM (91.5-month median follow-up) [43]
Mechanical malfunction Coloplast (former Mentor)	0.8–3.1%	5-year survival data; 0.8% first 3.5 years, then 3.1% yearly thereafter [11]
Corporal crossover	Common intraoperative finding	Avoid inadvertent inflatable device perforation by not placing cylinders until needles are through glans on each side
Corporal perforation/erosion	1–11% (distal)	Proximal perforation less common [44,45] More common in redo/fibrotic cases [46]
Urethral perforation	Rare	More common in fibrotic redo cases
Infection	0.68–1.06%	Inhibizone or hydrophilic coated devices; 6 months and 1 year, respectively [15,47]
Glans bowing (SST)	Up to 10%*	*Based on one group's experience [48]
Reservoir herniation	0.7%	Limited to the penoscrotal approach [49]
Deep venous thrombosis	Extremely rare	Reservoir compression of pelvic vessels due to lateral displacement [50]
Reservoir erosion into adjacent viscera	Extremely rare	Previous major abdominal pelvic operation predisposing factor [51–53]

AMS = American Medical Systems; SST = supersonic transport.

deviation was 92.1 ± 3.3% after 3 years and 86.2 ± 4.6% after 5 years. Postoperative infection and device malfunction developed in 3.2% and 17.5% of the cases, respectively. Of the 207 men interviewed by a neutral observer, 86% still had an AMS 700CX penile prosthesis implanted, including 87.1% with erection suitable for coitus [47]. More recently, an even longer follow-up study of the long-term mechanical reliability of the AMS 700CX trade mark/CXM inflatable penile prosthesis (IPP) was reported in 455 patients, with a median follow-up of 91.5 months. The authors reported 10-year Kaplan-Meier estimates of overall and mechanical survival at 74.9% and 81.3%, respectively [43].

In 1998, Dubocq et al. compared five different types of devices, and reviewed mechanical complication rates in 83 patients with two-piece and 283 patients with three-piece inflatable penile prostheses for a mean time of 66 months. All device-related complications were secondary to fluid leakage. All three-piece prostheses appeared to be more mechanically reliable than the two-piece implants, and the Coloplast (formerly Mentor) Alpha-1 device had a higher cumulative proportional survival (0.957) than all other evaluated devices [55].

Goldstein et al. conducted a multi-institutional retrospective study to assess safety and efficacy outcome pertaining to the Coloplast (formerly Mentor) Alpha-1. With a mean follow-up of 22.2 months, there were no morbidities of any type in approximately 90% of implant recipients. Fluid leak and autoinflation was reported in 2.5%. No cylinder aneurysms were reported, and only 2.5% required revision surgery for approximately 2 years from the original implant date. Cumulative survival of the prosthesis at 36 months was 85 ± 7% until device malfunction and 75 ± 7% until surgical intervention (revision or explantation) [56]. The newer Coloplast inflatable prostheses (i.e., Titan) feature the reservoir lock-out valve, a device improvement that limits autoinflation and may be helpful when ectopic reservoir placement is required (Figure 5).

Corporal Crossover

Both distal and proximal corporal crossover may be encountered during corporal dilation or cylinder placement, although the latter is more unusual. Neither occurrence is catastrophic and may be easily recognized and corrected during the procedure. If a crossover has occurred during inflatable prosthesis surgery, one of the cylinders may be punctured during placement of the contralateral cylinder when the Keith needle is placed. Inadvertent perforation is avoided by not pulling the cylinders into their final position distally until after *both* Keith needles, one from each corpus cavernosum, have passed through the glans. The initial correct lateral angulation of the Mezenbaum scissors during distal tunneling and gradual corporal dilation using laterally directed Brooks dilators will help avoid crossover. The best means of testing either proximal or distal crossover is side-by-side placement of the Brooks dilators in each corpus to check for symmetry and proper positioning. If a crossover is detected, the dilator may simply be redirected with the contralateral dilator left in place to prevent repeat crossover.

Corporal and Urethral Perforation

This complication may be encountered both distally and proximally and is more likely to occur during dilation of fibrotic corpora. Careful use of specialized Rossello or Mooreville cavernotomes will prevent uncontrolled tearing of the fibrotic corpus and avoid the need for extensive corporal excision. It should be noted that these instruments have sharp edges that could cause significant injury if used by inexperienced implanters [6,44,46]. A proximal crural perforation is suspected when there is asymmetry of proximally positioned dilators (i.e., when placed side by side) or a significant length differential.

A variety of techniques have been described for addressing this problem intraoperatively, and include direct repair of the perforation, placement of a windsock patch of Gore-Tex or Dacron on the proximal end of the cylinder, anchoring of cylinder tubing to the tunica, and placement of an absorbable polyglycolic acid patch in the defect (the "plug and patch" technique) [44,45,57]. Continued dissection to the level of the rear-tip extenders and anchoring the extender to the tunica is safe and widely adopted. This technique is employed after rerouting the proximal dilation in the affected corpus toward the proper crural tip against the tuberosity. Attachment of the rear tip to the tunica will prevent cylinder migration back into the perforation until healing is complete [58].

Carson and Noh reviewed 28 patients with distal corporeal extrusion to identify the optimum treatment outcome for this complication. Specifically, distal corporoplasty was compared with repair using a Gortex windsock. Distal corporoplasty was reported to have superior outcome measures, as compared with a windsock repair, with regard to pain, recurrence, and function [59].

Management of distal corporal perforation and urethral perforation is more likely to involve termination of the procedure and return at a later date, particularly if distal perforation occurs during dilation of the first side. If corporal dilation has been successfully accomplished on one side and it is the second side that is perforated, a single cylinder may be placed on the nonperforated side. The tubing from the other cylinder is removed and plugged with a standard metallic plug provided by the manufacturers. A single functioning cylinder may provide adequate rigidity for penetration, and the patient may elect not to undergo a second procedure for contralateral cylinder placement. Similarly, if urethral perforation occurs after one side has been successfully dilated, the cylinder from the perforated side is removed and the tubing is plugged. The urethral tear may be directly repaired or, if small, allowed to heal over a urethral catheter. Alternatively, a perineal urethrostomy or a suprapubic cystostomy may be performed for urinary diversion. Because of the potential for device infection, many surgeons will recommend abandoning the case if there is any indication of urethral injury. However, this decision must be balanced against the difficulty of repeat surgery in fibrotic corpora at a later date, especially in view of findings that associate increased operative time with a higher incidence of infections [60]. Satisfaction domain scores of patients with corporal fibrosis undergoing revision prosthesis surgery are reported to be lower than other revision implant groups [61].

The use of downsized IPP cylinders as tissue expanders in patients with corporal fibrosis is effective in patients in whom fibrotic corpora preclude adequate dilation (i.e., 12 mm) for placement of a standard cylinder. Initial placement of a "downsized" or narrow prosthesis such as the Coloplast Narrow Base Titan or AMS CXR, followed by prolonged inflation over an 8- to 12-month period, will allow the implant to act as a tissue expander for future implantation of wider, and possibly longer, prostheses [62].

Infection

Infection is a devastating and dreaded complication of penile prosthesis surgery that occurs in approximately 2–3% of first-time implants in most of the older series, but the reported range is widely variable. Most infections appear within the first 3 months after surgery and the vast majority will manifest within the first year after implantation, although delayed infections beyond 1 year have been reported [63,64]. Antibacterial coating of prostheses has been shown to reduce infection rates [65]. Reports of the newer antibiotic-coated or hydrophilic-coated implant infection rates indicate favorable results, with rates as low as 0.68% after 6 months and 1.06% after 1 year for the Inhibizone and hydrophilic-coated prostheses, respectively [14,15].

Inadequate perioperative prophylaxis and lax sterile protocol, prolonged hospitalization, prolonged operative time, and repeat implantations are some of the important predisposing factors. Carson reports that the combination of any other procedure (i.e., hernia repair, circumcision) with penile prosthesis surgery is associated with a significant increase in infections in his series [66]. A multi-institutional outcome study of closed-suction drainage of the scrotum for approximately 12–24 hours following three-piece IPP surgery revealed that this practice does not result in an increased infection rate and is associated with a very low incidence of postoperative hematoma formation, swelling, and ecchymosis [67].

Adherence to strict infection control protocol including antibiotic prophylaxis, intraoperative shaving, careful coverage of ostomy sites with an ioband-adhesive layer, minimization of operating room traffic during the procedure, 10-minute antibacterial scrubbing of the operative site with iodophore prior to the iodophore paint skin preparation, double gloving of all involved personnel, and an antibacterial shower the night or morning before surgery are helpful in preventing implant infections. Detection of urinary tract infection or any other infection at the time of surgery is cause for rescheduling the procedure. Antibiotic prophylaxis should be administered 1–2 hours prior to surgery. Agents effective against the most common organisms, *staphylococcus epidermidis* and *escherichia coli*, must be chosen and may include an aminoglycoside and vancomycin or a first-generation cephalosporin. Fluoroquinolones have also been shown to be equally effective against these organisms and may be administered orally [68].

Montague et al. evaluated infection rates and risk factors in penile prosthesis recipients. The study population for this retrospective study included 491 three-piece IPP recipients, with follow-up ranging from 1 to 168 months (mean 83). The authors reported seven infections (2.5%) in 285 primary prosthesis recipients. Interestingly, and in contrast to a number of other reports, the incidence of infections in secondary prosthesis recipients was actually lower: there were three

infections in 206 patients in this group (1.5%). The authors also did not find a statistically significant difference in infection rates between nondiabetics (2.0%) and diabetics (2.2%). Of the 10 reported infections, eight occurred 8 weeks or less following implantation [69].

The severity of infections may range from simple superficial infections that can be managed by conservative measures and wound care, to the extreme of penile gangrene which may be life threatening. The latter complication is fortunately rare and may be due to gram-negative organisms with or without anaerobic superinfection. It may be initiated by factors including local infection, pressure dressing, presence of a urethral catheter, edema, and ischemia of the corpus cavernosum, and appears to be more common in insulin-dependent diabetics [70–73].

Most infections are caused by gram-positive organisms that colonize normal skin, but 20% have been attributed to gram-negative bacteria in some reports [64]. The latter are typically early infections that manifest within the first 30 days after surgery. The causes of infection are controversial, but there is universal agreement that weakened host defense mechanisms and the presence of a synchronous infection at another site in the body will increase the risk. Late infections may be due to hematogenous spread or reemergence of bacteria previously embedded in the biofilm [66].

Jarow reported an infection rate of 1.8% in men without previous penile surgery, compared with 21.7% for procedures requiring reconstruction of the corpora. The infection rate after revision of a penile prosthesis was 13.3%, which was significantly greater than that following primary uncomplicated implantation, but not different from that for patients requiring reconstruction. This and other studies have not provided an explanation for the increased incidence of infection in patients undergoing revision who have an operative time similar to first-time implants [60].

Lynch et al. reported a higher incidence of infection in those receiving an inflatable device, and also reported a 22% incidence of infection in diabetic patients compared with 6.7% in nondiabetics [74]. Neither of these findings have been corroborated by other investigators [64,75,76]. Although Bishop reported on the direct relation between the degree of metabolic control in diabetics as measured by glycosylated hemoglobin and the risk of prosthesis infection, others have found no meaningful difference in the median or mean level of glycosylated hemoglobin A1C in the infected and noninfected patients regardless of diabetes [77,78]. Additionally, there was no correlation between elevation of fasting sugar or insulin dependence and an increased risk of infection in diabetics undergoing prosthesis implantation.

An interesting study by Licht et al. evaluated the presence of bacteria on implants undergoing mechanical revision and isolated low colony counts of *staphylococcus epidermidis* in 40% of uninfected penile prostheses [79]. The authors concluded that low colony counts of this organism are unlikely to cause an overt clinical infection, and that the role of *staphylococcus epidermidis* in infections is likely to be overestimated. This reasoning is further supported by documentation of ample vancomycin, gentamycin, and aztreonam levels in the corporal tissue of patients receiving antibiotic prophylaxis 1–2 hours prior to device implantation.

Henry et al. investigated washing out the implant space during revision surgery for noninfectious reasons and using an antibiotic-coated replacement prosthesis to determine whether it would decrease subsequent infection rates. Among the study subjects, 140 had the entire implant removed and subsequently underwent a revision washout. The latter was described as a modification of the original Mulcahy salvage procedure and was followed by replacement with a three-piece IPP. Forty-three patients underwent prosthesis explantation without antiseptic irrigation prior to replacement with an antibiotic-coated device. The authors found statistically significant differences between the two groups: with a 6- to 33-month follow-up, 4 of the 140 patients (2.86%) who underwent removal of the entire implant with irrigation of the implant spaces with antiseptic solutions developed an infection. In contrast, 5 of the 43 patients (11.6%) who did not undergo antiseptic irrigation developed an infection [80]. Based on the results of this study, revision washout is recommended as a noninvasive maneuver that will only marginally increase the operative time, but result in decreased infection rates.

Preventive measures are critical in the management of prosthesis infections and have been addressed in the section on perioperative care. The patient is instructed to report any signs or symptoms of infection which may include a purulent exudate, a pattern of increasing pain instead of gradual improvement, worsening erythema and induration, or high-grade fever. Pain is not unusual for as long as 4–6 weeks after surgery.

However, the normal course involves a gradual improvement rather than deterioration. Increasing pain, especially in the presence of chills, fever, or leukocytosis, is an indication of possible infection. Other clinical signs include erosion of device components and fluctuance in the scrotum or along the penile shaft. Most authorities recommend removal of the entire device in severely infected cases with overt purulence.

Some authors have advocated an early "salvage and rescue" procedure for mild to moderate infections [81,82]. This technique has gained increasing popularity among urologists for infections diagnosed in the earlier stages. Successful salvage and return to function has been reported in more than 80% of cases [81,83,84]. However, Carson has warned that the procedure is not indicated in insulin-dependent diabetics, immunocompromised patients, or those with copious purulent drainage [66]. The salvage procedure involves complete removal of all prosthesis components, copious irrigation of all affected chambers through a rubber catheter placed in each area with 5 L of vancomycin-gentamycin solution, and possible use of the "water-pik" or a similar high-pressure irrigation device as reported by Brant et al. [81]. In any redo prosthesis operation following an infection, particularly those referred from an outside practice, there should be a high index of suspicion for the possibility of retained fragments such as rear-tip extenders or pieces of tubing from the original operation. A thorough physical examination, with possible adjunctive imaging studies such as penile/pelvic MRI when there is any question of retained fragments, can help prevent a near-definite reinfection [85].

Erosion

Device extrusion beneath the penile skin may occur as an isolated phenomenon, but prosthesis erosion is often a telltale sign of device infection. Semirigid prostheses are more prone to erosion; similarly, those with distressed tissue and vascular supply, such as brittle diabetics or patients who have undergone "redo" implant surgery, are more likely to suffer this complication. Erosion has also been described as a complication of urethral catheterization. Erosion presented as a late complication several months after implantation in 80% of patients with indwelling urethral catheters or who were using intermittent clean catheterization and who had received a penile prosthesis. The incidence of this complication may be greatly reduced by using inflatable rather than semirigid prostheses and by construction of a perineal or suprapubic cystostomy [86]. Mulcahy has described a distal corporoplasty for lateral extrusion of penile prosthesis cylinders, whereby the cylinder may be repositioned in a more medial and secure position under the glans penis by creating a new cavity for the cylinder behind the back wall of the fibrotic sheath that contains it [87,88].

Glans Bowing (Supersonic Transport Deformity)

Supersonic transport (SST) deformity is named after the angulated tip of these aircraft. The problem may be secondary to small prosthesis sizing or incomplete distal dilation of the corpora. If the problem is recognized intraoperatively and adequate distal dilation has been achieved, a larger rear-tip extender may be placed to lengthen the cylinder and see whether the defect is corrected. If the problem is noted in the immediate postoperative period, it is wise to wait a few weeks and allow for complete healing and scar formation, which may result in glans fixation and resolution of the SST deformity [66]. Refractory cases may be surgically corrected by placement of two 3/0 PDS or permanent prolene sutures on the underside of the glans on each side through a circumcoronal incision. By tying these sutures to the tunica albuginea near the cylinder tip and away from the neurovascular bundle, the glans is effectively secured against the cylinder tip [48,89].

Reservoir Complications

Reservoir complications are infrequent and include herniation with inguinal scrotal migration or, rarely, erosion into adjacent viscera [49,51–53,85,90]. Reservoir herniation is a very unusual complication that occurs in approximately 0.7% of three-piece inflatable prosthesis surgery cases. The finding is almost exclusively limited to cases when the penoscrotal approach is used. It may be caused by vigorous postoperative coughing or failure of proper initial reservoir placement under the transversalis fascia. Reservoir protrusion through an unrecognized existing hernia or a large tranversalis defect created intraoperatively are other possible contributory factors [49]. Decreased spontaneous autoinflation of the cylinders in the immediate postoperative period (i.e., as with Coloplast [formerly Mentor] lock-out valve mechanism preventing unwanted emptying of the reservoir) may result in a lower incidence of this adverse event. The herniated intrascrotal reservoir may be repositioned through the original penoscrotal incision when recognized in the immediate

postoperative period. An alternative approach is to use a small inguinal incision to place the reservoir in the perivesical space and close the defect from above. If the patient is asymptomatic, some surgeons have reported leaving the reservoir in its herniated intrascrotal position without adverse effects.

Rajpurkar et al. have reported on the fate of the retained reservoir after replacement of a malfunctioning three-piece penile implant. During surgery for replacement of the malfunctioning implant, the cylinders and pump were removed, but the reservoir of the original three-piece device was left in situ. The authors did not observe any incidence of reservoir erosion in the 85 evaluable patients. They concluded that routine removal or the reservoir during revision surgery is not necessary, but warned that prior pelvic surgery and infection appear to be risk factors for reservoir erosion [91]. Despite this encouraging result, it may be more prudent to remove all nonworking hardware at the time of revision surgery unless extenuating circumstances call for a shortened operative time or make reservoir removal more difficult. It is critical that all parts be removed in an infected case.

In patients who have had previous pelvic surgery or radiation therapy, proper placement of a reservoir in the retropubic space can be challenging. Normal operation of the reservoir will require the creation of a paravesical, retropubic space of adequate size that will allow expansion of the reservoir without lateral migration. Where there is fibrotic tissue or thick adhesions, filling the reservoir may result in lateral displacement and compression of the ilieofemoral vessels with possible deep venous thrombosis as a complication. In these cases, awareness of this potential complication, and a more focused attempt at reservoir placement more medially and away from the lateral vessels through the penoscrotal incision, is prudent. In very difficult cases, the reservoir may be placed through a separate suprapubic incision [50,92].

Conclusion

Penile prosthesis surgery continues to occupy an invaluable role in the armamentarium of the urologists specializing in sexual health. Dramatic design and material improvements have resulted in excellent durability and low complication rates. It is always reassuring to know that, for the patient who fails to respond to phosphodiesterase inhibitors or other more conservative therapies, a surgical solution with outstanding patient satisfaction rates is readily available. The new pump designs described in this manuscript are certain to simplify the operation of the implants and result in further improvements in satisfaction rates.

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