EXPERT REVIEWS

Inflatable penile prostheses for the treatment of erectile dysfunction: an update

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Male erectile dysfunction (ED) is a common medical condition. Three oral medications (sildenafil, vardenafil and tadalafil, all phosphodiesterase type 5 inhibitors) have been developed and approved for the treatment of ED by the US FDA. Extensive worldwide marketing of these medications has raised public awareness of ED, and allowed many previously untreated men to seek and receive effective therapy. A variety of other ED treatments are available and approved by the FDA, including vacuum-constriction devices and intracavernous or intraurethral alprostadil. However, roughly 30–40% of men with ED are not adequately served by these treatments due to their cost, side effects, contraindications, the need to 'time' sexual activity, or lack of satisfactory erectile response. For men who do not respond to less invasive therapy, an inflatable penile prosthesis can provide a satisfying and effective alternative. This article will review and critique the inflatable penile prostheses that are currently available in the USA and the EU for the treatment of ED.

KEYWORDS: erectile dysfunction • impotence • inflatable penile prosthesis • penile implant

Normal penile erection is a neurovascular phenomenon, requiring the proper hormonal milieu. Sexual stimulation causes the release of nitric oxide and other neurotransmitters within the paired corpora cavernosa; this results in cavernosal arterial vasodilation, increased blood flow into the corpora, and veno-occlusion. Blood must be trapped in both corpora under high pressure to achieve a rigid penile erection. The normal penile erectile mechanism frequently becomes impaired in patients with vascular risk factors (e.g., obesity, diabetes, hypertension, metabolic syndrome, tobacco abuse or dyslipidemia), and in many other circumstances, resulting in erectile dysfunction (ED). When medical therapies (e.g., phosphodiesterase type 5 inhibitors, intracavernous or intraurethral alprostadil, vacuum constriction devices) are unsuccessful, a penile prosthesis will usually provide a satisfactory result. One study found that patients who received an IPP reported better treatment satisfaction and erectile function than those treated with sildenafil or intracavernous alprostadil [1].

Inflatable penile prostheses (IPPs) for the treatment of ED have been available for more than 30 years in the USA The seminal finding in the field of penile prosthetics was that the corpora cavernosa can be accessed surgically without damaging the penile vasculature, urethra and sensory nerves, allowing insertion of a pair of intracorporal cylinders. Beheri [2] pioneered the placement of intracorporal cylinders, and soon both inflatable [3] and noninflatable [4] penile prostheses became available.

During the ensuing years many penile prosthesis models and configurations were developed, and many proved unsatisfactory or unreliable and are no longer manufactured. These obsolete models will not be reviewed. Modern penile prostheses may be categorized by their mode of action (e.g., inflatable vs noninflatable), by the number of components (e.g., cylinders, cylinders plus pump, cylinders plus pump and separate fluid reservoir), and by manufacturer. Non-IPPs are comprised of a pair of intracorporal rods. IPPs employ two hollow intracorporal cylinders, one for each corpora cavernosa. These cylinders are inflated with saline solution (or isotonic radiographic contrast material) to produce penile rigidity, and then deflated after sexual activity. The interested reader is referred to prior reviews for further details concerning noninflatable

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prostheses and IPPs, which are no longer manufactured [5–9]. The remainder of this review will focus on IPPs that are currently available in the USA and EU.

IPPs: configurations & manufacturers

Approximately 20,000 penile implants are inserted in the USA annually. These implants are typically inserted via an incision in the scrotum (scrotal approach), or via an incision in the skin above the base of the penis (infrapubic approach). There are currently two major IPP manufacturers: Coloplast Corporation (MN, USA), and American Medical Systems (AMS; MN, USA). Coloplast Corporation purchased Mentor Corporation's IPP business in 2006. These manufacturers each have over 25 years' experience producing IPPs, and each produces products with unique advantages and limitations. Competitors have found it difficult or impossible to enter the field due to: first, the limited worldwide market for these devices; second, the difficulty in manufacturing an effective and reliable device without violating current patents and technologies; and third; the potential liability associated with producing an implantable device.

Coloplast produces IPPs in which the pump is made out of medical grade silicone, while the inflatable cylinders and fluid reservoir are comprised of Bioflex®. The exact composition and formulation of Bioflex is a long-standing trade secret. Bioflex is reported to be an aromatic polyether urea urethane elastomer comprised of hard and soft segments. During the manufacture of Bioflex, a methylene di-isocyanate and polytetramethylene ether glycol prepolymer is chain-extended with ethylene diamine, and then combined with silicone dioxide and polydimethylsiloxane. The ethylene diamine and isocyanate react to form the urea hard segments, and the aromatic polyether and isocyanate react to form the soft segments. The Bioflex components are then dip-molded [10].

The cylinders, pump and reservoir are interconnected via kink-resistant tubing made of silicone. Silicone connecting tubing is used by both Coloplast and AMS. Silicone tubing is biocompatible, stable and flexible. It is resistant to kinking, occlusion and bursting, and is manufactured via extrusion, which allows nylon reinforcement and tight tolerances. Bioflex is formulated as a dispersion and cannot be made into the requisite size tubing. Bioflex and silicone do not chemically bond to each other; the process used to bond the Bioflex components to the silicone tubing is proprietary and not disclosed by Coloplast.

Coloplast currently manufacturers an IPP named Titan™ (formerly called the Alpha I™), which comes in standard sizes (Figure 1) and a narrow version. Two identical, single-layer Bioflex cylinders are preconnected to a standard size pump, which must be connected using a TruLock™ polysulfone connector to a fluid reservoir at the time of implantation. The Titan is available in both infrapubic and scrotal versions, depending on the route of implantation (the scrotal version has a shorter length of tubing between the cylinders and the pump). The cylinders are available in 2-cm increments between 14–22 cm, and the assembly kit comes with six stackable rear-tip extenders (1.0, 2.0 and 3.0 cm) to allow for adjustment of the cylinder input tubing relative to the corporotomy. Titan and Titan narrow cylinders expand in girth but not in length. The Titan cylinder base maximum diameter is 13 mm, the input tubing exits at a 45° angle, the cylinder bladder diameter varies between 13 and 15 mm, and the rear tip extenders (RTEs) are 12.8 mm in diameter. Titan RTEs are made of silicone and barium (to facilitate radiographic identification). They have recently been modified with a polysulfone adherence mechanism allowing them to adhere to each other and to the inflatable cylinders, thus facilitating subsequent revision surgery.

Titan fluid reservoirs are available in 60, 75, and 100 cc capacities, and now have a Lock-out™ Valve. Previously manufactured reservoirs without a Lock-out Valve would occasionally result in IPP autoinflation (i.e., increases in intra-abdominal pressure resulted in fluid transfer from the reservoir, through the pump, to the cylinders and an unwanted partial erection). The Lock-out Valve has greatly decreased this problem; fluid only transfers from the reservoir in response to negative pressure from the pump, not in response to positive pressure on the reservoir [11]. However, if pressure or a distorting force is applied directly to the Lock-out Valve, it will render it ineffective; thus, care must be taken during reservoir implantation.

The Titan narrow device uses the same pump and reservoirs, but the cylinders and RTEs are narrower. The Titan narrow cylinder base maximum diameter is 10 mm, the input tubing exits at a 22.5° angle, the cylinder bladder diameter varies between 11 and 13 mm, and the RTEs are 9.0 mm in diameter. The Titan narrow is available in infrapubic and scrotal versions. The narrow cylinders are available in 2 cm increments from 10 to 18 cm, and each narrow assembly kit comes with 6 RTEs (1.0, 2.0 and 3.0 cm).

Figure 1. Photograph of Coloplast Titan™ inflatable penile prosthesis. Consists of paired inflatable Bioflex® cylinders, a scrotal pump and a fluid reservoir with autoinflation-preventing lock-out valve.
Reproduced from Coloplast Corporation, MN, USA, with permission.

The Titan narrow IPP was designed for special situations, for example, a penis which is narrow, or has severe intracorporal fibrosis due to priapism or previous IPP infection. The Titan and Titan narrow each requires a corresponding assembly kit which contains appropriate sized RTEs. Titan narrow RTEs do not have the same adherence mechanism that the standard RTEs have.

Both the Titan and Titan narrow devices are now treated with a hydrophilic coating. A polyvinylpyrrolidone (PVP)-based hydrogel is covalently bonded to the surface of all components. This hydrophilic coating absorbs and adsorbs roughly 23-times its weight in water, and was developed in an attempt to decrease the rate of postoperative implant infection. *In vitro* studies indicate that this hydrophilic coating decreases the ability of bacteria to attach to the device [12]. In addition, when a hydrophilic-coated implant is soaked in an antibiotic-containing solution immediately prior to implantation, the antibiotic molecules are adsorbed or absorbed onto the surface of the device, and then subsequently eluted into the surrounding tissues during the postoperative period. A recent review of over 2000 patients implanted with a Titan IPP revealed that the hydrophilic coating, when used with antibiotic soaking of the device preimplantation, resulted in a decreased rate of implant infection when compared to uncoated devices [13].

Coloplast has recently developed a new pump configuration, the One-Touch Release (OTR), which allows IPP deflation with one short squeeze of the deflation mechanism (Figure 2). The standard Titan pump requires continuous pressure on the deflation bars. At this time, the Titan OTR is not available in the USA. However, initial Titan OTR implants have been performed in Europe and Canada, with encouraging results. The OTR features a true, one-touch deflation system using 'touch pads', designed to create a discernible landmark for the patient to quickly and confidently access.

Coloplast also manufactures a two-component inflatable device, named the Excel™. The Excel is available in all EU countries, Switzerland, Chile, Egypt and the United Arab Emirates, but is not available in the USA. This hydrophilic-coated device consists of narrow-based Bioflex inflatable cylinders attached to a Resipump™ (a combined pump and fluid reservoir). The Resipump is constructed of a Bioflex bladder to contain the fluid, and silicone components for the injection site and pump cap. The Excel replaces previous two-component versions, which used regular-sized cylinders (Mentor GFS™ and Mark II™ devices), and is only manufactured for the scrotal route of implantation.

AMS has produced a wide variety of IPPs over the last three decades. They currently produce both two- and three-component inflatable implants. Their implants are based on silicone cylinders interconnected via kink-resistant silicone tubing.

The original AMS three-component IPPs employed single-layer silicone cylinders. However, these cylinders were highly prone to leakage and aneurysm formation [5]. AMS has substantially improved the cylinders used in their three-component devices, so that they are now triple-layer, coated cylinders. These cylinders are available as AMS 700 CX™ (girth-expanding cylinders), AMS 700 LGX™ (length and girth expanding cylinders, formerly called Ultrex®) and AMS 700 CXR™ (narrow cylinder) models. AMS 700 CX and 700 LGX™ cylinders are available in 12-, 15-, 18- and 21-cm lengths. AMS 700 CXR cylinders are available in 10-, 12-, 14-, 16- and 18-cm lengths.

All AMS 700 series inflatable cylinders consist of an inner silicone layer, which is coated on both sides with Parylene, a middle woven fabric layer to control the expansion of the inner cylinder, and an outer silicone layer which is coated internally with Parylene, with an optional external coating of Inhibizone™ antibiotic surface treatment.

The inner silicone layer is reinforced, and its expansion controlled, by the middle woven layer. The middle woven layer is either a uni-directional Dacron-Lycra weave, which only allows girth expansion (CX and CXR cylinders), or a bidirectional weave, which allows expansion in both length and girth (LGX cylinders, Figure 3).

In late 2000, AMS introduced Parylene microcoating to enhance the durability of their silicone cylinders by reducing friction between the three cylinder layers. Parylene is a medical grade polymer, which is applied via a vapor deposition process to the nontissue-contacting surfaces of the silicone cylinders. Parylene increases the lubricity of the silicone surface, thereby reducing friction and wear. This micro-thin (60 millionths of an inch) Parylene layer has been demonstrated in bench testing to add millions of stress cycles before detectable wear is measured on both sides of the inner cylinder component and the inside of the outer cylinder [14]. Parylene coating was

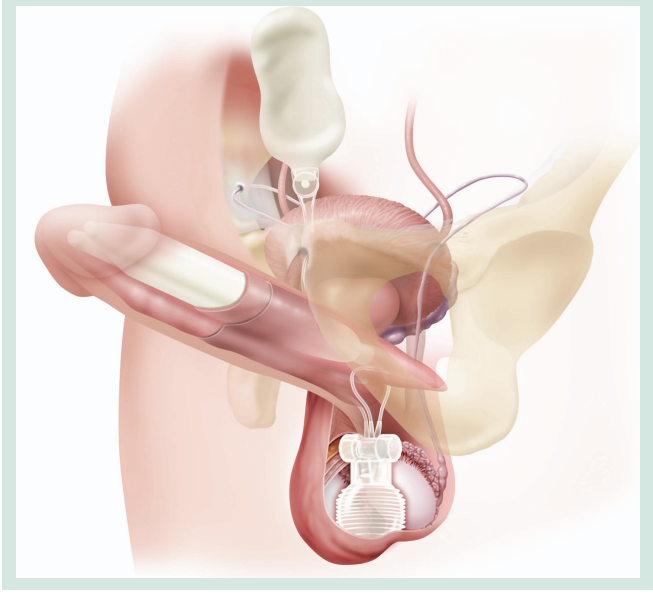

Figure 2. Artists rendering of Coloplast Titan™ implant with one-touch release pump, showing anatomic relationships.
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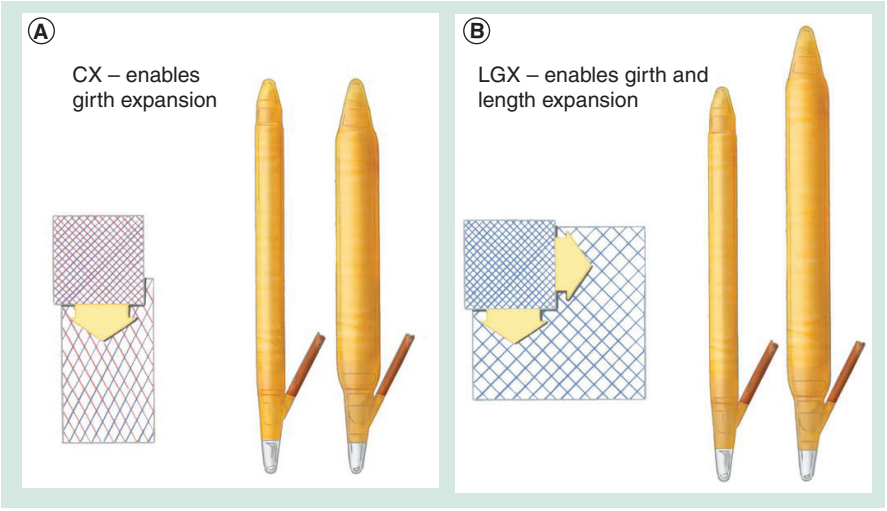

Figure 3. (A) Unidirectional Dacron-Lycra™ woven middle layer limits AMS 700 CX™ cylinders to girth expansion only. **(B)** Bidirectional Dacron-Lycra woven middle layer allows girth and length expansion for AMS 700 LGX™ cylinders. Both types of cylinder have Inhibizone™ coating. Rifampin and minocycline are impregnated onto the cylinder surfaces, imparting a characteristic orange hue.
Reproduced from American Medical Systems, MN, with permission.

employed to reduce the incidence of revisions with the 700 series inflatable implant, while not interfering with cylinder flaccidity and rigidity. All CX, CXR and LGX cylinders come with Parylene coating.

Inhibizone is a patented IPP antibiotic surface treatment introduced by AMS (Figure 3). Inhibizone coating involves the impregnation of 3–10 mg of minocycline hydrochloride and 9–25 mg of rifampin (depending on prosthesis size) into the external silicone surfaces of the cylinders, pump, reservoir and tubing (i.e., all components except the RTEs). This coating was developed to reduce the rate of prosthesis infection. *Staphylococcus epidermidis* is the most frequent pathogen cultured from IPPs removed due to infection, although other organisms may also be causative [15]. Most strains of *S. epidermidis* are sensitive to this antibiotic combination, and clinical studies have shown that the Inhibizone™ coating results in a statistically significant decrease in the rate of infection in an animal model [16] and during initial IPP procedures [17,18]. AMS cylinders with a standard pump are also available without the Inhibizone coating, for patients who are sensitive to rifampin or minocycline.

AMS manufactures three types of pump for their three-component devices: a standard 700 series pump, a Tactile Pump™ and a Momentary Squeeze™ pump (Figure 4). Compared with the standard AMS pump, the Tactile pump transfers more fluid during each squeeze of the pump bulb (resulting in faster inflation), has a 57% larger deflation site (making deflation easier) and has silicone ridges (which minimize pump slippage during inflation and deflation). Many patients find the Tactile Pump easier to locate, inflate and deflate, as compared with the standard pump [19]. The Momentary Squeeze pump offers a number of features, including a one-touch button for easier deflation, a lock-out valve that resists autoinflation, a smaller size than the Tactile pump, and silicone ridges for easier identification of the inflation site.

In addition to the aforementioned options, the CX, CXR and LGX models come either as separate components, or with preconnected cylinders and pump. The preconnected models must be ordered as either infrapubic or scrotal versions, depending on the operative approach. The regular and Tactile pumps come individually or preconnected; the Momentary Squeeze pump only comes preconnected. AMS RTEs have been modified so that they snap onto the inflatable cylinders, thus facilitating subsequent revision surgery. The AMS 700 Momentary Squeeze preconnnected implants have a narrower input tubing angle of 22° and a narrower proximal tip with corresponding Snap-Fit™ RTEs, which are available in 0.5-, 1.0-, 1.5-, 2.0-, 3.0-, 4.0-, 5.0- and 6.0-cm lengths (Figure 5). AMS RTEs are not available with Inhibizone coating. AMS fluid reservoirs are either 65 or 100 cc in capacity and now have Parylene coating applied to their inner surfaces to enhance durability. The CXR (narrow) model only requires a 65 cc reservoir and requires matching narrow RTEs, which are available in 0.5-cm increments from 0.5 to 3.0 cm in length.

AMS also manufactures a two-component inflatable implant, the Ambicor® (Figure 6). This device is currently the only two-component inflatable available in the USA. Introduced in 1994, it consists of two intracorporal cylinders, which have an outer silicione elastomer layer and a middle Dacron-Lycra™ woven layer. The two cylinders are prefilled with saline and preconnected to a scrotal pump via a silicone, kink-resistant tubing. The Ambicor is only available for implantation via the scrotal approach. Ambicor cylinders each have a fluid reservoir located in their proximal portion; squeezing the pump transfers fluid from the reservoirs into the distal, inflatable portion of each cylinder. Deflation is accomplished by flexing the device and holding it flexed for several seconds; this activates the release valve, allowing the fluid to transfer back to the reservoirs. This device is not currently available with Parylene or Inhibizone coatings. Ambicor cylinders are available in 2-cm increments from 14 to 22 cm, and in three different cylinder diameters (12.5, 14.0 and 15.5 mm). The 12.5 mm diameter cylinders are available in 14-, 16- and 18-cm lengths; the 14.0 mm diameter cylinders are available in 16-, 18- and 20-cm lengths; and the 15.5 mm diameter cylinders are available in 18, 20 and 22 cm lengths. The pump is a standard size, and the snap-on RTE's are 0.5,

1.0, 2.0 and 3.0 cm in length. In 1998 the proximal cylinder tips and corresponding rear tip extenders were enlarged and the junctions between the tubing and pump were reinforced.

Patient selection & preparation

An IPP is not usually the first treatment option for a man with ED. Nonoperative treatment options should be offered and tried, if possible. Currently available effective ED treatment options include oral PDE-5 inhibitors (e.g., Viagra®, Levitra® or Cialis®), vacuum-constriction devices, and intracavernous or transurethral alprostadil (e.g., Caverject® or MUSE®, respectively).

If these options fail, result in side effects, are contraindicated or unsatisfactory, then a penile prosthesis may be considered. Informed consent must be obtained, preferably in oral and written form. Briefly, the operative procedure, types of available implants, risks, alternatives, anticipated convalescence and expected outcome should be reviewed in detail. The risks of infection, malfunction and erosion should be discussed, as these complications often require surgical intervention. It is important to mention that the penis may be longer in the flaccid state and slightly shorter in the erect state, as compared with former erections. This is due to the fact that once the cylinders are implanted, they become encapsulated with scar tissue; this capsule does not expand in girth or length as much as normal tunica albuginea does. The glans will not engorge when an IPP is inflated. In addition, when intracorporal cylinders are installed, the erectile tissue is disrupted; the patient then becomes permanently dependent on a prosthesis for his erectile capabilities. Penile sensation, orgasm and ejaculation are usually unaffected by an IPP; the device simply allows for an erection on demand, as often as desired and for as long as needed.

Although evidence-based studies are lacking, most implanting urologists use a series of procedures to minimize the chance of IPP infection. Patients are advised to scrupulously wash their genitalia with soap and water or an antibacterial solution for a few days prior to their procedure; some urologists prescribe an oral antibiotic during this time. A culture should document sterile urine, and shaving is carried out with a hair-clipper immediately preoperatively, to prevent bacterial colonization of small kicks in the skin. Any active infection should be eradicated preoperatively, and an attempt should be made to optimize glycemic control in diabetic patients. Although one study [20] suggested a higher IPP infection rate in diabetics with elevated hemoglobin A1C levels, a subsequent larger series did not confirm this finding [21]. Prophylactic intravenous antibiotics are routinely administered prior to IPP insertion. After consultation with infectious disease specialists, this author uses vancomycin and gentamicin, starting 1 h prior to skin incision, followed by an oral quinolone for 5 days thereafter.

Prosthesis selection

Although this review is restricted to inflatable penile implants, noninflatable implants are also available and should be demonstrated to the patient. The device selected may depend on surgeon preference, insurance coverage, hospital purchasing contracts, along with the patient's preference, anatomy and medical/surgical history. For example, a patient who has ED due to an episode of priapism will often have severe intracorporal

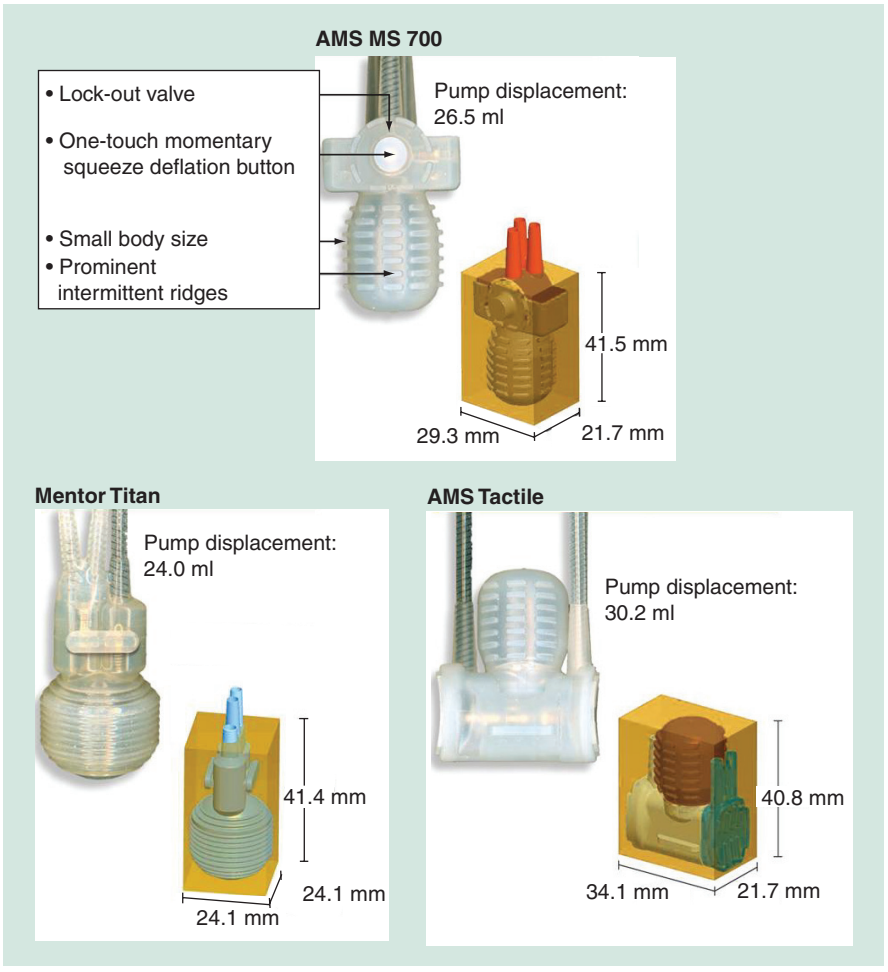

Figure 4. Comparison of inflatable penile prosthesis pump sizes and features.
AMS 700 Momentary Squeeze™ pump, Coloplast Titan™ standard pump, and AMS 700 Tactile™ pump.
Reproduced from American Medical Systems, MN, USA, with permission.

fibrosis; in this circumstance, a narrow cylinder (e.g., Coloplast Narrow Base™ or AMS 700 CXR) may be the best and often the only possible option. These narrow cylinders may be replaced subsequently with longer and/or wider cylinders after 8–12 months of healing, if the patient practices prolonged postoperative inflation [22].

A patient with ED, Peyronie's disease and penile curvature is best served by cylinders that expand in girth but not in length (e.g., Coloplast Titan or AMS 700 CX™). Length-expanding cylinders (e.g., AMS 700 LGX™) will exacerbate any penile curvature.

Patients with a large phallus will achieve the best erectile result with a three-component inflatable; this configuration allows transfer of the maximal amount of fluid in and out of the cylinders, and, consequently, the best rigidity and flaccidity. Although a two-component IPP inflates and deflates, the amount of fluid transferred in and out of the cylinders is limited; consequently, the rigidity and flaccidity provided by this type of device is inferior to that provided by a three-component IPP.

Patients who have had extensive abdominal or pelvic surgery, radiation, hernia repair using prosthetic mesh, colostomies, renal allografts, and so on, may be better candidates for a two-component inflatable (e.g., AMS Ambicor) so that intra-abdominal reservoir placement can be avoided. Alternatively, a three-component device can be used, and the reservoir can be placed ectopically into a nonoperated, nonradiated area of the abdomen in an extraperitoneal location. Of note, a recent series documents that patients who have undergone radical retropubic prostatectomy can be safely implanted with a three-component IPP via a scrotal incision, with transinguinal reservoir insertion [23].

Patients with limited mental capacity or manual dexterity are often best served by a noninflatable device, as they may have difficulty operating an IPP. Neurologically impaired patients may fare better with a multiple-component IPP, which has a lower rate of erosion compared to a semirigid device [24].

Operative approaches

IPPs are usually implanted through a transverse or longitudinal incision in the scrotum ('scrotal approach') or infrapubic area ('infrapubic approach'). These surgical approaches and variations thereof are well-described in the urologic literature [25]. The author's usual technique [26] is via a 3 cm vertical midline scrotal incision, held open with a self-retaining hook and ring retractor [101]. The urethra is delineated and preserved, then the right and left corpora cavenosa are defined, incised, dilated and measured. It is critically important to completely dilate, establish and measure the space within each corporal body, so that optimal-sized cylinders (with any needed RTEs) can be inserted. Particular attention must be given to dilating the distal aspect of each corpus all the way to its tip, to ensure proper support of the glans. If the cylinders are too long, they will buckle and curve; if they are too short, they will not support the glans and will not provide an adequate erectile result. Thereafter, the empty fluid reservoir is inserted through a small opening created in the floor of the inguinal canal into the space of Retzius (anterior to the bladder and posterior to the rectus muscles), then filled with sterile saline. The pump is placed between the testicles in the most dependent portion of the scrotum, and then the connection is made and the device tested. If needed, a penile straightening procedure can then be performed. A closed-suction drain is optional; placing a drain for 24 h has not been shown to increase the rate of prosthesis infection [27,28]. Most primary (virgin) implants can be accomplished on an outpatient basis.

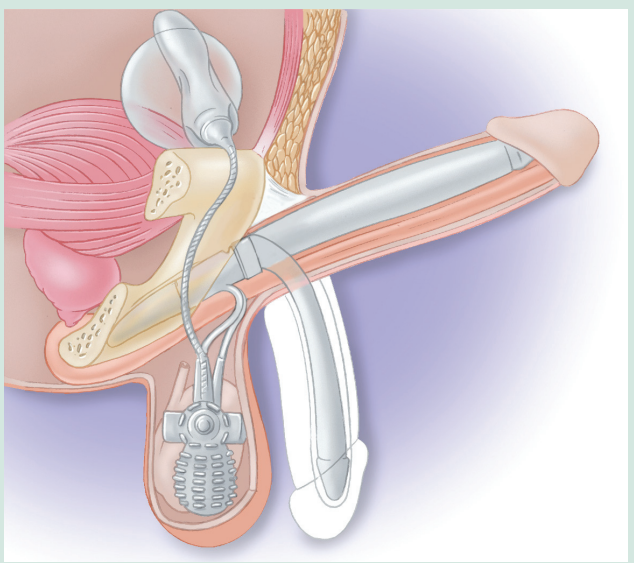

Figure 5. Diagram of AMS 700 Momentary Squeeze™ implant, showing one-touch deflate button for easier deflation, and pump ridges for easier inflation.
Reproduced from American Medical Systems, MN, USA, with permission.

The scrotal and infrapubic approaches each have advantages and disadvantages. The scrotal approach provides excellent access to the corpora, which is especially helpful in patients with corporal fibrosis or Peyronie's disease, who may require penile straightening procedures or extensive intracorporal dissection. It provides excellent access to the scrotum, so that the pump can be fixed in place, and usually allows the procedure to be done with less tissue dissection than that which is required via an infrapubic approach. The scrotal approach allows cylinder insertion with essentially no chance of injury to the dorsal penile nerves. However, the scrotal approach requires 'blind' transinguinal reservoir insertion, which may be difficult, risky or impossible in patients with prior hernia repair with prosthetic mesh, cystectomy, renal transplant or morbid obesity. The infrapubic approach requires more tissue dissection (through the infrapubic fat pad) and care must be taken to avoid injuring the dorsal penile nerves during cylinder insertion or replacement. However, it allows reservoir insertion into the prevesical or extraperitoneal space under direct vision.

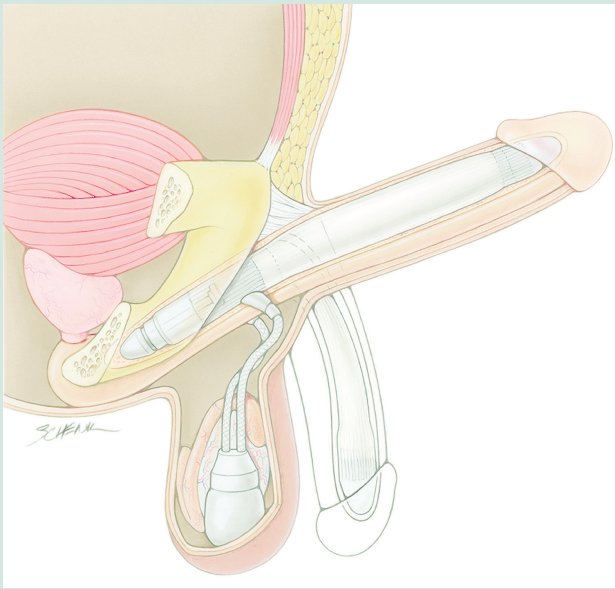

Figure 6. AMS Ambicor® penile prosthesis, consisting of paired inflatable cylinders and scrotal pump. Small fluid reservoirs are located in the proximal portion of each cylinder, obviating the need for an intra-abdominal reservoir. Reproduced from American Medical Systems, MN, USA, with permission.

Postoperative care

The author has for many years performed essentially all primary implant procedures on an outpatient basis [26]. Patients are discharged with preprinted instructions and prescriptions. If a drain was placed, the patient is instructed to return to the office the following day for drain removal. If the patient is unable to void, they are sent home with a urethral catheter and a leg bag, which can be removed the following day. An oral quinolone antibiotic is prescribed for 5 days. Oral analgesics are prescribed as needed and ice packs are used intermittently.

Patients are usually ready to use their IPP after 4–6 weeks of healing. They are then instructed to practice inflating and deflating the implant, and to attempt sexual activity when they feel comfortable. Patients should be cautioned to fully deflate the IPP after use. Leaving any of the three-component devices inflated for a prolonged period of time will result in scar encapsulation of the collapsed reservoir ('reservoir contracture') and inability to deflate the device. This complication usually requires operative revision.

Results of contemporary IPP implantation

Predecessors of today's IPPs were quite unreliable, with unacceptably high failure rates within 5 years of implantation [29]. However, in recent years both manufacturers have improved and reinforced their devices.

Concomitantly, implanting urologists have improved their surgical techniques and accumulated more experience with IPPs, contributing to improved success rates.

Many authors have reported on the durability of various IPPs. Daitch *et al.* in 1997 reported an actuarial mechanical failure rate of 9.1% for 111 AMS 700 CX devices, and 17.1% for 152 AMS 700 Ultrex devices at 5 years follow-up [30]. Debocq *et al.* in 1998 reported that the Mentor Alpha I IPP had a 96% cumulative proportional survival (CPS) at 63 months, versus an 84% CPS for the AMS 700 Ultrex™ and CX models [31]. Wilson *et al.* in 1999 studied the effect of the reinforced pump on the Mentor Alpha I IPP; they found that the 5-year survival rate increased from 75.3 to 92.6% [32]. Carson *et al.* in 2000 reported an 86% 5-year Kaplan–Meier survival in a retrospective study of the AMS 700 CX IPP [33]. Levine *et al.* in 2001 reported 93% survival at 3 years with the original Ambicor® prosthesis [34]. A subsequent study by Levine in 2007 using the redesigned Ambicor device revealed that 99.2% of patients were free from reoperation at 36 months, using Kaplan–Meier life table analysis [35]. Milbank *et al.* in 2002 reported an AMS 700 Ultrex IPP survival rate of 93.7% at 5 years [36]. In 2003, the author of this review analyzed site-specific malfunction data for a series of 442 Mentor Alpha I IPPs; the most frequent site of malfunction was at the junction of the silicone tubing with the pump strain reliefs [37]. Dhar *et al.* in 2006 assessed long-term mechanical reliability of the AMS 700 CX and CXM prostheses; they reported a mechanical failure rate of 10.3% in 380 patients with a median follow-up of 91.5 months [38].

Most recently, in 2007 Wilson's group used the Kaplan–Meier product limit method to estimate the long-term survival of 2,384 virgin implants, using four different IPPs [39]. Estimated 10 year mechanical survival for the AMS 700 CX, AMS 700 Ultrex and Mentor Alpha I devices were 67.7, 61.5 and 82.15%, respectively. Further analysis of their data revealed that Mentor's pump tubing reinforcement (introduced in 1992) increased the Alpha I's estimated 10-year mechanical survival from 65.1 to 88.75%. In addition, the Parylene coating (introduced in 2000) applied to the AMS 700 CX cylinders increased the 3-year estimated mechanical survival of this device from 88.4 to 97.9%.

Overall, patients can be informed that using the currently available enhanced IPPs, device malfunction rates in the range of 5–10% can be expected within 5 years of implantation. This makes the IPP one of the most reliable of all implanted devices.

Inflatable penile prosthesis complications

The most significant complications seen with IPP insertion are malfunction (Figure 7) and infection. When a patient develops IPP malfunction, there are several options available, including:

- No treatment
- IPP removal
- Replacement of the defective component
- Complete IPP replacement, with either the same or a different model

Elderly patients who are no longer sexually active may prefer no treatment. A patient who chooses IPP removal should be cautioned that the corporal spaces will fill with scar tissue, resulting in penile shortening and severe (if not total) erectile failure. The third and fourth options warrant further discussion.

While no immutable principles have been established, certain guidelines do exist [7,40]. Experienced prosthetic urologists generally suggest replacement of a malfunctioning component only if the IPP is relatively new (i.e., 1–2 years old). The patient should be cautioned that, if only the malfunctioning component is replaced, it is possible that one of the remaining components could malfunction in the not-too-distant future. IPP reservoirs rarely malfunction [37]; replacement of the preconnected cylinder-pump combination is usually a safe option. The 'd' option – complete device replacement – requires the most dissection, but gives the patient an entirely new device, with the highest chance of a long-lasting, functioning IPP.

When an AMS Ambicor malfunctions, the entire device must be replaced; there are no connectors and no separate components available. When an AMS 700 CX, CXR or LGX malfunctions, frequent sources of device failure are the cylinders and the silicone tubing. If one of the silicone tubes develops a crack, most of the fluid will leak out of the device. Occasionally, one of the innermost silicone cylinders will leak, but the fluid will be contained by the outer silicone cylinder. This results in asymmetric inflation and incomplete deflation, but no net fluid leakage out of the device. If the Dacron-Lycra layer loses its integrity, then a cylinder aneurysm can form. When any doubt exists about the integrity of a component during a revision, the best option is complete device replacement.

Replacing an AMS three-component IPP can present unique challenges. Tissue grows into the polytetrafluoroethylene sleeve, which surrounds each cylinder input tube; dissecting these sleeves out is sometimes difficult and tedious. Occasionally, the outer silicone layer of one of the cylinders will tear; this allows corporal tissue to grow into the middle woven layer and can make it difficult to dissect the cylinder out of the corpora.

The Coloplast Titan (and its nonhydrophilic coated predecessor, the Alpha I) has a different pattern of malfunction. The most common sites of device failure in this author's series are the junctions of the silicone tubing with the strain reliefs (reinforced areas where the silicone tubing is attached to the pump) [37]. Other authors have also noticed this propensity [40]. However, other parts of the device can occasionally malfunction; pump disruption (Figure 7), cylinder leakage and cylinder aneurysm formation have all been infrequently reported [41,42]. Tissue does not grow into any part of a Coloplast Titan IPP, so revisions are often technically easier than with the AMS implants.

Electrocautery may be used during IPP revision or replacement; however, low power settings should be employed, so as not to damage the prosthetic material [43]. A total of 25 W of coagulation power from an electrosurgical generator is usually sufficient during such dissections.

An interesting and somewhat unexpected finding is that clinically uninfected IPPs that have malfunctioned are often found to be colonized with pathogenic bacteria at the time of prosthesis revision. Licht *et al.* found that 43% of penile implants were colonized at the time of revision [44]; Henry *et al.* found that 70% were colonized [45]. Silverstein *et al.* found that 80% (8/10) of clinically uninfected IPPs removed for malfunction had evidence of bacterial biofilm formation when stained and examined via confocal scanning laser microscopy [46]. Most experienced implant surgeons report infection rates of 1–3% during initial implantation, whereas revision surgery has historically had a much higher risk, in the range of 7–18% [26,33,42,47]. Recent studies indicate that the higher risk of infection during revision surgery can be significantly decreased if the entire IPP is removed, the prosthesis spaces are copiously irrigated with antibiotic (e.g., cefazolin, tobramycin, vancomycin or gentamicin) and antiseptic (e.g., peroxide or povidone-iodine) solutions, and a new, antibiotic-coated IPP is inserted [48,49].

IPP infection is a dreaded complication of primary or revision implant surgery. If not attended to promptly and properly, infection can result in implant erosion through the skin or into adjacent organs, cellulitis, abscess formation, sepsis and necrosis of genital tissue. Consequently, all experienced implant surgeons take maximum precautions to prevent infectious complications during any implant procedure. These precautions may include:

- Use of presurgical scrubs
- Preoperative and postoperative oral and/or parenteral antibiotics
- Assurance of sterile urine
- Elimination of any other focus of infection
- Minimizing traffic in the operating room
- Hair clipping and scrubbing at the time of surgery
- Copious intraoperative irrigation with antibiotic solutions

Despite all precautions, experienced prosthetic urologists still report primary (virgin) implant infection rates of 1–3% [26,33,38,42,47]. Wilson's series of over 6000 noncoated IPPs revealed historical infection rates of 3% for nondiabetic virgin implants, 8% for diabetic virgin implants and 10% for revision operations performed without antiseptic solution washout [15,21]. Signs of infection include persistent pain, fever, erythema, wound drainage, cellulitis, fixation of the pump to the overlying skin, or erosion of a component through the skin. Antibiotics alone will not cure a penile prosthesis infection. Many organisms causing penile prosthesis infection produce a slime-like, exopolysaccharide biofilm which surrounds the prosthetic components [50]. This biofilm inhibits phagocytosis and decreases antibiotic penetration into the periprosthetic area.

When a penile prosthesis infection is diagnosed, operative intervention is mandatory. The wound should be explored and all components (i.e., cylinders, pump, reservoir and RTEs) must be removed, along with any other foreign material

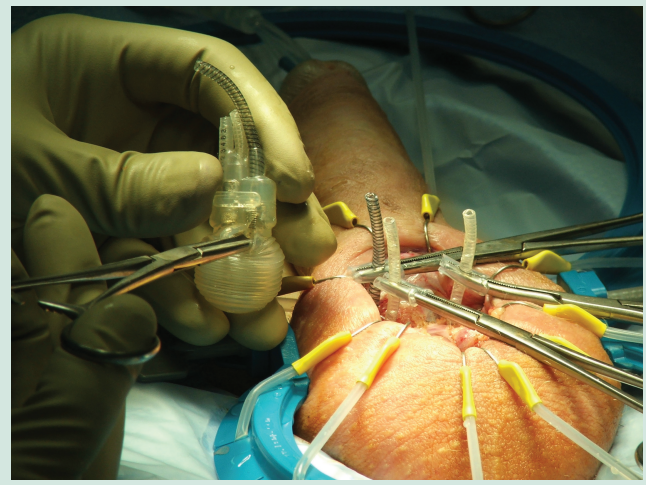

Figure 7. Coloplast Titan™ malfunction, due to fluid leak from silicone pump bulb. Hemostat is inserted into the site of disruption.

(e.g., permanent suture, graft material used during corporal reconstruction). There are no contemporary data that support removing only a portion of an infected IPP; attempts to do so usually result in persistent infection.

Once the infected device has been removed, several courses of action are available. The wound can be drained and closed, and the patient allowed to heal. However, removal of an implant without immediate replacement invariably results in severe intracorporal scarring and loss of penile length and elasticity. When the healing process is complete, the patient will not respond adequately to other ED treatments, and subsequent attempts at implant insertion will be extremely difficult or impossible.

To avoid this situation, immediate salvage procedures have been developed [51,52]. A salvage procedure consists of:

- Removal of all prosthetic parts and foreign material
- Copious wound irrigation with a series of antibiotic and antiseptic solutions
- Change of surgical gowns, gloves, drapes and instruments;
- Insertion of a new prosthesis
- Wound closure without drains
- Oral antibiotics for 1 month

Success rates of greater than 84% have been reported with this protocol; however, lower success rates occur when the surrounding tissues, in addition to the periprosthetic space, are infected. The advantage of a salvage procedure is that it allows immediate cylinder replacement into the intracorporal spaces and maintains most of the patient's penile length. The disadvantage is that infection may recur, mandating explantation. Attempted salvage of an infected IPP is contraindicated in the presence of tissue necrosis, sepsis, diabetic ketoacidosis or cylinder erosion into the urethra.

The most common pathogen cultured from primary penile implant infections [44,53] and from revisions which become infected [44] is *S. epidermidis*. The combination of rifampin and minocycline is effective against this organism, prompting AMS to develop, patent and introduce their Inhibizone-coating. As previously noted, preliminary studies indicated that Inhibizone coating results in a statistically significant reduction in primary IPP infection rates [17,18]. A recent series of 467 patients receiving an Inhibizone coated IPP revealed a statistically significant reduction in infection rates in virgin nondiabetic implants, virgin diabetic implants and revision surgeries when combined with an antiseptic washout protocol, as compared with historical controls [54].

Coloplast Corporation, with similar intent, now applies a hydrophilic coating to their Titan implant. When this hydrophilic-coated device is soaked in antibiotic solution, the antibiotics adhere and are eluted postoperatively; this approach has likewise been shown to reduce infection rates in primary implants [13]. When carrying out IPP revision surgery, experienced implanters now combine a hydrophilic- or antibiotic-coated implant with antibiotic and antiseptic irrigation of all the prosthetic spaces, striving for the lowest possible infection rates [48]. Although IPP infection and malfunction are serious complications, modern techniques allow the majority of patients to be successfully revised, and to achieve a functional IPP [55].

Other very rare complications of IPP insertion include cylinder erosion through the skin or urethra, cylinders which are too short and do not support the glans, cylinder crossover, corporal perforation, pump migration, redundant tubing in the scrotum, reservoir compression of pelvic veins, reservoir hernia, reservoir erosion into adjacent viscera, and so on [40]. These unusual complications occur in less than 1% of patients, and require individualized assessment and treatment. A description of treatment options for each of these complications is beyond the scope of this review.

Inflatable penile prosthesis satisfaction rates

Unlike any other ED treatment, an IPP allows a man to achieve a rigid erection on command, in a few seconds, as often as desired, and allows him to maintain the erection indefinitely. An IPP not only restores erectile capability, it can restore a man's sexual confidence, and this is a significant factor to consider. Men with ED often develop performance anxiety and a loss of confidence in their sexual capabilities; other ED treatments do not yield as certain a result as an IPP. Penile implants are the most invasive ED treatment available, but there are data indicating that implanted patients have a higher satisfaction rate compared with patients using other ED treatments.

A study of 138 patients published in 2003 reported statistically significant higher satisfaction rates among patients who received an IPP, compared with those using sildenafil or intracavernous prostaglandin E1 [1]. A multi-institutional, European study of 185 patients who received an AMS 700-series IPP revealed patient

and partner satisfaction rates of 92 and 96%, respectively [56]. A review of 50 patients who received a Mentor Alpha I IPP documented satisfaction rates of greater than 90% [27]. A review of 207 men who were implanted with an AMS 700 CX implant revealed that 86.5% would undergo the procedure again, and 88.2% would recommend an inflatable implant to a friend or family member [33]. A review of 112 patients who were implanted with an AMS Ambicor device revealed patient and partner satisfaction rates of 96.4 and 91.2%, respectively [34].

A recent review of 248 patients, implanted with multiple-component IPPs by an experienced surgical team, revealed an overall satisfaction rate of 69% [57]. In this series, 72% reported they would have the surgery performed again, 70% would undergo corrective surgery if needed and 75% would recommend an IPP to someone else. A recent study of 114 patients implanted with an IPP suggested, but did not conclusively prove, that men with Peyronie's disease, body mass index greater than 30 kg/m^2, or prior radical prostatectomy had lower satisfaction rates compared to men lacking these characteristics [58]. A review of 39 patients who required a total of 55 revision procedures revealed that 87% had a functional IPP at a mean follow-up of 6.5 months, and most were satisfied with their device [55].

Expert commentary

IPPs have undergone tremendous evolution and improvement over the last 30 years. Currently available IPPs offer a highly reliable, effective and satisfying correction of male ED. IPPs are available in regular and narrow cylinder sizes, with or without a separate fluid reservoir, and with cylinder girth and length expansion, so that an appropriate device can be selected for most patients. The manufacturers continually strive to improve the reliability and effectiveness of their devices. They have developed prosthetic coatings to reduce the risk of infection, along with device modifications to enhance durability, facilitate implantation, and to make the devices easier for patients to inflate and deflate. When conservative ED treatments are unsuccessful, an IPP may be an excellent choice for the well-informed patient.

Five-year view

IPPs will continue to evolve over the next 5 years. Guidelines for future research and development can be suggested. Although silicone is very biocompatible and stable, the silicone portions of an IPP are the most prone to failure. Research should be directed to determine if other biocompatible materials are suitable for penile implant construction. Efforts should be directed at improving the construction of the silicone tubing used to interconnect the IPP components, as this tubing (and the places where the tubing is joined to other components) is a frequent site of device failure. Silicone cylinders require reinforcing layers and further research should be conducted to improve this reinforcement to minimize the risk of cylinder aneurysm and rupture. Long-term results of the new PVP, Parylene and Inhibizone device coatings need to be reviewed; other coatings should be investigated to determine if they provide superior protection against infection and malfunction. Further research is needed to make the devices easier for patients to inflate and deflate.

Further research should also be directed at the two-component devices. Currently available two-component IPPs yield rigidity and flaccidity that is adequate, but inferior to their three-component counterparts. Some surgeons are reluctant to implant a three-component IPP due to the need to insert an intra-abdominal reservoir. Efforts should be directed at developing a two-component IPP that yields rigidity and

Key issues

- Inflatable penile implants (IPPs) have been available for over 30 years as an effective treatment for men with erectile dysfunction (ED).
- There are two major IPP manufacturers, each of whom produces two- and three-component devices.
- IPPs come in a variety of sizes and configurations so that an appropriate device can be selected depending on the patient's anatomy, surgical history and preferences.
- Modern IPPs are quite reliable, with failure rates of roughly 5–10% over a 5-year period.
- Recent enhancements to Coloplast Corporation's IPPs include a reservoir lockout valve (to prevent autoinflation), a hydrophilic coating (which decreases bacterial attachment and binds antibiotics to decrease the rate of infection), a narrow version (for men with scarred corpora), rear tip extenders, which adhere to the cylinders and to each other, and a one-touch deflation valve.
- Recent enhancements to American Medical System's IPPs include Parylene coating (to enhance durability), Inhibizone antibiotic coating (to decrease the rate of infection), three-pump configurations, a narrow version (for men with scarred corpora), rear tip extenders, which adhere to the cylinders, and a pump with a one-touch deflate valve and an autoinflation avoidance mechanism.
- IPPs are often the best solution for men with ED and Peyronie's disease, since they promote a straight and stiff erection and can be combined with a penile straightening procedure.
- Many clinically uninfected IPPs are colonized with pathogenic bacteria.
- Primary IPP infection rates have shown a statistically significant decrease, as a result of new hydrophilic and antibiotic prosthesis coatings.
- Revision IPP infection rates have shown a statistically significant decrease, as a result of new hydrophilic and antibiotic prosthesis coatings combined with antiseptic and antibiotic washout protocols.
- IPPs are the most invasive treatment option for ED, but they frequently result in the highest patient satisfaction rates.

flaccidity which approximates that which can be achieved by a three-component IPP; this will encourage more urologists to offer an IPP to men with refractory ED.

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