



Inflatable penile prostheses for the treatment of erectile dysfunction

Bruce Garber

Male erectile dysfunction is a common medical condition. Recent advances in our understanding of corpora cavernosa physiology have resulted in three effective oral medications (sildenafil, vardenafil and tadalafil – all phosphodiesterase type 5 inhibitors), which can effectively treat many men with erectile dysfunction. However, a large number of men are not adequately treated by these medications due to their cost, side effects, contraindications or lack of a satisfactory erectile response. For men who do not respond to less invasive therapy, an inflatable penile prosthesis can provide an excellent alternative. This article will review and critique the currently available inflatable penile prostheses in the treatment of erectile dysfunction.

Expert Rev. Med. Devices 2(3), 341–350 (2005)

Normal penile erection is a neurovascular phenomenon. Briefly, nitric oxide and other neurotransmitters released in response to sexual stimulation within the paired penile corpora cavernosa result in vasodilation and increased blood flow into the corpora and veno-occlusion. Blood is trapped in the corpora under high pressure, resulting in a rigid penile erection. The normal penile erectile mechanism is frequently impaired in patients with vascular risk factors (e.g., diabetes, hypertension, tobacco abuse and hypercholesterolemia), and in many other circumstances, resulting in erectile dysfunction (ED). When conservative therapies (e.g., phosphodiesterase type 5 inhibitors, intracavernous alprostadil and vacuum constriction devices) are unsuccessful, a penile prosthesis will often provide a satisfactory result. In fact, a recent study indicates that patients who receive an inflatable penile implant achieve better treatment satisfaction and erectile function than those being 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. A key discovery in the field of penile prosthetics was that the corpora cavernosa can be accessed surgically without damaging the penile vessels, urethra and sensory nerves; intracorporal cylinders can then

be installed. Beheri pioneered the placement of intracorporal cylinders [2], and soon both inflatable [3] and noninflatable [4] penile implants became available.

During the ensuing decades, a variety of penile prosthesis models and configurations have been developed; however, many have proven to be unsatisfactory or unreliable, and are no longer manufactured. Penile prostheses may be categorized by their mechanism 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 the manufacturer. Noninflatable penile implants work by virtue of paired intracorporal rods. Inflatable penile implants work via the inflation and deflation of paired intracorporal cylinders. The interested reader is referred to prior reviews for further information concerning noninflatable implants, and implants which are no longer manufactured [5–9]. The remainder of this review will focus on IPPs that are currently available.

Inflatable penile implants: configurations & manufacturers

Although exact figures are hard to establish, roughly 20,000 penile implants are inserted in the USA annually. These implants are usually inserted via an incision in the scrotum (scrotal

CONTENTS

Inflatable penile implants: configurations & manufacturers

Patient selection & preparation

Prosthesis selection

Operative approaches

Postoperative care

Inflatable penile prosthesis results

Inflatable penile prosthesis complications

Inflatable penile prosthesis satisfaction rates

Expert opinion

Five-year view

Key issues

References

Affiliation

*Drexel University College of Medicine,
Graduate Hospital,
Philadelphia, PA 19146, USA
Tel.: +1 215 893 2270
Fax: +1 215 893 2276
bgarber@comcast.net*

KEYWORDS:
erectile dysfunction, impotence,
inflatable penile prosthesis,
penile implants

approach), or via an incision in the infrapubic area just above the base of the penis (infrapubic approach). There are currently two major IPP manufacturers: Mentor Corp. (CA, USA) and American Medical Systems (MN, USA). These manufacturers each have over 20 years experience producing inflatable penile implants, and each produces unique products with unique advantages and limitations. Other manufacturers have found it difficult or impossible to enter the field due to:

- The limited market for these devices
- Difficulty in producing an effective and reliable device without violating current patents and technologies
- Potential liability that is associated with producing an implantable device

Mentor produces IPPs in which the pump is made from silicone, but the inflatable cylinders and fluid reservoir are made from Bioflex[®] [10]. The exact composition and formulation of Bioflex is a trade secret; however, it is reported to be an aromatic polyether urea urethane elastomer comprised of hard and soft segments. During manufacture, a methylene diisocyanate and polytetramethylene ether glycol prepolymer is chain-extended with ethylene diamine, and 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.

The cylinders, pump and reservoir are connected via kink-resistant tubing made of silicone. Silicone tubing is used by both Mentor and American Medical Systems. Silicone tubing is biocompatible, stable, flexible, 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 is not suitable for use as 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 Mentor. The tensile strength of Bioflex cylinders is reported to be 7500 psi, or roughly five-times that of silicone cylinders. In addition, laboratory testing reveals that Bioflex cylinders are more abrasion-resistant than silicone cylinders.

Mentor currently markets an inflatable penile prosthesis called the Titan[™], which comes in regular sizes (FIGURES 1 & 2) and a narrow-base version. Two cylinders come preconnected to a pump, which must be connected using a TruLock[™] connector to a fluid reservoir at the time of implantation. The Titan is available in both infrapubic and scrotal versions, depending upon 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 and 22 cm, and each cylinder comes with three rear-tip extenders (3, 2 and 1 cm) to allow for proper location of the cylinder input tubing relative to the corporotomy. Titan and Titan narrow-base cylinders expand in girth but not in length.

Titan fluid reservoirs are available in 60, 75 and 100 cc sizes, and now have a Lock-out[™] valve. Reservoirs without a Lock-out valve are subject to autoinflation (i.e., increases in

intra-abdominal pressure result in fluid transfer from the reservoir to the cylinders, and an unwanted partial erection). The Lock-out valve has virtually eliminated 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]. The Titan cylinder base maximum diameter is 13 mm, the 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.

The Titan narrow-base device uses the same pump and reservoirs, but the cylinders and RTEs are narrower. The Titan narrow-base cylinder base maximum diameter is 10 mm, the 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 narrow-base is available in infrapubic and scrotal versions. The narrow-base cylinders are available in 2-cm increments between 10 and 18 cm, and each cylinder comes with three rear-tip extenders (3, 2 and 1 cm) to allow for proper location of the cylinder input tubing relative to the corporotomy. The Titan narrow-base device was designed for special situations, for example a penis which is narrow, or has severe corpora cavernosa fibrosis due to priapism or prior penile prosthesis infection. The Titan and Titan narrow-base each requires a corresponding assembly kit, which contains appropriate sized RTEs, connectors and insertion needles.

Both the Titan and Titan narrow-base devices come 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. Experimental *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, the antibiotics are adsorbed or absorbed onto the surface of the device, and then subsequently eluted



Figure 1. Mentor Titan[™] penile prosthesis, consisting of paired inflatable cylinders, a scrotal pump and a fluid reservoir with Lock-out[™] valve.

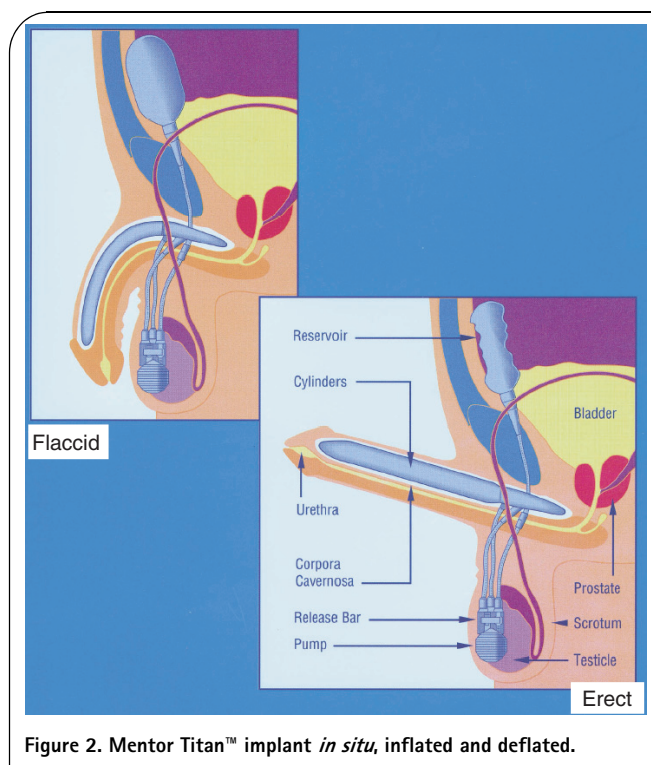


Figure 2. Mentor Titan™ implant *in situ*, inflated and deflated.

during the postoperative period. A recent review of over 2000 Titan implants reveals that the hydrophilic coating, when used with antibiotic soaking of the device preimplantation, results in a decreased rate of implant infection when compared to uncoated devices [13]. Mentor also manufactures a two-component inflatable device, named the Excel™ (FIGURE 3). The Excel is available in all European Union countries, Switzerland, Chile, Egypt and the United Arab Emirates, but is currently in clinical trials 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 comprises a Bioflex bladder to contain the fluid, and silicone components for the injection site and pump cap. The Excel replaces previous versions which used regular-sized cylinders (Mentor GFS™ and Mark II™ devices), and is only manufactured for the scrotal route of implantation.

American Medical Systems have produced a wide variety of inflatable penile implant configurations over the last three decades. They currently produce both two- and three-component inflatable implants. Their devices are based on silicone components interconnected via kink-resistant silicone tubing.

Their initial three-component device employed single-layer silicone cylinders. However, these cylinders were highly prone to leakage and aneurysm formation [5]. American Medical Systems have improved the cylinders used in their three-component devices, so that they are now triple-layer-coated cylinders. These cylinders are available as CX™ (girth-expanding cylinders), Ultrex™ (length- and girth-expanding cylinders) and CXR™ (narrow cylinders) models (FIGURE 4). All of these

cylinders consist of an inner silicone cylinder which is coated on both sides with parylene, a middle woven fabric layer to control the expansion of this inner cylinder, and an outer silicone cylinder which is coated internally with parylene, and has an optional external coating of Inhibizone™ antibiotic surface treatment (FIGURE 5).

The inner silicone cylinder is reinforced and its expansion controlled by the middle woven layer. The middle woven layer is either an unidirectional dacron–lycra weave which only allows girth expansion (CX and CXR cylinders), or a bidirectional weave which allows expansion in both length and girth (Ultrex cylinders).

In late 2000, American Medical Systems initiated parylene microcoating to enhance the 700 series' cylinder durability. Parylene is a medical grade polymer, which is applied via a vapor deposition process to nontissue-contacting surfaces of the cylinders (FIGURE 5). Parylene increases the lubricity of the silicone surface, thereby reducing friction and wear. This microthin (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 is expected to further reduce the incidence of revisions with the 700 series inflatable implant, while not interfering with cylinder flaccidity and rigidity.

Inhibizone is a patented antibiotic surface treatment which impregnates minocycline hydrochloride and rifampin into the external silicone surfaces of the cylinders, pump, reservoir and tubing (i.e., all components except the rear-tip extenders). This coating was developed in an attempt to reduce the rate of prosthesis infection. *Staphylococcus epidermidis* is the most frequent pathogen cultured from penile implants 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 does result in a statistically significant decrease in the rate of infection in an animal model [16], and during initial penile implant procedures [17].



Figure 3. Mentor Excel™ penile prosthesis, consisting of paired narrow-based inflatable cylinders and a combined pump/reservoir (Resipump™).

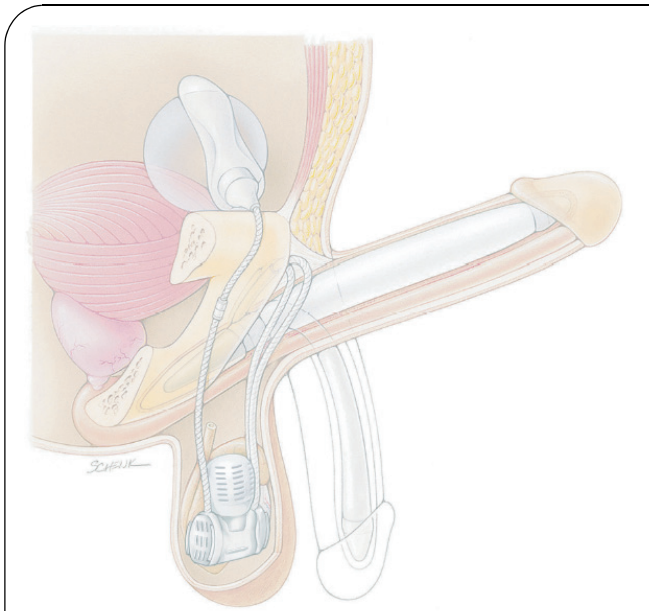


Figure 4. AMS 700™ Series Tactile Pump™ inflatable penile prosthesis.

A recent improvement to the American Medical Systems three-component devices is the Tactile Pump™ (FIGURE 4). Compared with the previous American Medical Systems pump, this new configuration 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).

In addition to the aforementioned options, the CX, CXR and Ultrex 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 CX and Ultrex cylinders are available in 3-cm increments from 12 to 21 cm, and are supplied with rear-tip extenders, which are used depending on proximal and distal corporal measurements. The fluid reservoirs are either 65 or 100 cc in capacity. The CXR (narrow) model comes in 2-cm increments from 12 to 18 cm and only requires a 65 cc reservoir. The CXR uses matching narrow RTE.

American Medical Systems also produces a two-component inflatable implant, the Ambicor® (FIGURE 6). This device is US Food and Drug Administration (FDA)-approved, and is currently the only two-component inflatable available in the USA. It consists of two cylinders which are prefilled with saline, and preconnected to a scrotal pump via silicone, kink-resistant tubing. It is only available for implantation via a scrotal approach. Ambicor cylinders each have a fluid reservoir

located in their proximal portion; activation of 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 yet available with parylene or Inhibizone coatings. The Ambicor cylinders are available in 2-cm increments from 14 to 22 cm, and also in three different cylinder diameters (11, 13 and 15 mm).

Patient selection & preparation

A penile prosthesis is not considered a first-line treatment for ED. Once a diagnosis of ED has been established, less-invasive treatment options should be offered and/or tried, if possible. Conservative treatment options include oral phosphodiesterase type 5 inhibitors, 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 should 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. In particular, the risks of bleeding, infection, malfunction and erosion should be discussed, as these complications often require surgical intervention. It is important to stress to the patient that his penis will usually be longer in the flaccid state and shorter in the erect state, as compared with his original erection. 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. In addition, when intracorporal cylinders are installed, the erectile tissue is disrupted; the patient then becomes permanently dependent on an implant for his erectile capabilities. Penile sensation, orgasm

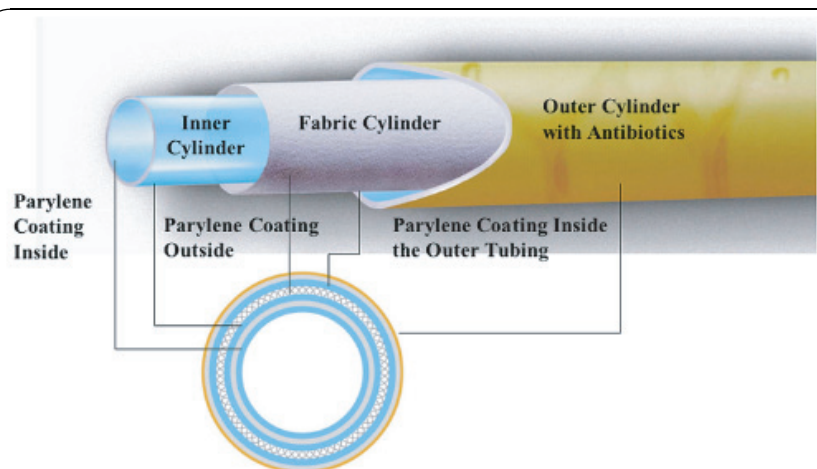


Figure 5. Cross section of AMS 700™ series inflatable cylinders, illustrating triple-layer construction with parylene and Inhibizone coatings.



Figure 6. Ambicor® penile prosthesis, consisting of paired inflatable cylinders and scrotal pump. Fluid reservoirs are in the proximal portion of each cylinder.

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 not scientifically proven, most implanting urologists use a series of preoperative procedures to minimize the chance of infection. Patients are advised to scrupulously wash their genitalia with soap and water for a few days prior to their procedure, and some urologists prescribe an oral quinolone antibiotic during this time. A culture should document sterile urine, and shaving is carried out in the operating room 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 suggested a higher infection rate in diabetics with elevated hemoglobin A1C levels [18], a subsequent larger series did not back this up [19]. Prophylactic intravenous antibiotics are routinely administered prior to IPP insertion; 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 often depends 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 a prior episode of priapism will often have severe intracorporal fibrosis; in this circumstance, a narrow cylinder (e.g., Titan narrow-base or 700 CXR) may be the best and perhaps

the only possible option. Similarly, a patient with ED, Peyronie's disease and penile curvature is best served by cylinders which expand in girth but not in length (e.g., Titan or 700 CX); length-expanding cylinders (e.g., 700 Ultrex) will only exacerbate the penile curvature. Patients with limited mental capacity or manual dexterity are often best served by a noninflatable device, as they may have difficulty operating an IPP. Patients with a very large phallus achieve the best erectile result with a three-component inflatable; this configuration allows the transfer of the maximal amount of fluid in and out of the cylinders, and consequently, the best rigidity and flaccidity. Patients who have had extensive abdominal or pelvic surgery, radiation, hernia repair using mesh, colostomies and renal allografts may be good candidates for a two-component inflatable (e.g., 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 non-operated, nonradiated area of the abdomen in an extraperitoneal location. 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.

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 [20]. The author's usual technique is via a 2.5-cm vertical midline scrotal incision, held open with a self-retaining retractor [21]. The urethra is delineated and protected, then the right and left corpora cavernosa are accessed, dilated and measured. It is critically important to completely dilate, establish and measure a space within each corporal body, so that optimally sized cylinders (with any needed rear-tip extenders) can be inserted. 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 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 in between the testicles in the most dependent portion of the scrotum, and then the connection is made and the device tested. A drain is optional – essentially all primary implants can be performed on an outpatient basis.

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 minimal tissue dissection compared with 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, pelvic surgery 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 space under direct vision.

Postoperative care

The author has, for many years, carried out essentially all primary implant procedures on an outpatient basis [21]. Patients are discharged with preprinted instructions after they have voided. If a drain was placed, the patient is instructed to return to the office the following day for drain removal. If the patient was 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 cycle the device after 4 to 6 weeks (FIGURES 7A & B). They are then instructed to practice fully inflating and deflating the implant, and to attempt sexual activity when they feel comfortable. Patients are 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 and an inability to deflate; this usually requires operative revision.

Inflatable penile prosthesis results

The predecessors of today's IPPs were quite unreliable, with unacceptably high failure rates within 5 years of implantation [22]. However, in recent years both manufacturers have improved and reinforced their devices so that contemporary IPPs are among the most reliable of implanted devices.

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

Several investigators have reported on the durability of various IPPs. When counseling patients, it is difficult to quote exact survival figures for a given prosthesis; new models are continually being introduced and survival figures are only available for the predecessor models which have been available for several years. Daitch and colleagues reported an actuarial mechanical failure rate of 9.1% for 111 CX devices, and 17.1% for 152 Ultrex devices at 5 years follow-up [23]. Wilson and colleagues studied the effect of an enhanced pump on the Alpha I™ IPP; they found that the 5-year survival rate increased from 75.3 to 92.6% as a result of product improvements [24]. Milbank and colleagues reported an Ultrex IPP survival rate of 93.7% at 5 years [25]. Levine and colleagues reported 93% survival at 3 years with the Ambicor prosthesis [26]. Carson and colleagues reported an 86% 5-year Kaplan–Meier survival in a retrospective

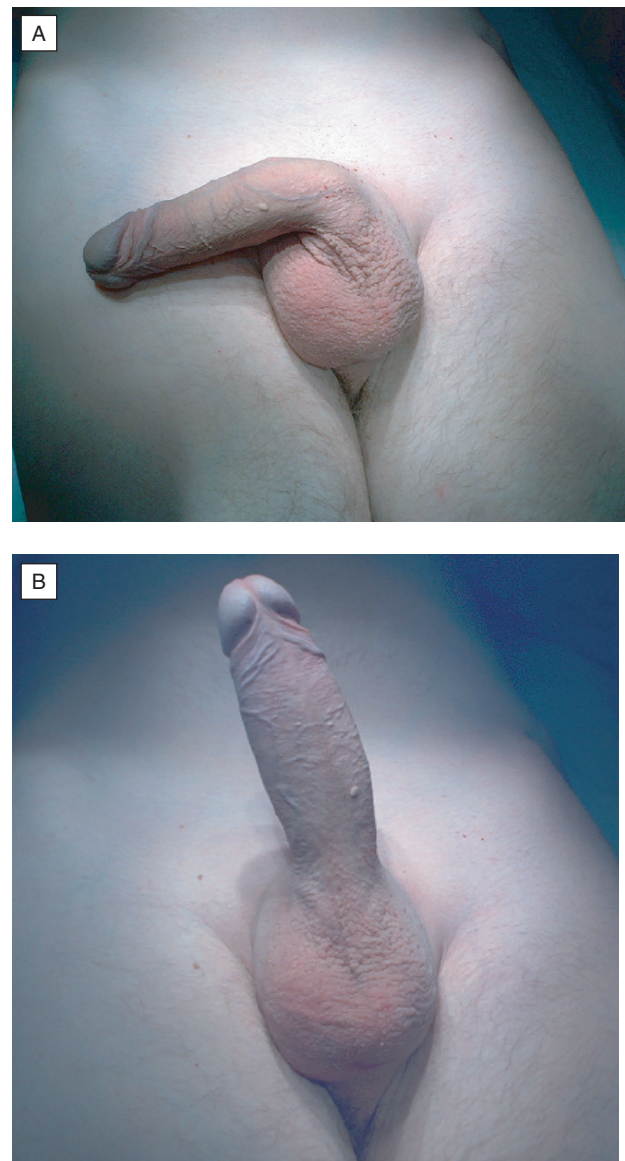


Figure 7. (A) Completely healed result: patient with Mentor Titan™ inflatable penile prosthesis, deflated. Note barely perceptible scrotal incision in median raphe. (B) Completely healed result: patient with Mentor Titan™ inflatable penile prosthesis, inflated.

study of the CX IPP [27]. Deboq and colleagues reported that the Alpha I IPP had a 96% cumulative proportional survival at 63 months, versus an 84% CPS for the Ultrex and CX models [28]. The author of this review carried out a site-specific malfunction analysis for a series of 442 Alpha I IPPs; the most frequent site of malfunction was at the junction of the silicone tubing with the pump strain reliefs [29].

Overall, patients should be informed that device malfunction rates in the range of 5 to 15% have been reported within 5 years of implantation. However, these studies are on older models; it is anticipated by the authors that the newer Mentor Titan and parylene-coated devices will improve upon these survival statistics.

Inflatable penile prosthesis complications

The most frequent complications seen with IPP insertion are malfunction and infection. When a patient develops IPP malfunction, there are a number of options available:

- 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 elect no treatment. A patient who chooses IPP removal should be cautioned that the cylinder 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 are published, certain guidelines do exist [7,30]. Experienced implanters 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. The option of 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 Ambicor malfunctions, the entire device must be replaced; there are no connectors and no separate components available. When a 700 CX, CXR or Ultrex malfunctions, frequent sources of device failure are the cylinders and the silicone tubing. If one of the tubes cracks, most of the fluid will leak out of the device. Sometimes, the innermost silicone cylinder 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. When any doubt exists about the integrity of a device 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 can often be 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 very difficult to dissect the cylinder out of the corpora.

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) [29]. Other authors have also noticed this propensity [30]. However, other parts of the device can occasionally malfunction; cylinder leakage and aneurysms, while rare, are not unheard of [31,32]. Tissue does not grow into any part of a Mentor IPP, so revisions are often technically easier than with the American Medical Systems devices.

Electrocautery may be used during IPP revision or replacement; however, low-power settings should be employed, so as not to damage the prosthetic material [33]. The author finds that 25 watts of coagulation power from the electrosurgical generator is more than sufficient during such dissections.

Another interesting and somewhat unexpected finding is that clinically uninfected penile implants which have malfunctioned are often found to be colonized with pathogenic bacteria at the time of prosthesis revision. Licht and colleagues found that 43% of penile implants were colonized at the time of revision [34]; Henry and colleagues discovered that 70% were colonized [35]. Most experienced implant surgeons report infection rates of 1 to 3% during initial implantation, whereas historically, revision surgery has had a much higher risk, in the range of 7 to 18% [21,27,32,36]. Recent studies indicate that the high risk of infection during revision surgery can be significantly decreased if the entire IPP is removed, the prosthesis spaces are copiously irrigated with antibiotic (i.e., cefazolin, tobramycin, vancomycin and gentamicin) and antiseptic (i.e., peroxide and povidone-iodine) solutions, and a new, antibiotic-coated IPP is inserted [37].

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 routinely include:

- The 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
- Shaving and scrubbing at the time of surgery
- Copious intraoperative irrigation with antibiotic solutions

Despite all precautions, experienced implanters still report primary implant infection rates of 1 to 3% [21,27,32,36]. 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. Parenteral antibiotics alone cannot cure a penile implant infection. Many organisms causing penile prosthesis infection produce a slime-like, exopolysaccharide biofilm which surrounds the prosthetic components [38]. This biofilm inhibits phagocytosis and decreases antibiotic penetration into the periprosthetic area.

When a penile implant 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 (e.g., permanent suture and graft material used during corporal reconstruction). There is no contemporary data which supports 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 (e.g., phosphodiesterase type 5 inhibitors), and subsequent attempts at implant insertion will be extremely difficult or impossible.

To avoid this situation, immediate salvage procedures have been developed [39,40]. 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 more 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 previously created corporal 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 [34,41] and from revisions which become infected [34] 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 indicate that Inhibizone coating results in a statistically significant reduction in primary penile prosthesis infection rates [17]. Mentor with similar intent, now produces devices that have a hydrophilic coating. When a 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, striving for the lowest possible infection rates [37].

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 large 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 treatments available, but studies indicate that implanted patients have the highest satisfaction rate compared with patients using other ED treatments.

One recent study of 138 patients reported statistically significant highest 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 700-series IPP revealed patient and partner satisfaction rates of 92 and 96%, respectively [42]. A review of 50 patients who received a Mentor Alpha I IPP documented satisfaction rates greater than 90% [43]. A review of 207 men who were implanted with 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 [27]. A review of 112 patients who were implanted with an Ambicor device revealed patient and partner satisfaction rates of 96.4 and 91.2%, respectively [26].

Expert opinion

Inflatable penile implants 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 clinical scenarios. Manufacturers continually strive to improve the reliability and durability of their devices, and have developed coatings to reduce the risk of infection. When conservative ED treatments are unsuccessful, an IPP is often an excellent choice for the well-informed patient.

Five-year view

It is difficult to accurately predict how inflatable penile implants will evolve over the next 5 years. However, some 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 and leakage. 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 carried out to improve this reinforcement to minimize the risk of cylinder aneurysm and rupture. RTEs should be modified so that they securely attach to the inflatable cylinder and to each other, facilitating revision surgery. Long-term results of the new hydrophilic and antibiotic device coatings need to be reviewed; other coatings should be investigated to determine if they provide superior protection against infection.

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 flaccidity equal to a three-component IPP; this will encourage more urologists to offer an IPP to men with refractory ED.

Acknowledgements

Thanks to Mentor Corp., CA, USA (www.Mentorcorp.com), for (FIGURES 1 TO 3) (reproduced with permission); to American Medical Systems, MN, USA, (www.AmericanMedicalSystems.com), for (FIGURES 4 TO 6) (reproduced with permission); and to both manufacturers for technical information about their products.

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 many different sizes and configurations, so that the most appropriate device can be selected depending on a patient's anatomy, surgical history and preferences.
- Modern IPPs are quite reliable, with failure rates of roughly 5 to 15% over a 5-year period.
- Recent enhancements to Mentor Corp's IPPs include a lock-out valve reservoir (to prevent autoinflation), a hydrophilic coating (which decreases bacterial attachment and binds antibiotics to decrease the rate of infection) and a narrow version (for men with scarred corpora).
- Recent enhancements to American Medical System's IPPs include parylene coating (to enhance durability), antibiotic coating (to decrease the rate of infection), an improved pump and a narrow version (for patients with scarred corpora).
- IPPs are often a satisfactory solution for patients with ED and Peyronie's disease, since they promote a straight and stiff erection.
- Many clinically uninfected IPPs are colonized with pathogenic bacteria.
- IPP infection rates have shown a statistically significant decrease, as a result of new hydrophilic and antibiotic coatings.
- IPPs are the most invasive treatment option for ED, but they consistently result in the highest patient satisfaction rates.

References

Papers of special note have been highlighted as:

- of interest
 - of considerable interest
- 1 Rajpurkar A, Dhabuwala CB. Comparison of satisfaction rates and erectile function in patients treated with sildenafil, intracavernous prostaglandin E1 and penile implant surgery for erectile dysfunction in urology practice. *J. Urol.* 170(1), 159–163 (2003).
 - **Direct comparison of patients taking sildenafil and intracavernous prostaglandin E1 with patients who received a penile prosthesis, using validated questionnaires.**
 - 2 Beheri GE. Surgical treatment of impotence. *Plast. Reconstr. Surg.* 38, 92–97 (1966).
 - 3 Scott FB, Bradley WE, Timm GW. Management of erectile impotence: use of implantable inflatable prosthesis. *Urology* 2, 80–82 (1974).
 - 4 Small MP, Carrion HM, Gordon JA. Small–Carrion penile prosthesis: new implant for management of impotence. *Urology* 5, 479–486 (1975).
 - 5 Mulcahy JJ. Overview of penile implants. In: *Topics in Clinical Urology: Diagnosis and Management of Male Sexual Dysfunction*. Mulcahy JJ (Editor), Igaku-Shoin Medical Publishers, Inc., NY, USA, 218–230 (1997).
 - 6 Montague DK, Angermeier KW. Penile prosthesis implantation. In: *The Urologic Clinics of North America* 28(2), WB Saunders Co., PA, USA, 355–362 (2001).
 - 7 Mulcahy JJ, Austoni E, Barada JH *et al.* The penile implant for erectile dysfunction. *J. Sex Med.* 1(1), 98–109 (2004).
 - 8 Montorsi F, Deho F, Salonia A *et al.* Penile implants in the era of oral drug treatment for erectile dysfunction. *BJU International* 94(5), 745–751 (2004).
 - 9 Montague DK. Genitourinary Prostheses. In: *The Urologic Clinics of North America* 16(1), WB Saunders Co., PA, USA (1989).
 - 10 Bioflex: a medical grade elastomer. Mentor Corporation, Santa Barbara, California, USA.
 - 11 Wilson SK, Henry GD, Delk JR, Cleves MA. The Mentor Alpha I penile prosthesis with reservoir lock-out valve: effective prevention of auto-inflation with improved capability for ectopic reservoir placement. *J. Urol.* 168, 1475–1478 (2002).
 - 12 Rajpurkar A, Fairfax M, Li H *et al.* Antibiotic soaked hydrophilic coated Bioflex: a new strategy in the prevention of penile prosthesis infection. *J. Sex Med.* 1(2), 215–220 (2004).
 - 13 Wolter CE, Hellstrom WJG. The hydrophilic-coated inflatable penile prosthesis: 1-year experience. *J. Sex Med.* 1(2), 221–224 (2004).
 - 14 Data on file, American Medical Systems, Inc., MN, USA.
 - 15 Wilson SK, Delk JR. Inflatable penile implant infection: predisposing factors and treatment suggestions. *J. Urol.* 153, 659–661 (1995).
 - 16 Darouiche RO, Mansouri MD, Raad II. Efficacy of antimicrobial-impregnated silicone sections from penile implants in preventing device colonization in an animal model. *Urology* 59(2), 303–307 (2002).
 - 17 Carson CC. Efficacy of antibiotic impregnation of inflatable penile prostheses in decreasing infection in original implants. *J. Urol.* 171, 1611–1614 (2004).
 - 18 Bishop JR, Moul JW, Sehelnik SA, Peppas DS, Gormley DS, McLeod DG. Use of glycosylated hemoglobin to identify diabetics at high risk for penile prosthesis infections. *J. Urol.* 147, 386–388 (1992).
 - 19 Wilson SK, Carson CC, Cleves MA, Delk JR. Quantifying risk of penile prosthesis infection with elevated glycosylated hemoglobin. *J. Urol.* 159, 1539–40 (1998).
 - 20 Mulcahy JJ. Implantation of hydraulic penile prostheses. In: *Atlas of the Urologic Clinics of North America*, WB Saunders Co., PA, USA, 71–92 (1993).
 - **Good review of penile implant surgical techniques.**

- 21 Garber BB. Outpatient inflatable penile prosthesis insertion. *Urology* 49, 600–603 (1997).
- **Successful protocol for outpatient, three-component inflatable penile prosthesis insertion, without routine use of a drain or urethral catheter.**
- 22 Gregory JC, Purcell MH, Standeven J. The inflatable penile prosthesis: failure of rear tip extenders in reducing the incidence of cylinder leakage. *J. Urol.* 131, 668–669 (1984).
- 23 Daitch JA, Angermeier KW, Lakin MM, Ingleright BJ, Montague DK. Long-term mechanical reliability of AMS 700 series inflatable penile prostheses: comparison of CX/CXM and Ultrex cylinders. *J. Urol.* 158, 1400–1402 (1997).
- 24 Wilson SK, Cleves MA, Delk JR. Comparison of mechanical reliability of original and enhanced Mentor Alpha I penile prosthesis. *J. Urol.* 162, 715–718 (1999).
- 25 Milbank AJ, Montague DK, Angermeier KW, Lakin MM, Worley SE. Mechanical failure of the American medical systems Ultrex inflatable penile prosthesis: before and after 1993 structural modification. *J. Urol.* 167, 2502–2506 (2002).
- 26 Levine LA, Estrada CR, Morgentaler A. Mechanical reliability and safety of and patient satisfaction with the Ambicor inflatable penile prosthesis: results of a two center study. *J. Urol.* 166, 932–937 (2001).
- 27 Carson CC, Mulcahy JJ, Govier FE. Efficacy, safety, and patient satisfaction outcomes of the AMS 700 CX inflatable penile prosthesis: results of a long-term multicenter study. *J. Urol.* 164, 376–380 (2000).
- 28 Deboq F, Tefilli MV, Gheilder EL, Li H, Dhabuwala CB. Long-term mechanical reliability of multicomponent inflatable penile prosthesis: comparison of device survival. *Urology* 52, 277–281 (1998).
- 29 Garber BB. Inflatable penile prosthesis: site-specific malfunction analysis. *Int. J. Impot. Res.* 15, 22–25 (2003).
- **One of very few papers analyzing the exact site of IPP malfunction.**
- 30 Wilson SK. Management of penile implant complications. In: *Topics in Clinical Urology: Diagnosis and Management of Male Sexual Dysfunction*. Mulcahy JJ (Ed.), Igaku-Shoin Medical Publishers, Inc., NY, USA, 231–253 (1997).
- **Excellent review of the diagnosis and treatment of intra- and postoperative penile implant complications.**
- 31 Garber BB. Mentor Alpha I inflatable penile prosthesis cylinder aneurysm: an unusual complication. *Int. J. Impot. Res.* 7, 13–16 (1995).
- 32 Garber BB. Inflatable penile prosthesis: results of 150 cases. *Br. J. Urol.* 78, 933–935 (1996).
- 33 Hakim LS, Kulaksizoglu H, Hamill BK, Uderson D, Goldstein IA. Guide to safe corporotomy incisions in the presence of underlying inflatable penile cylinders: results of *in vitro* and *in vivo* studies. *J. Urol.* 155, 918–923 (1996).
- 34 Licht MR, Montague DK, Angermeier KW, Lakin MM. Cultures from genitourinary prostheses at re-operation: questioning the role of *Staphylococcus epidermidis* in periprosthetic infection. *J. Urol.* 154, 387–390 (1995).
- 35 Henry GD, Wilson SK, Delk JR *et al.* Inflatable penile prosthesis culture during revision surgery. *J. Urol.* (Suppl. 169) 325, (2003) (Abstract 1263).
- 36 Garber BB, Marcus SM. Does surgical approach affect the incidence of inflatable penile prosthesis infection? *Urology* 52, 291–293 (1998).
- 37 Henry GD, Wilson SK, Delk JR *et al.* Revision washout decreases penile prosthesis infection in revision surgery: a multicenter study. *J. Urol.* 173, 89–92 (2005).
- 38 Nickel JC, Heaton J, Morales A, Costerton JW. Bacterial biofilm in persistent penile prosthesis-associated infection. *J. Urol.* 135, 586–588 (1988).
- 39 Mulcahy JJ. Long-term experience with salvage of infected penile implants. *J. Urol.* 163, 481–482 (2000).
- **Pioneering work on immediate salvage of infected IPPs.**
- 40 Kaufman JM, Kaufman JL, Borges FD. Immediate salvage procedure for infected penile prosthesis. *J. Urol.* 159, 816–818 (1998).
- 41 Carson CC. Infections in genitourinary prostheses. *Urol. Clin. North Am.* 16, 139–147 (1989).
- 42 Montorsi F, Rigatti P, Carmignani G *et al.* AMS three-piece inflatable implants for erectile dysfunction: a long-term multi-institutional study in 200 consecutive patients. *Eur. Urol.* 37, 50–55 (2000).
- 43 Garber BB. Mentor Alpha I inflatable penile prosthesis: patient satisfaction and device reliability. *Urology* 43(2), 214–217 (1994).

Affiliation

- Bruce Garber, MD, FACS
Clinical Associate Professor,
Drexel University College of Medicine; Urologist,
Graduate Hospital, Philadelphia, PA 19146,
USA
Tel.: +1 215 893 2270
Fax: +1 215 893 2276
bgarber@comcast.net