

REVIEW

Penile prosthesis implantation: past, present and future

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Penile prosthesis implantation is the oldest effective treatment for erectile dysfunction. This review examines the past, present and future of penile prosthesis implantation. Advances in prosthetic design and implantation techniques have resulted today in devices that produce nearly normal flaccid and erect states, and have remarkable freedom from mechanical failure. The future of prosthetic design holds promises for even more improvements.

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Before the early 1970s erectile dysfunction (ED), then known as impotence, was widely believed almost always to be due to psychogenic causes.^{1–3} Because of this belief, as well as the lack of effective therapy, there was little interest in the treatment of this disorder.

Three sentinel events have defined progress in our knowledge of the pathogenesis and treatment of ED. The first in 1973 was the introduction of the inflatable penile prosthesis.⁴ The second in 1983 was the introduction of intracavernous vasoactive drug injection.^{5,6} The third in 1998 was the introduction of sildenafil citrate, the first significantly effective oral therapy for ED.⁷

The attractiveness of oral therapy with the phosphodiesterase type 5 inhibitors and the widespread publicity concerning their use has made ED a household concept. While first line oral therapies are helpful for many men with ED, they are not helpful for all. Second line therapies (vacuum erection devices, intraurethral prostaglandin and penile injections) have mixed popularity and success. When first and second line treatments either fail or are unacceptable, penile prosthesis implantation is often considered.

This review will deal with the past, present and future of penile prosthesis implantation.

Past

Goodwin and Scott⁸ were the first to use acrylic stents in penile reconstructive procedures, and they included in their 1952 report Peter L Scardino's use of their stent to treat ED in a spinal cord injury patient. Lash, Zimmerman and Loeffler in 1964⁹ and Pearman in 1967¹⁰ reported on the use of single, silicone rods implanted under the fascia of the penile shaft. Pearman¹¹ later changed the location of his prosthesis to beneath the tunica albuginea. These early penile prostheses, often suffering from instability and erosion, did not gain widespread acceptance.

Beheri^{12,13} was the first in 1960 to use paired, intracorporeal polyethylene rods, and in 1966 he updated his experience with 700 patients.¹ In spite of Beheri's extensive experience, the use of his prosthesis did not gain general acceptance.

The first treatment for ED that became reasonably widespread among urologists was implantation of the Scott–Bradley–Timm inflatable prosthesis.⁴ This device, introduced in 1973, was the first to allow a man to have a prosthetic erection only when needed and to provide nearly natural flaccid and erect states. This implant would now be designated as a three-piece inflatable prosthesis: the three pieces being paired inflatable intracorporeal cylinders, a small scrotal pump and a large volume abdominal fluid reservoir. This device, constructed of silicone elastomer, was filled either with normal saline or

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isotonic contrast. In efforts to avoid implanting, this device in men with temporary or reversible ED, urologists began to learn how to take a good sexual history and to perform diagnostic testing.¹⁴ It soon became apparent that ED, rather than almost always being due to psychological factors, was very frequently caused by organic disorders.

This early inflatable penile prosthesis was associated with high mechanical failure rates ranging from 21 to 45% within a few years after implantation.^{15–19} A variety of noninflatable and later simpler inflatable prostheses were developed as alternatives to the Scott–Bradley–Timm device. While not completely free of mechanical failure, many of these devices proved more reliable from this standpoint.

Small *et al.*^{20,21} in 1975 described paired sponge-filled semirigid silicone implants which filled both corporeal bodies. Finney in 1977 introduced the Flexi-Rod prosthesis, a paired semirigid implant with a softer portion beneath the pubis to provide better concealment and a trimmable tail to reduce inventory.^{22,23} Jonas and Jacobi²⁴ in 1980 introduced the first malleable device. This paired silicone implant had a twisted silver wire core which increased rigidity and allowed the penis to be bent either downward or upward.

American Medical Systems (AMS) produced the AMS Malleable 600 prosthesis.^{25,26} This malleable silicone device contained a twisted stainless steel wire core wrapped in fabric. Three lengths were provided with length adjustment between sizes being made by the addition of rear tip extenders. Device diameter could be changed by removing an outer silicone sleeve.

Mentor Corporation produced two semirigid rod devices: the Mentor Malleable and the Acuform penile prosthesis.²⁷ Both were provided in three different diameters and both were adjustable in length by trimming and then applying a tail cap.

Dacomed produced the OmniPhase prosthesis which was a positionable paired rod device. This device suffered from breakage of its central cable.^{28,29} The OmniPhase was later replaced by the DuraPhase prosthesis.^{30–32} The central core of each of the two DuraPhase rods contained a central cable which ran through 12 articulating polysulfone

segments. A spring on each end maintained tension on each of the segments, which were movable over an angle of 17°. The DuraPhase device provided better positionability than malleable devices; however, cable breakage still remained a problem.³²

In 1986, two different one-piece inflatable prostheses were introduced: Surgitek's Flexi-Flate implant^{33–35} and AMS Hydroflex prosthesis.^{36–38} Surgitek is no longer manufacturing or marketing penile prostheses and the Hydroflex prosthesis was later replaced by the Dynaflex prosthesis.³⁹ With all three of these devices squeezing a small pump at the distal end transferred a small volume of fluid into a nondistensible central core. This provided rigidity comparable to a malleable device. When these devices were deflated, the central core collapsed producing some degree of flaccidity.

Mentor in 1988 introduced a two-piece inflatable prosthesis consisting of paired cylinders connected by tubing to a scrotal component, which was both pump and reservoir. This device was later named the Mentor GFS prosthesis,^{40,41} and after tubing connectors were eliminated, it was renamed the Mark II prosthesis.^{42,43} Surgitek introduced Uniflate 1000 in the mid 1990s. No publications in English language literature could be found for this device; however, a publication in Spanish recorded that two of seven of these devices had experienced mechanical failure in a larger series having a mean follow-up of 38 months.⁴⁴

Mentor introduced its three-piece inflatable prosthesis in 1983.⁴⁵ This device consisted of a silicone pump and tubing. The cylinders and reservoir were made of Bioflex. The exact composition of Bioflex is a proprietary secret. It is reported to be a polyether urea urethane elastomer. The Mentor Alpha 1 prosthesis was the designation for this device after the cylinders were supplied preconnected to the pump.^{46,47}

Present

Noninflatable prostheses

Today's penile prostheses can broadly be divided into noninflatable and inflatable devices. Currently

Table 1 Noninflatable penile prostheses

Name	Type	Company/contact	Country
Promedon tube	Malleable	cesaroriz@promedon.com.ar	Argentina
HR Penile Prosthesis	Malleable		Brazil
Silimed Malleable	Malleable	www.silimed.com.br	Brazil
Jonas (ESKA)	Malleable	www.Eska-medica.com	Germany
Shah Implant	Nonmalleable		India
Virilis I and II	Nonmalleable	Giant Medical (www.giant-medical.com)	Italy
Apollo Implant	Tissue expander	Giant Medical (www.giant-medical.com)	Italy
Genesis Malleable	Malleable	Coloplast	USA
AMS Malleable 650/600M	Malleable	American Medical Systems	USA
AMS Dura II	Positionable	American Medical Systems	USA

available noninflatable penile prostheses are listed in Table 1.

The Argentinean Promedon Tube Prosthesis is a malleable silicone implant with a polytetrafluoroethylene-coated silver core.⁴⁸ This device permits malleability up to a 130° angle. The proximal segments are trimmable every 5 mm and there are both 10 and 15 mm rear tips. The hardness of this device varies from soft at the tip to medium in the shaft and high in the tail. This implant is supplied in the following diameters: 9, 10, 11, 12 and 13 mm.

There are two Brazilian noninflatable implants. The HR Penile Prosthesis is supplied as two malleable devices, one with a steel core and the second with a silver core (Jonas model). The Silimed Malleable Implant is composed of silicone elastomer of medium hardness. The core is silver and rear tips allow length adjustments.

A German implant, the Jonas (ESKA) Prosthesis is a silicone malleable device with a silver core. It comes in 22 pairs of different sizes with three diameters.²⁴

The Shah Implant from India is a silicone nonmalleable device with four zones of stiffness. There is a soft distal tip followed by a stiff segment to produce shaft rigidity. Next is a soft zone to act like a hinge and finally there is a narrow, stiff proximal zone. There are two removable outer sleeves of 1 mm that permit adjustment of device diameters. The longer implants are supplied in 15 mm diameters. The removal of one or both outer sleeves produces diameters of 13 and 11 mm, respectively. The shorter implants are supplied in 13 mm diameters. The removal of one or both outer sleeves produces diameters of 11 and 9 mm, respectively.

The Virilis I Implants from Italy are made of completely soft medical grade silicone. These implants are 25 cm in length and are supplied in both 10 and 12 mm diameters. Proximal end caps (2 cm) are supplied. The total corporeal length is measured and the device is trimmed to 2 cm less than the length. The 2 cm rear end cap is then applied. The Virilis II Implant is similar to the Virilis I except that the distal portion is one-third firmer than the Virilis I, and the proximal portion is as soft as the Virilis I device.

Both of these soft implants are based on the Subrini concept^{49–52} that intracorporeal placement of these implants does not destroy but only displaces erectile tissue. These implants supply some support to the penis but the Subrini concept is also based on the belief that they reduce the volume of tissue which needs to be distended by the patient's reduced arterial inflow. Subrini states: 'Flexible penile implants not only allow sexual penetration due to their physical properties, but also frequently induce the restoration of real erection due to the reduction of the venous bed with preservation of the cavernous arteries.'⁵²

Another Italian device is the Apollo Implant which is a temporary implant designed to produce tissue length expansion by periodic injections of normal saline into the distal portion of the implant. The Apollo Implant is meant to be replaced by a more traditional prosthesis after length increase has been obtained. According to information provided by the manufacturer, Giant Medical Corporation, five men have been implanted with the Apollo device. Three of the five have undergone conversion to other devices: two malleables and one inflatable. The average length increase was reported to be 4 cm.

Coloplast Corporation manufactures the Genesis Malleable Penile Prosthesis. This device, previously manufactured by Mentor Corporation, was known as the Acuforn prosthesis. The Genesis device is the Acuforn prosthesis with a hydrophilic coating. The Genesis implant is available in three sizes: 14–23 cm length with 9.5 mm diameter, 16–25 cm length with 11 mm diameter and 27 cm length with 13 mm diameter.

American Medical Systems manufactures the AMS Malleable 650 and the AMS Malleable 600M devices.^{25,26} The AMS Malleable 650 device has a fabric-wrapped stainless steel core.²⁷ It comes in 12, 14, 16 and 18 cm lengths with adjustment between lengths being made by the addition of rear tip extenders. Each device has a 1 mm outer silicone sleeve. The diameter of the device with the sleeve on is 13 mm and with the sleeve off is 11 mm.

The AMS Dura II is a positionable noninflatable prosthesis. An inner core consisting of articulating high molecular weight polyethylene segments allows the device to be moved into any position while still maintaining an erection with sufficient rigidity for coitus.^{53,54}

Inflatable prostheses

Currently available inflatable penile prostheses are listed in Table 2. All inflatable penile prostheses are hydraulic devices. Two-piece prostheses consist of paired intracorporeal cylinders connected by tubing to a scrotal pump. The AMS Ambicor is a two-piece inflatable silicone prosthesis which is inflated by

Table 2 Inflatable penile prostheses

Name	Type	Company
AMS Ambicor	Two piece	American Medical Systems
Excel ^a	Two piece	Coloplast Corporation
AMS 700MS series	Three piece	American Medical Systems
Titan Inflatable Penile Prosthesis	Three piece	Coloplast Corporation

^aNot available in the United States.

squeezing the scrotal pump several times.^{55,56} This transfers fluid from rear tip cylinder reservoirs into central cylinder chambers which once full do not expand. The fluid within these chambers becomes pressurized resulting in penile rigidity approximating that achieved by noninflatable rod prostheses. The device is deflated by holding the penis in a bent position for several seconds. This device provides cylinders with the following widths: 11, 13 and 15 mm. For most patients erection and flaccidity are both less than can be obtained from the use of a three-piece device. The AMS Ambicor is marketed by AMS in the United States as well as internationally.

The Excel Inflatable Penile Prosthesis, marketed by Coloplast, is a two-piece inflatable prosthesis which is only available in markets outside the United States. The narrow base cylinders are made of Bioflex. The cylinders are connected by silicone tubing to a scrotal Resipump which serves both as a pump and a fluid reservoir. The Resipump is composed both of silicone and Bioflex and it incorporates an integrated injection port which is used for device filling. The entire device has a hydrophilic coating.

Table 3 lists the subtypes of three-piece inflatable penile prostheses. Coloplast's Titan Inflatable Penile Prosthesis (Figure 1) consists of paired single layered, Bioflex cylinders connected by silicone tubing to a silicone scrotal pump and a Bioflex abdominal fluid reservoir. The standard cylinders are used when the corpora can be fully dilated and the narrow base cylinders are useful when corporeal dilation is limited. On inflation, the Bioflex cylinders expand only in girth. In 2001, a lockout valve to prevent autoinflation was added to the Alpha-1 penile prosthesis and this was carried forward to the Titan prosthesis. This valve is located in the stem of the prosthesis. In a report comparing 160 men with the Alpha-1 device containing the lockout valve to 339 historical control patients implanted with the Alpha-1 without the valve, Wilson *et al.*⁵⁷ found 11% autoinflation in the controls with 2% requiring revision compared to two patients (1.3%) with autoinflation in the group having this valve and neither of these patients required revision.

The AMS 700MS inflatable penile prostheses (Figure 2) have silicone tubing, a silicone scrotal pump with a built-in lockout valve, and a silicone abdominal fluid reservoir. The cylinders have a triple-ply construction. The inner layer of the cylinder is a silicone tube into which fluid is pumped. The expansion of this inner tube is governed by a middle fabric layer. This fabric is a woven monofilament-knitted polypropylene and spandex synthetic fiber. In the case of the CX and CXR (formerly CXM) cylinders, the fabric is woven unidirectionally, and the cylinders expand only in girth. In the case of the LGX (formerly Ultrex) cylinders the fabric is woven bidirectionally, and the

Table 3 Three-piece inflatable penile prosthesis subtypes

Name	Cylinder type	Description
Titan	Standard Girth expanding	Normal use
Titan narrow base	Narrow base Girth expanding	Useful when corporeal dilation is limited
AMS 700 LGX	Girth and length expanding	Useful for most implants
AMS 700 CX	Girth expanding	Useful when penis needs straightening
AMS 700 CXR	Smaller diameter Girth expanding	Useful when corporeal dilation is limited



Figure 1 Titan Inflatable Penile Prosthesis (courtesy of Coloplast Corporation, Minneapolis, MN, USA).



Figure 2 American Medical Systems (AMS) 700MS inflatable penile prosthesis (courtesy of American Medical Systems Inc., Minnetonka, MN, USA).

Table 4 Inflatable penile prostheses: survival free of mechanical failure^a

References	Number of patients	Follow-up months range (mean)	Data pre- or post-modification	% of Devices free of mechanical failure ^b
<i>AMS 700 CX/CXM (not modified)</i>				
Deuk choi <i>et al.</i> ⁵⁹	273	6–100 (49)	NA	90.4
Carson <i>et al.</i> ⁶⁰	372	38–134 (57)	NA	86.2
Montorsi <i>et al.</i> ⁶¹	90	(60)	NA	93.1
Daitch <i>et al.</i> ⁶²	111	1–112 (47.2)	NA	90.8
Dubocq <i>et al.</i> ⁶³	103	(66 across 3 groups)	NA	83.9 ^c
<i>AMS 700 Ultrex (modified 1993)</i>				
Montorsi <i>et al.</i> ⁶¹	110	(58)	Both	79.4
Dubocq <i>et al.</i> ⁶³	103	(66 across 3 groups)	Both	84.2 ^c
Milbank <i>et al.</i> ⁶⁴	85	<1–136 (75)	Pre-1993	64.7
Milbank <i>et al.</i> ⁶⁴	52	<1–92 (46)	Post-1993	93.7
<i>Mentor α-1 (modified 1992)</i>				
Goldstein <i>et al.</i> ⁶⁵	434	<1–44 (22)	Both	85 ^d
Dubocq <i>et al.</i> ⁶³	117	(66 across 3 groups)	Both	95.7 ^c
Wilson <i>et al.</i> ⁶⁶	410	Not specified	Pre-1992	75.3
Wilson <i>et al.</i> ⁶⁶	971	Not specified	Post-1992	92.6

Abbreviation: NA, not applicable.

^aModified and used with permission of the AUA Drogo K Montague; Jonathan Jarow; Gregory A Broderick; Roger R Dmochowski; Jeremy PW Heaton; Tom F Lue; Aaron J Milbank; Ajay Nehra and Ira J Sharlip. Management of Erectile Dysfunction (2005; updated in 2006). American Urological Association Education and Research Inc. 2005.

^bKaplan–Meier survival estimates; 5-year estimates unless otherwise noted.

^c63-month estimate.

^d3-year estimate.

cylinders expand both in girth and length. The outer silicone layer prevents tissue ingrowth into the middle fabric layer.

Mechanical reliability of three-piece inflatable penile prostheses

For many years, clinical reports concerning results of penile prosthesis implantation used methods of reporting which did not allow meaningful comparisons with other reports. These earlier reports commonly presented the number of patients implanted, the minimum, maximum and mean follow-up times, and the number (percent) of devices which had failed. The American Urological Association's Update on the Management of Erectile Dysfunction in 2005 recommended that 'future research in penile prosthesis implantation should always express survival using Kaplan–Meier methods and include data on the numbers of patients censored.'⁵⁸ Eight such studies were found (Table 4).

Since the publication of the report, we have published a report of 455 men implanted with the AMS 700 CX or CXM penile prosthesis. Follow-up was obtainable in 380 (83%) and ranged from 0.49 to 231 months (median 91.5). A 10-year Kaplan–Meier estimates of overall device survival and device survival free of mechanical failure were 74.9% (95% CI: 69.2–81.1) and 81.3% (95% CI: 75.7–87), respectively.⁶⁷

Wilson *et al.*⁶⁸ recently reported long-term survival statistics using Kaplan–Meier estimates in a

series of 2384 patients undergoing first time inflatable penile prosthesis implantation. For the entire series, 10- and 15-year overall device survivals were 68.5 and 59.7%, respectively. Device survival free of mechanical failure was 79.4% at 10 years and 71.2% at 15 years. Because of the longtime period of this study, it was confounded by device improvements during the study. For example, in 1992 the Mentor Alpha 1 device had pump improvements increasing 10-year survival from 65.3 to 88.6%. In January 2001, a parylene coating was added to AMS 700 CX cylinders that increased 3-year mechanical survival from 88.4 to 97.9%.

Penile prosthetic infections

Infection is a possible outcome of any operation, but in prosthetic surgery infections are of paramount importance because when the infection is associated with the prosthesis, removal of the entire device is almost always necessary. In 2001, in an effort to reduce infection, AMS introduced InhibiZone, a minocycline and rifampin coating. This led to significant reductions in the rate of infection for both first time penile prosthesis recipients⁶⁹ and for revision surgeries.⁷⁰

Mentor in 2002 introduced a hydrophilic coating for its three-piece inflatable penile prosthesis renaming it the Titan Inflatable Penile Prosthesis. This polyvinylpyrrolidone coating reduces bacterial adherence. The coating also absorbs antibiotics from

a solution in which the prosthesis is immersed prior to implantation. This coating has also led to a significant reduction in the infection rate.⁷¹

Future

The ideal penile prosthesis would produce flaccid and erect penile states which closely resemble those occurring naturally. It would be easy for the recipient to transition between prosthetic flaccidity and erection. The ideal prosthesis would also be durable as well as resistant to infection.

Interestingly, to design a better corporal cylinder, we must look backward at the evolution of the penis and the corporal hydrostat mechanism. A hydrostat is defined as a centralized volume of incompressible fluid surrounded by membrane in tension. The incompressible fluid in the case of inflatable prostheses is saline, and the membrane in tension consists of either the polypropylene and spandex synthetic fiber and its associated silicone elastomer or Bioflex. In the natural state, the tunica albuginea is composed of layered collagen fibers arranged in a 90° orthogonal orientation. This orientation has evolved such that the fiber orientation provides maximal resistance to buckling forces when force is applied down the long axis of the penile shaft during intercourse.⁷² The use of this knowledge to enhance the design and fabrication of the prosthetic outer shell can enhance prosthesis performance and durability.

In terms of tumescence, current prosthetics provide excellent pressurization up to and exceeding 250 mm Hg. To achieve optimal pressurization, the man must pump the device to maximal capacity which can require a fair amount of strength and physical dexterity. Additionally, the act of manipulating the scrotal pump can be psychologically awkward for both the man and his partner. Novel designs incorporating mechanized methods for cylinder inflation could eliminate the need for the scrotal pump, and also could potentially more closely mimic the natural time course of tumescence and detumescence.⁷³ Interposition of a motorized pump between the cylinders and the reservoirs could allow for effective and rapid fluid transfer. Furthermore, the motor could be activated with a single 'click' of an intrascrotal switch or extracorporeally via a radiofrequency or infrared transmitter device not unlike an automotive keychain device. The motorized design also has the advantage of being able to be precisely controlled using widely available programmable servo and step motor technology. The current limitation of this approach is the need for a reliable and adequate power supply. Use of nonrechargeable batteries would necessitate surgery to replace them at periodic intervals which is clearly not an appealing prospect

to the patient. Rechargeable battery technology is evolving, and in the near future, these batteries could be recharged extracorporeally by wearing a belt-type recharging device during the night 3–4 days per month.

Much innovation of penile prosthetics is currently focused on modification of the three-piece design consisting of corporal cylinders, a pump and a reservoir. The ultimate future of prosthetics lies in simplification of the device to two self-contained corporal implants only. The battery, electronic controls and fluid transfer system would be self-contained within the corporal implant, obviating the need for connecting of components during surgery. Fewer parts would also likely equate to a lower infection rate as well as a lower mechanical failure rate. The design of these implants would rely on miniaturization of the fluid transfer system, battery and electronic controls. Our group is presently working on a device incorporating this type of technology.

Numerous technologies are evolving that could be potentially adapted for use to generate tumescence in the corporal cylinder. Bidirectional fluid transfer from the reservoir to the cylinder is an effective means to regulate pressurization. However, this paradigm may possibly shift toward the modulation of the properties of a static fluid component. Synthetic biomaterials are emerging that assemble and disassemble under specific conditions of pH, temperature, voltage or pressure. Peptide hydrogels have been designed that reversibly solidify and liquefy within a physiologic temperature range. Heating the hydrogel causes rigidification of the gel, and deactivation of the heating coil results in return of the hydrogel to its liquid state. An added advantage of such hydrogels is the fact that they demonstrate 'self-repair' such that when they are deformed they instantaneously repolymerize and remain rigid. Materials emerging from the field of nanotechnology hold promise for prosthetic design in that they demonstrate both rigidity and volume expansion properties. One such material involves DNA oligonucleotides that polymerize to form organized rigid three-dimensional polyhedral lattices.⁷⁴ In the polymerized state, these materials can expand in volume. Ultimately a device may be designed that has no moving parts and that obtains rigidity from a static material upon application of heat, electrical charge or pressurization.

Technologic advances are already impacting the performance of existing prosthetic designs. The ideal prosthesis has yet to be developed, and while current devices work effectively, there is room for improvement. To further improve penile prostheses discoveries from a wide range of medical and engineering fields must be applied. The current and future development of the penile prosthesis represents one of the largest multidisciplinary medical success stories in urology.

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