

## REVIEW ARTICLE



# History of penile implants: from implants made of bone to modern inflatable penile implants

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Penile prostheses are implantable devices used to definitively treat erectile dysfunction when previous forms of treatment have failed. The first example of a penile implant dates to 1935, when a rib was inserted in a neo-phallus reconstructed after a traumatic amputation. Since then, alternative artificial devices were adopted as penile prosthetic implants. The evolution of prosthetic devices had a dramatic thrust in 1973 when the first inflatable penile prosthesis was worldwide presented. Thanks to advances in device materials, design, surgical implant techniques, and perioperative management, nowadays inflatable penile prostheses are one of the most adopted definitive therapy for patients with drug-refractory erectile dysfunction or refusing alternative forms of treatments. Moreover, the clinical indications for inflatable penile prosthesis have also expanded, including female-to-male transmen or men underwent penile reconstruction due to congenital aphallia or traumatic or surgical penile amputation. In order to summarise the process behind the development and evolution of penile prosthesis, we aimed at performing a historical review of the currently available literature to provide an easy and comprehensive overview of the topic. The understanding of the historical process behind the evolution of inflatable penile prostheses will drive further innovation to increase efficiency and the rate of patients satisfaction.

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## INTRODUCTION

Penile prostheses are implantable devices used to treat erectile dysfunction (ED), when patients are not suitable or refuse pharmacological and alternative treatments or prefer a definitive therapeutic solution [1]. Through the history many medical options to treat ED have been described. Indeed, in 1985, Zorngiotti & Lefleur firstly showed the efficacy of intracavernosal auto-injection of vasoactive drugs in reaching a full erection [2]. In 1998, the management of ED switched to oral phosphodiesterase 5 inhibitors (PDE5-i) [3, 4]. However, unresponsiveness to available pharmacological therapies leads urologist to indicate the implant of a penile prosthesis [1].

The first example of a penile prosthesis is ascribed to Nikolaj A. Bogoras which published in 1936 the example of implant of a cartilage row into a rudimental neophallus created in a man who has suffered a traumatic penile amputation [5, 6]. Since then, medical research focused on finding an artificial solution capable of mimicking a natural erection. The year 1973 represents a tipping point in the evolution of penile prosthesis with the introduction of the first inflatable penile prosthesis (IPP) by doctors Bradley and Scott [7]. Furthermore, both the devices and the surgical implantation techniques have evolved in the last 50 years [8].

Thanks to the scientific advancements, nowadays penile prostheses are also used as treatment in cases of Peyronie's disease with concomitant ED [9], and to create rigid neo-phallus

after phalloplasty in gender reassignment surgery in female-to-male (FtoM) transmen or in men with congenital aphallia or underwent traumatic or surgical penile amputation [10–13].

Considering the growing interest and utilization of penile prostheses as definitive treatment for a drug-refractory ED, or as a device enabling penetrative intercourse to men with a neo-phallus, the current manuscript aimed at providing a review of the historical process behind the development of the currently available devices and components.

## PENILE PROSTHESIS HISTORY: FROM THE BEGINNING TO THE ADVENT OF INFLATABLE PENILE PROSTHESIS IN 1973

Current literature dates the first trace of a successful surgical intervention for the treatment of ED back to 1935 by O.S. Lowsley, as well as dates the first case of penile reconstruction, due to traumatic amputation and with the limited function of a conduct allowing micturition, in 1930s [14].

Through observations on the animal kingdom, the idea of implanting a rigid device to restore erection came up. Indeed, due to poor erectile tissues, many mammals possess a bone in their penis called *os penis*, or *baculum* [15, 16]. From this observation, in 1936 Nikolaj A. Bogoras firstly described the use of a rib cartilage, implanted into a tubularised tissue pocket, to restore not only the micturition, but also the rigidity in a man with traumatic penis amputation [6] (Table 1). However, despite the initial popularity of

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**Table 1.** Timeline of innovations in penile prostheses and technique from the first example of a rib cartilage to the modern inflatable penile prosthesis.

Data	Prosthesis	Features	Innovation
1936	Use of rib cartilage with tubular phalloplasty	Autologous implant	1st autologous prosthesis, simulates the baculum or os penis from the animal kingdom by Nikolaj A. Bogoras
1952	Acrylic splints, extracavernosal implantation	Acrylic implant	Extracavernosal approach
1958	Intracavernosal polyethylene rods	Polyethylene implant	Intracavernosal approach
1960	Intracavernosal acrylic rods	Acrylic material	
1964	Silicone penile implants	Silicone	Softer and better tolerated than the previous ones; reduced infection
1973	Small-Carrion prosthesis	1 malleable prosthesis silicone exterior with a silicone sponge interior.	Customized length, enhanced girth, more reliable, easier placement
1973	Small-Carrion prosthesis		First IPP
1977	Flexirod	Tapered distal tip	Soft hinge improved concealment
1983	AMS 700	PTFE sleeves, thick cylinders	
1983	Mentor 3-piece IPP	Polyurethane (Bioflex)	Enhanced strength over silicone
1985	Hydroflex and Flexi-Flate		Poor concealment, incomplete flaccidity
1986	AMS 700	Kink-resistant tubing added	
1987	AMS 700CX	3-ply design with woven fabric layer	Reduced cylinder aneurysms
1987	Mentor IPP (all IPP prosthesis)	Cylinder base reinforcement, pump modifications, nylon reinforced tubing	
1989	Mentor Alpha-1	Connectorless IPP	Reduced connector complications
1990	AMS 700CXM		Narrow version of the AMS 700CX model
1990	AMS Ultrex	Expanded girth/length	
1992	Mentor Apha-1	Reinforced tubing/pump	Enhanced mechanical reliability
1993	AMS Ultrex	Cylinders strengthened	Improved mechanical reliability
1994	AMS Ambicor	2-piece prosthesis	
1996	All prosthesis		Mulcahy salvage technique
2000	AMS 700		Added parylene coating: improved mechanical reliability; pre-connected cylinders, color-coded tubing: facilitated implantation
2000	Mentor (all prosthesis)	Lockout valve	
2001	AMS (all prosthesis)		AMS InhibiZone: antibiotic impregnation with minocycline/rifampin
2002	Mentor Titan	Hydroflex: hydrophilic substance absorbs aqueous solutions	Reduces bacterial adherence
2002	Mentor Alpha-1	Narrow Base	Narrow model
2006	Coloplast acquires Mentor		
2006	AMS 700 LGX		Length and girth expansion
2008	Coloplast One Touch pump		
2008	Titan XL Cylinders	24, 26, 28 cm	Various lengths
2010	AMS Conceal	Flat reservoir	
2011	No-touch technique: reduced infection		
2012	Coloplast 0 tubing	Moulded silicone contoured tip	
2013	Titan Touch 3-piece IPP		
2015	FDA approval for submuscular reservoir placement		
2016	ZSI 475 FTM		3-piece IPP designed as neophallus for female-to-male transgenders
2017	Coloplast 16/18 cm Narrow Base 0		
2018	AMS 700CX and 700LGX	Optimized tubing length	

IPP Inflatable penile prosthesis, PTFE politetrafluoroetilene, AMS American medical system, ZSI Zephyr Surgical Implants.

this technique, the use of the rib cartilage had a short success because of complications such as infections, extrusion, or pain. Furthermore, the cartilage could curve on itself or been completely reabsorbed within 18 months [17].

The first attempt in using artificial materials to improve the rigidity of the penis is dated back to 1952, when Goodwin & Scott described the use of an acrylic penile implant prototype into a neo-phallus leading to higher patients' satisfaction and fewer complications than the cartilage graft [18]. In order to limit the post-surgical oedema of the penis, in 1960 Loeffler & Sayegh improved the acrylic implant using a perforated acrylic prosthesis inserted between the corpora cavernosa, under the Buck fascia and the tunica albuginea, through a dorsal incision from the base of the glans penis to the pubic symphysis with successful response in two patients [19].

In 1964, Lash H. presented for the first time a penile prosthesis made of silicone [20]. The switch to silicone especially resulted in reduced rates of device post-operative infection [21].

In the wake of these impressive results, in 1967 Pearman, using the Lash's silicone implants, developed a novel surgical technique by placing the prosthesis in the dorsum of the penis, from the base of the glans to the suspensory ligament, beneath the Buck fascia and above the tunica albuginea [22]. Few years later, in 1972, Pearman changed his technique and inserted the prosthesis between the under surface of the tunica albuginea and the two corpora cavernosa, providing better both cosmetic and functional results [23].

Both acrylic and silicone implants were not devoid of complications, of all, important lymphatic oedema events were often observed. Moreover, patients commonly complained of inadequate proximal support, difficulty with penetration, irritation of the glans, intractable pain, and extrusion of the implant through the skin or the urethra [17]. In order to avoid those complications and complaints, acrylic and silicone implants were abandoned in favour of other materials, together with the development of new surgical techniques.

The first use a polyethylene prosthesis was reported in 1966 by the Egyptian surgeon G.E. Beheri. The innovation introduced in his work was also related to the newly developed paired intracavernosal penile implant, providing the basis for modern surgical technique [24]. Similar to an infra-pubic approach, Beheri's technique consisted of a midline dorsal incision near the root of the penis, opening of each corpus cavernosum (corporotomy), followed by dilations performed through Hegar dilators. Subsequently, through the corporotomy the thick distal portion of the implant was inserted into each corpus cavernosum and attached distally to the glans of the penis. Then, the thin proximal portion was brought towards the crus, thus completing the implantation

[17]. In 1972, Morales et al. modified the polyethylene implant, making it smaller in diameter trying to avoid the most common complications [25]. However, despite the smaller diameters, the polyethylene implants resulted to be quite stiff and not flexible enough. Indeed, they caused significant penile pain and pain to the partner during sexual activity. Moreover, the high risk of crus perforation and the high incidence of infection in this type of prosthesis led to its abandonment [23].

## PENILE PROSTHESIS HISTORY: FROM THE ADVENT OF INFLATABLE PENILE PROSTHESIS IN 1973 TO THE PRESENT

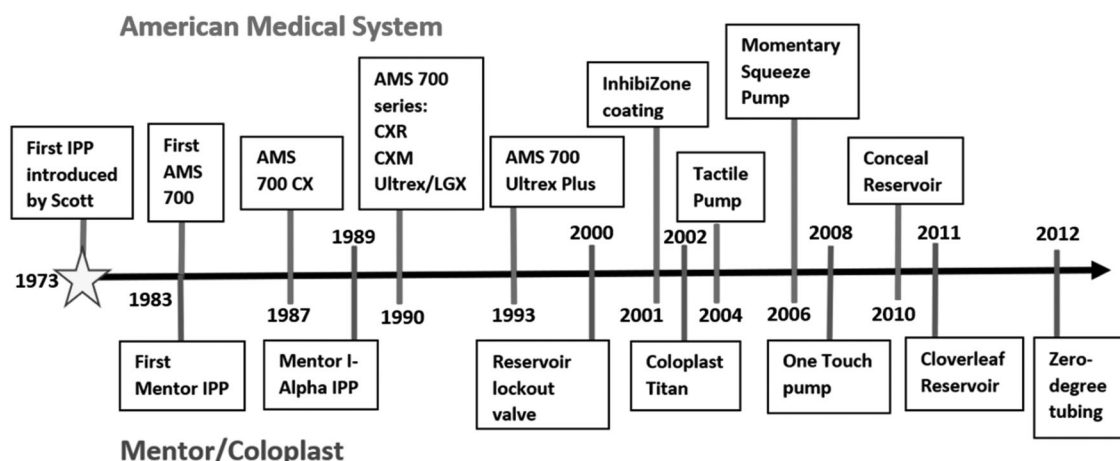
The development process of the IPP began in 1969 thanks to the cooperation among doctors Scott, Timm, and Bradley which were actively involved in bladder physiology and neurophysiology researches [26]. Their work was firstly aimed at creating the artificial urinary sphincter, and they had the idea of applying the same hydraulic technology in the pressurization of expandable cylinders to inflate corpora cavernosa. The idea helped to develop the first prototype of IPP in July 1973 (Fig. 1) [27].

### American medical systems

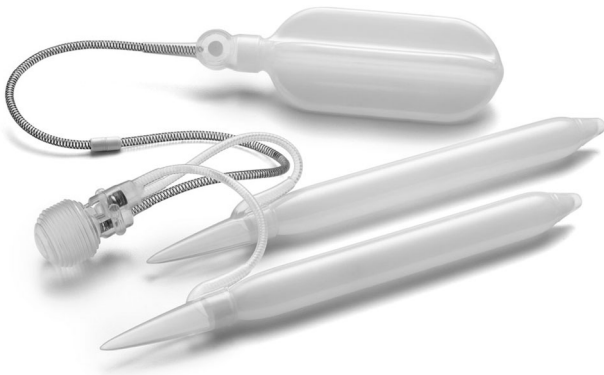
American Medical Systems (AMS) was the first brand to produce and commercialize the Brentley - Scott 4-piece IPP in 1973 [28]. The IPP was composed of a round and flat reservoir holding a radiopaque fluid necessary to activate the device, two separate pumping mechanisms connected by tubing to two single-layer silicone cylindrical bodies which were tapered at each end [7]. The principal issues were the formation of aneurysms of cylinders and the risk of kinking due to the flexibility of the tubes [17].

Ten years later, in 1983, AMS developed a new generation 3-pieces prosthesis called AMS 700. In this new version, the single-layer cylinders have been replaced by three-layer cylinders called penile non-distensible (PND) preventing the over-distension of the cylinders. Other improvements included kinking-resistant tubes, rear tip extenders created to better adapt the length of the prostheses to the original penile length, and polytetrafluoroethylene (Goretex) sleeves over the input tubing to improve the insertion of the prosthesis through the corpora [27, 29].

In 1985 AMS produced AMS Hydroflex (First 2-Piece Device) and Quick Connect tubing: this model consisted solely of 2 cylinders and a pump containing saline solution. The absence of the reservoir made it possible to use this prosthesis in men with a history of multiple abdominal procedures [30]. Indeed, the pelvic placement of the reservoir has the potential risk of damaging bladder, bowel, and vascular system, especially in case of local adhesions due to prior pelvic radiation therapy or surgery [31].



**Fig. 1** Timeline of the major innovations introduced by American Medical System and Mentor-Coloplast brands in the penile prosthesis.



**Fig. 2** Titan Touch inflatable penile prosthesis model by Coloplast brand.

The sequent model of IPP was introduced in 1987 with the AMS 700 CX (controlled expansion). The innovation introduced was the replacement of the inextensible layer with a polypropylene layer (Dacron), allowing for partial girth expansion of the cylinders during the inflation and furtherly reducing the likelihood of aneurysm and rupture of cylinders [32].

One of the most dangerous post-operative complications of IPP have always been recognized in infections due to gram-positive bacteria, such as *Staphylococcus epidermidis*, and gram-negative bacteria, such as *Escherichia coli*, *Serratia*, and *Proteus mirabilis* [33]. The recurrence of this complication may lead to skin necrosis, fistulation, prosthesis expulsion and to the need of a prosthesis explant with subsequent potential penile shortening. The most crucial moment has been recognized in the placement of prosthesis [34]. To deal with infections, from 2000 the AMS equipped all its devices with the “Inhibizone” technology consisting of a coating composed by rifampin and minocycline in order to reduce the post operative infection rates [35, 36].

One of the last major innovations produced by AMS came out in 2006, with the release of the AMS 700 LGX model. With the release of this newly developed model, cylinders were allowed to expand in length and girth [37]. Successively, in 2018, the LGX model was upgraded with the release of two new versions of 18 cm and 21 cm, respectively, in order to custom prostheses on patient penile length [38].

### Mentor-Coloplast

Among the other brands involved in the production of IPPs, in 1983 Mentor became the first competitor of AMS, with the release of a prosthesis made of Bioflex, a polyurethane structure. It had enhanced strength and higher resilience over silicone, creating a valid alternative on the market. Six years later, in 1989 Mentor released the Alpha I model [39]. This IPP was characterised by nylon reinforced kink-resistant and pre-connected cylinder tubing which could reduce complications related to the connectors and simplified the implantation procedure [32].

In 2006 Mentor was acquired by Coloplast, which, few years earlier equipped all its devices with a hydrophilic coating (HydroVANTAGE). This coat allows to lubricate IPP components and to absorb any water-based antibiotic selected in relation to local bacterial resistance [40]. A separate study compared the combination of rifampin/gentamicin, vancomycin/gentamycin, and InhibiZone for infection rates [41]. This latter revealed that with respect to vancomycin/gentamycin coated Coloplast Titan, the infection rate of both AMS with InhibiZone and Coloplast Titan with rifampin/gentamicin was lower. Thus, the authors of that study strongly recommended that Coloplast Titan implants be coated with a combination of rifampin/gentamicin solution [41].

In 2016, Scovell et al. compared the biomechanical characteristics of AMS 700 LGX and Coloplast Titan (Fig. 2). This one was superior in resisting longitudinal and horizontal forces than the AMS 700 LGX, whose performance depended more by the provided filling pressure and consequently was more variable according to patient experience [42].

### THE EVOLUTION OF THE PUMP MECHANISM COMPONENTS: THE PUMP AND THE RESERVOIR

#### Pump

The pump is a spherical device allowing the inflation and deflation of the prosthetic cylinders, usually hidden in the scrotum. IPP pumps have evolved over time with the aim of improving the handling and make them more comfortable and easier to use.

The first change to the IPP pump occurred in 1974, just a year after the IPP introduction, with the passage from a dual-pump to a single-pump design [27]. No other significant improvement in pump design was provided until 2004, with the introduction of the Tactile Pump by AMS. The new model incorporated ribs on the surface of the pump inflation bulb and pads on the deflation mechanism. This innovation made easier the grasping of the pump which was considered slippery by patients due to too smooth surfaces [43–45].

A dramatic improvement in pump design was introduced in 2006 by AMS with the Momentary Squeeze (MS) pump [27]. Indeed, the complete deflation of the previously adopted tactile pump required a two-finger squeeze for the whole duration of deflation. The new model made deflation easier, by incorporating a one-touch button allowing the complete deflation of the prosthesis with a single squeeze of few seconds [46]. Moreover, the MS pump firstly incorporated a lockout valve to resist auto-inflation of the penile cylinders against extensive force or sudden elevated pressure within the reservoir. Additionally, it was also smaller than the Tactile pump, facilitating the conceal in the scrotum and the grasping by the patient improving both the practical and aesthetical characteristics [47].

Similarly, the Coloplast pumps have also been improved across different generations such as the Genesis pump, One-Touch Release (OTR) pump, and the Titan touch pump.

Genesis pump was equipped with release bars and continuous pressure was required to allow a complete deflation, making it uncomfortable for patients [48]. A great improvement in Coloplast pump design and deflation mechanism arrived in 2008 with the release of the OTR pump [48]. It was considered more handle for patients because, differently from the Genesis pump, the OTR one was equipped with release pads, and only a single squeeze of these was required to deflate the IPP [27]. The AMS MS and Coloplast OTR are considered similar in terms of patient satisfaction rates [49].

A similar one-touch release pump, the Titan Touch, was introduced in 2013 with a smaller profile than the OTR pump [27].

Other IPP pumps are the Zephyr's pump, called ZSI 475 pump, and the Rigicon Rapid-Pump. The first one was composed of a simple open-close valve limiting the risk of mechanical failure, a reinforced valve that decrease the risk of auto-inflation, and a long exit tube decreasing the risk of breakage [50]. The second one is quite similar to the MS pump, but the deactivation button was placed on the side of the pump, rather than the ventral midline, making it easier to handle for the patient [51].

Current limitations of pumps include the need for manual deflation of the device and the risk of the Stiction Syndrome in which, if the IPP device has not been used for a long period of time, the pump becomes more rigid and requires higher filling pressure [52]. A technique intended to restore the functionality of the system, known as the “pull-stretch technique” was added to the product AMS 700 labelling at the direction of the FDA in 2013 [53].



## Reservoir

Both the design and placement of reservoir have significantly changed over the past fifty years and continue to evolve. The first reservoir was introduced in 1973 as a round and flat device placed in the space of Retzius, through the medial floor of the inguinal canal [7]. This position was also chosen to minimize the risk of auto-inflation in case of outer pressure [54].

Earlier innovations in reservoir design were the addition of coatings to prevent herniation and the development of “kink-proof” reservoirs preventing mechanical failures attributable to sharp angles between the reservoir and tubing [55].

A relevant improvement of the reservoir was introduced in 2000 when Mentor Corporation added a lock-out valve to decrease the risk of auto-inflation [56].

In 2002, Wilson reported his first experience with the Mentor reservoir and reported successfully placing below the abdominal musculature decreasing the rate of auto-inflation from 11% to 1.3% [56].

In 2010 Boston launched the AMS Conceal reservoir, in two different volumes (65 ml and 100 ml) and with a low-profile shape design. Differently from the previous AMS spherical reservoir, the flattened shape of the AMS Conceal reservoir allows submuscular concealment in the lower abdominal wall and enhances patients' comfort [32].

In the same year, Coloplast introduced the Cloverleaf reservoir available in two different sizes: 75 ml and 125 ml. This reservoir has a bellows-like configuration making it quite flat when underfilled but cylindrical when fully expanded, for this reason, is still considered the ideal reservoir to be placed behind the abdominal muscle in patients who have undergone pelvic surgery for prostate cancer [51]. Indeed, because of the post-operative adhesences, according to a 2013 survey, 81% of experienced implant surgeons agreed that the placement of the reservoir in the space of Retzius was more difficult in patients who underwent Robotic Assisted Laparoscopic Radical Prostatectomy (RARP) [57]. Moreover, the increasing popularity of RARP forced surgeons to consider an alternative reservoir placement (ARP) of the device. During the procedure, the parietal peritoneum overlying the bladder and anterior pelvis is incised, thus “dropping” the bladder and exposing the space of Retzius to the peritoneal cavity with the risk of perforating the conventional IPP reservoir [58, 59].

To this regard, in April 2015, the FDA approved the Coloplast Cloverleaf reservoir for ectopic placement, meaning with ectopic any alternative reservoir location from the space of Retzius [56]. Consequently to this approval by FDA, Hernandez et al. investigated the safety of AMS and Coloplast ARP in the sub-Scarpa space (deep to Scarpa's fascia and superficial to abdominal wall musculature) and submuscular space (between the rectus sheath and transversalis fascia) via the inguinal canal or abdominal counter incision [60]. The ARP approach has been recognized as safe and mechanically reliable, becoming particularly indicated in men with history of pelvic surgery. However, some risks are associated like muscle discomfort, tubing torsion, reservoir leakage, and unintended reservoir malposition [60]. In this setting, a large volume reservoir is placed and is filled to less than full capacity, so the reservoir lies flat just beneath the patient's rectus abdominus muscle either anterior (ATF) or posterior (PTF) to the transversalis fascia [61].

Finally, other reservoirs available are the AdaptiveReservoir marketed by Rigicon, and the ZSI 475 reservoir marketed by Zephyr. The first one is a cylindrical reservoir made of adaptive material which allows the reservoir to easily take the shape of the implantation site and actually available in three different volumes: 65 ml, 70 ml, and 110 ml [62]. Whilst the second one is a cylindrical reservoir available in only one volume of 80 ml and preconnected to the pump [50].

## THE SURGICAL APPROACH OVER TIME AND POST-OPERATIVE MANAGEMENT OF INFLATABLE PENILE PROSTHESIS

With the improvement of material and design of IPPs, also surgical techniques have improved significantly. In 1973 Doctors Scott and Bradley first introduced the intracavernosal placement of the IPP via a suprapubic approach with an umbilical-pubical incision [7].

In 1992, doctors Graydon and Berlin reported the placement of the IPP through a smaller transverse incision above the penis, naming it infrapubic approach [63]. This approach have been subsequently modified until the introduction of the minimally invasive infrapubic approach by Perito et al. [64]. Currently, the most common approaches for penile prosthesis implantation are the penoscrotal, infrapubic methods, with the suprapubic and perineal methods no longer in use due to technical limitations [65].

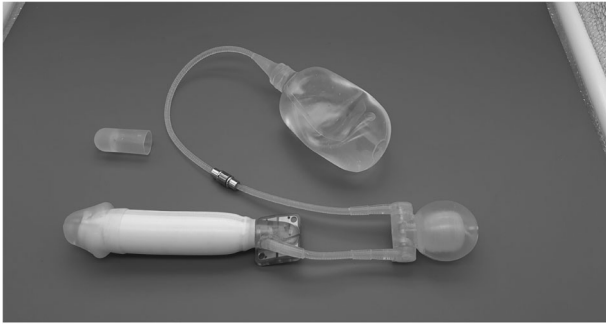
The penoscrotal approach provides better exposure of proximal corpora cavernosa, better concealment of the prosthesis, easier pump placement, and a more natural appearance. However, this approach is burdened by a higher risk of urethral injury and longer recovery time. On the other hand, the infrapubic approach allows direct access to the penile shaft, a direct vision in reservoir placement, shorter operative time, and an overall lower risk of infection. Controversies related to this approach are due to more visible scars and a higher risk of dorsal nerve injury [66].

In addition, the reconstruction of IPPs' history revealed the correct post-operative management. In prevention of postoperative oedema and haematoma, a compressive medication should be placed all around the penis, leaving the cylinders in partially erect mode to avoid penile retraction after the implant [67, 68]. Moreover, a scrotal drainage should be placed to decrease hematoma formation and increase patient comfort, even if this device has been controversial since opponents cite a risk of retrograde migration of bacteria [69]. In this context, in 2020, a retrospective study by Apoj et al. demonstrated that the placement of a short-term closed suction drain is a safe and effective approach, without a demonstrable increased risk of infection during the post-operative period [70].

## PENILE PROSTHESIS OVER THE ERECTILE DYSFUNCTION: IMPLANTS AFTER PHALLOPLASTY

The evolution of penile prosthesis has historically been guided by the will to find a definitive solution for ED capable of allowing a natural-like penetrative intercourse. In this regard, penile implants are also useful in creating a fully rigid neo-phallus in the process of gender-affirming surgery in transmen and of penile reconstruction after traumatic or surgical penile amputation. The first example of prosthesis implantation in a FtoM transgender patient was reported by Puckett and Montie in 1978 [71]. Since then several studies reported outcomes of penile implants after phalloplasty with commonly identified complications such as infection, protrusion, leak, dysfunction, and malposition [72].

With respect to the naïve penis, the implant of a prosthesis in a neo-phallus is more challenging due to the absence of the penis tunica albuginea, which gives a solid and protective anchored tissue, and the lower resistance of the neophallus tissues themselves [73]. Over the years, most reconstructive surgeons complained of the absence of specific devices for phalloplasty [74]. Finally, in 2016 was released the first phalloplasty-specific designed implant known as the Zephyr ZSI-475 FTM IPP [75]. This device is composed of a single inflatable cylinder of 21 mm in diameter and from 14 to 21 cm in length, with a distal glans-shaped stopper of 25 mm and a proximal anchorage plate made of stainless steel and silicone which could be sealed to the pubis periosteum with four non-adsorbable stitches allowing stability to the implant [76]. Moreover, the pump is a testicle-shaped implant that improves the aesthetical appearance of the scrotum [77]. Even if an optimal assessment of satisfaction of patients with IPP is still in



**Fig. 3** Zephyr ZSI-475 FTM inflatable penile prosthesis model.



**Fig. 4** 3D model of implanted and filled Titan Touch inflatable penile prosthesis by Coloplast brand.

development, current literature reports a high degree of satisfaction by patients with fully satisfying cosmetic and functional outcomes (Fig. 3) [73, 76, 78, 79].

#### FUTURE EVOLUTION OF PENILE PROSTHESIS AND CONCEPT

Technological development in recent years has not only aimed at the “naturalness” of sexual intercourse but also to solve potential technical aspects as well as make the implantation procedure safer (Fig. 4). Open questions of the scientific community, engineers and researchers are related to find the perfect materials, to make possible to build a touchless penile prosthesis, or even to make IPPs capable of function without fluid and without risk of leak of the hydraulic components.

Among the various concepts developed in the last years, there is the touchless IPP based on the principle of the self-filling of the cylinders with the sexual stimulus. This mechanism is possible thanks to a sacral neurostimulation-like implantable battery that receives central erectile stimulus and activates the filling of the pump [53].

Of particular importance in the development of new materials is the study of B. Le et al., published in 2016, in which a new penile prosthesis in nickel-titanium alloy (Ni-Ti) with shape memory (SMA) was presented. The thermoregulated Nitinol exoskeleton designed and prototyped with this IPP uses thermal variations induced by an external magnetic induction previously to any intercourse. This mechanism allows to modify the volume and prosthesis size demonstrating useful mechanical characteristics, including rigidity to buckling when activated, similar to a classic three-component IPP (2.62 kilograms-force (kgf) SMA vs 1.42 kgf inflatable penile prosthesis vs 6.45 kgf for a malleable prosthesis) [80, 81].

#### CONCLUSIONS

In a time interval of about 50 years there has been a constant improvement of penile implantable devices, to such an extent

that nowadays IPPs are associated with an extremely high patient and partner's satisfaction, excellent long-term outcomes and are considered the best treatment option not only for patients presenting with drug-refractory ED, but also for FtoM transmen and men who underwent penile reconstruction. An understanding of the historical process behind the evolution of currently available IPPs, as well as a better understanding of the state of art of modern devices, could drive further innovation to increase efficiency and satisfaction rates for patients.

#### DATA AVAILABILITY

Data and materials underlying this manuscript are available from online databases.

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## AUTHOR CONTRIBUTIONS

Conception and design of the study: PV, GC, SC. Data acquisition: AG, FS. Analysis and interpretation of data: FS, AG, SC, GC, CCR. Drafting the manuscript: AG, FS, SC, PV. Style revision: GC, CCR, PV. All authors revised the manuscript and read and approved the version submitted.

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## COMPETING INTERESTS

The authors declare no competing interests.

## ETHICS

The current manuscript is exempt from ethical committee approval.

## ADDITIONAL INFORMATION

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