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INVITED ORIGINAL ARTICLE

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Excellent long-term device survival of inflatable penile prosthesis over 27 years

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The study aimed to assess the long-term device survival of a 3-piece inflatable penile prosthesis (PP) in patients with erectile dysfunction (ED). This retrospective observational longitudinal study involved patients with drug-refractory ED who underwent primary 3-piece inflatable PP implantation at a single center from 1992 to 2019. The outcomes included complications of various inflatable PP models, and Kaplan–Meier analysis was used to estimate the probability of PP survival. Of the total 426 patients, 140 (32.9%) were implanted in the period of 1992–2000, 128 (30.0%) in the period of 2001–2008, and 158 (37.1%) in the period of 2009–2019. The PP used in the study included AMS 700 CX (62.0%, *n* = 264), AMS 700 CXR (7.7%, *n* = 33), AMS Ultrex Plus (10.3%, *n* = 44), and Alpha I (20.0%, *n* = 85). The overall complication rate was 28.2% (120/426), and the majority happened after 6 months. The causes of device removal included mechanical failure (11.0%, *n* = 47), infection (3.9%, *n* = 17), cylinder extrusion (6.3%, *n* = 27), and unspecified (0.2%, *n* = 1). Of the total mechanical failures (*n* = 47), 18 (38.3%) occurred in the cylinders, 10 (21.3%) occurred in the pump, 7 (14.9%) occurred in the reservoir, 6 (12.8%) occurred in the connections, and 6 (12.8%) were nonspecific. Global average survival rates of the PP at 1 year, 5 years, 10 years, and 15 years were 96.2%, 86.7%, 77.5%, and 58.7%, respectively. The 3-piece inflatable PP has an excellent device survival rate at 5 years and 10 years.
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Keywords: device survival; erectile dysfunction; infection; mechanical failure; penile prosthesis

INTRODUCTION

Erectile dysfunction (ED) is one of the most common sexual disorders in men[1] with an overall global prevalence of 13.1%–71.2% varying from mild-to-severe intensity across various age groups.[2] Vascular risk factors such as hypertension, hyperlipidemia, diabetes, metabolic syndrome, and smoking have been commonly implicated to cause endothelial damage leading to ED.[3]

Frederick *et al.*[4] reported that ED is very much undertreated, and only 25.4% of 6.2 million men with ED in the USA with commercial insurance received treatment for ED in 2010–2011. Pharmacological therapy with phosphodiesterase type 5 inhibitors (PDE5is) is usually the first choice in the absence of contraindications.[5] In case of failure of these drugs, other nonsurgical validated options include intracavernosal or intraurethral prostaglandin E1 and vacuum erection devices.[6] Medical treatment offers effective results; however, it is associated with a high percentage of nonadherence and/or tolerance and loss of effectiveness (up to 80.0%).[7] In these circumstances, the implantation of a penile prosthesis (PP) is considered a third-line therapy as per the European Association of Urology (EAU) guidelines.[8] PP can be malleable or inflatable devices (2–3 components). PP allows patients and their partners to obtain high rates of satisfaction in their sexual relationships, with percentages of over 80% in most publications.[9,10] Over the years, technological advances in PP have improved the mechanical reliability and durability of these devices. However, complications related to its implantation are known and can occur during or after the intervention.

We present the outcomes of primary 3-piece inflatable PP done on 426 new patients over 27 years (1992–2019) at Gregorio Maranon University General Hospital (Madrid, Spain), which included the type of devices used and the overall outcomes (infection, causes of mechanical failure, and long-term device survival) over a long period.

PATIENTS AND METHODS

This retrospective observational longitudinal study is based on the electronic clinical data registry of Gregorio Maranon University General Hospital. Institutional review board (IRB) approval was obtained from Gregorio Maranon University General Hospital (Approval No. HGUGM/24/121). The study population consisted of patients with drug-refractory ED who underwent 3-piece inflatable PP implantation for the first time during the period of 1992–2019. All these patients had signed the informed consent form before surgery, which mentioned that their clinical data would be used for academic purposes without their identity being revealed. The inclusion criteria were men aged ≥18 years with a diagnosis of ED refractory to drug treatment and underwent primary (first time) surgical placement of 3-piece

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inflatable PP. Patients who underwent reimplantations and concomitant penile reconstructive surgeries (phalloplasty) were excluded. All PP candidates were previously evaluated in the center's andrology clinic by a group of urology specialists who were experts in the treatment of ED. All ED patients were managed per the EAU guidelines.[8]

Clinical–demographic characteristics, complications, and device survival at the end of the review period were analyzed. Kaplan–Meier product limit method and comparison using the log-rank test were used to estimate the 5-, 10-, and 15-year device survival. Binary logistic and Cox regression analyses were used to assess whether baseline characteristics such as PP brand, PP model, InhibiZone coating, time period, and urethral injury were associated with device survival.

RESULTS

A total of 426 patients met the inclusion criteria. Of the total 426 patients, 140 (32.9%) were implanted in the period of 1992–2000; 128 (30.0%) in the period of 2001–2008, and 158 (37.1%) in the period of 2009–2019. The mean age of the patients at the time of implantation was 56.7 (range: 29–87, standard deviation [s.d.]: 10.2) years. The most frequently identified etiology was vascular (48.6%, n = 207), followed by radical prostatectomy (18.1%, n = 77) and Peyronie's disease (PD; 16.7%, n = 71). The mean follow-up time was 87.4 (s.d.: 53.6) months.

The time between the first consultation for ED and PP implantation was more than 60 days in 84.4% of the patients. Of the 426 patients, 63.8% (n = 272) received PDE5i, and 69.7% (n = 297) received intracavernosal prostaglandin E1 injections. There was adherence to ED treatment before PP in 79.8% (n = 340) patients. The most common reason for PP implantation was refractoriness to the previous treatment.

The commercial brand of PP used was AMS (currently owned by Boston Scientific, Marlborough, MA, USA, and previously owned by American Medical Systems, Minnetonka, MN, USA; 80.0%, n = 341) and Alpha I (currently owned by Coloplast, Minneapolis, MN, USA and previously owned by Mentor, Santa Barbara, CA, USA; 20.0%, n = 85), as shown in **Table 1.** The AMS models used were AMS 700 CX (62.0%, n = 264), AMS 700 CXR (7.7%, n = 33), and AMS Ultrex Plus (10.3%, n = 44). Alpha I (n = 85, 20.0%) was the only model from Coloplast implanted in all these cases. The cylinders (diameter) were "standard" in 393 (92.3%) cases, whereas narrow cylinders (narrow base, CXR, or equivalent) were required in 7.7% (n = 33) of cases. Antibiotic-coated devices (InhibiZone) were implanted in 209 (49.1%) patients. The flat conceal reservoir was placed in 94 (22.1%) patients, the rest conventional. The reservoir was placed in the space of Retzius in 402 (94.4%) patients. The most commonly done approach was penoscrotal in 414 (97.2%) patients, followed by infrapubic in the remaining 12 (2.8%) patients. The infrapubic approach was done in 12 (2.8%) patients for the following reasons: surgical demonstration of an alternative (infrapubic) technique for residents during training and patient preference. IPPs were placed by a single surgeon and sometimes by a resident directly supervised by the same surgeon, so the technique remained the same at the university hospital.

Table 1: Various models of 3-piece inflatable penile prosthesis implanted in our series

Inflatable penile prosthesis	*Patient (total=426), n (%)*
AMS 700 CX	264 (62.0)
Alpha I	85 (20.0)
AMS 700 CXR	33 (7.7)
AMS UltrexPlus	44 (10.3)

AMS: American Medical System

All patients undergoing surgery received antibiotic prophylaxis during anesthesia induction. A beta-lactam or cephalosporin antibiotics were primarily used in 325 (76.3%) cases. Quinolones were added along with primary antibiotics in 93 (21.8%) patients and fluconazole in 8 (1.9%) patients. Reconstituted rifampicin solution was used for intraoperative intracavernosal antibiotic irrigation in all patients. Gloves were changed a minimum of 2 times, and contact of the components of PP with the skin was avoided to the extent possible.

Complications

The various complications were categorized as follows. (1) Intraoperative (1.9%, n = 8): urethral perforation (1.2%, n = 5), and proximal perforation of the corpus cavernosum (0.7%, n = 3). (2) 0–1 month (4.4%, n = 19): early (30 days) complications were graded according to the modified Clavien system,[11] and all were grade 1–2. Hematoma was the most frequent complication (2.3%, n = 10), followed by wound infection in 8 (1.8%) cases and wound dehiscence in 1 (0.2%) case. (3) 1–6 months (4.2%, n = 18): the most frequent cause was a mechanical failure (1.8%, n = 8), followed by infection (0.9%, n = 4), cylinder extrusion (0.9%, n = 4), and supersonic transporter (SST) deformity (0.5%, n = 2). And (4) after 6 months (17.6%, n = 75): the most common cause was mechanical failure (9.1%, n = 39), followed by cylinder extrusion (5.4%, n = 23), delayed infection (1.6%, n = 7), and others (1.4%, n = 6).

Infection

The infection of PP leading to device removal was noted in 17 (3.9%) patients: 7 of 140 patients (5.0%) were removed in the period of 1992–2000, 5 of 128 patients (3.9%) in the period of 2001–2008, and 5 of 158 patients (3.2%) in the period of 2009–2019, without significant differences in the analysis by the time period (all $P > 0.05$). The majority (13/17, 76.4%) of the devices removed due to infection did not have InhibiZone coating. Multivariant study-binomial logistic regression revealed that the use of devices without InhibiZone ($P = 0.03$) and the occurrence of postoperative hematoma ($P < 0.001$) were the significant risk factors for developing infection. The time period ($P = 0.421$), the brand of PP (AMS *vs* Coloplast, $P = 0.126$), and mechanical problems ($P = 0.196$) had no impact on the infection outcome.

Mechanical failure

The incidence of mechanical failure was 47 (11.0%). The incidence of malfunction was almost equivalent in the period of 1992–2000 (15.0%, n = 21) and 2001–2008 (14.0%, n = 18). However, the mechanical failure was significantly lower in 2009–2019 (5.0%, n = 8). Of the total mechanical failures (n = 47), 18 (38.3%) patients occurred in the cylinders, 10 (21.3%) patients in the pump, 7 (14.9%) patients in the reservoir, 6 patients (12.8%) in the connections, and 6 (12.8%) patients were nonspecific. The majority (82.9%, 39/47) of these mechanical failures appeared after 6 months of implantation. Coloplast PP (21.1%, 18/85) showed a higher rate of mechanical problems compared to AMS (8.5%, 29/341). According to the binary logistic regression, the prosthesis brand (Coloplast *vs* AMS, $P = 0.009$), model of the device (Alpha I: 21.1%, n = 18; AMS 700: 8.4%, n = 25; and AMS UltrexPlus: 9.0%, n = 4; $P = 0.006$), and the time period (1992–2000, 2001–2009, and 2010–2019, $P = 0.006$) were significant risk factors to develop mechanical complications.

Mechanical failure-free survival of the PP at 5 years, 10 years, and 15 years in our series was 94.7%, 87.3%, and 72.9%, respectively (**Figure 1**)**.** Considering the different time periods, the rate of device removal was significantly lower in the period of 2009–2019 in comparison to the period of 1992–2000 and the period of 2001–2008 (13.3%, 27.8%, and 25.0%, $P < 0.05$; **Table 2**).

Table 2: Causes of device loss according to time period

Cause of device loss	*Total=426*	*1992–2000 (total=140)*	*2001–2008 (total=128)*	*2009–2019 (total=158)*
Mechanical failure, *n* (%)	47 (11.0)	21 (15.0)	18 (14.0)	8 (5.0)
Infection (requiring device removal), *n* (%)	17 (3.9)	8 (5.7)	5 (3.9)	4 (2.5)
Cylinder extrusion, *n* (%)	27 (6.3)	9 (6.4)	9 (7.0)	9 (5.7)
Nonspecified, *n* (%)	1 (0.2)	1 (0.7)	0 (0)	0 (0)
Total device lost, *n* (%)	92 (21.5)	39 (27.8)	32 (25.0)	21 (13.3)

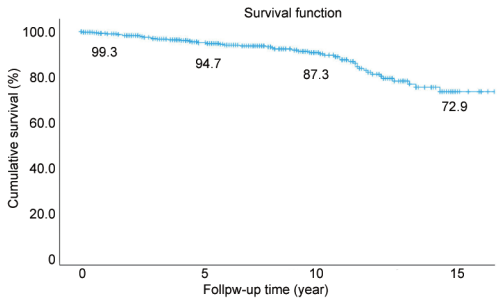

Figure 1: Device survival free of mechanical complications.

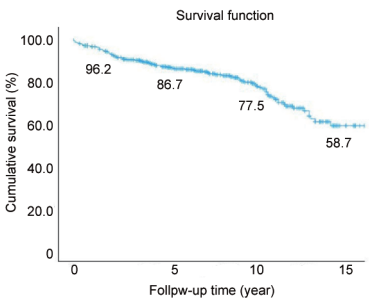

Figure 2: Cumulative survival of device at 1 year, 5 years, 10 years, and 15 years.

The maintained functionality of the PP at the last follow-up was 78.4% (n = 334). Global average survival rates of the PP at 1 year, 5 years, 10 years, and 15 years were 96.2%, 86.7%, 77.5%, and 58.7 %, respectively (**Figure 2**). According to the brand of PP (AMS *vs* Coloplast) at the same time period, AMS had slightly better device survival but was not statistically significant (P = 0.17; **Figure 3**). However, AMS UltrexPlus showed significantly lesser device survival at 5 years, 10 years, and 15 years (log-rank [Mantel-Cox]: 0.032) when global survival rates were analyzed based on the model of PP. In the logistic binomial regression analysis, risk factors significantly influencing the functioning of the PP at the last follow-up were the brand of PP (AMS *vs* Coloplast, P < 0.04), model of PP (Alpha I *vs* AMS 700 CX *vs* AMS UltrexPlus, P = 0.03), time period (P = 0.012), use of InhibiZone devices (P = 0.003), urethral comorbidity/iatrogenic injuries (P < 0.001), infection (P < 0.001), and mechanical problems (P < 0.001), as shown in **Table 3**.

DISCUSSION

We analyzed a consecutive series of 426 primary 3-piece inflatable PP implantations at a single center over 27 years. The results corroborate that the 3-piece inflatable PP implantation constitutes a safe and effective treatment for the treatment of ED considering the acceptable intra- and post-operative complications. We recorded an intraoperative complication rate of 1.9%, with proximal perforation of the corpora cavernosa and urethra as the causes. Similarly, Pozza *et al.*[12] reported an intraoperative complication rate of 5.2% in a series of 500 patients, whereas Chung *et al.*[13] reported 1.1% of intraoperative complications among the 955 PP surgeries performed.

The risk of infection in PP surgeries varied widely, ranging between 3% and 25%, depending on surgical indication, patient characteristics, and study design.[14–16] The overall infection rate was 3.9% in our series after having followed the standard infection control practices of our center. Manufacturers have invested significant resources in designing their devices to improve their performance and reduce infectious and mechanical complications.[17,18] Measures to alleviate infection, changes in the material composition of the cylinders, the security of the connections, and the manageability of the pump are some of the main milestones in the evolution of modern-day PP.[19] Our series included patients who underwent surgery before and after the introduction of PP with antibiotic coating and/or hydrophilic surfaces. AMS introduced InhibiZone coating composed of minocycline and rifampin in 2000.[20] We observed significant differences in infection rates between the use of PP with and without InhibiZone coating (1.9% with InhibiZone *vs* 6.0% without InhibiZone, P = 0.03). The severity of the infection was greater in the period of 1992–2000 (before InhibiZone introduction) with 66.6% of Gram-negative bacterial purulent infections compared to the other groups. We are currently reconsidering our perioperative antibiotic prophylaxis guidelines. The addition of systemic antifungal medications in the infectious prophylaxis of certain patients (especially those with diabetes) is being considered in the background of recent studies,[21,22] highlighting the importance of antifungal prophylaxis.

Device survival rates of 86.7%, 77.5%, and 58.7% at 5 years, 10 years, and 15 years, respectively, in our study are comparable with other major studies.[10,13,23] A meta-analysis published in 2022 reported similar rates of 87.2% and 76.8% at 5 years and 10 years, respectively.[23] Similarly, Chung *et al.*[13] reported overall device survival of 90.8% and 85.0% at 5 years and 10 years among the 955 PP implantations. An Italian academic center reported a device survival rate of 53% for inflatable PP at 20 years.[10] Overall, we had 78.4% (334/426) functioning devices in our PP program for 27 years. The type of prosthesis (both brand and model; better device survival with AMS), iatrogenic urethral injury, infection, and mechanical failure were the factors that affected the long-term survival of PP. Chung *et al.*[24] reported a slightly better 5-year device survival rate with AMS 700 PP when compared to Coloplast Titan but was statistically insignificant (91% *vs* 87%, P > 0.05). Overall functioning rates of PP in our series were 61.4% with AMS Ultrex, 70.6% with Alpha I, and 83.1% with AMS 700 CX.

There have been progressive improvements in the inflatable PP technology to provide a more durable PP with lower infection rates. Notable improvements include the incorporation of kink-resistant tubings, changes in the weave or addition of shear- and infection-resistant coatings to cylinder layers, pump and tubing connection modifications, the addition of rear-tip extenders, and the incorporation of lockout valves to prevent autoinflation.[25]

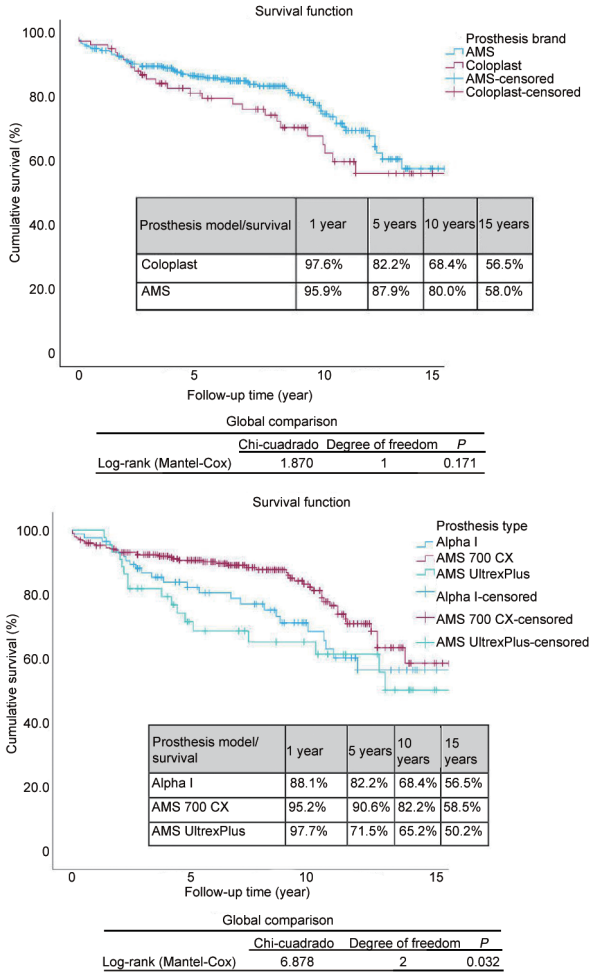

Figure 3: Device survival at 1 year, 5 years, 10 years, and 15 years based on various models of penile prosthesis.

Table 3: Cox regression analysis of various factors influencing device function at the last follow-up

Factors influencing device function at last the follow-up	*P*	*Hazard ratio*
Brand (AMS *vs* Coloplast)	0.146	2.170
Model of prosthesis	0.024	2.263
InhibiZone coating	0.382	1.301
Urethral comorbidity and iatrogenic injuries	<0.001	6.885
Infection	<0.001	48.109
Mechanical problems	<0.001	17.655
Time period	0.651	1.099
Postoperative hematoma	0.9	1.082
Cylinders length	0.690	1.021
Rear tip extender length	0.621	1.063

AMS: American Medical System

AMS Ultrex Plus was designed to provide controlled cylinder expansion in girth and length. Compared to other PP in our series, AMS Ultrex Plus showed the worst results; 95.4% of AMS Ultrex Plus were implanted in the period of 1992–2000 and the remaining 2 (4.6%) in the period of 2001–2008. Cylinder extrusion (47.0%) and infection (29.4%) were the most common causes of loss of the Ultrex Plus PP. Similarly, Montague *et al.*[26] recommended using girth-expanding CX cylinders for better penile straightening properties than girth and length-expanding Ultrex cylinders in Peyronie's disease. In the time period of 1992–2000, Alpha 1 devices were lost mainly due to mechanical problems (86.6%), but only 13.4% of these Alpha I PP suffered infection as a main cause of failure. The limitations of our study are the retrospective nature of the study and recall bias, as some of the clinical data of the patients were collected over a telephonic interview.

The developments in the design technology of the PP, improvements in surgical techniques, reduced operative time, and optimized antibiotic prophylaxis have a global influence on the outcomes of PP surgery. Also, the accuracy in reducing urethral morbidity and the use of PP with fewer mechanical problems allow for better long-term results providing excellent patient and partner satisfaction rates.

CONCLUSIONS

Penile prosthesis implantation should be the treatment of choice in patients who do not respond adequately or become intolerant to nonsurgical treatment strategies. However, the implantation of PP may have a nonnegligible rate of potential complications that must be counseled to all patients before the surgical intervention to help patients and their partners have realistic expectations. The availability of various models of PP and their long-term outcomes depending on various clinical scenarios should be discussed with the patient. We recommend that the penile prosthesis surgery be performed in high-volume and experienced centers for the best satisfaction rates and least complications.

AUTHOR CONTRIBUTIONS

IM and ELG conceived and designed the study and collected the data. ELG and PK performed the statistical analysis. IM, PK, and ELG wrote the manuscript. IM, PK, JIMS, LPPH, FJGG, CHF, and ELG interpreted the data and revised the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

All authors declare no competing interests.

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