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Original Article

Initial experience of a single center with the use of ZSI 475 penile prosthesis

Fulvio Colombo [a], Giorgio Gentile [a,*], Valerio Vagnoni [a], Alessandro Fiorillo [b], Pietro Piazza [b], Fabrizio Sartorio [b], Alessandro Franceschelli [a]

[a] *Andrology Unit, University Hospital S. Orsola-Malpighi, Bologna, Italy*
[b] *Department of Urology, University of Bologna, Bologna, Italy*

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Abstract *Objective:* To evaluate surgical outcomes after implantation of the Zephyr ZSI 475 inflatable penile prosthesis (IPP) and patients' quality of life.
Methods: From December 2014 to September 2018, 15 patients underwent prosthesis implantation with ZSI 475. A retrospective review of clinical data was performed. Patients' quality of life after implantation was investigated with Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire.
Results: The median age of patients was 57 years and the average follow-up time was 22 months. Twelve patients received a standard implantation due to severe erectile dysfunction (ED); three patients also presented penile curvature and additional corporoplasty with grafting was necessary. Three procedures had to be interrupted due to defects of the insertion tools. In one case a manufacturing defect resulted in a pump leak. In one case, a severe postoperative complication occurred, which requested explanation of the device. During the follow-up, four patients experienced mechanical failure of the prosthesis. Results of QoLSPP questionnaire at 12 months were skewed toward the positive end of the scale in all domains.
Conclusion: In our initial experience, ZSI 475 suffered a high rate of mechanical failures; on the other hand, the company showed great commitment in order to improve the quality and reliability of the device. The lower cost of ZSI 475 may add to the chances of the product to become a cost-effective alternative to treat those patient who need a IPP.
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* Corresponding author.
E-mail address: dr.giorgio.gentile@gmail.com (G. Gentile).
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1. Introduction

The implantation of a penile prosthesis (PP) is the first line of treatment for men with severe medical-refractory erectile dysfunction (ED) and also in the case of associated penile deformity due to Peyronie's disease (PD) [1—3].

Since 1970, the time of their first appearance, PP devices have progressively improved, becoming not only more reliable but also easier to be implanted and to be used; currently, the three-piece inflatable penile prosthesis (3p-IPP) is considered as the "gold standard" in this field [4,5].

The three components of this device consist in a reservoir that is placed in the abdomen, a pump that is positioned into the scrotum and two cylinders inserted into the corpora cavenosa.

In comparison with any other treatment for ED, IPP is associated with the highest satisfaction rate for the patient [6].

A possible reason of unsatisfaction after IPP implantation is the patient's perception of a shortening of the penis, which is more frequent in patients who have previously undergone radical prostatectomy and in those with concurrent PD [1].

In the last 40 years, many modifications to IPP have been introduced, in order to prevent mechanical failure of the devices and postoperative complications.

The better build quality of the devices, as well as the standardization of the surgical steps, have helped to reduce operating time and infection rates, improving general outcomes [7].

The two principal companies producing PP-AMS (American Medical Systems Inc., Minnetonka, Minnesota, USA) and Coloplast (former Mentor, Humlebæk, Denmark) have both proposed major improvements in their products over time [5].

The most relevant technical advancements in IPP concerned the quality and sturdiness of the cylinders that nowadays are less subject to structural stress (pseudo-aneurysms) as well as their greater resistance to infections.

The pump has been also modified, in order to facilitate cylinders inflation and deflation (the so-called "momentary squeeze" for AMS, and "One-Touch Release" for Coloplast) [8].

In recent years, also an European company, the Zephyr Surgical Implants (Switzerland), introduced a new IPP model: The ZSI 475 (Table 1). The device is provided in a standard size kit (Fig. 1) that contains all the necessary components for surgical implantation. Different sizes of inflatable cylinders are included. The woven fabric of the cylinders consists of an inflatable part, made of three layers (silicone-tissue-silicone), a cover with hydrophilic polyvinylpyrrolidone (PVP) coating. The proximal part is narrow and flexible (Fig. 2), allowing an easier insertion and reducing perineal pain after the procedure.

The armed tubings exit 4 cm away from the proximal extremity, in order to reduce the portion of tubing left inside the corpus cavernosum. The pump has a simple mechanism with open/close valve in order to reduce the risk for mechanical failure; moreover, there is a reinforced valve to decrease the risk of incidental auto inflation of the cylinders.

In this paper, we report a single-center initial experience with this new device, concerning its mechanical reliability and the postoperative patient's satisfaction rate.

2. Materials and methods

In recent times, Zephyr' 450 IPP won a public tender in our hospital (Sant'Orsola-Malpighi University Hospital, Bologna, Italy) thanks to technical characteristic considered as equivalent to those of the competitors and with a significant lower cost (30% less).

From December 2014 to September 2018, 15 patients with severe ED undergone surgical implant of ZSI 475 3p-IPP, in our institution.

Patients' features, causes of ED and possible cardiovascular risk factors were collected. Indication for surgery was given in case of organic ED refractory to any medical treatment. Each patient received a detailed explanation about risks related to the procedure, and a specific informed consent was obtained ("Evaluating oncologic and functional outcomes of patients treated for the most common benign and malign urological diseases in the Sant'Orsola-Malpighi University Hospital Urologic Department"; protocol number: STUD-OF, Ethics Committee of Alma Mater Studiorum, University of Bologna). Exclusion criteria included psychiatric illness, genital or systemic infections and any condition affecting wound healing.

A retrospective review of all clinical reports was performed and data were collected. Each patient was then contacted by phone and asked to return to out-patient visit for long-term clinical examination. On this occasion, every patient was asked to fill the validated Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire [9].

As described by Caraceni and Utizi [9], this specific questionnaire was the result of a conceptual model that considers four components of QoL, according to the fundamental parameters identified in the World Health Organization's (definition of health as biological and psychosocial-relational well-being) [10]: Functional, to evaluate the patient's degree of satisfaction regarding the functionality of the prosthesis; relational, to investigate the relationship with their partner in terms of quality of sexual intercourse; social, to evaluate the quality with the relation to the outside world and personal well-being, to assess post-implantation self-esteem.

Results are structured according to a six-point Likert scale [11], in most cases ranging from "never" (0) to "always" (5), where higher values represent more positive responses. Each interview was conducted by the same physician. During the interview, the patient and his partner were accommodated in different areas.

The study was performed according to the principles of Good Clinical Practice 1996 (Directive 91/507/EEC; D.M. 15.7.1997) and the Declaration of Helsinki. All patients provided written informed consents.

Means, medians and interquartile ranges were reported for continuous variables. Frequencies and proportions were reported for categorical variables. Kaplan—Meier method was used to assess the overall survival of the 3p-IPP in the entire population. All analyses were carried out using SPSS IBM Statistics® v. 22.0 (IBM Corp., Armonk, NY, USA).

Table 1 Comparative table: Main characteristics of AMS-Boston, Coloplast and Zephyr surgical implants devices.

Company	Model	Access	Length (cm)	Cylinders, tubing and coating	Pump and reservoir
AMS-Boston	AMS 700 LGX™ preconnect AMS 700 CX preconnect AMS 700 LGX AMS 700 CX AMS 700 CXR preconnect	Infrapubic Penoscrotal	12-15-18-21 (AMS 700 LGX) 12-15-18-21-24 (AMS 700 CX) 10-12-14-18 (AMS 700 CXR Preconnect)	- Three-ply design of the cylinders consisting of an inner silicone layer that abutted a silicone-coated unidirectional woven Dacro-Lycra fabric layer - With—without InhibiZone™ coating (antibiotic impregnation rifampicin and minocycline hydrochloride) - Kink-resistant tubing	- Momentary Squeeze pump (smaller than previous pump and easier deflation due to the quick squeeze button) - Lockout valve (within the pump) in order to reduce the risk of auto-inflation - Conceal Reservoir (flat reservoir)
Coloplast	Titan touch Titan touch narrow base	Infrapubic Penoscrotal	14-16-18-20-22 (Titan touch) 11-14-16-18 (Titan touch narrow base) 24-26-28 (XL sizes)	- Bioflex® (polyurethane material) allows very good tensile strenght without compromising biocompatibility of the cylinders - Soft-molded cylinder tips - Hydrophilic coating - Zero-degree tubing	- Touch pump (single touch button that allows natural deflection of the device) - Cloverleaf reservoir (low risk of self-inflation with the block valve ™)
Zephyr Surgical Implant	ZSI 475	Penoscrotal	12-15-18-21 22-25 (XL sizes)	- Cylinders: three layers (silicone-tissue-silicone) reducing the risk of accidental piercing during the procedure; narrow and flexible proximal portion - Hydrophilic PVP coating - Armed tubings with a redoubt portion running inside the corpus cavernosum	- Pump with open/close valve (reduced risk for mechanical failure), longer exit tube to decrease the risk of breakage and softer valve axle with button to ease deflation - Reinforced valve within the pump (low risk of incidental auto-inflation) - Reservoir preconnected to pump

PVP, polyvinylpyrrolidone.

Figure 1 ZSI 475 standard size kit.

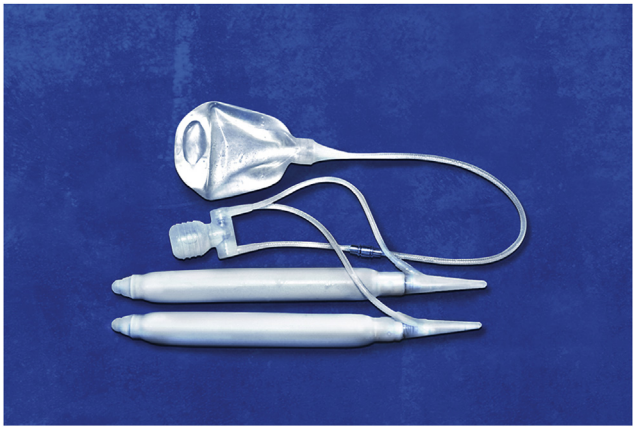

Figure 2 ZSI 475 aspect with flexible rear tips.

3. Results

Between December 2014 and September 2018 a total of 15 patients were implanted using the new ZSI 475 3p-IPP. The peno-scrotal approach was performed in all cases. The median age of patients was 57 years (range, 40—78 years) and the average follow-up was 22 months (range, 3—48 months). Twelve patients received a standard implantation due to severe ED; three patients presented penile deformity due to Peyronie's disease and requested associated surgical treatment consisting in albugineal incision and grafting, or covering (two bovine pericardial matrix and one fibrin-coated collagen fleece).

Median operating time was 130 min. At the beginning of our experience with the new devices, three procedures had to be interrupted due to defects of the insertion tools and then resumed after resolution of the technical problem, with consequent extension of the operating time. In two of these three cases, the eye of the needle broke during insertion, and in one case the tympanum of the introducer was defective. In all three cases, the opening of a new prosthetic kit was necessary. In one patient a manufacturing defect resulted in leakage from the pump, which was detected during the last check before the end of the procedure and required immediate prosthesis substitution. In one patient, an accidental needle prick of the pump-cylinders connection-tube occurred, and needed prosthesis substitution. No intraoperative complications were observed in the 10 patients and blood transfusion was never required.

Only one severe postoperative complication was observed, consisting in the ischemia and partial necrosis of the glans, which requested urgent explantation of the device, with subsequent evidence of prosthesis infection. During hospitalization, one patient experienced hyperpyrexia that has been controlled by antibiotic therapy.

During the out-patient follow-up, four patients (26%) experienced mechanical failure of the prosthesis due to rupture or kinking of the pump-cylinders connection-tube: In all of these cases, a surgical revision was needed with prosthesis replacement. No complaints of genital pain were recorded. Estimated overall survival according to the Kaplan Meier method of ZSI 475 is reported in Fig. 3.

Results of QoLSPP questionnaire at 22 months (14 patients) were skewed toward the positive end of the scale in all domains: 41% of responses to several items were maximum values.

About each specific conceptual area of the questionnaire we only registered the minimal value one of four domains (relationship with partner).

In "functional domain", in order to assess satisfaction of the prosthesis function, we found that the mean of answers to the all questions of the area ran from 4 to 5, which means "almost always to always", in over 92% of patients. Only one patient answered by using value 2 (half of times) in adequacy and expectation questions. More than 50% of the patients reported increased rigidity of their penis after the implant, in comparison with that obtained before the operation.

With regards to the "relationship with partner" domain, in terms of quality of sexual intercourses, we registered that two of 14 patients answered in a mean of maximum value (5). In 87% of patients, each response fell in the positive side of the scale. Three patients used the value 1 ("less than half of times") to refer to partner satisfaction.

Interestingly, in order to evaluate the quality of relation to the outside world, 100% of mean values of patient answers in the "social domain" fell in the positive side of the scale. Only one patient (7%) reported a "more negative than positive sensation" about feeling like "others".

We found more differentiated values in "personal well-being domain", in which exactly 50% of means values of patients responses were 5, which means "very satisfied". Five patients released responses obtaining mean values between 3 and 4, which means "quite satisfied". Only two patients (14%) registered mean values under equal to 2 (poorly satisfied) (Table 2).

4. Discussion

The 3p-IPP is the gold standard for the treatment of severe medical-refractory ED and the only possible treatment in order to restore both erectile function and penile straightening in patients with PD associated with ED. Worldwide, over the last decades, 3p-IPPs have been produced and

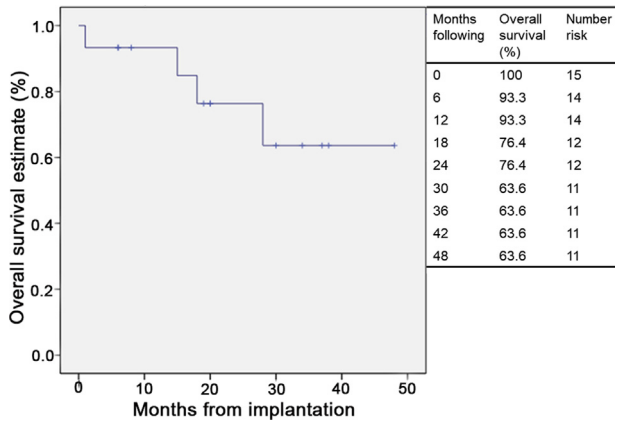

Figure 3 ZSI 475 Kaplan-Meier overall survival estimate (%).

marketed by two brands: AMS and Coloplast [1]. In the recent years, Zephyr surgical implants have been proposed on the market, a new 3p-IPP, the ZSI 475, and some preliminary reports on these devices have been published [12—13].

In our initial experience with this new prosthesis, the operating time resulted significantly longer than our standard. This was caused by problems occurred during the first 10 procedures, mainly represented by defects of the prosthesis' insertion tools and, in two cases, by prosthesis damage requiring substitution. Subsequently to these initial issues, our feedback to the company led to some technical modifications and improvements: The needle and the introduction thread were modified, while the introducer provided remained unchanged. The latter still represents, in our opinion, a weak point of this product, less handy than the traditional Furlow introducer.

The surgical procedure does not present any particular difference in comparison with the standard 3p-IPP implantation, and there is no need of a learning curve for surgeons already experienced with AMS or Coloplast prosthesis [13].

As regards to prosthesis reliability, at the median follow-up of 22 months we found a very high rate of mechanical failure 26%, occurring mostly after the first year of implantation which doesn't appear to be the most critical period for PP implantation as stated by other authors [13]. Overall prosthesis survival appears to be considerably lower compared to the ones described about other devices [13—14]. In all cases of our series, the prosthesis failure was caused by rupture or kinking of the pump-cylinders connection-tube that seems to be a critical part of the device, also in the early models of the other penile prosthesis [8].

Recently, Zephyr Surgical Implants modified the pump-cylinders connection tube of ZSI 475 developing an additional reinforcement that should provide more sturdiness to the prosthesis.

QoLSPP questionnaire, the only tool specifically designed to measure patient satisfaction after IPP implantation [9], showed in all this four domains (functional, relational, social and personal well-being) a very good satisfaction rate with 91% of responses falling on the positive side of the scale and 41% of responses with maximum values.

In particular the functional domain, which explored the prosthesis function, showed a very high level of satisfaction considering that the mean of the answers to all questions of the area ran to "almost always to always", in over 92% of patients, despite the high rate of mechanical failure 26%. This data can be explained by the intensive pre- and post-operative counseling that every patient received, which allowed us to provide the patient with realistic expectations about the IPP implantation, to instruct the patient to a correct use of the device and to promptly detect and manage postoperative technical issues [15,16]. Furthermore, as many authors suggest, being all surgical procedures performed by the same surgeon with a wide experience in penile implantation, we think that surgeon's experience could be a predictor of satisfaction in this kind of surgery [17].

Also the "relationship with partner" domain showed a high rate of satisfaction, with 87% of patients' responses

Table 2 QoLSPP questionnaire item scores.

Domains	Item	Valid responses (*n*)	Mean	Median
Functional	Prosthesis adequacy	15	4.38	5
	Ease/simplicity of use	15	4.50	5
	Duration of implant	15	4.53	5
	Penile rigidity	15	4.00	4
	Fulfillment of expectations	15	3.92	4
Personal	Sexual desire	15	4.23	4
	Liveliness and wit	15	3.76	4
	Security	15	3.92	4
	Sexual experience	15	4.15	4
Relational	Well-being of the couple	15	3.76	4
	Frequency of orgasms	15	4.30	4
	Frequency of sexual intercourse	15	3.30	3
	Partner satisfaction	15	3.53	4
Social	Daily life	15	4.07	4
	General well-being	15	3.84	4
	Feeling like others	15	3.84	4

QoLSPP, Quality of Life and Sexuality with Penile Prosthesis.

falling in the positive side of the scale, even if this data are lower compared with the results of other domains. Partner satisfaction is an important factor in the overall satisfaction perceived by patient who has undergone IPP [18], however, as appears in our study, satisfaction rates between patient and partner can be dissimilar [19,20].

Interestingly, the best result of QoLSPP questionnaire was obtained in the social domain, which evaluates the quality of relation of the patient with the outside world, whereby the 100% of mean values of patient answers fell in the positive side of the scale. This result can be influenced by the psychosocial effect of IPP implant, which could lead to more positive emotions, improved self-esteem and enhancement of male identity [16,21].

In the last domain, investigating the "personal well-being", 86% of patients were found to be satisfied after surgery. This is the lowest value obtained and maybe it could be influenced by the high number of complications that required a surgical correction (four prosthesis replacement due to mechanical failure and one prosthesis explantation due to postoperative infection). In all cases of mechanical failure, the patients accepted or requested to undergo a replacement surgery, confirming the acceptable tolerance for surgery, and mainly, a high compliance with the patient's expectations despite the failure of the first device [18,22,23].

This study has several limitations: First of all its retrospective nature could entail limitations to assessment satisfaction, since the passage of time can change or blur our patient's point of view [24]. The small number of patients involved in the study is another important limitation, as well as the short duration of the follow-up: Larger cohorts with and longer follow-up are doubtlessly needed.

Besides, considering the accuracy of data collection and the innovative tool used to assess patient's satisfaction, in our opinion this study could be considered an interesting report about a new IPP model that is still poorly known. At the best of our knowledge this is the first single center study about ZSI 475 IPP.

5. Conclusion

The new Zephyr ZSI 475 IPP seems to be burdened by a higher rate of mechanical failures, if compared with the data of literature and also with our previous experience with other devices. This can be related to the running-in period of the device manufacturing. We observed a persistent technical improvement of the device over the course of the period considered in this study, with a decreasing rate of mechanical failures.

We observed a very high level of satisfaction associated with the complete restoration of sexual activity in all of our patients, which is the most important goal in penile prosthesis surgery.

PP is a really expensive procedure, and cost can be considered an important drawback since only few patients can really afford the device. The retail price of the ZSI 475 is around 30% lower than competitors', which may add to the chances of the product to become a cost-effective alternative to treat those patients who need a penile prosthetic implant.

Author contributions

Study design: Giorgio Gentile, Fulvio Colombo.
Data acquisition: Giorgio Gentile, Pietro Piazza, Fabrizio Sartorio, Valerio Vangogni, Alessandro Fiorillo.
Data analysis: Giorgio Gentile, Valerio Vagnoni.
Drafting of manuscript: Giorgio Gentile, Alessandro Franceschelli, Fulvio Colombo.
Critical revision of the manuscript: Fulvio Colombo, Giorgio Gentile.

Conflicts of interest

The authors report no conflict of interest.

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