

# Safety and efficacy outcomes of ZSI 475 penile prosthesis

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## ABSTRACT

**Objective:** The aim of this study was to demonstrate safety and efficacy of ZSI 475 hydraulic penile prosthesis three components. Preparation, procedure and functional results are similar to AMS 700 and Coloplast Titan. This study was conducted from September 2012 to December 2016.

**Patients and method:** From September 2012 to December 2016, 29 ZSI 475 hydraulic penile prostheses three components were implanted by six surgeons in 28 patients in five European centres. Mean age of patients was 60 years old (44-75). Standard peno-scrotal incision procedure was performed for the 28 patients. Erectile function was assessed by IIEF-5 self-administered questionnaire.

**Results:** Median follow-up was 35.11 months (8-47). Postoperative complications were limited to scrotal pump torsion that required a revision, an armed tubing breakage and a scrotal haematoma. At the end of follow-up, 100% of patients had a functional prosthesis and 92.86% were satisfied.

**Conclusions:** Implantation, risks of complications, functional outcome and patient satisfaction with penile implant ZSI 475 are similar to standard hydraulic penile implants three components as AMS 700 and Coloplast Titan.

**Keywords:** Coating, Efficacy, Erectile dysfunction, Penile prosthesis ZSI 475, Safety

## Introduction

The prevalence of erectile dysfunction (ED) is more than 40% after 40 years (1, 2). Erectile dysfunction is a common problem whose support is well codified. Neglecting the management of this disorder can lead patients to depression (3). The penile implant is proposed after the failure of other techniques such as oral treatments, vacuums and intra-cavernous injections. Inflatable implants three components are the most popular with patients and they give the best functional outcomes.

Standard hydraulic penile implant three components from AMS (Boston Scientific, Malborough, USA) and Coloplast (Coloplast Corp., Minneapolis, USA) have been studied in many articles for many years. We are now able to evaluate

the efficiency of penile implant with standard questionnaire and we know more about intraoperative complications and postoperative complications to study efficiency and complication of a new hydraulic three components penile implant.

We present the results of a study about 28 patients implanted with ZSI 475 penile implant (Zephyr Surgical Implants, Geneva, Switzerland). The ZSI 475 is designed as a standard hydraulic penile prosthesis three components. We studied preparation, surgical procedure, post-operative events and functional outcome of this implant comparing to standard hydraulic penile prostheses three components as AMS 700 and Coloplast Titan.

## Materials and methods

### Population

From September 2012 to April 2016, 29 hydraulic penile implants three components ZSI 475 were implanted in 28 patients by six operators from five European centres (Lodz, Pulawy, Hamburg, Baden Baden, Reims). Mean age of patients was 60.07 years old [44-75]. The cause of ED was a radical prostatectomy for 14 patients, radical prostatectomy and radiotherapy for one patient, diabetes for four patients, priapism for two patients, colectomy for one patient, vascular

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surgery for one patient and Peyronie's disease for one patient. No particular cause of ED for 4 patients. The indication of ZSI 475 penile implants procedure was proposed after failure or refusal of other treatments as oral treatment vacuum and intra-cavernous injections.

Twenty-six patients did not have penile implant surgery history, one patient did have an AMS 700 pump mechanical failure and one patient an Ambicor prosthesis failure. Both patients needed a replacement of their prosthesis. IIEF-5 score was 6 [5, 8] (4, 5).

### Prosthesis

All penile prosthesis implanted were ZSI 475. Two kits of ZSI 475 were used: the standard size kit (Fig. 1) covering penis from 12 cm to 24 cm (ZSI 475) (n = 15) and "big size" kit (ZSI 475-22 cm; Fig. 2) covering penis size from 21 cm to 25 cm with large diameter (n = 1) (Fig. 3). All ZSI 475 have hydrophilic PVP coating (Polyvinylpyrrolidone) to ease intra-operative antibiotic absorption and fight against infection. Penile Implant were immersed in a bath of solution of antibiotic diluted in normal saline solution: Rifampine 10 mg/ml + Gentamicine 1 mg/ml.

### Surgical procedure

The surgical procedure was similar to implantation of standard hydraulic penile prosthesis three components AMS 700 or Coloplast Titan. The patient had a shower with Povidone-iodine scrub solution the day before and the morning of surgery. At surgical theatre, the patient had a skin preparation with Povidone-iodine again. The incision was peno-scrotal in 100% of cases with a space for pelvic tank following the spermatic cord through the inguinal region with or without inguinal incision. After corpus cavernosa dilatation with dilators to 13 Fr Ch, corpus cavernosum length was measured and the right size of inflatable prosthesis was elected. The inflatable parts were screwed to the proximal part to reconstitute the corpus cavernosum prosthesis. The three components of the prosthesis (corpus cavernosa implants, pump and reservoir) were filled with saline solution and bubble removed.

The two corpus cavernosa prostheses were placed in the corpus cavernosa using the introducer and needle provided in kit. Corpus cavernosa were closed. A sub-dartos pouch was performed in the scrotum receiving the pump. The tank was pushed blank in its pelvic area, and then filled with saline solution. Connecting the various tubes was then performed with the connectors. In two patients a Redon was introduced.

During procedure, antibiotic prophylaxis consisted of a single dose of 2 g cefazolin intravenously. Antibiotic therapy was continued for 7 days postoperatively.

### Follow-up

The study was conducted retrospectively. Median follow-up was 35.11 months [8-47 Months]. Postoperative consultations were 1 month after procedure, 3 months, every year and at the end of study.



Fig. 1 - Photograph of the penile implant ZSI 475 standard box with three sizes included (13 cm, 16 cm and 19 cm), extenders and accessories.



Fig. 2 - Photograph of the penile implant ZSI 475-22 cm box of the 22 cm with extenders and accessories.



Fig. 3 - Photograph of the penile implant ZSI 475 connected and inflated.

Erectile function was assessed by IIEF-5 self-administered questionnaire (five-item version of the International Index of Erectile Function) preoperatively and postoperatively to evaluate the quality of erections and comfort of the implant.

## Results

### *Intraoperative complications*

The intraoperative period was event full for the 28 patients.

### *Postoperative complications*

There was one postoperative scrotal haematoma. Haematomas occur in 7.3% with prostheses references (5).

There was no infection for 28 patients, but usual perineal pain in 2 patients from 15 days to 3 weeks as standard hydraulic three components penile implant. We did not have long-term pain: Pain after 3 months is present in 5% of cases especially with Coloplast prosthesis (5).

The main complications associated with AMS 700 and Coloplast prosthesis is infection in 3.2%-11.5% within 2.9 months (5).

Depending on series (5, 6) revisions, except for infection, are due mostly to a mechanical problem.

During the follow-up of 28 patients with penile implant ZSI 475 we did have one pump torsion which needed revision 3 months after implantation, and an armed tubing breakage needed a revision with exchange of the prosthesis, 3 years after implantation. Twenty-six patients out of 28 were first-time implanted with a penile implants. 1 patient had a previous AMS 700 with pump mechanical failure and one patient had an Ambycor prosthesis failure. They needed a full replacement of the prosthesis.

### *Functional results and patient satisfaction*

Postoperatively, the self-assessment questionnaire was IIEF5 23 (20-25) against 6 (5-8) preoperatively. This result is equivalent to the results obtained with reference implants an average IIEF5 of 21 (5-25) against six (5-22) preoperatively (5).

At the end of follow-up, intra-scrotal pump was of easy use for 26 patients. Two critical patients have problem to use the pump, meanwhile the pumps work perfectly well.

Penile rigidity was good for 2 patients and very good for 26 patients (92.86%).

## Discussion

First year remains the most critical period for the implantation of prosthesis. This clinical trial shows safety and effectiveness of ZSI 475 prosthesis equivalent to prosthesis of reference AMS 700 and Coloplast Titan.

### *Intraoperative*

The major intraoperative complications with three components penile implants are urethral perforation (unusual),

perforations of the corpus cavernosum (1-11%) or crosses of cavernous prostheses during the procedure (7, 8). None of these complications arose in our group of 28 patients.

### *Postoperative*

#### *Infection*

The most serious complication is infection because it leads to the removal of the prosthesis (9). Regarding factors of risk for postoperative infection, diabetes is being discussed as an aggravating factor (6, 10); other study do not show relation with diabetes and infection (5, 11).

The patients in our series did not have any infection. Our diabetic patient did not present infection. To reduce the risk of infection our patient did have a strict control of blood sugar. He was hospitalized for 48 hours before surgery to control his diet and blood sugar.

The advantage of the use of prostheses with a hydrophilic coating (prosthesis Coloplast Titan kind) or soaked with antibiotics for reducing the risk of infection remains controversial. One study show an equivalent result with and without local antibiotic (5). The ZSI 475 are coated with hydrophilic PVP and were immersed in a bath of antibiotics to fight against infection.

#### *Migration*

Regarding the risk of prosthesis postoperative migration, it occurs more than 6 months after procedure(5), especially in implanted patients after priapism, may be due corpus cavernosa fibrosis (10). During follow-up, we did not observe migration with the ZSI 475 prostheses although two patients suffered from priapism.

#### *Bleeding/haematoma*

Regarding the risk of bleeding, the rate of postoperative haematoma is 7.3% with hydraulic implants three components (5). One patient did have a scrotal haematoma.

#### *Pain*

Usual perineal pain was observed in two patients for 15 days to 3 weeks as standard hydraulic three components penile implant. Pain after 3 months is present in 5% of cases especially with Coloplast prosthesis (5).

#### *Reliability*

About 68.5% of inflatable penile implants (first implantation) work for 10 years without any revision and 59.7% work for 15 years (11).

During our follow-up, we did observe one armed tubing breakage leading to a full replacement of the prosthesis. The pump torsion needed a new procedure to place the pump in the right position.

Reference penile prostheses obtain a satisfaction score of 93% (12). The functional results for our 28 patients fit this score with 92.86%.



## Conclusion

ZSI 475 is very similar to standard penile implant from AMS and Coloplast in terms of functioning and procedure. No learning curve is needed.

Our median follow-up of 35.11 months (8-47 months) is long enough to show ZSI 475 safety efficacy as main complications arose during the first year with standard penile implant AMS and Coloplast (only one patient from our series had a follow-up <14 months). A longer follow-up and a larger group of patients are needed to confirm these good early results.

## Disclosures

Financial support: None.

Conflicts of interest: Dr. Christophe Llorens is shareholder of ZSI company.

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