

# Surgical outcome and patient' satisfaction after ZSI 475 penile prosthesis implantation

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## Introduction

Erectile dysfunction is a common problem. The penile implant is proposed after the failure of other techniques such as oral treatments, vacuums and intra-cavernous injections. Hydraulic penile three components prosthesis give the best functional outcomes

## Aim

The aim of this study was to demonstrate safety and quality of life of patients after ZSI 475 hydraulic penile prosthesis three components implantation.

## Method

From December 2014 to October 2016, 10 ZSI 475 hydraulic penile three components prostheses were implanted by one surgeon. Standard peno-scrotal incision procedure was performed for all the patients. Erectile function was assessed by IIEF-15 (International Index of Erectile Function) self-administered questionnaire and quality of life after implantation was investigated with Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire at 12 months after the implantation. The study was conducted in accordance with the principles of the Declaration of Helsinki of World Medical Association.



Penile implant ZSI 475 standard box with three sizes included (13 cm, 16 cm and 19 cm), extensors and accessories

Penile implant ZSI 475 connected



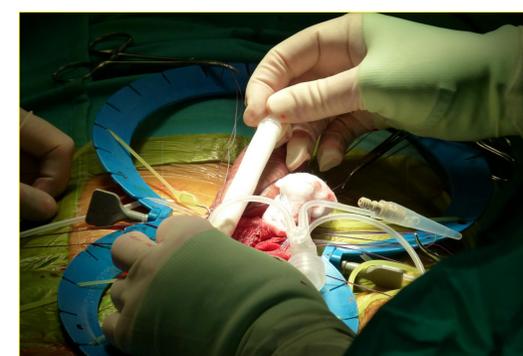
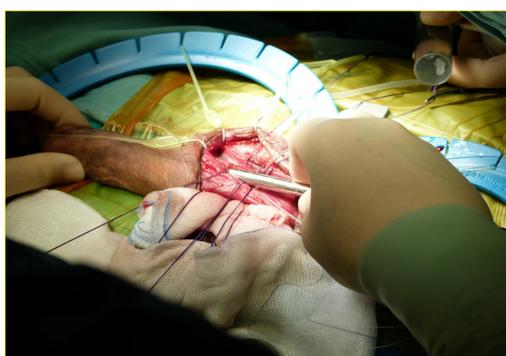
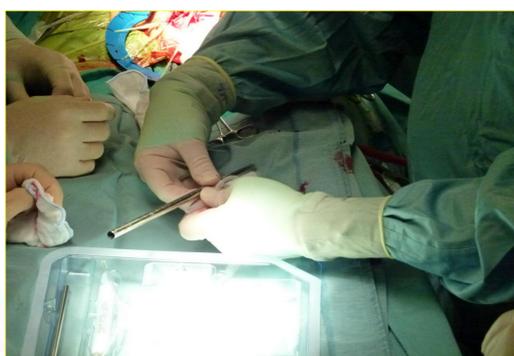
## Results

Median follow-up was 20 months (range, 12-34), mean age of patients was 59 years old (range, 40-78). No intraoperative complications were observed in 9 patients. In the remaining one, an armed tube leakage, due to manufacturing defect, needed immediate prosthesis substitution. No major complications as glans ischemia, necrosis or persistent anaesthesiae were recorded postoperatively.

Domain	Item	Valid cases	Mean (Min-max; SD)	Median
Functional	Prosthes adequacy	10	4.1 (2-5; 1.1)	5
	Ease/simplicity of use	10	4.2 (3-5; 0.9)	5
	Duration of implant	10	4.2 (3-5; 0.82)	5
	Penile rigidity	10	3.4 (2-5; 0.96)	3
	Fulfillment of expectations	10	3.9 (2-5; 1.2)	4
Personal	Sexual desire	10	4.3 (3-5; 0.82)	5
	Liveliness and wit	10	3.4 (1-5; 1.5)	4
	Security	10	4.0 (2-5; 1.5)	4
	Sexual experience	10	4.1 (2-5; 1.2)	5
Relational	Well-being of the couple	10	3.8 (2-5; 1.2)	4
	Frequency of orgasms	10	4.0 (0-5; 1.6)	5
	Frequency of sexual intercourse	10	3.0 (2-4; 0.7)	3
	Partner satisfaction	10	3.5 (1-5; 1.8)	5
Social	Daily life	10	4.2 (3-5; 0.9)	5
	General well-being	10	4.0 (3-5; 0.9)	4
	Feeling like other	10	3.6 (2-5; 1.1)	3

Quality of life and Sexuality with QoLSPP questionnaire at 12 months after the implantation

One patient experienced hyperpyrexia that has been controlled by antibiotic therapy; no patients recorded any infection. During the follow-up, 2 patients experienced mechanical failure of the prosthesis due to a rupture of the pump-cylinders connection-tube: a revision was needed and a prosthesis exchange was made. At the end of follow-up, no prosthesis migration or long-term pain were recorded; all of the patients had a functional prosthesis. The mean preoperative IIEF-score was 14.3±4.3; the mean postoperative IIEF-scores resulted 52.9±2.9. Table 1 shows mean and median values of the 16 items of QoLSPP questionnaire at 12 months. Results were skewed toward the positive end of the scale in all domains: Forty per cent of responses to several items were maximum values and 86% of responses falling on the positive side of the scale. Interestingly, only 20% of the patients reported a harder rigidity of the prosthesis in comparison with that obtained before the implantation; moreover, none of the patients reached daily or almost daily sexual intercourses while 60% reported a frequency of 4-6 times per month.



Intraoperative steps: two corpus cavernosa prostheses were placed in the corpus cavernosa using the introducer and needle provided in kit.

## Conclusion

Optimal functional outcome and very good patient satisfaction were obtained with implantation of ZSI 475 hydraulic penile prosthesis; no major intra- or post-operative complication were reported.