

## Penile prosthesis: Patient satisfaction, use and preference for malleable vs inflatable

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**Author contributions:** Boronat Tormo F had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis; Rogel Bertó R, López-Acón JD and Luján Marco S conceived and designed the study; López-Acón JD and Conca Baenas MA acquired the data; Ordaz Jurado DG analyzed the data; Rogel Bertó R drafted the manuscript; Luján Marco S, López-Acón JD, Rogel Bertó R, Delgado Oliva F, Conca Baenas MA and Boronat Tormo F critically revised the manuscript for important intellectual content; Ordaz Jurado DG contributed to the statistical analysis; Luján Marco S and Boronat Tormo F supervised the manuscript.

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Received: March 31, 2014 Revised: May 5, 2014

Accepted: June 27, 2014

Published online: July 24, 2014

designed ad hoc by urologist in our Department, with three multiple choice questions and a grading answer. After verbal consent was obtained, proposed questions concerned global satisfaction regarding to the procedure, quality of sexual intercourses graded from 0 to 10, frequency of sexual intercourse and about undergoing the same procedure again. SPSS™ version 20.0 was used for the descriptive analysis of the data.

**RESULTS:** Sixty seven (64%) patients underwent a MPP and 41 (36%) an IPP. The mean age was  $52.6 \pm 3.6$  years in the MPP group and  $57.2 \pm 2.8$  years in the IPP group ( $P = 0.02$ ). Total respond rate was 55.5% (60/108). Twenty six out of 33 MPP patients (78.9%) and 19 of the 27 IPP subjects (70.3%) were satisfied or very satisfied with the procedure. The quality of sexual intercourse was rated  $7.13 \pm 0.39$  points in the MPP group and  $6.16 \pm 0.47$  points in the IPP group. Frequency of sexual intercourse was 1 or more times per week in 15 (46.9%) patients with MPP and in 12 (46.1%) of the IPP patients. Twenty-eight (84.9%) patients who received a MPP would undergo the procedure for the same device again as well as 24 (88.9%) of the IPP group. There were no statistical differences between groups regarding the four items in the survey.

**CONCLUSION:** Patients show high satisfaction rate and no statistical differences exist regarding to global satisfaction, use of the device and quality of sexual intercourse depending on the type of penile prosthesis.

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**Key words:** Penile prosthesis; Patient satisfaction; Erectile dysfunction; Medical survey

**Core tip:** retrospective study of 108 patients implanted with either malleable penile prosthesis or inflatable penile prosthesis designed to investigate results in

### Abstract

**AIM:** To evaluate and compare long-term patient satisfaction and use after either malleable penile prosthesis (MPP) or inflatable penile prosthesis (IPP) implantation.

**METHODS:** we present a retrospective unicenter study of 108 patients implanted with either 2 or 3-piece American Medical System™ (AMS™) or Coloplast™ inflatable penile prosthesis (AMS 700CX™, AMS 700CXR™, AMS Ambicor™ or Coloplast TITAN™) or malleable (AMS Spectra™ or Coloplast Genesis™) in our Centre between 1993 and 2011. We collected data from the medical record including follow-up, age and type of prosthesis. We used a four-question telephone survey

terms of use of the device and satisfaction. Patient satisfaction after prosthetic surgery is multifactorial and it should be considered when exposing the pros and cons of prosthesis to patient before surgery. We collected data with a four-question telephone survey. After analyzing our results, we concluded that patients show high satisfaction rate and no statistical differences exist regarding to global satisfaction, use of the device and quality of sexual intercourse depending on the type of penile prosthesis.

Rogel Bertó R, López-Acón JD, Luján Marco S, Ordaz Jurado DG, Delgado Oliva F, Conca Baenas MA, Boronat Tormo F. Penile prosthesis: Patient satisfaction, use and preference for malleable vs inflatable. *World J Clin Urol* 2014; 3(2): 134-138 Available from: URL: <http://www.wjgnet.com/2219-2816/full/v3/i2/134.htm> DOI: <http://dx.doi.org/10.5410/wjcu.v3.i2.134>

## INTRODUCTION

Surgical treatment for erectile dysfunction (ED) by implantation of penile prosthesis is considered a safe and efficient option to treat those cases non responding to pharmacological agents<sup>[1]</sup>. Both, prosthesis materials and prosthesis design, have evolved in time, in the same way that surgical techniques have, in order to achieve a better durability and quality of the device.

Patient satisfaction after the penile prosthesis surgery is considered multifactorial and depends on issues like presurgery expectations and the success of the implant as ED treatment option<sup>[2]</sup>. If compared with the other options to treat ED like phosphodiesterase five (PDE-5) inhibitors, intraurethral alprostadil, intracavernous injection of alprostadil or mechanical devices, penile prosthesis is the one showing better satisfaction rates<sup>[3]</sup>.

The objective of our study was to evaluate and compare long-term patient satisfaction and use after either malleable or inflatable penile prosthesis implantation. Patients were offered both types of prosthesis if no contraindication. Most of the papers published so far concerning patient satisfaction with the device have used non-validated questionnaires designed by each Hospital or Investigation Group<sup>[1]</sup>. Two validated questionnaires exist concerning sexual intercourse satisfaction: the satisfaction domain of the International Index of Erectile Function (IIEF) and the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS)<sup>[4-7]</sup>.

## MATERIALS AND METHODS

We present a retrospective study on 108 patients implanted with either 2 or 3-piece American Medical System™ (AMST™) or Coloplast™ inflatable penile prosthesis (AMS 700CX™, AMS 700CXR™, AMS Ambicor™ or Coloplast TITAN™) or malleable (AMS Spectra™ or Coloplast Genesis™) in our Hospital between 1993 and 2011. We collected data from medical record like follow-up, age

**Table 1 Etiology, infection rate and reoperation n (%)**

		MPP	IPP	P
Main etiology	Diabetes mellitus	21 (31.3)	17 (41.5)	0.505
	Vasculogenic	14 (20.9)	8 (19.5)	
	LaPeyronie disease	9 (13.4)	5 (12.2)	
	Radical Prostatectomy	2 (3)	3 (7.3)	
	Neurogenic	8 (11.9)	4 (9.7)	
	Unknown	13 (19.4)	4 (9.7)	
Implant Infection		7 (10.5)	5 (12.2)	0.202
Reoperation		10 (14.9)	7 (17.5)	0.787

MPP: Malleable penile prosthesis; IPP: Inflatable penile prosthesis.

and type of prosthesis. We made contact with each patient for a telephone survey. Prior to the survey each patient was informed of the content and objective of the survey and consent was obtained. Survey was designed by the authors based in the penile prosthesis satisfaction papers published to date. We configured a first version which was examined by several other urologists in the Department to evaluate clarity and precision of the questions. After this first version, we configured the final version. We obtained a four-question telephone survey with three multiple choice questions and a grading answer question. First of them made reference to global satisfaction concerning the procedure with four possible answers being: (1) Not satisfied; (2) Partially satisfied; (3) Satisfied; and (4) Very satisfied. Second question asked about the quality of sexual intercourses graded from 0 to 10, being zero “very bad quality” and 10 “very good quality”. We asked in question number three about the frequency of sexual intercourse being answer: (1) More than once per week; (2) Once per week; (3) Once per for night; (4) Once per month; and (5) Less than once per month; and last, we requested about the fact of undergoing the same procedure again, and the two possible answer were (1) Yes or (2) No.

## Statistical analysis

Data were analysed using the SPSS™ 20.0 (IBM corp™). Statistical analysis was performed using Fisher test to detect differences between different groups. A value of  $P < 0.05$  was considered to be statistically significant.

## RESULTS

A total of 67 (64%) patients underwent a MPP and 41 (36%) an IPP. The mean age was  $52.6 \pm 3.6$  years in the MPP group and  $57.2 \pm 2.8$  years in the IPP group ( $P = 0.02$ ). Total respond rate was 55.5% (60/108); 27 (25%) had deceased and the remaining 21 (19.4%) did not respond. Among those who attended to the survey, 33 patients (55%) had MPP and 27 (45%) had IPP. There were no statistical differences between the groups regarding to etiology of erectile dysfunction (ED) ( $P = 0.505$ ), incidence of implant infection ( $P = 0.202$ ) or reoperation rate ( $P = 0.787$ ) (Table 1).

The median time from surgery to the survey was 161 (6-199) mo for the MPP group and 37 (3-161) for the IPP group. As shown in Table 2, 26 of the 33 MPP

**Table 2** Results of the survey *n* (%)

Question	MPP		IPP		P
Satisfaction	No satisfied	2 (6.1)	No satisfied	6 (22.2)	0.157
	Partially satisf.	5 (15.2)	Partially satisf.	2 (7.4)	
	Satisfied	15 (45.5)	Satisfied	13 (48.1)	
	Very satisfied	11 (33.3)	Very satisfied	6 (22.2)	
Quality	7.13 ± 0.39		6.16 ± 0.47		0.314
Frequency	> 1/wk	8 (25)	> 1/wk	7 (26.9)	0.413
	1/wk	7 (21.9)	1/wk	5 (19.2)	
	1/15 d	5 (15.6)	1/15 d	5 (19.2)	
	1/mo	3 (9.4)	1/mo	3 (11.2)	
	> 1/mo	9 (13.4)	> 1/mo	6 (23.1)	
Undergo again	YES	28 (84.9)	YES	24 (88.9)	0.774
	NO	5 (15.1)	NO	3 (11.1)	

MPP: Malleable penile prosthesis; IPP: Inflatable penile prosthesis.

patients (78.9%) and 19 of the 27 IPP subjects (70.3%) were satisfied or very satisfied with the procedure. The quality of sexual intercourse was rated  $7.13 \pm 0.39$  points in the MPP group and  $6.16 \pm 0.47$  points in the IPP group. Frequency of sexual intercourse was 1 or more times per week in 15 (46.9%) patients with MPP and in 12 (46.1%) of the IPP patients. Twenty eight (84.9%) patients who received a MPP would undergo the same device procedure again as well as 24 (88.9%) of the IPP group. There were no statistical differences between groups regarding the four items investigated in the survey.

## DISCUSSION

Penile prosthesis as an ED treatment option is considered to have a high satisfaction rate among the patients implanted<sup>[3]</sup>. On the other hand, there is a small number of unsatisfied patients with surgery, esthetic and/or functional results. When perceived, it is about rigidity, length, infection of the device, spontaneous deflation or mechanical failure the main reasons for those cases of patient dissatisfaction. Patient has to know before surgery which are the real expectations, the way prosthesis will modify or not penile length and girth, penile sensitivity, glans status, if circumcision is going to be performed as well as infection, mechanical failure and prosthesis removal rates<sup>[1,8]</sup>.

In our unicenter retrospective study we have obtained a high rate global satisfaction in both groups showing no statistically significant differences between them. Another result to pay attention is that most of patients are located in highest or lowest frequency groups of use, at the expense of the middle positions. More than 1 per week is 25% in MPP group and 26.9% in IPP; and the opposite position, less than 1 per month is 13.4% in MPP group and 23.1% in IPP. Concerning to satisfaction, most of the patients in both groups would undergo the procedure again.

Focusing in global satisfaction with the inflatable prosthesis, our percentages of 70.3% of satisfied or very satisfied, are less evident than the ones in other references. In a study that involved 145 patients implanted

with IPP AMS 700 Ultrex™, after the satisfaction questionnaire, 85% were satisfied against 76% of partner satisfaction<sup>[9]</sup>. Another study of 207 patients implanted with IPP AMS 700CX™, performing a telephone survey, showed 79% use the device at least twice monthly and 88.2% would recommend an implant to a relative or friend<sup>[10]</sup>. Two other studies, one conducted with 200 consecutive patient who underwent IPP AMS Ultrex™ and CX™ showed an overall satisfaction of 92%<sup>[11]</sup>. The other one, 80 cases implanted with IPP AMS 700CX™ responded to a nine-point telephone survey and 97% of patients use the device frequently; 69% affirmed they never had problems with its use; and 97% reported they would suggest this treatment to other people<sup>[12]</sup>.

In relation to IPP Mentor alpha-1™, one study showed that 89% of men had fulfilled expectations with the prosthesis. Regarding intercourse ability, confidence and device rigidity and function satisfaction rate was 80% or greater<sup>[13]</sup>.

One study was conducted to rate patient satisfaction with 3 types of penile prosthesis. A random sample of 330 patients (of 1298 patients implanted) with either AMS700™, Mentor Alpha 1™ or Mentor Alpha NB™ responded to a computer assisted telephone survey. The overall satisfaction rate was 69%, and there was no significant difference by implant type<sup>[14]</sup>.

Another multicentre study comprising several types of prosthesis (IPP AMS700 CX™, AMS Ambicor™ and AMS 600-650™) in terms of satisfaction, use the EDITS validated questionnaire. Patient satisfaction rates were 97%, 81% and 75% respectively<sup>[15]</sup>.

Two different papers included two-piece IPP patient satisfaction. The first one evaluated 146 patients implanted with IPP AMS Ambicor™ and found that 91% said that it was easy to use. Overall patient satisfaction was 85%, and 86% would recommend the prosthesis to friends or undergo the procedure again if necessary<sup>[4]</sup>. The second paper regarding IPP AMS Ambicor™ satisfaction involved 131 patients and they collected data from their own mailed questionnaire and from a modified EDITS mailed questionnaire. Overall patient satisfaction was 96.4% and 92.9% would recommend it to others. Of the 85 men who completed the modified EDITS survey,

90.6% were satisfied and 82.6% were very satisfied with the prosthesis<sup>[16]</sup>.

A review article published recently 2012 concluded that nine studies, which met their criteria for review over the past 20 years, showed high satisfaction rates with the 3-piece IPP<sup>[1]</sup>.

The limitations of this study are our low number of patients collected, which downs the statistical potency. In the same way, results might have been affected by the fact of being unicenter and retrospective. We consider that prostheses conditions and characteristics through time and the different surgeons performing the implantation could have modified the patients satisfaction as well, and it has not been taken into account to perform the analysis. Another important issue is that we have not used a standarized and validated questionnaire which makes our results difficult to correlate or compare with the ones published by other authors using them.

On the other hand, we present a long term follow up study with low representation in the literature by the fact that we compare malleable and inflatable two or three component in terms of satisfaction. This results offer a new extra tool for the urologist. Because of the absence of differences between malleable or inflatable penile prosthesis in terms of satisfaction, frequency or quality of sexual intercourse, these results could be used as an extra parameter to consider and should be added to the ones used normally to assist ourselves and the patient to choose the more suitable type of prothesis.

Using a non validated questionnaire in our retrospective, unicenter study, our results show high satisfaction rate in patients implanted with either IPP or MPP, similar to literature, and indicate that there are no statistical differences with regard to patient global satisfaction, frequency use of the device and quality of sexual intercourse depending on the type of penile prosthesis. More prospective studies using validated questionnaires are needed in order to obtain more powerful results and conclusions regarding satisfaction in patients implanted with penile prosthesis. In terms of sexual satisfaction, those studies should consider partner satisfaction as well.

## COMMENTS

### Background

Surgical treatment for erectile dysfunction (ED) by implantation of penile prosthesis is considered a safe option. High satisfaction rates have been reported in the literature.

### Applications

Satisfaction rates should be used as an extra item to consider and should be added to the ones used normally (infection and mechanical failure rates, possibility of prosthesis removal, patient preference, anatomical conditions and comorbidities) to assist ourselves and the patient to choose the more suitable type of prothesis.

### Peer review

This is a interesting article using a retrospective design, but less innovation. The results of the data are acceptable. Overall the manuscript is well written especially for the authors with English as non-native language.

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**P- Reviewer:** McPhail EF, Wang XH **S- Editor:** Ji FF  
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