

# Penile Prosthesis Implant: Analysis of Patient and Partner Satisfaction in two Hospitals in Bogotá, Colombia

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## ABSTRACT

**Purpose:** The objective of this study was to establish the rates of sexual satisfaction in both the patient and his partner, after penile prosthesis implantation (PPI). **Materials and Methods:** This is an observational cross-sectional study, in which 32 individuals who underwent PPI between the years 2009 and 2016 in two university hospitals, in Bogotá, were selected. Demographic data and medical history were collected from the medical records. Subsequently, the erectile dysfunction (ED) Inventory of Treatment Satisfaction survey was applied. Finally, the data were processed in Excel, and a descriptive analysis was made for the continuous variables, with measures of central tendency (medium and medium). For the categorical variables, frequency measures were used and interpreted with percentages. **Results:** Thirty-two patients were interviewed. 78% had an inflatable prosthesis and 22% malleable. The most frequent complication was infection in 4 patients (16%), which led to extrusion and removal of the prosthesis in 3 cases. 55% report that the implant increased the number of sexual intercourse per week. The overall satisfaction was 75% in men and 66.7% in their partners. For 70% the prosthesis met their expectations, 80% were satisfied with the speed and 90% with the duration of the erection, and 93% of couples considered that men wish to continue using this method. **Conclusion:** We found high rates of sexual satisfaction in patients and their partners that allow us to deduce that the penile prosthesis is a feasible option in patients with ED refractory to the first- and second-line treatment.

**Key words:** Andrology, erectile dysfunction, orgasm, penile prosthesis, sexual behavior

## INTRODUCTION

Erectile dysfunction (ED), defined as the inability to obtain an erection that allows vaginal penetration, is one of the most prevalent disorders in men.<sup>[1]</sup> According to the Massachusetts Male Aging Study, it affects 52%, more than half of men between 40 and 70 years old.<sup>[2]</sup>

At this time, the first-line treatment is 5-phosphodiesterase inhibitors; however, up to 35% of patients do not respond adequately, so they require alternative treatments, such as negative-pressure devices, intracavernous therapy, and penile prosthesis implants (PPIs).<sup>[1]</sup>

The PPIs have been described since the 60s and are currently the gold standard in those who have failed, do not want, or

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do not tolerate the first and second lines of treatment; mainly because they offer a definitive solution, regardless of the etiology.<sup>[1,3]</sup>

The most important outcome that best estimates the success of the implant is sexual satisfaction, both in the patient and his couple. Accordingly, in 1999 the ED Inventory of Treatment Satisfaction (EDITS) survey<sup>[4]</sup> was developed, which includes questions to evaluate the subjective perception of success in the different impotence treatments.

The objective of this study was to establish the rates of sexual satisfaction in both the patient and his partner, after PPI. Our data are taken from patients who underwent PPI between 2009 and 2016, in two university hospitals in Bogotá.

## MATERIALS AND METHODS

This is an observational cross-sectional study, in which 44 patients who underwent PPI between the years 2009 and 2016 in two university hospitals, in Bogotá, were selected. 32 individuals could be contacted. Demographic data and medical history were collected from the medical records. Subsequently, the EDITS survey was applied in person or by telephone, depending on the availability of patients and their partners. Finally, the data were processed in Excel, and

a descriptive analysis was made for the continuous variables, with measures of central tendency (medium and medium). For the categorical variables, frequency measures were used and interpreted with percentages.

## RESULTS

Of a total of 44 patients, it was possible to contact and interview 73% (32 patients). Five patients were excluded from the analysis due to the presence of post-operative complications that led to the removal of the prosthesis and one patient was not included in the study because he did not use the penile prosthesis due to lack of partner; however, we took into account his demographic data [Table 1].

### Inflatable prosthesis

The majority of the sample (78%, 25 patients) corresponds to those who were implanted with an inflatable prosthesis.

In this group, the average age was 58.5 years (31–76) for the patients and 51.1 years (between 71 and 20) for their partners, who were all female. The ED was secondary to a radical prostatectomy in 48% of the cases, 20% had vascular etiology, 24% neurogenic, in 4%, it was mixed (vascular and neurogenic), and in the remaining 4% the etiology was undefined.

**Table 1: Description of the patients data**

Patients demographics	Inflatable (n=25)	Malleable (n=7)
Patient's age (years)		
Average	58.5	53.6
Maximum	76	72
Minimum	31	30
ED etiology		
Vascular	20%	43%
Radical prostatectomy	48%	14%
Neurogenic	24%	29%
Mixed (vascular/neurogenic)	4%	-
Undefined	4%	14%
Partner's age (years)		
Average	51.1	64
Maximum	71	67
Minimum	20	60
Previous medical treatment		
Yes	96%	86%
No	4%	14%
Surveys		
Patients	20	6
Partners	15	3

ED: Erectile dysfunction

The first two lines of treatment were offered to 96% of the sample, before choosing the surgical option.

Regarding complications, the majority of patients had a satisfactory post-operative result (60%). The most frequent complication was infection in 4 patients (16%), followed by mechanical dysfunction (12%), chronic pain (8%), and abnormal curvature (4%).

There were four cases in which the prosthesis was removed (16%), three of them in relation to infection with subsequent extrusion of the prosthesis and another in relation to chronic pain.

In addition to the withdrawals, one of the patients had not used the prosthesis since he had no partner. A total of 20 surveys were applied to the patients and to 15 of their couples.

The global satisfaction with the prosthesis was 75%, 40% being very satisfied. For 70% of the patients, the implant fulfilled completely or considerably their expectations. To date, the proportion of patients who estimate that it is very likely or moderately likely to continue using this method is 85%. For 70% of them, the method was easy to use and 80% were satisfied with the speed of erection. The duration of the erection satisfied 90%, and the confidence was increased in 70% of the sample. With regard to the naturalness of the erection, 45% indicated that it is natural, while 35% considered it artificial for others, it was indifferent. Finally, regarding stiffness, 60% of patients rated it as superior; and for 25%, they were somewhat less rigid than before [Table 2].

When asked about the influence on frequency of sexual intercourse per week, for 55%, there was an improvement and for 35%, there was no impact.

Regarding the patients' perception of their partners' satisfaction, 55% considered that their couples were sexually satisfied and up to 70% perceived that their partners wanted them to continue using the PPI.

For the partners, an overall satisfaction of 67% was found, and the expectations with the procedure were met in this same proportion. 53% of the partners indicated that the implant did not influence their sensation of being sexually desirable, while 40% reported that this perception had improved. The duration of the erection was obtained with the prostheses satisfied 73% of the couples. On the other hand, to date, 93% of couples surveyed consider that patients wish to continue using the prosthesis [Table 3].

### **Malleable prosthesis: Inflatable**

With respect to the malleable penile prosthesis, the sample was smaller (22%, 7 patients). In this group, the average age for the patients was 53.6 years (between 30 and 72) and 64 years (between 60 and 67) for their partners, who were all

female. The etiology of ED was vascular in 43%, neurogenic in 29%, and secondary to radical prostatectomy for 14%. In 14% of the patients, the etiology was undefined.

57% of the patients (4/7) did not present any complication. The most frequent complications found were infection in a patient (1/7), with subsequent removal of the prosthesis, extrusion, in the absence of signs of acute infection, in another patient (1/7) and the presence of anomalous curvature in another patient (1/7), which required mechanical revision, with resolution of the defect. The prosthesis was removed in one of the patients, because of infection and extrusion (1/7), thus we did not take into account his data.

A total of 6 surveys were applied to the patients and 3 of the couples agreed to answer.

Overall satisfaction with the prosthesis was 50%; for 50% of the patients, it fulfilled their expectations; 66% would possibly continue using this method; for 50%, it was easy to use; and 50% was satisfied with the duration of the erections. 66% of the patients felt confident when having sex, for 50%, the erection was artificial, and 50% considered their erections more rigid than before. 50% of the patients consider that their partner wishes to continue using the prosthesis and 50% consider that they are satisfied. The overall satisfaction in the couples was 66%.

Regarding the frequency of sexual intercourses per week, for 67%, there was no impact on frequency, 17% had improvement, and in the other 17%, it decreased.

Finally, in the couples, a total satisfaction rate of 66.7% was found, and in the same proportion, they perceived that the men prefer to continue using the prosthesis.

## **DISCUSSION**

The penile prosthesis is a device implanted to restore sexual function that allows the acquisition of a rigid erection. Ideally, it should imitate the physiological process of erection and allow vaginal penetration, in addition to resembling a flaccid penis and being discreet. Likewise, it should not interfere with urination or daily life activities.<sup>[1]</sup>

The EDITS evaluates all these aspects. In our results, we found that, in general, patients who were implanted with an inflatable prosthesis are satisfied with their operation considering the PPI a feasible and easy method to use. Most patients agree that it resembles a natural erection, which results in an increase in the frequency of weekly sexual intercourse. The perception of patients, about how satisfied their partners were, is inferior to their actual satisfaction rate.

When reviewing the multiple specialized publications on this participant, most observational studies describe satisfactory

Table 2: Patients survey

EDITS Questionnaire for patients	Inflatable <i>n</i> =20	Malleable <i>n</i> =6	EDITS Questionnaire for patients	Inflatable <i>n</i> =20	Malleable <i>n</i> =6
In general, how satisfied are you with this treatment?			How confident do you feel with this treatment during intercourse		
Satisfied	75%	50%	Confident	70%	67%
Indifferent	5%	17%	Indifferent	10%	0%
Dissatisfied	20%	33%	Not confident	20%	33%
Has the treatment met your expectations?			How satisfied do you think your partner is with this treatment?		
Yes	70%	50%	Satisfied	55%	50%
Half	15%	17%	Indifferent	15%	17%
No	15%	33%	Dissatisfied	30%	33%
How likely is it that you will continue using this method?			How does your partner feel about continuing with this method?		
Likely	85%	67%	Continue	70%	50%
Indifferent	10%	0%	Indifferent	30%	50%
Unlikely	5%	33%	Not continue	0%	0%
How satisfied are you with how quickly this treatment works?			How natural does the erection feel when using this method?		
Satisfied	80%	33%	Natural	45%	33%
Indifferent	10%	50%	Indifferent	20%	17%
Dissatisfied	10%	17%	Artificial	35%	50%
How satisfied are you with how long the erection lasts?			How would you rate the erection's hardness and naturalness compared to your erections before you had ED?		
Satisfied	90%	50%	Harder	60%	50%
Indifferent	10%	17%	The same	15%	17%
Dissatisfied	0%	33%	Less hard	25%	33%
How easy was it for you to use this treatment?					
Easy	70%	50%			
Indifferent	20%	17%			
Difficult	10%	33%			

ED: Erectile dysfunction

rate; Levine *et al.* in 2001 found an overall satisfaction rate of 90.6% in patients and 82.6% in their partners with the two-component inflatable prosthesis (Ambicor two-piece penile prosthesis).<sup>[5]</sup> In 2007, Lux *et al.* reported overall satisfaction rates of 85% in patients and 76% in their partners, with the same prosthesis.<sup>[6]</sup> In 2014, Lindeborg *et al.* presented 33 patients with a PPI (Titan one-touch release penile implant) and reported an overall satisfaction rate of 85%.<sup>[7]</sup> In 2015, Ji *et al.* reports a global satisfaction in patients of 86.6% and in their partners of 83%, however, it is based on the International Index of Erectile Function (IIEF) and not in

the EDITS.<sup>[8]</sup> Vakalopoulos *et al.* in 2013 found satisfaction rates of 75.48% in patients and 70% in their partners, using a three-piece inflatable prosthesis.<sup>[9]</sup>

These studies, in general, report high rates of sexual satisfaction in both patients and their partners and these are close to those found in our analysis.

On the other hand, there is concern about the post-operative complications such as chronic pain, extrusion, malfunction, and infection, which lead to the removal of the device.

Table 3: Partners' survey

EDITS Questionnaire for partners	Inflatable <i>n</i> =15	Malleable <i>n</i> =3	EDITS Questionnaire for partners	Inflatable <i>n</i> =15	Malleable <i>n</i> =3
In general, how satisfied are you with this treatment?			How does your partner feel about continuing with this method?		
Satisfied	66.7%	66.7%	Continue	93.3%	66.7%
Indifferent	20.0%	0.0%	Indifferent	6.7%	0.0%
Dissatisfied	13.3%	33.3%	Not continue	0.0%	33.3%
Do you think that this treatment has influenced your perception of being sexually desirable?			How satisfied are you with the erection's duration?		
Positively	40.0%	66.7%	Satisfied	73.3%	66.7%
Indifferent	53.3%	0.0%	Indifferent	20.0%	0.0%
Negatively	6.7%	33.3%	Dissatisfied	6.7%	33.3%
Has the treatment met your expectations?					
Yes	66.7%	66.7%			
Half	6.7%	0.0%			
No	26.7%	33.3%			

In our analysis, we identified four cases of infection in 25 patients. One of them received oral antibiotic treatment with resolution and continued using the prosthesis. He was globally satisfied at the time of the survey; three of them presented secondary extrusion, so the prosthesis was removed, and the patients were not interviewed.

Regarding mechanical dysfunction, there were three cases in 25 patients. One of them was taken to surgical revision with correction of the defect. The other two were identified during the interrogation of the patients; however, the dysfunction has not been verified by our working team.

There were two cases of chronic pain; one of them reported being satisfied and achieving an adequate sexual relationship despite the pain described as occasional and intermittent. The other had been taken to surgical review previously for mechanical dysfunction with correction of the defect; however, he later presented pain of moderate intensity and would prefer the removal of the prosthesis.

One of the patients reported anomalous curvature; however, he has not used the prosthesis due to lack of a partner, although he indicated that it works properly.

There are multiple studies that describe the complications, and very variable rates are observed. Since the introduction of antibiotic-coated implants (rifampin and minocycline), a reduction in infection rates has been reported, from 1.61% to 0.68% according to Carson *et al.*<sup>[10]</sup> In our analysis, we found infection rates higher than those reported by Carson

*et al.* However, the literature is wide, and other authors have found different and higher rates of infection and other complications. Levine *et al.* reported a prosthesis infection rate of 4.6% and mechanical dysfunction of 2.3%.<sup>[5]</sup> In 2005, Jensen *et al.* evaluated 52 patients undergoing PPI (Mentor Alpha-1 IPP), finding a surgical revision rate due to mechanical dysfunction or infection of 15%, with three cases of withdrawal.<sup>[11]</sup> On the other hand, Lux *et al.* found low prosthesis revision rates due to infection, mechanical dysfunction, and pain (0.7%, respectively).<sup>[6]</sup> Lindeborg *et al.* found a mechanical dysfunction rate of 9% and one case of removal of the prosthesis due to infection (3%).<sup>[7]</sup>

Perhaps, one of the most important studies on this topic was carried out by Natali *et al.* in 2008,<sup>[12]</sup> where he evaluates sexual satisfaction and outcomes with three types of prostheses (AMS 700 CX, AMS 600/650, and AMS Ambicor) using the EDITS, where the results can be compared between malleable and inflatable prosthesis of two and three components.

He found that the highest rates of satisfaction correspond to the AMS 700 CX prosthesis (97% in patients and 91% in their partners), followed by the AMS Ambicor prosthesis (81% in patients and 91% in their partners) and the malleable prosthesis AMS 600/650 (75% in patients and 75% in their partners).

In addition, the complication rates were reported to be 12.5%, 7.5%, and 2.5% for infection for AMS 700 CX, AMS Ambicor, and AMS 600/650, respectively; of 25%, 15%, and 5% for mechanical dysfunction; and of 10%, 5%, and 17.5%, respectively, for erosion, which correlates with our findings.

Given the diversity of the results, the readers' attention should be drawn to prefer non-sponsored studies with samples that represent the prototype of the population to be treated.

Regarding malleable prostheses, there are few studies available that have evaluated sexual satisfaction in patients and couples.

In 2013, Falcone *et al.* found an overall satisfaction of 86.4% in patients and 52.6% in their partners, in 22 patients who were taken to implant of malleable penile prosthesis (AMS spectra) between 2010 and 2012, through the IIEF and EDITS surveys.<sup>[3]</sup>

In 2004, Salama *et al.* evaluated 50 patients who had been implanted with a malleable prosthesis (AMS 650 or Acuflex) between 1991 and 2002, finding an overall satisfaction of 70% in patients and 57% in their partners. This was evaluated through non-validated questionnaires.<sup>[13]</sup>

Regarding complications, one of the patients who was taken to removal of the prosthesis due to infection had a neurogenic etiology due to spinal trauma and had a history of penile trauma.

The patient with extrusion had a history of ST due to a traffic accident that caused displacement of the prosthesis through the crura and asymmetry of the penis, and the removal was considered; however, he did not want it and kept using the PPI regardless. At the time of the interrogation, he was partially satisfied with it.

In our experience, the patients chosen for the placement of a malleable prosthesis are those that have the most difficult conditions from the anatomical and prosthetic point of view: ST, multiple surgeries, scars, deformities, intestinal, and urinary derivations significantly increase the risk of infection and extrusion.

The group size of malleable prosthesis was not significant to make comparisons. The malleable prosthesis seems to have rates of sexual satisfaction in patients and their partners lower than those reported in inflatable prostheses, possibly for the reasons already mentioned. Besides the prototype of the patient and another speculative reason, it probably is preferred by professionals with low experience. In any case, the available information is limited, scarce, and divergent, so we consider it leads to sub-registration and publication bias.

The inclusion criteria were clear and strict; however, as it is well known, the prosthesis does not necessarily restore the pre-morbid length and, in fact, may involve a loss of it due to the lack of tumescence of the glans. These facts must be explicitly warned to diminish unrealistic pre-operative expectations.

Our limitations included the difficulties in the post-operative follow-up related to the origin of the patients, their health insurance, and dispersed medical controls.

In our experience, we found high rates of sexual satisfaction in patients and their partners that allow us to deduce that the penile prosthesis is a feasible option in patients with ED refractory to the first- and second-line treatment. The selection criteria and realistic presentation of the outcomes are crucial for the patients' expectations.

Although there are multiple series of patients treated with PPI, few explore the reasons of dissatisfaction in technically successful cases. Future studies need to be designed to address this problem.

## LIMITATIONS

The EDITS questionnaire is originally published in English and is not validated in Spanish; therefore, it was adapted to Spanish by consensus of experts, and subsequently, the counter translation was carried out by a participant external to the project. With this, the interview instrument was obtained.

The type of design does not allow assuring a sample superior to the obtained one, more approximate to the ideal, since it was a retrospective study.

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