

Penile Prosthesis and Couple Satisfaction: A Prospective Study

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Abstract: *The management of erectile dysfunction refractory to medical treatment is still a challenge that is faced by clinicians worldwide. The penile prosthesis surgical intervention (PPSI) remains the mainstay effective alternative given the high incidence of couple satisfaction achieved by this surgical technique. This is a prospective study including 50 patients who benefited from the PPSI that were conducted at the Mohammed VI and Cheikh Khalifa International University Hospitals in Casablanca, Morocco between January 2019 and January 2020. The satisfaction of the patients benefiting from the penile prosthesis and of their respective partner were assessed via a questionnaire consisting of 20 questions. There were high patient and partner satisfaction rates. 74% of the patients that benefited from the penile prosthesis were completely satisfied with the post-operative results. In addition, 88% of the partners felt a marked improvement in their sexual experience after the surgical intervention. The age group that formed the majority of the patient population was between 45 and 65 years. The cross sorting of the following two variables: the satisfaction of the patient and the respective patient age group had a significant p-value estimated at 0.019 (<0.05). We also cross sorted the satisfaction of the patient with the improvement of their respective partner's sexual experience after the PPSI with a p-value of 0 (<0.05). This study showed significant satisfaction rates of the patients who benefited from the PPSI and their respective partner. These results may suggest that the PPSI remains the most suitable therapy for patients with erectile dysfunction refractory to medical treatment.*

Keywords: couple satisfaction, penile prosthesis, erectile dysfunction, sexual experience

1. Introduction

Erectile dysfunction (ED) is defined as the persistent or repeated inability to achieve and / or maintain a sufficient erection until the completion of sexual activity [1]. It is the most common sexual disorder, even more prevalent than premature ejaculation. It has been a public health problem since the dawn of time, the description of which dates back to the scriptures of the ancient Egyptians to the works of Hippocrates [2].

A large study on the prevalence of ED in men between 20 - 75 years old in 8 countries showed an overall prevalence of 16%, which increases with age and estimated at 37% in the 70 - 75 years old age group [3].

Only in rare cases of secondary ED are cured after the primary pathology has been treated. In fact, the treatment of ED has been revolutionized by the advent in 1998 of Phosphodiesterase 5 (PDE 5) inhibitors due to their efficacy,

low-cost and safety [4]. However, around 40% of patients with ED do not respond to, or even tolerate medical treatment, especially older patients for whom cardiovascular risk factors are more severe. Thus, intra-cavernous injections and urethral instillations can represent a treatment option; notably with autologous Plasma Rich Platelets (PRP) or Stem Cell preparations. The latter two therapies still under evaluation whose high cost and poor compliance to follow-up constitutes a major cause of lack of proven efficacy [5].

The penile prosthesis represents a treatment option for ED that cannot be cured with previous means. Though it is an invasive procedure, it is without a doubt a surgery associated with a high efficacy and increased patient satisfaction rates [6].

In the United States, the number of penile prostheses has increased from 17,540 in 2000 to 31,802 in 2019, constituting around 80% of all implants placed [8].

There are mainly 2 types of penile prosthesis, the flexible

semi-rigid and the inflatable penile prosthesis. The latter being certainly the most used in Western countries, but their cost remains excessive and their mechanical breakdown are quite frequent. The less expensive semi-rigid implants on the other hand are easier to handle by the patient with virtually no mechanical breakdowns [9].

The primary aim of our study is to report the satisfaction of our patients at our center who benefited from the treatment of ED by semi-rigid prosthesis and their spouses; in terms of patient profiles, surgical results and complications.

2. Materials and Methodology

This is a prospective study carried out between January 2019 and January 2021, approved by the ethics committee of the Mohammed VI University of Health Sciences, alongside the Mohammed VI and Cheikh Khalifa International University Hospitals in Casablanca, Morocco. All patients and their partners were fully informed that the prosthesis would treat their ED and had no effect on sexual desire, orgasm, ejaculation or fertility. The survey was designed and targeted the eligible patients, who were operated by the same experienced surgical team according to a strict aseptic protocol during the aforementioned 1-year time frame.

Two brands of semi-rigid penile prostheses were used, the "Coloplast" and the "Rigicon", with the same standardized operating technique. Patients learned to handle the implanted device 3-5 weeks post-op when the patient has fully recovered according to the institution's standard protocol. Thereafter, the patients had follow-up consultations 3 months, 6 months and one year post-operatively. During these time frames the current state of the prosthesis and the satisfaction of patients and their spouses with the penile prosthesis were assessed and the surveys were given to the patients either by telephone or face to face, depending on the preference of each patient after informed consent.

The survey design, data collection and interpretation processes were conducted using the SPHINX software documentation generator.

The P value was calculated by the chi-square test of the SPSS software. The studied variables were analyzed by two different methods:

The flat sorting method consisted of studying the following variables: age, patient satisfaction, partner satisfaction, etiology of the erectile dysfunction.

In parallel, the Cross Analysis method included the sexual satisfaction of the partner pre- and post-op, the patient's sexual satisfaction and the partner's sexual satisfaction.

3. Results

50 patients benefited from the semi-rigid penile prostheses. The ages of the patients are between 38 and 78 years old, however the majority of the patient population were between 45- and 65-years old age group.

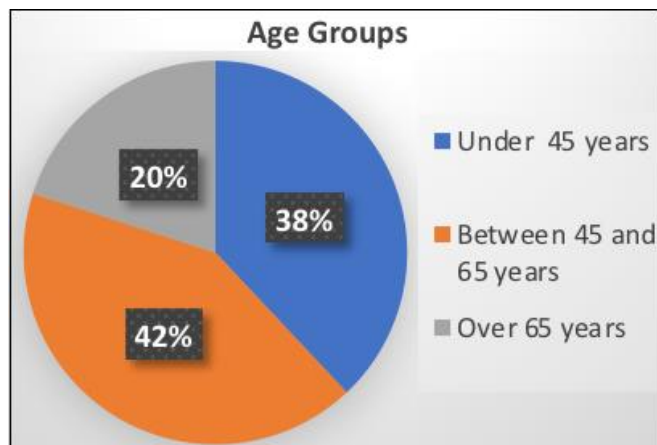


Figure 1: Pie Chart showing the different age groups of the patients benefitting from the PPSI

The most predominant etiology in our study was diabetes with 19 patients, 10 patients had a history of radical prostatectomy, 7 who had cysto-prostatectomy, 5 who suffered from uncontrolled hypertension, 2 who had Peyronie's Disease. However, 7 patients had idiopathic ED that did not respond to medical treatment.

Table 1: Chart showing the prevalence of the various ED etiologies among our patient population

Etiology	Number of Patients	Percentage
Type II Diabetes Mellitus	19	38%
Radical Prostatectomy	10	20%
Cysto-Prostatectomy	7	14%
Un-controlled HTN	5	10%
Peyronie's Disease	2	4%
Non-Specified ED	7	14%

3.1 Pre-Operative Complications

Only one patient suffered an intraoperative urethral lesion, that was repaired by simple interrupted sutures on the spot. The patient kept the Foley's Catheter post-op for 8 days. This patient's urethral injury recovery had a favorable outcome without any urinary disorder after 18 months of follow-up.

3.2 Early Post-Operative Complications:

4 patients had acute urinary retention after the removal of their Foley's catheters day 2 post-op. They were re-catheterized for an additional 48 hours, with no other immediate episodes of urinary retention.

5 patients suffered from post-operative penile shaft pain during the 1st week, the evolution was marked by a disappearance of the pain after treatment with palliative analgesia.

1 patient presented with a slight hematoma of the glans, which was spontaneously resolved day 6 post-op.

3.3 Late Post-Operative Complications:

We did not identify any late complications from the surgery.

3.4 Results of Patient and Partner Satisfaction Rates:

The study showed high patient and partner satisfaction rates with their implanted prosthesis; with 74% of patients being very satisfied with the surgery while 12% were not at all satisfied.

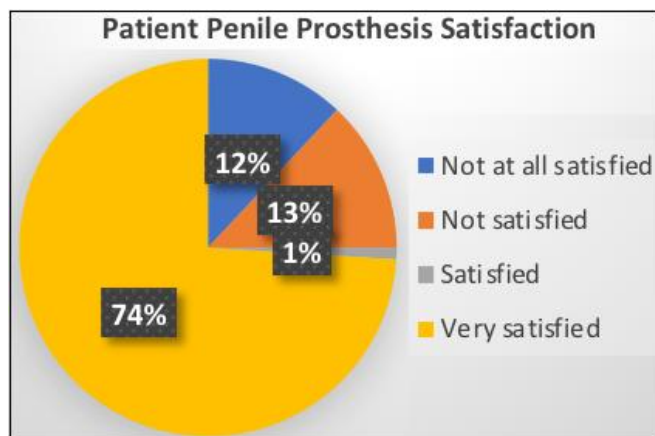


Figure 2: Pie Chart showing Patients' Post-Operative Satisfaction

We cross analyzed the following two variables: patient satisfaction and their age group. The 45-65 years age group represented the most satisfied population group with their implant surgery outcome having a significant P value of 0.019 (<0.05)

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	11,782 ^a	4	,019
Likelihood Ratio	14,882	4	,005
Linear-by-Linear Association	2,771	1	,096
N of Valid Cases	50		

The survey targeted the partners showed that 88% of them felt a marked improvement in their sexual experience after their husband's benefitted from a penile prosthesis.

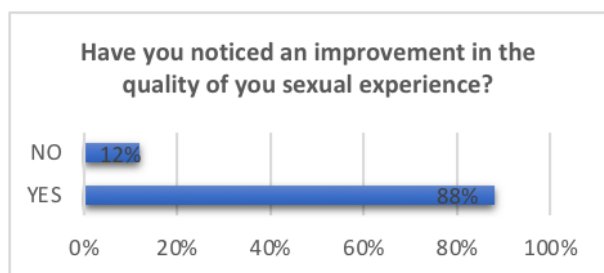


Figure 2: Bar Graph illustrating patient's detecting a positive change in their sexual activity after PPSI

Through the cross-analysis methodology, we compared the satisfaction of sexual intercourse in the partner pre-op with the improvement in their sexual life post- PPSI. Among the 33 partners initially not at all satisfied, we noted an improvement in the sexual experience in 30 of the partners after the placement of the penile implant. Out of the 14 not satisfied partners, an improvement in the sexual experience is described in 11 of them. The P value was evaluated at

0.0304 (<0.05), thus signifying a significant correlation between these two variables.

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1,852 ^a	3	,304
Likelihood Ratio	2,038	3	,564
Linear-by-Linear Association	,096	1	,756
N of Valid Cases	50		

In addition, we compared the satisfaction of the patient after the surgery and the improvement of the partner's sexual experience as shown in the chart below. We also found an important correlation between these two variables with a P value estimated at 0 (<0.05)

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	33,992 ^a	2	,000
Likelihood Ratio	25,544	2	,000
Linear-by-Linear Association	26,125	1	,000
N of Valid Cases	50		

4. Discussion

Erectile dysfunction (ED) or impotence is a common disorder affecting men's social, psychological and mental well-being. ED is defined as the inability to achieve and / or maintain an erection sufficient to achieve a lasting pleasurable sexual intercourse (14).

Epidemiological studies show that the prevalence of ED is estimated between 11% and 44%, depending on whether one considers different age groups or levels of erectile dysfunction of mild, moderate or severe intensity. All the prevalence surveys have also shown a correlation between ED and age: between 40 and 70 years the relative risk of erectile dysfunction is multiplied by 2 to 4 and the age threshold age to be between 50 and 60 years (15).

More than twenty years after the introduction of PDE 5 inhibitors, long-term efficacy studies range from 59% to 69% for Sildenafil, Tadalafil, Vardenafil or Avanafil. The effectiveness of these drugs depends mainly on the cause of the erectile disorder (16). Men who have a history of vascular disease as a result of diabetes or heart disease have favorable outcomes 50% of the time. On the other hand, only 30% of men who have undergone radical prostatectomy have shown a response to medical treatment. Additionally, some men cannot take erectile dysfunction (ED) medications (17).

The semi-rigid penile prosthesis constitutes an excellent alternative in the event of unsuccessful response or contraindication to medical treatments. The affordable cost, the standardized surgical technique, easy usage for the patient, and the rarity of mechanical breakdowns have made the semirigid penile prosthesis an effective and reliable ED last-line treatment option (18). In our study, the main etiologies of ED refractory to medical therapy were mainly:

diabetes, prostatectomies and cysto-prostatectomies.

The risk of infection remains the most feared complication with a risk of 7%, the most common responsible infective organism being *Staphylococcus Epidermidis*. The incidence of this complication requires a mandatory removal of the implant and rescheduling an alternative PPSI 6 months later. The causes of such a complication may be linked to "patient-dependent" factors such as immunosuppression such as but not limited to: uncontrolled diabetes, HIV infection, long-term corticosteroid therapy, "operator-dependent" factors in particular the omission of washing with gentamycin or a prolonged contact of the prosthesis with the skin or more rarely sterilization failure (20). In our study, no infection of the prosthetic material was recorded.

Intraoperative penile prosthesis placement urethral injuries are rarely described in the literature (2%), however known to possibly cause serious complication sequelae for the patient, notably urethral fistulas and strictures.

However, the iatrogenic injuries discovered intra-operatively allows for immediate correction and a better prognosis (21). In our study, a single peri-operative urethral injury was recorded, sutured immediately with an excellent outcome.

Post-operative penile pain is the most common complication described in literature constituting 12% of the patient population, with a favorable outcome in most cases. In our study, 10% of the patients experienced postoperative pain with a good response to analgesia. Other types of complications have also been described in the literature such as hematomas and surgical wound infections (22).

The most important long-term complication is the atrophy of the cavernous bodies following compression by the prosthesis, reported at 4% in the literature (23).

The main outcome measured for this surgery in our study is patient satisfaction, which can be clearly affected by a number of parameters such as patient expectations, their comorbidities, partner attitudes, as well as surgical complications (23).

In addition to the literature, the satisfaction of patients with penile implants has been reported in several studies. Bernal and Henry et al. have published a literature review from 20 years of literature on patient satisfaction after penile prosthesis insertion. The conclusion was that despite the variability of the parameters used in these studies and the lack of validated questionnaires to determine patient satisfaction, patients were generally satisfied with this surgery. Porena et al. was the first to study to evaluate the effectiveness of prostheses with regards to couple satisfaction and demonstrated that 82% of patients and their partners said they were satisfied up to 1 year after surgery (26).

Bettochi et al. Evaluated the correlation between the fitting of a penile prosthesis and the improvement of the partner's sexual function through a survey consisting of 9 questions. All of the patients and their partners gave a score of at least

7/10, with 97% saying they would recommend this therapy to others. (24).

Moskovic et al. compared male satisfaction after implant placement using a questionnaire consisting of 11 questions showing an overall 78% satisfaction rate (25).

In our study 74% of the patients were satisfied with the penile prosthesis intervention, while 88% of the partners felt a marked improvement in their sex life with a clear positive correlation between the penile prosthesis placement and the sexual satisfaction of the partner.

The penile implant appears to be a relevant solution for patients whose medical treatment is ineffective or contraindicated especially for those who have undergone radical prostatectomy; implantation of the penile prosthesis is associated with low morbidity and great satisfaction (26).

Based on the results of our study, PPSI appears to be an effective treatment for ED, with a high rate of satisfaction for the couple.

5. Conclusion

Erectile dysfunction resistant to medical treatment poses a major challenge to clinicians, the prevalence of which continues to increase and the stigma continuing to become more disabling to the male psyche.

This study confirmed that male satisfaction correlates positively with partner satisfaction and among dissatisfied men we find the cause of sexual dysfunction to be of concern to the partner.

The semi-rigid penile implant is an effective, uncomplicated, inexpensive solution with well-designed aesthetic and functional results for the patient.

Our study showed very high satisfaction rates for patients and their partners, with a marked improvement in the couple's sexuality.

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