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Patient Satisfaction and Retrospective Evaluation of Benefits of Penile Prosthetic Implantation Surgery: The OEDIPUS Study

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Abstract

Introduction: Penile Prosthetic Implantation (PPI) is the method of choice for patients not responding to or contra indicated for conservative treatment of Erectile Dysfunction (ED). Complete satisfaction has not been expressed in all cases.

Aim: Using validated questionnaires, this study sought to assess the satisfaction of patients who underwent PPI and of their partners, along with potential determinants of satisfaction. It also assessed the benefits afforded by PPI on the subjects' and their partners' sexual satisfaction, general mood, and quality of life.

Methods: This was a retrospective, single-center, open label study, including patients who had undergone PPI between 2009 and 2012 at our center.

Main outcome measures: Patient/partner satisfaction with PPI was assessed using the EDITS scale. Patient and partner attitude towards PPI were evaluated using the API and AAPPI scales, respectively. Each subject's satisfaction with PPI size was assessed with answer grades ranging from 1 to 5. Patient and partner personal, sexual, and relationship well-beings were evaluated using an answer scoring system.

Results: Study questionnaire responses were received from 96 patients who underwent PPI at our center, and from 56 partners. The mean EDITS scores of patients and partners were 82.78 (± 15.58) and 83.30 (± 15.41), respectively, suggesting high satisfaction. The mean attitude score towards PPI of patients and partners were 18.87 (± 8.42) and 14.45 (± 5.06), on the API and AAPI scales, respectively. EDITS scores significantly correlated with the patients' satisfaction with the implanted penis size, and patients' and partners' attitudes towards PPI, on the API and AAPIP scores, respectively.

Conclusions: PPI exerts an excellent impact on patient and partner satisfaction, sex-life, and overall quality of life.

Keywords: Penile prosthesis implantation; Patient satisfaction; Partner satisfaction; Erectile dysfunction

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Abbreviations

OEDIPUS: Odds of Curing Erectile Dysfunction with Implantation of Penile Prosthesis for Ultimate Patient Satisfaction; CETISM: Center for the Study and Interdisciplinary Treatment of Male Sexual Health

Introduction

Erectile Dysfunction (ED) disturbs the sexual quality of sufferers and of their partners by damaging their self-esteem, mood, and relationship. Among the treatment options, Penile Prosthetic Implants (PPI) is considered a last resort, to be employed only when all non-invasive options to achieve

Table 1: Attitude towards Penile Implant (API) and Attitude Attributed to the Partner towards Penile Implant (AAPPI) scales.

API: Attitude towards prosthetic Penile Implant					
1. The prosthesis makes sexual intercourse artificial					
2. Activating the prosthesis disrupts sexual activities					
3. Penile prosthesis is a 'plastic virility'					
4. The prosthesis damages the charm of sexual activities					
5*. Whether the erection is prosthetic or natural does not matter, as long as there is an erection					
6. With a prosthesis, sexual intercourse cannot be said to be 'normal'					
7. Activating the prosthesis may be awkward for a man in sexual meeting with a new partner					
8. Having a penile prosthesis is shameful for a man					
AAPPI: Attitude Attributed to the Partner towards Prosthetic Penile Implant					
1. If the erection is due to a prosthesis, my partner cannot measure either my sexual desire or my arousal					
2. A priori, my partner is not willing to have sexual intercourse with a man having a penile prosthesis					
3. My partner considers the penile implant mainly as a means to please me since she does not enjoy prosthesis assisted sex 4* My partner thinks that the penile prosthesis is a good means to express my virility					
5. Since the implantation, my partner is more hesitant to touch my penis 6* Since the implantation, my partner feels more desirable					
Response scale					
	2	3	4	5	6
strongly false	rather false	more false than	more true than	rather true	strongly true
		TRUE	FALSE		

*The note of agreement must be reversed for the items marked by an asterisk

natural erection have been exhausted. Patients having undergone PPI generally express high satisfaction levels, and this approach is often more appreciated by the patient than other therapies like oral intake of phosphodiesterase type 5 inhibitors or intra cavernous injection of vasoactive drugs [1-5]. Complete satisfaction is nevertheless not expressed in all cases [6,7]. Several factors responsible for lower satisfaction were identified, notably complications occurring post surgery or difficulties in using the device [8]. Longer term complaints about the size of penile implants were also found likely to negatively influence satisfaction [9]. In 2004, Kempeneers et al. [3] claimed that these latter complaints could be accounted for by a more general attitude aimed at disparaging prosthesis assisted sexuality, associating it with trickery, shame, or diminished virility [10]. Several authors are thus advocates for systematic psychoexological counseling for penile implant candidates to improve their functional and psycho-emotional assimilation of the device [11,12]. This study sought to evaluate the satisfaction of patients who underwent PPI at our center, along with that of their partners. We also analyzed the impact of factors like ED cause, age, relationship duration, complaints relating to the PPI dimensions, and attitudes towards prosthesis assisted sexuality, on their satisfaction level. Additionally, we explored the PPI-afforded benefits on subjects' sexual satisfaction, anxiety, self-esteem, relationship quality, and general mood, comparing feelings after several months of living with the implant (T3) to those of the preceding period when they experienced ED (T2), and to those of the period prior to ED onset (T1).

Methods

We performed a retrospective, open label analysis of patients who underwent PPI at our center from 2009 to 2012. All patients received routine preoperative counseling regarding surgical risks, benefits, and realistic expectations as to final outcome. PPI procedures were performed by one single surgeon (RA) with extensive experience in prosthetic surgery. The prostheses implanted were AMS devices, except two patients for whom the PPI device could not be established. The initial study phase comprised a retrospective analysis, with data pertaining to patient characteristics at implantation, type of surgery performed, and possible complications collected from patient medical records. For the second phase, patients were contacted by telephone several months post PPI for a comprehensive clinical interview. At that time, patients were invited to fill in satisfaction questionnaires, with questions relating to three chronological time periods: 1) prior to ED onset (T1); 2) while experiencing ED symptoms before PPI (T2); 3) in the aftermath of PPI (T3). The T1 and T2 documents were thus filled in retrospectively, whereas the T3 questionnaires concerned the patient satisfaction and well being at the time when the patient was interviewed.

Outcome measures

•To assess patients' satisfaction, we employed the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) scale, designed by Althof et al. [13]. EDITS has proven reliable and valid, thus enabling the scale to assess patients' and partners' satisfaction with various ED treatments. This scale is marked from 0 to 100, with higher scores representing higher satisfaction. The attitude of patients (or "Patient attitude") towards PPI and that which they attributed to their partners (or "Partner attitude") were evaluated by the Attitude towards Penile Implant (API) and Attitude Attributed to the Partner towards Penile Implant (AAPPI) scales, respectively, developed by Kempeneers et al. [3] These scales, outlined in Table 1, propose several opinions regarding PPI to which the subjects are invited to express their agreement level using a graduated scale from 1 (strongly false) to 6 (strongly true). The scores vary from 8 to 48 points for API and from 6 to 36 points for AAPPI. While low scores express a highly favorable attitude, high scores indicate a very unfavorable mind set. According to Kempeneers et al. [10], API scores >27 suggest severe difficulty adapting to PPI. Each subject's satisfaction as to PPI dimensions was assessed by the question "to what extent are you satisfied with the length of your erect penis since receiving PPI?" The answer grades ranged from 1 "highly satisfied" to 5 "very dissatisfied".

Table 2: Sexual, relational, and personal functioning before ED (T1, retrospectively), during ED (T2, retrospectively), and following prosthetic penile implantation (T3).

	T1 (before ED)	T2 (during ED)	T3 (following PPI)	T1 vs. T2				T2 vs. T3			
	Mean (SD)	Mean (SD)	Mean (SD)	t	df	p	d	t	df	p	d
Implanted patients											
Sexual satisfaction	2.10 (1.11)	4.26 (0.88)	1.74 (1.00)	16.35	93	< 0.001	3.39	17.8	93	< 0.001	3.69
Sexual anxiety	3.17 (2.00)	5.00 (2.27)	2.74 (2.18)	5.69	88	< 0.001	1.21	5.61	87	< 0.001	1.2
Sexual self esteem	5.01 (1.66)	2.31 (1.61)	5.51 (1.67)	13.1	90	< 0.001	2.76	12.96	91	< 0.001	2.72
Quality of the marital relationship	5.04 (1.66)	3.89 (1.91)	5.70 (1.42)	7.28	82	< 0.001	1.61	7.55	83	< 0.001	1.66
Communication	5.21 (1.49)	4.49 (1.93)	5.72 (1.34)	4.61	83	< 0.001	1.01	5.96	84	< 0.001	1.3
General mood	5.21 (1.64)	2.79 (1.63)	5.72 (1.45)	10.95	93	< 0.001	2.27	12.92	93	< 0.001	2.68
Frequency of penetrative intercourse	1.36 (0.64)	2.27 (0.83)	1.35 (0.59)	9.91	85	< 0.001	2.15	9.96	83	< 0.001	2.19
Frequency of non penetrative intercourse	2.16 (0.89)	2.22 (0.88)	2.13 (0.91)	0.74	82	ns		1.12	82	ns	
Frequency of masturbation	2.04 (0.91)	2.15 (0.94)	2.25 (0.88)	1.49	79	ns		0.71	76	ns	
Partners											
Sexual satisfaction	1.94 (0.99)	3.23 (1.00)	1.63 (0.77)	6.67	46	< 0.001	1.97	8.7	50	< 0.001	2.46
Sexual anxiety	1.86 (1.55)	4.09 (2.14)	2.55 (2.25)	5.56	42	< 0.001	1.71	4.03	48	< 0.001	1.16
Sexual self esteem	5.08 (1.74)	4.31 (1.89)	5.24 (1.92)	2.79	44	< 0.01	0.84	4.22	50	< 0.001	1.19
Quality of the marital relationship	6.07 (1.13)	4.62 (2.11)	6.23 (1.12)	4.82	41	< 0.001	1.51	6.02	47	< 0.001	1.76
Communication	6.00 (1.14)	5.39 (2.06)	6.33 (0.94)	2.13	43	< 0.05	0.65	3.61	48	< 0.001	1.04
General mood	5.86 (1.29)	4,43 (1.76)	6.16 (1.23)	4.46	43	< 0.001	1.36	6.12	48	< 0.001	1.77

ED = Erectile Dysfunction; PPI = Penile Prosthetic Implant

The patients' personal, sexual, and relationship well being, and that of their partners, was evaluated at T1, T2, and T3, using the following questions and scoring system:Sexual satisfaction: "To what extent were you or are you currently satisfied with your sexual activity?" Scored from 1 (highly satisfied) to 5 (very dissatisfied).

•Sexual anxiety: "To what extent were you or are you currently anxious during sexual intercourse?" Scored from 1 (anxious at all) to 7 (extremely anxious).

•Sexual self esteem: "How high was or is your sexual self esteem?" Scored from 1 (very low self esteem) to 7 (very high self esteem).

•Quality of relationship: "How would you rate your relationship (specifically the nonsexual aspect)?" Scored from 1 (very troubled relationship) to 7 (very satisfactory relationship).

•Communication: "How would you rate your communication with your partner?" Scored from 1 (very poor communication) to 7 (very good communication).

•General mood: "To what extent did you or do you currently feel happy or unhappy?" Scored from 1 (very unhappy) to 7 (very happy).

The frequency of sexual intercourse was assessed at T1, T2, and T3. The corresponding questions were focused on penetrative intercourse, non penetrative intercourse, and individual masturbation, with three answers, namely 1: >once per week; 2: >once per month; 3: <once per month.

Statistical analysis

Correlations between EDITS scores and parameters like age, relationship length, time since PPI, attitude towards PPI, and satisfaction regarding penis size were evaluated via Spearman's rank order coefficient. Correlations between EDITS scores and ED etiology were investigated using Tukey's range test. The alpha error risk was set at <5%, defining statistical significance. The differences between scores at T1, T2, and T3, as well as differences between opinions of patients and partners in terms of sexual and relationship well being were assessed via the t test the effect size was computed by Cohen's d. All analyses were performed using the STATISTICA 10 (Stat Soft. Inc. software, Tulsa, USA).

Results

Study questionnaires were received from 96 patients previously implanted in our center. On average, PPI surgery was conducted 62.7 months prior, with extreme values ranging from 6 to 230 months. The patients' mean age at the time of the study was 60.96 (± 9.58) years old, and was 55.81 (± 10.14) at the time of PPI, with extreme values ranging from 25 to 75 of the 96 patients, ED etiology was identified in 93, namely vascular disease in 47, radical prostatectomy in 22, diabetes in five, Peyronie's disease in four, neurological disorder in three and of mixed origin in 12. Overall, 84 patients (91.67%) declared having at least one regular partner; 62 (75.61%) were already in a relationship with their current partner at the time of PPI. Among these 62 couples, 59 partners returned the questionnaires.

Implanted devices

The prostheses implanted were essentially AMS devices, including 77 700 CX models, two 700 CX InhibiZone, and 15 LGX 700. For the remaining two, the model could not be determined.

EDITS scoring

The satisfaction scores achieved following PPI were rather high. The mean EDITS score of the 86 penile implanted patients' valid questionnaires was 82.78 (± 15.58), ranging from 30 to 100 points, and that of the 56 partners' valid questionnaires was 83.30 (± 15.41), ranging from 35 to 100 points. The differences between patients' and partners' satisfaction were negligible.

API and AAPPI scoring

Using the API scale, the mean score for the patient attitude

towards PPI was 18.87 points (± 8.42), ranging from 8 to 45 points. Overall 13 subjects (14.29%) reported attitude scores exceeding 27. Using the AAPPI scale, patients scored their partner's attitude towards PPIs at 14.47 (± 5.06) points, on average, ranging from 6 to 28 points.

Satisfaction determinants

EDITS scores, from implanted patients and their partners, were not significantly influenced by ED etiology or other variables like patient's age, partner's age, age upon PPI, relationship length upon PPI, and time since PPI, none significantly correlating with EDITS scores. However, significant correlations ($p < 0.05$) were found between EDITS scores of implanted subjects and their professed satisfaction degree with the size of the penis after penile implant ($\rho = 0.58$), attitude towards PPI (AIP scores) ($\rho = 0.42$), and partners' attitude regarding PPI (AAPIP scores) ($\rho = 0.51$). Likewise, partners' EDITS scores correlated with satisfaction regarding the size of the penis ($\rho = 0.42$), AIP score ($\rho = 0.34$), and AAPIP score ($\rho = 0.46$). The subjects' attitudes towards prosthesis assisted sexuality (API score) and satisfaction they expressed concerning the size of the penis significantly correlated ($\rho = 0.43$).

Benefits of prosthetic penile implantation

As shown in Table 2, indicators of sexual and relationship well being significantly differed between T1 (before erectile difficulties manifested) and T2 (during ED difficulties, before implantation), while largely declining. Conversely, from T2 to T3 (following PPI), indicators significantly improved. The frequency of sexual activity was found to follow a similar pattern. After considerably diminishing in frequency at T2, penetrative sexual intercourse returned once the PPI was inserted; to once per week on average, as before the difficulties began. The frequency of extra coital acts and masturbation remained, however, unchanged (data not shown). When considering only the opinion of the 62 subjects who were still in the same couple since the ED onset and that of their 59 partners, the evolution from T1 to T3 corresponded to a return to the previous *status quo*. When comparing these two time points, there were no significant differences found in the indicators regarding sexual intercourse frequency or sexual and relationship well being. At T2, there were some differences in opinion between the patients and their partners regarding sexual satisfaction (4.29 ± 0.80 *vs.* 3.10 ± 1.06, $p < 0.001$), anxiety during intercourse (5.23 ± 2.22 *vs.* 4.13 ± 2.05, $p < 0.02$), self esteem (2.22 ± 1.52 *vs.* 4.20 ± 1.87; $p < 0.001$), and general mood (2.85 ± 1.78 *vs.* could have contributed to the high satisfaction ratings found in our trial. The disproportionate expectations, inadequacy of sexual scripts, as well as misgivings due to either some symbolic virility or specific ideas regarding natural sexuality are all psycho relational factors well known to affect satisfaction with implants. For further details, we refer the reader to the research conducted by Trost 4.48 *vs.* 1.79, $p < 0.001$). Based on these observations, we conclude that the patients felt more affected by their ED than their partners. Of note is also that the patients reported feeling slightly more anxious about sexual intercourse than their partners ($p < 0.02$), along with a slightly poorer relationship quality ($p < 0.05$) even before ED onset (T1). These differences between patients and partners had all disappeared by T3, following PPI.

Discussion

What is interesting about our data is the high satisfaction shared by both the patients and their partners with respect to PPI. In comparison with other investigations assessing satisfaction by the EDITS scale, the scores obtained in our research were among the highest [14,15]. In their long term trial on patient/partner satisfaction following PPI, Vitarelli et al. [14] reported satisfaction rates slightly exceeding 80%. In the Akin Olugbade et al. [1] trial evaluating determinants of patient satisfaction following PPI on 114 ED patients, all groups demonstrated statistically significant differences between pre and post operative EDITS scores, with Peyronie's disease patients exhibiting significantly lower scores than the general implanted population [1]. In the Vakalopoulos et al. [15] Study involving 90 ED patients who underwent IPP, the mean EDITS scores of patients and partners in the post operative period were 75.48 ± 20.54 and 70.00 ± 22.92, respectively, which compares unfavorably with our data set [15]. One explanation for this discrepancy could be our relatively long follow up period, thereby diminishing the classically negative impact of postoperative complications like penile pain, infection, or failure of the device. Additionally, difficulties of functional adaptation to the implanted device must often be overcome in the aftermath of surgery. While most of these problems are generally reported in the months following IPP surgery, they were perhaps largely resolved by the end of our follow up, meaning that satisfaction levels were no longer impacted by typical post surgical complaints. We can logically assume that the counseling sessions offered to all of our patients prior to carrying out PPI surgery may have reduced such deleterious influences. As outlined by published research, the dissatisfaction expressed by patients and their partners notably consists of complaints regarding penis size after PPI [9]. While not wholly separate from certain patients' general distrust towards PPIs and the distrust they believe is equally felt by their partner, incorrect sizing is a common complaint in the literature. For long term success, it proves crucial that PPIs are of the correct size [16]. If implants are too short, the glans may be hyper mobile and tend to drop at the prosthesis' end [16]. On the other hand, when inflatable cylinders are too long, an S shaped deformity may result [16]. Such patient and partner attitudes, addressed in our study by the API an AAPPI scales, respectively, are known to exert a negative influence on satisfaction scores. We did in fact observe significant correlations between EDITS scores and implanted patients'/partners' professed satisfaction with the size of the penis post PPI, as well as their API and AAPIP scores. These results confirm those of a previously published report by Kempeneers et al. [3], in which the authors drew conclusions on the detrimental effect resulting from a normative representation of sexuality that associates "the male erotic value with strong, natural, spontaneous, and non assisted erections", claims the inability of prosthetic surgery to alone "restore male self image based on such criteria", and postulates the need to supplement surgery "with appropriate psycho sexological guidance". In our series, such problems were encountered despite psycho sexological counseling systematically offered to implantation candidates. Of note is that mean API scores, as well as the number of subjects scoring over 27 points ($n = 13$), remained similar to those reported by Kempeneers et al. [10]. Such attitudes thus constitute real challenges that may hinder the full optimization of PPI surgery. Besides complaints regarding the size of the penis post PPI and distrust towards PPIs, no other variables were found to significantly impact satisfaction levels. Particularly interesting is the lack of any link between ED etiology and satisfaction ratings, in contrast to observations made by Akin-Olugbade et al.[1], reporting lower EDITS scores in patients with Peyronie's disease patients or following radical prostatectomy. Though these evaluations may have been tainted by the bias inherent to the study's retrospective open label design, experiencing ED appears to be damaging, leading to deterioration

not only of sexual function but also of the couple's functioning and general mood. Based on our findings, the penile implant appears to offer the benefit of a return to the tatus quo, no more any less. While these effects were also experienced by the partners, they were more significant in the patients, both direct sufferers of ED and recipients of the implant. We were in no way surprised to note that the frequency of penetrative sexual intercourse was notably decreased while patients were suffering from ED. It was yet interesting to note that no increase in non penetrative sexual activity or masturbation occurred during this time period aimed to replace in frequent penetrative intercourse.

Conclusions

PPI constitutes a valid treatment modality for ED patients, with a significant impact on patients' and their partners' satisfaction, sex life, and overall quality of life. In the hands of experienced surgeons, satisfaction rates score high and complication rates low.

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