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Predictors of Satisfaction in Men After Penile Implant Surgery

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Abstract

Introduction: Despite the high satisfaction with penile implant (PI) surgery reported in the literature, a significant proportion of patients remain dissatisfied.

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Aim: To evaluate satisfaction after PI surgery, using a single question and a scoring system. Furthermore, we attempted to define factors that predicted high patient satisfaction.

Methods: The study population consisted of all patients undergoing PI surgery between 2009 and 2015. Comorbidity, demographic, and implant information were recorded. Complications recorded included: minor (requiring no re-operation) such as penile or scrotal hematoma, superficial wound breakdown; major (requiring hospitalization or re-operation) such as device infection, erosion, and mechanical malfunction. Patient satisfaction was defined using a single question posed to the patient 6 months after surgery using a 5-point Likert scale (5 being the most satisfied). Descriptive statistics were used to define complication rates and multivariable analysis (MVA) was performed to define predictors of high satisfaction (score 4), including presence and degree of complications, Peyronie's disease (PD), diabetes mellitus (DM), number of vascular comorbidities, body mass index (BMI) > 30, and patient age.

Main Outcome Measure: Patients with a major complication, with or without an additional minor complication, had a higher likelihood of being dissatisfied (25%) compared to patients with no complication or only minor complication 1.9% (no complications) and 3.7% (only minor complications), P < .001.

Results: 902 patients were analysed. Mean age was 56.6 ± 10.6 years. Mean BMI was 30 ± 5 . Comorbidity profile was diabetes 75%, dyslipidaemia 44%, hypertension 33%, cigarette smoking 32%, and PD 34%. 76% had a malleable implant (MPP) and 24% an inflatable implant (IPP). 31% had a minor complication and 9% a major complication. 93% had high satisfaction (score 4). Patients with any complication had a reduced rate of high satisfaction (97.5% vs 87.7%; P<.001) and even more pronounced with a major complication (96.7% vs 64.2%; P<.001). On MVA, only the absence of a major complication was a significant predictor of high satisfaction (OR 20, 95% CI 9–50, P<.001).

Conclusion: A high percentage of men are satisfied after penile implant surgery. Only the presence of a major complication is linked to a lower likelihood of achieving high satisfaction.

Keywords

Penile Implants; Complications; Satisfaction; Predictors

INTRODUCTION

When compared with other treatments for erectile dysfunction (ED), including erectogenic pharmacotherapies and vacuum devices, the current literature suggests that patients who have penile implant (PI) surgery have the highest satisfaction rates. 1–3 Penile implants are divided into inflatable devices and malleable devices. Currently, the preferred type of penile implant in North America and Western Europe is the inflatable device (IPP), but in many parts of the world, malleable penile prosthesis (MPP) is the most commonly used, often for cost reasons. 4

The aims of PI surgery are to achieve high patient satisfaction combined with the low complication rates. Numerous studies have reported high satisfaction rates for patients after PI surgery for the treatment of ED. The highest patient-reported rates of satisfaction have

been associated with the 3-piece IPP.^{5,6} But in general, patient satisfaction rates range were from 75% to 98% for the general penile implant population.^{1–7}

Many predictors for patient satisfaction following PI surgery have been suggested, including presence of Peyronie's disease (PD), obesity, prior radical prostatectomy (RP), type of implant, postoperative complications, and patient age.^{1,3–5,8,9} There is no specific tool for accurate patient satisfaction level after PI surgery. Some have relied on surgeon self-assessment whereas others have used a variety of questionnaires, including the international index of erectile function (IIEF) questionnaire, ^{1,3,6,9,10} and the erectile dysfunction inventory of treatment satisfaction (EDITS) questionnaire.^{4,7,8,10} Others used simplified postoperative satisfaction scales.¹¹ It is worth mentioning that none of these measurements tools have been validated to measure post-PI satisfaction specifically.

The aim of this study was not only to measure satisfaction level, as previously published, but also to further understand satisfaction predictive factors. Understanding these factors may potentially lead to identification of modifiable clinical practice improvements and to the ultimate goal: higher patient satisfaction.

PATIENTS AND METHODS

Study Population

This study is based on a prospectively built large multicentre database including all cases of primary (non-redo) penile implant surgery performed in the years 2009 to 2015. The data collected for each procedure included identification of the center and surgeon, patient data including demographic, medical and sexual history, age and indication for surgery, procedure-related data including implant type used, follow-up-related data including duration of follow-up and early and late complications. Complications were defined as minor (not requiring hospitalization or re-operation), such as penile or scrotal ecchymosis, hematoma, superficial wound breakdown; and major (requiring hospitalization or re-operation), such as device infection, mechanical failure, and erosion.

Preoperative Counselling

The preoperative discussion focused on the goal of surgery of obtaining a "functional erection," an erection permitting sexual intercourse. Advantages and disadvantages of both types of implants, MPP and IPP, were explained thoroughly for all patients. Choosing MPP versus IPP was the patient's decision. The surgeon's role was to explain the advantages and disadvantages of each type of implant using educational videos. Choosing MPP versus IPP was based on patient's preference including factors such as concerns regarding concealment, ease of use but often relied heavily on cost, because PI surgery is not covered by insurance in our geographic location. This consent form signed by all patients included all the potential complications listed above.

Operative Considerations

For malleable implants, the preferred approach was a ventral raphe incision. For inflatable implants, all were done through a penoscrotal approach. MPP patients were discharged the

same day while IPP patients were discharged the next morning. The patients were seen in the outpatient clinic twice a week for the first 2 weeks, weekly in the third and fourth weeks and every 3 months until loss to follow-up.

Patient Satisfaction

This was defined using a single question posed to the patient by the surgeon 6 months after surgery using a 5-point Likert scale (1: dissatisfied; 2: somewhat dissatisfied; 3: neutral; 4: satisfied; 5: mostly satisfied). Satisfaction was defined as having a score 4.

Statistics

Descriptive statistics were used to describe the study group and to define outcomes, including complications rates and satisfaction. Univariate analysis (a chi square test for discrete variables, and a t-test for continuous variables) was performed to identify potential predictors of satisfaction (score 4), including severity of complications (minor and major), PD, diabetes mellitus (DM), number of vascular comorbidities (hypertension, dyslipidemia), BMI > 30, patient age, and implant type. Multivariable analysis (logistic regression) was used to define predictors of satisfaction as a dichotomous variable as well as a continuous variable.

RESULTS

Study Population

902 patients were included in the database, of which 872 had primary surgery, and of them 773 had satisfaction data available. Mean patient age was 56.2 ± 10.7 years, and mean BMI was 30.2 ± 5.1 . Patient characteristics and implant data are presented in Table 1. Median follow-up duration was 28.5 ± 16.9 months.

Complications

485 (62.7%) experienced no complication. 216 (27.9%) had at least 1 minor complication without any major complication, whereas 72 (9.3%) experienced at least 1 major complication, with or without additional minor complication(s). Detailed data about type and frequency of complications are shown in Figures 1 and 2.

Patient Satisfaction

35 (4.5%) were not satisfied (score 1–2), 131 (16.9%) were neutral (score 3), and 607 (78.5%) were satisfied (score 4–5; Table 2). Patients with a major complication, with or without an additional minor complication, had a higher likelihood of being dissatisfied (25%) compared with patients with no complication (1.9%) or only minor complications (3.7%; P < .001 for both). In the study, 79.6% of patients without any complications were satisfied, and 84.3% of patients with only minor complications were satisfied, but only 54.2% of patients who experienced a major complication (with or without additional minor complications) were satisfied (P < .001). Table 3 shows results of comparing those who were satisfied and those were dissatisfied using dichotomous variables, whereas Table 4 shows

the same comparison using continuous variables. Finally, the predictors of being satisfied on multivariable analysis are shown in Table 5.

DISCUSSION

Since their introduction more than 60 years ago, PIs have remained the standard therapy for the management of patients with ED who have failed first- and second-line treatments or have found these unacceptable. ¹² PIs enable the patient to consistently engage in penetrative sexual relations. Modifications and improvements of the devices and surgical techniques have resulted in reduced complication profile and increased patient satisfaction. The most frequently implanted PI in the United States and Western Europe is the IPP, ^{1,5,6} whereas the MPP is the most-commonly implanted device in other parts of the world. ^{4,11} Numerous factors play a role in which implant is used, but cost remains a major issue. IPPs have the advantages of a better penile flaccidity profile and greater ease of concealment. However, IPPs are more expensive and, for the infrequent implanter, are technically more challenging. The MPPs have the advantages of easy implantation, low cost, and ease of use. The main disadvantage is permanent rigidity that results in difficulty in concealment. ⁴

The most important end-point of PI surgery is patient satisfaction. Overall, patient and partner satisfaction with PI appear to be reasonably high. Patient satisfaction is a complex and multifactorial issue that may be related to numerous factors including the degree of postoperative pain, occurrence of postoperative complications, cosmetic outcome, device function, ease of use, and partner acceptance and satisfaction.

There is no PI-specific tool for measuring patient satisfaction postoperatively. Thus, a variety of questionnaires have been used for this purpose. Most studies have utilized the IIEF questionnaire, 1,3,6,9,10 or the EDITS questionnaire, 4,7,8,10 although neither has been validated for the PI population, thus interpreting data from such studies is fraught with problems. Some investigators have used a simple postoperative satisfaction 1 to 5 scale, 11 while others have used simple questions about the procedure by structured telephone interviews. 13

There is little data in the literature on satisfaction rates for MPP. In a recent study analysing the satisfaction rates of the AMS malleable implant, Spectra (Boston Scientific, Marlborough, MA, USA), the overall satisfaction rates were 96.2% for patients and 84.6% for partners. Salama et al reported 70% and 57% long-term satisfaction rates with AMS 650 (Boston Scientific, Marlborough, MA, USA), and Mentor Acu-Form (Mentor Corp, Santa Barbara, CA, USA) devices respectively. Fathy et al also reported similar results with low complication rates with the Tube MPP (Promedon, Cordoba, Argentina). In a large European study, the authors reported that the most common reasons for dissatisfaction were penile shortness, unhappiness with the appearance of the penis, and pain, but only 26% of the dissatisfied men wanted the implant removed. The patient and partner satisfaction rates have been reported to be higher in functioning inflatable implants. Although it is claimed that the ease of concealment is one of the main advantage of IPP, interestingly only half of men were satisfied with the deflation mechanism in a study that examined 3 types of inflatable devices.

The main purpose of the present study was to evaluate satisfaction following PI surgery. The main cause for dissatisfaction in our study population was the presence of any major complication, specifically, infection, erosion, or mechanical failure. Of the 35 (4.5%) patients who were unsatisfied and had removal of their implants, the results were 26 because of infection, 4 because of erosion, and 5 because of mechanical failure. Those who were intermediately satisfied (131 patients, 17%), attributed their scores of being not highly satisfied to different reasons: 41 patients because of postoperative penile size, 25 because of postoperative pain and wound problems, 13 patients complained of instability of implants (with MPP), 6 because of pump problems (with IPP), and the remaining for a variety of postoperative complications. Overall the vast majority (78.5%) of patients were satisfied, as defined as a score of 4 on a 5-point Likert scale. The postoperative overall (minor and major) complication rate was overall 37.2%. This figure is likely because we were meticulous in defining and collecting complication data.

Many predictors for patient satisfaction after IPP surgery have been suggested, including presence of PD, BMI $> 30 \text{ kg/m}^2$, prior radical prostatectomy (RP), type of implant, postoperative complications, and patient age. $^{1,3-5,8-10}$ In a recent study by Ziegelmann et al, 19 the authors concluded that enhanced patient selection and counseling improved patient satisfaction and overall outcomes in penile implant surgery, and we agree that careful and thorough counseling are critical to avoid unrealistic expectations (such as postoperative penile enlargement), which ultimately lead to dissatisfaction.

We evaluated many possible predictors of satisfaction, specifically obesity, smoking, dyslipidemia, hypertension, DM, type of implant (malleable vs inflatable), surgeon volume, and the presence of PD. On MVA, only the absence of a major complication was a significant predictor of patients being satisfied.

We, like other authors, ^{1,5,6,10} have found that satisfaction is significantly higher in patients with inflatable devices (86.8%) compared with those with malleable devices (76%). The frequency of sexual activity had no significant impact on overall satisfaction. Most of our patients were sexually active 1 or 2 times or more per week. About 10% reported infrequent sexual activity because of social reasons (eg, wife is not interested in sex). 1 patient attributed infrequent sex to inadequate penile size.

Our data suggest that major complications have a major impact on patient satisfaction. Although this appears intuitive, we have defined this through multivariable analysis and have furthermore shown that obesity, PD, and patient age are not predictors in contrast to prior data. This could be related to the use of different tools for patient assessment between studies or sociocultural factors.

This study has some limitations. The most important are the somewhat limited nature of the Likert scale used to assess patient satisfaction and the absence of data for partner satisfaction. On the other hand, the strengths of the study include (but are not limited to) that it is based on a large multicenter prospective database with long follow-up; that the outcomes and satisfaction with different types of prosthesis are presented; and that complications are carefully categorized and thoroughly analyzed.

CONCLUSION

As previously reported, a high percentage of men are satisfied after penile implant surgery. The overall satisfaction rate is higher in patients with an IPP than with an MPP. The presence of a major complication is the major predictor of patient dissatisfaction. Other factors that have negative impact on patient satisfaction include postoperative penile size and mechanical problems with an implant.

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Еа	rly post-opera	itive complica	ntions	
	Frequency	Percent	Valid Percent	Cumulative
				Percent
<u>None</u>	514	66.5	66.5	66.5
Delayed healing	4	0.5	0.5	67.0
Dysuria	1	0.1	0.1	67.1
Ecchymosis	4	0.5	0.5	67.7
Edema	12	1.6	1.6	69.2
Scrotal edema	2	0.3	0.3	69.5
Edema/Hematoma	2	0.3	0.3	69.7
Wound gap	2	0.3	0.3	70.0
Hematoma	3	0.4	0.4	70.4
Hematoma/Pain	7	0.9	0.9	71.3
Hematoma/Infection	1	0.1	0.1	71.4
Infection	15	1.9	1.9	73.4
Penile edema	92	11.9	11.9	85.3
Pain	71	9.2	9.2	94.4
Peno-scrotal edema	1	0.1	0.1	94.6
Scrotal hematoma	32	4.1	4.1	98.7
Stitch sinus	1	0.1	0.1	98.8
Wound infection/undersized	1	0.1	0.1	99.0
Wound infection	6	0.8	0.8	99.7
Wound Ulceration/delayed	2	0.3	0.3	100.0
healing				
Total	773	100.0	100.0	

Figure 1. Frequency and details of early postoperative complications (First 4 weeks of follow-up).

L	ate post-opera	ative complic	ations	
	Frequency	Percent	Valid Percent	Cumulative Percent
<u>None</u>	634	82.0	82.7	82.7
Removal	1	0.1	0.1	82.8
Removal 1 cylinder	1	0.1	0.1	82.9
Undersize	5	0.6	0.7	83.6
Hematoma	9	1.2	1.2	84.7
Pain	18	2.3	2.3	87.1
Instability	3	0.4	0.4	87.5
Infection	48	6.2	6.3	93.7
Wound infection	12	1.6	1.6	95.3
Delayed healing	11	1.4	1.4	96.7
Tunica erosion	1	0.1	0.1	96.9
Small size penis	3	0.4	0.4	97.3
Glanular numbness	1	0.1	0.1	97.4
Gangrenous glans	1	0.1	0.1	97.5
Discomfort	13	1.7	1.7	99.2
Edema	1	0.1	0.1	99.3
Discomfort/Feels	2	0.3	0.3	99.6
unstable	1	0.1	0.1	99.7
Hematoma/Infection	1	0.1	0.1	99.9
Residual curvature	1	0.1	0.1	100.0
UTI	767	99.2	100.0	
Total				
Missing System	6	0.8		
Total	773	100.0		

Figure 2. Frequency and details of late complications.

Table 1.

Study population characteristics

Variable analyzed	%
Diabetes	71.3
HbAlc	
<6.5	28.7
6.5–7.5	12.6
7.5–8.5	21.6
8.5–9.5	17.6
> 9.5	19.5
Hypertension	32.9
Dyslipidemia	43.3
Smoker	31.8
Vascular risk factors number	
0	11.7
1	31.6
2	29.7
3	19.4
4	7.3
5	0.3
BMI > 30	45.8
Surgeon implant volume (Number of cases)	
<30	8.4
30	91.6
Peyronie's disease	66.6
Implant type	
Malleable	74.5
Inflatable	25.5

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Table 2.

Patient satisfaction data

		Type of prosthesis	sis
	Cumulative $(n = 792)$ MPP $(n = 588)$ IPP $(n = 204)$	MPP (n = 588)	IPP $(n = 204)$
Patient satisfaction *			
Low satisfaction (1—2)	35 (4.5%)	28 (4.8%)	7 (3.4%)
Intermediate satisfaction (3) 133 (17.0%)	133 (17.0%)	113 (19.2%)	20 (9.8%)
High satisfaction (4—5)	624 (78.5%)	447 (76.0%)	177 (86.8%)

* Patient satisfaction was graded on a 1–5 scale. Low satisfaction: 1–2; intermediate satisfaction: 3; high satisfaction: 4–5.

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Satisfied versus dissatisfied groups comparison (Dichotomous variables)

	Dissatisfied group (n = 35) Satisfied group (n = 607) P Value	Satisfied group (n = 607)	P Value
Age (years)	59.4	56.2	NS
HbA1c (%)	9.2	7.8	<.001
Number of vascular risk factors	2.1	1.8	SN
BMI	29.5	30.1	NS

Table 3.

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Table 4.

Satisfied Group versus Dissatisfied Group Comparison (Continuous Variables)

	Dissatisfied group $(n = 35)$ Satisfied group $(n = 607)$ P Value	Satisfied group (n = 607)	P Value
Peyronie's disease	28.6%	36.1%	SN
Diabetes	91.4%	70.5%	.007
BMI > 30	45.7%	43.8%	NS
VRF 3	28.6%	27.4%	NS
High vol. surgeon (> 30)	80.0%	91.9%	SN
Inflatable PI (vs malleable)	20.0%	28.2%	900.
Any complication	73.5%	36.3%	<.001
Minor complication	51.4%	35.1%	.05
Major complication	51.4%	6.4%	<.001
Infection	51.4%	5.3%	<.001

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 Table 5.

 Predictors of High Satisfaction on Multivariable Analysis

Factor	Odd ratio	95% CI	P Value
Peyronie's disease	2.4	0.99-6.06	.05
BMI > 30	1.4	0.6-3.1	.43
Number of VRF	1.1	0.7-1.7	.57
Inflatable PI	1.1	0.6-1.8	.62
Diabetes	0.3	0.08-1.25	.09
Absence of major complication	19.0	7.95–45.5	<.001