

Clinical Evaluation of Outcomes of Penile Prosthesis Implantation and Partner Satisfaction

ORIGINAL INVESTIGATION Adem Altunkol¹, Hakan Erçil¹, Nevzat Can Şener¹, Sabahattin Ceber¹, Ediz Vuruşkan¹, Ferhat Ortoğlu¹, Halil Çiftçi²

ABSTRACT

Objective: We aimed to compare the outcomes of malleable and inflatable penile prosthesis implantations and partner satisfaction.

Materials and Methods: Data of 34 patients who underwent penile prosthesis implantation in two centers between September 2009 and March 2013 were retrospectively analyzed. Types of prosthesis and complication rates were compared. A telephone interview was performed to assess the satisfaction rates of patients and their partners by EDITS (Erectile Dysfunction Inventory of Treatment Satisfaction) questionnaire.

Results: The mean age was 56.16 ± 14.49 years for Group 1 and 58.13 ± 10.41 years for Group 2. The mean follow-up durations for Groups 1 and 2 were 29.39 ± 9.38 and 24.13 ± 10.27 months, respectively. The mean hospital stay was 3.56 ± 2.85 and 3.38 ± 2.27 days for Groups 1 and 2, respectively. No significant difference was observed in terms of age, hospital stay, and follow-up duration between groups. Satisfaction questions were similar between the two groups. Patients using the malleable device found it easier to use (p<0.05).

Conclusion: Using EDITS, we found that it was easier to use the malleable devices, but both patients and their partners had equal satisfaction rates. Randomized controlled trials addressing bigger populations should be conducted to support our findings.

Keywords: Erectile dysfunction, complication, penile prosthesis, satisfaction

INTRODUCTION

Erectile dysfunction (ED) is the consistent inability to develop or maintain an erection for achieving satisfying sexual function (1). It is estimated that about more than 70% of men at the age of 70 years have ED disorder (2). The use of oral phosphodiesterase type-5 inhibitors has helped many men to reacquire their sexual functions and has taken its place at the top of the treatment methods for ED, which is one of the important health problems for men. Penile prosthesis implantation is an effective treatment alternative for ED patients not responding to oral and intracavernous pharmacological agents (3, 4). In cases of insufficient conservative treatment or when oral treatment is not appropriate for patients, multi-component inflatable penile prosthesis is the gold standard treatment (5).

The penile prosthesis was first developed 30 years ago (6). Nowadays, current penile prostheses have reached better reliability and durability, and so, the rate of mechanical breakdown has decreased remarkably. These devices are put into two general groups: semi-rigid (malleable and mechanical) and inflatable prostheses. All types of penile prostheses enhance penile rigidity; however, inflatable prostheses enable better cosmetic results, since they allow penile flaccidity (7). The advantages of penile prosthesis implantation include high technical success rate, long-term mechanical reliability, and also good patient and partner satisfaction. Moreover, the success is independent of injections or tablet intake, and this approach is beneficial for patients with penile fibrosis. Penile prosthesis implantation can provide patients to achieve penile erection and to reacquire their normal sexual function (8). This study evaluated the files and recordings of patients having undergone malleable and inflatable penile prosthesis implantation retrospectively and compared them with regard to complications and partner satisfaction levels.

MATERIALS and METHODS

Malleable and inflatable penile prosthesis implantation was performed for 34 patients, who had not responded to primary care and secondary care, such as oral and intracavernous pharmacotherapy, or had not received these therapies for any reason, in two different health centers between September 2009 and March 2013, and their data were evaluated retrospectively. Eighteen patients exposed to malleable penile prosthesis (AMS Spectra, American Medical Systems, Minnetonka, Minnesota, USA) were named Group 1, and 16 patients exposed to inflatable penile prosthesis (AMS 700 CX, American Medical Systems, Minnetonka, Minnesota, USA) were named Group 2.

¹Department of Urology, Adana Numune Training and Research Hospital, Adana, Turkey

²Department of Urology, Harran University Faculty of Medicine, Şanlıurfa, Turkey

Submitted 02.07.2013

Accepted 14.01.2014

Correspondance Nevzat Can Şener MD, Department of Urology, Adana Numune Training and Research Hospital, Adana, Turkey Phone: +90 505 332 84 74 e.mail: cansener14@gmail.com

©Copyright 2014 by Erciyes University School of Medicine - Available online at www.erciyesmedj.com

Table 1. EDITS investigation form			
1. Are you generally pleased with penile prosthesis?	Dissatisfied	Somewhat satisfied	Very satisfied
2. To what extent did penile prosthesis meet your expectations?	Never met	Somewhat met	Completely met
3. How appropriate is penile prosthesis for continuous use?	Inappropriate	Somewhat appropriate	Very appropriate
4. Is it easy to use the penile prosthesis for you?	Not easy	Somewhat easy	Very easy
5. How much do you trust your competence of sexual pleasure during sexual intercourse?	Never	Sometimes	Always
6. Are you generally satisfied with your partner's penile prosthesis?	Dissatisfied	Somewhat satisfied	Very satisfied

*The first and second questions in the EDITS form were asked to both members of the couple; the third, fourth, and fifth questions were asked only to the patient; and the sixth question asked only to the partner.

Patients' demographic features, the types of prostheses used, and the rates of complications were evaluated. The patients and their partners were interviewed face to face before the operation and on the phone after the operation. Then, the EDITS (Erectile Dysfunction Inventory of Treatment Satisfaction) form, which was developed and tested for reliability by Althof et al. (9), was used for evaluation (Table 1). Since a validated Turkish version was not available, the investigation was carried out by translating it into Turkish. The first and second questions in the EDITS form were asked to both members of the couple; the third, fourth, and fifth questions were asked only to the patient; and the sixth question was asked only to the partner. The questions were evaluated separately, and the two methods were compared. For the first two questions, a common response was required from the couples.

Positive and negative aspects of different types of prostheses were explained. Following the patients, malleable penile prosthesis was suggested to patients with poor hand skills, and the inflatable prosthesis was suggested to patients with lower urinary tract symptoms. Local cleaning with povidone iodine was carried out for the patients the night before the surgery. On the morning of the surgery and after the operation, prophylactic antibiotic was applied. Before the operation, the skin was washed with povidone iodine for 10 minutes. The length of the cavities was measured by using a Furlow instrument after dilatation of the corpus cavernosum. During the operation, corpora cavernosa were irrigated with solution, including gentamicin. For inflatable prostheses, the pump was placed in the scrotum, and the reservoir was placed into the Retzius space. The Foley catheter, inserted during the operation in all patients, was removed on the first postoperative day. The patients were discharged with oral quinolone therapy. Inflatable prostheses of the patients remained semi-inflated.

The patients were evaluated on the 15th day and at the 1st and 2nd months after the surgery. They were allowed to have sexual intercourse 2 months after the operation. All patients were asked to fill out the EDITS (Erectile Dysfunction Inventory of Treatment Satisfaction Questionnaire) form in order to evaluate their satisfaction with the surgery (Table 2). They were informed about the use of inflatable prostheses by the doctors of our clinic.

Statistical Analysis

Statistical analysis was performed by using SPSS 20 for Mac. Continuous variables were expressed as mean±SD, and categorical variables were expressed in percentages. A comparison of Group 1 and Group 2 in terms of categorical and continuous variables was carried out by using chi-square test and independent samples t-test. A P value <0.05 was accepted to be statistically significant.

RESULTS

The mean age was 56.16±14.49 years in Group 1 and 58.13±10.41 years in Group 2. The mean follow-up duration was 29.39±9.38 months in Group 1, while it was 24.13±10.27 months in Group 2. The mean hospital stay was 3.56±2.85 and 3.38±2.27 days for Groups 1 and 2, respectively. Both groups were found to be statistically similar in terms of age, hospital stay, and follow-up duration (p>0.05). In the etiological evaluation, the patients had histories of radical prostatectomy, diabetes mellitus (DM), hypercholesterolemia, hypertension (HT), arterial insufficiency, and venous insufficiency. In both groups, age was statistically insignificant with regard to DM, HT, hypercholesterolemia, arterial insufficiency, and venous insufficiency (p>0.05). Twelve patients in Group 1 and 3 patients in Group 2 were operated on under spinal anesthesia, and 6 patients in Group 1 and 13 patients in Group 2 were operated on under general anesthesia (Table 3). Infection developed in 2 patients (1 patient in each group), and their prostheses were removed. Moreover, temporary pain occurred in 3 patients with the malleable penile prosthesis and in 1 patient with the inflatable penile prosthesis, which improved soon. No complication was observed in the other patients. In the comparison of the questionnaire forms designed for evaluating satisfaction, it was found that the responses given to the questions, except on the one about the ease of use of the penile prosthesis, were similar in both groups, and there was no significant difference between them (p>0.05). Based on the responses given to the 4th question of the questionnaire ("Is it easy to use the penile prosthesis for you?"), it was found that the patients in Group 1 used the penile prosthesis more easily than the ones in Group 2, which was statistically significant (p < 0.05).

DISCUSSION

An ideal penile prosthesis should be inserted easily without any unwanted side effects, provide good cosmetic and functional results, imitate natural penile erection well, and provide a high level of patient and partner satisfaction. All types of prostheses have different advantages and disadvantages that can affect patient satisfaction (10). Compared to malleable penile prostheses, inflatable penile

The 2. Data derived from the LDFTS forms completed by patients						
1. Are you generally satisfied with your penile prosthesis?	Dissatisfied	Somewhat satisfied	Very satisfied			
	Group 1: 5/18 (27.7%)	Group 1: 11/18 (61.1%)	Group 1: 2/18 (11.1%)			
	Group 2: 3/16 (18.75%)	Gr0up 2: 6/16 (37.5%)	Group 2: 7/16 (43.75%)			
2. To what extent did penile prosthesis meet your expectations?	Never met	Somewhat met	Completely met			
	Group 1: 4/18 (22.2%)	Group 1: 12/18 (66.6%)	Group 1: 2/18 (11.1%)			
	Group 2: 2/16 (12.5%)	Gr0up 2: 7/16 (43.75%)	Group 2: 7/16 (43.75%)			
3. How appropriate is penile prosthesis for continuous use?	Inappropriate	Somewhat appropriate	Very appropriate			
	Group 1: 1/18 (5.55%)	Group 1: 16/18 (88.8%)	Group 1: 1/18 (5.55%)			
	Group 2: 2 /16 (12.5%)	Group 2: 7 /16 (43.75%)	Group 2: 7 /16 (43.75%)			
4. Is it easy to use the penile prosthesis for you?	Not easy	Somewhat easy	Very easy			
	Group 1: 1/18 (5.55%)	Group 1: 4/18 (22.2%)	Group 1: 13/18 (72.2%)			
	Group 2: 10/16 (62.5%)	Group 2: 3/16 (18.75%)	Group 2: 3/16 (18.75%)			
5. How much do you trust your competence of sexual pleasure during sexual intercourse	Never ?Group 1: 1/18 (5.55%) Group 2: 2 /16 (12.5%)	Sometimes Group 1: 15/18 (83.3%) Group 2: 7 /16 (43.75%)	Always Group 1: 2/18 (11.1%) Group 2: 7 /16 (43.75%)			
6. Are you generally satisfied with your partner's penile prosthesis?	Dissatisfied	Somewhat satisfied	Very satisfied			
	Group 1: 1/18 (5.55%)	Group 1: 10/18 (55.5%)	Group 1: 7/18 (38.8%)			
	Group 2: 2 /16 (12.5%)	Group 2: 3/16 (18.75%)	Group 2: 11/16 (68.75%)			
AND A LAL A LA A A DEPENDING (

Table 2. Data derived from the EDITS forms completed by patients

*The first and the second questions in the EDITS form were asked to both members of the couple; the third, fourth, and fifth questions were asked only to the patient; and the sixth question was asked only to the partner.

Table 3. Demographic features of patients							
	Malleable	Inflatable					
	penile prosthesis (Group 1)	penile prosthesis (Group 2)	p value				
Number of patients	18	16	-				
Age	56.16±14.49	58.13±10.41	0.15				
DM	9	11	0.28				
HT	3	7	0.09				
Hypercholesterolemia	2	3	0.54				
Arterial Insufficiency	8	9	0.5				
Venous Insufficiency	5	10	0.05				
Type of anesthesia (spinal\general)	12\6	3\13	0.01				
Duration of follow-up (month)	29.39±9.38	24.13±10.27	0.13				
Hospital stay (day)	3.56 ± 2.85	3.38±2.27	0.84				

prostheses, especially three-piece ones, provide better cosmetic results and imitate natural erections better by increasing penile length and penile girth and also allow for endoscopic interventions. However, mechanical device malfunction is the greatest disadvantage in the use of inflatable prostheses (11). Malleable prostheses can curve downward during dressing and micturition and upward during sexual intercourse. The advantages of this prosthesis type include its not consisting of pieces that can lead to mechanical malfunction, easy insertion in a short time, and low cost. On the other hand, it can raise difficulties for endoscopic procedures in the future, since it always remains rigid (12). Souillac et al. reported that prosthesis infection developed in 11 (11.5%) of 118 patients who underwent inflatable penile prosthesis implantation (13). Moreover, Villarreal et al. stated that infection developed in 8 (14.2%) of 56 patients who underwent inflatable penile prosthesis implantation, and they removed the prostheses (5). In a clinical evaluation of patients who underwent penile prosthesis implantation, Carreño et al. reported the most important reason for failure to be prosthesis infection (14). The most crucial complication of penile prosthesis implantation is probably prosthesis infection. For decreasing this complication risk, the genital region should be washed with povidone iodine beginning 3 days before the operation, and the duration of hospitalization should be kept shorter by admitting him/her on the morning of surgery or 1 day before surgery and by discharging the patient from the hospital as soon as possible. In addition, antibiotic prophylaxis should be initiated preoperatively, the genital region should be shaved just before the surgery, the surgical site should be washed with antiseptic solution for 10 minutes, and operating room traffic should be decreased (15). Although all of these surgical principles were followed in our cases and although the patients stayed in the hospital for a short time, an infection developed in 1 patient from Group 1 (5.5%) and in another patient from Group 2 (6.25%), which required the prostheses to be removed. We think that morbidities, such as DM and HT, might have contributed to the development of infection in these groups. The rate of prosthesis infection with a low number of patients was found to be lower than in the literature.

The primary target of ED treatments should be not only to provide a rigid penis, because it is not always enough for patient satisfaction. Therefore, ED treatment should be planned after evaluating the expectations of the patient and his partner. If it is decided that a penile prosthesis be inserted into a patient, he and his partner should be informed about the operating mechanism of the prosthesis and its complications in order to eliminate wrong expectations. Otherwise, postoperative dissatisfaction will be inevitable. Among ED treatments, insertion of penile prostheses is the method providing the highest level of patient and partner satisfaction (16). Jin et al. performed 110 inflatable and 36 single-piece prosthesis implantations and compared the satisfaction levels of patients in their study. They reported that inflatable penile prostheses were found to be better than malleable penile prostheses in terms of patient satisfaction (17). Patient satisfaction depends on many factors, including preoperative expectations, postoperative pain and edema, unwanted complications and problems, functionality of the prosthesis, ease of use, and acceptability by partners (12). In our study, the patients who underwent malleable penile prosthesis implantation were dissatisfied because of the uncomfortable feeling in their clothes and insufficient education about these prostheses, but this problem was overcome in time. On the other hand, in patients having undergone inflatable penile prosthesis implantation, disturbances due to the pump being placed into the scrotum and older patients' not being able to find the pump were often encountered as problems. However, education given by the specialists facilitated the patients to overcome these problems. Removal of the prosthesis due to dissatisfaction or not being able to use it was not needed in any patient. In the literature, it was specified that the highest levels of satisfaction were reached between the 6th and 12th postoperative months (18). Selection of the appropriate prosthesis is important both for the patient and his partner (19). In our series, the EDITS investigation form was used in order to compare the satisfaction levels of patients in whom malleable and inflatable penile prosthesis implants were inserted. Based on the questionnaire results, it was detected that the satisfaction levels of both patient groups were similar, but the responses given to the 4th question ("Is it easy to use the penile prosthesis for you?") revealed that malleable penile prostheses were used more easily and were more satisfying.

CONCLUSION

In erectile dysfunction cases that are organic in origin and resistant to medical treatment, penile prosthesis implantation keeps its place as the gold standard treatment. It is anticipated that it will be preferred, owing to the lower rate of complications, higher rate of success, and high level of patient satisfaction, provided that the selection of proper patients and observance of hygienic measures are taken into consideration. It was found in the evaluation of the EDITS questionnaire forms that patients who underwent prosthesis implantation and their partners in both groups had similar satisfaction levels and that the malleable prosthesis type was reported to be easier to use than the inflatable prosthesis type. Nevertheless, it is obvious that further studies on this topic should be conducted with a larger population.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Authors' Contributions: Conceived and designed the experiments or case: AA, HE, NCŞ. Performed the experiments or case: AA, HE, SC, EV, FO, HÇ. Analyzed the data: AA, NCŞ, HÇ. Wrote the paper: AA, HE, NCŞ. All authors have read and approved the final manuscript. **Conflict of Interest:** No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

REFERENCES

- Wespes E, Eardley I, Guiliano F, Hatzichristou D, Hatzimouratidis K, Moncada A et al. Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation. Uroweb 2013.
- Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and psychosocial correlates: results of the Massachusetts Male Aging Study. J Urol 1994; 151(1): 54-61.
- Şimşek A, Kurt Ö, Özbek E, İlbey YÖ, Özcan L, Ersöz C. Penil protez implantasyonu: Otuz olgunun değerlendirilmesi. J Kartal TR 2009; 20(3): 130-3.
- Bae JH, Song PH, Kim HT, Moon KH. Assessment of erectile and ejaculatory function after penile prosthesis implantation. Korean J Urol 2010; 51(3): 202-7. [CrossRef]
- 5. Villarreal HG, Jones L. Outcomes of and satisfaction with the inflatable penile prosthesis in the elderly male. Adv Urol 2012; 2012: 240963
- Al-Enezi A, Al-Khadhari S, Al-Shaiji TF. Three-piece inflatable penile prosthesis: Surgical Techniques and Pitfalls. J Surg Tech Case Rep 2011; 3(2): 76-83. [CrossRef]
- Bettocchi C, Palumbo F, Spilotros M, Palazzo S, Saracino GA, Martino P, et al. Penile prostheses. Ther Adv Urol 2010; 2(1): 35-40.
 [CrossRef]
- Falcone M, Rolle L, Ceruti C, Timpano M, Sedigh O, Preto M, et al. Prospective analysis of the surgical outcomes and patients' satisfaction rate after the AMS Spectra penile prosthesis implantation. Urology 2013; 82(2): 373-6. [CrossRef]
- Althof SE, Corty EW, Levine SB, Levine F, Burnett AL, McVary K, et al. EDITS: development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. Urology 1999; 53(4): 793-9.
 [CrossRef]
- Anafarta K, Safak M, Bedük Y, Baltaci S, Aydos K. Clinical experience with inflatable and malleable penile implants in 104 patients. Urol Int 1996; 56(2): 100-4. [CrossRef]
- Lux M, Reyes-Vallejo L, Morgentaler A, Levine LA. Outcomes and satisfaction rates for there designed 2-piece penile prosthesis. J Urol 2007; 177(1): 262-6. [CrossRef]
- Turna B, Umul M, Altay B, Apaydın E, Semerci B, Çıkılı N. Penil protez yerleştirilmesi cerrahisinde klinik deneyimlerimiz. Türk Üroloji Dergisi 2007; 33(2): 151-5.
- Souillac I, Pignot G, Galiano M, Hastert V, Sibaud O, Virag R. Inflatable penile prostheses: results, complications and prognostic factors. Prog Urol 2009; 19(8): 563-71. [CrossRef]
- Carreno Rodríguez J, Martínez Abreu J, Toledo Viera A. Clinical evolution in patients with penile prosthesis implant. Arch. Esp Urol 2009; 62(6): 466-72.
- Talas H, Reşorlu B, Yaman Ö, Aydos K, Anafarta K. Outcome of penile prosthesis implantation for treating erectile dysfunction: experience with 335 cases. Turkish Journal of Urology 2008; 34(2): 177-9.
- Rajpurkar A, Dhabuwala CB. Comparison of satisfaction rates and erectile function in patients treated with sildenafil, intracavernous prostaglandin E1 and penile implant surgery for erectile dysfunction in urology practice. J Urol 2003; 170(1): 159-63. [CrossRef]
- Jin Z, Zhu YC, Cui WS, Liu T, Li WR, Yuan YM, et al. Clinical efficacy and patient satisfaction with penile prosthesis implantation for the treatment of severe erectile dysfunction. Beijing Da Xue Xue Bao. 2010; 42(4): 413-7.
- Mulhall JP, Ahmed A, Branch J, Parker M. Serial assessment of efficacy and satisfaction profiles following penile prosthesis surgery. J Urol 2003; 169(4): 1429-33. [CrossRef]
- Montague DK, Angermeier KW. Current status of penile prosthesis implantation. Curr Urol Rep 2000; 1(4): 291-6. [CrossRef]