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Patient and partner outcome of inflatable and semi-rigid penile prosthesis in a single institution

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ABSTRACT

Introduction: Penile prostheses are subject to a continuous development and have gained better mechanical reliability and safety during the last decades. In this study, we aimed to investigate the outcomes and satisfaction rates of inflatable penile prosthesis (IPP) and semirigid penile prosthesis (SPP) implantation.

Materials and Methods: From August 2001 to June 2012, 257 men with erectile dysfunction (ED) underwent penile prosthesis implantation (PPI) at our institution. Of the 257 patients, 118 underwent implantation of IPP and 139 underwent SPP implantation. The pre-operative and post-operative erectile status of the patients were assessed by international index of erectile function (IIEF) questionnaire. The satisfaction of patients and partners were evaluated by a telephone interview using the erectile dysfunction inventory of treatment satisfaction (EDITS) questionnaire and EDITS partner survey.

Results: The overall major complication rate was higher in IPP group. PPI led to a significant improvement in IIEF scores in both groups. For IPP and SPP groups the average EDITS scores were 78±11and 57±8, respectively, and that for the partners were 72±10 and 49±7, respectively ($p<0.05$).

Conclusion: Although the IPP implantation have better satisfaction rates, the SPP implantation is still a viable treatment option in the surgical treatment of ED because of low cost and high durability with acceptable satisfaction rates.

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INTRODUCTION

Erectile dysfunction (ED) affects more than half of men between 40-70 years of age (1). Penile prosthesis implantation (PPI) is the gold standard of treatment for ED patients who have failed the first and second line treatments or have found them unacceptable (2). Penile prosthetic devices can be broadly divided into two groups; inflatable devices and semirigid ones. The first inflatable penile prosthesis (IPP) was designed in 1973 by Scott et al. (3) which was associated with high mechanical failure rates ranging from 21-45% within a few years after implantation (4-6). Currently, different types of IPP with high mechanical reliability can be found on the market.

The satisfaction of the patient and the partner is the most important end point of this surgery. To anticipate the functional results of PPI, it is important to assess the psychosocial status of the couple and to inform them about the procedure to avoid unrealistic expectations.

Currently, the preferred type of penile implant in developed countries is the inflatable ones. Although there are several studies examining the outcomes and satisfaction rates of IPP and semi-

rigid penile prosthesis (SPP) for different types of devices, as far as we know there is not a single center study comparing the outcomes and satisfaction rates of procedures with the modern devices. In this study, we retrospectively analyzed the results of PPI surgery in our clinic and investigated the outcomes and satisfaction rates of IPP and SPP implantations.

MATERIAL AND METHODS

From August 2001 to June 2012, 257 men with ED underwent PPI in our institution. Because of the insurance policy in our country, most of the SPP were implanted before 2008. After 2008, all types of penile prosthesis were included in the general insurance system, so that IPP could be implanted more commonly. The choice of either prosthesis model was made based on the availability and changing of the insurance system. Of the 257 patients, 118 underwent IPP implantation (97 AMS Ambicor, 13 AMS 700 CX and 8 AMS Ultrex (AMS, Inc., Minnetonka, MN, USA)) and 139 underwent SPP implantation (72 AMS 600-650, 67 Mentor Acu-Form (Mentor, Goleta, CA, USA)). All patients had completed a minimum one year follow-up period after PPI before being enrolled in the study group. Approval of institutional review board was obtained for this study.

All operations were performed by two experienced surgeons in a single center under intravenous antibiotic prophylaxis under spinal anesthesia. The skin of surgical field was scrubbed with povidone-iodine solution for 10 minutes. In most of the cases a single penoscrotal incision was used, an infrapubic incision was rarely required, particularly for three-piece IPP.

The etiology of ED in the IPP and SPP groups were: radical pelvic surgery in 44 and 51 patients, vasculogenic in 52 and 71 patients, Peyronie's disease in 12 and 13 patients, spinal cord injury in 5 and 3 patients, pelvic trauma in 4 and 0 patients and post priapism in 1 and 1 patient, respectively. Duplex ultrasound of the penis, intracavernous injection test and/or nocturnal penile tumescence and rigidity test were used as diagnostic tools.

The data about pre-operative assessment and complications were obtained from the patients' records retrospectively. The pre-operative erectile status of the patients were assessed by international index of erectile function (IIEF) questionnaire (7). The IIEF is a readily self-administered questionnaire that adresses the relevant domains of male sexual function like erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction (7). The satisfaction of patients and partners were evaluated by a telephone interview using the erectile dysfunction inventory of treatment satisfaction (EDITS) questionnaire and erectile dysfunction inventory of treatment satisfaction partner survey (8). EDITS is a validated questionnaire to be used to assess satisfaction with treatment modalities for erectile dysfunction and to explore the impact of patient and partner satisfaction on treatment continuation (8). During the satisfaction analysis of patients with functional prosthesis, those with moderate to severe urinary incontinence and those without a regular partner were excluded from the study. The patients' characteristics are summarized in Table-1.

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) software version 17.0, Chicago IL. Categorical variables were analyzed using the chi-square or Fisher exact test and continuous variables were analyzed using Mann-Whitney U test. Comparative differences were considered statistically significant when the p value was <0.05.

RESULTS

Patients in IPP and SPP groups had a mean age of 63 (40-71), and 59 (46-76) years, respectively (p=0.670). Mean duration of time with ED in the pre-implantation period was 43.4 ± 26.6 and 40.3 ± 28.1 months in IPP and SPP groups, respectively (p=0.810). In IPP and SPP groups 83.0% and 66.1% of the patients were administered phosphodiesterase type 5 (PDE5) inhibitors, and 21.1% and 25.8% were administered intracavernosal injections before PPI, respectively. None of the patients had tried vacuum device previously in both groups. The mean operation time was 46.6 ± 10.9 and 52.9 ± 11.1 in SPP and IPP groups, respecti-

Table 1 - Patients' characteristics.

CHARACTERISTICS	IPP	SPP	p value
Patients, n	118	139	
Age (years), mean (range)	63 (40-71)	59 (46-76)	0.670
Follow-up (months), mean±SD	34±22	52±30.6	<0.05
Pre-op IIEF score, mean±SD	10.1±4.5	8.2±5.5	0.520
Previous ED treatments			
Oral treatment, n (%)	98 (83.0%)	92 (66.1%)	<0.05
ICI, n (%)	25 (21.1%)	36 (25.8%)	0.376
Duration of ED until surgery (months), mean±SD	43.4±26.6	40.3±28.1	0.810

IPP = Inflatable penile prosthesis; **SPP =** Semirigid penile prosthesis

vely. No statistically significant difference was found between both groups in terms of operation time (p=0.095). The most common intraoperative complications were corporeal crossover (5 in SPP, 2 in IPP), corporeal perforation (1 in SPP, 3 in IPP) and urethral perforation (1 in SPP, 1 in IPP). In case of urethral perforation, the mucosa was repaired with absorbable sutures and the patient was catheterized. The operation was postponed for a second session.

Most of the postoperative complications were minor complications including superficial wound infection, penoscrotal hematoma, urinary retention that resolved with conservative treatment. Postoperative major complications were detected in 14 (11.8%) and 5 (3.5%) patients in IPP and SPP groups, respectively. Mechanical failure necessitating surgical correction occurred only in one patient in SPP group, which was a case of rod fracture after eight years. Most of the mechanical failures were seen in IPP group, fluid leakage from the tubing in 4 cases (3 with 2 piece and 1 with 3 piece IPP) being the most common one. All of the 2 piece prostheses with tubal leakage were replaced with a new IPP. The 3 piece IPP case with tubal leakage was repaired and functioned normally thereafter. Pump failure was detected in 1 patient in IPP group that required surgical revision. Five patients in IPP group and two patients in SPP group experienced prosthesis infection. Three cases in IPP and one in SPP group with infection could be successfully managed with Mulcahy (9) salvage protocol while the remaining two IPP and one SPP necessitated the explantation of the device and implantation of a new device two months later. In SPP group, unilateral erosion occurred in two cases and resulted in explantation of the ipsilateral rod. Erosion occurred in the pump area of 4 patients in IPP group that required surgical revision. The management of infection and erosion are shown in Table-2.

A total of 152 patients (80 IPP, 72 SPP) could be contacted and accepted to respond to the survey together with their current partners in the satisfaction analysis. Mean follow-up was significantly longer in SPP group, 52±30.6 vs. 34±22.1. Preoperative average IIEF scores were 10.1±4.5 and 8.2±5.5 in IPP and SPP groups, respectively. PPI led to a significant improvement in IIEF scores in both groups. Mean post implantation IIEF score for IPP and SPP groups were 23.4±1.5, 22.8±1.8, respectively (p=0.815). For IPP and SPP groups the average EDITS scores were 78±11and 57±8, respectively, and that for the partners were 72±10 and 49±7, respectively (p<0.05). The mean frequency of sexual intercourse per month were 5.7 (3-19) and

Table 2 - Management of infections and erosions.

	Infections (n=7)		Erosions (n=6)	
	IPP (n)	SPP (n)	IPP (n)	SPP (n)
In situ treatment	0	0	4	0
Extrusion+new prosthesis	3	1	0	0
Extrusion+new prosthesis (2 months later)	2	1	0	0
Extrusion	0	0	0	2[a]

[a] Unilateral extrusion

IPP = Inflatable penile prosthesis; **SPP =** Semirigid penile prosthesis

3.9 (1-16) for IPP and SPP groups, respectively (p=0.06). The satisfaction outcomes of the patients are summarized in Table-3.

DISCUSSION

Penile prosthesis are subject to a continuous development and have gained better mechanical reliability and safety during the last decades (10), but device related complications together with the well-known complications of PPI still can occur (11, 12). The most important end-point of PPI surgery is to achieve the highest patient and partner satisfaction with the lowest complication rates. Cost has been an important factor for the developing countries through all times which currently is under investigation in developed countries, too, with changing economic circumstances. IPP have the advantages of penile flaccidity when deflated, ease of concealment and low risk of chronic pain. However, the IPP are expensive, have increased risk of mechanical failure and the implantation process is more sophisticated. The SPP have the advantages of easy implantation, low cost, less mechanical failure and ease of use. The main disadvantage is permanent rigidity that results in difficulty in concealment and chronic pain.

In our study, none of the patient had tried vacuum devices pre-operatively because of the traditional characteristics of our people. Also, the rate of intracavernosal injection for ED preoperatively is lower compared to the literature (13) due to the hesitance of our patients to make injections to their penis. ED is still a hard topic to discuss with the patients in our country. The use of oral medication for ED was found to be higher in the IPP group which can be attributed to the increased socio-economic status of our patients during the last years.

In our study, major postoperative complications were seen in 4.3% of the SPP group and

Table 3 - Satisfaction and outcomes of the patients.

	IPP	SPP	p value
Post-op IIEF score, mean±SD	23.4±1.5	22.8±1.8	0.815
EDITS score			
Patients' score±SD	78±11	57±8	<0.05
Partners' score±SD	72±10	49±7	<0.05
Frequency of sexual intercourse (per month), mean (range)	5.7 (3-19)	3.9 (1-16)	0.06

IPP = Inflatable penile prosthesis; **SPP =** Semirigid penile prosthesis

14.4% of the IPP group. A malleable rod fracture was detected after eight years in SPP group. Minervini et al. also reported two cases of rod fracture with two different malleable devices at long term (14).

It was reported that the erosion with SPP was more frequently encountered in the spinal cord injury patients compared with the general population (15). In our study, consistent with the previous reports, one patient with spinal cord injury who was implanted SPP experienced erosion from the glans penis. The other erosion of SPP was encountered in a patient with diabetes mellitus and after a vigorous sexual activity. The erosion of the pump area was detected at 4 patients in IPP patients. In two patients the etiology were spinal cord injury which may be a contributing factor and the rest two patients had uncontrolled diabetes and poor hygiene habbits.

It is stated in the literature that either immediate or delayed replacement of a new device after the removal of all the pieces of the device is necessary (16, 17). But we have the experience of 4 IPP patients with erosion of the pump area to whom a salvage surgery was performed as quickly as possible. During the salvage surgery, we separated the tunica albuginea at the point of insertion of the pipes. If there was any purulent drainage coming out from the corpum cavernosum with mild massage, the device was completely extruded, and a new device was implanted after the debridement of necrotic tissue and lavage of the area as explained elsewhere (9). But if there was no purulent discharge, the pump was washed and rubbed aggressively with the same solutions and relocated in a new pouch. The patients with diabetes mellitus also underwent a strict control of blood glucose level under consultation of endocrinology.

Infection was reported to be more common in men with IPP than SPP (14, 18) which is consistent with our findings. Some authors proposed that the increased risk of infection with inflatable prosthesis might reflect the longer operative duration, increased at the risk period when colonization of the implant could take place (14, 19). However, operation time was not significantly different between two groups in our series. In secondary or tertiary implant surgeries it is more presumably that the operation time is prolonged and that may promote bacterial growth (20). Prosthesis infection is a hard topic in andrology. There are two main options in this situation. The first is to extrude the prosthesis and reimplant a new one after some delay for healing (21). In this case, formation of fibrosis can complicate the further surgery. The second option is complete removal of all prosthetic material followed by the use of Mulcahy salvage procedure to reimplant a new penile prosthesis at the same session (9). In our cases the selection of treatment modality was determined on the patient basis and experience of the surgeon.

There is scarce data reporting the outcomes and satisfaction rates of semirigid prostheses in the literature. In a recent prospective study analyzing the satisfaction rates of AMS Spectra penile prosthesis, Falcone et al. reported 86.4% of patients and 52.6% of their partners confirmed that they felt completely satisfied (22). Salama et al. reported 70% and 57% satisfaction rates with AMS 650 and Mentor Acu-Form, respectively at long term (23). Fathy et al. also reported similar results with low complication rates with Tube (Promedon, Cordoba, Argentina) malleable penile implant, however the satisfaction rates were not assessed by a confirmed questionnaire (24). Minervini et al. reported that the most common reasons for dissatisfaction were the shortness of the prosthesis, unhappiness with the appearance of the penis and pain with the malleable devices. But only 26% of the dissatisfied men wanted the prosthesis to be removed (14).

The patient and partner satisfaction rates are reported to be high in well functioning IPP (10, 14, 25). 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 deflate mechanism in a study that examined 3 types of IPP (25). Wilson et al. reported an estimated 10-year revision-free survival of 68.5% calculated for fourteen different IPP (26). Chung et al. analysed 955 PPI, and reported 184 penile prosthesis malfunction, all of which had occurred in the inflatable group (12).

There was no statistically significant difference between IPP and SPP in terms of IIEF

scores, which are indicators of erectile function in our study. IPP group had significantly higher scores on EDITS questionnaire for both patients and partners compared to SPP ($p<0.05$). It was shown in the literature that the main cause for dissatisfaction was removal of the prosthesis (14). In this recent study main dissatisfaction factors were difficulty in concealment and chronic pain for SPP and malfunctioning for IPP.

The two limitations of our study were that most of the IPP used in our series were 2-piece devices, outnumbering 3-piece ones. This is because the selection of prosthesis model was made based on availability and insurance system. And cost analysis could not be achieved, because of variability of costs in time and the changing criteria of the insurance system.

Patient and partner expectations must be modeled according to the results of comparative studies about satisfaction rates which have included the malfunction and durability of the devices. Further studies using confirmed surveys are needed for appropriate counseling of ED patients who are candidates for PPI.

CONCLUSIONS

Although the IPP implantation have better satisfaction rates, the SPP implantation is still a viable treatment option in the surgical treatment of ED because of low cost and high durability with acceptable satisfaction rates.

CONFLICT OF INTEREST

None declared.

REFERENCES

1. 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;151:54-61.
2. Trost LW, McCaslin R, Linder B, Hellstrom WJ. Long-term outcomes of penile prostheses for the treatment of erectile dysfunction. Expert Rev Med Devices. 2013;10:353-66.
3. Scott FB, Bradley WE, Timm GW. Management of erectile impotence. Use of implantable inflatable prosthesis. Urology. 1973;2:80-2.
4. Furlow WL. Inflatable penile prosthesis: Mayo Clinic experience with 175 patients. Urology. 1979;13:166-71.
5. Kabalin JN, Kessler R. Five-year followup of the Scott inflatable penile prosthesis and comparison with semirigid penile prosthesis. J Urol. 1988;140:1428-30.
6. Montague DK. Experience with semirigid rod and inflatable penile prostheses. J Urol. 1983;129:967-8.
7. Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The international index of erectile function (IIEF): a multidimensional scale for assessment of erectile dysfunction. Urology. 1997;49:822-30.
8. Althof SE, Corty EW, Levine SB, Levine F, Burnett AL, McVary K, EDITS: development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. Urology. 1999;53:793-9.
9. Mulcahy JJ, Brant MD, Ludlow JK. Management of infected penile implants. Tech Urol. 1995;1:115-9.
10. Bettocchi C, Palumbo F, Spilotros M, Palazzo S, Saracino GA, Martino P, Penile prostheses. Ther Adv Urol. 2010;2:35-40.
11. Sadeghi-Nejad H. Penile prosthesis surgery: a review of prosthetic devices and associated complications. J Sex Med. 2007;4:296-309. Erratum in: J Sex Med. 2007;4:1520.
12. Chung E, Van CT, Wilson I, Cartmill RA. Penile prosthesis implantation for the treatment for male erectile dysfunction: clinical outcomes and lessons learnt after 955 procedures. World J Urol. 2013;31:591-5.
13. Menard J, Tremeaux JC, Faix A, Pierrevelcin J, Staerman F. Erectile function and sexual satisfaction before and after penile prosthesis implantation in radical prostatectomy patients: a comparison with patients with vasculogenic erectile dysfunction. J Sex Med. 2011;8:3479-86.
14. Minervini A, Ralph DJ, Pryor JP. Outcome of penile prosthesis implantation for treating erectile dysfunction: experience with 504 procedures. BJU Int. 2006;97:129-33.
15. Collins KP, Hackler RH. Complications of penile prostheses in the spinal Cord injury population. J Urol. 1988;140:984-5.
16. Hellstrom WJ, Montague DK, Moncada I, Carson C, Minhas S, Faria G, et al. Implants, mechanical devices, and vascular surgery for erectile dysfunction. J Sex Med. 2010;7:501-23.
17. Carson CC, Noh CH. Distal penile prosthesis extrusion: treatment with distal corporoplasty or Gortex windsock reinforcement. Int J Impot Res. 2002;14:81-4.
18. Lynch MJ, Scott GM, Inglis JA, Pryor JP. Reducing the loss of implants following penile prosthetic surgery. Br J Urol. 1994;73:423-7.
19. Cumming J, Pryor JP. Treatment of organic impotence. Br J Urol. 1991;67:640-3.
20. Mulcahy JJ. Current approach to the treatment of penile implant infections. Ther Adv Urol. 2010;2:69-75.
21. Bettocchi C, Ditonno P, Palumbo F, Lucarelli G, Garaffa G, Giammusso B, et al. Penile prosthesis: what should we do about complications? Adv Urol. 2008:573560.

22. 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;82:373-6.
23. Salama N. Satisfaction with the malleable penile prosthesis among couples from the Middle East--is it different from that reported elsewhere? Int J Impot Res.2004;16:175-80.
24. Fathy A, Shamloul R, AbdelRahim A, Zeidan A, El-Dakhly R, Ghanem H. Experience with Tube (Promedon) malleable penile implant. Urol Int. 2007;79:244-7.
25. Brinkman MJ, Henry GD, Wilson SK, Delk JR 2nd, Denny GA, Young M, et al. A survey of patients with inflatable penile prostheses for satisfaction. J Urol. 2005;174:253-7.
26. Wilson SK, Delk JR, Salem EA, Cleves MA. Long-term survival of inflatable penile prostheses: single surgical group experience with 2,384 first-time implants spanning two decades. J Sex Med. 2007;4:1074-9.

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