

Surgical Treatment of Erectile Dysfunction and Peyronie's Disease Using Malleable Prosthesis

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Purpose: Peyronie's disease (PD) is a condition of middle aged men and frequently accompanied by erectile dysfunction (ED) which was attributed to penile deformity, vascular pathology and psychological components. The implantation of semi-rigid penile prosthesis allows for these patients to undergo a simple procedure aimed at correction both penile deformity and ED. The aim of this study was to investigate surgical and clinical outcomes and patient satisfaction rate at long term follow-up after semi-rigid penile prosthesis implantation (PPI) in men with PD and ED.

Materials and Methods: A total of 66 patients with mean age of 49.2 (range, 30-76) years old underwent semi-rigid PPI between 1995 and 2006. Genesis (Coloplast®) was used for implantation in a standard manner by penoscrotal approach without using any graft and remodeling technique. In all patients, dilatation of corpora was performed without any difficulty and straightening of the penis was achieved. A retrospective review of clinical database and prospective telephone survey were conducted in all patients.

Results: The mean follow-up time was 9.7 years (range, 6 to 17). There wasn't any clinical infection and complication during follow-up period. Fifty-nine patients were sexually active at the time of the interview. None of the patients reported residual curvature. The overall patient satisfaction was 91.5% (54 patients). Primary reasons for dissatisfaction were decreased penile length and prosthesis problems.

Conclusion: Based on our results semi-rigid PPI is effective and easy procedure for treatment of men with PD and ED without any complication and with high patient satisfaction rate in long-term follow up period.

Keywords: penile induration; surgery; penile prosthesis; erectile dysfunction; patient satisfaction; questionnaires; penis.

INTRODUCTION

Peyronie's disease (PD) which was first described by a French physician de la Peyronie in 1743, is an acquired local connective tissue disorder including changes in the collagen composition and characterized by development of a fibrotic plaque over the tunica albuginea on the corporal bodies of penis.⁽¹⁾ This fibrous plaque occasionally calcifies and leads to painful penile erection, penile deformities and associated sexual dysfunction.⁽²⁾ PD appears to be a sexual medicine condition of middle aged men and frequently accompanied by erectile dysfunction (ED) which is attributed to penile deformity, vascular pathology and psychological problems.

The typical presentations of the disease are pain during erection, ED and penile deformities.^(3,4) PD is accompanied by ED which was attributed to penile deformity, vascular pathology and psychological components. ED has been reported in a range of 20%-54% of men with PD;⁽⁵⁾ however ED-PD concomitance may increase up

to 83%.⁽⁶⁾ Several procedures have been described to manage penile curvature and ED. Chung et al reported patients who had severe penile curvature (greater than 60) underwent graft surgery and about 65% of them dissatisfied with the treatment outcomes such as ED development in their study.⁽⁷⁾ Penile prosthesis surgery with or without corrective surgery for curvature is one of the valuable choice in the literature.⁽⁸⁻¹⁰⁾ Implantation of semi-rigid penile prosthesis allows for these patients to undergo a simple procedure aimed at correction both penile deformity and ED.

In this study, we evaluated our experience in 66 patients with PD and ED in whom a semi-rigid penile prosthesis was implanted and deformities were corrected with a simple procedure and at long-term follow-up. Surgical and clinical outcomes and patient's satisfaction rate were assessed.

MATERIALS AND METHODS

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Table 1. Characteristics of study subjects.

Variables	Values
Age, years (IQR mean)	49.2 (30 - 76)
Degree of curvature, no. (%)	
< 30°	28 (42.4)
30°- 60°	29 (43.9)
61°- 90°	9 (13.7)
Direction of curvature, no. (%)	
Dorsal	32 (48.5)
Lateral	15 (22.7)
Ventral	10 (15.2)
Dorsolateral	9 (13.6)

Abbreviation: IQR, Inter Quartile Range.

Age is presented as median (range, minimum-maximum).

Study Population

Between 1995 and 2006, a total of 66 patients aged from 30 to 76 years old (mean 49.2) with PD and ED were underwent malleable penile prosthesis implantation (PPI) without additional plaque surgery including graft and remodeling technique. Most of the patients were evaluated in our Andrology department, also some of them were referred to our clinic.

Evaluations

Initially, a detailed history and physical examination were performed and patients completed International Index of Erectile Function (IIEF) questionnaire. All patients had various severity of difficulty to have sexual intercourse which was refractory to the conservative treatment such as phosphodiesterase type 5 (PDE5) inhibitors. In this study one stage procedure was planned for both ED and PD treatment. Degree of the penile curvature was less than 30° in 28 patients (42.4%), between 30°-60° in 29 patients (43.9%) and more than 60° in 9 patients (13.7%). Direction of the curvature was dorsal in 32 (48.5%), lateral in 15 (22.7%), ventral in 10 (15.2%) and dorsolateral in 9 patients (13.6%) (**Table 1**). The median preoperative duration of PD was 27 months (range, 13-66). None of the patients in our series had undergone previous penile surgery.

Patients with stable disease, defined as at least one year from onset and at least six months of stable deformity were admitted to the surgery. Patients with very hard and calcified plaques were excluded and treated mostly with grafting procedure. Penile vascular conditions were assessed with Doppler ultrasonography and vascular pathologies such as arterial insufficiency and/or veno-occlusive dysfunction were determined. All patients were informed about the procedure and we ob-

tained a written consent for PPI. A retrospective review of clinical database and prospective telephone survey were conducted in all patients. At the time of review, all patients were specifically asked about of satisfactory sexual intercourse and recurrent curvature for which they underwent surgery. Patient satisfaction was defined as successful and satisfactory sexual intercourse at each attempt.

Surgery Procedure

Perioperative antibiotic prophylaxis included intravenous injection of 200 mg teicoplanin and 80 mg gentamycin 1 h preoperatively to be repeated before discharge and followed by an oral quinolone every 12 h for 5 days. Semi-rigid malleable Genesis (Coloplast®) penile prostheses were implanted by a standard manner by a single surgeon (MC) using penoscrotal approach without using any additional surgery.

Tunica albuginea was incised vertically approximately 3-4 cm and the corporal bodies were dilated with Hegar dilators of 7-13 French before the insertion of the malleable prosthesis. In patients who had less than 60° of curvature, we achieved penile straightening and adequate dilatation without additional procedure. We measured the corporal body length at the maximal stretch position with Furlow inserter, and the appropriate size of malleable penile prosthesis was implanted. Particularly, in 3 patients who had more than 60° of curvature, penis is not adequately straightened as a result of cylinder implantation. The cylinders are then forcibly counter-flexed in the direction opposite that of the curvature and relaxing incisions were made using scissors to the most fibrotic part of the tunica, not so deeply, avoiding any tunical rupture. In one patient the plaque was incorporated into the neurovascular bundle, the latter was dissected through the plaque. After straightening of the penis in all patients, the closure of the tunica albuginea was performed with interrupted 2-0 polyglactin absorbable sutures. The subcutaneous tissue and skin were closed with continues 3-0 polyglactin absorbable sutures. The penis was dressed with an elastic bandage and a Foley catheter was inserted for one day. Prophylactic antibiotics were used in all patients for seven days.

A retrospective review of clinical database and prospective telephone survey were conducted in all patients. Patients questioned about the sexual activity, prosthesis problems, satisfactory sexual intercourse and residual curvature. The IIEF-5 Questionnaire was used to obtain sexual function and satisfaction data (**Table 2**). Standard *t*-test was used to compare various means and proportions and *P* value less than .05 accepted as statis-

Table 2. Comparison of preoperative and postoperative IIEF scores.

IIEF Domains	Preoperative	Postoperative	P Value*
Erectile function (Q 1. 2. 3. 4. 15)	8	28	.01
Orgasmic function (Q 9. 10) 5.3	5.3	8.8	.01
Sexual desire (Q 11. 12)	6.1	9	.01
Intercourse satisfaction (Q 6. 7. 8)	4.1	11.1	.01
Overall satisfaction	3.1	8.8	.01

Abbreviations: IIEF, International Index of Erectile Function; Q, question.

* The *P* values obtained in the *t*-test results.

tically significant.

RESULTS

Mean age of patients, degree and direction of curvatures were summarized in **Table 1**. Median IIEF scores were significantly high in postoperative period than in preoperative (**Table 2**, $P < .001$). The mean degree of the penile curvatures was 39.77° (range, 20° - 90°). In 9 patients the degrees of curvature were $\geq 60^\circ$. Corporal perforation and/or urethral injury during the procedures were not seen. As far as postoperative early complications were concerned, we determined hematoma and edema in few patients that resolved spontaneously without any morbidity. Mean follow-up period was 9.6 years (range, 6 to 17). During the follow-up period, no implant infection and any other complications were observed.

Overall, 59 patients were sexually active at the time of review. Five patients were lost in the follow-up period. The median IIEF-5 domain score for erectile function of the sexually active men was 28 (27 to 29). Three patients (4.5%) were very depressed about the decreased penile length. Two of the 59 men (3.3%) complained with prosthesis problems inhibiting them for sexual intercourse due to inadequate girth of the penis. None of the patients reported residual curvature, glans hypermobility and penile sensitivity impairment. The overall patient satisfaction was 91.5% (54 patients). Primary reason for dissatisfaction was decreased penile length. The other reason was prosthesis problems which lead to unsatisfactory sexual intercourse owing to inadequate girth.

DISCUSSION

ED has been reported in a wide range of 20%-83% in

patients with PD.^(5,6) Recently penile vascular abnormalities are found preoperatively in more than 50% of the patients who had PD.⁽¹¹⁾ Although corporal veno-occlusive dysfunction is the most frequent pathological finding, cavernous artery inflow can also be affected.⁽⁶⁾ PD causes an increased incidence of veno-occlusive abnormalities and ED caused by venous leak. Therefore straightening procedures are not always successful in restoring erectile function in patients with PD.^(12,13) Many surgical procedures used to correct penile deformities and type of procedure is dependent on the type of deformity, erectile function, penile length, hour-glass deformity, patient expectations, and surgeon's preference.⁽¹⁴⁾ PPI is the standard of care for patients with PD and concomitant ED nonresponsive to medical treatment to achieve curvature straightening and for definitive mechanical erection.

Incision of the fibrotic plaque followed by implantation the Small-Carrion penile prosthesis was first described by Raz and colleagues.⁽¹⁵⁾ The authors reported successful treatment in 11 of 12 patients with the follow-up of 6 months to 2 years. A single prosthesis removal owing to prosthesis infection was reported. Kelami and colleagues⁽¹⁶⁾ treated 15 of 22 patients with PD and ED with implantation of Small-Carrion semi-rigid penile prosthesis using infrapubic approach without excision and/or incision of the fibrous plaque. No complication was noted with the follow-up period of 2-12 months except penile edema which was seen in the first weeks of the operation. Ghanem and colleagues⁽¹⁷⁾ reported an 80% success rate using semi-rigid penile prosthesis in patients with PD and ED without any plaque surgery. No operative complication was encountered in their study. The procedure was performed in 20 patients using sub-coronal incision and had satisfactory straightness and

rigidity of the penis. A total of 16 patients achieving minimum 12 months follow-up were identified in the study. All of them were engaged in sexual intercourse successfully. Among them, only 2 patients were dissatisfied with glans hypermobility leading to deviation of urine stream and cosmetic appearance. Cohen and colleagues⁽¹⁸⁾ presented a proximal approach while performing semi-rigid PPI in 22 patients with PD and ED. Overall, 94% of patients were able to resume the sexual intercourse at the time of review. Vascular compromise and/or skin slough were noted in 3 patients at the follow up period. All these studies reported the short term follow-up results of their surgical outcomes after PPI in patients with PD and ED. Furthermore, similar to our study, they did not perform any additional surgery regarding to penile plaque. Although our follow-up period was higher than those of above stated studies, we concluded similar satisfaction rate.

Similar study was carried out by Montorsi and colleagues.⁽⁹⁾ They treated a total of 50 patients with PD using semi-rigid penile prosthesis without any additional surgical procedures and maneuvers. The authors re-evaluated 48 patients 60 months after the surgery and did not encounter any major peri- and post-operative complications. Overall, 44 (92%) patients were sexually active at the time of review. In their opinion the actual rate of satisfied patients should be assess at long term follow up. Twenty three of 48 patients were totally satisfied with the sexual activity after the surgery. The most common reason for dissatisfaction was loss of the penile girth. Avoiding additional plaque surgery, using semi-rigid penile prosthesis and long-term follow-up period are similar to our study. However, our study group was larger than Montorsi and colleagues' study. We performed relaxing incisions in three patients. Considering the dissatisfaction rates of both studies, patient expectations may be different between these two different study groups.

In the literature, there are some studies in which the outcomes of semi-rigid and inflatable PPI procedures have been reported. Ganabathi and colleagues⁽¹⁹⁾ used PPI in the treatment of the PD in 8 patients with a mean follow-up period of 49 months. Penoscrotal approach was used for implanting semi-rigid penile prosthesis in 6 and inflatable penile prosthesis in 2 patients. They reported penile prosthesis infection in one man in semi-rigid group 3 months after the surgery and removed the prosthesis. In inflatable group, one patient has died at the time of review. Remaining 6 patients were evaluated and all of them had satisfactory sexual intercourse. There was no patient with recurrent penile

curvature. They did not compare these 2 groups because of low number of patients.

Eigner and colleagues⁽⁸⁾ also reported 35 men who had undergone PPI for the treatment of PD with ED. Of the 26 patients who underwent semi-rigid PPI with infrapubic approach, only 5 required further surgical intervention for Peyronie's plaque to achieve an adequate cosmetic result. In inflatable penile prosthesis group, additional plaque surgery was performed in 6 of 9 patients to achieve adequate straightness. Two complications were encountered in their study; moderate hematoma required no specific therapy and urethral perforation during corporal dilation in semi-rigid group. Their overall satisfaction rate was 88% with a mean follow-up of 6.9 years. The difference of this study from the current one is additional plaque surgery in both groups. Comparing semi-rigid and inflatable penile prosthesis for PD was the advantage of this study. PPI without any additional procedure and manual modeling correct the majority of the curvatures during prosthetic surgery. Eigner and colleagues⁽⁸⁾ considered the infrapubic approach allowing access to Peyronie's plaque without degloving the penile shaft.

The other study that reported the results of semi-rigid and inflatable prosthesis in PD was carried out by Djordjevic and colleagues.⁽¹⁴⁾ The authors used malleable semi-rigid and inflatable penile prosthesis in 49 and 13 patients with PD, respectively. In patients whose curvatures degree ranged from 45° to 85°, additional relaxing tunical incisions were performed. Overall, 95% of the patients had complete penile straightness with a median follow-up of 35 months. In semi-rigid group, there was decrease of penile girth in 7 of 49 patients, 3 of which were treated with replacement of inflatable penile prosthesis. No device infection or mechanical failure was reported. In semi-rigid group, 23 men had glans numbness which spontaneously decreased and disappeared in 6 months after the surgery. In patients with mild degrees of curvature, straightening can be achieved with only PPI without any plaque surgery. The satisfaction rate and absence of recurrent curvature were similar to our study.

Some authors used only inflatable PPI in the treatment of PD and ED. Malloy and colleagues reported use of inflatable PPI in 19 patients, 18 of them were treated successfully using inflatable penile prosthesis.⁽²⁰⁾ The authors achieved adequate straightness and rigidity in 10 patients with performing only placement of the prosthesis. Additional surgery as incision of the plaque was necessary for obtaining satisfactory results in 8 patients.⁽²⁰⁾ Levine and colleagues used inflatable penile pros-

thesis in 90 men for the treatment of PD and ED refractory to medical treatment.⁽²¹⁾ A complete penile straightness was achieved in 4% of patients with PPI alone. To accomplish complete straightness manual modeling, plaque incision and graft requirement were needed in 71%, 4%, and 13% of patients, respectively. Only one patient had prosthesis infection and 7% of patients reported mechanical failure of the prosthesis. The overall satisfaction rate of curvature correction was 84% with mean follow up of 49 months.

Inflatable penile prostheses may have an advantage for the correction of minimal or mild residual curvatures (less than 30°). It acts as a tissue expander at each inflation during attempts at sexual intercourse.⁽²⁾ Both inflatable and malleable implants can be used for the treatment of both procedure, but inflatable prostheses are associated with higher functional satisfaction and lower persistent curvature rates.⁽¹⁴⁾ In our series we also did not observe any residual curvature, additional relaxing incisions were made in three patients and 5 patients were dissatisfied with the prosthesis. Advantage of our study was higher follow-up period and large study sample size.

This study is not without limitations. First we did not address the partner satisfaction. Second there was no an inflatable penile prosthesis group to make an appropriate comparison. Further prospective studies with semi-rigid and inflatable PPI are needed to draw final conclusion.

CONCLUSIONS

Our experience suggests that implantation of a semi-rigid prosthesis in patients with PD and ED, leads to the satisfactory straightening of the penis without curvature recurrence, and provides high patient satisfaction rate in long-term follow-up, despite inadequate penile girth.

CONFLICT OF INTEREST

None declared.

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