MALLEABLE PENILE IMPLANT IS AN EFFECTIVE THERAPEUTIC OPTION IN MEN WITH PEYRONIE’S DISEASE AND ERECTILE DYSFUNCTION

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Abstract:
Background: Inflatable penile prosthesis (IPP) is typically the preferred implant in Peyronie’s disease (PD) and malleable penile implants (MPP) have been discouraged.

Objectives: We aimed to evaluate the effectiveness and patient satisfaction of MPP compared to IPP in patients with PD.

Design, Setting, and Participants: Men with PD and erectile dysfunction (ED) who elected for penile implant surgery constituted the study population. Preoperatively, demographic and comorbidity parameters were recorded. Curvature was measured with a goniometer at maximum rigidity after intracavernosal vasoactive agent injection (ICI). Postoperatively, overall satisfaction was measured at 3, 6, 12 and 24 months on a 5-point Likert scale from 1 (dissatisfied) to 5 (very satisfied).

Outcome Measurements and Statistical Analysis: 166 men with a mean age of 59±10 years were analyzed. The mean preoperative curvature in the entire cohort was 65 (30-130) degrees. 94% of MPP patients had total resolution of their curvature at end of operation, while 8 patients (6%) had residual curvature (25-40 degrees). In IPP group (25/30; 83.3%) had straight penis at the end of surgery while (5/30; 16.7%) still have residual curvature, with the mean magnitude being 33 degrees in MPP and 30 degrees in IPP groups.

Results: 86% of all patients were diabetic. There were no differences between the 2 implant groups in age, HbA1c, BMI or smoking status. The mean patient satisfaction was 4.42±0.70 (range = 2-5) and there was no difference between the two groups. The mean follow up period was 23.4 months (6-29 months).

Limitations: Relatively small number IPP and non-randomized study.

Conclusion: We have shown that MPP is as effective as IPP in curvature correction in PD patients with similar patient satisfaction for both groups.
ABSTRACT

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INTRODUCTION

Implanting a penile prosthesis is often the best treatment for patients with severe erectile dysfunction (ED) that does not respond to pharmacotherapy. Pharmacotherapy often fails in patients with diabetes, radical prostatectomy, PD, and severe penile fibrosis. Penile prosthetic surgery has high long-term mechanical reliability and patient satisfaction rates of more than 85%. (1) Penile prosthesis implantation is the standard procedure for patients with PD and concomitant ED that does not respond to medical treatment [2]. 20-30% of patients with PD have ED refractory to medical therapy and may benefit from a combined procedure addressing both conditions [3]. Penile implant placement in these patients can treat both problems, by providing both the penile rigidity and deformity correction required. While patients with mild degrees of curvature can have complete penile straightening by placement of the prosthesis alone, many patients have residual curvature requiring intraoperative adjuvant maneuvers such as, modeling, plaque incision with or without grafting. (4,5)

Garaffa et al. reported that among the additional straightening procedures, modelling was more successful in achieving straightening when performed on an inflatable device (84%) than on a malleable implant (54%). If the curvature persisted after modelling or if the curvature was ventral, straightening was achieved with tunical plications or incision with or without grafting. (6) In another study, Levine et al., reported a single-center experience with IPP and straightening maneuvers as necessary in 90 men with medication-refractory ED and Peyronie disease. Additional intraoperative maneuvers used to straighten the penis following placement of the prosthesis included manual modeling, plaque incision and, if the defect created with incision was big enough (2 cm or more), grafting might be used in such cases. In their study, IPP placement allowed reliable and satisfactory coitus for the great majority of men (91%). (7)

Although all types of penile implants can be used, implantation of an inflatable penile prosthesis (IPP) has been reported to be the most effective and preferred in those patients based on the published data (8,9,10). In certain regions of the world, malleable penile prosthesis (MPP) is the penile implant of choice for ED, often because of economic reasons. However, it has been suggested the MPP are not ideal for patients with PD (10).

Our Hypothesis is that MPP are as effective as IPP in management of patients having both ED&PD. Our clinical experience suggests that MPP are an effective strategy in the treatment of patients with combined PD and ED. Our effort here aimed to compare the
outcome and satisfaction rate in PD patients with ED receiving MPP compared to those obtaining an IPP.
METHODS

This study was approved by the Ethics Committee at our institution.

Study Population: Between July 2011 and June 2014, men with PD and ED not responding to medical therapy for PD were counseled regarding penile implant surgery. Patients who had favorable clinical response with ICI and refused ICI as therapeutic option for their ED were included in this study. For the purposes of this analysis, we included only those who had favorable clinical response to ICI so that we could accurately measure the magnitude of curvature before surgery. Some of them requested to put penile implants after they noticed that they are losing penile size significantly. Others who had significant deformity didn’t wish to be operated on for correction surgery (e.g. Nesbit) with subsequent risk of ED and losing more penile size. They wanted to address their problems with one final solution. After good counselling and explaining all therapeutic options, patients who had favorable clinical response with ICI but who found ICI unpalatable and refused further treatment with ICI were opted for penile implant. Penile implant surgery is the treatment of choice in such men in our practice and this is supported by ICSM guidelines. (11) Those who opted for this procedure constituted the study population. The criteria for penile implant surgery in this population included (i) men in a stable relationship, (ii) with penile curvature ≥30 degrees, (iii) and with ED refractory to medical therapy. (iv) Surgery was performed when the curvature had been stable for at least 9 months. Complete medical and sexual history, physical examination, and comorbidities were recorded for all patients. Basic investigational work up included penile duplex ultrasound study with intracavernosal injection for all patients. The malleable implant used was the Genesis (Coloplast, Minneapolis, MN, USA) and the inflatable implant used was the Titan OTR (Coloplast, Minneapolis, MN, USA). The study was approved by our institution Ethical Board Committee.

Penile Deformity Assessment: Curvature was measured with a goniometer at maximum rigidity after intracavernosal injection using intracavernosal quadrimix (prostaglandin E1 5 mcg, papaverine 15 mg, phentolamine 1mg, atropine 20mcg per 1ml of saline). Repeated dosing was administered to ensure full erection in all patients (mean dose 0.3 ml; range: 0.1 -1 ml).

Preoperative Counseling for Implant Type: The preoperative discussion was focused on the goal of obtaining ‘functional straightness’ and patient were informed that a residual curvature of 20° or less in any direction would not compromise sexual activity and that curvature <20 degrees was the goal and further maneuvers would not be employed if such residual curvature existed. 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. At our center, the majority of patients chose malleable implants, primarily because of cost as the patient pays by his own (no insurance covering). The average cost of a malleable device in our center was 1300 US dollars, and the total cost of implanting malleable prosthesis ranged from 5500-6000 US dollars. On the other hand, the cost of inflatable device three pieces was 5800 US dollars and the total cost of implanting IPP was ranging from 12,000-13,000 US dollars. Some chose MPP because of fear of IPP mechanical failure and others because of simplicity of usage of the MPP. The main reason for choosing IPP was the likelihood of increased girth compared to MPP. Concealment was of minor importance in our patient’s decision making. An informed consent was signed by all of our patients. This consent form included all the potential complications about both types of implants. This consent included a statement that penile implant surgery is an irreversible surgery so if the patient decided to remove the implant he will not be able to have erection again with ICI or oral therapy. Men dissatisfied with their malleable implant when asked were not likely to change their mind and suggest they should have chosen an inflatable implant. This is multifactorial but cost was a major consideration.

**Implant Surgery:** This study was conducted at a single center including patients operated on by four high-volume surgeons (≥ 50 implants/year). MPP was implanted through ventral penile approach in all patients. A midline incision 4-6 cm length is done at the ventrum of proximal penile shaft. Dissection of Dartos and Bucks fascia is done with exposure of tunica albuginea and corpus spongiosum. The Genesis (Coloplast, Minneapolis, USA) is the implant used by our center and the size used is according to the measured length and the diameter used is 1 mm below the largest dilator inserted.

IPP were implanted using standard scrotal or penoscrotal approach in all patients. Dilation in these cases used the Brooks dilators proximally and distally. After insertion of the cylinders and maximal inflation, residual curvature was measured as outlined above. If residual curvature >20 degrees remains, the technique of modeling popularized by Wilson and Delk is used. (5) For the IPP It was necessary during modeling to initially clamp the cylinder input tubes to protect the pump from back-pressure flow. The prosthetic cylinders are inflated to high pressure, the input tube is clamped with rubber-shod clamps, and the penis is grasped with both hands and bent over the inflated cylinders at the region of maximum curvature. Bending is maintained for 90 seconds and then relaxed. In MPP if placement of the rods did not adequately straighten the erection, modelling procedure was
used (12) and in our practice, we found it much easier. The rest of the patients who failed modelling required additional procedures for residual curvatures such as plaque incision or excision. One or more relaxing transverse incisions (H shape) were made in the plaque using electro-cautery. Incisions were made carefully over the any existing prosthesis and were limited to the tunica, preserving the underlying cavernosal tissue. In some patients, plaque excision was required to accomplish complete straightening. For the purposes of accessing the plaque for patients requiring plaque incision or excision the neurovascular bundle was routinely elevated. Neurovascular bundle was dissected and mobilized when needed according to standard surgical techniques. The same was done for corpus spongiosum. After these maneuvers, re-assessment of corporal length was conducted to optimize implant length. In some patients, plaque excision was needed and this was performed by extending the corporotomy so that the plaque excision was done under direct vision. Using the cutting current in electrocautery with the aid of toothed forceps to dissect the scarred tissue (plaques) from the wall of tunica albuginea. Reassessment of corporal length after these maneuvers was done as above and if extra cylinder length was needed it was added using rear tip extenders.

**Questionnaire:** The sexual health inventory for men (SHIM) questionnaire was collected as part of the preoperative evaluation of patients presenting to our clinic complaining of ED. Postoperatively, overall satisfaction was measured at 3, 6, 12 and 24 months on 5-point Likert scale as follows: 1(dissatisfied), 2(not satisfied), 3(moderately satisfied), 4(satisfied), 5 (very satisfied).

**Statistical Analysis:** Descriptive statistics are reported. Statistical analysis was done using IBM SPSS Statistics software (IBM Corporation, Armonk, New York, USA). Independent measures simple t-tests (2-tail T-test) were used for satisfaction and SHIM scores, while chi-squared were used for group comparisons. A p value of <0.05 was considered statistically significant.
RESULTS

**Patient Population:** 166 men were included. Patient demographic and comorbidity data are presented in Table 1. 82% received a MPP and 18% received an IPP. In the overall cohort, preoperative penile curvature was distributed as follows: dorsal 34%, lateral 31%, ventral 23%, and multi-planar curvature in 12%. The mean preoperative curvature in the entire cohort was 65 degrees (30-130); 67 degrees in MPP group, and 63 degrees in the IPP group (p = 0.55)

**Implant Outcomes:** Of the whole cohort, 92% had total resolution of their curvature (zero degrees), while 8% had residual curvature with a mean of 32 degrees (25-40 degrees) requiring adjuvant maneuvers (plaque incision and/or excision). Implant outcomes in both groups are presented in Figure 1. At the end of surgery (placement of prosthesis with/without extra maneuvers: in MPP group, curvature was completely fixed in 94%, while in the IPP group, curvature was completely fixed in 83% (p = 0.48). There was no significant difference in complication rate between the MPP and IPP. Major complications included four cases with wound infection (3 MPP and 1 IPP). All responded well to conservative therapy and achieved complete healing. Minor complications included temporary penoscrotal edema, ecchymosis and local pain occurred in most men.

**Questionnaire Outcomes:** There was no statistically significant difference between malleable and inflatable groups in post-operative satisfaction scores or SHIM scores (data presented in Table 2). The postoperative SHIM score was done 3 months after surgery and repeated at 6,12 and 24 months. This satisfaction rate was sustained in both groups with a mean follow up period of 23.4 months (6-29 months).
DISCUSSION

Prevalence rates of PD of 0.4–9% have been published [13]. PD is frequently associated with erectile dysfunction, and a variety of other comorbid disorders, including diabetes, hypertension and radical prostatectomy. Two-thirds of patients with PD are likely to have risk factors for arterial disease and therefore worsening long-term erectile function. (14) Usta et al reported that erectile dysfunction in men with PD ranged from 20-54%. (15) Because PD is associated in many patients with impaired sexual functioning, true sexual dysfunction as a result of the penile deformity must be assessed. Inability of the patient to engage in penetrative sexual intercourse may primarily relate to three reasons: penile deformity, which physically limits penile penetration; pain (during sexual activity) experienced by either the patient or partner as a result of the penile deformity; or ED, by which the penis cannot achieve or maintain the rigidity necessary for the completion of intercourse. (16)

The purpose of surgery for the treatment of PD is to enable the patient to resume satisfactory sexual activities. This requires a functionally straight and sufficiently rigid penis to enable him to accomplish penetrative intercourse. Penile implant can address both issues simultaneously. (16)

Historically, inflatable penile implants are associated with higher functional satisfaction and lower persistent curvature rates. The three-piece inflatable implant cylinders allow more flexible sizing. It is generally recommended that cylinders that expand in length should be avoided. The two-piece hydraulic prosthesis, the Ambicor (AMS, Minneapolis, MN, USA), can be used in PD when placement of an intra-abdominal reservoir poses a problem. However, these devices do not deflate fully (as they are pre-filled) and can be difficult to place when there is some degree of constriction within the corpus cavernosum. (7,12,17)

Malleable penile implants may also be used in patients with Peyronie’s disease although some authors have argued against them (10). Also the AUA guidelines 2015 for PD states: (Clinicians should use inflatable penile prosthesis for patients undergoing penile prosthetic surgery for the treatment of Peyronie’s disease), but this recommendation is based on expert opinion. (18) These devices (MPP) are more suitable for the patients with impaired manual dexterity and for whom placement of an inflatable device may prove difficult. Montorsi et al reported that placement of a malleable implant for PD was associated with a significant patient-partner dissatisfaction rate. They assessed the long-term acceptance of and satisfaction with penile implants in PD patients and their partners.
From 1985-87, 50 men with PD and associated ED were treated with a malleable implant without additional plaque surgery. A total of 48 patients and 29 partners were re-assessed at a follow-up of at least 60 months. Only 23 patients (48%) and 12 partners (40%) were totally satisfied with the long-term functional result and would repeat the same operation. Among the 25 dissatisfied patients (52%), loss of natural tumescence resulting in a pencil-like penis, decrease in penile sensitivity, poor concealment and persistence of penile deviation were the major complaints. Of the partners, 17 (60%) were dissatisfied due to poor penile girth, sensation of a cold glans, sensation of unnatural intercourse and dyspareunia (10). How different the patient or partner satisfaction would have been with inflatable implants is not known from this study. (7)

In our study, 94% of our MPP group achieved a completely straight penis at end of the operation and this continued till the end of follow up period. In the MPP group, the mean satisfaction score, three months postoperatively, was comparable to that of IPP group. This satisfaction rate was also durable with a mean follow up period of 23.4 months (6-29 months). We believe that the reason we were able to achieve such excellent straightening of curvature without adjuvant maneuvers is that during corporal dilation we have to dilate aggressively to create a wide enough space for the malleable implant. We believe this to be a critical factor in disrupting intracorporal synechiae, which might play some role in curvature in men with PD to straighten the penis. Optimal outcomes with MPP may utilize the modeling procedure as for IPP. 20% of our MPP patients required this for significant residual curvature after implant placement. Modeling failed to correct the residual curvature in 21% and plaque incision was required for the remainder of the MPP patients. This is comparable to the need for this in the IPP group in our analysis.

Supporting our findings, Ghanem et al reported their experience in a much smaller group (20 men) with PD who underwent placement of a malleable penile prosthesis. They reported complete straightening of penile shaft in 65% of their patients while the remaining have some degree of deviation. Also they reported high rate of satisfaction (87%). They concluded the safety and effectiveness of MPP in management of PD associated with ED. (19)

Added to the lower cost of MPP, the simplicity of the procedure for the surgeon and patient is a potential significant advantage. Based on our data, we believe that MPP is a reasonable approach for patients who are suffering from PD and ED. In certain regions of the world where patients pay for the implant (no insurance coverage), MPP becomes an excellent choice for those patients. There is little doubt that cultural milieu and
socioeconomic factors have played some role in the acceptance of the malleable implant. We think that insurance covering for penile implant surgery in countries like USA, has a major role in domination of IPP, which might not be the case if it does not. However, the fact is that malleable implants were capable of correcting penile curvature in men with PD.

As a strength, to our knowledge, this is the largest published series assessing the outcome of MPP in PD patients and there is some form of comparison to the outcomes of IPP at the same center. However, as limitations, this is not a randomized control study, although RCTs in the surgical space are notoriously difficult to conduct. Furthermore, no assessment of postoperative penile length or long-term residual deformity was performed which would have added value to the study. To be honest, a RCT would likely only impact upon patient satisfaction outcomes but have little effect on the data pertaining to implant correct curvature. Other limitations, it has only medium term follow-up, has a small number of IPP patients and did not use a validated instrument for satisfaction after surgery.

Therefore, although a consensus on the ideal surgical method for the reconstruction of penile deformity in men with ED does not exist; current efforts should focus on reaching a consensus on the ideal way to follow these patients in the long term and compare the outcome in all aspects including cost.
Conclusions

We have demonstrated that the ability of MPP to restore functional erections is excellent, as good as IPP, at least if adjuvant intra-operative manoeuvres are utilized when residual curvature is encountered. Furthermore, there appears to be no difference in satisfaction between the MPP and IPP patients.
References


17-Kowalczyk JJ, Mulcahy JJ. Penile curvatures and aneurysmal defects with the ultiex penile prosthesis corrected with insertion of the AMS 700 CX. J Urol 1996;156: 398-401.


Table 1: Patient demographic and comorbidity data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Entire Cohort N=166</th>
<th>MPP group N=136</th>
<th>IPP group N=30</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>59 (SD 9.8, range 24 - 81)</td>
<td>58.7 (SD 9.7, range 24 - 81)</td>
<td>59.1 (SD 10.0, range 29 - 75)</td>
<td>P= 0.75</td>
</tr>
<tr>
<td>Mean HBA1C</td>
<td>8±1.6%</td>
<td>8.1% (SD 1.5, range 4.9 – 12.0)</td>
<td>7.5% (SD 1.6, range 5.3 - 10.7)</td>
<td>P=0.03</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>30±5</td>
<td>30.2 (SD 4.7, range 20 - 48)</td>
<td>30.7 (SD 4.8, range 16 - 38)</td>
<td>P=0.61</td>
</tr>
<tr>
<td>Mean preoperative curvature (degrees)</td>
<td>65 (30-130)</td>
<td>67</td>
<td>63</td>
<td>P=0.55</td>
</tr>
</tbody>
</table>

* IPP vs MPP groups
### Table 2: Questionnaire Data Outcome

|                        | MPP group                   | IPP Group                    | P value  
|------------------------|-----------------------------|------------------------------|--------
| **Preoperative SHIM Score** | 9.1 (SD 2.6, range 6 – 16) | 8.6 (SD 2.5, range 6 – 14) | P=0.32 |
| **Postoperative SHIM Score** | 22.5 (SD 2.5, range 12 - 25) | 22.3 (SD 2.5, range 13 - 25) | P=0.64 |
| **Postoperative Mean satisfaction** | 4.4 (SD 0.7, range 2 – 5) | 4.3 (SD 0.8, range 2 – 5) | P=0.032 |

* IPP vs MPP groups
FIGURE 1: Summary of implant outcomes in both groups (malleable, MPP and inflatable penile implants, IPP)
Penile implant
N=166

MPP
N= 136

Completely straight after insertion of rods
N= 82 (60%)

Completely straight after penile modelling
N= 28 (21%)

Completely straight after multiple manoeuvres
N= 18 (13%)

Partial straightening after multiple manoeuvres
N= 8 (6%)

IPP
N= 30

Completely straight after insertion of rods
N= 16 (57%)

Completely straight after penile modelling
N= 6 (20%)

Completely straight after multiple manoeuvres
N= 2 (7%)

Partial straightening after multiple manoeuvres
N= 5 (16%)