

SURGERY

Malleable Penile Implant Rod Diameter Predicts Complications and Patient Satisfaction



Mohamad Habous, MD, FEBU, FECSM,¹ Mohamed Omar, MD,² Mohammed Farag, MD, FECSM,³ Osama Abdelwahab, MD,⁴ Osama Laban, MD, FEBU,⁵ Saleh Binsaleh, MD, FECSM,⁶ John P. Mulhall, MD, FECSM,⁷ David Ralph, MD, FECSM,⁸ and Mohammed Aziz, MD²

ABSTRACT

Background: One of the most common complaints after malleable prosthesis implantation (MPI) is thinning of the penis and decreasing girth. Some surgeons try to insert the largest diameter they can to improve patient satisfaction

Aim: To investigate if malleable rod diameter (MRD) has an impact on outcome and patient satisfaction

Methods: Consecutive malleable prosthesis implantation (MPI) was assessed in a high-volume center over 1 year. The same preoperative, intraoperative, and postoperative protocols were used for all patients and one brand of the malleable device was used only. We recorded MRD and length for all patients. All patients had data on comorbidities including glycated hemoglobin (HbA1c) and clinical Peyronie's disease (PD). Revision cases and those who lost for follow-up were excluded from the study. We also excluded patients operated on by low-volume surgeons. All complications, minor (edema, ecchymosis, pain), and major (infection and erosion) were recorded. After 1-year, patients were assessed and given a Likert scale from 1 to 5 where 5 is most satisfied with their MPI. We stratified patients according to MRD into 2 groups: group A for diameter 9.5 and 11 mm and group B for 13 mm.

Outcome: Larger diameter of malleable penile implants may be associated with more complications

Results: 183 patients had full data and filled the questionnaire after 1-year follow-up. All patients had Coloplast, Genesis penile implants. Major complications rate (infection, erosion, and removal) was significantly higher in group B 11% vs 1.2% in group A ($P = .016$). At 4 weeks postoperative visit, 90 % of group A showed no complications vs 60% only in group B that was statistically significant ($P = .0003$). Satisfaction rate was more in patients in group A (88.6%) compared to patients in group B (75.7%) but this did not reach to be statistically significant ($P = .0519$)

Clinical Implications: MRD predicts outcome.

Strengths & Limitations: The strengths of our study include that it is the first prospective study with good number of malleable implants. Limitations include: no validated satisfaction instrument and MRD choice was based on surgeon preference.

Conclusions: Larger diameter of malleable penile implants are not associated with a higher rate of patient satisfaction **Habous M, Omar M, Farag M et al. Malleable Penile Implant Rod Diameter Predicts Complications and Patient Satisfaction. Sex Med 2022;10:100486.**

Copyright © 2022, International Society of Sexual Medicine. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Key Words: Malleable Penile Implants; Malleable Rod Diameter; Satisfaction; Erectile Dysfunction

Received December 14, 2021. Accepted December 24, 2021.

¹Al-Thermal Medical Center, Abha, Saudi Arabia;

²Urology Department, Menofia University, Egypt;

³Urology Department, Azhar University, Assuit Branch, Egypt;

⁴Urology Department, Benha University, Egypt;

⁵Urology Department, King Fahad Hospital, Tabuk, Saudi Arabia;

⁶Division of Urology, Department of Surgery, Faculty of Medicine, King Saud University, Riyadh, Saudi Arabia;

⁷Sexual & Reproductive Medicine, Memorial Sloan Kettering Cancer Center, New York City, NY, USA;

⁸St. Peters Institute of Andrology, University College London Hospital, London, UK

Copyright © 2022, International Society of Sexual Medicine. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.esxm.2021.100486>

INTRODUCTION

Erectile dysfunction (ED) affects more than 50% of men aged 40 years or older.¹ Penile prosthesis implantation (PPI) is the gold standard therapy for patients with ED, who have failed first (phosphodiesterase type-5 inhibitors) and second-line treatments (intraurethral suppository, intracavernosal injections, vacuum devices), or have found them unacceptable.²

Historically, Nikolaj Bogoraz, in 1936, was the first to insert a tailored rib cartilage into a reconstructed penis to make it rigid.³ In 1966, Dr Beheri, an Egyptian plastic surgeon, was the first to describe the placement of polyethylene rods inside the corpora cavernosa. This resulted in an erect penis that was more rigid, less painful, and less likely to erode than previous implants.⁴ In 1975, Carrion and Small published their initial experience of utilizing a silicone implant. Their work was considered the precursor to the current malleable penile implant (MPP) consisted of a pair of rods made of silicone sponge on the inside and another outer silicone layer.⁵

The major disadvantages of inflatable penile prosthesis (IPP) are the need for adequate manual dexterity and the possibility of mechanical failure requiring repair. Being cheaper, MPP represents the most frequently used device outside of Europe and the United States, with advantages including their ease of implantation and relative freedom from mechanical failure. However, difficulty with concealment and an increased risk of erosion represent the main disadvantages. In Europe and the USA, the MPP represents less than 20% of all devices implanted.^{6–10}

One of the greatest contributors to patient dissatisfaction after penile implant surgery is patient concern about postoperative penile length and girth.¹¹ For MPP, failure of the device to expand may lead to a narrow penis, which for some men is a concern, and for men with a longer penis may lead to penile instability despite good rigidity.^{12,13} Thus, some surgeons attempt to circumnavigate to this issue by inserting the largest diameter MPP rod possible in an effort to maximize patient satisfaction.

This prospective analysis was conducted to investigate if malleable rod diameter (MRD) had an impact on function and patient satisfaction.

METHODS

Study Population: Patients undergoing MPP at a high-volume center were prospectively enrolled in this study over a 12-month period (June 2015–2016). Exclusion criteria included: re-implant surgery, patients who had complex procedures such as grafting for Peyronie's disease, patients operated on by low-volume surgeons (<12 procedures per year and those who were lost to follow-up during the study period). The data collected for each procedure included: identification of the surgeon, patient data including demographic, medical, and sexual history, and

procedure-related data including rod diameter used, data on follow-up, and complications profile.

Complications: these were defined as minor (not requiring hospitalization or re-operation), such as penile or scrotal ecchymosis, hematoma, pain, superficial wound breakdown, and major (requiring hospitalization or re-operation), such as device infection and erosion.

Preoperative Counselling: The preoperative discussion focused on the goal of surgery of obtaining a "functional erection," one sufficient for satisfactory sexual intercourse. Advantages and disadvantages of both types of implants, MPP and IPP, were explained in detail to all patients. The advantages of IPP included greater naturalness in appearance in both erect and flaccid states; greater girth compared to MPP; better stability and rigidity compared to MPP. The disadvantages discussed included: the possibility of mechanical failure; lower life expectancy and greater expensive. The advantages of MPP cited included: ease of use; lower rates of mechanical failure; longer life-expectancy; decreased expensive. MPP disadvantages discussed were: poorer concealability; reduced girth; relative instability and rigidity compared to IPP.^{7–10,12,11,13} Choosing the type of device was based on the patient's preference.

Preoperative Considerations: Patients were instructed to take a shower with antibacterial soap for the 3 nights before surgery, shaving was done in the operating room, 240 mg of intravenous gentamycin was given 2 hours before the operation began in addition to ceftriaxone 1 g given at anesthesia induction.

Operative Considerations: The standards of infection control for implant surgery are applied in our center including but not limited to minimization of human traffic inside the operating room and application of strict rules for scrubbing and dressing for staff members inside the operation room. Combined gentamicin and rifampin in saline was used as the irrigation solution. All of the devices used were hydrophilic coated. The operative area was scrubbed with povidone-iodine for 10 minutes then painted with isopropyl alcohol and allowed to dry. All operations were performed through a ventral penile median raphe incision. A single type of MMP was utilized (Genesis, Coloplast, Minneapolis, MN, USA). We recorded malleable rod diameter (MRD) and length for all patients. We stratified patients according to MRD into 2 groups: group A, circumference 9.5 and 11 mm, and group B, 13 mm.

Postoperative Care: Patients were discharged from hospital the evening of the same day of surgery and were on pain management (usually Ibuprophen or diclofenac sodium) and amoxicillin-clavulanic acid 1 g twice daily for 1 week. They were followed as follows: twice a week for the first 2 weeks, weekly for weeks 3 and 4, and every 3 months thereafter for 1 year. A diagnosis of implant infection was made based on local signs: pain, discharge, redness in addition to systemic

signs such as leucocytosis and fever (temp $\geq 38^{\circ}\text{C}$). This was confirmed using bacterial and fungal cultures at the time of explantation surgery.

Outcomes: All complications, either minor (edema, ecchymosis, pain) or major (infection and erosion) were recorded during follow-up visits. After 1-year, patients had their satisfaction assessed using a single question scored using a 5-point Likert scale from 1 to 5 where 5 was highly satisfied, 4 is satisfied, 3 is neutral, 2 is dissatisfied and 1 is most dissatisfied with their PPI procedure. This was done face to face by the center administrator.

Statistical Analysis: Statistical analysis was done using Chi-square and statistical software: Stata Release 13 and P value less than .05 was considered statistically significant.

RESULTS

183 patients had full data and filled the questionnaire after 1-year follow-up. The mean age was 56 years in group A and 57 years in group B. All the patient's implants were malleable of the same brand of the malleable device; Genesis (Coloplast, Minneapolis, MN, USA). Patient's characteristics and demographics are outlined in [Table 1](#).

Implant Outcomes

There was no significant difference in complication rate between the 2 groups either early ($P = .205$) or after 2 weeks ($P = .097$). However, at 4 weeks postoperative visit, 90 % of group A showed no complications vs 60 % only in group B that was statistically significant ($P = .0003$). Postoperative minor complications included temporary penile edema, ecchymosis, local pain, lower urinary tract symptoms (LUTS), and wound problems (ulceration, delayed healing). After 4 weeks the most encountered complications were: local pain, LUTS, and delayed healing; they were more frequent in group B (40% vs 10% in group A, $P = .0003$).

Major complications included 5 cases of implant infection (2 in group A and 3 in group B) and 1 case of rod erosion (group B). All 6 cases had to be removed in theatre (re-operation). The overall infection rate was 3.3% (1.33% in group A and 12% in group B) [Table 2](#).

Table 1. Patient characteristics

Variable	Group A	Group B	P value
Mean age	56	57	.8
Diabetes (HbA1c > 6.5)	61%	57%	.6
Current smoker	36%	27%	.3

Table 2. Implant outcome

	Rod		
	Size 9,5 or 11 N = 150	Size 13 N = 33	
Percentage of patients without complications			
"Early"	90%	78%	$P = .205$
At 2 wk	78%	65%	$P = .097$
At 4 wk	90%	60%	$P = .0003$
Final outcome			
Good or Fair	91%	81%	$P = .236$
Removed implant	1.20%	11%	$P = .016$

Table 3. Satisfaction outcome

Patient satisfaction (From 0 to 5)	Group A	Group B	P value
4 – 5	88.60%	75.70%	$P = .0519$
3	8%	12%	$P = .238$
0 – 2	3%	9%	$P = .236$

Questionnaire Outcome

After 1 year most patients were satisfied with their implants. The satisfaction rate was more in patients in group A (88.6%) compared to patients in group B (75.7%) but this did not reach to be statistically significant ($P = .0519$) [Table 3](#).

DISCUSSION

According to EAU Guidelines on male sexual dysfunction, implantation of a penile prosthesis is a valid, third-line therapeutic option for treatment of ED, when first-line oral therapy (PDE5I), second-line injection therapy and vacuum devices prove to be ineffective, unsatisfactory or contraindicated.¹⁴ In the middle east and Africa, MPP are the most commonly used implants with high satisfaction rates compared to IPP which have the downside of an increased cost, as penile implant surgery is not covered by insurance in many developing countries.^{12,15}

When compared with other treatment modalities for ED like PDE5I or injection therapy, the current published data suggests that patients who have PPI surgery have the highest satisfaction rates.^{16,17} However subjective loss of penile size (length and/or girth) remains a significant patient concern. Up to 30% complain of decreased penile size following PPI insertion.¹¹ While some authors have found that there are no statistically significant differences in penile size after surgery compared to preoperative measurements, the majority of patients (72%) report a decrease in penile length,¹⁸ while others report significant decrease in the erect penile size.^{13,19}

Levine et al attributed this complaint to the fact that some patients compare their post-PPI erection to that from when their erection was functional, often years previously.¹⁷ Unrealistic expectations and weight gain (excess pre-pubic fat) are additional contributors.¹¹

No doubt that the best implant size for a certain patient is the best fitting, neither the oversize nor the undersize. One of the most common complaints after MPI is decreased girth.^{12,11,13} For that reason, some surgeons try to insert the largest diameter (13 mm in this study) in an attempt to improve patient satisfaction. We think that overstretching and oversizing may result in more complications which results in reduced patient satisfaction. Clearly, attempting to fit a larger cylinder in a narrow penis will render closure of the tunica albuginea and of the skin harder and the tension is likely to promote wound dehiscence and infection of the device. One more important factor in decreasing patient satisfaction in group B is less concealment with a larger rod diameter. In contrast to the postulate that larger diameter rods are associated with better the satisfaction rates, our results demonstrated the opposite. Our results showed that the largest diameter group (13 mm) was associated with more major complications (12%) vs (1.3%) for the smaller and medium diameter group ($P = .016$). Also, after 4 weeks, minor complications were also more frequent in the largest diameter group 13 mm (40% vs 10% in the other group, $P = .0003$). Our data showed that complications (major and minor) have a major impact on patient satisfaction. A recent multicenter large study (902 implants) agreed with our results and showed that only the presence of a major complication is linked to a lower likelihood of achieving high satisfaction.¹⁶

Our results showed that postoperative size is not the only predictor of patient satisfaction as other factors might be more important like postoperative complications and concealment. We recommend surgeons try to put the best-fitted implant, neither oversize nor undersize, and discuss with patients prior to surgery other issues like concealment as not every patient will favor more rigidity and girth at the expense of concealment.

The strengths of our study include that it is the first prospective study with good number of malleable implants of the same manufacturer comparing rod diameter with the outcome in high-volume center by high volume surgeons. Limitations include: small patient number; no validated satisfaction instrument (however none exist for the MPP); MRD choice was based on surgeon preference.

CONCLUSIONS

Larger diameter of malleable penile implants are not always associated with higher patient satisfaction as there are other predictors like postoperative complications and concealment. The best implant size for a certain patient is the best fitting, neither the oversize nor the undersize.

Corresponding Author: Mohamad Habous, MD, FEBU, FECSM, Consultant Urologist, Al-Themal Medical Center, 8137 Alkhaleej Street, Alrabei Distrect, Khamis Mushait, 62454, Saudi Arabia. Tel: 00 9665 99950131; E-mail: drmhobos@hotmail.com

Conflict of Interest: The authors report no conflicts of interest.

Funding: None.

STATEMENT OF AUTHORSHIP

Conceptualization: M.H., J.M.; Methodology: M.H., M.A., J.M.; Software: M.H., S.B.; Validation: M.H., D.R.; Formal Analysis: M.O., O.L.; Investigation Resources: M.H., O.A.; Data Curation: M.H., O.A., M.F., S.B.; Writing - Original Draft: M.H., M.A., M.O.; Writing - Review & Editing: M.H., D.R., J.M.; Visualization, Supervision: M.H.; Project Administration: M.H.; Funding Acquisition: M.H.

REFERENCES

1. Feldman HA, Goldstein I, Hatzichristou DG, et al. 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, et al. Long-term outcomes of penile prostheses for the treatment of erectile dysfunction. *Expert Rev Med Devices* 2013;10:353–366.
3. Jonas U. The history of erectile dysfunction management. *Int J Impot Res* 2001;13(Suppl 3):S3–S7.
4. Beheri GE. Surgical treatment of impotence. *Plast Reconstr Surg* 1966;38:92–97.
5. Small MP, Carrion HM, Gordon JA. Small-Carrion Penile Prosthesis: New Implant for Management of Impotence. *Urology* 1975;5:479–486.
6. Martinez DR, Terlecki R, Brant WO. The evolution and utility of the small-carrion prosthesis, its impact, and progression to the modern-day malleable penile prosthesis. *J Sex Med* 2015;12(Suppl 7):423–430.
7. Nielsen KT, Bruskewitz RC. Semirigid and malleable rod penile prostheses. *Urol Clin North Am* 1989;16:13–23.
8. Kılıçarslan H, Kaynak Y, Gökçen K, et al. Comparison of patient satisfaction rates for the malleable and two piece-inflatable penile prostheses. *Turk J Urol* 2014;40:207–210.
9. Oberlin DT, Matulewicz RS, Bachrach L, et al. National practice patterns of treatment of erectile dysfunction with penile prosthesis implantation. *J Urol* 2015;193:2040–2044.
10. Jain S, Goddard JC, Summerton DJ, et al. An audit of implanted penile prostheses in the UK. *BJU Int* 2006;98:918–919.
11. Habous M, Giona S, Tealab A, et al. Penile length is preserved after implant surgery. *BJU Int* 2019;123:885–890.
12. Habous M, Tealab A, Farag M, et al. Malleable penile implant is an effective therapeutic option in men with peyronie's disease and erectile dysfunction. *Sex Med* 2018;6:24–29.

13. Montorsi F, Guazzoni G, Bergamaschi F, et al. Patient-partner satisfaction with semirigid penile prosthesis for Peyronie's disease: A 5-year follow-up study. *J Urol* 1993;150:1819–1821.
14. Hatzimouratidis K, Giuliano F, Moncada I, et al. Erectile Dysfunction, Premature Ejaculation, Penile Curvature and Priapism. EAU Guidelines; 2016.
15. Bozkurt I, Arslan B, Yonguç T, et al. Patient and partner outcome of inflatable and semi-rigid penile prosthesis in a single institution. *Int Braz J Urol* 2015;41:535–541.
16. Habous M, Tal R, Tealab A, et al. Predictors of satisfaction in men after penile implant surgery. *J Sex Med* 2018;15:1180–1186.
17. Levine LA, Becher E, Bella A, et al. Current recommendations from the International Consultation on Sexual Medicine. *J Sex Med* 2016;13:489–518.
18. Deveci S, Martin D, Parker M, et al. Penile length alterations following penile prosthesis surgery. *Eur Urol* 2007;51:1128–1131.
19. Wang R, Howard GE, Hoang A, et al. Prospective and long-term evaluation of erect penile length obtained with inflatable penile prosthesis to that induced by intracavernosal injection. *Asian J Androl* 2009;11:411–415.