Modified malleable prosthesis with a fixed mesh: case series for the Ghattas technique

Osama Ghattas1, Mohamed Fahmy Doheim2, Hossam Kotb3, Arthur L Burnett3

Penile prosthetic implantation represents a cornerstone for patients with organic erectile dysfunction (ED) that is refractory, unsatisfactory, or contra-indicated for other approved medical or mechanical options. In this study, we introduce the “Ghattas technique,” wherein we constructed a polypropylene mesh sheath that surrounds and is fixed to a 13-mm malleable prosthesis cylinder, which can increase the cylinder diameter for cases that need a larger prosthesis. All patients underwent preoperative evaluation and completed the five-item International Index of Erectile Function questionnaire (IIEF-5). Postoperative outcomes were evaluated by IIEF-5 and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaires at final follow-up. The mean age of the 23 included patients was 57.9 (standard deviation [s.d.]: 11.4) years and the mean duration of ED was 8.5 (s.d.: 7.9) years. Erection improvement was determined by comparing mean preoperative and postoperative IIEF-5 scores (8.3 [s.d.: 3.9] vs 24.6 [s.d.: 0.6], P < 0.001). High treatment satisfaction was determined according to a mean EDITS score of 94.9 (s.d.: 9.9). The proposed Ghattas technique was safe and effective in our patients, and provides opportunity for cases that need a diameter larger than 13 mm. Further studies are needed to confirm these results.

Keywords: erectile dysfunction; mesh; penile prosthesis; surgical technique

INTRODUCTION

Penile prosthetic implantation is a main line of treatment for patients with organic erectile dysfunction (ED) that is refractory, contra-indicated, or unsatisfactory for other approved options.1,2 A malleable (noninflatable or semi-rigid) penile prosthesis provides a valid implant option. Although inflatable prostheses are associated with higher satisfaction rates, malleable devices require less complex and cheaper surgical procedures and exhibit infrequent mechanical failure.3 Moreover, malleable prostheses may be the preferred choice under indications such as poor hand dexterity, a posttraumatic “hostile” pelvis, neobladders, prior bilateral hernia surgery, major fibrosis of the corpus cavernosum, complex anatomies, or infection after salvage surgery.4

A malleable prosthesis typically comprises a pair of rods made of either a spiral wire core or silicone material, encased in fabric such as a silicone or polyurethane jacket. Among the market varieties, there is no diameter larger than 13 mm. However, during clinical practice, we have encountered some special cases that require diameters larger than 13 mm because of an enlarged penis. We have observed that the implantation of prostheses of 13-mm diameter usually resulted unsatisfactory or contra-indicated for prosthesis implantation. Informed consent was taken from all the patients, with information explaining the types of implantation technique, wherein we used a sheath constructed from a polypropylene mesh (Ethicon US, LLC, Cincinnati, OH, USA) that was fixed to a 13-mm prosthesis cylinder.

PATIENTS AND METHODS

We examined patients with organic ED who underwent the Ghattas implantation technique, described below, from October 2018 to May 2020 at Mary Markus Hospital, Alexandria, Egypt. All patients underwent preoperative evaluation, including medical history, physical examination, lab testing, and penile color Doppler ultrasonography. In all patients, past treatment had failed or had been rejected (oral, intracavernous self-injection, or vacuum devices). Preoperatively, patients were evaluated using the five-item International Index of Erectile Function questionnaire (IIEF-5) to determine their erectile function domain scores.5 All patients underwent a psychiatric evaluation preoperatively and those with psychiatric disorders were found unsuitable for prosthesis implantation. Informed consent was taken from all the patients, with information explaining the types and technical characteristics of the device. Patients were asked to give consent for their photos to be taken during surgery.

Surgical technique

At the beginning of surgery, after inserting a transurethral catheter, a ventral incision was made to reveal both corpora cavernosa. Bilateral sling sutures were placed on both cavernous bodies and a coronotomy incision of approximately 2.5 cm in each corporal body was performed. After measuring intracorporal
dimensions, irrigation was performed with an antibiotic solution and gloves were changed. For intracorporal diameters 13 mm or less after dilation, prostheses were implanted without modification. For intracorporal diameters more than 13 mm after dilatation, we constructed a sheath of polypropylene mesh, as used in surgeries such as hernia repair, that was approved as safe and sterile. This technique entails wrapping the mesh around a 13-mm penile prosthesis cylinder and modifying the number of layers of mesh wrapped around the prosthesis to fit the apparent size of the corporal body. Then, the mesh was fixed to the prosthesis using polypropylene stitches (Figure 1). After placing the ensheathed penile prosthesis cylinder within the corporal body (Figure 2), the surgical wound was closed in layers and the penis dressed with an elastic bandage.

Outcome measures
Outcomes were further evaluated by IIEF-5 and the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire at the final follow-up. Complications were also assessed.

Statistical analyses
Statistical analyses were performed by SPSS version 25 (Statistical Packages for the Social Sciences, Chicago, IL, USA). Qualitative data were described using number and percentage. We described quantitative data using range, mean, and standard deviation (s.d.). To compare preoperative and postoperative IIEF-5 scores, the Wilcoxon signed-rank nonparametric test was used. P < 0.05 was considered statistically significant.

RESULTS
We identified 39 patients, of which 23 had complete datasets and follow-up examinations that were suitable for inclusion in this study. The mean age of patients was 57.9 (s.d.: 11.4, range: 37–73) years, and the mean duration of ED was 8.5 (s.d.: 7.9) years. Among the 23 patients, 14 were diagnosed with vasculogenic ED and the others had nonvasculogenic ED. Our cases included six patients who underwent the Ghattas surgical technique as a revision because of complications associated with prior undersized prosthetic cylinders (five had broken cylinders). The mean follow-up was 5.5 (s.d.: 3.4) months with the longest follow-up of 18 months. Patients’ demographics and comorbidities are summarized in Table 1.

Erection status was significantly improved following surgery, comparing preoperative and postoperative IIEF-5 domain values in all domains and overall scores (Table 2). The assessment of each domain is summarized in Supplementary Table 1. We found increased IIEF-5 scores for the six patients who underwent surgical revisions with the new technique, with mean baseline scores of 5.7 (s.d.: 0.8) to postoperative scores of 24.3 (s.d.: 0.8; P < 0.001). The mean follow-up was 8.2 (s.d.: 5.3) months for all patients. High treatment satisfaction was also shown by EDITS (Table 2). A summary of responses for EDITS questions are provided in Supplementary Table 2. For postoperative complications, postoperative mild to moderate penile pain was reported subjectively in four (17.4%) patients and was relieved gradually through follow-up, and delayed ejaculation was reported in two (8.7%) patients.

DISCUSSION
Historically, Bogoras used cartilage from the ribcage of animals to enable penile erection in the 1930s. As early as the 1970s, penile prostheses with different functional and structural characteristics were developed with advanced technology. Penile prostheses have been frequently used as a tertiary treatment in cases with ED that do not respond to nonsurgical treatments, such as oral therapies and intracavernosal injections, or for those who cannot use these treatments for different reasons. During the selection of prosthesis type, it is important to consider the features, expectations, and wishes of patients. Our study presents a new technique, in which we used a polypropylene mesh sheath fixed to a 13-mm prosthesis to increase the prosthesis diameter for specific cases requiring a diameter larger than 13 mm. The current outcome results were promising, with a significant increase in IIEF-5 scores after surgery compared with baseline showing the clinical importance of this technique. Likewise,
the results of EDITS were very satisfactory after surgery. These results were considered successful and included scores higher than previous reports by other authors that assessed malleable prostheses using standard techniques.9,10

The new technique has clinical importance for special cases that need a cylinder diameter of more than 13 mm (the largest available diameter). To date, the implantation of a prosthesis with a cylinder diameter of 13 mm for such cases usually results in unsatisfactory intercourse outcomes reported by patients and shrinkage in penile size occurs after a few months. We highlight that the current study did not aim to produce oversized penile augmentation because this may lead to several known problems but intended to achieve an optimal cylinder diameter when there was the likelihood of an undersized prosthesis. For instance, such situations may occur when a patient needs a prosthesis with a 13-mm diameter and we start with a cylinder diameter of 9 mm, or where a patient needs a prosthesis with a 17-mm diameter and we start with a cylinder diameter of 13 mm. We can increase the diameter as needed for each of these cases by modifying the number of layers of mesh wrapped around the prosthesis. There are two benefits possible with this surgical modification: optimization of the prosthesis diameter and more comfortable positioning of the prosthesis in the penis, together achieving greater satisfaction for the patient. The malleability was decreased slightly, depending on the number of wrapped layers, but not to a significant extent, because we used a mesh that was too soft to interfere in a noticeable way. We also speculate that prosthesis cylinders with a diameter larger than 13 mm, if made available, would be too cumbersome for manipulation in a normal position when not performing sexual intercourse. Additionally, a longer corporotomy was not needed to insert the implant that was used in this study. It is worth noting that six of our patients underwent previously failed implantations because of diameter limitations and subsequent complications as mentioned above. These patients achieved highly satisfactory results following revision surgery with our new Ghattas technique. Thus, the Ghattas technique could provide benefits in these specific situations.

Our surgical technique presented with minimal complications in the form of pain and delayed ejaculation, both of which resolved over time through follow-up. In a recent study, postoperative complications from standard prosthesis surgery included penile edema (13.1%), penile pain (8.7%), delayed ejaculation (6.5%), infection (2.2%), cylinder crossover (2.2%), distal cavernosal erosion (2.2%) and numbness of the glans (2.2%).4 Infection is typically the most serious complication of prosthesis implantation. Infection rates have been reported to be reduced by frequent disinfection of the surgical area, preoperative use of prophylactic antibiotics and sustaining them 3–7 days postoperatively, care of the surgical area, and surgery being performed by experienced surgeons.11,12 There were no infected cases observed in our study. A patient undergoing our proposed technique (not included in this study) underwent a revision. In this case, the patient had a large penis but small glans penis, and he was not satisfied with the Rigicon prosthesis after implantation. A revision was done using a Coloplast prosthesis, which had a tapering end tail that was well-fitted to his small glans penis. During exploratory surgery 6 months after his initial surgery, the mesh was almost adherent to the pseudocapsule tunica and the prosthesis was freely mobile with a space filled with blood between the mesh and prostheses. The prosthesis was easily extracted and the mesh was removed without difficulty. It is noteworthy that the patient underwent the Ghattas technique with new mesh fixed to the Coloplast prosthesis and he was very satisfied at follow-up.

This study used a type of mesh that was the most available and typically used safely in humans, as in hernia repair. However, on the basis of the case mentioned above, we note that this material for ensheathing the cylinder may be one limitation of this technique, because in some cases, the mesh may not be easily dissected from the tunica during re-exploration. This study may provide the foundation to encourage specialized companies to find more suitable materials to be used as the outer jacket, with adjustable layers or customized diameters as needed in certain cases.

To the best of our knowledge, this is the first study to investigate and report the use of mesh fixed to a cylinder to increase the prosthesis diameter when needed during implantation. The application of adjunct materials as acellular dermal matrix tissues with prosthetic cylinders in penile implantation surgery was previously described for tunica albuginea replacement and reconstructive purposes.13 However, the use of mesh in the current work was to fortify and stabilize the cylinders and ensure optimal penile girth, but not to provide a tunica substitute.

To summarize, we present the Ghattas technique in which a polypropylene mesh sheath is fixed to a 13-mm prosthesis to increase the prosthesis size for cases that need a diameter larger than 13 mm. The technique was safe and effective in our patients. Further prospective studies with larger sample sizes and long-term follow-up are needed to confirm these results.

**AUTHOR CONTRIBUTIONS**
OG set the idea and concept of the study, collected data, led the writing of the manuscript, and revised and edited the manuscript. MFD analyzed and interpreted the data and shared in the writing of the manuscript. HK collected data and shared in the writing and editing of the manuscript. ALB revised and edited the manuscript and supervised this study. All authors read and approved the final manuscript.

**COMPETING INTERESTS**
All authors declare no competing interests.

Supplementary Information is linked to the online version of the paper on the *Asian Journal of Andrology* website.
REFERENCES
1. Evans C. The use of penile prostheses in the treatment of impotence. *Br J Urol* 1998; 81: 591–8.
2. Burnett AL, Nehra A, Breau RH, Culkin DJ, Faraday MM, *et al*. Erectile dysfunction: AUA guideline. *J Urol* 2018; 200: 633–41.
3. Vitarelli A, Divenuto L, Fortunato F, Falco A, Pagliarulo V, *et al*. Long-term patient satisfaction and quality of life with AMS700CX inflatable penile prosthesis. *Arch Ital Urol Androl* 2013; 85: 133–7.
4. Martinez DR, Terlecki R, Brant W. 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: 423–30.
5. Ghattas O, Doheim MF, Burnett AL. A letter to the editor on the original article: spontaneous penile tumescence by sparing cavernous tissue in the course of malleable penile prosthesis implantation. *J Sex Med* 2020; 17: 1405.
6. Bettocchi C, Palumbo F, Spilotros M, Palazzo S, Saracino GA, *et al*. Penile prostheses. *Ther Adv Urol* 2010; 2: 35–40.
7. Althof SE, Gurt EW, Levine SB, Levine F, Burnett AL. EDITS: development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. *Urology* 1999; 53: 793–9.
8. Schultheiss O, Gabouev AI, Jonas U, Nikolaj A, Bogoraz (1874–1952): pioneer of phalloplasty and penile implant surgery. *J Sex Med* 2005; 2: 139–46.
9. Akdemir F, Okulu E, Kaygıl O. Long-term outcomes of AMS Spectra® penile prosthesis implantation and satisfaction rates. *Int J Impot Res* 2017; 29: 184–8.
10. Casabé A, Sarotto N, Gutierrez C, Bechara AJ. Satisfaction assessment with malleable prosthetic implant of Spectra (AMS) and Genesis (Coloplast) models. *Int J Impot Res* 2016; 28: 228–33.
11. Adrianne R, Balde S, De Leval J, Kempeners P, Mormont C. Penile prosthesis in case of impotence: 12 years of clinical experience. *Acta Urol Belg* 1995; 63: 89–96.
12. Xin ZC, Guo YL, Choi HK. A retrospective study of 548 cases of erectile dysfunction treated by penile prosthesis implantation. *Chin J Urol* 2005; 21: 755–7.
13. Haney NM, Huang MM, Liu JL, hawksworth DJ, Burnett AL. Acellular dermal matrix tissues in genitourinary reconstructive surgery: a review of the literature and case discussions. *Sex Med Rev* 2020. Doi: 10.1016/j.sxmr.2020.07.003. (Epub ahead of print).

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## Supplementary Table 1: The results of Erectile Dysfunction Inventory of Treatment Satisfaction patients’ survey

| Questions                                                                 | Answers (n=23), n (%) |
|---------------------------------------------------------------------------|----------------------|
| 1. Overall how satisfied are you with penile prosthesis?                  |                      |
| Very satisfied                                                            | 19 (83)              |
| Somewhat satisfied                                                        | 3 (13)               |
| Neither satisfied nor dissatisfied                                        | 1 (4)                |
| Somewhat dissatisfied                                                     | 0                    |
| Very dissatisfied                                                         | 0                    |
| 2. To what degree has penile prosthesis met your expectations?            |                      |
| Completely                                                                | 17 (74)              |
| Considerably                                                              | 5 (22)               |
| Half way                                                                  | 1 (4)                |
| A little                                                                  | 0                    |
| Not at all                                                                | 0                    |
| 3. How likely are you to continue using penile prosthesis?                |                      |
| Very likely                                                               | 21 (91)              |
| Moderate likely                                                           | 1 (4)                |
| Neither likely nor unlikely                                               | 0                    |
| Moderate unlikely                                                         | 1 (4)                |
| Very unlikely                                                            | 0                    |
| 4. How easy was it for you to use penile prosthesis?                      |                      |
| Very easy                                                                 | 22 (96)              |
| Moderately easy                                                           | 0                    |
| Neither easy nor difficult                                                | 0                    |
| Moderately difficult                                                      | 0                    |
| Very difficult                                                            | 0                    |
| 5. During the past four weeks, how satisfied have you been with how quickly are treatment work? | 23 (100) |
| Very satisfied                                                            | 0                    |
| Somewhat satisfied                                                        | 0                    |
| Neither satisfied nor dissatisfied                                        | 0                    |
| Somewhat dissatisfied                                                     | 0                    |
| Very dissatisfied                                                         | 0                    |
| 6. During the past four weeks, how satisfied have you been with how long the treatment lasts? | 21 (91) |
| Very satisfied                                                            | 21 (91)              |
| Somewhat satisfied                                                        | 2 (9)                |
| Neither satisfied nor dissatisfied                                        | 0                    |
| Somewhat dissatisfied                                                     | 0                    |
| Very dissatisfied                                                         | 0                    |
| 7. How confident has penile prosthesis made you feel about your ability to engage in sexual activity? | 23 (100) |
| Very confident                                                            | 23 (100)             |
| Somewhat confident                                                        | 0                    |
| It has had no impact                                                      | 0                    |
| Somewhat less confident                                                   | 0                    |
| Very much less confident                                                  | 0                    |
| 8. Overall how satisfied do you believe your partner is with effects of penile prosthesis? |                    |
| Very satisfied                                                            | 19 (83)              |
| Somewhat satisfied                                                        | 2 (9)                |
| Neither satisfied nor dissatisfied                                        | 0                    |
| Somewhat dissatisfied                                                     | 2 (9)                |
| Very dissatisfied                                                         | 0                    |
| 9. How does your partner feel about your continuing to use penile prosthesis? |                    |
| Absolutely wants me to continue                                          | 21 (91)              |
| Generally prefers me to continue                                          | 0                    |
| Has no opinion                                                            | 1 (4)                |
| Generally prefers me to stop                                              | 0                    |
| Absolutely wants me to stop                                               | 1 (4)                |
| 10. How natural did the process of achieving an erection feel when you used this treatment over the past 4 weeks? | 18 (78) |
| Very natural                                                              | 18 (78)              |

Contd...
Supplementary Table 1: Contd...

| Questions                                                                 | Answers (n=23), n (%) |
|---------------------------------------------------------------------------|-----------------------|
| Somewhat natural                                                          | 4 (17)                |
| Neither natural nor unnatural                                             | 0                     |
| Somewhat unnatural                                                        | 1 (4)                 |
| Very unnatural                                                            | 0                     |

11. Compared to before you had an erection problem how would you rate the naturalness of your erection when you used this treatment over the past 4 weeks in terms of hardness?

| A lot harder than before I had an erection problem                         | 19 (83)               |
| Somewhat harder than before I had an erection problem                      | 3 (13)                |
| The same hardness as before I had an erection problem                      | 0                     |
| Somewhat less hard than before I had an erection problem                   | 1 (4)                 |
| A lot less hard than before I had an erection problem                      | 0                     |

Supplementary Table 2: Preoperative and postoperative the five-item International Index of Erectile Function questionnaire domain values of the patients

| Preoperative                  | Postoperative (new technique) | P      |
|-------------------------------|------------------------------|--------|
| How do you rate your confidence that you could get and keep an erection? | 1.64±0.85                    | 5±0    | <0.001 |
| When you had erections with sexual stimulation, how often were your erections hard enough for penetration? | 1.86±1.13                    | 5±0    | <0.001 |
| During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner | 1.55±0.91                    | 5±0    | <0.001 |
| During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse? | 1.55±1.05                    | 5±0    | <0.001 |
| When you attempted sexual intercourse, how often was it satisfactory for you? | 1.59±0.85                    | 4.64±0.58 | <0.001 |
| IIEF-5 (overall)              | 8.27±3.87                    | 24.64±0.58 | <0.001 |

IIEF-5: the five-item International Index of Erectile Function questionnaire. P < 0.05 is considered statistically significant