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BRIEF COMMUNICATION

A Single-Surgeon Retrospective and Preliminary Evaluation of the Safety and Effectiveness of the Penuma Silicone Sleeve Implant for Elective Cosmetic Correction of the Flaccid Penis

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ABSTRACT

Background: Silicone blocks and sleeves are simple devices used in cosmetic surgery. They are generally viewed as safe and effective; however, there is little information on their use in the penis.

Aim: This study evaluates a large single-surgeon series using a novel silicone sleeve penile implant (Penuma) to cosmetically correct the flaccid penis.

Methods: 526 patients underwent elective cosmetic penile surgery using a silicone sleeve penile implant between 2009 and 2014. Institutional Review Board approval was obtained for a retrospective analysis, and study consent was obtained from 400 patients. Penile circumference was measured before surgery, immediately after surgery, and 30–90 days after the implant surgery. Using the nonvalidated Augmentation Phalloplasty Patient Selection and Satisfaction Inventory (APPSSI), changes in self-confidence, self-esteem, and satisfaction scores were assayed 6–8 weeks postoperatively. Scores were again assayed 2–6 years postoperatively in 77% of patients. The questionnaires rated patient self-confidence, self-esteem, and satisfaction as very low, low, medium, high, or very high.

Main Outcome Measure: Outcomes include changes in penile measurements; changes in APPSSI satisfaction, self-confidence, and self-esteem scores; and incidences of adverse events.

Results: In the 400 patients, the implantation of the Penuma silicone implant increased midshaft circumference from an average of 8.5 ± 1.2 cm to 13.4 ± 1.9 cm (56.7% increase; $P < .001$). A 2-category improvement in self-confidence and self-esteem was noted in 83% of patients 6–8 weeks postoperatively. On long-term follow-up (2–6 years; mean 4 years), 72% patients remained improved (2-category improvement in APPSSI scoring), and 81% of subjects reported "high" or "very high" levels of satisfaction. The most frequently reported postoperative complications were seroma (4.8%), scar formation (4.5%), and infection (3.3%). No patients reported any changes in sexual function, erections, or ejaculation. 3% experienced adverse events necessitating device removal.

Clinical Implications: The Penuma silicone implant can help patients cosmetically correct the penis with increased flaccid penile girth and achieve enhanced self-confidence and self-esteem over the short- and long term.

Strengths and Limitations: Strengths include the large number of subjects (400 men) and the long-term follow-up period (2–6 years). Limitations include the retrospective and single-surgeon (inventor) nature of the study; the presence of 126 non-consenting subjects, potentially impacting the complication rate; and the APPSSI's lack of validation.

Conclusion: Retrospective analysis of 400 men electing to have penile cosmetic correction with the Penuma device demonstrates improvements in girth (56.7% increase) and high and sustained patient satisfaction, self-confidence, and self-esteem with minimal and manageable adverse events. **Elist JJ, Valenzuela R, Hillelsohn J, et al. A Single-Surgeon, Retrospective, and Preliminary Evaluation of the Safety and Effectiveness of the Penuma Silicone Sleeve Implant for Elective Cosmetic Correction of the Flaccid Penis. J Sex Med 2018;15:1216–1223.**

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Key Words: Implant; Penile Girth; Phalloplasty; Siilicone; Cosmetic; Penuma; Flaccid Penis; Erect Penis; Penile Size; Self-Confidence

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INTRODUCTION

Most urologists and other medical professionals have often faced questions from men asking about methods to improve the size and overall appearance of their penis. Until now, surgical penile cosmetic correction was generally reserved for men who had a penis that was buried in the suprapubic pannus or one obviously quite small. Methods for these patients have focused on improving the appearance of the flaccid penis by bringing more of the penis outside the body plane. Techniques have included cutting the suspensory ligament and the implantation of autologous fat or artificial grafts. Outcomes are often poorly documented, and reported complications may be unacceptably high.[1–3]

To improve these outcomes, a new soft silicone sleeve was developed for the cosmetic correction of the penis in patients presenting with a perception of small penis, a buried penis from prepubic recession, micropenis, and other related diagnoses.[4,5] The objective of this study was to assess the safety and efficacy of penile cosmetic correction surgery using this new implant.

METHODS

Patients

A total of 526 patients underwent implantation of the Penuma implant between January 1, 2009, and January 30, 2014. All patients were contacted to participate in this study by mail or via an Institutional Review Board (IRB)-approved telephone script and received an IRB-approved consent form to allow access to their medical records for this retrospective analysis. 400 patients (76%) consented to participate. The remaining 126 patients did not return the forms and were excluded from the study.

The 400 patients included in the study were ages 22–68 years, with a mean age of 35 years. Overall, 236 participants (59%) consumed alcohol regularly, 56 participants (14%) were currently smokers, 36 (9%) reported excessive alcohol use, 28 (7%) reported regular use of cannabis, and 7 (1.8%) reported being former smokers. Any current smokers were required to cease all tobacco use for 1 month prior to surgery and for 3 months after the surgery. With regard to comorbidities, the patients were quite healthy (Table 1). 15% had undergone previous penile cosmetic procedures such as (i) injections of autologous fat, (ii) implantation of AlloDerm (LifeCell, Branchburg Township, NJ, USA) or dermis grafts, and (iii) transection of the suspensory ligament. All participants had been circumcised at least 2 months before implantation of the Penuma penile implant (Table 1).

Ethical Conduct of the Study

This study was conducted with the oversight of Quorum Review IRB (Seattle, WA, USA), an independent IRB. The retrospective evaluation protocol was IRB approved March 31, 2015, and closed June 12, 2015.[6]

Table 1. Medical and surgical history

	N	Percentage
Chronic disease		
Hypertension/heart disease	10	2.8
HIV	5	1.3
Diabetes	4	1.0
Penile surgical history		
Circumcision	400	100
Injection of autologous fat*	11	2.3
Implantation of AlloDerm or dermis grafts*	22	5.5
Transection of the suspensory ligament only	27	6.8

*All patients with the injection of autologous fat or the implantation of AlloDerm or dermis grafts also had a transection of the suspensory ligament.

Implant Specifications

This report introduces the use of a subdermally inserted penile implant made of a medical-grade silicone material and designed specifically for penile cosmetic correction.[4–6] This implant is registered with the U.S. Food and Drug Administration (FDA) and has received premarket notification for its use in the cosmetic correction of soft tissue deformities, and to be contoured at the surgeon's discretion to create a custom implant to aid in the reconstruction process,[7] and an FDA-registered manufacturer produces the Penuma implant (Figure 1) for International Medical Devices (Beverly Hills, CA, USA). Wall thickness varies longitudinally from 1.5–2.5 cm proximally to 2–3 mm at the distal circumference. The implant is available in 3 sizes of 14, 16, and 18 cm in length, and implant weight before eventual cropping is 42, 50, and 60 g, respectively.

For stability, 2 Dacron (DuPont, Wilmington, DE, USA) mesh layers are inserted during manufacture of the device to prevent cracks and to facilitate trimming and suturing. A double layer of soft polypropylene mesh (Parietex; Covidien, Dublin, Ireland) is folded over the distal end to encourage tissue ingrowth, thereby diminishing the possibility of perforation or erosion in the area of the corona of the glans.

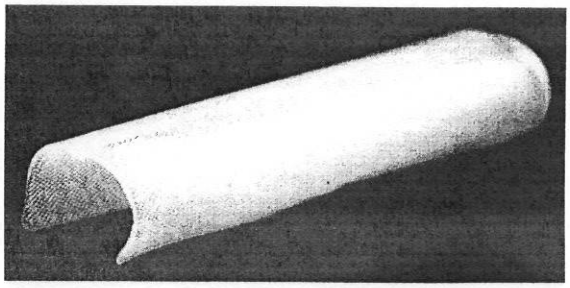

Figure 1. Penuma silicone implant. Figure 1 is available online in color at www.jsm.jsexmed.org.

Patient Selection Criteria

1. Circumcised penis (the patient must have been circumcised at least 2 months before the procedure).
2. No prior subcutaneous/subdermal penile insertion procedures, such as dermal grafting, AlloDerm, and polymethylmethacrylate injections. These prior subdermal inclusions reduce the likelihood of a satisfactory outcome. Patients with prior fat injection may be candidates for the procedure if the fat is surgically removed and the resultant skin thickness after fat injection removal is thought adequate by the surgeon.
3. No active infection in the body.
4. No clinically persistent or recurrent cancer.
5. No exhibition of psychological instability that may affect outcome, which can be screened using validated dysmorphia surveys.[8]
6. Sufficient tissue to adequately cover the implant.
7. No systemic disorders that could lead to poor wound healing or soft tissue deterioration over the implant.
8. Willingness by the patient to comply with all postoperative instructions.
9. Non-smoker within 30 days of the elective procedure.
10. Not currently on blood thinners.

Operative Technique

Under general anesthesia, a 6-cm transverse incision is made 2–3 cm above the pubic symphysis. After dissection of the subcutaneous tissues to Buck's fascia overlying the tunica albuginea of the penis, the tissue around the suspensory ligament is released to prevent the implant from sliding back beneath the symphysis. The suspensory ligament is preserved during this surgery. Blunt and sharp dissection distally in the loose plane between the superficial Dartos fascia and Buck's fascia allows the shaft to be degloved and the corona of the glans to be reached subdermally by intussuscepting the penis. After the penis is degloved, it is necessary to carefully define the coronal sulcus by sharp dissection. This allows the surgeon to nestle the distal border of the implant adjacent to the junction of tunica and glans (Figure 2).

The distal end of the implant is covered with a double layer of the polypropylene mesh. The mesh-covered distal end of the implant is sutured to the distal tunica with 6–8 sutures of non-absorbable 2-0 and 3-0 Ethibond (Ethicon, Somerville, NJ, USA). The degloved penile skin is returned to normal over the implant and then the thick proximal end is trimmed and rounded to the maximum length that the corpora will allow. The implant's proximal abutment is the intact suspensory ligament underneath the pubic bone. The implant's proximal end is fitted snugly between corona and suspensory ligament to limit its mobility to either side but allow easy up-and-down movement of the penis. Throughout the procedure, lavage of the wound with an antibiotic solution is performed. A 19 French, closed-suction drain is inserted, and the wound is closed in 2 layers. Vertical suturing of the subcutaneous tissue helps maintain the positioning of the proximal end of the implant. The drain is removed when the daily drain volume is less than 20 mL.

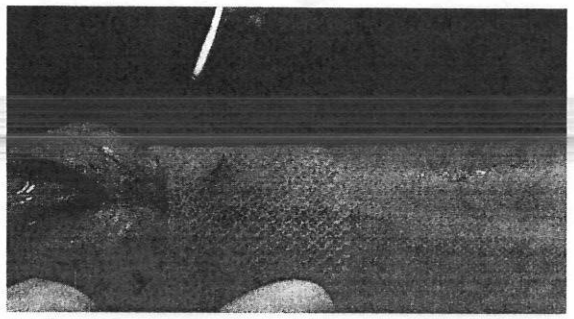

Figure 2. The distal sharp edge of the implant is covered with a soft polypropylene mesh. Mesh and implant are fixed with non-absorbable braided 3-0 sutures to the tunica albuginea beneath the corona. Figure 2 is available online in color at www.jsm.jsexmed.org.

The patient is strongly advised that sexual activity, including masturbation, should be avoided for at least 4–6 weeks postoperatively or until clearance is given by the physician.

Main Outcome Measure

Penile size was measured repetitively. Flaccid penile circumference was measured preoperatively 1–7 days prior to surgery. Postoperative measurements were taken 30–90 days after the implant surgery; the mean number of days after surgery was 64.4. Patient self-confidence, self-esteem, and satisfaction with the device were assessed using the non-validated Augmentation Phalloplasty Patient Selection and Satisfaction Inventory (APPSSI) questionnaire before surgery and at 6–8 weeks postoperatively. The same test was also used for long-term follow-up, ranging from 2.1–6.3 years after implantation; the mean number of years after implantation is 4 years.

Adverse events including infections and device removal were recorded. Any self-reported changes in ejaculation or a patient's ability to achieve and maintain an erection were also noted.

Statistical Analysis

Changes in anatomic measurements were assessed using a paired *t*-test. Changes in self-esteem and confidence before and after surgery and over long-term follow-up were assessed using both the paired *t*-test and a Bowker test. In addition, counts and percentages of participants showed the frequency and magnitude of any changes in patient-reported scores (eg, 1-point increase in self-confidence 6–8 weeks postoperatively, 2-point increase in self-esteem 6–8 weeks postoperatively). All tests were performed at a 5% level of significance.

RESULTS

Penile Measurements

The Penuma silicone implant increased midshaft girth 56.7% from a preoperative average of 8.5 ± 1.2 cm to a postoperative

Table 2. Flaccid penile circumference (n = 400)

Statistic	Preoperatively	6–8 weeks postoperatively	Change (post-/preoperatively)
Mean (cm)	8.5	13.4	4.8
SD (cm)	1.24	1.87	0.71
Median (cm)	8.5	13.3	5.0
Min (cm)	5	8	4
Max (cm)	12	18	7
P value*			<.001

*Student *t* test comparing within group change.

average of 13.4 ± 1.9 cm ($P < .001$) (Table 2). The size of the glans was unchanged. As has been reported in other studies, measuring the exact length of a flaccid penis proved to be challenging. Flaccid length was found to be dependent on time of day, environment, and time period following surgery. To minimize the possible technical challenges that could adversely affect flaccid measurement, a single researcher was used to take the measurements and followed a strict routine of taking measurements immediately after the patient disrobed for evaluation. The average flaccid length was 9.1 ± 0.7 cm preoperatively and 11.3 ± 0.4 cm ($P < .01$) 3 months after Penuma device implantation.

Patient Self-Confidence, Self-Esteem, and Satisfaction

Self-confidence (defined as very low, low, medium, high, or very high) was measured preoperatively, at 6–8 weeks postoperatively, and long-term, all using the APPSSI survey. Preoperatively, fewer than 2% reported high or very high levels of self-confidence. Postoperatively, at 6–8 weeks, 91.5% reported high or very high levels of self-confidence. On the long-term follow-up questionnaire, which was completed an average of 4 years after implantation, 83.5% of subjects reported high or very high levels of self-confidence. Overall, a 2-category improvement in self-confidence was noted in 83% of patients at 6–8 weeks postoperatively and in 72% patients at long-term follow-up. Self-esteem was measured in similar fashion, and short- and long-term results are similar (2-category improvements in 83% of patients at 6–8 weeks postoperatively and in 72% of patients at long-term follow-up). Satisfaction with the surgical outcome was also assessed via the APPSSI and yielded similar results: 81% of subjects reported high or very high levels of satisfaction on the long-term follow-up questionnaire.

Primary Outcome: Adverse Events

1 objective of this investigation was to explore patient safety following implantation. The most common adverse event reported was the development of seroma. 19 subjects (4.8%) reported a seroma persisting 4–8 weeks postoperatively. 12 (3%) were treated with compressive pressure only and recovered completely in 2–4 weeks. 7 (2%) required aspiration of the seroma in addition to the compressive pressure, and all 7 recovered 3–5 days following the aspiration. Hypertrophic scar formation was reported in 18 patients (4.5%) at the incision site. 10 (3%) required therapy at 3–5 months. They were treated with a systemic enzyme therapy (Scarase; International Surgical Devices, Menlo Park, CA, USA) with or without the local injection of a steroid (Kenalog; Bristol-Myers Squibb, New York, NY, USA). 5 of 10 were resolved 10–12 months after implantation, but the remaining 5 were unresolved at the time of study completion. The other 8 (2%) reported scars late (2–3 years after implantation) and were successfully treated with local steroids (Table 3).

13 of the 400 subjects (3.2%) experienced a wound infection. The infections presented between 5 and 12 months after

Table 3. Adverse events (n = 400)

Adverse events	N (%)	Device removal, total 12 (3.0%)	Device revision, total 4 (1.0%)
Seroma	19 (4.8)		
Scar formation (hypertrophic at incision)	18 (4.5)		
Scar formation (fibrosis of capsular tissue)	14 (3.5)		
Implant infection	9 (2.3)	4 (1.0)	
Implant infection and implant breakage	4 (1.0)	4 (1.0)	
Implant breakage	1 (0.25)	1 (0.25)	
Temporary loss of skin sensitivity/sensation	6 (1.5)		
Detachment/breakage of sutures	6 (1.5)	2 (0.5)	4 (1.0)
Penile skin ulcer (superficial)	5 (1.3)		
Hematoma	4 (1.0)	1 (0.25)	

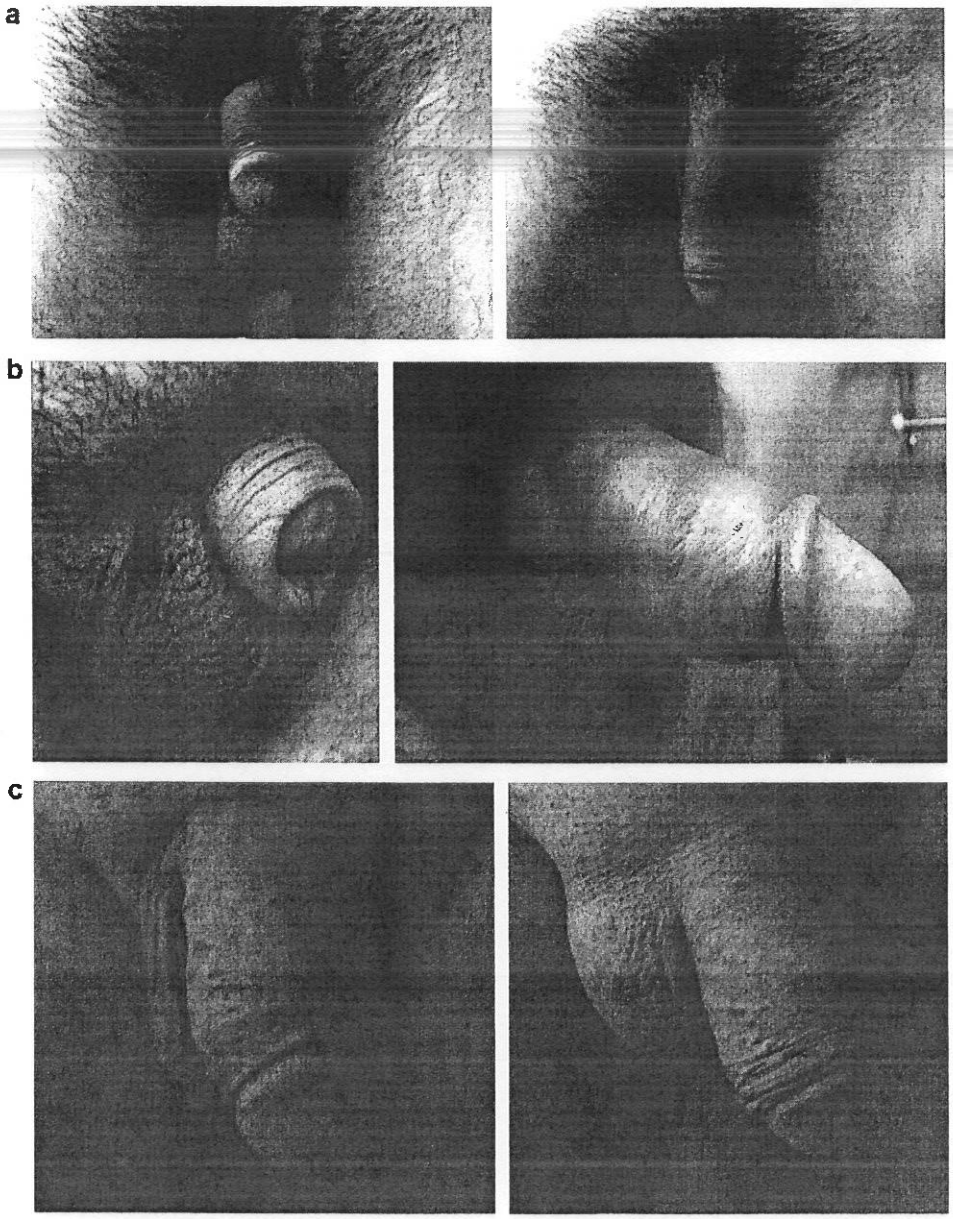

Figure 3. A, Photo of patient penis before and 9 months after implant insertion procedure. B, Photo of patient penis before and 3 months after implant insertion procedure. C, Photo of patient penis before and after implant removal procedure. Figure 3 is available online in color at www.jsm.jsexmed.org.

implantation. 5 subjects were successfully treated with oral antibiotics. The remaining 8 infections (2%) persisted despite therapy and necessitated removal of the device. 4 of these patients (1%) had implant breakage and subsequent implant extrusion/perforation in addition to infection of the device at presentation.

Other adverse events reported include temporary loss of glans sensitivity/sensation 2–3 days postsurgery by 6 subjects (1.5%), superficial ulcerations of penile skin in 5 subjects (1.25%), hematoma in 4 subjects (1%), and suture breakage in 6 subjects with resultant implant malposition (1.5%). Overall, 12 subjects (3%) experienced adverse events necessitating device removal. The causes included implant breakage with implant perforation and infection (1%), implant infection (1%), suture detachment (0.5%), implant breakage (0.25%), and hematoma (0.25%). No thrombosis, implant migration, sepsis, venous or arterial injury, urinary difficulty, or penile curvature was reported. No erectile dysfunction or problems with ejaculation were reported.

DISCUSSION

This study assessed the safety and efficacy of penile cosmetic correction using the Penuma silicone sleeve implant. The procedure was shown to be effective at increasing penile girth and thereby improving the appearance of the pendulous nonerect penis (Figure 3A and B). The authors postulate additional gains in flaccid length were owing to the weight of the implant (42–60 g) stretching loose penile tissue, overcoming prepubic recession and thus creating the appearance of a longer pendulous penis. Moreover, implantation with the Penuma implant resulted in immediate and durable improvements in self-confidence, self-esteem, and satisfaction for most patients.

Alternative treatments available for penile cosmetic correction have been autologous fat transplantation, injection of silicone fluid, or dermal fillers beneath the penile skin. These methods of penile cosmetic surgery have drawbacks and known significant risks or complications.[9–14] Perhaps the most popular cosmetic procedure has been autologous fat injection. Researchers found that only 10% of fat cells are intact in the final result after a postoperative recovery period and that "a significant number of adipocytes are ruptured or reabsorbed."[1] Other risks and complications inherent in existent penile cosmetic procedures include operative procedures of long duration with extended recovery periods, discomfort at the site of graft removal or liposuction, formation of hard lumps and nodules under the penile skin, and penile deformity resulting from partial absorption of fat or AlloDerm.[1,2] Any of these complications may require additional surgical procedures with associated expense and inconvenience to the patient. The Penuma silicone sleeve implant was developed to overcome many of these issues.

The operative procedure is simple and safe. It can be performed by any surgeon familiar with penile surgery. As with any implant surgery, the major risk is device infection. Reported infection rates are comparable to those for other penile implants, including non-inflatable penile prostheses (4.55%).[15,16] An investigation is currently under way to determine whether the addition of an infection retardant coating would lower our infection rate 50% as it did with inflatable penile implants.[17]

12 of the patients necessitated device removal for device breakage, malposition, or wound infection. The operative procedure for the device removal is straightforward. Our preferred procedure consists of reopening the same suprapubic incision that was made for the initial insertion procedure particularly in the clinical setting of device infection. After opening the subcutaneous tissue, the implant is identified. Using the implant as an anchor, the penis is everted, the nonabsorbable sutures at the distal end of the implant are released, and the implant is removed. Any residual mesh that has had tissue ingrowth is removed using sharp dissection. In patients who are not infected, the device can also be removed via a subcoronal incision.

We recommend a manipulation rehabilitation of the penis after removal of the implant. This can be accomplished through a combination of manual/vacuum stretching for approximately 2–3 months following the procedure. Patients did not report any long-term disfigurement of the penis (Figure 3C). It is remarkable that 7 of the 12 patients (58%) who necessitated device removals returned to the clinic after 4–6 months to have the implant reinserted.

A legitimate query to this study is for whom is this procedure indicated? Many of our patients had a penis that would have been considered normal by statistical standards. However, in the patient's mind, his appearance is flawed. Therefore, it is the degree to which the perceived flaw becomes debilitating that may define patients who are or are not appropriate candidates for this procedure. Men who suffer from body dysmorphic disorder often obsess over the size of their penis, and they can be at high risk for postoperative dissatisfaction.[8,18] Prior to electing the surgical therapy, 16% of patients in our study sought counseling. All had failed conservative management with antidepressants, serotonin reuptake inhibitors, and cognitive behavioral therapy.

The larger portion of patients in this study (84%) had not sought counseling help regarding the size of their penis, and most had a penis that was statistically normal before implantation. Nevertheless, these men were quite unhappy with their penile conformation in the flaccid state. It is acknowledged that this implant surgery is not the recommended therapy suggested by any urology guideline. Despite this disclaimer, these patients strongly desired a correction of their perceived deficiency; were briefed on the risks, benefits, possible complications, and alternatives of the procedure; and elected this cosmetic surgery for correction of penile size and consequent personal satisfaction.

The results demonstrate that this therapy offers an immediate and durable increase in penile girth and often an improved perceived length of the flaccid pendulous penis. We emphasize the perceived nature of penile size because flaccid penile length is not the recommended measure of penile length because stretched length is the standard in other studies. Additional desired achievements accompanying this physical change were substantial improvements in self-confidence and self-esteem, and high levels of long-term patient satisfaction.

We believe that the risks associated with this cosmetic surgery are minimal, and more importantly, the possible complications do not create quality of life alterations should the implant require removal for infection, breakage, malposition, or dissatisfaction. Although adverse events may occur, because the implant is subdermal and does not violate the corporal body, the patient is not left with erectile dysfunction, loss of penile length, or diminished sensation. It is notable that 57% of the patients who required implant removal had reinsertion of the device.

There are several limitations of this study. It is retrospective in nature, and the study consents were received from patients retrospectively. The APPSSI questionnaire is not a validated

study. Regretfully, 126 (24%) of the 526 patients during the study time period did not respond to the request for consent and could not be included in the study. This impacts the true rate of complications. Finally, this article chronicles the experience of a single surgeon (J.E.), who happens to be the inventor of the implant. A prospective study with multiple investigators is presently commencing and will mitigate many of these limitations.

CONCLUSION

Penile implantation of a soft silicone device is reasonably safe and works well for penile cosmetic correction, including girth enhancement. Given the high long-term patient satisfaction and the demonstrated durability of the cosmetic correction, the Penuma silicone implant can be offered as a treatment option for the cosmetic correction of the perception that one's penis is smaller than that of other men. Long-term follow-up will be required to ensure implant performance and lasting cosmetic results.

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Conflict of Interest: Dr. James J. Elist is the founder of IMD, Inc, which manufactures the Penuma silicone implant and sponsored this study. Dr. Robert Valenzuela is a paid consultant with IMD, Inc.

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REFERENCES

1. Vardi Y, Harshai Y, Gil T, et al. A critical analysis of penile enhancement procedures for patients with normal penile size: surgical techniques, success, and complications. **Eur Urol 2008;54:1042-1050.**
2. Nabil N, Hosny H, Kadah A, et al. Evaluation of surgical outcome of penile augmentation and lengthening procedures. **Urol Int 2013;90:465-469.**
3. Chevallier D, Haertig A, Faix A, Droupy S. La chirurgie esthétique des organes génitaux masculins [Aesthetic surgery of male genital organs]. **Prog Urol 2013;23:685-695.**
4. Shirvanian V, Lemperle G, Araujo Pinto C, et al. Shortened penis post penile prosthesis implantation treated with subcutaneous soft silicone penile implant: case report. **Int J Impot Res 2013;10:100-104.**
5. Elist JJ, Shirvanian V, Lemperle G. Surgical treatment of penile deformity due to curvature using a subcutaneous soft silicone implant: case report. **Open J Urol 2014;4:91-97.**
6. Kamrava A. Retrospective analysis of the safety and effectiveness of the silicone block in penile surgery; Clinical Investigation Report #IMD-0115; August 29, 2015.
7. U.S. Food and Drug Administration. 510(k) premarket notification. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K042380 (2004); https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K162624 (2017); Accessed June 12, 2018.
8. Veale D, Miles S, Read J, et al. Penile dysmorphic disorder: development of a screening scale. **Arch Sex Behav 2015; 44:2311-2321.**
9. Moullot P, Nguyen PS, Philandrianos C, et al. Hypertrophie de greffon adipocytaire et lipopénosculpture: gestion d'une complication rare [Hypertrophy of fat graft and lipopenosculpture: management of a rare complication]. **Ann Chir Plast Esthet 2014;59:355-359.**
10. Silberstein J, Downs T, Goldstein I. Penile injection with silicone: case report and review of the literature. **J Sex Med 2008;5:2231-2237.**
11. Sasidaran R, Zain MA. Low-grade liquid silicone injections as a penile enhancement procedure: is bigger better? **Urol Ann 2012;4:181-186.**
12. Kwak TI Oh M, Kim JJ, Moon DG. The effects of penile girth enhancement using injectable hyaluronic acid gel filler. **J Sex Med 2011;8:3407-3413.**
13. Alei G, Letizia P, Ricottilli F, et al. Original technique for penile girth augmentation through porcine dermal acellular grafts: results in a 69-patient series. **J Sex Med 2012;9:1945-1953.**
14. Solomon MP, Komlo C, Defrain M. Allograft materials in phalloplasty: a comparative analysis. **Ann Plast Surg 2013; 71:297-299.**
15. Nehra A, Carson CC III, Chapin AK, et al. Long-term infection outcomes of 3-piece antibiotic impregnated penile prostheses used in replacement implant surgery. **J Urol 2012; 188:899-903.**

16. Grewal S, Vetter J, Brandes SB, et al. A population-based analysis of contemporary rates of reoperation for penile prosthesis procedures. **Urology 2014;84:112-116.**
17. Mandava SH, Serefoglu EC, Freier MT, et al. Infection retardant coated inflatable penile prostheses decrease the incidence of infection: a systematic review and meta-analysis. J Urol 2012; **188:1855-1860.**
18. Wang Q, Cao C, Guo R, et al. Avoiding psychological pitfalls in aesthetic medical procedures. **Aesthetic Plast Surg 2016; 40:954-961.**

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EDITORIAL

Wilson's Workshop

Patient selection protocol for the Penuma® implant: suggested preoperative evaluation for aesthetic surgery of the penis

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Penuma is a soft silicone, subcutaneous penile implant indicated for the aesthetic improvement of penile appearance in men who have retractile penis, mild penile indentation deformities, inadequate girth, and other related irregularities. Proper patient selection for any surgical procedure, particularly in aesthetics, is critical to ensure realistic patient expectations and successful outcomes. Patient selection for the Penuma implant involves a comprehensive, rigorous protocol, which, if properly followed, is more likely to result in a satisfied patient.

The spirit of our evaluation could be summed up in Wilson's wise admonition, "never implant a stranger" [1]. Patient selection for the Penuma implant considers the patient's health status, history of the underlying issue(s) for which he seeks help, and the complexity of his particular habitus. Most importantly we seek assessment of his psychological state, particularly perceived body image distortion, including small penis anxiety and penile dysmorphic disorder (PDD), which is a variant of body dysmorphic disorder (BDD) [2] Patients with BDD have consistently been identified as having a higher likelihood of unsatisfactory outcomes from most aesthetic surgeries [3–8].

To help potential patients make an informed decision, detailed information about the Penuma procedure is provided (e.g., possible risks, complications, benefits and alternatives, including no surgery). Patients are then evaluated based on psychological and physical factors through phone and virtual consultations, in-office visits, and mandatory self-reported questionnaires. We review reports from other specialists and may refer the patient to other medical evaluators. Our goal is to ensure all patients are fully informed and physically and mentally qualified. If any evaluation gives pause, the patient is returned for more visits, referred out for third-party evaluation, or informed of his noncandidacy.

Patient physical factors

The physical factors discussed in this section may increase the chance of complications, but do not automatically exclude a patient from undergoing surgery. Rather, they factor into an analysis weighing the risks and benefits of surgery.

The three initial physical factors include:

(1) Previous penile enhancement surgery: Any previous surgery for penile enhancement, such as those involving Polymethyl methacrylate, hyaluronic acid, AlloDerm, dermal graft, and fat injection, is considered an exclusion criterion. Based on our extensive experience, these surgeries often result in excess scar formation, poor skin quality, delayed and prolonged recovery, and increased risk of infection and skin perforation.

(2) Circumcision: Given the girth enhancement following the Penuma insertion, circumcision is required as the foreskin in uncircumcised patients may not retract even in the flaccid state. Patients who are uncircumcised must be circumcised and completely healed before the surgery.

(3) Use of any tobacco products: All patients must refrain from smoking/tobacco use months before and after surgery. Tobacco use is associated with higher risk

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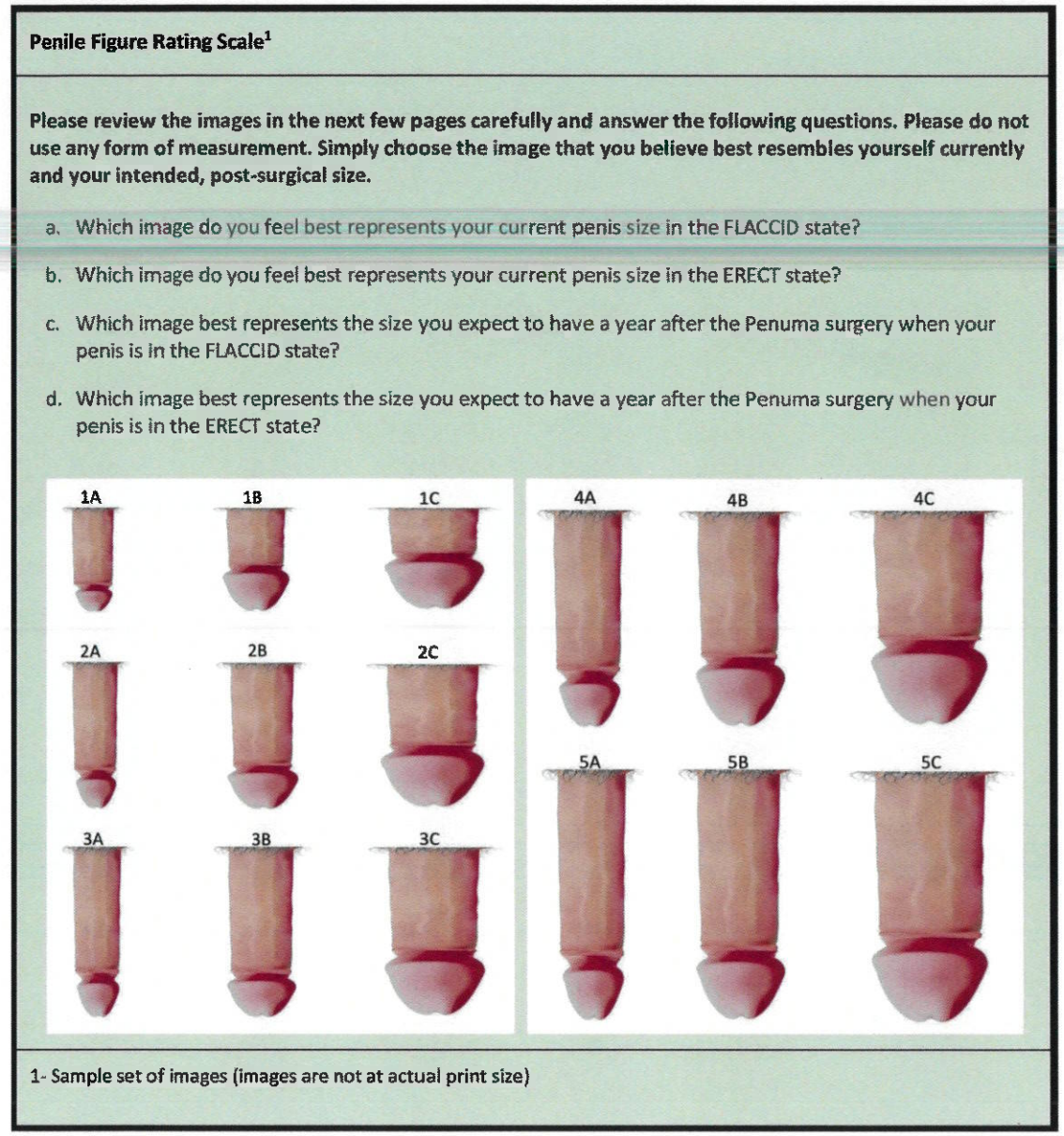

Fig. 1 A figure rating scale from the original Stunkard Figure Rating Scale [14], which helps assess the patient's perception of body image and levels of realistic patient expectation.

anaesthesia, poor wound healing, surgical site infection, excessive scar formation, and significantly higher overall complications [9, 10].

Ancillary physical evaluation

(1) Every candidate is evaluated for comorbid conditions such as uncontrolled diabetes, previous penile aesthetic surgery, and sexually transmitted infection. The patient may be excluded from the surgery, the surgery may be postponed, or the patient may be referred to appropriate specialist(s) for further evaluation and clearance.

(2) A set of medications may increase the likelihood for perioperative complications, such as blood thinning medications, or may interact with postoperative medications, such as Lisinopril that may have serious interactions with trimethoprim/sulfamethoxazole. Accurate and detailed medication history is taken from all patients, and alteration of medication usage may be required.

(3) Drug or alcohol abuse can increase the risk of perioperative complications and may impair the patient's postoperative behaviour. These patients are referred to mental health professionals for evaluation and counselling prior to aesthetic surgery.
(4) Evaluation of genital skin health and quality, skin elasticity, skin lesions, retractile penis, buried penis, and other genitalia abnormalities are conducted through detailed physical examination. Any anatomical abnormality, skin lesion, skin or soft tissue attachments, scar tissue or fibrosis is addressed appropriately and may decrease the likelihood of a patient's candidacy for surgery. Photographs are taken to document preoperative appearance.

Patient psychological factors

Identification of patient objectives and expectations is critical. Candidates are evaluated for psychological appropriateness through:

(1) Several validated questionnaires help evaluate the subject's self-image, distress level, functional impairment, and BDD. These questionnaires include the Cosmetic Procedure Screening Scale for PDD [2], BDD Modification of the Yale-Brown OCS [11], Belief About Penis Size Questionnaire [12], and the Male Genital Self-Image Scale [13]. Based on the clinic's review of the patient's responses, patients may be referred to a mental health professional to assess psychological appropriateness for the surgery.
(2) A figure rating scale (Fig. 1) from the original Stunkard Figure Rating Scale [14] helps assess the patient's perception of body image and levels of realistic patient expectation. Examples of penises varying in girth and length are presented. Patients choose the figures that most closely resemble their (a) current flaccid and erect penis and (b) expected postoperative flaccid and erect penis. The discrepancy between the patient's perceived size in the figures and the actual size measured by physical examination may represent body image misperception. Patients with significant discrepancies (e.g., actual penile measurement of 4″ in length by 4″ in circumference vs. a patient's perception of 2″ by 2″) are referred to a mental health professional for evaluation, clearance or exclusion from surgery. Moreover, should the test reveal unrealistic patient expectations, he may be excluded from surgery if the out of reach expectations cannot be corrected through education.
(3) The risk of patient postsurgical dissatisfaction and the patient's psychological capacity to cope with any potential postoperative scenarios are assessed by the surgeon and other medical staff throughout the selection process. This assessment is based on the previously published mnemonic, "CURSED Patient", which describes patients undergoing penile prosthesis surgery who are at a high risk for dissatisfaction [15, 16].

Conclusion

The process of patient selection for the Penuma surgery, from initial evaluation to a final decision by both the clinic and the patient, can take weeks, and even months. Experience dictates us to never implant a stranger. We get to know the patient, and as Wilson says, "just because he wants one does not mean he gets one" [1].

Compliance with ethical standards

Conflict of interest SKW is consultant for International Medical Devices. LL and RW are participants in a clinical investigation for International Medical Devices. JJE is the inventor of Penuma and owner of International Medical Devices.

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References

1. Wilson SK. The top five surgical things I wish I had known earlier in my career. Lessons learned from prosthetic urology. J Sex Med. 2018;15:809–12.
2. Veale D, Miles S, Read J, Troglia A, Carmona L, Fiorito C, et al. Penile dysmorphic disorder: development of a screening scale. Arch Sex Behav. 2015;44:2311–21. https://doi.org/10.1007/s10508-015-0484-6.
3. Lee K, Guy A, Dale J, Wolke D. Adolescent desire for cosmetic surgery: associations with bullying and psychological functioning. Plast Reconstr Surg. 2017;139:1109–18. https://doi.org/10.1097/PRS.0000000000003252.
4. Bouman TK, Mulkens S, van der Lei B. Cosmetic professionals' awareness of body dysmorphic disorder. Plast Reconstr Surg. 2017;139:336–42. https://doi.org/10.1097/PRS.0000000000002962.
5. Tignol J, Biraben-Gotzamanis L, Martin-Guehl C, Grabot D, Aouizerate B. Body dysmorphic disorder and cosmetic surgery: evolution of 24 subjects with a minimal defect in appearance 5 years after their request for cosmetic surgery. Eur Psychiatry. 2007;22:520–4. https://doi.org/10.1016/j.eurpsy.2007.05.003.
6. Bjornsson AS, Didie ER, Phillips KA. Body dysmorphic disorder. Dialogues Clin Neurosci. 2010;12:221–32.
7. Crerand CE, Phillips KA, Menard W, Fay C. Nonpsychiatric medical treatment of body dysmorphic disorder. Psychosomatics. 2005;46:549–55. https://doi.org/10.1176/appi.psy.46.6.549.
8. Phillips KA, Grant J, Siniscalchi J, Albertini RS. Surgical and nonpsychiatric medical treatment of patients with body

dysmorphic disorder. Psychosomatics. 2001;42:504–10. https://doi.org/10.1176/appi.psy.42.6.504.
9. Rodrigo C. The effects of cigarette smoking on anesthesia. Anesth Prog. 2000;47:143–50.
10. Nolan MB, Martin DP, Thompson R, Schroeder DR, Hanson AC, Warner DO. Association between smoking status, preoperative exhaled carbon monoxide levels, and postoperative surgical site infection in patients undergoing elective surgery. JAMA Surg. 2017;152:476–83. https://doi.org/10.1001/jamasurg.2016.5704.
11. Veale D, Eshkevari E, Read J, Miles S, Troglia A, Phillips R, et al. Beliefs about penis size: validation of a scale for men ashamed about their penis size. J Sex Med. 2014;11:84–92. https://doi.org/10.1111/jsm.12294.
12. Phillips KA, Hollander E, Rasmussen SA, Aronowitz BR, DeCaria C, Goodman WK. A severity rating scale for body dysmorphic disorder: development, reliability, and validity of a modified version of the Yale-Brown Obsessive Compulsive Scale. Psychopharmacol Bull. 1997;33:17–22.
13. Herbenick D, Schick V, Reece M, Sanders SA, Fortenberry JD. The development and validation of the Male Genital Self-Image Scale: results from a nationally representative probability sample of men in the United States. J Sex Med. 2013;10:1516–25. https://doi.org/10.1111/jsm.12124.
14. Stunkard AJ, Sørensen T, Schulsinger F. Use of the Danish Adoption Register for the study of obesity and thinness. Res Publ Assoc Res Nerv Ment Dis. 1983;60:115–20.
15. Ziegelmann M, Köhler TS, Bailey GC, Miest T, Alom M, Trost L. Surgical patient selection and counseling. Transl Androl Urol. 2017;6:609–19. https://doi.org/10.21037/tau.2017.07.19.
16. Trost LW, Baum N, Hellstrom WJ. Managing the difficult penile prosthesis patient. J Sex Med. 2013;10:893–906. https://doi.org/10.1111/jsm.12115.