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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;XX:XXX–XXX.**

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.

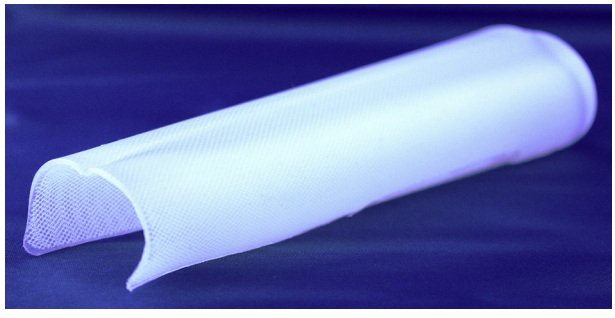

Figure 1. Penuma silicone implant.