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A multi-institutional update on surgical outcomes after penile silicone sleeve implantation

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Abstract

Background: The increasing popularity of the silicone sleeve penile implant has been accompanied by concerns over potential risks and adverse events.

Objectives: To provide multi-institutional data on safety outcomes in patients undergoing silicone sleeve penile implant surgery across high-volume implant surgeons. In addition, we discuss preventative techniques to minimize postoperative complications and the management of these events.

Design and methods: We performed a retrospective analysis of men undergoing penile silicone sleeve implants between November 2020 and November 2022 with four surgeons, each from a separate institution. Perioperative and postoperative adverse events, including unsatisfactory cosmetic outcomes requiring revision, were determined by physician follow-up. Flaccid penile length and girth were measured preoperatively and postoperatively.

Results: A total of 299 male patients underwent silicone sleeve implant surgery, with an average age of 42.5 ± 10.5 years and an average body mass index of 28.5 ± 4.0. The patient cohort exhibited minimal comorbidities, with 5% having hyperlipidemia, 2% being smokers, 2% having cardiovascular disease, and 1% having diabetes. Patients experienced an average increase of 4.1 ± 1.5 cm in their flaccid penile length (a 50% increase) and an average increase of 3.4 ± 1.5 cm in their flaccid girth (a 37% increase) ($p < 0.01$). Complication rates included new-onset postoperative erectile dysfunction (0%), infection (1.3%), seroma (2.0%), and erosion (5.0%). The average follow-up time was 11.6 months. Notably, our rates of infection and seroma were lower than those reported in a previous single-center review, while erosion rates were higher.

Conclusion: This is the largest study to characterize the safety of the penile silicone sleeve implant across multiple institutions. In men who desire cosmetic size augmentation, silicone sleeve implant surgery is associated with significantly increased flaccid penile length and girth. Complications are mainly cosmetic and may be corrected; however, patients should be appropriately counseled on the risk of erosion, which appears to be higher than previously reported.

Plain language summary

Outcomes for penile silicone sleeve surgery

This is the largest study to characterize the safety of the penile silicone sleeve implant across multiple institutions. In men who desire cosmetic penile size improvement, the silicone sleeve implant surgery is associated with significantly increased flaccid penile length and girth. Complications are mainly cosmetic and may be corrected, however, patients should be appropriately counseled on the risk of erosion, which appears to be higher than previously reported.

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Introduction

Penile size – both length and girth – is a common point of fixation and possible anxiety in adult men.[1] This has led to a multi-million-dollar male enhancement industry; however, there are no proven non-surgical methods to augment penile size. The penile silicone sleeve implant, also known as 'Penuma' or 'Himplant', is the first subcutaneous soft silicone sleeve penile implant FDA-cleared for cosmetic augmentation and correction of penile deformities. This implant is intended for men with the perception of a small flaccid penis (both in terms of length and girth) and retractile penis who seek a cosmetic procedure for penile enhancement. Implantation should be avoided in patients with any conditions that increase the risk of poor wound healing (such as uncontrolled diabetes or immunocompromised status), prior penile cosmetic surgery, lack of circumcision, or current tobacco use.[2] There is no hydrophilic coating on the device. After being cleared by the FDA in 2004, penile silicone sleeve implantation began to gain traction in 2018; since then, approximately 5000 devices have been implanted across participating urology providers.

Studies on subjective satisfaction with the penile silicone sleeve implant have proven to be positive with patients and their partners.[3–5] In an initial single surgeon retrospective review of 400 patients who underwent implantation, Elist *et al.* noted postoperatively, 92% of patients reported 'high' or 'very high' levels of self-confidence compared to 2% preoperatively; at 4 years this number was 84%. Furthermore, 81% had high or very high satisfaction at long-term follow-up.[3] These results were confirmed by two additional retrospective studies.[4,5] Wilson and Picazo[4] added that 83% of partners are 'highly' or 'very highly' satisfied. Salkowski *et al.*[5] found that 85% of patients would choose to have the surgery again. Despite the high level of satisfaction with the implant, the increasing popularity has been accompanied by concerns over potential risks and adverse events. These possible postoperative complications include infection or erosion requiring removal of the implant, wound dehiscence, hematoma, seroma, prosthesis displacement, and a flaring deformity of the device proximal to the coronal sulcus.

Due to the small number of surgeons certified in penile silicone sleeve implantation, beginning in 2018, there are a limited number of studies on adverse events.[3–6] Our objective is to provide a review of multi-institutional data on safety and efficacy outcomes in patients undergoing penile silicone sleeve implant surgery among multiple high-volume implant surgeons. In addition, we discuss preventative techniques to minimize postoperative complications and the management of these events.

Materials and methods

Study design

We performed a retrospective analysis of all men undergoing penile silicone sleeve implants between 23 November 2020 and 30 November 2022 with four surgeons, each from a separate geographically diverse institution. This time frame allowed us to capture a median of 1-year follow-up data. Patients were included if they had at least one postoperative follow-up visit. All institutions had programs in place to ensure at least one office visit after surgery; subsequent follow-up was determined on an as-needed basis. Fitness to participate in implant surgery was determined by the guidelines published in Elist *et al.*[2] These are the same criteria used in the study by Siegal *et al.*[6] Exclusion criteria included uncircumcised patients. Uncircumcised patients were offered to undergo circumcision prior to surgery; circumcision was completed at least 3 months prior to the surgery. Those who have had previous penile enhancement surgery such as dermal grafting, fat injections, injection of any material for penile enhancement, or suspensory ligament release were also excluded. Smokers were encouraged to cease all tobacco use 1 month prior to surgery. No

patients had active infections, erectile dysfunction, current or recurrent cancer, or disorders that could lead to poor wound healing.

The surgical technique was standardized as per training by Dr James Elist. However, minor variations may exist depending on surgeon preferences. Specific details of this technique are outlined in Siegal *et al.*[6] For example, in the infrapubic approach, dissection is carried out directly to the fundiform ligament sharply and bluntly. This space may also be reached using the lateral scrotal approach in which an incision is made in the left lateral folds of the scrotum; in this approach, scrotal contents are avoided by remaining close to the penoscrotal junction. The postoperative protocol involved educating the patient on wrapping their penis with a mesh tube wrap that protects the skin without creating pressure, avoiding regular activity for 1 week, masturbation and vigorous physical activity for 4–6 weeks, and intercourse for 6 weeks postoperatively. Patients are instructed to avoid any behavioral or sexual practices that apply prolonged pressure to the penis, particularly constriction created by penile rings.

Data were collected on demographics, body mass index (BMI), and comorbidities. Preoperative measurements included flaccid penile length (from pubis to glans) and flaccid girth (at mid-shaft). Postoperative measurements included flaccid penile length and girth; these were measured before the patient emerged from anesthesia. Perioperative and postoperative adverse events, including unsatisfactory cosmetic outcomes requiring revision, were determined by physician follow-up. Institutional Review Board approval for patient chart review was obtained (IRB-20-01505).

Data analysis

Statistical analysis was performed using SPSS statistical software (IBM SPSS Statistics for Macintosh Version 25.0, Armonk, NY, USA). Demographic information, patient characteristics, adverse outcomes, and changes in penile length and girth were assessed. Changes in anatomic measurements were assessed using a paired *t*-test. Statistical significance was defined as p value <0.05.

Results

A total of 299 male patients underwent penile silicone sleeve implant surgery between 23 November 2020 and 30 November 2022. The median follow-up time was 11.6 [interquartile range (IQR): 6.5–17.9] months. All men had at least one postoperative visit. The patients in this study were from 21 to 68 years old, with a mean age of 42.5 ± 10.5 years. The mean BMI was 28.5 ± 4.0. Our patient population had minimal comorbidities (5% hyperlipidemia, 2% smokers, 2% cardiovascular disease, and 1% diabetes).

Table 1. Preoperative and postoperative penile measurements.

Measurement	Preoperative flaccid (cm)	Postoperative (cm)	% Change (p value)
Length	7.9 ± 2.1	11.8 ± 2.3	50.0 ($p<0.01$)
Girth	9.1 ± 1.1	12.5 ± 1.1	36.9 ($p<0.01$)

Center 1 completed 93 cases, center 2 completed 117, center 3 completed 65, and center 4 completed 24. Two sites reported the number of infrapubic *versus* scrotal approach (center 1 used the infrapubic approach for 13 cases and center 2 used the infrapubic approach for 42 cases); the other two sites used both techniques but did not differentiate in their reporting. This lateral scrotal incision within the scrotal folds was thought to aid in better wound healing and cosmesis. Six penile silicone sleeve implantation cases were completed under local anesthesia only, the remainder were performed under general.

As described in Table 1, the preoperative mean flaccid penile length was 7.9 ± 2.1 cm. The postoperative mean length was 11.7 ± 2.3 cm. Patients added an average of 4.1 ± 1.5 cm to their flaccid penile length (50.0% increase, $p<0.01$). The preoperative mean flaccid penile girth was 9.1 ± 1.1 cm. The postoperative mean girth was 12.5 ± 1.1 cm, adding an average of 3.4 ± 1.5 cm to their flaccid penile girth (36.9% increase) ($p<0.01$). Figure 1 provides side-by-side esthetic results of a patient's erect penis before (silicone model) and after penile silicone sleeve implantation.

Complications rates included infection 1.3%, seroma 2.0%, and erosion 5.0% (Table 2). Seven percent ($n=21$) of patients had Clavien–Dindo grade III b non-cosmetic complications (all resulting in device explant); there were no grade IV or V complications (Table 3). For example, all cases of infection and erosion led to surgical intervention

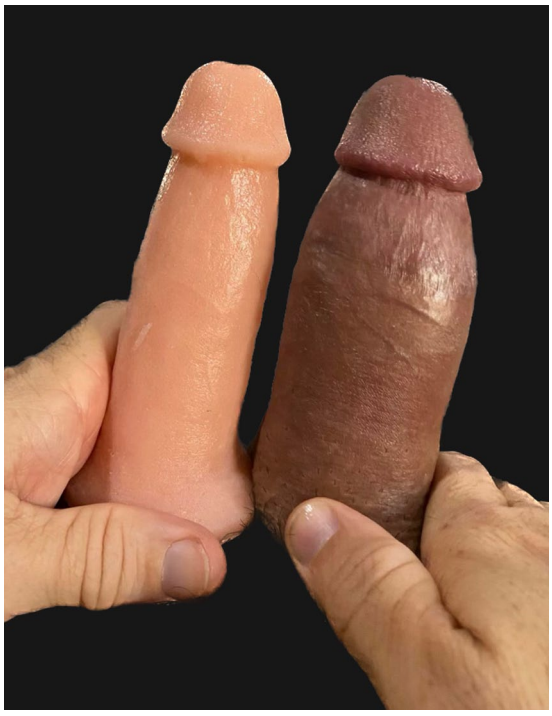

Figure 1. Side-by-side esthetic results of a patient's erect penis before (silicone model) and after penile silicone sleeve implantation.

Table 2. Overall complications ($N = 299$).

Type of adverse event	*N* (%)
Flaring of the penile silicone sleeve proximal to the coronal sulcus *requiring revision*	17 (5.7)
Flaring of the penile silicone sleeve proximal to the coronal sulcus does *not* require revision	16 (5.4)
Erosion	15 (5.0)
Seroma	6 (2.0)
Infection	4 (1.3)
Hypertrophic scar formation	0 (0)
Erectile dysfunction/problems with orgasm or ejaculation	0 (0)

and device explant while 66% of cases of seroma ($n = 4$) were managed conservatively with pressure dressings or simple needle decompression. In the cases of infection, none were associated with skin necrosis. For patients with any type of complication who had approach type reported, 93% ($n = 15$ out of 16) underwent an initial infrapubic *versus* lateral scrotal incision. At a median of 11.6 (IQR: 6.5–17.9) month follow-up, 93% of implants were maintained. No patients who had an explanted silicone sleeve underwent reimplantation, as prior penile surgery is a contraindication to replacing the device. If replacement were attempted, there would be an inability to safely recreate or enter the correct subcutaneous penile compartment due to fibrosis.

Table 3. Clavien–Dindo classification for non-cosmetic complications ($N = 21$).

Grade	*N* (%)
III a: Intervention not under general anesthesia	0 (0)
III b: Intervention under general anesthesia	21 (7.0)
IV: Life-threatening complication	0 (0)
V: Death of a patient	0 (0)

All III b complications resulted in device removal.

Of all the patients that underwent implantation, 5.7% reported unsatisfactory cosmesis that resulted in revision without explantation; all had persistent flaring of the penile silicone sleeve at the coronal sulcus (Table 2, Figure 2). Of these cases, 23.5% ($n = 4$) were revised under local anesthesia only. Based on subjective physician assessment, all revisions had satisfactory outcomes. No patients raised concerns after their revision procedure. No cases of hypertrophic scar formation were noted in our patient population. No *de novo* erectile dysfunction, orgasmic, or ejaculatory dysfunction were reported.

Discussion

This is the largest multi-institutional study evaluating the outcomes of the silicone penile sleeve implant. Our study demonstrates that at the 1-year median length of follow-up in appropriately selected patients, penile silicone sleeve implantation results in significantly increased flaccid penile length (50.0%) and girth (36.9%). In our cohort, preoperative flaccid penile length increased by 4.1 ± 1.5 cm. Likewise, we observed that preoperative flaccid penile girth added 3.4 ± 1.5 cm. There were no complications related to hypertrophic scarring or changes in erectile, orgasmic, or ejaculatory function. Infection occurred at a rate of 1.3%, seroma 2.0%, and erosion 5%. Subcoronal flaring of the

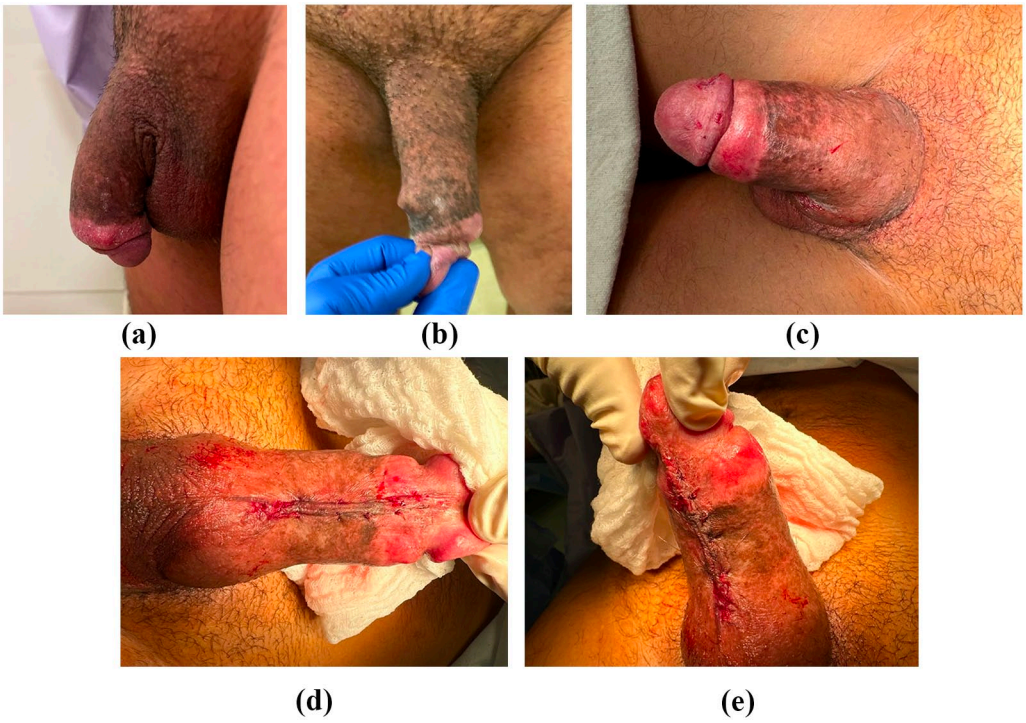

Figure 2. Preoperative imaging shows persistent flaring of the penile silicone sleeve at the coronal sulcus (a and b), and postoperative imaging shows surgically corrected flaring (c–e).

silicone implant was the most frequently encountered complication occurring in over 10% of patients; nevertheless, only about half of these cases required surgical revision (Figure 2). These rates of complication are comparable to experiences in other esthetic procedures, such as breast and gluteal implant augmentation.[7,8]

Our complication rates of scar formation, infection, and seroma were lower and erosion rates were higher than those previously reported in the largest single-center review by Elist *et al.*[3] The Elist *et al.*'s review initially reported the most frequent postoperative complications were seroma (4.8%) and infection (3.3%), with 3% of patients requiring device explant due to adverse events. A multicenter update by Wilson and Picazo[4] noted a similar infection rate (5.0%) as well as suture line dehiscence (4.0%), which we had no reports of. A more recent single surgeon retrospective review of 49 patients by Siegal *et al.*[6] reported lower infection (2.0%) and seroma (0.0%) rates, but higher device and flaring (6.1%) necessitating revision. An even higher incidence of seroma formation (27%) was documented in a review of 70 surgeries completed by two surgeons in the Salkowski *et al.*[5] study; a majority of those seromas occurred with the infrapubic incision approach. In addition, Wilson and Picazo[4] noted that the implant was retained in 90% of patients at 12 (IQR: 6–17) month follow-up. Similarly, we found that 93% of implants were maintained at a 12 (IQR: 6.5–17.9) month follow-up. Comparative results are summarized in Table 4.

Erosion is the most serious complication as it necessitates explantation of the penile silicone sleeve device. This occurred in 5% of cases. The penile shaft skin is inherently thin and its integrity is vital to preventing erosion.[9] Patient selection criteria have been previously described.[2] This protocol includes requiring all patients to have had circumcision at least 3 months prior to implantation, refrain from tobacco use, and exclude patients who have had previous penile enhancement surgery (such as dermal grafting or injections), as significant preexisting sub-dartos scarring requires greater dissection and can therefore impair skin integrity. Throughout the operation, care is taken to protect the penile skin. Techniques for this include (1) careful inspection of the skin for any signs of injury throughout the case and prior to closure, (2) avoidance of any crushing or penetrating retraction of the penile skin, (3) preoperative cancellation of cases in which patients are noted to have defects of the

Table 4. Current literature summary of an adverse event.

Type of adverse event	Siegal (2023) *N* = 299	Elist *et al.* (2018)[3] *N* = 400	Wilson and Picazo (2022)[4] *N* = 234	Siegal *et al.* (2023)[6] *N* = 49	Salkowski *et al.* (2022)[5] *N* = 70
Erosion	5.0%	–	–	4.1%	–
Seroma	2.0%	4.8%	–	0.0%	27%
Infection	1.3%	3.3%	5.0%	2.0%	–
Hypertrophic scar formation	0%	4.5%	–	0.0%	–
Suture line dehiscence	0%	1.5%	4.0%	0.0%	–
Overall explanation rate (any reason)	7.0%	3.0%	10.0%	6.1%	11%

penile skin (i.e. rash), (4) minimal or no use of electrocautery on the penile skin flap, and (5) careful sizing of the implant in relation to glans size, shaft girth, and available skin to minimize pressure on the overlying skin. The penile silicone sleeve comes in multiple sizes, both in the thickness and width of the silicone sleeve (large, XL, XXL) as well as length (regular, extra-long). It should be trimmed to fit the unique anatomy of each patient for optimal cosmesis and to mitigate any possible pressure points that could lead to erosion. Anecdotally, some erosions appear to have been related to early vigorous physical activity, early or aggressive sexual activity, and other behavioral issues that are contradicted by our postoperative protocol.

Additional complications include seroma and infection. Prior to this study, seromas were reported at higher rates than we observed (4.8–27% *versus* 2.0%).[3,5] The reduction in seroma formation may be related to progression in operative techniques such as judicious use of electrocautery and minimization of the dissection area. Our infection rate was also lower than previously reported (1.3% *versus* 3.3–4.0%) and comparable to that of prostheses placed for erectile dysfunction.[3,4,10] All urologists in this study are high-volume prosthetic surgeons who utilize techniques for infection minimization such as meticulous skin preparation, limited contact between the prosthesis and skin, and frequent glove changes. In addition, implants were dipped in an antibiotic solution or 0.05% chlorhexidine gluconate (Irrimax Corporation, Innovation Technologies, Inc., GA, USA) per surgeon preference, which was not done in the initial single-center case series by Elist *et al.*[3] Notably, our comparative reduction in infection rate is comparable with previous penile implant studies that have demonstrated antibacterial solutions and antibacterial coating decreases infection by 50%.[11,12]

Patients with penile silicone sleeve erosions or infections were offered removal of the device. These patients were managed with a postoperative rehabilitation protocol that included daily use of a traction device and PED5 inhibitors. Secondary placement of the penile silicone sleeve is possible only in rare scenarios; this is typically not recommended after removal for infection, as the subcutaneous penile compartment becomes very fibrotic. To maximize beneficial outcomes, the authors of this review recommend referral back to the original provider for any complications found in the community.

The authors of this study hypothesize that the flaring phenomenon may be related to the weight of the silicone implant, penile retraction, or capsular contracture. The penile silicone sleeve is fixed to the subcoronal tunica albuginea distally with a non-absorbable suture; the proximal end is not fixed, but rather placed in a pocket created 2 cm distal to the penile suspensory ligament. Not fixing the implant proximally allows it to adapt without buckling to changes in the size of the penis when erect *versus* flaccid. It also allows it to move freely in all directions without restriction. However, in some individuals, the lateral aspect of the distal implant buckles under the weight of the relatively heavy silicone implant. This results in the appearance of subcoronal flares. Photo examples of these flares as well as the complete

surgical revision technique are provided in Figure 2 and Siegal *et al.*[6] This technique includes carrying an incision, which is proximal to the fossa navicularis, down to the level of the urethra. The implant is then exposed laterally, the protrusion is resected, and a segment is mesh is used to secure the implant. In about half of these cases, the flaring did not require surgical revision as it did not bother the patient, had no tension on the skin, and/or was dealt with by manually manipulating the position of the implant. In those that require surgical revision, it can be performed under local anesthesia alone ($n=4$) or in general and is well tolerated with satisfactory cosmetic outcomes.

Strengths of our study include its multi-institutional design and large cohort, as this allows for analyses of a collective experience. The limitations of this study include the short length of follow-up and its retrospective nature. The longest reported follow-up for penile silicone sleeve surgery in the literature is a single surgeon case series with a mean length of follow-up of 4 years, whereas ours is a median of 1 year. We also did not have a standardized method of follow-up. The cosmetic outcomes of the silicone sleeve implant are immediate thus length of follow-up is less relevant; however, some complications such as erosion and infection could potentially occur beyond the follow-up period reported in this study. Long-term reporting on this cohort and prospective studies with standardized follow-up are necessary in the future. Future studies will also focus on patient-reported outcomes and measures. Lastly, retrospective studies can be inherently affected by selection and recall bias; this was minimized by including all patients from multiple practices and recording measurements at the time of operation.

Conclusion

This is the largest study to characterize the safety of the penile silicone sleeve implant across multiple surgeons. In conclusion, the penile silicone sleeve can be used to significantly increase flaccid penile length and girth in patients who desire cosmetic augmentation or correction of retractile penis. Rates of complications are comparable to experiences in other esthetic procedures. When cosmetic complications occur, corrections may be completed with low risk or under local anesthesia. Nevertheless, patients should be appropriately counseled on the risk of implant erosion, which appears to be higher than previously reported.

Declarations

Ethics approval and consent to participate

The Institutional Review Board of the Mount Sinai School of Medicine approved this study (IRB-20-01505). Informed consent was waived by the Institutional Review Board.

Consent for publication

Both written and verbal informed consent for publication was provided by the participants.

Author contributions

Alexandra R. Siegal: Conceptualization; Data curation; Formal analysis; Writing – original draft.

Kenan E. Celtik: Conceptualization; Data curation; Writing – original draft.

Shirin Razdan: Writing – review & editing.

Michaela Sljivich: Writing – review & editing.

Bryan Kansas: Data curation; Writing – review & editing.

Bhavik Shah: Data curation; Writing – review & editing.

Laurence A. Levine: Data curation; Writing – review & editing.

Robert J. Valenzuela: Conceptualization; Data curation; Methodology; Resources; Supervision; Writing – review & editing.

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

Data are available upon request.

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