

High Surgical Complication Rates after Silicone Implant Use for Improvement of Glans Ridge Appearance

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Background: Construction of the glans is an important aspect of gender-affirming phalloplasty. In these surgeries, the glans ridge is commonly constructed using the Norfolk technique or a similar technique. In cases of glans ridge flattening after creation, we generally recommend a redo/revision glansplasty, which is often curative. However, in situations when the glans ridge flattens again, we developed a silicone glans implant technique in an effort to create a satisfactory and lasting glans ridge.

Methods: We conducted a pilot study of our first 12 glans implant cases. A retrospective chart review and brief, ad-hoc patient survey measured patient demographics, implant status, and patient satisfaction.

Results: A total of 12 patients received a silicone glans implant between November 2017 and February 2020. One patient had the glans implant removed before the survey, and also could not be contacted. Three patients did not respond to the survey. Of the eight patients who responded, only five (5/8, 63%) patients still had the silicone implant at the time of the survey. The average satisfaction score was 3.25 (range 1 = very satisfied and 5 = very dissatisfied). Common complaints cited included dissatisfaction with implant appearance, as well as infection, discomfort, and pain.

Conclusions: Patients and surgeons should be aware of the possibility of a novel silicone implant technique to create a glansplasty in those with failed/flattened previous glansplasty surgery. However, the technique is in development: patient satisfaction remains spotty and complication rates are high, although technical improvements may increase future success rates. (*Plast Reconstr Surg Glob Open* 2022;10:e4433; doi: 10.1097/GOX.0000000000004433; Published online 22 July 2022.)

INTRODUCTION

Most patients receiving phalloplasty surgery undergo a glansplasty to create a glans ridge and recapitulate the appearance of a circumcised phallus. While several techniques have been described, most are variations of the Norfolk technique, in which a nearly circumferential skin flap is folded on itself and affixed with suture to make the glans ridge, and the proximal skin defect is covered by a

split-thickness skin graft to create the sulcus.¹ Despite the frequent use of this technique, one study comparing the Norfolk technique to a revised version of the technique found that, at 12-month follow-up, only 40% of patients who underwent the Norfolk technique and 55% of assessors considered the glans acceptable.² One major complication of the technique is flattening of the coronal ridge.³ At our center, patients with glans ridge flattening are offered redo/revision glansplasty, in which the original incision is reincised and the flap refolded, usually without additional skin graft placement. Because this procedure, too, can periodically fail, we developed a novel procedure that requires a hand-carved, solid silicone implant to be placed under the ridge in an attempt to increase its prominence. This pilot study aimed to determine whether the use of a silicone glans implant is an acceptable treatment for patients with flattening of the glans ridge after standard techniques have failed.

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MATERIALS AND METHODS

After institutional review board approval, a retrospective chart review was conducted on the first 12 phalloplasty patients who had a glans implant placed between November 2017 and February 2020. These patients were identified by “nature of visit”/procedure code (“IMPLANT”) in an administrative database, and the patients who specifically received a glans implant were identified and isolated. Data for a total of 12 female-to-male transgender patients were collected, using the two-step method for gender identity collection. A brief, ad-hoc survey was then created and sent to patients via email (excluding one patient who could not be contacted, but whom we knew previously had the implant removed). The survey asked patients (1) whether the implant was still in place, (2) patient satisfaction with the implant, and (3) any problems that arose. Patients were asked to rate their satisfaction with the implant on a scale of 1–5, with 1 expressing complete satisfaction and 5 expressing complete dissatisfaction. Primary variables studied included type of glansplasty (initial, redo, etc.), time between initial glansplasty and implant placement, age at time of implant placement, and average number of procedures required.

Surgical Technique

The same surgical technique to place the glans implant was implemented at two different surgical centers by three different reconstructive surgeons. An incision is made at the appropriate point at the distal phallus and the distal phallus skin flap developed as the gland ridge, as described in most glansplasty techniques.^{1–4} A 100% medical-grade silicone carving block is used to create a hand-carved glans ridge implant of the correct length, tapered at both ends. It is generally 5×5 mm in maximum thickness and triangular in cross section (Fig. 1). The implant is placed under the distal skin flap and closed with two layers of running absorbable suture (Fig. 2). Care is taken to leave adequate thickness of the skin flap to avoid skin necrosis.

RESULTS

A glans implant was placed in 12 patients, of average age 41 years old (range 29–61). Patients were followed for an average of 717 days (approximately 24 months) (range 364–1163 days). In three patients (3/12, 25%), placement of the glans implant occurred at the time of their initial glansplasty in an attempt to make a satisfactory glans in a novel way without the initial risk of flattening from the Norfolk technique. The insertion of the glans implant was placed during a redo glansplasty for the other nine patients (9/12, 75%). Out of the nine patients who had glans implant placement during a redo glansplasty procedure, six patients (6/9, 67%) had the implant placed after one previous glansplasty. Three of the nine patients (3/9, 33%) had the implant placed after a second revisional glansplasty was performed. Patients required an average of 2.0 total glansplasties. The average time from

Takeaways

Question: Is the use of a silicone glans implant a reasonable alternative for constructing the glans in phalloplasty patients with a previously failed standard glansplasty?

Findings: Out of the 12 patients who received the implant, only two deemed the results very satisfactory or satisfactory (10/12 failure rate, or 83%). Complications included infection, discomfort, and pain.

Meaning: Although this is a novel technique to create a glansplasty in those with failed previous glansplasty surgery, it is currently not recommended: patient satisfaction varies and complication rates are high.

the first failed glansplasty to the implant glansplasty for the eight patients with documented dates (one patient did not have the date of their first glansplasty in the documentation) for previous redo glansplasties was 511 days (approximately 17 months, range 6–31 months). No patients have returned for a revision glansplasty after placement of the glans implant. Of the 12 patients who received an implant, 11 were sent a survey (one patient could not be contacted and already had known removal of the implant). Of these 11 patients, eight patients responded (Table 1). Satisfaction was rated on a scale of 1–5, with 1 being completely satisfied and 5 being completely dissatisfied. The average satisfaction rating was 3.25, which scores between “neither satisfied nor dissatisfied” and “dissatisfied.” Responses ranged from 1 (“very satisfied”) to 5 (“very dissatisfied”). Three patients total had the implant removed from the time of receiving the implant to the time of the survey due to erosion. One of these patients was the patient who was not sent a survey, and the other two patients were patients who had the implant placed at the time of a redo glansplasty. Common complaints from patients included an “unnatural look,” infection, impending implant erosion, concerns for future erosion, and “pain when sitting” (Fig. 3). Of note, one patient responded that they felt personal satisfaction with the glans appearance (“greatly improved the appearance of my glans”); out of the patients who kept the implant in, two patients (2/8, 25%) out of the eight who responded to the survey reported that they were either “very satisfied” or “satisfied” with the implant (Fig. 4). However, a majority of the patients (6/8, 75%) who responded to the survey expressed dissatisfaction with the results, with responses including “neither satisfied nor dissatisfied”, “dissatisfied”, and “very dissatisfied.” Including patients who had the implant removed and those who expressed dissatisfaction and/or indifference (response scores ranging from 3–5), the failure rate of the implant was significant at 83% (10/12).

DISCUSSION

Our institution attempted to create a novel method of glansplasty that prevented the commonly cited complication of the Norfolk technique: glans ridge flattening.



Fig. 1. Creation of the glans implant by hand carving from a silicone carving block.



Fig. 2. After glans implant placement.

However, it can be concluded from the results of this study (ie, failure rate of 83%) that the method of glansplasty using a silicone implant was not acceptably satisfactory to supplant the Norfolk glansplasty technique, nor as a revision procedure to augment a previously created glansplasty that has flattened, and should thus not be recommended for glans ridge improvement in patients with failed Norfolk technique in its current stage of development.

Generally, an aesthetically acceptable glans should have a relatively prominent coronal ridge and a retroglanular

coronal sulcus.^{2,3} Over the past few decades, many procedures and techniques for glans sculpting have been devised in an attempt to create this optimal glans, although most of the procedures are a variant of the Norfolk technique, where a distal skin flap is raised and sewn in place using mattress sutures.

The first to pursue glans sculpting was Munawar⁵ in 1957, when he introduced a primitive form of the Norfolk technique in which a circumferential skin flap was rolled into itself to create a coronal ridge. Puckett and Montie⁶ later developed a technique in which diamond-shaped excisions were used to create a prominent coronal ridge. The Norfolk technique, which builds on Munwar's original method but integrates a skin graft, is currently most popular, due to its ability to create a circumcised appearance of the glans with low complications. Other procedures, such as the Gottlieb design⁷ (to improve pigmentation) and various alternative methods of coronoplasty,^{2,4,8} have been described to optimize the results of the classic Norfolk technique. Still, none yet seem to be provably superior to the base concept of Norfolk: a distal skin ridge folded over with a more proximal skin graft, and a skin graft proximal to this to cover the defect left by the glans creation.

In only two out of 12 (17%) patients was the implant glansplasty fully successful; that is, it did not require removal and was aesthetically satisfactory. In 10 out of 12 patients (83%), including the patient who could be contacted and those who had the implant removed, the implant glansplasty failed. Specific aesthetic and/or functional dissatisfaction centers around inability of the implant to maintain the shape of the glans and the fact that the implant was less soft and malleable than was initially expected by the patient. Additionally, it should be suspected that insertion of a foreign body like the silicone implant, especially due to its structure and texture, especially in an area subject to increased friction and movement, decreased the likelihood of maintaining proper and permanent implantation. To mitigate this irritation from foreign body implantation, there are certain measures that could be practiced going forward. One technical change could be the use of a custom-made silicone implant, individualized to each patient, rather than a hand-carved block created before the surgery. Adjustments in insertion technique may also have a role in decreasing complication rates. One adjustment that may be implemented in the future is pulling the custom silicone band with a long clamp through a subcutaneous pocket of 5 mm width along the corona. Through a 5-mm incision on the bottom, the band could then be pushed upward with the help of the clamp, then grasped on the opposite side and pulled down to connect it to the incision with a nonabsorbable suture. Additional prevention of complications could relate to administration of prophylactic antibiotics into the cavity before insertion of the implant.

In regard to the survey method utilized for this study, the survey used to collect patient-reported outcomes was solely created for research purposes. However, with improvement of the surgical technique surrounding the implant, the survey questions may need to be modified themselves to better measure, objectively and subjectively,

Table 1. Survey Score Responses and Surgical Outcomes in 12 Patients Who Received Glans Implants

Patient	Survey Response	Surgical Outcome
1	NR (no response)	N/A due to lack of survey response
2	4	Implant still in place; pain when sitting, aesthetically inadequate
3	NR (no response)	N/A due to lack of survey response
4	N/A (survey not sent)	Implant removed prior due to infection, implant erosion
5	3	No issues reported; implant still in place
6	2	Concerns for erosion; glans still flat. Implant still in place.
7	NR (no response)	N/A due to lack of survey response
8	5	Breakthrough of implant; implant removed
9	4	No issues reported; implant still in place
10	4	Erosion of implant in the first month; implant removed
11	1	Improved appearance of glans; implant still in place
12	3	No issues reported; implant still in place

results of the implant treatment. Additionally, if the survey continues to be used in the future to record satisfaction among patients receiving the glans implant, care may need to be taken going forward to train the staff in administering the survey in a controlled manner to best acquire accurate patient-reported outcomes.

Although a majority of patients were not adequately satisfied, success in the small minority may create solid ground for pursuing the use of a future, improved glans implant technique. Currently, for patients undergoing phalloplasty, we recommend an initial “Norfolk-type” glansplasty, then a redo/revision glansplasty with or without skin graft if flattening occurs. Only after the revision glansplasty has failed do we offer a third procedure utilizing glans implant, after thorough disclosure of its high failure and complication rate, as well as the high possibility of a mediocre aesthetic result. Ours and others’ future efforts will undoubtedly center around an improved

glans implant technique with fewer complications and better results. Already we have significantly modified the procedure to be less invasive, placing the implant through only a few 1 cm “windows”/incisions around the glans ridge, placing the ridge under a thicker flap of skin to provide better cushioning, and placing a more prominently protruding implant to make up for the fact that lack of significant backing under the implant limits its protrusion.

LIMITATIONS

This pilot study has the limitations of most pilot studies: a small sample size and the use of retrospective chart review. Another limitation is that the operative reports for one of



Fig. 3. Fully healed glans implant in an RFF phalloplasty patient, showing minor improvement but some persistent flattening of the glans ridge. RFF, radial forearm flap.



Fig. 4. Fully healed glans implant in the same patient shown in Figure 2, with some improvement in glans ridge prominence.

the 12 patients did not include the patient's past glansplasty history (we did not have access to the date of their previous glansplasties). An additional limitation is the lack of a true control group for the study. One limitation in the implementation of the study was that an implementation theory was not used to administer the survey, but will be considered in future endeavors. Another limitation lies in the creation and implementation of an ad-hoc survey. A validated survey instrument for evaluation of the glans penis appearance or any glans implant, of course, does not exist, although one study developed the first patient-reported outcome measure for gender-affirming services,⁹ which may be useful in the future to measure treatment effectiveness of the glans implant. The acknowledgment of the limitation of an ad-hoc survey is important, as there is incredible value in using validated surveys to have stronger results and conclusions.^{10,11} In this pilot study, an easily interpretable (by the patient) Likert-style instrument is used. Future studies can include more in-depth patient surveys, third-party evaluation concerning the glans appearance, and specific, validated instruments, should they improbably become available in the near future.

CONCLUSIONS

Although a silicone glans implant theoretically could be used in certain situations based on the patient's desires, a majority of patients who received the implant developed major complications or aesthetic failure to improve the glans ridge to the patients' satisfaction. While glans implant may have a role in patients with two previous failed glansplasties as a last-ditch attempt, it is not currently recommended as a solution for creating a lasting glans ridge with satisfactory prominence. Future efforts to improve the procedure will be necessary to produce improved results, decreased complications, and better patient-perceived outcomes.

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REFERENCES

1. Kalkan S, Purohit R, Djordjevic M. V06-02 glansplasty: the Norfolk technique. *J Urol*. 2020;203(suppl 4):e556.
2. Akhoondinasab MR, Saboury M, Shafaei Y, et al. The comparison of a new durable coronoplasty technique with Norfolk method for glans reconstruction after phalloplasty. *World J Plast Surg*. 2020;9:39–43.
3. Fang RH, Kao YS, Ma S, et al. Glans sculpting in phalloplasty—experiences in female-to-male transsexuals. *Br J Plast Surg*. 1998;51:376–379.
4. Sommeling CE, De Wolf EJ, Salim A, et al. A new technique for coronoplasty in penile reconstruction. *J Sex Med*. 2018;15:920–923.
5. Munawar A. Surgical treatment of the male genitalia. *J Int Coll Surg*. 1957;27:352.
6. Puckett CL, Montie JE. Construction of male genitalia in the transsexual, using a tubed groin flap for the penis and a hydraulic inflation device. *Plast Reconstr Surg*. 1978;61:523–530.
7. Gottlieb LJ, Levine LA. A new design for the radial forearm free-flap phallic construction. *Plast Reconstr Surg*. 1993;92:276–283.
8. Salgado CJ, Licata L, Fuller DA, et al. Glans penis coronoplasty with palmaris longus tendon following total penile reconstruction. *Ann Plast Surg*. 2009;62:690–692.
9. Klassen AF, Kaur M, Johnson N, et al. International phase I study protocol to develop a patient-reported outcome measure for adolescents and adults receiving gender-affirming treatments (the GENDER-Q). *BMJ Open*. 2018;8:e025435.
10. Santesso N, Barbara AM, Kamran R, et al. Conclusions from surveys may not consider important biases: a systematic survey of surveys. *J Clin Epidemiol*. 2020;122:108–114.
11. Ioannidis JP, Greenland S, Hlatky MA, et al. Increasing value and reducing waste in research design, conduct, and analysis. *Lancet*. 2014;383:166–175.