



Complications Following Gender-Affirming Phalloplasty: A NSQIP Review

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Abstract

Keywords ► phalloplasty

complications

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► predictors

Background Gender-affirming phalloplasty has a complication rate as high as 76.5%. This is the first study to determine the predictors of 30-day complications following phalloplasty using a national registry.

Methods The National Surgical Quality Improvement Program database (2012–2021) was queried for transgender men and Current Procedural Terminology codes pertaining to flap or microsurgery procedures to select for single- and first-stage phalloplasty cases. Included were patients with a length of total hospital stay \geq 5 days and operating time > 4 hours to select for primary phalloplasty cases. The primary outcome was incidence of major and minor complications, and the secondary outcome was indication for unplanned reoperation. Bivariate analysis and multivariate logistic regression were performed to determine significant predictors of complications.

Results Of 90 patients, 18 (20.0%) patients developed at least one complication. The most common complication was unplanned reoperation (n = 10, 11.1%) due to hematoma evacuation (n = 3, 30.0% of reoperations, 3.3% of all patients). A total of 43 (47.8%) underwent single-stage phalloplasty, and 47 (52.2%) underwent first-stage phalloplasty. Compared with patients without complications, those with minor complications are more likely to have had single-stage phalloplasty (n = 37 [45.1%], n = 6 [75.0%]; p = 0.145), but the association was not statistically significant. Longer operating time was associated with greater odds of major complications (adjusted odds ratio [aOR] 95% confidence interval [CI] 1.01 [1.002–1.018]). Patients who smoked within 1 year of surgery had 123 times the odds of 30-day minor complications (surgical site infection, urinary tract infection, wound dehiscence, pneumonia) compared with nonsmokers (aOR [CI] 123.3 [1.4– > 100.0]).

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Address for correspondence Fan Liang, MD, Department of Plastic and Reconstructive Surgery, Center for Transgender and Gender Expansive Health, Johns Hopkins Hospital, 600 North Wolfe Street, 21287 Baltimore, MD (e-mail: fliang6@jh.edu). **Conclusion** There were no significant differences in complication rates between single- and first-stage phalloplasties. Patients should be counseled about the overall risk of 30-day complications following phalloplasty. Reducing operating time, smoking cessation, and strict preoperative nicotine testing may assist in mitigating odds of 30-day complications following phalloplasty.

Approximately 0.6% of the U. S. population are identified as transgender and nonbinary (TGNB).¹ Subsequent to relaxed insurance criteria, there has been increasing demand for gender-affirming surgery, including metoidioplasty and phalloplasty.^{2–4} Around 69.2% of phalloplasty procedures are performed for gender-affirming purposes⁵ whereby nascent female genital structures are removed and flaps are used for creation of masculine genitalia. It is most frequently performed for transgender men but can also be applied to patients requiring reconstruction after penile trauma or oncologic resection.^{6,7}

Phalloplasty encompasses the creation of the phallic shaft and penile urethroplasty. As a way to decrease complication rate and improve esthetics, different phalloplasty techniques have been proposed, and the staging of phalloplasty components has been described. Single-stage phalloplasty is a combination of phallic shaft creation, urethral lengthening, glansplasty, perineal reconstruction, vaginectomy, and scrotoplasty.⁸ A multistage or staged phalloplasty separates these components, namely, shaft creation from urethral lengthening, and is performed over the course of several months. There is still a lack of consensus in regard to whether phalloplasty should be staged, the ways by which staging can occur, and the ideal flaps for shaft creation. The most frequently used flap is the radial forearm free flap (RFFF), though other flaps such as the free or pedicled anterolateral thigh (ALT) flap and latissimus dorsi flap have been employed as well.^{7,9–12} Surgical decision-making is contingent on patient goals for surgery such as standing micturition, penetrative intercourse, and donor-site scar placement.

Phalloplasty remains a complex procedure with high complication rates regardless of stage or flap choice.^{7,8,13,14} The most common complications following phalloplasty include urethral fistulas, persistent vaginal cavities, and neourethral strictures, resulting in urinary and sexual dysfunction.^{13,15} Additionally, flap complications can include hematoma, necrosis or wound dehiscence, cellulitis, vascular/arterial thromboses, and infection.¹⁶ Multistage procedures have demonstrated poor urethral and flap-related outcomes, with complication rates of 34 and 10%, respectively.^{17,18} In a large review comparing flap choice in genderaffirming phalloplasty, urethral strictures and fistulas were more common in RFFF, but flap failure rates were higher in the pedicled ALT phalloplasty.⁸ With the high rate of complications across phalloplasty techniques, understanding risk factors for these complications could improve patient outcomes and clinical decision-making.^{8,13,19}

Previous studies have used the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database and shown that older age, body mass index, and longer total operating times to be independent predictors of 30-day postoperative complications following any masculinizing bottom surgery, including hysterectomy.^{20,21} However, the high variability in the type of procedure performed and the decision whether or not to stage phalloplasty were not ascertained. In addition, the analyses did not differentiate between primary phalloplasty for second- or third-stage phalloplasty, metoidioplasty, or revision surgery, making it difficult to draw conclusions for each approach. Herein, we use the ACS NSQIP database to conduct a retrospective study examining predictors of complications following single and staged phalloplasties with phallus creation. Although different stages are performed using different techniques, our cohort was limited to stages encompassing microsurgical phallus creation to homogenize our patient population in terms of procedural risks and complications. We hypothesize that longer operating times will predict postoperative complications. Our findings will help guide surgical planning, informed decision-making, and patient counseling.

Methods

Dataset

This study was reviewed and approved by the Johns Hopkins University Institutional Review Board. We queried the ACS NSQIP from years 2012 to 2021 for transgender men who underwent single- or first-stage phalloplasty. Information in NSQIP is longitudinal data collected by surgical clinical reviewers on patient demographics, comorbidities, surgical characteristics, and postoperative outcomes up to 30 days postoperatively.²²

Inclusion and Exclusion Criteria

Transgender men who underwent single or staged phalloplasty with phallus creation were identified using the flow diagram shown in **~ Fig. 1**. Staged phalloplasty with phallus creation was referred to as "first of a multistage phalloplasty" throughout the text.

The codes used for the selection of our study population are shown in **– Supplementary Table S1**. First, TGNB patients were identified using International Classification of Diseases (ICD)-9 and ICD-10 codes pertaining to gender dysphoria. Second, patients who underwent masculinizing genital surgery were identified using Current Procedural Terminology



Fig. 1 Flowchart of our study population selection process. CPT, Current Procedural Terminology; NSQIP, National Surgical Quality Improvement Program.

(CPT) codes. Third, these patients were grouped according to hysterectomy and phalloplasty. Finally, patients who underwent phalloplasty were stratified according to the stage of phalloplasty. Single- and first-stage phalloplasty cases had CPT codes pertaining to flap surgery or microsurgery. Patients with a length of total hospital stay \geq 5 days and operating time > 4 hours were included in our final study sample to ensure proper patient selection of primary phalloplasty cases. Patients who underwent metoidioplasty or multistage phalloplasty beyond the first stage did not have CPT codes pertaining to flap surgery or microsurgery and were excluded from our analysis. The reason for the exclusion of the latter group of patients is that the CPT codes included in NSQIP do not allow the differentiation between metoidioplasty, second-, and third-stage phalloplasty cases. Furthermore, we wanted to homogenize our patient population in terms of procedural risks and complications.

Patient Stratification

Patients who were included in our final analysis were stratified based on stage of phalloplasty (single- and first-stage phalloplasties) using different combinations of principal and concurrent CPT codes (**>Supplementary Table S1**). Single-stage phalloplasty cases had CPT codes pertaining to

flap surgery or microsurgery, urethroplasty, and vaginectomy simultaneously. First-stage phalloplasty cases had CPT codes pertaining to flap surgery or microsurgery without urethroplasty. First-stage phalloplasty cases were further stratified according to concurrent procedures: first stage with flap alone; first stage with flap, scrotoplasty, and vaginectomy; first stage with flap and scrotoplasty, without vaginectomy; and first stage with flap and vaginectomy, without scrotoplasty.

Outcomes and Covariates

The primary outcome of our study was the incidence of at least one major and at least one minor complications within 30 days following single- and first-stage phalloplasties. Major complications analyzed were myocardial infarction, cardiac arrest requiring cardiopulmonary resuscitation, stroke, acute renal failure, pulmonary embolism, deep venous thrombosis, sepsis, septic shock, bleeding requiring transfusion, unplanned intubation, unplanned reoperation, unplanned readmission within 30 days, and prolonged hospital stay beyond 30 days postoperatively. Minor complications analyzed were urinary tract infection, surgical site infection (SSI), pneumonia, and wound disruption without reoperation.

The secondary outcome of the study was the indication for unplanned reoperation, a major complication, within 30 days of phalloplasty. As defined by NSQIP, unplanned reoperation is "a return to the operating room that was not planned at the time of the primary procedure."²²

Patients who developed at least one major complication versus those who did not and patients who developed at least one minor complication versus those who did not were compared based on the following demographics, comorbidities, and surgical characteristics. These included flap type (latissimus dorsi flap; ALT flap), phalloplasty stage (single stage; first of multistage), and phalloplasty concurrent procedures (single stage; first stage with flap alone; first stage with flap and scrotoplasty, without vaginectomy; first stage with flap and vaginectomy, without scrotoplasty). Complete definitions of variables collected by NSQIP can be found in the User Guide for the ACS NSQIP Procedure Targeted Participant Use Data File.²²

Statistical Analysis

We performed univariate exploratory analysis for all patients, patients who developed any major complication, and patients who developed any minor complication. Normally distributed numerical data were reported using the mean \pm standard deviation, while nonnormally distributed numerical data were reported using the median and interquartile range (IQR).

We performed bivariate analysis to compare demographics, comorbidities, and surgical characteristics between patients who developed at least one major complication versus those who did not and patients who developed at least one minor complication versus those who did not. Continuous variables were compared between patient cohorts using the independent *t*-test, while categorical variables were compared using the chi-square and Fisher's exact tests. Bivariate and multivariate logistic regression were performed using variables that had a p < 0.2 on bivariate analysis to predict significant predictors of major and minor complications following single- and first-stage phalloplasties. The crude odds ratio (cOR), adjusted odds ratio (aOR), and 95% confidence interval (CI) were used to measure the strength of association in the logistic regression models. The discriminatory capacity and the calibration of each regression model were assessed using the area under the receiver operating characteristic curve and the Hosmer-Lemeshow's test, respectively.²³ Statistical analysis was performed using IBM SPSS Statistics 28.²⁴ The p < 0.05 was considered statistically significant.

Results

Demographics and Surgical Characteristics

A total of 90 patients were included in our final analysis (**-Fig. 1**). **-Table 1** shows patient demographics, comorbidities, and surgical characteristics of our study population.

The median (IQR) age was 30.0 (24.0-39.0) years. Of 90 patients, 43 (47.8%) underwent single-stage phalloplasty, and 47/90 (52.2%) underwent first-stage phalloplasty. When further stratified by concurrent procedure, 41/90 (45.6%) patients underwent first-stage phalloplasty with flap alone, 2/90 (2.2%) underwent first-stage phalloplasty with flap and scrotoplasty, without vaginectomy, and 4/90 (4.4%) underwent first-stage phalloplasty with flap and vaginectomy, without scrotoplasty (>Table 1). The median (IQR) operating time for overall phalloplasty procedures, regardless of staging, was 379 (315-465) minutes. Compared with single-stage phalloplasty procedures which had a median (IQR) operating time of 419 (368-489) minutes, firststage phalloplasty procedures had significantly shorter median (IQR) operating time of 323 (284-398) minutes (p < 0.001).

A total of 18 (20.0%) patients developed any complication: the majority (n = 16/18 (88.9%) developed a major complication, and 8/18 (44.4%) developed a minor complication. Patient demographics, comorbidities, and surgical characteristics were compared between patients who developed any major complication versus those who did not and patients who developed any minor complication versus those who did not in **-Table 1**. Patients who developed any major complication within 30 days of phalloplasty were significantly more likely to have longer operating times (median [IQR] 483 [383–562], 365 [301–442] minutes; p = 0.011) and length of total hospital stay (median [IQR] 7 [6–9], 6 [5–7] days; p = 0.035) compared with patients who did not develop any major complication postoperatively. Patients who developed any minor complication within 30 days of phalloplasty were significantly more likely to have had longer operating times (median [IQR] 435 [367-557], 374 [312-459] minutes; p = 0.047) and to have smoked within a year of surgery (n = 4/8 [50.0%], n = 5/82 [6.1%]; p = 0.003). Compared with patients without complications, those with minor complications are more likely to have had single-stage phalloplasty

(n = 37 [45.1%], n = 6 [75.0%]; p = 0.145), but the association was not statistically significant (**>Table 1**).

Postoperative Complications

Fig. 2 shows the frequency (%) of major and minor complications within 30 days of phalloplasty in our study population.

The most common major complication was unplanned reoperation (n = 10/90 [11.1%]). The most common minor complication was SSI (n = 5/90 [5.6%]) followed by wound disruption (n = 3/90 [3.3%]).

Predictors of Complications

- Table 2 shows the bivariate and multivariate logistic regression evaluating predictors of major and minor complications.

On both bivariate and multivariate logistic regression, longer total operating time (cOR [95% CI] 1.011 [1.004– 1.018], aOR [95% CI] 1.01 [1.002–1.018]) was significantly associated with greater odds of major complications within 30 days of phalloplasty. Smoking was associated with greater odds of 30-day minor complications on bivariate (cOR [95% CI] 15.4 [2.9–80.6]) and multivariate logistic regression (aOR [95% CI] 123.3 [1.4– > 100]). Compared with single-stage phalloplasty, first-stage phalloplasty was associated with decreased odds of minor complications on bivariate (cOR [95% CI] 0.3 [0.1–1.4]) and multivariate logistic regression (aOR [95% CI] 0.13 [0.0–4.3]), but the association was not statistically significant (**\leftarrowTable 2**).

Indications for Unplanned Reoperation

The frequency (%) of indications for unplanned reoperation is shown in \blacktriangleright Fig. 3.

Within 30 days of phalloplasty, hematoma evacuation was the most common indication for unplanned reoperation (n = 3, 30.0% of unplanned reoperations, 3.3% of all patients). Only one patient $(n = 1/90 \ [1.1\%])$ experienced flap failure following phalloplasty.

Discussion

Phalloplasty represents a collection of procedures to construct esthetic and functional masculine genitalia.^{25,26} Although patients' surgical goals vary, patients often desire a physiologic-appearing and functional masculine genitalia characterized by an average-sized phallus and a pouch-like scrotum, in addition to the ability to void while standing and achieve penetrative intercourse.^{25,27} It requires surgical expertise to manage the high rate of postoperative complications.^{14–16,28,29} Existing evidence does not confirm a significant difference in complication rates with either flap choice or phalloplasty staging. Understanding other risk factors for these complications could improve patient outcomes and clinical decision-making.^{8,13,14,19} Hence, we conducted a retrospective study using the ACS NSQIP database to examine predictors of complications following single- and first-stage phalloplasties.

We found a 20% overall 30-day complication rate following phalloplasty regardless of phalloplasty staging or flap

Age, median (QR), $\sqrt{100}$ 30.0 (24.0-39.0) 28.5 (20.5-44.5) 30.5 (24.8-38.3) 0.829 BMI, median (QR), $kg/m2$ 25.8 (23.5-30.4) 24.1 (22.3-30.6) 26.2 (23.7-30.4) 0.498 Total operating time, median (QR), min 379 (315-465) 883 (383-562) 365 (301-442) 0.011 Length of total hospital stay, median (QR), d 6 (5-7) 7 (6-9) 6 (5-7) 0.035 Diabetes mellitus 2 (2.2) 1 (6.3) 1 (1.4) 0.035 Urrent smoker (within 1 y preoperatively) 9 (10.0) 3 (18.8) 6 (8.1) 0.147 ASA classification 1 2 (2.2) 1 (6.3) 1 (1.4) 0.147 ASA classification 1 1 (6.3) 1 (1.4) 0.147 ASA classification 1 2 (2.2) 3 (18.8) 0.147 Phalloplasty categories 1 2 (2.2) 3 (18.8) 0.147 Intervision 1 0 (37.5) 2 (6.7) 0.147 Phalloplasty categories 1 1 (6.3) 1 (1.4) 0.205 Intervision 2 (2	riable	Overall $(n=90)$	Any major complication (n = 16)	No major complication (n = 74)	<i>p</i> -Value	Any minor complication $(n=8)$	No minor complication (n = 82)	<i>p</i> -Value	
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	ll, median (IQR), kg/m2		25.8 (23.5-30.4)	24.1 (22.3–30.6)	26.2 (23.7-30.4)	0.498	23.3 (21.3–29.0)	26.0 (23.6–30.6)	0.189
	tal operating time, media	an (IQR), min	379 (315–465)	483 (383–562)	365 (301-442)	0.011	435 (367–557)	374 (312–459)	0.047
	ath of total hospital stay	y, median (IQR), d	6 (5–7)	7 (6-9)	6 (5-7)	0.035	8 (6–10)	6 (5–7)	0.152
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Phalloplasty stage Single stage 43 (47.8) 8 (50.0) 35 (47.3) 1.000 First of multistage 47 (52.2) 8 (50.0) 39 (52.7) 1.000 Flap type- Latissimus dorsi 1 (1.1) 0 (0.0) 1 (1.4) 0.504	<u> </u>	First stage: flap + vaginectomy/ vulvectomy without scrotoplasty	4 (4.4)	0.0) 0	4 (5.4)		0 (0.0)	4 (4.9)	
First of multistage 47 (52.2) 8 (50.0) 39 (52.7) 50 (50.0) Flap type- Latissimus dorsi 1 (1.1) 0 (0.0) 1 (1.4) 0.504	alloplasty stage	Single stage	43 (47.8)	8 (50.0)	35 (47.3)	1.000	6 (75.0)	37 (45.1)	0.145
Flap type- Latissimus dorsi 1 (1.1) 0 (0.0) 1 (1.4) 0.504 Antroletorial thick 23 / 35 EV 4 / 35 OV 20 / 35 OV 0.504	1	First of multistage	47 (52.2)	8 (50.0)	39 (52.7)		2 (25.0)	45 (54.9)	
	p type-	Latissimus dorsi	1 (1.1)	0 (0.0)	1 (1.4)	0.504	0 (0.0)	1 (1.2)	1.000
	L	Anterolateral thigh	32 (35.6)	4 (25.0)	28 (37.8)		3 (37.5)	29 (35.4)	
Not reported 57 (63.3) 12 (75.0) 45 (60.8)	L	Not reported	57 (63.3)	12 (75.0)	45 (60.8)		5 (62.5)	52 (63.4)	

Notes: Frequency data are reported as n (%). Percentages shown were calculated as a fraction of respective groups (n = 90 for all patients; n = 16 for patients with any major complication; n = 74 for patients with no minor complication). Significant p-values < 0.05 are in bold.

Table 1 Patient demographics, comorbidities, and surgical characteristics of all patients, patients who developed any major complication compared with those who did not, and patients



Fig. 2 Frequency (%) of postoperative major and minor complications following phalloplasty. SSI, surgical site infection; UTI, urinary tract infection.

Table 2 Bivariate and multivariate regression evaluating patient demographics and surgical characteristics associated with majorand minor complications following single- and first-stage phalloplasties

Demographics and surgical characteristics		Major complications		Minor complications	
		cOR (CI)	aOR (CI)	cOR (CI)	aOR (CI)
Age		-	-	1.071 (1.001–1.146)	1.01 (0.91–1.11)
BMI		-	-	0.89 (0.75–1.06)	0.84 (0.64–1.11)
Total operating time		1.011 (1.004–1.018)	1.01 (1.002–1.018)	1.004 (1.000–1.008)	1.007 (0.997–1.016)
Length of total hospital stay		1.572 (1.126–2.194)	1.275 (0.837–1.943)	1.56 (1.08–2.26)	1.2 (0.6–2.3)
Diabetes mellitus		-	-	11.57 (0.65->100)	>100 (0.0->100)
Smoking		2.6 (0.6–11.8)	2.6 (0.4–17.0)	15.4 (2.9–80.6)	>100 (1.4->100)
Hypertension		3.2 (0.7–15.0)	1.06 (0.1–8.3)	1.5 (0.2–14.2)	0.01 (0.0–5.3)
ASA class	ASA class II	-	-	3.2 (0.4–27.7)	22.1 (0.2->100)
	ASA class III	-	-	28.0 (0.9->100)	>100 (0.7->100)
First stage		-	-	0.3 (0.1–1.4)	0.13 (0.0–4.3)
C-statistic		-	0.8	-	0.95
Hosmer–Lemeshow		-	0.828	-	0.99

Abbreviations: aOR, adjusted odds ratio; CI, 95% confidence interval; cOR, crude odds ratio; C-statistic, concordance statistic or area under the receiver operating characteristic curve.

Note: Significant 95% CIs are in bold.

used. In our study population, 18% of patients developed a major complication and 9% developed a minor complication within 30 days of single- or first-stage phalloplasty. Longer operating time and smoking were significantly associated with greater odds of major and minor complications, respectively. The association with smoking is unsurprising given the effect of nicotine on impedance of wound healing.³⁰ Additionally, smoking causes vasoconstriction where resultant ischemia may contribute to stricture formation down the line.^{31,32} This highlights the importance of patient counseling on immediate postoperative complications and the importance of nicotine testing in the preoperative management of patients interested in phalloplasty.

Complications occur in up to 50 to 76% of phalloplasty procedures and can be grouped into flap-related and urethral complications.^{7,13,14} A pedicled or free flap is used to reconstruct the shaft of the neophallus.⁷ In transgender men, the overall flap complication rate has been reported to be around 10.8%, with risks including flap failure, flap necrosis, and donor-site morbidity.^{7,13,26} Urethral lengthening is the component of phalloplasty that aims to allow standing micturition via the neourethra. However, with a urethral complication rate of 39.4%, even patients of experienced surgeons are regularly afflicted by urologic dysfunction.^{13,26,29,33} A recent review by Wang et al found high rates of urethral complications in gender-affirming phalloplasty: 31% of patients developed



Fig. 3 Frequency (%) of indications for unplanned reoperation following phalloplasty.

fistulas and 25% developed strictures.¹⁴ A major limitation of our study is the inability to capture urethral complications that develop beyond 30 days of surgery due to the 30-day window of NSQIP.

Our results also demonstrate that longer operating time is significantly associated with greater odds of major complications following phalloplasty. This is congruent with a study by Chaya et al who similarly utilized the ACS NSQIP database and found that total operating time was an independent predictor of 30-day postoperative complications following masculinizing bottom surgery.²⁰ However, the study analyzed all patients with masculinizing bottom surgery together, including hysterectomy, metoidioplasty, and other genital reconstruction procedures. Longer operating time was also identified as a predictor of complications for microsurgical flap reconstruction.^{20,34–37} In a previous study by Wong et al on 639 patients who underwent microsurgical free flap reconstruction, those with longer operating times were twice as likely to develop flap failure.³⁶ In our study population, only one patient experienced flap failure following phalloplasty. The association between longer operating time and postoperative complications here may be attributed to surgeon expertise and the steep learning curve associated with phalloplasty.

Urethral lengthening at the time of shaft reconstruction defines the single-stage phalloplasty.^{38–40} Since longer operating time was associated with greater odds of major complications in our study population, it was expected that single-stage phalloplasty (which encompasses various phalloplasty procedures and necessitates longer operating time) would be associated with greater odds of major complications compared with first-stage phalloplasty. However, there was no significant difference in the incidence of major or minor complications between the two staging techniques, despite a trend toward lower complications in firststage phalloplasty procedures. The complications reported in NSQIP within 30 days, however, do not encompass the urethral complications that might arise following phalloplasty and which are a major concern for genderaffirming surgeons and their patients. This might explain the relatively lower incidence of postoperative complications in our study population. Hence, according to our results, staging does not significantly impact the odds of 30-day complications following phalloplasty, but this remains unclear for complications arising beyond that 30-day window. These complications were studied by Huayllani et al who demonstrated significantly higher complication rates in two-stage phalloplasties.¹⁸ Similar findings were reported by Remington et al when specifically comparing staging of urethroplasty, where staged procedures had higher rates of flap and urethral complications.¹³ Although there is a paucity of evidence to support staging versus no staging in phalloplasty, our results show no significant difference in 30-day complications, including flap failure causing unplanned reoperation, between the two techniques.

ALT was the most common flap type used in our study population, though in half of the patients, flap choice was not specified. We hypothesize that the unspecified flaps in NSQIP used in phalloplasty procedure are actually RFFF. The RFFF is typically the most common flap choice, which has been reported to be used in 75% of 1,731 procedures, due to the reliable vascular pedicle, pliability of the flap, well-established functional and esthetic satisfaction, and preservation of erogenous and tactile sensation.^{14,17,33} Challenges for this flap include donor-site morbidity, atrophy of the neophallus, requirement of prosthesis, and requirement for microsurgical technique and equipment.^{7,9,16,41} The ALT flap offers improved color match, an easily concealed donor-site scar, preserves sensation, and can be a pedicled or free flap.^{7,17} Although the pedicled ALT does not require extensive microsurgical techniques, the bulky subcutaneous layer might explain the significantly higher overall urethral complication rate of 32.8% versus a 24.2% in the RFFF cohort.¹⁷

Future research is needed to demonstrate the effect of perioperative variations to improve efficiency for phalloplasty specifically. Advancing technology, increasing number of experienced surgeons operating, and preoperative imaging to guide flap design may help drive efficiency.^{34,36,41,42} Preoperative counseling should include the risk of 30-day postoperative complications and urge the importance of smoking cessation to reduce minor complications. Adherence to smoking cessation recommendations can be further confirmed with urine cotinine testing the morning of surgery.⁴³

This study has several limitations associated with a retrospective review of a national database. The nongranularity of the CPT codes for TGNB procedures and genderaffirming phalloplasty in the NSQIP database precluded precise construction of our cohort or differentiating single from double tube phalloplasty. Additionally, NSQIP does not report sexual orientation and gender identity demographic information. To mitigate this limitation, we followed robust inclusion/exclusion criteria using proxy identifiers of ICD-9 and ICD-10 codes of gender dysphoria for proper patient selection and a meticulous search of principal and concurrent CPT codes for proper patient categorization into masculinizing genital surgery and phalloplasty stages. The urethral lengthening component of phalloplasty is a large driver of long-term complications, for example, urethral strictures, which might not be captured within the 30 days window of NSQIP. Other outcomes not captured by NSQIP include sexual functioning, late wound complications, and reoperations occurring after 30 days. There was heterogeneity of the included patients by concomitant surgery, unknown type of primary flap, and unknown data about surgical team makeup or experience. However, care teams will still benefit from the knowledge of risk factors of immediate phalloplasty complications in the immediate postoperative period thus improving preoperative patient counseling. While the institutions participating in the ACS NSQIP data collection are not necessarily a representative sample of the population undergoing phalloplasty, the multi-institutional nature of the database increases generalizability of the results. Our study is the first to use the NSQIP database to analyze surgical outcomes following phalloplasty and categorize patients according to phalloplasty stages. Previous research regrading phalloplasty outcomes had not used the NSQIP data or briefly discussed the procedure in aggregate with other surgeries.

Conclusion

Multistage phalloplasty may be associated with lower 30day complications. Reducing operating times, smoking cessation, and strict preoperative nicotine testing may assist in mitigating odds of complications following phalloplasty. Future prospective studies with long-term follow-up are needed to properly assess the predictors of complications following phalloplasty.

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- The 68th Annual Meeting of the Plastic Surgery Research Council, April 13–16, 2023, Cleveland, Ohio.

- The 101st Annual Meeting of the American Association of Plastic Surgeons, April 29–May 2, 2023, Chicago, Illinois.

Conflict of Interest

None declared.

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References

- 1 Herman JL, Flores AR, O'Neill KK. How Many Adults and Youth Identify as Transgender in the United States? The Williams Institute; Los Angeles, California; 2016
- 2 Canner JK, Harfouch O, Kodadek LM, et al. Temporal trends in gender-affirming surgery among transgender patients in the United States. JAMA Surg 2018;153(07):609–616
- 3 Lane M, Ives GC, Sluiter EC, et al. Trends in gender-affirming surgery in insured patients in the United States. Plast Reconstr Surg Glob Open 2018;6(04):e1738
- 4 Tran BNN, Epstein S, Singhal D, Lee BT, Tobias AM, Ganor O. Gender affirmation surgery: a synopsis using American College of Surgeons National Surgery Quality Improvement Program and National Inpatient Sample Databases. Ann Plast Surg 2018;80(4, suppl 4):S229–S235
- 5 Sarıkaya S, Ralph DJ. Mystery and realities of phalloplasty: a systematic review. Turk J Urol 2017;43(03):229–236
- 6 Frey JD, Poudrier G, Chiodo MV, Hazen A. A systematic review of metoidioplasty and radial forearm flap phalloplasty in female-tomale transgender genital reconstruction: is the "ideal" neophallus an achievable goal? Plast Reconstr Surg Glob Open 2016;4(12):e1131
- 7 Morrison SD, Shakir A, Vyas KS, Kirby J, Crane CN, Lee GK. Phalloplasty: a review of techniques and outcomes. Plast Reconstr Surg 2016;138(03):594–615
- 8 Wu CA, Jolly D, Boskey ER, et al. A systematic review of staging and flap choice in gender-affirming phalloplasty. Journal of Reconstructive Microsurgery Open. 2022;07(02):e13–e26
- 9 Falcone M, Preto M, Timpano M, et al. The surgical outcomes of radial artery forearm free-flap phalloplasty in transgender men: single-centre experience and systematic review of the current literature. Int J Impot Res 2020;33(07):737–745
- 10 Garaffa G, Christopher NA, Ralph DJ. Total phallic reconstruction in female-to-male transsexuals. Eur Urol 2010;57(04):715–722
- 11 Lee GK, Lim AF, Bird ET. A novel single-flap technique for total penile reconstruction: the pedicled anterolateral thigh flap. Plast Reconstr Surg 2009;124(01):163–166
- 12 Orandi A. Phalloplasty and saphenous vein urethroplasty. Invest Urol 1965;3(02):111–116
- 13 Remington AC, Morrison SD, Massie JP, et al. Outcomes after phalloplasty: do transgender patients and multiple urethral procedures carry a higher rate of complication? Plast Reconstr Surg 2018;141(02):220e–229e
- 14 Wang AMQ, Tsang V, Mankowski P, Demsey D, Kavanagh A, Genoway K. Outcomes following gender affirming phalloplasty: a systematic review and meta-analysis. Sex Med Rev 2022;10(04):499–512
- 15 Schardein JN, Zhao LC, Nikolavsky D. Management of vaginoplasty and phalloplasty complications. Urol Clin North Am 2019;46(04): 605–618
- 16 Leriche A, Timsit MO, Morel-Journel N, Bouillot A, Dembele D, Ruffion A. Long-term outcome of forearm flee-flap phalloplasty in the treatment of transsexualism. BJU Int 2008;101(10):1297–1300
- 17 Ascha M, Massie JP, Morrison SD, Crane CN, Chen ML. Outcomes of single stage phalloplasty by pedicled anterolateral thigh flap

versus radial forearm free flap in gender confirming surgery. J Urol 2018;199(01):206-214

- 18 Huayllani MT, Boczar D, Saleem HY, et al. Single versus two-stage phalloplasty for transgender female-to-male patients: a systematic review of the literature. Ann Transl Med 2021;9(07):608
- 19 Frey JD, Poudrier G, Thomson JE, Hazen A. A historical review of gender-affirming medicine: focus on genital reconstruction surgery. J Sex Med 2017;14(08):991–1002
- 20 Chaya BF, Berman ZP, Boczar D, et al. Gender affirmation surgery on the rise: analysis of trends and outcomes. LGBT Health 2022;9 (08):582–588
- 21 Scott KB, Thuman J, Jain A, Gregoski M, Herrera F. Genderaffirming surgeries: a national surgical quality improvement project database analyzing demographics, trends, and outcomes. Ann Plast Surg 2022;88(5, suppl 5):S501–S507
- 22 User Guide for the 2021 ACS NSQIP Procedure Targeted Participant Use Data File (PUF): ACS NSQIP; 2022. Accessed April 2, 2023, at: https://www.facs.org/media/tjcd1biq/nsqip_puf_userguide_2021_ 20221102120632.pdf
- 23 Cook NR. Statistical evaluation of prognostic versus diagnostic models: beyond the ROC curve. Clin Chem 2008;54(01):17–23
- 24 IBM SPSS Statistics 28 Brief Guide. Accessed April 2, 2023, at: https://www.ibm.com/support/pages/node/6442933
- 25 Hage JJ, De Graaf FH. Addressing the ideal requirements by free flap phalloplasty: some reflections on refinements of technique. Microsurgery 1993;14(09):592–598
- 26 Heston AL, Esmonde NO, Dugi DD III, Berli JU. Phalloplasty: techniques and outcomes. Transl Androl Urol 2019;8(03):254–265
- 27 Chen ML, Safa B. Single-stage phalloplasty. Urol Clin North Am 2019;46(04):567–580
- 28 Medina CA, Fein LA, Salgado CJ. Total vaginectomy and urethral lengthening at time of neourethral prelamination in transgender men. Int Urogynecol J Pelvic Floor Dysfunct 2018;29(10):1463–1468
- 29 Santucci RA. Urethral complications after transgender phalloplasty: strategies to treat them and minimize their occurrence. Clin Anat 2018;31(02):187–190
- 30 Chan LK, Withey S, Butler PE. Smoking and wound healing problems in reduction mammaplasty: is the introduction of urine nicotine testing justified? Ann Plast Surg 2006;56(02): 111–115

- 31 Massie JP, Morrison SD, Wilson SC, Crane CN, Chen ML. Phalloplasty with urethral lengthening: addition of a vascularized bulbospongiosus flap from vaginectomy reduces postoperative urethral complications. Plast Reconstr Surg 2017;140(04):551e–558e
- 32 Nikolavsky D, Hughes M, Zhao LC. Urologic complications after phalloplasty or metoidioplasty. Clin Plast Surg 2018;45(03): 425–435
- 33 Fang RH, Lin JT, Ma S. Phalloplasty for female transsexuals with sensate free forearm flap. Microsurgery 1994;15(05):349–352
- 34 Gösseringer N, Mani M, Cali-Cassi L, Papadopoulou A, Rodriguez-Lorenzo A. Benefits of two or more senior microsurgeons operating simultaneously in microsurgical breast reconstruction: experience in a Swedish medical center. Microsurgery 2017;37(05):416–420
- 35 Studinger RM, Bradford MM, Jackson IT. Microsurgical training: is it adequate for the operating room? Eur J Plast Surg 2005;28(02): 91–93
- 36 Wong AK, Joanna Nguyen T, Peric M, et al. Analysis of risk factors associated with microvascular free flap failure using a multiinstitutional database. Microsurgery 2015;35(01):6–12
- 37 Hassan B, Abou Koura A, Makarem A, et al. Predictors of surgical site infection following reconstructive flap surgery: a multiinstitutional analysis of 37,177 patients. Front Surg 2023; 10:1080143
- 38 Chang TS, Hwang WY. Forearm flap in one-stage reconstruction of the penis. Plast Reconstr Surg 1984;74(02):251–258
- 39 Gottlieb LJ, Levine LA. A new design for the radial forearm freeflap phallic construction. Plast Reconstr Surg 1993;92(02):276– -283, discussion 284
- 40 Song R, Gao Y, Song Y, Yu Y, Song Y. The forearm flap. Clin Plast Surg 1982;9(01):21–26
- 41 Blaschke E, Bales GT, Thomas S. Postoperative imaging of phalloplasties and their complications. AJR Am J Roentgenol 2014;203 (02):323–328
- 42 Sinove Y, Kyriopoulos E, Ceulemans P, Houtmeyers P, Hoebeke P, Monstrey S. Preoperative planning of a pedicled anterolateral thigh (ALT) flap for penile reconstruction with the multidetector CT scan. Handchir Mikrochir Plast Chir 2013;45(04):217–222
- 43 Hart A, Rainer WG, Taunton MJ, Mabry TM, Berry DJ, Abdel MP. Cotinine testing improves smoking cessation before total joint arthroplasty. J Arthroplasty 2019;34(7S):S148–S151