Predictors of Patient Satisfaction and Postoperative Complications in Penile Inversion Vaginoplasty

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Background: Penile inversion vaginoplasty is the current gold standard procedure for male-to-female transgender patients seeking gender-confirming genital surgery. Although complication data have been reported extensively in the literature, studies on patient-reported outcomes are sparse. This study aimed to report both postoperative complications and patient-reported outcomes from the largest cohort in the United States to date to undergo penile inversion vaginoplasty. Ultimately, the authors hoped to identify the predictors of postoperative complications and patient satisfaction.

Methods: A retrospective chart review of a single surgeon's experience with penile inversion vaginoplasty was performed from July of 2014 to June of 2016. Patient demographic data, postoperative complications, and patient-reported outcome data were collected. Data were correlated by binary logistic regression to determine predictors of postoperative complications and patient satisfaction.

Results: A total of 117 patients underwent penile inversion vaginoplasty. The most common complications were granulation tissue (26 percent), intravaginal scarring (20 percent), and prolonged pain (20 percent). Overwhelmingly, patients reported "feeling positively about their genitals" (94 percent) and "would do this operation again" (94 percent). Seventy-one percent of patients reported resolution of their gender dysphoria. The top predictors of patient dissatisfaction were intravaginal scarring, prolonged pain, excessive external scarring, loss of sensation, and hematoma/excessive bleeding.

Conclusions: This is the largest study of penile inversion vaginoplasty in the United States to report on both postoperative complications and patient-reported outcomes. Despite moderate complication risk, patient satisfaction remains very high after penile inversion vaginoplasty, with the majority of patients reporting improvement of their gender dysphoria. (*Plast. Reconstr. Surg.* 141: 911e, 2018.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, III.

Penile inversion vaginoplasty is the most common genital surgical procedure for male-to-female transgender gender-confirming surgery.[1,2] Regardless of surgical technique, gender-confirming surgery has been shown to have a profound psychosocial benefit for transgender patients.[3–7] With suicide rates as high as 40 percent in the general transgender population,[8] gender-confirming surgery is increasingly recognized as

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not only a cosmetic procedure, but as a therapeutic intervention and a medical necessity. With growing societal acceptance, gender-confirming surgery will continue to mature as a field. It is therefore imperative to understand and establish best practice techniques for this patient population.

Although there have been various reports of postoperative complications in penile inversion vaginoplasty,[2,9–17] studies on patient-reported outcomes of this technique are sparse.[18–20] Patient-reported outcomes help link the expectations and perceptions of the provider and the patient to offer a complete understanding of the outcomes after any surgical procedure. Complication or physiologic data alone do not translate to effective outcomes research. Only by understanding the overall satisfaction and outcomes as experienced from the patient perspective can best practice techniques be developed. Patient-reported outcomes are increasingly reported in the male-to-female transgender literature and recognized as a requisite outcome metric.[19–23] This study aimed to add to this growing body of literature and report both postoperative complications and patient-reported outcomes from the largest cohort to date in the United States to undergo penile inversion vaginoplasty. Ultimately, the study intended to determine the correlation between complications and patient-reported outcomes in an effort to identify specific predictors of patient satisfaction to help guide both provider and patient expectations.

PATIENTS AND METHODS

Patient Selection and Data Collection

A retrospective chart review of a single surgeon's experience with penile inversion vaginoplasty was performed. All patients operated on by the senior author (T.S.) between July of 2014 and June of 2016 who received penile inversion vaginoplasty were included in the study. Patient demographic data and all postoperative complications were recorded. The study was performed in a retrospective manner, with no use of identifiable personal information from patients, and with data and surveys collected in an anonymous fashion. A private institutional review board firm was used for review and approval.

Penile Inversion Vaginoplasty

Procedures were all performed under general anesthesia with the patient in lithotomy position. A kite-shaped flap including the perineum and scrotal skin was marked (Fig. 1, *above*, *left*). The scrotal skin was then removed as a full-thickness skin graft. High ligation orchiectomy was then carried out with silk ties and Bovie electrocautery transection (Fig. 1, *above*, *right*).

The base of the penis was dissected and the bulbospongiosus muscle was removed from the underlying urethra. After sharp division of the central tendon, dissection of the vaginal canal was aided with a lighted retractor in the prerectal space between the urethra and the rectum (Fig. 1, *center*, *left*). Careful dissection was performed with blunt, sharp, and low-setting electrocautery, using a rectal dilator and Foley catheter to guide dissection until a depth of 13 to 15 cm was achieved.

The penile shaft was dissected from underlying erectile tissue in a plane above the tunica albuginea to avoid the neurovascular bundle within the Buck fascia. The urethra was transected midshaft, and the proximal urethra was dissected from the corpora cavernosa until the crus of the corpora was reached. A Satinsky clamp was placed at the base of the remaining penis, and longitudinal incisions were made in the tunica albuginea to free the neurovascular bundle that supplies the glans from underlying erectile tissue. The ventral penis was then transected at the level of the Satinsky clamp and discarded. The corpora cavernosa stumps were then closed. At this point, the penile skin, proximal urethra, and glans with associated neurovascular bundle were separated (Fig. 1, *center*, *right*).

The neoclitoris was then designed from the glans using a zigzag or M-shaped pattern with removal of excess glans tissue (Fig. 1, *below*). The neoclitoris was sutured to the corpora cavernosa stump, which is typically located on the same transverse plane as the adductor tendon, below the pubic symphysis. The tunica albuginea and neurovascular bundle were folded and sutured onto the mons.

The proximal urethra was incised on the ventral aspect to splay it open and prepare for the creation of the new urethra and inner aspects of the labia minora. A midline dorsal incision approximately 1.5 cm in length was made, through which the neoclitoris was introduced and inset (Fig. 2, *above*, *left*). The clitoral hood was fashioned from 1 to 2 cm of excess urethra that extends beyond the superior aspect of the neoclitoris.

After hemostasis was ensured in the neovaginal cavity, a silicone dilator was placed in the degloved penile skin. Defatted and depilated scrotal skin was then grafted as a full-thickness skin graft to the distal aspect of the inverted penile skin to add

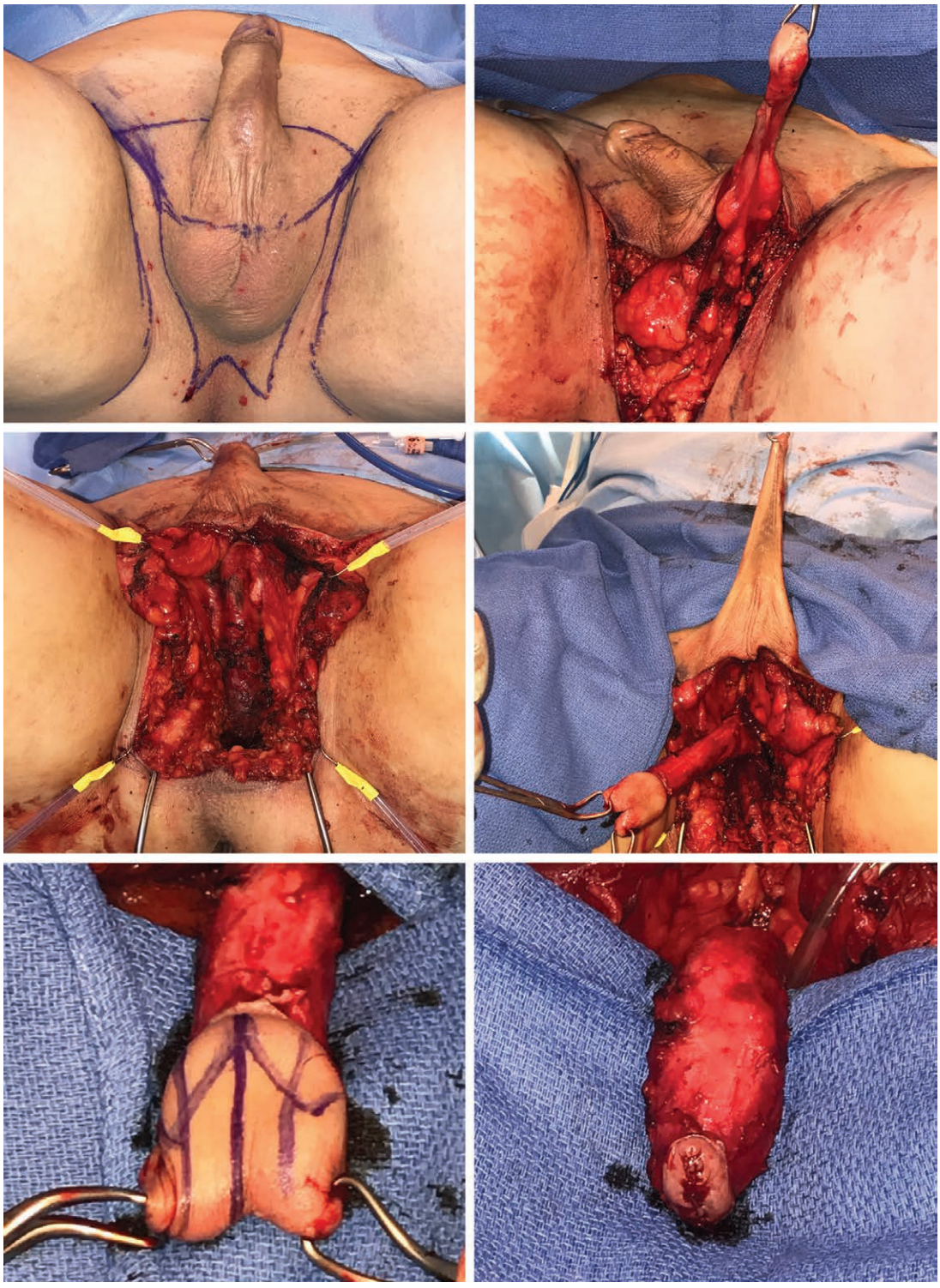

Fig. 1. Penile inversion vaginoplasty. (*Above*, *left*) Intraoperative markings. (*Above*, *right*) Scrotal skin removed as a full-thickness skin graft with high ligation orchiectomy. (*Center*, *left*) Dissection of prerectal space between the urethra and rectum. (*Center*, *right*) The glans with associated neurovascular bundle separated from the penile skin. (*Below*, *left*) Markings for neoclitoris on the glans. (*Below*, *right*) Removal of excess glans tissue.

to vaginal vault length (Fig. 2, *above*, *right*). The stented penile and scrotal skin was then inserted into the vaginal canal, and a bolster was placed within the neovagina (Fig. 2, *center*, *left*). A 3-cm vertical slit was created on the base of the inverted penile skin to allow for insetting of the neoclitoris,

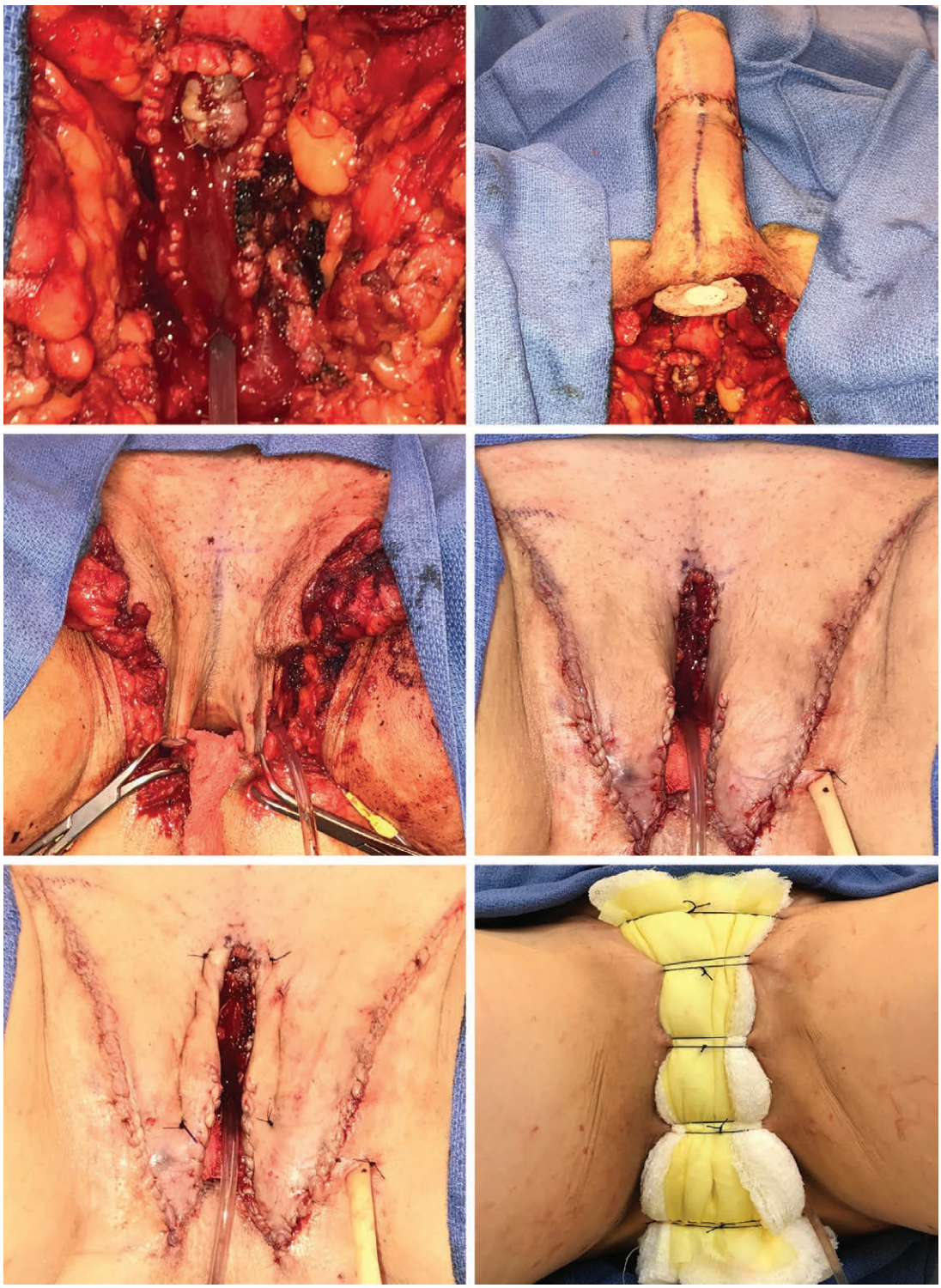

Fig. 2. Penile inversion vaginoplasty (continued). (*Above*, *left*) Neoclitoris inset. (*Above*, *right*) Scrotal skin grafted to the distal aspect of penile skin to add to vaginal vault length. (*Center*, *left*) Penile and scrotal skin inserted into the neovaginal canal. (*Center*, *right*) Skin closure with placement of a Penrose drain. (*Below*, *left*) Imbrication of labia minora. (*Below*, *right*) Surgical bolster in place.

Fig. 3. Surgical outcome of penile inversion vaginoplasty 1 year postoperatively.

neourethra, and labia minora, and the labia majora incisions were subsequently closed after placement of a Penrose drain (Fig. 2, *center*, *right*). The labia minora were then imbricated to create anterior projection (Fig. 2, *below*, *left*).

A bolster was sutured in place over the surgical site (Fig. 2, *below*, *right*). Patients were placed on bedrest for the first 24 hours and began ambulating on postoperative day 1. The bolster, vaginal packing, and Foley were removed at 1 week postoperatively, at which time patients began vaginal dilation. For the first 3 months, patients dilated three times daily, for 10 minutes each time. The dilation regimen then decreased to twice daily from months 3 to 6, once daily from months 6 to 9, and every other day from months 9 and beyond. Every 3 months, patients progressively increased the size of the dilator until 9 months postoperatively, when they reached the largest dilator. Once patients engaged in penetrative sexual intercourse two or three times per week, dilation was no longer required. Final surgical outcome at 1 year is shown in Figure 3.

Patient-Reported Outcomes Collection

An online 20-question survey was sent to all 117 patients who underwent penile inversion vaginoplasty. Surveys were administered to all patients in December of 2016. Patients were sent weekly reminders to complete the online survey for 6 weeks total. The survey was adapted from the Female Genital Self-Image Scale, a seven-question survey validated in nontransgender women.[24] The adapted version included in this study and individual questions can be viewed in the Results (i.e., Table 4) and was partially used previously in transgender women who underwent intestinal vaginoplasty.[23] Answers to this questionnaire were coded in binary as either "yes" or "no."

Data and Statistical Analysis

To identify significant predictors of postoperative complications and patient satisfaction, univariate binary logistic regression was performed on all variables. Patient demographics and comorbidities were correlated to postoperative complications in this fashion. In addition, patient demographics and complications were correlated to patient-reported outcomes. Significantly identified variables from univariate analysis were then adjusted for follow-up time using multivariable binary logistic regression for each outcome. Results were reported as an odds ratio. A Bonferroni correction was used to account for multiple comparisons. Statistical significance was held at $p < 0.05$.

RESULTS

Patient Demographics

A total of 117 patients underwent penile inversion vaginoplasty performed by a single surgeon at our center (Table 1). The average age at the time of surgery was 38 years (range, 16 to 78 years), and the mean follow-up time was 21 months (range, 13 to 34 months). The average body mass index was 25.5 kg/m^2 (range, 18 to 42 kg/m^2), and the average duration of hormone therapy before vaginoplasty was 5.7 years (range, 1 to 40 years). The majority of patients were employed (72 percent) and had at least a collegiate level of education (58 percent), with 30 percent of patients having a graduate degree. Thirty-five percent of patients had attempted suicide at some point in their life, and 35 percent and 25 percent of patients reported a history of physical and sexual abuse, respectively. The most prevalent patient comorbidities included a history of tobacco use (15 percent), a history of drug use (13 percent), hypertension (11 percent), diabetes (7 percent), and human immunodeficiency virus infection (7 percent). Other patient comorbidities are listed in Table 1.

Postoperative Complications

Overall, a total of 82 patients (70 percent) experienced some form of postoperative complication (Table 2). Experiencing a complication was not significantly associated with undergoing surgery earlier in the senior surgeon's career (OR, 0.96; $p = 0.24$). The most common minor postoperative complications were granulation tissue (26 percent),

Table 1. Patient Demographics

Characteristic	No. (%)
Total no. of patients	117
Highest level of education*	
High school	12 (12)
College	56 (58)
Graduate school	29 (30)
History of mental health disease	
Sexual abuse†	20 (25)
Physical abuse‡	28 (35)
Suicide attempt§	29 (35)
Employed‖	77 (72)
In long-term relationship¶	47 (42)
Comorbidities	73 (62)
Diabetes	8 (7)
HIV	8 (7)
Liver disease/hepatitis	7 (6)
Hypertension	13 (11)
Heart disease	4 (3)
Pulmonary disease	7 (6)
History of tobacco use	18 (15)
History of drug use	15 (13)
History of cancer	3 (3)
History of bleeding disorder	4 (3)
History of PE, DVT, clotting disorder	2 (2)
Age, yr	
Average	38.4
Range	16–78
Length of follow-up, mo	
Average	21.1
Range	13–34
BMI, kg/m^2	
Average	25.5
Range	18–42
Length of time on hormones, yr	
Average	5.7
Range	1–40

HIV, human immunodeficiency virus; PE, pulmonary embolism; DVT, deep venous thrombosis; BMI, body mass index.
*Ninety-seven patients with available data.
†Seventy-nine patients with available data.
‡Eighty patients with available data.
§Eighty-two patients with available data.
‖One hundred seven patients with available data.
¶One hundred eleven patients with available data.

Table 2. Complications after Penile Inversion Vaginoplasty

	No. (%)
Total no. of patients	117
Total complications	82 (70)
Minor complications	
Granulation tissue	30 (26)
Intravaginal scarring	24 (20)
Prolonged pain	22 (19)
Urinary issues (incontinence, disrupted stream)	18 (15)
Prolonged swelling	16 (14)
Excessive vaginal drainage	15 (13)
Excessive external scarring	11 (9)
Urinary retention requiring catheter placement	10 (9)
Introital stenosis	8 (7)
Anorgasmia	8 (7)
Pain with sex	8 (5)
Hypersensitivity	1 (1)
Major complications	
Necrosis requiring dressing changes	20 (17)
Hematoma/excessive bleeding	12 (10)
Urinary tract infection	8 (7)
Emergent reoperation	7 (6)
Complete vaginal stenosis	5 (4)
Loss of sensation	4 (3)
Need for transfusion	3 (3)
Infection	3 (3)
Inpatient psychiatric care required postoperatively	3 (3)
Rectovaginal fistula	2 (2)
Prolapse	2 (2)
Intraoperative urethral injury	0 (0)
Intraoperative rectal injury	0 (0)
Urethral stenosis	0 (0)
Reoperation	58 (50)
Request for revision	37 (32)

intravaginal scarring (20 percent), and prolonged pain (20 percent). The most common major postoperative complications were necrosis (primarily along the inferior wound edge, which is the point of most tension) requiring dressing changes (17 percent), hematoma/excessive bleeding (10 percent), and urinary tract infections (7 percent). Only seven patients (6 percent) required emergent reoperation. However, a total of 36 patients (31 percent) ultimately requested revision surgery for aesthetic refinements, and 56 patients (48 percent) underwent some form of reoperation. A full list of postoperative complications can be found in Table 2.

Predictors of Postoperative Complications

On binary logistic regression analysis, significant predictors of postoperative complications were identified and adjusted for follow-up time (Table 3). A history of a bleeding disorder was associated with having the most postoperative complications, including the need for transfusion (OR, 15.5; $p = 0.026$), urinary tract infection (OR, 17.2; $p = 0.019$), and hematoma/excessive bleeding (OR, 9.4; $p = 0.019$). Hypertension was significantly correlated to the postoperative complications of the need for transfusion (OR, 17.1; $p = 0.026$) and granulation tissue (OR, 4.3; $p = 0.017$). All significant predictors of postoperative complications are listed in Table 3.

Patient-Reported Outcomes

Patient-reported outcomes were collected from 66 patients who underwent vaginoplasty (56 percent response rate) by an online questionnaire (Table 4). (**See Table, Supplemental Digital Content 1**, which shows demographic data of respondents and nonrespondents, ***http://links.lww.com/PRS/C792***.) In general, respondents were more likely to be employed and to have a lower body mass index than nonrespondents. Otherwise, the groups were well matched. Survey respondents reported on 20 indicators of patient

Table 3. Significant Predictors of Postoperative Complications in Vaginoplasty Adjusted for Length of Follow-Up

Postoperative Complication	Predictor	OR	*p*
Minor complications			
Granulation tissue	Diabetes	5.4	0.027
	HTN	4.3	0.017
	BMI	1.1	0.014
Prolonged swelling	History of drug use	3.9	0.033
Anorgasmia	Increased education level	34.2	0.007*
Major complications			
Necrosis requiring dressing changes	Pulmonary disease	8.2	0.015
	Diabetes	5.7	0.022
Hematoma/excessive bleeding	History of bleeding disorder	9.4	0.035
Urinary tract infection	History of bleeding disorder	17.2	0.019
Need for transfusion	HTN	17.1	0.026
	History of bleeding disorder	15.5	0.049
Inpatient psychiatric care required postoperatively	HTN	17.6	0.024
	History of bleeding disorder	16.4	0.043
	Heart disease	14.6	0.047
Prolapse	BMI	1.2	0.039

HTN, hypertension; BMI, body mass index.
*Significant after adjusting for 22 multiple comparisons ($p < 0.023$).

Table 4. Patient-Reported Outcomes after Penile Inversion Vaginoplasty*

	Percentage of Respondents Answering "Yes"
1. "I feel positively about my genitals."	94
2. "I would do this operation again."	94
3. "I am happier now after my operation than before my operation."	94
4. "I feel comfortable letting a health care provider examine my genitals."	93
5. "I would recommend this operation to a friend."	91
6. "I am not embarrassed about my genitals."	88
7. "I am able to get sexually aroused."	88
8. "I am satisfied with the appearance of my genitals."	79
9. "I would feel comfortable letting a sexual partner look at my genitals."	80
10. "I think my genitals smell fine."	86
11. "I think my genitals work the way they are supposed to work."	83
12. "My sexual partners are satisfied with my genitals."	83
13. "I am satisfied with the sexual function of my vagina."	75
14. "I have achieved more than two dots on the dilator."	72
15. "My orgasm is better now compared to before my operation."	72
16. "My dysphoria is resolved."	71
17. "I was able to achieve orgasm within 6 months of operation."	67
18. "I am satisfied with the depth of my vagina."	60
19. "I am engaging in penetrative sexual intercourse weekly."	57
20. "I am engaging in penetrative sexual intercourse more than twice a week."	36

*66 respondents (56% response rate).

satisfaction, with satisfaction ranging from 36 percent in the lowest indicator to 94 percent in the highest indicator. Overall, patient satisfaction was over 50 percent in 19 of the total 20 indicators. Overwhelmingly, patients reported "feeling positively about their genitals" (94 percent) and "would do this operation again" (94 percent). In addition, 94 percent of respondents indicated "they are happier now after their operation than before their operation." The majority of respondents (71 percent) indicated "resolution of their gender dysphoria." Orgasm was achieved within 6 months of operation by 67 percent of respondents, and 57 percent of respondents indicated having penetrative sexual intercourse on a weekly basis. The full patient questionnaire and response rates are listed in Table 4.

Predictors of Patient Satisfaction

Multivariable binary logistic regression was used to identify significant predictors of patient satisfaction adjusted for follow-up time at survey administration (Table 5). A subgroup analysis was performed for patients with greater than 1-year follow-up at survey administration. (**See Table, Supplemental Digital Content 2**, which shows significant predictors of patient satisfaction/dissatisfaction adjusted for length of follow-up at the

Table 5. Significant Predictors of Patient Satisfaction/Dissatisfaction Adjusted for Length of Follow-Up at the Time of Survey Administration*

Patient-Reported Outcome	Predictor	OR	*p*
1. "I feel positively about my genitals."	Infection	0.001	0.039
	Loss of sensation	0.040	0.012
	Intravaginal scarring	0.038	0.010
	Excessive external scarring	0.073	0.022
	Hematoma/excessive bleeding	0.077	0.026
2. "I would do this operation again."	Loss of sensation	0.015	0.009
	Excessive external scarring	0.062	0.019
	Hematoma/excessive bleeding	0.093	0.032
3. "I am happier now after my operation than before my operation."	Loss of sensation	0.014	0.008†
	Excessive external scarring	0.060	0.017
	Hematoma/excessive bleeding	0.090	0.029
4. "I feel comfortable letting a health care provider examine my genitals."	Introital stenosis	0.037	0.008
	Prolonged pain	0.050	0.019
	Excessive external scarring	0.074	0.021
5. "I would recommend this operation to a friend."	Infection	0.033	0.012
	Prolonged pain	0.030	0.004
	Loss of sensation	0.058	0.019
	Intravaginal scarring	0.064	0.005
	Excessive external scarring	0.097	0.035
6. "I am not embarrassed about my genitals."	Request for revision	0.043	0.007
	Prolonged pain	0.071	0.004
	Excessive vaginal drainage	0.083	0.005
	Excessive external scarring	0.096	0.014
	Hematoma/excessive bleeding	0.11	0.019
	Intravaginal scarring	0.11	0.011
	Introital stenosis	0.12	0.057
7. "I am able to get sexually aroused."	Intravaginal scarring	0.006	<0.0001†
	Infection	0.023	0.016
	Hematoma/excessive bleeding	0.10	0.018
	Necrosis	0.15	0.021
	Granulation tissue	0.21	0.050
8. "I am satisfied with the appearance of my genitals."	Urinary tract infection	0.051	0.012
	Excessive external scarring	0.092	0.012
	Request for revision	0.10	0.002
	Reoperation	0.17	0.028
	Intravaginal scarring	0.25	0.050
	Prolonged pain	0.26	0.043
9. "I would feel comfortable letting a sexual partner look at my genitals."	Excessive external scarring	0.089	0.010
	Urinary tract infection	0.12	0.036
	Intravaginal scarring	0.20	0.027
	Employed	6.2	0.012
10. "I think my genitals smell fine."	No significant predictors	NA	NA
11. "I think my genitals work the way they are supposed to work."	Intravaginal scarring	0.080	0.001†
	Request for revision	0.15	0.011
	History of physical abuse	0.17	0.018
	Prolonged pain	0.23	0.042
12. "My sexual partners are satisfied with my genitals."	Hematoma	0.058	0.020
	Prolonged pain	0.072	0.001†
	Request for revision	0.095	0.007
	Urinary tract infection	0.13	0.040
13. "I am satisfied with the sexual function of my vagina."	Intravaginal scarring	0.062	0.001†
	Loss of sensation	0.089	0.048
	Necrosis	0.12	0.004
	Request for revision	0.17	0.006
	Prolonged pain	0.21	0.019
14. "I have achieved more than two dots on the dilator."	Intravaginal scarring	0.24	0.038
15. "My orgasm is better now compared to before my operation."	Intravaginal scarring	0.083	0.003
	Prolonged swelling	0.14	0.013
16. "My dysphoria is resolved."	Urinary tract infection	0.086	0.035
	History of physical abuse	0.23	0.017
	Higher education level	2.6	0.038
17. "I was able to achieve orgasm within 6 months of operation."	Prolonged swelling	0.099	0.007
	Prolonged pain	0.28	0.049
	Higher education level	0.35	0.026

(*Continued*)

Table 5. ***Continued***

Patient-Reported Outcome	Predictor	OR	*p*
18. "I am satisfied with the depth of my vagina."	Intravaginal scarring	0.051	0.007
	Request for revision	0.17	0.002
	Any complications	0.19	0.023
	Prolonged pain	0.24	0.036
	History of suicide attempt	0.24	0.012
	Reoperation	0.29	0.025
	History of physical abuse	0.29	0.032
19. "I am engaging in penetrative sexual intercourse weekly."	Hematoma/excessive bleeding	0.10	0.039
	Intravaginal scarring	0.11	0.010
	Granulation tissue	0.13	0.006
	Prolonged pain	0.20	0.017
20. "I am engaging in penetrative sexual intercourse more than twice a week."	History of physical abuse	3.4	0.027

*Sixty-six total patient respondents.
†Significant after adjusting for 40 multiple comparisons ($p < 0.0013$).

time of survey administration, ***http://links.lww.com/PRS/C793***.) Overall, having a minor complication correlated more to patient dissatisfaction than having a major complication (40 minor complication predictors versus 32 major complication predictors). The top predictors of patient dissatisfaction were intravaginal scarring (negatively correlated to 12 patient-reported outcomes), prolonged pain (negatively correlated to 11 patient-reported outcomes), excessive external scarring (negatively correlated to eight patient-reported outcomes), loss of sensation (negatively correlated to seven patient-reported outcomes), and hematoma/excessive bleeding (negatively correlated to seven patient-reported outcomes).

Resolution of gender dysphoria was positively associated with a higher education level (OR, 2.6; $p = 0.038$) and negatively associated with experiencing a urinary tract infection (OR, 0.086; $p = 0.035$) or a history of physical abuse (OR, 0.23; $p = 0.017$). Of the patient-reported outcomes with the highest patient satisfaction, predictors negatively associated with "feeling positively about their genitals" included infection (OR, 0.001; $p = 0.039$), loss of sensation (OR, 0.040; $p = 0.012$), intravaginal scarring (OR, 0.038; $p = 0.010$), excessive external scarring (OR, 0.073; $p = 0.022$), and hematoma/excessive bleeding (OR, 0.077; $p = 0.026$). Predictors negatively associated with "doing this operation again" included loss of sensation (OR, 0.015; $p = 0.009$), excessive external scarring (OR, 0.062; $p = 0.019$), and hematoma/excessive bleeding (OR, 0.093; $p = 0.032$). Achieving orgasm within 6 months of operation was negatively associated with prolonged swelling (OR, 0.099; $p = 0.007$), prolonged pain (OR, 0.28; $p = 0.049$), and a higher educational level (OR, 0.35; $p = 0.026$). Engaging in penetrative sexual intercourse at least once weekly was negatively associated with hematoma/excessive bleeding (OR, 0.10; $p = 0.039$), intravaginal scarring (OR, 0.11; $p = 0.010$), granulation tissue (OR, 0.13; $p = 0.006$), and prolonged pain (OR, 0.20; $p = 0.017$). Table 5 provides a full list of predictors of patient satisfaction.

DISCUSSION

In this single-surgeon case series, we report the largest study to specifically examine patient-reported outcomes in penile inversion vaginoplasty in the United States, and correlate them to complication data. As such, this study helps clarify how postoperative complications drive overall patient satisfaction. Vaginoplasty is not performed without risk, and in our patient cohort, complications were experienced by 70 percent of all patients. Understanding how these complications correlate to patient-reported outcomes is imperative. Surprisingly, complications that were classified as "minor" at the discretion of the lead surgeon were more commonly negatively associated with patient satisfaction than those complications that were labeled as "major" (40 minor complication predictors versus 32 major complication predictors). In part, this may be attributable to the chronicity of many of the complications labeled as minor. In contrast, many of the major complications were acute issues that did not have a chronic impact on patient well-being.

The complications most associated with negative patient satisfaction included intravaginal scarring, prolonged pain, excessive external scarring, hematoma/excessive bleeding, and loss of sensation. Intravaginal scarring occurred in 20 percent of patients in this study. Unfortunately, no significant predictors for intravaginal scarring were identified (of 22 independent variables examined). However, as full-thickness scrotal skin

grafts were used to increase vaginal vault length in all patients in this study, this may have been a contributing factor. Future studies investigating intravaginal scarring in separate cohorts that receive skin grafts versus those who do not would be particularly interesting. Hematoma/bleeding-related complications are reported to range from 3 to 10 percent in the primary literature,[2] and 10 percent of patients in our group experienced hematoma/excessive bleeding. We identified a history of a bleeding disorder as a major predictor of hematoma formation (OR, 9.4; $p = 0.035$). Careful preoperative counseling should therefore be undertaken in this patient population. In our study, prolonged pain was experienced by 19 percent of patients, excessive external scarring by 9 percent of patients, and loss of sensation by 3 percent of patients. Other reports of these complications are sparsely reported in the literature; therefore, it is difficult to compare these results to other groups' experiences. We were unable to identify significant predictors of prolonged pain, excessive external scarring, or loss of sensation and therefore cannot offer recommendations as to which patient populations may be particularly vulnerable to these complications.

As gender-confirming surgery may act not only as a cosmetic procedure but as a therapeutic intervention, it is important to assess the resolution of gender dysphoria postoperatively. Seventy-one percent of respondents in our study indicated resolution of their gender dysphoria after penile inversion vaginoplasty. Although other studies have reported on patient-reported outcome in penile inversion vaginoplasty, lacking from their analyses were indications of resolution of patient gender dysphoria.[19,20] Factors negatively associated with resolution of gender dysphoria in our study included experiencing a urinary tract infection postoperatively and a history of physical abuse. History of physical abuse can lead to poor psychological function affecting postoperative patient satisfaction. Prior studies have shown that patients with poor psychosocial function preoperatively have worse postoperative outcomes.[25] Patients with a history of physical or sexual abuse may require more intense mental health intervention perioperatively. A higher education level was positively associated with resolution of gender dysphoria.

Other important milestones postoperatively include the ability to achieve orgasm and penetrative sexual intercourse. Sixty-seven percent of respondents were able to achieve orgasm within 6 months of surgery and 57 percent indicated having penetrative sexual intercourse at least once per week and 36 percent twice per week. Predictors negatively associated with the ability to achieve orgasm within 6 months of operation included prolonged swelling, pain, and a higher education level. Intuitively, these complications may prevent patients from attempting penetrative or nonpenetrative sexual intercourse, in which case orgasm may be delayed postoperatively. Factors negatively associated with engaging in penetrative sexual intercourse included hematoma/excessive bleeding, intravaginal scarring, granulation tissue, and prolonged pain.

The main strength of this study is its extensive analysis of postoperative complications and their relation to patient-reported outcomes in penile inversion vaginoplasty. With 66 respondents to our online questionnaire, our study includes the largest respondent cohort to date to report on patient-reported outcomes for this procedure. Few other studies have reported on patient-reported outcomes in penile inversion vaginoplasty.[19,20] The majority of patients in these studies reported being entirely satisfied with the result of their surgery (57 percent), and 83 percent of patients were able to achieve orgasm.[20] However, notably lacking from these studies was a measure of resolution of gender dysphoria. Nonetheless, these results help corroborate the results found in our study: despite complications, patients are generally satisfied with the appearance and function of their genitals after penile inversion vaginoplasty.

The questionnaire used to evaluate patient-reported outcomes in our study represents a major limitation. Although adapted from the Female Genital Self-Image Scale, this tool is validated only for nontransgender women.[24] This brings up the need for specific validated metrics to assess patient-reported outcomes in transgender patient populations. As penile inversion vaginoplasty is the current gold standard in male-to-female genital surgery, this would serve as the ideal procedure to develop such a tool.[18] Other validated metrics such as the BREAST-Q have helped enforce reliable and standardized reporting across studies in the breast literature.[26] Development of a similar metric for specific use in gender-confirming procedures would help provide similar clarity in the transgender literature.

Overall, despite a high complication risk profile, patient satisfaction is very high in penile inversion vaginoplasty for gender-confirming surgery. Over 90 percent of respondents reported feeling positively about their genitals, would undergo the operation again, felt happier after their operation,

and would recommend this operation to a friend. In addition, penile inversion vaginoplasty provided relief of gender dysphoria in 71 percent of respondents. Through a thorough understanding of postoperative complications and their association to patient satisfaction, we can begin to establish best practice techniques for our transgender patients.

CONCLUSION

This is the largest study of penile inversion vaginoplasty in the United States to report both postoperative complications and patient-reported outcomes. Despite moderate complication risk, patient satisfaction remains very high after penile inversion vaginoplasty, with the majority of patients reporting relief of their gender dysphoria.

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