

Longitudinal patient-reported outcomes of vaginal dilation after penile inversion vaginoplasty

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Abstract

Background: Penile inversion vaginoplasty (PIV) is a commonly performed gender-affirming procedure that requires postoperative dilation to maintain vaginal canal patency.

Aim: To characterize patient-reported dilation experiences and evaluate temporal trends in postoperative outcomes.

Methods: Consecutive patients undergoing primary PIV at a single center were prospectively surveyed at 1, 3, 6, 9, and 12 months postoperatively. Surveys were author-developed based on clinical experience and clinical review. Surveys assessed dilation frequency, session duration, depth achieved, and challenges encountered. Univariate analyses were used to evaluate changes over time.

Outcomes: The primary outcome was the proportion of patients reporting any dilation-related challenge over time. Secondary outcomes included adherence metrics (frequency, days/week, session duration), depth achieved, and specific challenges.

Results: Seventeen of 27 patients completed all survey time points (63% response rate). On average, participants dilated 6.6 ± 1.4 days/week and 2.4 ± 0.9 times/day; sessions lasted 38.3 ± 16 minutes. Mean depth achieved was 4.05 ± 1.32 (13 cm standardized dilator set), with no significant decline over time. All patients reported at least one difficulty, most commonly tightness (71%), bleeding (71%), pain (65%), discharge (47%), and logistical barriers (24%). The prevalence of reported challenges declined significantly after six months ($P < .05$).

Clinical Implications: Early dilation-related difficulties are nearly universal and should be anticipated with proactive counseling and structured postoperative support, though symptoms improve over time.

Strengths and Limitations: This is the first prospective, longitudinal study of dilation following PIV, using an author-developed survey instrument to capture patient-reported outcomes. Limitations include modest sample size, potential response bias, and lack of assessment of challenge severity.

Conclusion: Reported dilation adherence following PIV is high, but most patients experience early challenges that diminish over time, highlighting the need for anticipatory counseling and individualized, symptom-responsive dilation protocols.

Keywords: penile inversion vaginoplasty; gender-affirming surgery; dilation; patient-reported outcomes.

Introduction

Penile inversion vaginoplasty (PIV) is the most frequently performed gender-affirming genital surgery for transfeminine and gender-diverse individuals.^{1,2} The primary objectives of this procedure are to create a neovagina and vulva that are esthetically satisfactory, functional for receptive intercourse if desired, support vulvar erogenous sensation, and facilitate a downward-directed urine stream.^{3,4} Studies consistently report significant psychosocial benefits following PIV, with reported satisfaction rates ranging from 82% to 94%.^{5,6} As gender-affirming surgery is increasingly recognized as a medically necessary intervention to alleviate gender dysphoria, rigorous evaluation of patient-reported outcomes is essen-

tial to inform surgical practice and optimize postoperative care.⁷

PIV is a complex procedure that requires diligent long-term postoperative care. Specifically, dilation of the neovaginal canal is universally indicated following the procedure in order to maintain patency (both depth and width) and prevent vaginal stenosis.^{8,9} Nonetheless, studies have reported a significant decrease in compliance with dilation over time, and no consensus exists regarding the optimal dilation protocol.¹⁰ Non-adherence has been associated with an increased risk of neovaginal stenosis.⁹ Factors that impair a patient's ability to dilate, including preoperative mental health conditions, HIV status, and postoperative wound healing complications, have

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also been associated with increased dilation difficulty and may indirectly increase stenosis risk.¹¹

To date, no studies have systematically evaluated patient-reported barriers to dilation following PIV. Prior literature has largely relied on retrospective complication reporting and clinical outcomes.^{11,12} The absence of such data limits the development of evidence-based, patient-centered dilation protocols, with current dilation protocols varying widely.⁹ To address this gap, we conducted a prospective study to characterize patient-reported dilation practices and identify barriers to adherence. The findings from this study aim to inform future dilation regimens and enhance postoperative care for individuals undergoing gender-affirming vaginoplasty.

Methods

Study design and participants

We performed a prospective study of consecutive patients undergoing PIV over a 3-month period at a single gender-affirming surgery center. Eligible participants included transfeminine individuals 18 years or older who were undergoing primary PIV. Patients who received minimal depth vaginoplasties or revisional vaginoplasties were excluded. All patients met the World Professional Association for Transgender Health Standards of Care, Version 8, criteria for genital GAS prior to surgery.¹³ The study received institutional review board approval and informed consent was obtained from all patients. This study adhered to the STROBE guidelines checklist.¹⁴ All providers utilized trauma-informed practices, and preoperative evaluation included review of medical, psychiatric, and psychosocial factors that could impair postoperative self-care. At the time of data collection, the practice applied a BMI threshold of 33 kg/m² based on technical and safety considerations; although this threshold influenced the BMI distribution of the cohort, institutional practice has since evolved and a strict BMI cutoff is no longer routinely enforced aside from anesthetic limitations.¹⁵

Survey characteristics

Eligible patients received surveys using Qualtrics XM (Qualtrics, Provo, UT), a secure, HIPAA-compliant survey tool. Survey distribution began during the first month of dilation following PIV, and continued for one year postoperatively, administered at 1, 3, 6, 9, and 12 months after surgery. As there are no validated questionnaires examining patient-reported challenges with dilation, survey questions were author-developed based on the senior authors' clinical experience and literature review and were reviewed internally for clinical relevance and clarity.¹⁶ Survey questions addressed weekly dilation frequency, depth, duration, and challenges encountered (Supplemental Figure 1). In this study, a "challenge" was defined as a report of ≥ 1 predefined symptoms within the assessment window. A free text box was included at the end of the questionnaire to allow participants to optionally elaborate on their previous responses.

Data analysis

The primary outcome was the proportion of patients reporting any dilation-related challenge at each postoperative timepoint and its temporal trend over the first postoperative year. Secondary outcomes included adherence metrics (frequency, days per week, session duration), dilation depth

achieved, and specific reported challenges. Statistical and descriptive analyses were performed using SPSS, Version 29.0.2.0 (SPSS Inc., Chicago, Ill., USA). Only patients with complete responses across all study timepoints were included in the analysis. Descriptive statistics were used to summarize demographic, surgical, and dilation-related variables and are reported as mean $\pm$ standard deviation or median with interquartile range, as appropriate. Temporal trends in continuous variables (dilation depth and session duration) were evaluated using linear regression with postoperative time as the independent variable. Changes in the proportion of patients reporting dilation-related challenges over time were analyzed using regression modeling of proportions across timepoints, as presented in the figures. Statistical significance was defined as $P < .05$.

Dilation education

Dilation education followed a structured, team-based protocol beginning preoperatively. Prior to surgery, patients received written instructional materials and were encouraged to establish care with a pelvic floor physical therapist. A minimum of four postoperative appointments during the first postoperative month were scheduled in advance to ensure early follow-up. Patients traveling from outside the region were required to arrange local housing and were advised to remain locally for approximately 3.5–4 weeks to support supervised early aftercare. During the first postoperative visit at week one, designated nursing staff and physician assistants supervised the initial dilation session after packing removal and provided hands-on instruction. Patients were then evaluated weekly for the first four postoperative weeks, with a speculum examination performed at week four to assess canal healing. Patients were instructed to dilate for a minimum of 30 minutes three times daily, gradually advancing to their largest comfortable dilator by 6–8 weeks postoperatively. This schedule was maintained for the first postoperative year, after which patients could modify one component of the regimen (frequency, dilator size, or session duration) based on comfort and clinical guidance.

Results

During the 3-month study period, a total of 27 patients underwent PIV. Of these, 17 patients (63%) completed all five postoperative assessments, contributing a cumulative total of 85 weeks of dilation data. There were no significant differences in baseline demographic characteristics between survey completers and non-completers. Demographic and surgical characteristics are summarized in Table 1. The mean age at the time of surgery was 31.8 ± 8.2 years, with a mean BMI of 24.7 ± 4.6 kg/m². All patients had a documented history of hormone therapy, with an average duration of 4.1 ± 2.1 years. Prior gender-affirming procedures included facial feminization surgery (35%), breast augmentation (24%), and orchiectomy (6%). Postoperative complications included superficial wound breakdown requiring local wound care in 47% ($n = 8$), and symptomatic granulation tissue necessitating surgical excision under anesthesia in 18% ($n = 3$).

Patients initiated vaginal dilation, on average, on postoperative day 8.3 ± 1.1 . The majority adhered to a recommended frequency of approximately three sessions per day (mean 2.4 ± 0.86 sessions/day), with high consistency across the

Table 1 Respondent demographic and surgical characteristics.

Patient no.	17
Age at surgery, mean (SD) years	31.82 (8.20)
BMI (kg/m ²), mean (SD)	24.70 (4.60)
Previous hormone use, n (%)	17 (100)
Length on hormones, mean (SD) years	4.11 (2.10)
Prior gender-affirming surgery, n (%)	9 (53)
Orchiectomy	1 (6)
Breast augmentation	4 (24)
Facial feminization surgery	6 (35)
Postoperative complications	
Wound breakdown requiring topical treatment, n (%)	8 (47)
Granulation tissue requiring excision under anesthesia, n (%)	3 (18)

Table 2 Postoperative dilation patterns.

Variable	Value
Postoperative dilation start (days), mean (SD)	8.29 (1.10)
Number of dilation days per week, mean (SD)	6.55 (1.38)
Number of dilation sessions per day, mean (SD)	2.4 (0.86)
Mean dilation depth, mean (SD); median [IQR]	4.05 (1.32); 4 [IQR 3-5]
Dilation duration per session (minutes), mean (SD); median [IQR]	38.25 (16); 30 [IQR 30-40]
Dilator used, n (%)	
#P1	0
#P2	0
#1	2 (2.4%)
#2	17 (20.2%)
#3	29 (34.5%)
#4	36 (42.9%)
Any challenge reported during the study period, n (%)	15 (88%)
Tightness	12 (71%)
Bleeding	12 (71%)
Pain	11 (65%)
Discharge	8 (47%)
Time or personal constraints	4 (24%)
Forgot to dilate	0

week (mean 6.55 ± 1.38 days/week; Table 2). Each session lasted an average of 38.3 ± 16.0 minutes, with a median of 30 minutes [IQR 30-40].

During the study period, the mean dilation depth achieved was 4.05 ± 1.32 , with a median of 4 [IQR 3-5], on the standard Soul Source dilator scale (GRS Vaginal Trainers, Soul Source Therapeutic Devices, Inc., Hollywood, CA). At 12-month follow-up, the average self-reported dilation depth was 3.94 ± 0.36 , corresponding to an estimated neovaginal length of approximately 13 cm. The most frequently used dilator sizes were #4 (42.9%) and #3 (34.5%), with less frequent use of smaller sizes (#2: 20.2%; #1: 2.4%). At one year postoperatively, 53% of patients reported continued use of the largest dilator (#4; 1.5 inches in diameter), while 29% used size #3 (1.375 inches in diameter), 12% used size #2 (1.25 inches in diameter), and 6% used size #1 (1.125 inches in diameter).

Most patients (88%, $n = 15$) reported at least one challenge with dilation during the study period (Table 2). The most frequently reported difficulties included vaginal tightness (71%), bleeding (71%), pain (65%), discharge (47%), and time or personal constraints (24%). Notably, no patients reported forgetting to dilate.

On univariate analysis, there was no statistically significant change in mean dilation depth over time ($P = .0828$, Figure 1).

Average depth remained stable at 4.2 and 3.9 at months 1 and 12, respectively. The proportion of patients reporting *any* challenge with dilation decreased significantly from 71% at one month to 18% at twelve months ($R^2 = 0.81$, $P = .0287$, Figure 2). Reported pain decreased from 59% at one month to 0% at twelve months ($P = .0336$, Figure 3). Bleeding peaked at three months (47%) and decreased to 6% by month twelve, though the overall trend did not reach statistical significance ($P = .0562$, Figure 4). Discharge peaked at six months (24%) and declined thereafter (18% at month one to 6% at month twelve, $P = .2791$, Figure 5). Tightness was reported by 53% of patients at both one and six months, but fell to 12% by month twelve ($P = .0563$, Figure 6). Time or personal constraints remained low across the study period, reported by 18% of patients at one month and 12% at six months (Figure 7). When stratified into early (1-6 months) and late (9-12 months) postoperative intervals, all patient-reported dilation challenges showed a statistically significant reduction over time (Table 3).

Discussion

This study presents one of the first characterizations of patient-reported outcomes with dilation following PIV. PIV is a complex procedure involving inversion of the penile

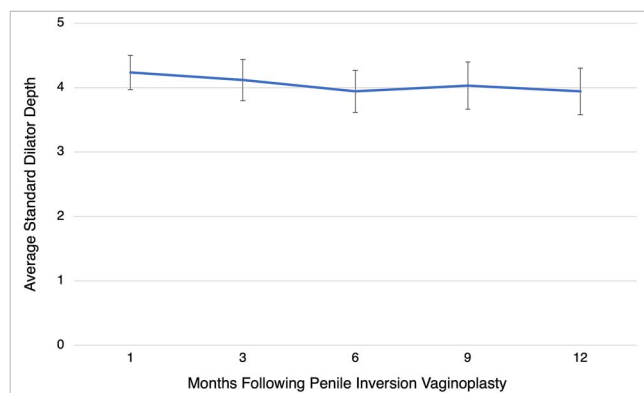


Figure 1 Average reported dilation depth on a standard dilator (1 - 5 dots) at 1, 3-, 6-, 9-, and 12-months following PIV. No significant decrease in depth was observed over time ($P = .0838$).

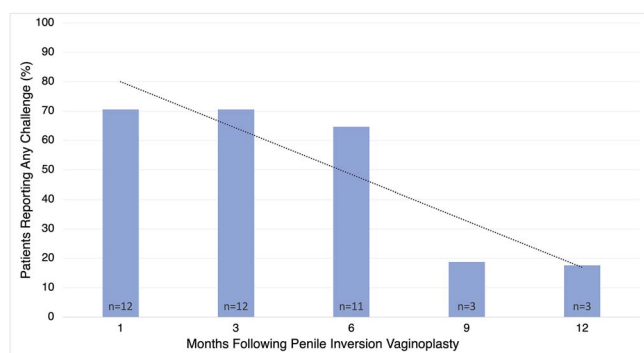


Figure 2 Percentage of patients reporting any dilation-related challenge at 1, 3-, 6-, 9-, and 12-months following PIV. A significant decrease in challenges was observed over time ($R^2 = 0.81$, $P = .0287$).

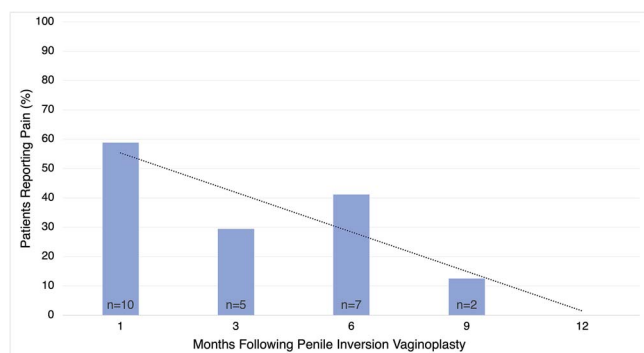


Figure 3 Percentage of patients reporting dilation-related pain at 1, 3-, 6-, 9-, and 12-months following PIV. A significant decrease in pain was observed over time ($R^2 = 0.84$, $P = .0336$).

skin to create a neovagina, utilizing the scrotal skin and tissue grafts as a full-thickness graft to line the vaginal canal.¹⁷ Postoperative dilation is a cornerstone of care, critical for maintaining vaginal patency and preventing neovaginal stenosis.^{11,12} Yet, despite its importance, the natural healing process and lived experiences of patients navigating this long-term and demanding process have remained largely unexplored. Our findings reveal that while reported challenges with dilation are common in the early postoperative period—particularly within the first six months—most patients report substantial improvement in symptoms and high adherence thereafter. These results offer new insights into the trajectory

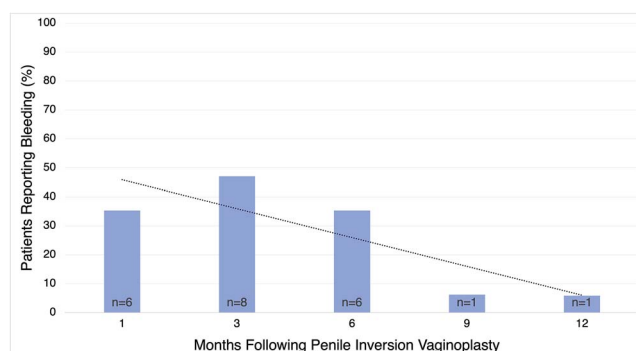


Figure 4 Percentage of patients reporting dilation-related bleeding at 1, 3-, 6-, 9-, and 12-months following PIV. No significant decrease in bleeding was observed over time ($R^2 = 0.70$, $P = .0562$).

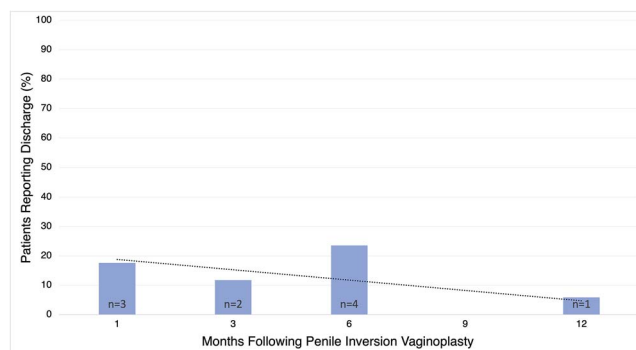


Figure 5 Percentage of patients reporting dilation-related discharge at 1, 3-, 6-, 9-, and 12-months following PIV. No significant decrease in discharge was observed over time ($R^2 = 0.36$, $P = .2791$).

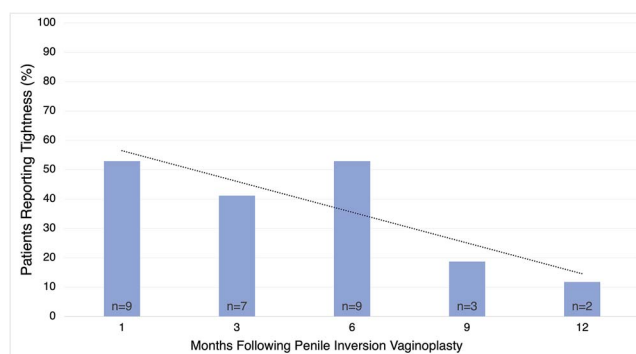


Figure 6 Percentage of patients reporting dilation-related tightness at 1, 3-, 6-, 9-, and 12-months following PIV ($R^2 = 0.74$, $P = .0563$).

of patient-reported outcomes over time and underscore key opportunities for early postoperative support and targeted interventions to enhance both physical outcomes and the overall patient experience.

Neovaginal stenosis remains one of the more devastating complications following PIV. A large systematic review by De Rosa et. al reported an overall incidence of neovaginal stenosis of 5.7% following primary PIV, although its association with dilation adherence was not examined.⁹ The pathophysiology of stenosis parallels that observed in other reconstructed tubular structures and is driven by fibroblast and myofibroblast activation, excessive collagen deposition, and progressive tissue contraction.¹⁸ In our experience, sustained nonadherence to dilation is strongly associated with the development of

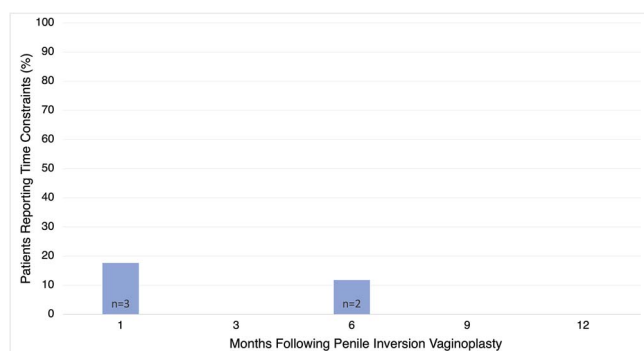


Figure 7 Percentage of patients reporting dilation-related time or personal constraints at 1, 3-, 6-, 9-, and 12-months following PIV.

clinically significant stenosis. Additional contributing mechanisms described in the literature include high-tone pelvic floor disorder, tissue retraction from the neovaginal apex, and partial or complete loss of scrotal skin grafts.^{19,20}

Based on our clinical experience, patients in our cohort were instructed to begin dilation approximately one week after surgery, gradually progressing to their largest comfortable dilator by 6–8 weeks. They were advised to dilate a minimum of 30 minutes three times daily for the first year, with the option—after one year—to modify one aspect of the regimen (either the frequency of weekly or daily dilations, the dilator size, or the duration of each session). Our results indicate that dilation depth remained stable over the study period, with no significant decline observed. Specifically, the mean reported depth was equivalent to 4.2 dots on the standard dilator at one month postoperatively, compared to 3.9 dots at twelve months. Considering that each dot represents 1.5 cm (with 5 dots approximating 14.5 cm and 4 dots roughly 13 cm), these figures are consistent with previously reported intraoperative neovaginal depths following PIV—which have a median of 14 cm (range: 10–16 cm).²¹ However, few studies have assessed the durability of neovaginal depth over time. Our findings not only corroborate existing depth measurements but also contribute novel long-term data demonstrating sustained depth beyond the immediate postoperative period.

Our study revealed that reported adherence to the recommended regimen was high, with most patients reporting consistent use three times per day. These data affirm the feasibility of the recommended protocol and suggest that, in a supportive clinical environment, patients can maintain the frequency and intensity of dilation over time. In our experience, successful early recovery is anchored by intensive follow-up during the first postoperative year, including weekly visits and hands-on dilation training during the initial month. Unrestricted access

to nursing and support staff allows for timely troubleshooting, while proactive counseling empowers patients to seek assistance at the first sign of difficulty. Preoperative and ongoing postoperative pelvic floor physical therapy further reinforces these efforts and should be considered a standard component of care when available.

Despite high adherence, dilation was not without burden. Nearly all patients reported one or more challenges in the early postoperative period, most commonly pain, bleeding, tightness, and discharge. However, these symptoms improved over time, consistent with tissue remodeling and increasing patient proficiency. By 12 months postoperatively, no patients reported ongoing pain, and the overall prevalence of any challenge had declined to 18%. This trajectory of symptom resolution highlights the capacity for physical recovery and psychological adaptation, offering reassurance to patients experiencing early discomfort and reinforcing the importance of anticipatory guidance and sustained support throughout the first six months of recovery.

Several complications emerged as particularly impactful and warrant closer clinical attention. Superficial wound breakdown requiring local wound care was observed in 47% of patients. While this rate appears high in isolation, published PIV series report wound separation rates that vary widely depending on definitions and reporting thresholds, with many studies capturing only major complications requiring operative intervention.¹² Reported minor wound healing issues in the literature range from 3.3%–33%.^{12,16,22,23} In our cohort, breakdown included any minor superficial separation managed conservatively, which likely contributed to the higher observed rate.

Granulation tissue requiring operative excision was observed in 18% of patients. Prior series focused exclusively on PIV report granulation rates of 7.3% to 26%,^{2,22} while mixed-technique cohorts describe rates up to 38.8%.²⁴ Importantly, few studies distinguish between conservatively managed granulation tissue and cases requiring operative intervention; in one PIV series, only 12.5% of patients with granulation tissue required operative excision.²² Timely identification and management using topical agents—such as silver nitrate or corticosteroids—and surgical intervention when persistent are essential to prevent delays in dilation progression.²⁵

Neovaginal tightness, likely multifactorial in origin, may respond well to early referral for pelvic floor physical therapy.²⁶ Adjunctive treatments, including topical estrogen for tissue softening, botulinum toxin for pelvic floor hypertonia, and steroid injections for scar bands, may also be employed. Pain, when present, was addressed through a multimodal, non-opioid approach, including topical benzocaine-lidocaine-tetracaine cream, cannabinoid-based suppositories, and sys-

Table 3 Comparison of patient-reported dilation difficulties between early and late postoperative periods following PIV.

Patient-reported challenge	Months 1-6	Months 9-12	P-value ^a
Pain (%)	65%	12%	0.0027
Bleeding (%)	71%	12%	0.0027
Discharge (%)	47%	6%	0.0082
Tightness (%)	71%	24%	0.0143
Time or personal constraints (%)	24%	0%	0.0455
Forgetting to dilate (%)	0%	0%	NS

^aNemar's test; NS: Not Significant.

temic medications such as ibuprofen, acetaminophen, and gabapentin. These strategies may optimize symptom management while minimizing reliance on opioids.

Strengths of this study include its prospective design and the use of author-developed instruments to assess patient-reported outcomes. To our knowledge, this is the first longitudinal analysis to document the dilation experience following PIV in such granular detail. Several limitations warrant consideration. The number of participants who completed the full study period was modest, which limited statistical power and the ability to detect small effect sizes. In addition, enrollment was limited to a 3-month surgical window, which may reduce representativeness. Because analyses included only participants with complete follow-up, exclusion of non-completers may bias results toward individuals with higher adherence or more favorable recovery experiences, although no differences in baseline demographic characteristics were identified between both cohorts. We were also unable to assess whether external factors (eg, pelvic floor therapy, employment, social support, partner dynamics, and financial resources) influenced adherence and recovery. We did not examine challenge severity (mild/moderate/severe), which limits insight into the clinical significance of reported difficulties. Lastly, the survey format may have functioned as a behavioral reminder (Hawthorne effect), potentially influencing adherence behaviors and limiting generalizability. Additionally, the BMI distribution of this cohort reflects institutional eligibility criteria at the time of enrollment and may not apply to all patients undergoing PIV. Nonetheless, these findings offer a valuable foundation for future research and provide practical guidance for enhancing postoperative care in gender-affirming genital surgery. As current dilation regimens vary widely with no universally-accepted protocol, multi-institutional collaboration is necessary to compare dilation strategies and develop evidence-based recommendations based on patient-reported outcomes.

Conclusion

This prospective study provides valuable insight into the lived experiences of patients undergoing postoperative dilation following PIV. While nearly all participants reported challenges early in the postoperative course—most commonly pain, bleeding, tightness, and discharge—these symptoms declined significantly over time, with only 18% reporting any difficulty by 12 months and no patients reporting ongoing pain. Adherence to the recommended dilation regimen appeared high in this cohort, suggesting that, within a supportive clinical framework emphasizing education, access to care, and early intervention, patients can sustain intensive dilation practices. These findings underscore the importance of robust postoperative support systems and highlight key areas for future patient-centered interventions aimed at enhancing comfort, compliance, and long-term surgical success.

Author contributions

D.A.G.: Conceptualization-Equal, Data curation-Lead, Formal analysis-Lead, Investigation-Lead, Methodology-Equal, Project administration-Lead. M.L.: Data curation-Equal, Investigation-Equal. A.C.H.: Conceptualization-Equal, Data curation-Equal, Formal analysis-Equal, Methodology-Equal. D.A.Y-A.: Data curation-Supporting,

Methodology-Supporting. A.G.: Investigation-Equal, Methodology-Equal, Project administration-Equal. T.S.: Conceptualization-Equal, Data curation-Equal, Project administration-Equal. J.H.P.: Conceptualization-Lead, Investigation-Equal, Methodology-Equal, Project administration-Equal.

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Conflicts of interest

None declared.

Ethical approval

The study was approved by the Institutional Review Board (Advarra [Columbia, MD] IRB Protocol 00069065) and adhered to the principles outlined by the Declaration of Helsinki for Ethical Principles in Medical Research.

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