Vaginal Stenosis After Gender-affirming Vaginoplasty: A Systematic Review

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OBJECTIVE To review the literature and report the incidence of vaginal stenosis (VS) after vaginoplasty and compare the incidence rates by surgical technique and follow-up duration.

METHODS We performed a systematic literature review according to PRISMA guidelines. Original research on primary vaginoplasty was included. Exclusion criteria included non-English studies, mixed cohorts without subgroup analysis, revision vaginoplasty, and papers without stenosis rates. The search was ran in Pubmed, Embase, Scopus, and Cochrane on September 9, 2022. Stenosis rates were compared with descriptive statistics using SPSS.

RESULTS Fifty-nine studies with a cumulative 7338 subjects were included. The overall incidence of VS was 5.83% (range 0%-34.2%). Combining VS with introital stenosis (IS) and contracture results in a cumulative incidence of 9.68%. The rate of VS in the penile inversion vaginoplasty subgroup (PIV) was 5.70%, compared to 0.20% in primary intestinal vaginoplasty. The rate of IS in the PIV group was 3.13% and 4.7% in the intestinal vaginoplasty subgroup.

CONCLUSION The overall rate of VS was 5.83%, which is lower than previously documented. This may be related to the inclusion of more recent studies and analysis limited to primary vaginoplasty. The similar rate of IS in PIV and intestinal vaginoplasty subgroups may be secondary to multiple suture lines and the need for dilation through this anastomosis. Our research demonstrates a need for a standardized definition of VS. UROLOGY 186: 69–74, 2024.

Treatment of gender dysphoria among transgender people is individualized and can include counseling alone, hormone replacement, and/or a variety of gender-affirming surgical options.[1] Transfeminine and gender-expansive people may choose to proceed with gender-affirming vaginoplasty for which several techniques have been described, including skin graft vaginoplasty, penile inversion vaginoplasty (PIV) with or without scrotal skin graft, peritoneal flap vaginoplasty, and intestinal vaginoplasty. PIV remains the most common variation of vaginoplasty. Peritoneal flaps can be harvested robotically as another means to augment the vaginal apex.[2] Intestinal vaginoplasty, commonly using a segment of the sigmoid colon, (IV) can also be used as a primary surgery; or as a salvage procedure when PIV has failed.[3]

Several studies have shown the benefits of vaginoplasty with improvement in quality of life, sexual activity, and improvement of gender dysphoria.[4] These procedures are successful in terms of patient satisfaction with esthetics and function as well as overall satisfaction with the procedure.[5,6] In part, because of the success of vaginoplasty, the number of transfeminine people electing to undergo genital gender-affirming surgery is increasing.[7]

Despite the increasing success and popularity of these surgeries, studies evaluating vaginoplasty outcomes and complications using standardized instruments are sparse. One of the more devastating complications of vaginoplasty is vaginal and/or introital stenosis (IS). To minimize stenosis, patients are committed to perform regular dilation with dilators indefinitely. Vaginal stenosis (VS), when it does occur, typically requires aggressive dilation or surgery to correct. Surgical interventions range from dilation under anesthesia to a complete reconstruction of the vagina with intestinal or peritoneal augmented vaginoplasty. While studies reporting complications of vaginoplasty do exist, the majority have relatively small sample sizes with heterogeneous outcome measures and definitions.[8] In this review, we report the incidence of VS after vaginoplasty and compare the incidence rates by surgical technique and follow-up duration.

MATERIALS AND METHODS

A systematic literature review was performed according to PRISMA guidelines (Fig. 1).[9] A search strategy (included in Appendix) was crafted in the PICO format. The

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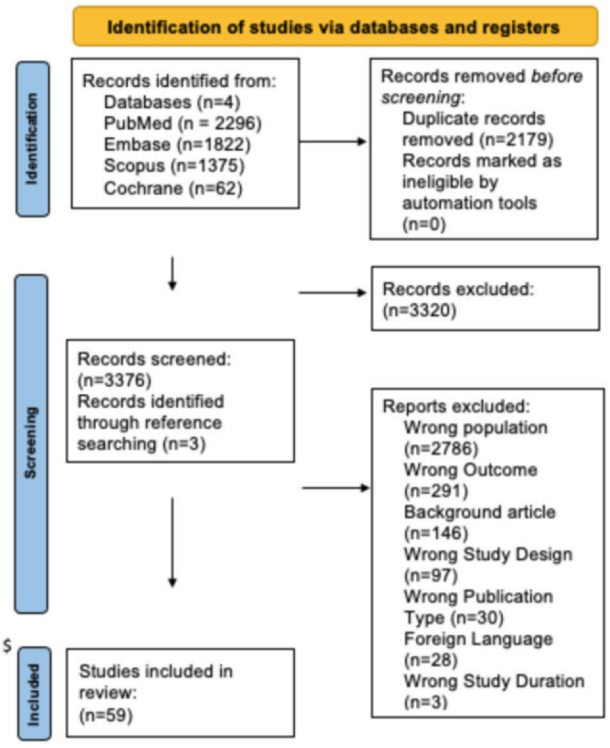

Figure 1. PRISMA flowchart. (Color version available online.)

population is transfeminine people, the intervention is vaginoplasty, the outcome is presence of vaginal or introital stenosis. Our inclusion criteria was original research on primary vaginoplasty. Exclusion criteria included studies that were published in a language other than English, a mixed cohort of cis-gender patients without subgroup analysis, revision vaginoplasty, mixed cohort of revision and primary vaginoplasty without subgroup analysis as well as papers without explicit mention of VS or IS and/or vaginal stricture or stoma stenosis or vaginal narrowing or contracture or scarring. All review articles of surgical outcomes after gender-affirming surgery were evaluated for original article content and references were reviewed for potential sources. The search was translated and ran in four databases including Pubmed, Embase, Scopus, and Cochrane on September 9, 2022. References were also searched for relevant articles with three articles identified in this manner. Stenosis rates were compared with descriptive statistics using SPSS (IBM Corp Released 2022. IBM SPSS Statistics for Macintosh, Version 29.0. Armonk, NY: IBM Corp).

RESULTS

Fifty-nine studies with a cumulative 7338 subjects met inclusion criteria (Fig. 2). VS was not consistently defined in any of the papers evaluated. The overall incidence of VS reported was 428/7338 or 5.83% (range 0%-34.2%). The overall incidence of IS was 231/7338 or 3.15%. Overall incidence of vaginal contracture was 51/7338 or 0.70%. Combining VS with IS and contracture indicates a cumulative incidence of 710/7338 or 9.68%.

Forty-five studies with 7223 cumulative patients described a version of PIV (Fig. 3). These techniques included penile skin only or with the addition of scrotal graft/flap or addition of tunica vaginalis graft or urethral flap. VS occurred 412 times in the PIV group, with a rate of 5.70% (range 0%-34.2%). IS occurred 226 times in the PIV group, with a rate of 3.13%. Vaginal contracture occurred 50 times, with a rate of 0.70%.

Six studies described intestinal vaginoplasty for a cumulative 471 patients. There was 1 report of VS reported in this group by Djordjevic et al regarding their technique of robotic-assisted sigmoid vaginoplasty meaning an incidence rate of 0.2%.[10] IS was documented 22 times with a rate of 22/471 or 4.7%. In intestinal vaginoplasty, researchers typically described stenosis as occurring at the mucocutaneous junction where the intestine is anastomosed to the skin.

Three studies described peritoneal flap vaginoplasty with cumulative 185 patients. VS was described 15 times in this subgroup for a rate of 8.10%. Additionally, novel techniques including autologous buccal micro-mucosa free grafts, autologous fibroblast seeded amnion and autologous oral epithelium have been utilized in crafting neovaginas. Three studies were identified in our review with a cumulative 39 patients and 0 reported incidences of VS. However, 1 patient in Dessy et al, 2014 as noted to have loss of vaginal depth which we included under contracture.[11]

Follow-up is not consistently reported in the literature with some studies reporting median follow-up, others mean follow-up duration, range, and other studies omitting duration of follow-up entirely. Peritoneal flap or graft vaginoplasties accounted for an average 17.8 months of follow-up. Novel techniques including autologous graft documented an average 30.7 months of follow-up. PIV surgeries accounted for an average of 31.5 months of follow-up. Colon vaginoplasties had an average of 22.2 months of follow-up. We computed the average of the overall available mean follow-up data and noted average follow-up to be approximately 28.21 months (Fig. 4). Given limited follow-up data, analysis of Pearson correlation of follow-up duration with VS rate was not statistically significant.

We also analyzed VS by year of publication by grouping results published prior to 2010 and those published after 2010 to reflect a more contemporary experience. We included studies Goddard et al, Lawrence, Rehman et al, Siemssen et al, Karim et al, Eldh et al, Kruk et al, Stein et al, Small, and Huang et al in the prior to 2010 analysis.[12-21] These early studies all describe PIV outcomes with a cumulative 854 patients with 59 cases of VS documented for a rate of 6.91%. The remainder of the studies with a cumulative 6484 patients had a total of 369 cases of VS for a rate of 5.69%, as well as 228 cases of IS for a rate of 3.52% and 51 cases of vaginal contracture for a rate of 0.79%.

Title	Type of Vaginoplasty	N	Vaginal Stenosis	Vaginal Stenosis Rate
Yatsenko et al 2022	Robotic Assisted Sigmoid Vaginoplasty	4	1	25.0
Sachan et al 2022	Laparoscopic pedicled peritoneal flap vaginoplasty	2	0	0.0
Maurer et al 2022	PIV	108		0.0
Gupta et al 2022	PIV	183		0.0
Dy et al 2022	PIV	35	12	34.3
Shoureshi et al 2021	PIV	200	8	4.0
Patel et al 2021	PIV	182	29	15.9
Opsomer et al 2021	PIV	384	18	4.7
Moisés da Silva et al 2021	PIV	214		0.0
Kozato et al 2021	PIV	560	83	14.8
Kim et al 2021	3D laparoscopic rectosigmoid colon vaginoplasty	12		0.0
Dy et al 2021	Robotic-assisted peritoneal flap gender-affirming vaginoplasty	145	7	4.8
Raigosa et al 2020	PIV with clitorolabiaplasty	64	3	4.7
Raigosa et al 2020	PIV	103	3	2.9
Loree et al 2020	PIV	28		0.0
Ferrando et al 2020	PIV	71	3	4.2
Cocci et al 2020	PIV with scrotal graft	102	9	8.8
Watanyusakul 2019	Suporn technique	580		0.0
Trombetta et al 2019	Vaginoplasty with inverted penoscrotal flap and clitoroplasty with urethral f	37	0	0.0
Timpano et al 2019	PIV	60		0.0
Timpano et al 2019	PIV with modifications	55		0.0
Levy et al 2019	PIV	240	5	2.1
Kaushik et al 2019	sigma-lead SRS	386		0.0
Christofari et al 2019	PIV	189	12	6.3
Cocci et al 2019	PIV with M-shape neoclitorolabioplasty	94	6	6.4
Boas et al 2019	PIV	117		0.0
Salgado et al 2018	Sigmoid vaginoplasty	12		0.0
Manrique et al 2018	Pedicle transverse colon flap	15		0.0
Gaither et al 2018	PIV	330	10	3.0
Armstrong et al 2018	Robot assisted penile inversion vaginoplasty	31		0.0
Tabassi et al 2017	Foldback perineoscrotal flap plus penile inversion vaginoplasty	112	7	6.3
Schwarz et al 2017	PIV	174	59	33.9
Papadopulos et al 2017	PIV	40		0.0
Buncamper et al 2016	PIV	475	15	3.2
Bouman et al 2016	Laparoscopic sigmoid vaginoplasty	42		0.0
Franceschelli et al 2015	Double skin flap vaginoplasty	41		0.0
Franceschelli et al 2015	PIV with urethral flap inversion	25		0.0
Falcone et al 2014	PIV	58	9	15.5
Dessy et al 2014	Autologous oral epithelium	6		0.0
Rossi Neto et al 2013	PIV	332	39	11.7
Arcaniolo et al 2013	PIV	213	7	3.3
Amend et al 2013	PIV	24	1	4.2
Pottek et al 2012	PIV	13		0.0
Perez et al 2012	PIV	15	7	46.7
Reed 2011	PIV	250	3	1.2
Wagner et al 2010	PIV	50	5	10.0
Goddard et al 2007	PIV	202	12	5.9
Lawrence 2006	PIV	232	19	8.2
Rehman et al 1999	PIV	28	3	10.7
Siemssen et al 1997	PIV	11	5	45.5
Karim et al 1995	PIV	200		0.0
Eldh et al 1993	PIV	20	3	15.0
Kruk et al 1992	PIV	15	5	33.3
Stein et al 1990	PIV	14	2	14.3
Small 1987	PIV	11	1	9.1
Huang et al 1995	PIV	121	9	7.4
Wei et al 2018	Autologous Buccal Micro-Mucosa Free Graft	9	0	0.0
Seyed-Forootan et al 2018	Autologous Fibroblast-Seeded Amnion	24	0	0.0
Ayyala et al 2022	Robotic Assisted PIV with peritoneal free graft	38	8	21.1

Figure 2. Manuscripts included in analysis and vaginal stenosis rates. (Color version available online.)

DISCUSSION

In our analysis, comprised of 7338 patients, we examined the incidence of VS and IS after vaginoplasty and compared the incidence rates among the most common vaginoplasty techniques. The overall rate of VS, which includes all surgical techniques, was 5.83%. VS was 5.70% and IS was 3.13% in the PIV subgroup. VS occurred at a rate of 0.20% in the intestinal vaginoplasty group and IS was 4.70%.

Our overall rate of VS is lower than others in the literature. A review performed by Manrique et al found an overall incidence of 14% (10%-18%) of stenosis and strictures. Importantly, patient-reported outcomes still show a high satisfaction rate of 93% with overall

Type of Vaginoplasty	Vaginal Stenosis	Introital Stenosis	Contracture
Overall	5.83%	3.15%	0.70%
Penile Inversion	5.70%	3.13%	0.70%
Intestinal	0.20%	4.70%	
Peritoneal	8.10%		
Autologous free grafts	0%		2.50%

Figure 3. Type of vaginoplasty and percentage of vaginal stenosis, introital stenosis, and contracture. (Color version available online.)

Correlations

		Vaginal Stenosis Rate	Follow-Up Duration Mean (Months)
Vaginal Stenosis Rate	Pearson Correlation	1	-.166
	Sig. (2-tailed)		.449
	N	59	23
Follow-Up Duration Mean (Months)	Pearson Correlation	-.166	1
	Sig. (2-tailed)	.449	
	N	23	24

Figure 4. Vaginal stenosis vs mean follow-up duration. (Color version available online.)

results.[22] Our work does include more recent studies as well as was limited to primary vaginoplasty surgeries which may partially explain the discrepancy. In our analysis, we found a slightly higher rate of VS of 6.91% in historical outcomes (published prior to 2010) vs 5.69% in contemporary studies. However, while there has been a small improvement in VS rates recently datasets suggest VS has remained a significant complication despite novel techniques and modern postsurgical care.

Hontscharuk et al, in 2021, reviewed complications of PIV and reported rates of VS from 0% to 12% and IS from 2.5% to 15%. They commented on the role that local tissue ischemia and postoperative infection may play in stenosis. They also reviewed "loss of vaginal depth," to occur ranging from 0% to 12%, which here was attempted to be captured through "contracture."[23]

When comparing penile inversion techniques to intestinal vaginoplasty, the incidence of overall VS was 5.70% in penile vaginoplasty, compared to 0.20% in primary intestinal vaginoplasty. However, the rate of IS was relatively similar between PIV and intestinal vaginoplasty groups at 3.13% and 4.7%, respectively, with a slightly higher rate of IS in the intestinal vaginoplasty subgroup.

We note that follow-up documentation is inconsistent in the literature and ranged greatly from none to over 8 years of follow-up reported. Overall average follow-up was approximately 28.21 months. Consistent with the larger number of studies on PIV procedures, this average is consistent with our subgroup analysis in which PIV surgeries follow-up was on average 31.5 months. This is similar to autologous graft techniques at 30.7 months. Colon and peritoneal vaginoplasties accounted for 22.2 months and 17.8 months of follow-up respectively, which may reflect that these surgical techniques are newer in comparison to PIV with a smaller pool of literature. One might suspect vaginal and introital stenosis rates to be lower in studies with shorter follow-up duration however our findings suggest there are other factors at play. For example, colon vaginoplasties with follow-up at 22.2 months had VS rate of 0.20% as compared to PIV at 5.7% at 31.5 months average follow-up. However, we also found a VS rate of 8.10% in peritoneal vaginoplasty which had the shortest overall follow-up duration. In addition to inconsistent follow-up reporting, it is unclear to the extent patients have been lost to follow-up. This may contribute to under-reporting of stenosis rates.

In our experience, stenosis occurs in intestinal vaginoplasty at the anastomotic site where the bowel meets the skin. This is where patients must dilate past to maintain patency. This is typically the area farthest from the vascular pedicle and therefore the most ischemic and on the most tension. The similar rate of stenosis at the introitus may be in part due to the similar need for consistent dilation at this area and the multiple suture lines necessary at this anastomosis in both groups. Anecdotally, we have found intestinal IS to be easier to treat as opposed to PIV where the entire vaginal vault needs to be corrected.

Buncamper et al reviewed PIV with and without additional full-thickness skin graft and did not find a significant difference in "shrinkage," and they noted that the largest reduction in vaginal depth tends to occur in the first 3 weeks after surgery.[24]

Many writers attributed loss of vaginal length and stenosis to nonadherence to a postoperative dilation regimen or high-tone pelvic floor.[3] We found wide variation in postoperative cares and dilation regiments. Most described protocols included a vaginal packing in place in the initial postoperative period, usually around 5-7 days. After removal of the vaginal packing, many authors described instructing patients to dilate the neovagina regularly. This included using silicone dilators from 5 minutes to 3 hours a day for a period of 3 months.[25] Dy et al, 2021 report their protocol: patients are on bed rest

for 1 day postoperatively with gradual mobilization and begin dilation regimen on postoperative day 5 after removal of vaginal packing. Patient starts dilation with a 32 or 35 mm dilator and discharges home on regimen of dilation four times a day with progression to a 38 mm dilator with depth of 14.5 cm as able.[2] In the cohort described by Christofari et al, patients had a soft vaginal shaper in place for 24 hours a day until complete healing was attained. They recommended soft dilation if patient had incomplete healing and hard dilation in situations with stenosis or shorter-length dilation.[26] Wagner et al report postoperative cares of vaginal tamponade with rolled soft compresses and antibiotic maintained in place for 7 days, followed by a vaginal dilation system for 10 days and then manual dilation with vibrators for a total of 7 weeks.[27] Dilation was noted to be able to be reduced or ceased if patient was engaging in receptive vaginal penetration in many reports.[28-31]

Pelvic floor physical therapy has become part of the peri-operative protocol at some centers. Patients see pelvic floor physical therapists preoperatively and to continue to work with them postoperatively on dilation and pelvic floor relaxation. In one retrospective study of gender-diverse patients undergoing vaginoplasty, 42% of patients evaluated by pelvic floor physical therapists had pelvic floor dysfunction. This study found that 69% patients with pre-existing pelvic floor dysfunction had resolution by the first postoperative visit and that 89% of all referred patients were successfully dilating the neovagina at 3 months.[32]

A retrospective chart review on all transfeminine patients who underwent gender-affirming vaginoplasty between January 2016 and September 2020, Kozato et al identified 147 patients with 209 revisions, suggesting that some patients had to undergo multiple revision procedures. As seen in several other studies, we also noted performing 19 revisions on 17 patients who had undergone primary vaginoplasty at other institutions. Eighty-three patients in total underwent 100 procedures for VS and 47 patients underwent 50 revision procedures for IS or skin bridges. In agreement with anecdotal findings and supported in the literature, the majority, 73.5%, of those who underwent revision for VS had difficulty dilating in the postoperative period. Diabetes mellitus, history of keloids, or history of smoking were not strongly associated with VS.[33]

This study is not without limitations. There is no standard definition of vaginal or IS. It is therefore likely that studies included in our analysis defined stenosis differently. Ultimately, individual clinicians likely have varying criteria for stenosis. Most studies reported VS or IS without stating the criteria or the change in anatomy that led to this diagnosis. Often, the rate of VS/IS was discussed in association with subsequent management, if needed. We may then glean that reported stenosis rates likely reflect detected clinically significant stenosis. Many studies could not be included because they included cis- and transgender patients without subgroup analysis. Some large cohorts such as that described by Wangjiraniran et al in 2015, with ~3000 patients, were not able to be included as they did not report on VS.[34] Despite our best efforts to craft an inclusive search strategy, there are also likely studies that we did not identify. Additionally, we limited the review to primary vaginoplasty surgeries. The historic and on-going practice of many providers offering PIV as primary surgery and limiting use of intestinal or peritoneal vaginoplasty to revision surgeries is evident in our review.

Additionally, more centers that specialize in transgender care are emerging. This allows better preoperative patient optimization and education. Patients treated by centers specializing in transgender care are also likely to have better follow-up and continued education, minimizing complications including VS. Several surgeons have investigated the learning curve related to gender-affirming vaginoplasty. For example, Ferrando et al reported that surgeries after the first 50 cases had lower surgical times, lower urinary stream abnormalities, reduced IS and rates of revision surgery, even when controlled for age, diabetes status, and history of smoking.[35] As centers gain more experience, we may see reduced incidence of complications such as VS.

It is also important to consider that VS may occur at any point after surgery so it is unclear if longer-term follow-up will reveal an overall higher incidence of VS. Future directions include a prospective study analyzing VS using a standardized definition.

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.urology.2024.02.005.

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