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PII: S0090-4295(21)00471-4
DOI: <https://doi.org/10.1016/j.urology.2021.05.045>
Reference: URL 22978

To appear in: *Urology*

Received date: 8 March 2021
Revised date: 10 May 2021
Accepted date: 12 May 2021

Please cite this article as: Matthew R. Beamer , Jessica Schardein , Nabeel Shakir , Min Suk Jun , Rachel Bluebond-Langner , Lee C. Zhao , Dmitriy Nikolavsky , One or Two Stage Buccal Augmented Urethroplasty has a High Success Rate in Treating Post Phalloplasty Anastomotic Urethral Stricture, *Urology* (2021), doi: <https://doi.org/10.1016/j.urology.2021.05.045>



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ONE OR TWO STAGE BUCCAL AUGMENTED URETHROPLASTY HAS A HIGH SUCCESS RATE IN TREATING POST PHALLOPLASTY ANASTOMOTIC URETHRAL STRICTURE

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Key words: anastomotic stricture, urethroplasty, neophallus, phalloplasty, buccal mucosa graft

Funding: No funding was received.

Conflicts of Interest: The authors declare that they have no conflicts of interest.

Abstract Word Count: 237

Manuscript Word Count: 2437

ABSTRACT:

Objective: To describe the outcomes of single-stage and staged repairs in properly selected patients with phalloplasty anastomotic strictures.

Methods: A bi-institutional retrospective review was performed of all patients who underwent anastomotic stricture repairs between 7/2014-8/2020. Those who had prior augmented urethroplasties or poorly vascularized tissue underwent two-stage repairs (Group-2), all others underwent single-stage repair with a double-face (dorsal inlay and ventral onlay) buccal mucosal graft urethroplasty (Group-1). Postoperatively, urethral patency and patient reported outcome measures (PROMs) were assessed.

Results: Twenty-three patients with anastomotic strictures were identified. Fourteen patients met inclusion criteria and had 1-year follow-up (9 in Group-1; 5 in Group-2). Nine patients (64%) had prior failed interventions (56% Group-1; 80% Group-2). At a mean follow-up of 33.9 (Group-1) and 35.2 months (Group-2) there were two stricture recurrences in Group-1 (22%) and none in Group-2. PROMs were completed by 12 patients. All patients reported the ability to void standing. Post-void dribbling was present in the majority of patients (7/7 Group-1; 2/4 in Group-2). Mean IPSS was 3.9 (0-14) for Group-1 and 1 (0-3) for Group-2. All reported at least a moderate improvement in their condition on GRA (Group-1 +3 71%, +2 29%; Group-2 +3 100%).

Conclusion: Single-stage repairs are feasible for patients with anastomotic strictures who have well vascularized tissue and no prior single-stage buccal mucosa augmented urethroplasty failures. Staged repairs are feasible for patients with poor tissue quality. Proper patient selection is important for successful reconstruction.

INTRODUCTION:

Previous reports estimate that 355 individuals per 100,000 experience gender dysphoria to various degrees, and approximately 9.8 per 100,000 seek some form of affirmation therapy.¹ Up to 98% of transgender men cite voiding from a standing position as an important goal and many undergo construction of a neourethra to achieve this.²⁻⁵ However, complication rates of various phalloplasty techniques are high with up to 73% of patients requiring revision surgery.⁶ While fistulas are the most common urologic complication after a phalloplasty, urethral strictures occur in 25% to 58% of patients.⁷⁻¹⁰ Specifically, strictures at the anastomotic urethra between the *pars fixa* (perineal urethra) and *pars pendulans* (penile urethra) are the most common, accounting for 41% of all neophallus strictures.^{8, 11} This is likely due to poor blood flow at the anastomotic site leading to ischemia and contracture of the neourethral tissue during healing.^{10, 12,}

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Treatment options for anastomotic strictures included endoscopic management with dilation or direct visualization internal urethrotomy, excision and primary anastomosis, free graft urethroplasty, pedicle flap urethroplasty, and 2-stage urethroplasty.^{7, 11} Stricture repair in a neophallus is challenging due to the lack of corpus spongiosum and an unreliable blood supply.^{9,}
¹⁴ Endoscopic repair has been shown to have failure rates of up to 88%.^{9, 13, 14} There are limited series in the literature citing various open revision urethroplasty techniques in patients after phalloplasty with failure rates ranging from 30-62%.^{11, 15}

A staged repair has the highest reported success rate but, is less desirable for many patients due to the need for two procedures and prolonged time to treatment completion.¹¹ We hypothesized that patients could be risk stratified to be offered a single-stage or 2-stage repair to

optimize outcomes. We aim to describe a treatment algorithm that limits multiple procedures while also leading to high patient satisfaction and low rates of recurrence.

METHODS:

Patient Selection:

After an institutional board review approval (IRB# 1553078-1), we performed a retrospective chart review of all patients who underwent stricture repair following creation of a neophallus between 7/2014 and 8/2020 at two referral centers for reconstruction of complications following gender affirmation surgery. All patients with anastomotic strictures of neophallus who had undergone either a single-stage double-face (dorsal inlay and ventral onlay) buccal mucosal graft (BMG) urethroplasty or 2-stage urethroplasty were included. Patient with less than 1-year follow-up were excluded. Preoperatively, all patients were evaluated via cystoscopy, retrograde urethrogram (RUG) and/or voiding cystourethrogram (VCUG) to confirm presence of anastomotic strictures. Patient demographics, neophallus type, stricture length, and prior treatments were recorded. Those patients who had previously undergone a failed augmented urethroplasty or had poorly vascularized tissue, underwent a two-stage repair (Group-2). All others underwent a single-stage repair (Group-1).

Surgical Repair:

All patients underwent standard pre-operative consultation where informed consent was obtained. Preoperative antibiotics were administered, and the procedure was performed under general anesthesia. Patients were offered either a single-stage procedure (Group-1) or a 2-stage procedure (Group-2) based on availability of local tissue, per previously described algorithm.¹⁶

Those who had relatively healthy local tissue available for mobilization (i.e., gracilis flap placed during the initial phalloplasty¹⁷ or presence of a well perfused labial fat pad), no concurrent perineal abscess and no history of prior failed augmented urethroplasty were offered a single-stage procedure (Group-1). Patients with local infection, paucity of tissue for mobilization or those with prior failed augmented urethroplasty were offered staged technique (Group-2)

Patients in Group-1 underwent a single-stage double-face (dorsal inlay and ventral onlay) buccal mucosal graft (BMG) urethroplasty as previously described (Figure 1).¹⁸⁻²⁰ In detail, *pars fixa* was exposed through a single perineal incision and dissection followed antegrade to expose the ventral aspect of proximal *pars pendulans*. If needed, for better visualization of proximal *pars pendulans* the perineal incision was advanced 1-2 centimeters into the posterior neoscrotum, and a perineal Bookwalter fitted with a small Richardson blade was used to expose the area of the anastomosis. A ventral sagittal urethrotomy followed by a dorsal urethrotomy was made and carried out 1-2 cm beyond the stenotic area. An Asopa-type BMG inlay was placed dorsally, quilted in place and anastomosed to the edges of the dorsal urethrotomy. A separate ventral onlay BMG was also secured with absorbable sutures to the edges of the ventral urethrotomy. Due to the lack of corpus spongiosum it is often necessary to mobilize well-perfused local tissue such as a labial fat pad (analogous to a Martius flap) to provide vascular graft bed for the BMG, as previously demonstrated by Schardein et al.¹⁹

A 2-stage repair was performed by creating an excision of the stenotic urethra, augmenting the urethral plate with a 4-cm wide BMG, and then performing tubularization over a foley catheter during a second stage procedure at 3-6 months as described elsewhere (Figure 2).¹¹

A subset of patients in both the single-stage and 2-stage groups underwent evaluation with intraoperative perfusion imaging to supplement evaluation of local tissue quality (Figure 1E; Figure 2E).

Follow-up:

Patients after a first-stage procedure returned on postoperative day 7 for catheter removal and trial of void. Patients after a single-stage urethroplasty or after a second-stage urethroplasty (tubularization) were seen three weeks postoperatively for retrograde urethrogram and foley catheter removal. Patients then were followed at 4 to 6-month intervals for the first year and yearly afterwards. For patients who traveled a considerable distance for their initial surgery an option of in-person and telemedicine follow-up visits were offered. Patients were assessed for evidence of recurrence and need for subsequent procedures. When possible, a post-operative PVR and Uroflow was obtained.

Patient reported outcome measures:

Two validated questionnaires were given to patients at follow-up to assess urinary symptoms, including the International Prostate Symptom Score (IPSS) and the Urethral Stricture Surgery Patient Reported Outcome Measures (USS PROM).^{21, 22} The validated Global Response Assessment (GRA) was used to evaluate patients' overall perception of improvement following their procedure.²³ The GRA scores range from -3 (markedly worse) to +3 (markedly improved). An additional set of non-validated questions was used to assess overall satisfaction and outcomes specific to neophallus stricture repair including questions on standing to void, post-void dribbling or urinary spraying, and penile sensation.

RESULTS:

Baseline Characteristics:

Between 7/2014 and 8/2020 82 patients presented for urethral reconstruction after phalloplasty, all of which were referrals from outside facilities. Of these patients 26 (32%) had an anastomotic stricture between *pars fixa* and *pars pendulans*, which was reconstructed based on patient goals of standing micturition. A total of 19 (73%) underwent a single-stage repair (Group-1) and 7 (27%) underwent a two-stage repair (Group-2). Two patients in Group-2 had not yet completed both stages and were excluded. One patient treated with an excision and primary anastomosis (EPA) and was excluded. An additional nine patients from Group-1 were excluded due to insufficient follow up (4 lost to follow up and 5 <12 months since the surgery). The remaining 9 patients in Group-1 and 5 patients in Group-2 had follow-up for 12 months or more, meeting inclusion criteria for the study.

The median age was 35 (24-54) for Group-1 and 29 (23-38) for Group-2 (Table 1). All patients were transgender men who underwent phalloplasty creation as part of gender affirmation surgery. All patients had previously undergone a radial forearm free flap phalloplasty (RFFP). Among them 2 (22%) of the patients in Group-1 had undergone a staged RFFP, where a urethra was created first at the forearm site using a “prelamination” technique.²⁴ All remaining phalloplasties were performed as a single-stage “tube-within-a-tube” technique.^{10, 25} Patient phalloplasty completion to stricture repair mean time was 8.1 (3-28) months for Group-1 and 16 (10-22) months for Group-2 (Table 1).

Mean stricture length was 3.4 (2-6) centimeters and 2.0 (1-4) centimeters in Group-1 and Group-2, respectively. Half the patients (56%) in Group-1 had undergone prior treatment of their

stricture (3 Endoscopic, 1 Anastomotic Urethroplasty, 1 Both). No patients in Group-1 had previously undergone an augmented urethroplasty. In Group-2, prior failed procedures included augmented urethroplasty in 3 (60%) patients, prior EPA in one patient, and failed endoscopic intervention in 2 (40%) patients. One patient had no prior intervention but had an active perineal infection. The majority of patients presented with additional concurrent post-phalloplasty complications (Group-1 – 89%; Group 2 – 75%) including fistulas, retained vaginal remnant/mucocele, loculated infections and additional strictures at other sites (Table 1).²⁶⁻²⁸

Single-stage Surgical Repair:

Of the 9 patients who underwent a single-stage repair 8 of the patients underwent simultaneous surgical correction of additional pathology at the time of anastomotic stricture repair. These included treatment of concurrent meatal stenosis (4), fistula (2), and/or retained vaginal remnant/mucocele (2; Table 1).

At a mean follow up of 33.9 (12-60) months 2/9 patients had stricture recurrence (Table 2). Of those two patients, one elected to undergo a perineal urethrostomy. The second patient initially underwent endoscopic intervention but ultimately underwent a staged urethroplasty. No Clavien II-V complications were experienced. Of the 10 patients with who were excluded from the study there were no stricture recurrences at last known follow-up.

Patient-reported outcome measures were collected for the 7 patients who did not require additional surgical intervention for a failed stricture repair at their last known follow-up (Table 2). They reported a mean IPSS of 3.6/35 and mean USS PROM of 1.4/24. All patients reported that they were satisfied with the procedure and that they would recommend the procedure to a friend. Post-void dribbling was experienced by all patients and 5 (63%) reported spraying of

urine. Two patients did report a poor cosmetic outcome following the procedure and two reported minor residual pain. However, all 8 patients reported overall improvement in their condition on GRA (5 Markedly improved, 3 Moderately improvement).

Two-Stage Surgical Repair:

Five patients were treated with a two-stage repair. Four of the 5 patients had associated complications on presentation and 3/5 underwent concurrent surgical intervention at the time of stricture repair. These included: cystolitholapaxy (1); excision of vaginal remnant cavity (2), fistula repair (2), and treatment of a stricture at an additional site (1). Mean time between stage 1 and 2 was 5.8 (4.6-6.3) months.

At a mean follow-up of 35.2 (17-66) months, no patients had recurrence. There were no Clavien II-V complications. All patients had telemedical follow-up and 4 patients were willing to complete questionnaires. Mean IPSS score was 1/35 and mean USS PROM score was 1.7/24. All patients achieved the ability to void in a standing position. One patient reported a poor cosmetic outcome of the original phalloplasty and underwent a glansplasty. No patients reported spraying of urine and 2/4 reported post-void dribbling. None of the patients reported residual post-operative pain and all had preserved penile sensation. All patients were overall satisfied with the procedure and reported that they would recommend it. On GRA, all patients rated their condition as markedly improved (+3).

DISCUSSION:

Here we have described an effective treatment algorithm for patients with anastomotic strictures following phalloplasty. The number of patients undergoing gender affirmation surgery

has been increasing every year.²⁹ There are various phalloplasty techniques available with complications as high as 73%.⁶ Among other reported complications, urethral strictures occur in up to 50% of these patients, with anastomotic strictures being most common.⁷⁻¹⁰

Despite the frequency of anastomotic strictures, publications describing repair of post-phalloplasty anastomotic strictures are limited. In a retrospective review of a heterogeneous post-neophallus stricture population, Lumen et al. shows that a two-stage repair has a 70% success rate, higher than any other described method.¹¹ However, this option requires two surgeries and increased time to definitive treatment.

There are only a few papers describing the use single-stage repair in this setting.^{8, 9, 15} Furthermore, failure rates for specific single-stage techniques are difficult to elucidate due to small sample sizes and the heterogeneous nature of both the treatment type and stricture location in many previous publications.^{8, 9} While EPA is highly effective in cis-gender men, Verla et al. recently reported a 49% failure at 1 year and a 57% (25/44) failure rate at a mean of 5 years follow-up for patients with anastomotic strictures treated with EPA.³⁰ Similarly, Pariser et al. reports at 50% failure rate (5/10 patients) with a ventral BMG onlay procedure at a mean follow-up of 9.5 months.¹⁵ The use of a double-faced BMG urethroplasty was originally described in 2008 by Palminteri et al.²⁰ The use of this technique in post-neophallous anastomotic strictures was more recently described.¹⁹

Here we report an 80% success rate for single-staged procedures, a higher rate than is found elsewhere in the literature in this population. Furthermore, in patients deemed poor candidates for a single-stage repair and treated with the two-stage approach, we report a 0% failure rate. One of the single-stage urethroplasty failure patients had originally undergone neophallus creation with osteofasciocutaneous forearm flap, prior history of perineal abscess,

and was concurrently treated for a distal 5cm stricture, arguing that he may have been better served initially with a two-stage repair.

Patient-reported outcome measures are not commonly described in similar studies but are important to consider for a quality-of-life intervention. While many patients reported post-void dribble or spraying of urine (a problem likely related to meatal construction), all patients reported satisfaction with the procedure and considerable improvement in their condition. When questioned, even the two treatment failure patients were satisfied with the end result.

This study is limited by the retrospective design. Based on the nature of the disease, patients were very heterogeneous on presentation. The unexplained presence of urine spraying exclusively in patients treated with a single-stage technique (63%) and not in patients after staged urethroplasty is unlikely due to the type of anastomotic reconstruction, and the difference is expected to be eliminated in a larger cohort. While many studies in the field are of comparable size, the study is limited by a small number of patients. A number of the questionnaires utilized in this study have not been validated for this specific patient population. The IPSS is widely used in evaluation of lower urinary tract symptoms but is not validated following stricture repair. Furthermore, the UPSS PROM is validated following urethroplasties but not in the neophallus population. While perfusion imaging was used in a subset of patients, the decision to proceed with a two-stage repair was often made intra-operatively based on the surgeon's subjective assessment of the tissue quality. Future studies may examine the standardized use of tissue perfusion imaging or other objective measure of tissue quality to provide reproducibility across centers.

CONCLUSION:

We introduce a treatment algorithm in an area with limited research. Single-stage repairs are feasible for patients with anastomotic strictures who have well vascularized tissue and no prior augmented urethroplasty failures. Staged repairs are feasible for patients with poor tissue quality. Proper patient selection is important for successful reconstruction and leads to low recurrence rates with high patient satisfaction.

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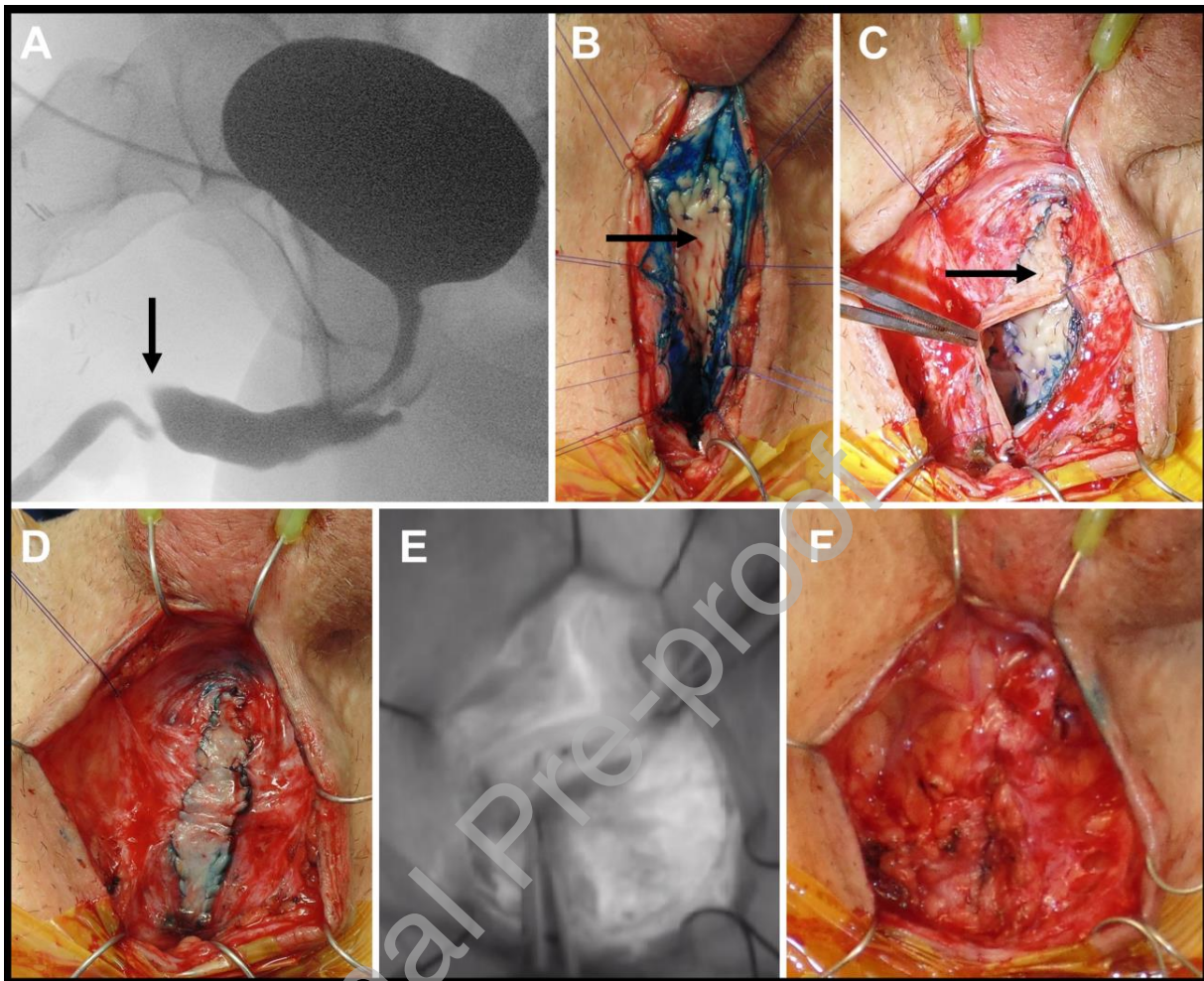


Figure 1: Single-Stage Repair

A) A preoperative retrograde urethrogram shows an anastomotic stricture (arrow) at the junction between the pars fixa and pars pendulans. B) Through a perineal incision the anastomotic stricture is exposed. A dorsal on-lay graft is secured (arrow). C) A second buccal mucosal graft is secured as a ventral in-lay (arrow). D) The urethra is intact with the ventral and dorsal grafts secured. E) Perfusion imaging is performed by injecting 3mL of a diluted indocyanine green (ICG) solution (25mg in 10mL normal saline) intravenously followed by a 10mL normal saline flush. Imaging was then performed with a hand-held SPY Portable Handheld Imager (SPY-PHI,

Stryker) device and shows adequate blood flow to the periurethral tissue. F) The perineal tissue is closed in multiple layers over the graft to prevent future fistula formation.

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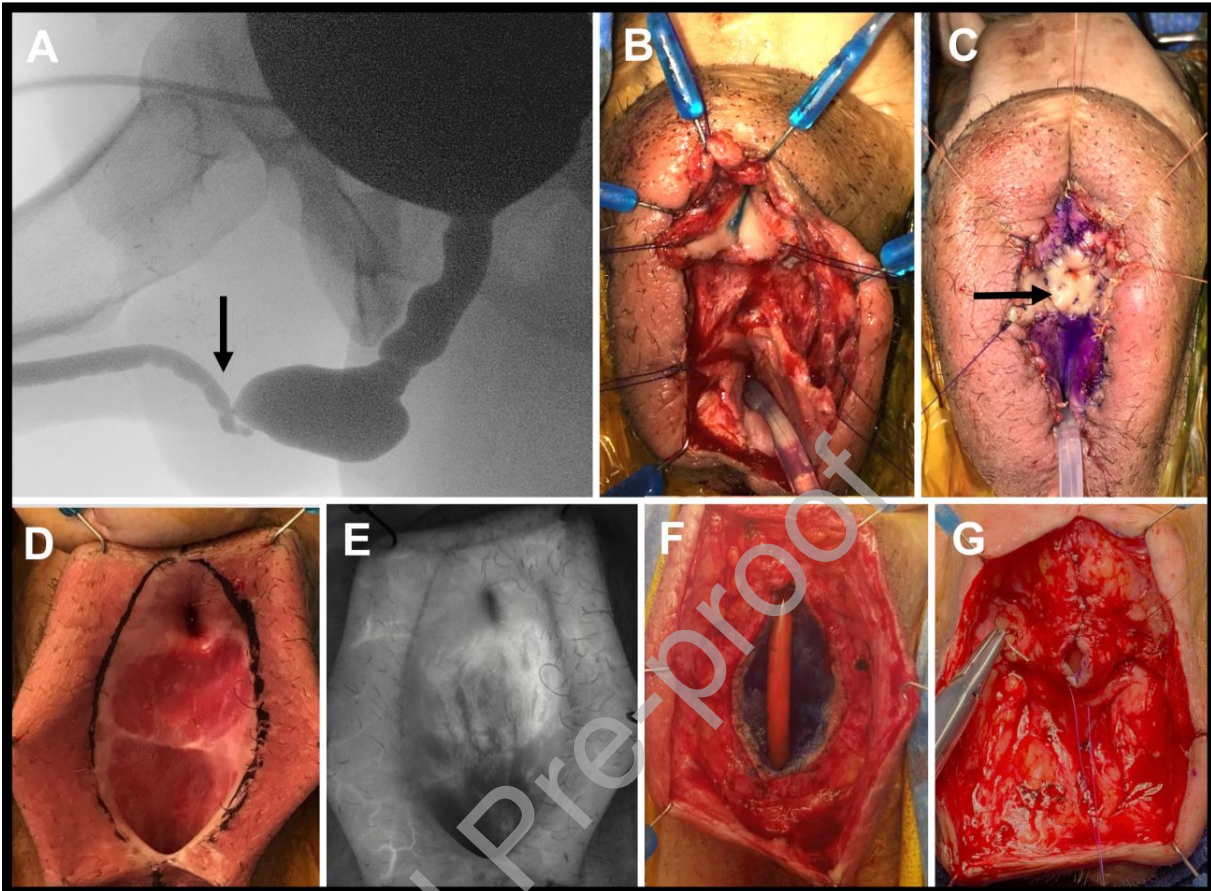


Figure 2: Two-Stage Repair

A) A preoperative retrograde urethrogram shows an anastomotic stricture (arrow) at the junction between the pars fixa and pars pendulans. B) Through a perineal incision the anastomotic stricture is exposed. A Foley catheter is placed through the pars fixa and native urethra. C) A dorsal buccal mucosal graft is placed (arrow). D) Three to six months following the first stage the patient returns to the OR and the buccal mucosal graft is exposed. E) Perfusion imaging is performed by injecting 3mL of a diluted indocyanine green (ICG) solution (25mg in 10mL normal saline) intravenously followed by a 10mL normal saline flush. Imaging was then performed with a hand-held SPY Portable Handheld Imager (SPY-PHI, Stryker) device and shows adequate blood flow to the periurethral tissue. F) The urethral tissue is freed from the

subcutaneous tissue and a foley catheter is placed through the entire urethra. G) The graft is tubularized over the foley catheter and overlaying tissue is closed in multiple layers.

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Table 1: Patient and Surgical Characteristics

	Group 1 Single-Stage	Group 2 Two-Stage
Total Patients	9	5
Mean Age (range)	35 (24-54)	29 (23-38)
Mean BMI (range)	25.9 (17.9-36.1)	31.7 (25.0 - 38.4)
Race		
<i>Caucasian</i>	9 (100%)	4 (80%)
<i>African American</i>	0 (0%)	0 (0%)
<i>Other</i>	0 (0%)	1 (20%)
Smoking History	4 (44%)	0 (0%)
Phalloplasty Type		
<i>Radial Forearm Free Flap (RFFF)</i>	9 (100%)	5 (100%)
<i>Anterior Lateral Thigh (ATL)</i>	0 (0%)	0 (0%)
Staged Prelamination	2 (22%)	0 (0%)
Prior Treatment of Strictures		
<i>Dilation</i>	4 (44%)	2 (40%)
<i>DIVU</i>	1 (11%)	0 (0%)
<i>EPA</i>	1 (11%)	1 (20%)
<i>Stricturoplasty</i>	1 (11%)	0 (0%)
<i>BMG urethroplasty</i>	0 (0%)	2 (40%)
<i>Skin Graft urethroplasty</i>	0 (0%)	1 (20%)
Length of Stricture (cm, range)	3.4 (2-6)	2.0 (1-4)
Associated Pathology		
<i>Meatal Stenosis</i>	4 (44%)	1 (20%)
<i>Vaginal Remnant</i>	3 (33%)	4 (80%)
<i>Abscess</i>	1 (11%)	1 (20%)
<i>Urethral-Cutaneous Fistula</i>	4 (44%)	1 (20%)
<i>Fistula to Vaginal Remnant/Mucocele</i>	1 (11%)	2 (40%)
<i>Stricture other locations</i>	2 (22%)	1 (20%)
<i>IPP Infection</i>	1 (11%)	0 (0%)
Time from phalloplasty (months, range)	8.1 (3 – 28)	16 (10-22)
Concurrent Procedure Performed		
<i>Fistula Repair</i>	2 (22%)	2 (40%)
<i>Excision Vaginal Remnant/Mucocele</i>	2 (22%)	2 (40%)
<i>Meatoplasty</i>	4 (44%)	0 (0%)
<i>Urethroplasty, other location</i>	2 (22%)	1 (20%)
<i>Cystolitholapaxy</i>	0 (0%)	1 (20%)
<i>Gracilis Flap</i>	2 (22%)	0 (0%)

Table 2: Outcomes

	Group 1 Single-Stage n=9	Group 2 Two-Stage n=5
Mean follow-up (mn; range)	33.9 (12-60)	35.2 (17-66)
Recurrent Stricture	2 (22%)	0 (0%)
Peak uroflow (mL/s; range)	22.8 (10-39; n=6)	26.1 (15-48; n=3)
PVR (mL; range)	75 (0-190; n=6)	24 (0-71; n=3)
Patient Reported Outcomes	n = 7	n = 4
IPSS (range)	3.9 (0-14)	1 (0-3)
IPSS QOL (range)	13 (0-3)	0 (0)
USS PROM (range)	4.7 (1-12)	1.7 (1-2)
USS PROM QOL (range)	0.7 (0-4)	0 (0)
GRA		
+2 (<i>moderately improved</i>)	2 (29%)	0 (0%)
+3 (<i>markedly improved</i>)	5 (71%)	4 (100%)
Satisfied w/ procedure	7 (100%)	4 (100%)
Recommend to friend	7 (100%)	4 (100%)
Weak stream	0 (0%)	0 (0%)
Spraying of urine	5 (71%)	0 (0%)
Post-void dribbling	7 (100%)	2 (50%)
Stand to urinate	7 (100%)	4 (100%)
Poor cosmetic outcome	2 (29%)	1 (33%)
Pain		
Mouth	1 (14%)	0 (0%)
Perineum	0 (0%)	0 (0%)
Penis	1 (14%)	0 (0%)
Penile sensation	6 (86%)	4 (100%)