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Graft Plus Fasciocutaneous Penile Flap for Nearly or Completely Obliterated Long Bulbar and Penobulbar Strictures

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Abstract

Background: Graft plus flap urethroplasty is gaining momentum in patients with nearly or completely obliterated urethral strictures, in whom staged procedures or perineal urethrostomy is the only possible alternative. However, graft plus flap urethroplasty is mainly adopted for strictures involving the penile urethra.

Objective: To report our experience on graft plus flap urethroplasty for bulbar and penobulbar reconstruction.

Design, setting, and participants: Between January 2014 and June 2020, patients with nearly or completely obliterated long (>4 cm) bulbar or penobulbar strictures, who required graft plus flap urethroplasty, were considered for this study.

Surgical procedure: The bulbar and the penile urethra were accessed through a perineal incision and penile invagination when required. Grafts were harvested from cheek, lingual, or preputial skin and quilted over the corpora to reconstruct the dorsal plate of the neourethra. The fasciocutaneous penile flap recreated the ventral plate of the neourethra. The corpus spongiosum was flapped over the neourethra to prevent the formation of diverticula.

Measurements: Any need for instrumentation after surgery was defined as the primary failure. Obstructive symptoms or maximum flow rate (Qmax) below 10 ml/s, with or without a need for instrumentation, was defined as a secondary failure.

Results and limitations: We identified 15 patients who met the inclusion criteria. The median stricture length was 7 cm (interquartile range [IQR] 5–8 cm). The inner cheek was the preferred site for graft harvesting (53.3%). No perioperative complication of Clavien-Dindo grade ≥III were recorded in the first 30 postoperative days. The median Qmax at catheter removal was 23 ml/min (IQR 21.5–26 ml/min). The median follow-up was 25 mo (IQR 10–30 mo). The primary success rate was...
86.7% (13/15) and the secondary success rate was 73.3% (11/15). Post-traumatic strictures represent a contraindication for this technique.

**Conclusions:** In referral centers, graft plus flap urethroplasty represents a feasible option for patients with nearly or completely obliterated long (>4 cm) strictures. Our study demonstrated that this option is also feasible for strictures involving mainly the bulbar urethra.

**Patient summary:** Perineal urethrostomy should be considered as the last option in patients with a nearly or completely obliterated bulbar urethral stricture. Nowadays, graft plus fasciocutaneous penile flap augmentation enriched our armamentarium of bulbar urethra reconstruction.

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1. **Introduction**

The complexity of urethroplasty is directly proportional to the length of the stricture and inversely proportional to the caliber of the urethral lumen. Thus, when extensive segments of the urethra are severely compromised and the existing urethral plate is unsalvageable and completely obliterated, urethroplasty becomes extremely challenging. Options for these patients include tubularized pedicle skin flap [1], double face buccal mucosa grafting [2], staged procedures, or definitive perineal urethrostomy [3]. However, all these techniques present limitations and contraindications [4]. A tubularized pedicle skin flap relies on a single source of blood supply with non-negligible chances of ischemia, it is associated with a high risk of complications [5], and it requires a 3-cm-wide skin flap, which is not easily harvested in circumcised patients. Double face grafting requires a large amount of buccal mucosa, which is frequently unavailable in redo cases; moreover, the grafts need healthy edges of an existing urethral plate to be anastomosed, which is by definition absent in an obliterator stricture. Finally, multistage or definitive perineal urethrostomy is associated with high morbidity and considerable discomfort for the patient [6]. Over a time of 4 yr, we have refined our technique of graft plus flap substitution urethroplasty for patients with long (>4 cm) segments of urethral loss involving the bulbar and/or the penile urethra. This technique represents a rescue solution for patients with unfavorable features such as previous failed urethroplasty, infection-induced stricture, and scarred and ischemic urethra, in whom single graft or flap augmentation urethroplasty is likely to fail. However, graft plus flap urethroplasty has been adopted mainly for penile urethral reconstruction, and not for bulbar strictures. According to the principles of this technique, the neo urethral lumen is recreated using a graft, either from oral mucosa or from preputial penile skin, and a fasciocutaneous flap from the penile skin. We developed this approach for patients with a bulbar stricture with variable involvement of the penile urethra. The exposure of the entire anterior urethra was provided by the invagination of the penis through a single perineal incision, which avoids scrotal splitting. In the current study, we described our technique and reported our surgical outcomes.

2. **Patients and methods**

2.1. **Patient population**

From January 2014 to June 2021, we performed 15 graft plus flap urethroplasties in 15 patients presenting with long segments of urethral loss. In this series, strictures always involved the bulbar urethra, with variable extension to the penile urethra.

All patients were evaluated preoperatively with physical examination to assess the status of the external genitalia, the status of the penile and preputial skin, and the status of the buccal or lingual mucosa. All patients were investigated with uroflowmetry, retrograde urethrography, and urethroscopy with a small caliber ureteroscope (4.5/6.5Ch) to assess the severity of the stricture [7]. All patients signed an informed consent form.

2.2. **Harvesting flap plus graft**

Fasciocutaneous penile flaps were variably harvested from the prepuce or distal penile skin. The flap was generally 10–12 cm in length depending on penile circumference and skin laxity. When the prepuce was intact, we preferably harvested a foreskin flap [8]. When the prepuce was missing because of previous circumcision or balanitis xerotica obliterans (Bxo) involvement, the circular fasciocutaneous penile flap was harvested from distal penile uncompromised skin [9]. In patients with extensive segments of urethral loss (above 12 cm), we harvested a Q-flap [10]. Flap width was approximately 1.2–1.5 cm. The graft was usually harvested from the oral mucosa of the cheek or from the tongue when both cheeks were utilized previously [11]. We used the inner layer of preputial skin as the last resource for grafting. Graft width was 1.5 cm, while graft length was adjusted according to stricture length and conformation of the mouth, with a maximal length of 7.5–8 cm per cheek. The objective was to achieve a total circumference of 3 cm for the neourethra, which corresponds to approximately 28.6Ch of urethral caliper.

2.3. **Surgical technique**

Under general anesthesia, patients were positioned in the social lithotomy position [4]. Pneumatic compression pumps were used to reduce the risk of deep vein thrombosis. Perineal vertical incision was taken, and tissue was opened using sharp dissection. The bulbar urethra was mobilized on one side (left patient side for right-handed surgeon) according to the Kulkarni et al.’s [12] technique, preserving the vascular supply of the bulbospongiosum muscle and the urethra on the opposite side. In those cases where the stricture involved the penile urethra, the penis was invaginated through the scrotum in order to have a full exposure of the anterior urethra [13]. Dorsal urethrotomy was performed, and the urethra was opened fully across the stricture. The portion of
the urethra with complete loss of the native urethral plate was marked. A buccal or skin graft was placed dorsally and quilted to the corpora to reconstruct the dorsal plate of the neourethra exactly in that segment of complete loss of the native urethral plate. The penile flap, which was harvested following the techniques described above, was transposed with its vascular pedicle to the perineum, from the left side of the patient, and placed ventrally. Mobilization of the flap on the left side of the patient was driven by the fact that mobilization of the urethra and corpus spongiosum was also carried out from the same side, allowing the allocation of the flap. The most proximal and distal portions of the flap were secured to the native healthy urethra using interrupted 5-0 polyglyconate sutures. Two vertical watertight sutures between the edges of the flap and the graft completed the urethral augmentation, over a 14Ch silicon catheter. Finally, the corpus spongiosum was wrapped around the flap to offer a vascularized support and prevent sacculcation (Fig. 1). The penis was reinverted to its proper position. Perineal as well as circumcoronal incisions were closed in layers. Compressing dressing was done. The catheter was left in place for 6 wk.

2.4. Follow-up and surgical outcomes

Patients underwent uroflow after catheter removal; thereafter, the uroflow was repeated yearly. The urethral stricture surgery patient-reported outcome measure (USS PROM) questionnaire [14] was administered to all patients 12 mo after the surgery. Perioperative complications within 30 d after surgery were assessed using the standardized methodology [15,16]. Retrograde urethrography and/or urethroscopy was performed only in symptomatic patients to assess the site and extension of recurrence. We defined two different outcomes of treatment failure. The primary failure was defined as the requirement of any kind of instrumentation (dilatation, direct visual internal urethroty, or intervention) for the patient after surgery, regardless of symptoms or the maximum flow rate (Qmax). The secondary failure was defined as the onset of obstructive symptoms or Qmax below 10 ml/s, with or without a need for instrumentation (dilatation or direct visual internal urethroty or intervention).

3. Results

The median age, body mass index, and stricture length at the time of surgery were 39 yr (interquartile range [IQR] 30.5–52 yr), 23.9 kg/m² (IQR 21.9–24.8 kg/m²), and 7 cm (IQR 5–8 cm), respectively. Of all patients, nine (60%) underwent urethroplasty before the current treatment. Of the remaining six patients, three (20%) had previous direct visual internal urethroty or dilatation. Five patients presented a stricture that was localized to the bulbar urethra.

Fig. 1 – Step-by-step description of surgical operation. (A) The bulbospongious muscle is dissected on one side (Kulkarni technique) sparing the vascular supply on the other. Likewise, the urethra is mobilized on one side until the dorsal surface (dotted line) is visible. (B) The penis is then invaginated through the perineal incision and the urethra is dissected from the corpora on one side until the glans. Then, the urethra is open at 12 o’clock position (dorsally) at the level of the stricture until normal urethral caliber (22Ch dilator) is identified, either proximally or distally. (C) A preputial or distal fasciocutaneous flap is harvested from the penis and then transpose to the perineum with its dartos pedicle. A buccal mucosa graft is quilted to the corpora to augment dorsally the urethral plate. (D) The fasciocutaneous flap is secured to the graft on the side opposite to the native urethral plate. (E) The urethral lumen is closed over a 14Ch catheter by suturing the lateral edge of the flap with the lateral edge of native urethra. (F) The corpus spongiosum is wrapped over the new urethra as support and to prevent the formation of diverticula.
For the remaining ten patients, the bulbar stricture extended to the penoscrotal junction and penile urethra. Table 1 summarizes the patient characteristics of our cohort. The inner cheek was the preferred site for graft harvesting (eight patients, 53.3%). In three patients (20%), because of a long stricture gap (approximately 8 cm for all three patients), two buccal grafts were taken from both cheeks. A lingual graft was harvested only in one patient, in whom oral mucosa of both cheeks was severely compromised due to tobacco chewing. A skin graft from the inner preputial skin was harvested in three patients (20%) due to unavailability of oral mucosa. All of these three patients underwent previous buccal mucosa urethroplasty. After surgery, no perioperative complication of Clavien-Dindo grade ≥III was recorded in the subsequent 30 postoperative days. Two patients presented with penile hematoma that was treated conservatively (Clavien-Dindo I–II), one patient had urinary infection requiring shifting to a different antibiotic treatment (Clavien-Dindo II), and one patient developed skin dehiscence (Clavien-Dindo I). The median Qmax at catheter removal was 23 ml/min (IQR 21.5–26 ml/min). The median follow-up time was 25 mo (IQR 16–30 mo). The primary success rate was 86.7% (13/15), while the secondary success rate was 73.3% (11/15). Of the four patients with a secondary failure, two reported a Qmax of <10 ml/min with obstructive symptoms. One patient developed a perineal proximal fistula with collateral anastomotic narrowing, 6 mo after surgery, but refused to treat it. One patient received one dilatation 14 mo after surgery due to distal anastomotic narrowing. To date, no patient underwent redo surgery. Results of the USS PROM questionnaire are reported in Table 2. Nine patients (60%) reported postvoiding dribbling.

4. Discussion

The use of combined graft plus flap for single-stage urethral reconstruction was introduced by Morey et al [17] in 2001. In this pioneering study, the authors described the technique of graft plus flap augmentation in three men and one boy with a deficient or an absent urethral plate. After 2.6 yr of follow-up, the success rate was 100%. Later on, other studies with a higher number of treated patients have enlarged our knowledge on graft plus flap single-stage urethral reconstruction. In 2011, Gelman and Sohn [18] reported on 12 patients with glans, fossa navicularis, and penile urethra stricture, in whom the single-stage graft plus flap reconstruction was performed. Three patients reported postoperative fistula and urethral narrowing (25%) after a median follow-up of 39 mo, reaching a success rate of 75%. Again in 2012, Erickson et al [19] reported on 14 men undergoing urethroplasty in whom a segment of the urethra was replaced completely using a dorsal onlay buccal mucosa graft and a ventral onlay fasciocutaneous flap in a single stage. In this series, patients variably presented with strictures involving the penile and/or the bulbar urethra. Specifically, 12 patients presented with a penobulbar stricture and two with only bulbar involvement. The success rate was 64.3% (nine out of 14), after a median of 2.5 yr of follow-up. In 2019, Kojovic et al [20] published the largest series of single-stage graft plus flap reconstruction including 51 patients. Of these patients, 38 presented a penile stricture, seven patients had a stricture involving the penile and the bulb urethra, and six presented only with a bulbar stricture. After 24 mo from surgery, 40 (86.9%) patients were stricture free. Last in chronological order, Giudice and colleagues [21] presented their results on graft plus flap single-stage urethroplasty in 21 patients with long obliterator strictures. Of all included patients, 14 (67%) presented stenosis limited to the penile urethra. Of the remaining men, one presented a stricture limited to the bulbar urethra and six presented strictures involving both penile and bulbar segments. The success rate was 85.7% after a mean follow-up of 25 mo. What all these studies had in common is that graft plus flap urethroplasty was recommended mainly for patients with strictures that were localized in the pendulous urethra. For those few patients, in whom the stricture also involved the distal bulbar urethra, the authors followed a descending approach, which required scrotal splitting or a second perineal incision. Our study stands up to its predecessors bringing two important innovations. First of all, our approach started with a perineal incision because in our cohort, the bulbar urethra was always involved. Thus, the exposure of the penile urethra was achieved, if necessary, with the perineal invagination of the penis avoiding scrotal splitting or combined incisions. The perineal invagination of the penis, as described by our group previously [13], gives a full exposure of the anterior urethra from the bulbomembranous junction up to the glans. This approach allowed a precise estimation of the segment of the urethra that is involved by the disease, facilitating the correct harvesting of the penile flap and oral graft(s). Additionally, the allocation of flap and graft became technically easier because the scrotum is not interposed in between, as it happens in penoscrotal strictures that are approached without penile invagination. The second important difference from previous studies is that the urethra was opened dorsally after the one-side dissection, instead of ventrally. This approach brings two important advantages. First, the vascular supply to the urethra and bulbospongiosum muscle are preserved, on one side, reducing the risk of ischemia and neural dysfunction. Second, the ventral aspect of the corpus spongiosum is preserved. The corpus spongiosum represents an important source of blood supply, but also a support to the neourethra. Indeed, after urethral augmentation, the ventral flap was covered with the preserved corpus spongiosum, decreasing the risk of diverticulum formation. Another important consideration is that our study included the USS PROM questionnaire [14] for the evaluation of outcomes after surgery, as well as two guideline-approved definitions [22,23] of treatment success. The adoption of these two important metrics will facilitate further comparison with similar studies in the future.

We acknowledge that our study presents a relatively short follow-up, which limits the number of complications that may occur after this complex surgery, including late stricture recurrence, formation of diverticula, or micturition dysfunction. Second, we also acknowledge that our study lacks data on sexual dysfunction before and after treatment. Indeed, erectile function scores and penile Doppler findings...
Table 1 – Patient characteristics

| ID | Age at surgery (yr) | BMI | Previous DVIU or dilatation | Previous urethroplasty | Type of urethroplasty | BXO | Smoke | Stricture etiology | Site of stricture | Length of stricture | Type of flap | Type of graft | Site of graft |
|----|---------------------|-----|-----------------------------|------------------------|-----------------------|-----|-------|-------------------|------------------|-------------------|-------------|--------------|--------------|
| 1  | 45                  | 23.9| Yes                         | Yes                    | BMG urethroplasty      | No  | Never | Trauma           | Penobulbar       | 7                 | Preputial flap | Skin graft   | Prepuce      |
| 2  | 63                  | 24  | Yes                         | No                     | BMG urethroplasty      | No  | Never | Instrumentation   | Penobulbar       | 5                 | Preputial flap | Oral graft   | Left cheek   |
| 3  | 38                  | 29.3| Yes                         | Yes                    | BMG urethroplasty      | No  | Never | Idiopathic        | Panurethral       | 13                | Preputial flap | Skin graft   | Prepuce      |
| 4  | 68                  | 26.6| Yes                         | Yes                    | BMG urethroplasty      | Yes | Never | BXO               | Penobulbar       | 6                 | Distal penile skin flap | Oral graft | Right cheek |
| 5  | 49                  | 21.6| Yes                         | Yes                    | Anastomotic            | No  | Never | Idiopathic        | Penobulbar       | 4                 | Preputial flap | Oral graft   | Left cheek   |
| 6  | 26                  | 21.5| No                          | No                     | Trauma                 | 2   | Never | Hypospadias       | Bulbar           | 4                 | Preputial flap | Oral graft   | Right cheek  |
| 7  | 22                  | 22.2| Yes                         | Yes                    | Hypospadias repair     | No  | Never | Penobulbar        | 5                | Distal penile skin flap | Oral graft | Left cheek   |
| 8  | 35                  | 23  | No                          | No                     | Chewing tobacco        | No  | Never | Instrumentation   | Penobulbar       | 6                 | Penile flap | Oral graft   | Lingual      |
| 9  | 26                  | 24  | Yes                         | Yes                    | Unknown                | Yes | Never | Trauma           | Bulbar           | 10                | Preputial flap | Skin graft   | Prepuce      |
| 10 | 55                  | 26  | Yes                         | Yes                    | Anastomotic            | Yes | Never | Trauma           | Bulbar           | 8                 | Penile flap | Oral graft   | Bilateral cheek |
| 11 | 38                  | 25.3| Yes                         | No                     | Hypospadias            | No  | Never | Idiopathic        | Bulbar           | 8                 | Penile flap | Oral graft   | Bilateral cheek |
| 12 | 39                  | 24.2| Yes                         | No                     | Anastomotic            | Yes | Never | Instrumentation/ infection | Penobulbar | 5                 | Preputial flap | Oral graft | Right cheek  |
| 13 | 22                  | 21  | No                          | No                     | No                     | Yes | Never | Trauma           | Bulbar           | 8                 | Preputial flap | 2 Oral grafts | Bilateral cheeks |
| 14 | 46                  | 17.7| Yes                         | Yes                    | Perineostomy           | No  | Never | Infection        | Penobulbar       | 7                 | Distal penile skin flap | Oral graft | Left cheek   |
| 15 | 55                  | 23.2| No                          | Yes                    | Hypospadias repair     | No  | Never | Hypospadias       | Penobulbar       | 8                 | Penile flap | 2 Oral grafts | Bilateral cheeks |

BXO = balanitis xerotica obliterans; BMG = buccal mucosa graft; BMI = body mass index; DVIU = direct visual internal urethrotomy.
Table 2 – PROM score 12 mo after surgery of all patients

| ID | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Q10 | Mobility | Self-care | Usual activities | Pain/discomfort | Anxiety/depression | Scale QoL |
|----|----|----|----|----|----|----|----|----|----|-----|----------|-----------|----------------|---------------|------------------|----------|
| 1  | 0  | 1  | 2  | 0  | 0  | 1  | Not at all | Yes, satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 8         |
| 2  | 0  | 0  | 0  | 0  | 0  | 0  | Not at all | Yes, satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 8         |
| 3  | 0  | 2  | 4  | 0  | 0  | 4  | Somewhat | Yes, satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 7         |
| 4  | 1  | 0  | 1  | 0  | 0  | 0  | Not at all | Yes, very satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 9         |
| 5  | 0  | 0  | 1  | 0  | 0  | 1  | Not at all | Yes, very satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 10        |
| 6  | 4  | 4  | 4  | 4  | 4  | 4  | A lot | No, very unsatisfied | Urinary condition improved, but there was some other problems | I have some problems washing or dressing myself | I have some problems with performing my usual activities | I have moderate pain or discomfort | I am not anxious or depressed | 3         |
| 7  | 0  | 0  | 0  | 0  | 0  | 0  | Not at all | Yes, very satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 10        |
| 8  | 0  | 0  | 0  | 0  | 0  | 0  | Not at all | Yes, very satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 10        |
| 9  | 0  | 1  | 1  | 0  | 0  | 0  | Not at all | Yes, very satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 10        |
| 10 | 2  | 2  | 2  | 2  | 1  | 1  | Somewhat | Yes, satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 7         |
| 11 | 0  | 2  | 2  | 0  | 0  | 1  | Not at all | Yes, satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 9         |
| 12 | 0  | 0  | 0  | 0  | 0  | 2  | Somewhat | Yes, satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 5         |
| 13 | 0  | 0  | 0  | 0  | 0  | 0  | Not at all | Yes, satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 10        |
| 14 | 0  | 0  | 0  | 0  | 0  | 0  | Not at all | Yes, very satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 10        |
| 15 | 0  | 0  | 0  | 0  | 0  | 0  | Not at all | Yes, very satisfied | Not applicable | I have no problems in walking about | I have no problems with self-care | I have no problems with performing my usual activities | I have no pain or discomfort | I am not anxious or depressed | 8         |

PROM = patient-reported outcome measure; QoL = quality of life.
were not assessed in our patients. Lastly, we acknowledge that no routine retrograde urethrogram were performed 12 mo after surgery, as it is now recommended by guidelines in these complex cases [23]. In summary, our study joins previous publications on single-stage graft plus flap urethroplasty expanding our knowledge on this challenging reconstructive surgery. Our study reported on the largest series of patients with predominantly bulbar urethral stricture in whom this technique was offered. Thanks to our approach, we proved that single-stage graft plus flap urethroplasty is a valuable option not only for penile strictures but also for completely obliterated bulbar strictures. Accordingly, single-stage graft plus flap urethroplasty can become part of the armamentarium for reconstructing the bulbar urethra if it is nearly or completely obliterated.

5. Conclusions

Patients with a nearly or completely obliterated long segment of the urethra are commonly treated with multistage urethroplasty or perineal urethrostomy. However, reconstruction during second stage is extremely challenging. Moreover, perineal urethrostomy should not be an option in referral centers. Single-stage reconstruction with graft plus flap represents a valuable and feasible solution, which exponentially increases the quality of life of patients. Every reconstructive urologist should be able to master this technique. If not, patients must be referred to tertiary care centers. Our approach with a single perineal incision and penile invagination proved that graft plus flap urethroplasty is feasible also for bulbar strictures with or without penile urethral involvement, decreasing the surgical burden, as occurred during the descending approach.

Author contributions: Marco Bandini had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Bandini.
Acquisition of data: Bandini, Bafna, Yepes, Sharma, Patil, Bhadranavar.
Analysis and interpretation of data: Bandini.
Drafting of the manuscript: Bandini.
Critical revision of the manuscript for important intellectual content: Joshi, Kulkarni.
Statistical analysis: Bandini.
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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2021.10.009.

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