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Decision regret and long-term success rates after ventral buccal mucosa graft urethroplasty

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Objectives

To characterise the long-term success rate of ventral onlay buccal mucosa graft urethroplasty (vBMG) in the management of bulbar urethral stricture disease (USD), assess patient-reported postoperative satisfaction and decision regret, and delineate clinical factors impacting patient-reported metrics.

Subjects and Methods

Patients with prior vBMG for bulbar USD, performed at Cleveland Clinic between 2003 and 2022, were contacted and brief structured interviews were performed. Stricture recurrence and need for secondary procedures, baseline demographics, and patient-reported outcome surveys were collected. The surveys included the Decision Regret Scale (DRS), the Urethral Stricture Symptom Impact Measure (USSIM) and the 10-item Patient-Reported Outcomes Measurement Information System Short Form, version 1.2 (PROMIS-10). Descriptive, univariate and multivariable analyses were performed for clinical outcomes and survey responses.

Results

A total of 104 patients recorded responses. The median patient age was 49 years and the median follow-up was 7.4 years at time of survey. The median graft length was 5 cm and 38% of patients underwent partial thickness augmented anastomotic urethroplasty. At time of follow-up, 10 patients underwent a secondary procedure. Moderate to severe regret on the DRS was found in 12% of patients, and greater regret was associated with recurrence. The mean physical and mental health PROMIS-10 Global Health T-scores were 52 and 53. The mean total USSIM score was 56. A significant correlation was found between USSIM and DRS scores, with higher DRS score and recurrence negatively impacting USSIM score. USSIM scoring across all domains was significantly worse in the moderate to severe DRS group.

Conclusion

This study showed that vBMG for bulbar USD confers both high success rates and patient-reported satisfaction at extended follow-up, based on emerging and validated patient-reported outcome measures.

Keywords

urethroplasty, buccal mucosa graft, bulbar urethral stricture, patient-reported outcomes, decision regret, ventral onlay

Introduction

The management of bulbar urethral stricture disease (USD) has continued to evolve with the advent of new endoscopic treatments and modifications in urethroplasty techniques [1]. In the surgical management of bulbar urethral strictures for which anastomotic urethroplasty is either not feasible or suboptimal on account of patient-specific factors,

augmentation urethroplasty with utilisation of a graft or flap is warranted. Oral mucosal grafts are the current standard in augmentation urethroplasty, with multiple graft placement options available depending on stricture location, clinical history, and surgeon preference. With regard to the latter, the advantages of the different techniques have been a subject of ongoing debate and clinical study, but, to date, the superiority of one approach over another has not been established [2].

Patient-reported outcomes are the subject of increasing interest in the field of urethroplasty, helping to guide the study of technique modifications [3,4]. Traditionally, surgical success has been reported either as functional success indicating no secondary treatment after urethroplasty or as cystoscopic success indicating ability to pass a 17-F cystoscope through the area of repair [5]. While several studies utilising patient-reported outcomes have demonstrated correlation between these success measures and overall patient satisfaction [6–8], discrepancy between surgeon-reported and/or voiding function-based success and patient satisfaction can occur [9–11]. There is a clear need for a patient-reported outcome measure (PROM) capable of addressing the nuances of patient-perceived experience specific to USD not otherwise measured by common definitions of success [12].

To date, the majority of urethroplasty studies with patient-reported outcomes have used non-validated measures [6,7,9–11], with the exception of the validated Urethral Stricture Surgery (USS)-PROM, which was developed by incorporating items from non-USD-specific questionnaires based on a patient focus group and expert opinion [8]. More recently, the 13-item Urethral Stricture Symptoms and Impact Measure (USSIM) has been developed by the Trauma and Urologic Reconstructive Network of Surgeons (TURNS) using a four-step patient-centred process that assesses USD-specific urinary, sexual, quality of life, and satisfaction domains [13]. The USSIM is currently undergoing validation for preoperative and postoperative comparative assessment.

In this study we aimed to: (1) characterise the long-term success of ventral onlay buccal mucosal graft urethroplasty (vBMG) in the management of bulbar USD; (2) assess postoperative patient-reported satisfaction and decision regret after vBMG; and (3) understand the factors impacting postoperative patient-reported outcomes after vBMG.

Materials and Methods
Study Design

This study was conceived and approved by our institutional review board (#22-361) as a survey-based, cross-sectional study. Additionally, we conducted a retrospective electronic medical record review, whereby relevant demographic and clinical variables were captured in an institutional database, REDCap®.

Patient Population and Enrolment

Potential participants were screened through queries to our institutional database of urethroplasty patients. Inclusion criteria were: age 18 years or older; diagnosis of bulbar urethral stricture; having undergone a 1-stage vBMG for bulbar urethral stricture with a complete operative report available for review; and minimum follow-up of 6 months. All patients underwent postoperative catheter removal (urethral ± suprapubic), with or without voiding cystourethrogram at 3 weeks, per institutional protocol. Success was defined as not requiring secondary treatment after urethroplasty for recurrence of stricture.

Those meeting the enrolment criteria were contacted via an information letter sent through the mail outlining the study's rationale and goals, the nature of the information to be collected, and the terms of participation, including their right to withdraw from the study at any time or not to participate in the study. Patients were then enrolled through a follow-up telephone call in which surveys were delivered in a brief structured interview. Alternatively, unreachable patients were sent individual links to the REDCap-based, electronic version of the survey materials through e-mail and MyChart®, with the full-text information letter and investigators' contact information attached.

Survey Instruments

Surveys for the study included: (1) the USSIM, designed to quantify voiding and sexual symptoms, postoperative satisfaction, and impact on health-related quality of life after anterior urethroplasty [13]; (2) the Decisional Regret Scale (DRS), validated to assess regret following major decisions in a healthcare setting [14]; and (3) the 10-item Patient-Reported Outcomes Measurement Information System Short Form, version 1.2 (PROMIS-10) [15], a non-disease-specific instrument for global physical and mental health assessment. USSIM scores are divided into four subdomains, with higher scores pointing towards positive outcomes. The DRS scores for each patient's response were converted to a 0–100 scale by subtracting 1 from each response item (strongly agree to strongly disagree on a 5-point Likert scale), multiplying by 25, and calculating the average [14]. Higher scores represent a higher level of regret. A categorisation system of no regret (score 0), mild regret (1–25), and moderate to high regret (26–100) was used [16]. A normally distributed population was used as reference for the PROMIS-10 Global Health T-scores, with an average T-score in the United States of 50 points. Higher scores represent a healthier patient.

Data Management

As survey responses were collected or received, we conducted our retrospective electronic medical record review focused on obtaining basic demographic, diagnostic, operative and follow-up information relevant to the condition and procedures. Extracted data were stored in a dedicated project in our institution's REDCap server for the duration of the

study and de-identified for analysis once coupled with survey responses.

Descriptive statistics were employed for demographic and operative variables. Mean values were reported with SD and median values with interquartile ranges (IQRs; Q_1–Q_3). For the DRS, univariate and multivariable binary logistic regression analyses were performed, with reporting of odds ratio (OR) estimates with 95% Wald's CIs, utilising 'none' and 'greater than none' regret, and ANOVA was performed with reporting of F-statistics (F_{DRS}). For USSIM, univariate and multivariable linear regression analyses were performed, with reporting of unstandardised coefficients (β values) with CIs. Spearman rank correlation was performed for DRS and USSIM, with reporting of Spearman's rank correlation coefficient (r_s). An unpaired t-test was performed to compare USSIM domains between two DRS groups, with reporting of P values. Kaplan–Meier survival analysis was performed for recurrence-free survival. Statistical analyses were performed using IBM SPSS v29 (Armonk, NY, USA) with a two-sided type I error of 5% indicating statistical significance.

Results

We identified 510 male patients with bulbar urethral strictures who underwent vBMG at our institution between 2003 and 2022. We received 104 replies to the surveys, with a response rate of 20%. Table 1 illustrates the baseline demographic and clinical characteristics of survey responders.

The median (IQR) follow-up at time of survey administration was 7.4 (3.2–11) years, median (IQR) age of responders at surgery was 49 (38–58) years, median (IQR) BMI was 29 (25–32) kg/m^2, and median (IQR) Charlson Comorbidity Index was 1 (0–2). Relevant comorbidities included essential hypertension (39%), smoking (34%), stone disease (18%), diabetes mellitus (17%) and chronic kidney disease (8.7%). Eighty-nine patients (86%) had a history of urethral dilatations, direct visual internal urethrotomy, or both, and 10 (9.6%) had previously undergone anterior urethroplasty. Bulbar urethral stricture location was as follows: proximal (57%), followed by mid (49%) and distal (17%). In 17 patients (16%) strictures were pan-bulbar (i.e., all three segments involved). Overlapping segments most commonly included contiguous penile (18%) and membranous (13%) urethra, but concurrent strictures also included the meatus/fossa navicularis (10%) and, in two patients, non-contiguous bladder neck (1.9%).

The median (IQR) graft length was 5 (4–6.1) cm, and most harvests were unilateral (92%). In 40 patients (38%), a partial thickness augmented anastomotic urethroplasty was also performed. The median (IQR) estimated blood loss was 100 (75–200) mL. Two postoperative complications greater than Clavien–Dindo grade III occurred: one was cardiac-related

Table 1 Demographics, treatment history, and stricture characteristics at presentation.

Variables	N	
Age at surgery, years	104	
Median (IQR)		49 (38–58)
Age at diagnosis, years	104	
Median (IQR)		35 (23–46)
Body mass index, kg/m^2	104	
Median (IQR)		29 (25–32)
Charlson Comorbidity Index score	104	
Median (IQR)		1 (0–2)
Comorbidities, n (%)	104	
Essential hypertension		40 (39)
Diabetes mellitus		18 (17)
Chronic kidney disease		9 (8.7)
Previous pelvic EBRT		1 (1.0)
Tobacco smoking		35 (34)
Stone disease		19 (18)
Prior treatments, n (%)	104	
Endoscopic (dilatation, DVIU)		89 (86)
Anastomotic urethroplasty		5 (4.8)
Substitution urethroplasty		5 (4.8)
Total		90 (87)
Number of previous instrumentations, n	84	
Median (IQR)		3 (1–5)
Bulbar urethral involvement, n (%)	104	
Proximal		59 (57)
Mid		51 (49)
Distal		18 (17)
Pan-bulbar		17 (16)
Non-bulbar urethral involvement, n (%)	104	
Meatus		10 (9.6)
Penile		19 (18)
Membranous		14 (14)
Prostatic		0 (0)
Bladder neck		2 (1.9)

DVIU, direct visual internal urethrotomy; EBRT, external beam radiation therapy; IQR, interquartile range.

and the other was wound infection requiring operative debridement.

The median (IQR) post-void residual urine volume was 0 mL (0–37) at catheter removal. The median (IQR) follow-up time was 7.4 (3.2–11) years. At time of survey, 10 responders required further treatment for recurrent symptoms after vBMG. Stratified by bulbar stricture location at time of urethroplasty, recurrences occurred as follows: 6 of 59 patients with proximal bulbar, 5 of 51 with mid-bulbar, 1 of 18 with distal, and 2 of 17 with pan-bulbar strictures. No patients for whom augmented anastomotic urethroplasty was performed experienced recurrence. Kaplan–Meier analysis of recurrence-free survival is shown in Fig. 1, with estimated 5-year recurrence-free survival of 96% (CI 91–99).

Survey scores and subcomponents are summarised in Table 2. As measured by PROMIS-10 Global Health T-scores, the average physical health score was 52 (SD 9.1), and average mental health score was 53 (SD 8.4), both within 1 SD (10) of mean health.

Fig. 1 Kaplan–Meier recurrence-free survival curve for urethral stricture recurrence requiring secondary procedure.
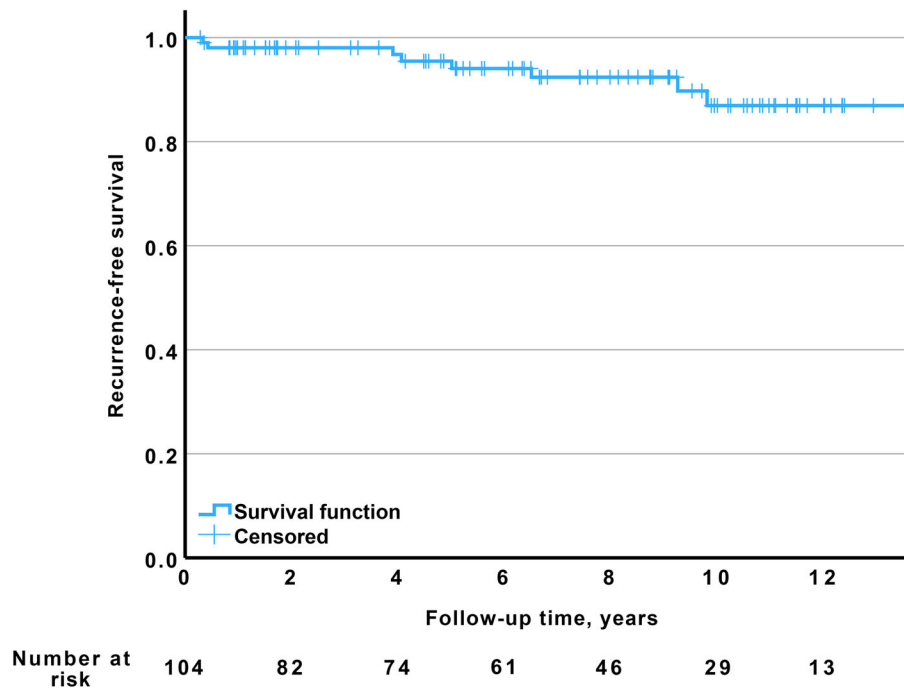
The mean (SD) total DRS score was 10.5 (17). For the statement 'It was the right decision', the mean (SD) score was 8.2 (18), for 'The decision was a wise one,' it was 9.1 (18), for 'I regret the choice that was made,' it was 10 (21), for 'I would go for the same choice if I had to do it again,' it was 11.5 (23), and for 'The choice did me a lot of harm,' it was 13 (20). A score of 0 (no regret) was reported by 57% of patients, while mild (scores 1 to 25) and moderate to high regret (scores ≥26) was evident in 32% and 12% of patients, respectively. Recurrence rates for each DRS category were as follows: none: 3.3%; mild: 10%; and moderate to high: 42%. Higher regret by category (mild 1–25, moderate 26–50, high 51–100) was associated with recurrence as follows: mild: OR 2.9, CI 0.5–18 ($P = 0.27$); moderate: OR 14, CI 1.6–130 ($P = 0.018$); and high: OR 29, CI 3.4–241 ($P = 0.002$). Total numeric DRS score was also significantly associated with recurrence (OR 1.06, CI 1.03–1.09; $P < 0.001$). On multivariable analysis for prediction of regret above 'none', tobacco use (OR 2.9; $P = 0.024$) and USSIM score (OR 0.91; $P = 0.001$) were associated with DRS score, as shown in Table S1.

The USSIM scores are detailed in Table 3. The mean health-related quality of life score was 5.7 (scored 1–7); for voiding symptoms the mean score was 34 (scored 8–40), for sexual symptoms it was 12 (scored 3 to 14 points) and for postoperative satisfaction it was 3.9 (scored −5 to 5). The mean total USSIM score was 56. A significant correlation was found between DRS score and USSIM score ($r_s = -0.48$;

$P < 0.001$) on Spearman rank correlation analysis. DRS severity group was significantly associated with USSIM score on ANOVA ($F_{DRS} = 12$; $P < 0.001$). Each individual domain of the USSIM was associated with DRS score as follows: health-related quality of life: $P < 0.001$; voiding: $P = 0.015$; sexual: $P < 0.001$; and satisfaction: $P < 0.001$. Further, in each domain of the USSIM, there were significantly higher scores in the none to mild DRS group compared to the moderate to severe DRS group, as shown in Table 2: health-related quality of life: $P < 0.0001$; voiding: $P = 0.0026$; sexual: $P < 0.0001$; satisfaction: $P < 0.0001$; and total: $P < 0.0001$. Total USSIM score was significantly negatively associated with recurrence ($\beta = -9.9$; $P < 0.001$) and total DRS score ($\beta = -0.26$; $P < 0.001$) on multivariable analysis, as shown in Table S2. No association was found between DRS or USSIM score and time from surgery (<5 years vs ≥5 years).

Discussion

Although less popular than dorsal urethroplasty in North America, ventral onlay can afford advantages and comparable outcomes with respect to durability and postoperative sexual function and it is the preferred approach for bulbar strictures at our centre [17–20]. To our knowledge, this is the first study to evaluate patient-reported outcomes and decision regret specifically for a ventral approach.

We found most patients had no or mild decision regret after vBMG, with rates of moderate to severe regret (12%) that

Table 2 Decision regret, USSIM and PROMIS-10 Global Health findings.

Variable	n
DRS (0–100) score, mean (SD)	104
'It was the right decision'	8.2 (18)
'The decision was a wise one'	9.1 (18)
'I regret the choice that was made'	10 (21)
'I would go for the same choice if I had to do it again'	12 (23)
'The choice did me a lot of harm'	13 (20)
Final score	11 (17)
Level of regret, n (%)	104
None (0 points)	59 (57)
Mild (1 to 25 points)	33 (32)
Moderate to high (≥26 points)	12 (12)
USSIM score, mean (SD)	104
Health-related quality of life score (scored 1 to 7)	5.7 (1.4)
None to mild regret	5.9 (1.2)
Moderate to high regret	3.7 (0.4)
Voiding symptom score (scored 8 to 40)	34 (6.2)
None to mild regret	35 (5.6)
Moderate to high regret	29 (8.3)
Sexual symptom score (scored 3 to 14)	12 (2.4)
None to mild regret	12 (2.2)
Moderate to high regret	9.3 (2.5)
Postoperative satisfaction score (scored −5 to 5)	3.9 (1.7)
None to mild regret	4.2 (1.3)
Moderate to high regret	1.8 (2.4)
Total score (scored 7 to 66)	56 (10)
None to mild regret	57 (8.7)
Moderate to high regret	44 (13)
PROMIS-10 Global Health scores, mean (SD)	102
Physical health T-score	52 (9.1)
Mental health T-score	53 (8.4)

DRS, Decision Regret Scale; PROMIS-10, 10-item Patient-Reported Outcomes Measurement Information System Short Form, version 1.2; USSIM, Urethral Stricture Symptoms and Impact Measure.

closely approximated the recurrence rate at time of survey (9.6%). However, just under half of the patients with moderate to severe regret (42%) experienced recurrence, thus, although it is associated with DRS score, recurrence does not exclusively explain regret. There were highly significant

differences in USSIM scoring in all domains when comparing the none to mild and moderate to severe groups, and we found a mild but significant negative correlation of decision regret with USSIM score. These findings suggest that patients with greater decision regret feel this way on account of an interplay of measurable urinary and non-urinary symptoms, in addition to whether recurrence occurred or not. Additionally, USSIM score was negatively impacted by presence of recurrence. The USSIM is undergoing validation for use in comparing pre- and post-urethroplasty symptoms, thus commentary on the scoring is limited by only post-urethroplasty scoring. However, it is notable that in a cohort of patients in whom success rates were high from a surgeon's perspective, patient-reported satisfaction was similarly positive, with scores nearing maximum satisfaction in all domains. As previously noted, the existing landscape of PROMs in urethroplasty has been explored through a variety of primarily unvalidated surveys. Patient satisfaction has correlated well with surgical success in most such studies, as shown in Table 3. However, Redmond et al. [10] demonstrated an ~10% discrepancy between success and satisfaction at 6 months in a 60% bulbar urethral stricture population. We found tobacco smoking history and USSIM score were most associated with patient regret. IPSS, standing to void [10], Sexual Health Inventory for Men score, and ejaculatory function [7] have been associated with higher satisfaction, while de novo curvature [7,10,11], penile shortening [7,11], erectile dysfunction [10], decreased sex frequency [7], recurrence [6,7], and oral complaints [6] were associated with dissatisfaction. Most patients underwent bulbar urethroplasty in these studies (60%–89%), however, other stricture sites comprised a significant PROM population. Additionally, utilisation of augmentation with oral mucosal grafts widely varies in the PROM literature. A comparison of the impact of augmentation urethroplasty technique (i.e., ventral or dorsal) on PROMs is not feasible due to a paucity of studies in which technique is specified.

Table 3 Satisfaction after urethroplasty.

Study, author, year	N (% bulbar)	Follow-up, months	BMG, %	Onlay location	Success definition	Success, %	Satisfaction measure	≥Satisfied
Santiago, 2024	104 (100)	89	100	Ventral	Functional	N/A*	DRS USSIM	88% none or mild regret
Redmond, 2023 [10]	387 (60)	6	51	N/A	Anatomical	96	Likert	82%
Vetterlein, 2021 [6]	534 (82)	33	100	Ventral in bulbar	Functional	85	Likert	84%
Bertrand, 2016 [7]	433 (89)	14	N/A	N/A	Anatomical	86	Likert	89%
Jackson, 2013 [8]	46 (83)	5	N/A	N/A	Functional	85	USS-PROM	87%
Kessler, 2002 [9]	233 (69)	37	12	N/A	Functional	87	Likert	79%

*BMG, buccal mucosal graft urethroplasty; DRS, Decisional Regret Scale; USSIM, Urethral Stricture Symptoms and Impact Measure; USS-PROM, Urethral Stricture Surgery Patient-Reported Outcome Measure. *Estimated 5-year recurrence-free survival = 96%.*

The focused bulbar USD patient population in our study, along with the longer follow-up (median 7.4 years), provide a unique view of the patient experience after bulbar buccal mucosal graft urethroplasty (BMG) and, specifically, provide a reference point for BMG technique.

The literature on augmentation urethroplasty with oral mucosal grafts in bulbar USD demonstrate >80%–85% success rates, and to date, comparisons of success rates between ventral and dorsal onlay techniques with BMG have not shown meaningful difference [2,19,21,22]. In a 2011 meta-analysis, vBMG specifically in bulbar USD had a success rate of 89% at 34 months [22]. The considerations and limitations of success definitions, e.g. anatomical vs functional, have been described elsewhere [5]. In line with our cross-sectional methodology and the extended time since surgery, we used a functional definition of success, which has the benefit of aligning with a patient-centric and practical characterisation of the patient's outcome. Erickson et al. [23] reported both anatomical and functional success at 1 year in BMG for bulbar USD, demonstrating 87% functional success and 77.5% anatomical success. The anatomical success rate at our long median follow-up of 7.4 years is not known, but notwithstanding the limitations related to survey non-responders and variable follow-up, our reported estimated functional recurrence-free survival suggests a durable repair.

Over the past two decades, as a referral centre for urological reconstruction, our department at Cleveland Clinic has amassed a vast amount of experience with augmentation urethroplasty as a definitive treatment for bulbar USD, primarily employing the vBMG technique when amenable. In a substantial proportion of this cohort (38%) we commonly use a partial thickness augmented anastomotic approach, involving ventral urethrotomy, excision of excessively narrowed dorsal urothelium, with preservation of dorsal spongiosum, anastomosis of healthy-appearing and wider calibre dorsal urethra, and vBMG. A similar technique has also been recently described as mucomucosal anastomotic non-transecting augmentation urethroplasty, in which a functional success rate of 93% was reported at a median 41-month follow-up [24]. vBMG, when sufficient ventral corpus spongiosum is present, remains our preferred technique for urethroplasty. While controversial since, as previously noted, an advantage of the dorsal vs ventral approach has not been clearly demonstrated, vBMG holds several advantages including avoiding circumferential dissection and potential damage to the nerves and vessels coursing along the dorsal tunica and a more technically simple dissection. In our experience, the sacculation concern associated with vBMG is not born out.

Several notable limitations to the study include its retrospective nature and cross-sectional design, as there is the potential for having not captured patients who ultimately experienced recurrence and needed secondary procedures. The omission of non-responders (~20% response rate) has the potential to introduce bias related to which patients would choose to respond – e.g., if dissatisfied patients or those who had recurrence were more likely to not respond – however, as we do not know the reason for non-response, the impact of this on the data is uncertain. Additionally, there may be patients who have relatively asymptomatic recurrence; however, one would imagine that if a clinically significant stricture were to recur that it would impact on the patient's PROM scores. Ultimately, comparative and prospective studies on urethroplasty to better weigh the advantages of one technique vs another are needed, and thankfully such studies are underway [25]. As our knowledge on patient priorities continues to evolve, our field ought to strive to use this information to marry surgical success with patient satisfaction.

Disclosure of Interest Statement

Our authorship conflict of interests are as follows: Hadley Wood declares consultant status for Elsevier and the US Centers for Disease Control and Prevention; Ken Angermeier declares consultant status for Boston Scientific; and Benjamin Breyer declares fellowship support by Boston Scientific. No other conflicts to report.

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Abbreviations: BMG, buccal mucosal graft urethroplasty; DRS, Decisional Regret Scale; IQR, interquartile range; PROM, patient-reported outcome measure; PROMIS-10, 10-item Patient-Reported Outcomes Measurement Information System Short Form, version 1.2; USD, urethral stricture disease; USSIM, Urethral Stricture Symptoms and Impact Measure; USS-PROM, Urethral Stricture Surgery Patient-Reported Outcome Measure; vBMG, ventral onlay buccal mucosal graft urethroplasty.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Predictors of decision regret score.

Table S2. Predictors of Urethral Stricture Symptom and Impact Measure (USSIM) score.