Patient-Reported Outcome Measures in Urethral Reconstruction

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Abstract
Purpose of Review Treatment of anterior urethral stricture disease (USD) has shifted from endoscopic approaches to urethroplasty with significantly higher success rates among reconstructive urologists. This academic stance has led to a critical evaluation of “success” and developing disease-specific instruments to assess surgical outcomes focusing on patients’ satisfaction rather than the historical goal of avoiding secondary procedures.

Recent Findings Many disease non-specific and/or non-validated patient-reported outcome measures (PROMs) have been utilized to evaluate the voiding symptoms and sexual function of patients after urethroplasty in the literature. Urethral Stricture Surgery PROM (USS PROM) is the first validated, disease-specific PROM for anterior USD which has been designed in 2001. Urethral Stricture Symptoms and Impact Measure (USSIM) is a comprehensive PROM and is currently being validated at multiple institutions.

Summary This article reviews the tools used to assess success after urethroplasty and elaborates the need to develop a comprehensive USD-specific PROM.

Keywords Urethral stricture · Patient-reported outcome measures · Treatment outcome · Sexual dysfunction · Urination disorders

Introduction
Urethral stricture disease (USD) occurs in 0.6% of the general population, and despite known risk factors (including trauma, endoscopic interventions, inflammation, and infection), the most common etiology is idiopathic [1]. In the year 2000, the estimated cost burden of USD in the USA was $200 million [2]. The most common presentation is obstructive symptoms; however, hematuria, recurrent urinary tract infection, inability to catheterize at the time of unrelated surgeries, or bladder stone also occur. Successful treatment of USD in males is known to dramatically improve urinary function, sexual health, and overall quality of life.

There has been a shift among urologists over the past decade towards treatment of USD in men from endoscopic approaches with low success rates to urethroplasty with significantly higher success rates. [3–5] In recent years, there has been a growing interest in academic centers towards urethral reconstruction resulting in increased number of fellowship-trained reconstructive urologists. This expanding interest in the field of urethral reconstruction has led to a more critical evaluation of “success” as well as developing disease-specific instruments to assess surgical outcomes more accurately with a more focus on patients’ satisfaction. [6] Historically, most of this reported “success” has been based on avoidance of secondary procedures. Measurements of success from the patient’s perspective have unfortunately been neglected in urethral reconstruction, and only recently, collaborative attempts have been initiated at designing and standardization of patient-reported outcome measures (PROMs) for anterior urethral reconstruction.

This article reviews the tools used to assess success after urethroplasty and elaborates the need to develop a comprehensive patient-reported outcome measures specific for USD.
Evolution of Urethral Stricture Treatment

The goal of urethral reconstruction is to restore urinary flow while maintaining quality of life with minimal side effects. An increase in the number of fellowship-trained reconstructive urologists has aided the shift from palliative, minimally invasive procedures such as repeated urethral dilations or direct vision internal urethrotomy towards definitive repair via urethral reconstruction. For example, in 2004, a USD was treated by urethroplasty in only 2.3% of the time as opposed to 7.6% in 2012. [6] This change in attitude has resulted in durable patency rates with lower need for repeated procedures, including self-obturation by patients. With increasing utilization of urethroplasty, however, some patients with a patent urethra after urethroplasty are not “satisfied” with their surgery experience despite unobstructed voiding. This can lead to discordance of perceived success between patients and physicians [7]. In addition, given that the primary focus of urethral reconstruction is improving quality of life, urologists have become more interested in the patient’s subjective experience following urethroplasty. This includes addressing aspects of urethroplasty that are not related to obstructed voiding including sexual function, pain, cosmetic results, and overall voiding quality (e.g., lack of post-void dribbling or urine spraying). As such, there is growing consensus among reconstructive urologists that there should be standardized documentation of the patient’s subjective assessment of their symptoms to better understand their perspective and to allow improved comparison of surgical outcomes among surgeons.

What Is a “Successful” Urethroplasty?

A historical perspective towards a “successful” urethroplasty is the lack of need for secondary procedures after urethroplasty. Over 75% of published literature between 2000 and 2008 used this definition as “success” due to ease of quantification for scientific research [3]. However, there are many disadvantages that include lack of input from patients or clinical evaluation of the reconstructed urethra and urine flow. For instance, there are patients with significant bother from post-void dribbling or persistent dysuria after urethroplasty with no anatomic recurrence of stricture or a need for re-intervention who are overall not happy with their surgical experience. This group needs to be recognized in order to achieve the ultimate goal of patient satisfaction after urethroplasty [8].

Other clinical and patient-reported tools have been used to demonstrate success after urethroplasty. One non-invasive modality for screening of USD and also identifying recurrence of disease is uroflowmetry in combination with post-void residual measurement. It has never been validated as a standalone tool for recurrence screening; however, when these voiding curves were combined with patient-reported symptoms, it has demonstrated 51% sensitivity, 98% specificity, 90% positive predictive value, and 86% negative predictive value. [9] Morey et al. were first to use the American Urological Association Symptom Score (AUA-SS) in correlation with uroflowmetry and retrograde urethrogram findings to predict recurrence of USD. [10] In a prospective report, Heyns et al. has combined uroflow with AUA-SS and demonstrated 68% specificity for initial diagnosis of USD but its role in the postoperative setting is unknown. [11] Erickson et al. correlated uroflow parameters with anatomic recurrence on cystoscopy after urethroplasty and showed good predictive value but only in men less than 40 years old. [12] They hypothesize that contributing factors such as enlarged prostate or altered bladder dynamics in older men can make the results unreliable in the older age group. These results also lack input from patients and are not validated in a prospective setting.

Cystoscopic evaluation of reconstructed urethra is considered gold standard after urethroplasty to identify stricture recurrence; however, heterogeneous methods of reporting “success” can hinder reporting of successful outcomes. Using a large multi-institution database, it has been shown that anatomic recurrence, defined as stricture that is visible on postoperative cystoscopy, occurs in 11.5% and 22.5% of patients undergoing excision/primary anastomotic urethroplasty or graft urethroplasty, respectively [13•]. However, up to 35% of these subjects are asymptomatic and would have been considered a success if “the need for intervention” was used as a definition for success. The natural history and long-term outcomes of this group with functional success but anatomical recurrence are unknown but it highlights the need for refining these definitions and adding a patient-reported component to consider patient’s perspective when comparing different urethroplasty techniques.

Given that outcomes following urethral reconstruction are very subjective beyond urethral patency (e.g., terminal dribbling, urine spraying following meatal reconstruction, scrotalgia), standardized assessment of subjective outcomes is essential. A condition-specific patient-reported outcome measure can help to meet this need. Bertrand et al. in 2016 demonstrated that unsatisfied men after urethroplasty had higher rates of disease recurrence on cystoscopy and worse uroflow parameters as expected. However, on multivariate analysis including both patient-reported and clinical parameters after adjusting for disease recurrence and age, persistence in voiding symptoms (weak stream), genitourinary pain, and postoperative sexual function alterations were the greatest independent drivers of postoperative dissatisfaction and uroflow parameters fail to demonstrate significant contribution to satisfaction. [14] This study emphasizes that patient-reported symptoms are equally, if not more, important drivers of overall patient satisfaction and should be included in any instrument used to assess success after urethroplasty.
What Is a PROM?

Patient-reported outcome measures (PROMs) are health questionnaires that patients complete before and after an intervention to determine whether their symptoms, daily function, or health-related quality of life have changed. [15, 16] Several validated PROMs are routinely used in surgical and nonsurgical fields in order to indicate patient-perceived benefit from an intervention. They are necessary for preoperative patient counseling, performance benchmarking, and resource allocation [17••]. There are many PROMs currently in routine urologic practice, and probably the most well recognized is the AUA-SS, also known as the International Prostate Symptom Score. The most useful PROM is the one that is validated for a specific condition with patient input at each phase of development. Urethral stricture disease has a relatively expanded physical and emotional impact on an individual’s life from voiding and sexual function to emotional consequences such as worry, embarrassment, and depression. All these aspects need to be considered when designing a comprehensive disease-specific PROM, and there is an emerging field of research addressing this need in urethroplasty literature.

A comprehensive PROM development process involves the patient during each step. These steps include (1) identifying the conceptual model, (2) adjusting the conceptual model/drafting a preliminary instrument, (3) confirming the conceptual model/assessing other measurement properties, (4) collecting/analyzing/interpreting data, and (5) modifying the instrument. Terwee et al. has provided explicit criteria, based on recommendations from the Scientific Advisory Committee of the Medical Outcomes Trust that oversees development of PROMs [18]. These criteria include the following:

1) Content validity: How well is the conceptual domain covered by the instrument?
2) Internal consistency: The precision of a measurement scale based on intercorrelations.
3) Criterion validity: How well do instrument scores relate to gold standard?
4) Construct validity: Do scores on a particular questionnaire relate to other measures in a manner that is consistent with measured hypotheses?
5) Reproducibility: (a) Agreement, how well do scores on repeated measures agree with another? (b) Reliability, how well are patients distinguished from another despite measurement error?
6) Responsiveness: How well does a questionnaire detect change over time?
7) Floor and ceiling effects: The number of patients who achieved the highest/lowest possible score.
8) Interpretability: How well can you assign easily understood meaning to an instrument’s quantitative scores?

Currently, the Trauma and Urologic Reconstruction Network of Surgeons (TURNS: www.turnsresearch.org) are in the process of developing a comprehensive PROM that addresses all the issues discussed above. The initial steps of the PROM construction are published by Breyer et al. and discussed in more detail below [19••].

Common PROMs Used in Urethroplasty Literature

Disease Non-specific Voiding PROM

Table 1 summarizes the common PROMs related to voiding complaints used in the urethroplasty literature. The AUA-SS is one of the first symptom score questionnaires used in urology that was introduced in 1992. It was originally designed for men with benign prostatic hyperplasia, and despite poor specificity, it has good utility in assessing symptom severity and treatment outcomes. [20, 23, 24] The utility of AUA-SS as an outcome assessment tool in USD was initially investigated by Morey et al. in 1998. They correlated symptom scores obtain by AUA-SS with radiographic retrograde urethrogram and uroflow rates postoperatively and observed a significant reduction in AUA-SS following urethroplasty and a significant inverse correlation between AUA-SS and maximum urinary flow rates and concluded that this index has clinical validity as an adjunct outcome assessment tool after urethroplasty. [10] In a prospective study of anterior strictures treated with dilation or DVIU, a combination of AUA-SS and uroflow parameters has yielded 93% sensitivity, 68% specificity, 78% positive predictive value, 89% negative predictive value, and 82% overall accuracy. [11] The use of AUA-SS has shown internal consistency and reliability for men with lower urinary tract symptoms from benign prostatic hypertrophy, but it does not have content validity in USD and is considered an incomplete PROM.

Nuss et al. have investigated this concern where urinary symptoms of 214 patients who underwent urethroplasty were retrospectively reviewed. They concluded that although most common presenting symptoms are addressed in AUA-SS (weak stream 49%, incomplete emptying 27%), up to 21% of patients’ symptoms would not be captured by the AUA-SS. The most common symptoms were spraying of urine and dysuria that were present in 13 and 10% of their population. Less common symptoms included post-void dribbling, hesitancy, and incontinence. In addition, the AUA-SS has been specifically inadequate in capturing symptoms of patients with penile urethral strictures and trauma-related and lichen sclerosus-related strictures and 10% of men with USD did not have any voiding symptoms calling for the need for disease-specific PROM [25].
Table 1 Voiding PROMs in urethral stricture literature

<table>
<thead>
<tr>
<th>PROM</th>
<th>Publication</th>
<th>Specific condition</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUA-SS</td>
<td>Barry et al. 1992 [20]</td>
<td>Benign prostatic hypertrophy</td>
<td>• Significant correlation with postoperative uroflow</td>
<td>• Not specific for urethral stricture</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Adequate reliability, internal consistency</td>
<td>• Floor effect in 21% of patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Lack of content validity</td>
</tr>
<tr>
<td>CLSS</td>
<td>Homma et al. 2008 [21]</td>
<td>Mix of conditions affecting urinary tract</td>
<td>• Addressing multiple urinary complains</td>
<td>• Not specific for urethral stricture</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life component</td>
<td></td>
</tr>
<tr>
<td>ISI</td>
<td>Wei et al. 2003 [22]</td>
<td>Urinary incontinence</td>
<td>• Addressing bother related to incontinence</td>
<td>• Utilized in few studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Not specific for urethral stricture</td>
</tr>
<tr>
<td>Expert created</td>
<td>Kessler et al. 2002 [7]</td>
<td>Urethral stricture</td>
<td>• Assessing urinary and sexual impact</td>
<td>• Not validated</td>
</tr>
<tr>
<td>USS PROM</td>
<td>Jackson et al. 2011 [17••]</td>
<td>Urethral stricture</td>
<td>• Excellent psychometric parameters</td>
<td>• Not addressing sexual function/oral mucosa complains</td>
</tr>
<tr>
<td>USSIM</td>
<td>Breyer et al., 2017 [19••]</td>
<td>Urethral stricture</td>
<td>• Most comprehensive PROM</td>
<td>• Questions are not constructed according to patients’ complaints</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Urethral stricture specific</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Significant patient input and quality of life component</td>
<td>• In the process of validation</td>
</tr>
</tbody>
</table>

AUA-SS American Urological Association Symptom Score, CLSS Core Lower Urinary Tract Symptom Score, ISI Incontinence Symptom Index, USS PROM Urethral Stricture Surgery PROM, USSIM Urethral Stricture Symptoms and Impact Measure

Another PROM that has been applied to USD is the Core Lower Urinary Tract Symptom Score (CLSS). This instrument was designed in 2008 in order to provide a comprehensive questionnaire to assess ten core urinary symptoms from the symptom panel of the International Continence Society. This PROM evaluates frequency, nocturia, urgency, urinary incontinence, quality of urinary stream, pain, and quality of life. Although it has an overall quality of life measure and two questions assessing bladder and urethral pain which are known predictors of postoperative dissatisfaction after urethroplasty, during the validation process of this PROM, no patients with USD were included, and it fails to assess common complaints in USD such as urine spraying and dysuria. [21] The Incontinence Symptom Index (ISI) is another instrument that has been used in conjunction with the AUA-SS to assess urethroplasty success. [26] This instrument was developed in 2003, and although there is a bother component, it emphasizes primarily on urinary incontinence and has never been validated for USD [22].

Disease-Specific Voiding PROM

In 2002, the first disease-specific PROM was published in the urethroplasty literature by Kessler et al. [7] It was not validated and was never adopted for widespread clinical use. It includes questions assessing urinary tract, voiding and sexual function, overall satisfaction, and miscellaneous impairments after urethroplasty. Using this non-validated PROM, they reported 78% overall satisfaction with surgery and noted that the impact on sexual function was a significant marker for potential disappointment. An interesting finding of this study was how differently patients consider the outcomes of urethroplasty compared to surgeons. Of 30 patients in whom urethroplasty was considered a failure by clinical measures, 24 were “satisfied or highly satisfied” with the surgical outcome.

The only PROM that has been designed specifically for patients with USD is published in 2011 by Jackson et al. (Urethral Stricture Surgery PROM or USS PROM) [17••]. The researchers used a previously published research method to expedite PROM creation in a cost-efficient manner. [27] PROM development involved interviews of a patient focus group to gather important content. Existing PROMs not specifically validated for USD were then explored for relevant content based on the patient interviews and then included in the planned PROM based on expert opinion from physicians. The subsequently developed USS PROM includes a lower urinary tract symptoms (LUTS) construct of six summative questions, one separate LUTS-related quality of life question, and a voiding picture. It is then followed by a five-item questionnaire to assess overall quality of life and two questions addressing overall patient satisfaction and a visual analog scale of health status [17••]. The pilot study of this PROM demonstrated excellent psychometric values including validity, test-retest reliability, internal consistency, and responsiveness and was found to correlate with maximum flow rates as criterion validity [17••]. The results of application of this PROM before and 2 years after bulbar and penile urethroplasty in 46 men showed durable improvement in all domains assessed. [28] The subgroup of patients who required re-intervention due to stricture recurrence (15%) reported lower scores in all domains of USS PROM which demonstrates correlation between anatomic and functional outcomes. In a critical review of all PROMs in USD, Voelzke concluded that USS PROM is the only PROM that shows adequate
psychometric values and is considered a “key first step” towards using a condition-specific PROM [29•]. However, this PROM is not perfect; the questions were generated from questionnaires validated for other health conditions and not generated de novo from the words of the patients. This has resulted in a lack of uniformity among items and response choices (i.e., choices vary from three to five responses across the included items). In addition, sexual function and oral mucosa morbidity are not included in this PROM. Further, only one stricture-specific quality of life question is present [19••].

**Disease Non-specific Sexual PROM**

The summary of the PROMs used to assess sexual function before and after urethroplasty is presented in Table 2. In a historical cadaveric study on neuroanatomy of erection, Lue et al. showed that most of the cavernous nerve fibers that supply the corpus spongiosum occupy the 1 and 11 o’clock positions at the level of convergence of the crura of the corpora cavernosa. Given the elasticity of the corpus spongiosum, anterior urethral reconstruction should not predispose patients to long-term erectile dysfunction (ED). [35] However, Mundy et al. initially raised the concern for sexual dysfunction after urethroplasty in 1993 when they reported 5% rate of permanent ED after anastomotic urethroplasty and 0.9% rate after graft patch urethroplasty. [36] The topic has been controversial and several authors have reported different and often contradicting sexual function outcomes after urethroplasty [37].

The first authors to systematically evaluate sexual dysfunction after urethroplasty using a PROM were Coursey et al. in 2001. They used a validated questionnaire designed by the authors to assess perceived changes in satisfaction with erection, erect penile length and angle, and change in these parameters over time and used patients undergoing circumcision as the control group. They reported on average 30% decreased satisfaction with erections with slight difference based on technique of urethroplasty. The authors were surprised by the high rate; however, they noted that the deterioration improves over time and erectile dissatisfaction is similar among the control group after routine circumcision. The authors emphasized the importance of unfiltered data that was collected by patients at home and not subject to physician bias, coaching, or misinterpretation [30].

The well-recognized International Index of Erectile Function (IIEF) and the short five-item score version (IIEF-5) have been used more commonly in previous reports. These tools are validated, multi-dimensional, self-report instruments widely used for evaluation of male sexual function and recommended as primary endpoints for clinical trials of ED. It is divided into five domains of sexual function including erectile function, orgasm, intercourse satisfaction, sexual desire, and overall satisfaction [32].

The complete IIEF PROM has been used by Anger et al. in 2007 to assess sexual function before and after different variations of bulbar urethroplasty, and after 6 months of follow-up, no significant difference before and after surgery was observed. [38] In a prospective study, Erickson et al. used the IIEF-5 to evaluate erectile function before and after different types of urethroplasty. They noted 38% overall rate of ED postoperatively, of which 90% fully recovered after a mean of 190 days. Bulbar compared to penile and primary anastomosis and compared to graft urethroplasty had more deleterious effect on erections [39•]. The same IIEF-5 PROM in addition to the Sexual Life Quality

**Table 2**  Sexual function PROMs in urethral structure literature

<table>
<thead>
<tr>
<th>PROM</th>
<th>Publication</th>
<th>Specific condition</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert created</td>
<td>Coursey et al. 2001 [30]</td>
<td>Urethral stricture</td>
<td>• Validated for urethral stricture</td>
<td>• Not evaluating voiding symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life component</td>
<td>• Psychometric quality measures lacking</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• All aspects of sexual function including penile function and cosmesis</td>
<td></td>
</tr>
<tr>
<td>Expert created</td>
<td>Barbagli et al. 2007 [31]</td>
<td>Urethral stricture</td>
<td>• Assessing ejaculatory function, penile function and sensation, overall satisfaction</td>
<td>• Not validated</td>
</tr>
<tr>
<td>IIEF/IIEF-5</td>
<td>Rosen et al. 1997 [32]</td>
<td>Erectile dysfunction</td>
<td>• Assessing all aspect of sexual function, erection, ejaculation, and overall satisfaction</td>
<td>• Not urethral stricture specific</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Most widely used PROM for erectile dysfunction</td>
<td>• Short form does not evaluate ejaculation</td>
</tr>
<tr>
<td>BMSFI</td>
<td>O’leary et al. 1995 [33]</td>
<td>Erectile dysfunction</td>
<td>• Validated specifically for sexual function change before and after urologic intervention</td>
<td>• Not urethral stricture specific</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Assessing erectile function, drive, ejaculation</td>
<td></td>
</tr>
<tr>
<td>MSHQ</td>
<td>Rosen et al. 2004 [34]</td>
<td>Erectile dysfunction</td>
<td>• Assessing all domains of sexual health</td>
<td>• Not urethral stricture specific</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Excellent psychometric properties</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Includes men with lower urinary tract symptoms</td>
<td></td>
</tr>
</tbody>
</table>

BMSFI Brief Male Sexual Function Inventory, IIEF International Index of Erectile Function, IIEF-5 International Index of Erectile Function Short 5-item Score, MSHQ Men’s Sexual Health Questionnaire
Questionnaire (SLQQ) was used in a study by Xie et al. in 2009. The latter PROM addresses specific aspects of sexual quality, including frequency of lovemaking, duration of lovemaking, ease of insertion, ease of achieving orgasm, ease of initiating lovemaking, pleasure of anticipation, carefree feelings, pleasure of orgasm, pleasure of overall experience, and partner’s pleasure of experience in addition to overall quality of life. Xi et al. observed significant decline in sexual function 3 months after urethroplasty that was more pronounced in younger patients and after posterior urethroplasty. They eventually noted a rebound to pre-op values after 6 months but identified stricture location and end-to-end anastomosis of stricture as predictors of worse ED.

Other sexual function PROMs that have been used in urethroplasty literature are Brief Male Sexual Function Inventory (BMSFI) and Men’s Sexual Health Questionnaire (MSHQ). In a retrospective study, Erickson et al. used the three ejaculatory function sections of BMSFI and found an overall increase in postoperative ejaculatory score; however, as the patients were asked to complete preoperative scores after the surgery, the conclusions of the study were criticized by recall bias among the participants. In a subsequent prospective study, Erickson et al. studied the effect of urethroplasty on ejaculatory function using the seven-question section of MSHQ on ejaculatory frequency, latency, volume, force, pain and pleasure, and dry ejaculation in 59 men. The overall rate of poor preoperative ejaculatory function was 25% and most common presentations were poor volume, poor vigor, and pain with ejaculation. Overall change in MSHQ scores was minimal; however, closer inspection of individual patients revealed that ejaculatory function was stable in 70%, improved in 19%, and decreased in 11%. MSHQ is a validated questionnaire that was developed in 2004 by Rosen et al. and is specifically designed to evaluate different aspects of ejaculatory function although the psychometrics of application of this questionnaire to the urethroplasty population has not been thoroughly investigated. In particular, it has been hypothesized that patients perceive improvement in one domain (e.g., relief of pain at ejaculation) associated with global improvement in ejaculatory function and tend to report subjective improvement in volume and vigor. Similar to voiding PROMs, none of these questionnaires have been vigorously validated in pre- and post-urethroplasty population.

Disease-Specific Sexual PROM

An initial attempt at creating a disease-specific PROM for sexual function change after urethroplasty has been proposed by Barbagli et al. who used an expert-created but non-validated PROM. This PROM was used to examine the effect of bulbar anastomotic urethroplasty on sexual function. The PROM focused on changes in ejaculatory function (force of ejaculation and fertility), neurovascular penile disorder (change in penile sensation and glans abnormalities), and overall satisfaction. In a retrospective review of 153 young patients undergoing EPA for bulbar stricture, they noted no chordee or de novo ED after surgery. However, they reported 23% ejaculatory dysfunction, 1.6% a cold glans during erection, 11.6% a glans that was neither full nor swollen during erection, and 18.3% decreased glans sensitivity. This study lacks preoperative measures and the timing of postoperative interviews has been inconsistent, making the interpretation of the results difficult.

The only validated sexual function PROM is reported by Coursey, as discussed previously. This PROM focuses only on erectile function and does not address ejaculatory function, overall patient satisfaction, or quality of life. In addition, although content validity is addressed by the designers of the PROM, other quality criteria for an adequate disease-specific PROM including internal consistency, construct validity, reproducibility, responsiveness, floor/ceiling effect, and interpretability are lacking.

Special Cases

As urethroplasty continues to gain popularity as the gold standard for treatment of anterior urethral strictures, similar surgical principles are applied to urethral reconstruction related to other etiologies. In particular, posterior urethroplasty after trauma or radiation damage has different success rates, and the effect of the initial insult (e.g., prostate radiation) on sexual/voiding function makes assessment of postoperative success more complicated. Females also undergo urethral reconstruction for urethral diverticulum or iatrogenic complications from anti-incontinence procedures, and there are no disease-specific PROMs designed for this population. Patients with neurogenic bladder from various etiologies also have a different perception of success when it comes to urethral reconstruction, and current conventional PROMs do not apply to them.

Future Direction

As discussed in previous sections, there is discordance regarding what patients perceive as successful urethroplasty relative to physicians. The TURNS groups are in the process of constructing the most comprehensive PROM specific to USD. In a recent publication on the early stages of PROM development from this group, qualitative interviews of men with a
stricture were performed using open-ended questions to gather important content relative to the impact of a urethral stricture [19••]. The TURNS group partnered with the Seattle Quality of Life group (http://depts.washington.edu/seaqol/), a respected leader in the field of PROM development, to aid creation of a comprehensive USD-specific PROM (Urethral Stricture Symptoms and Impact Measure—USSIM). The specific steps are listed below:

1) Qualitative, semi-structured, concept elicitation patient interviews before and after urethroplasty using open-ended questions to explore as many symptom and life impacts as possible without limiting the participant to an a priori structure.

2) Cognitive interviews with patients where the participants assessed the relevance, importance, and comprehension of the draft items.

3) Prioritization interviews with patients where they rated the items in order of personal perceived bother relative to their stricture experience.

4) Item prioritization survey with clinicians expert in urethral stricture surgery who rated the importance of each item for making treatment decisions.

As a result, a 32-item instrument called USSIM was constructed and is currently being validated at multiple high volume centers within the TURNS network.

Of note, during these qualitative interviews, urinary issues compared to sexual concerns predominated among the top 15 items that patients rated by bother. The patient cohort was most bothered by anxiety about being unable to void, post-void dribbling, and trouble aiming the stream. The sexual side effect of the worst concern for patients was slow force of ejaculation. Comparing the item prioritization list from patients and clinicians yielded some important findings. Patients and clinicians agreed on 8 of the 15 items (53%) that they independently rated of highest importance. Items of high importance for patients that clinicians did not recognize as high on the list included the following: “I had trouble aiming my urine stream,” “I sat down to pee,” and “I had to plan ahead.” Of note, the emotional impact of the USD was a common theme that impacted patients with a urethral stricture.

Conclusions

Fulfilling patient expectations from urethroplasty goes beyond technical outcomes and should ultimately serve the patient with improved overall quality of life. A well-designed, disease-specific PROM should be constructed around the perception and expectations of patients. A successful PROM is a balance between what patients consider as satisfaction and what experts consider as success. Only by widespread implementation of such PROMs, we can objectively compare different surgical outcomes and ultimately refine techniques towards improved outcomes for patients.

Compliance with Ethical Standards

Conflict of Interest Nima Baradaran, Lindsay A. Hampson, Todd C. Edwards, Bryan B. Voelzke, and Benjamin N. Breyer each declare no potential conflicts of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

References

Papers of particular interest, published recently, have been highlighted as:
• Of importance
•• Of major importance


10. Morey AF, McAninch JW, Duckett CP, Rogers RS. American urological association symptom index in the assessment of


21. Breyer BN, Edwards TC, Patrick DL, Voelzke BB. Comprehensive qualitative assessment of urethral stricture disease: toward the development of a patient centered outcome measure. J Urol. 2017;198(5):1113–8. https://doi.org/10.1016/j.juro.2017.05.077. This is the preliminary publication of the process to develop the most comprehensive urethral stricture-specific PROM to date. The instrument is being validated at several centers in the USA.


