Development and Validation of A Male Anterior Urethral Stricture Classification System

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OBJECTIVE To develop and validate a clinical classification system for urethral stricture disease (USD) based on the retrograde urethrogram (RUG), physical exam, and stricture-specific patient history.

MATERIALS AND METHODS Three elements were chosen to be included in the classification system: 1) Length of urethral stricture (L); 2) Stricture segment/location (S); 3) Stricture Etiology (E) (LSE classification system). Each element was divided into clinically relevant sub-categories. A three-step development and validation process then ensued, culminating in an in-person Trauma and Urologic Reconstruction Network of Surgeons (TURNS) meeting, at which the final classification system was unanimously agreed upon by attendees based on interrater reliability data obtained from the classifying of 22 clinical vignettes. A final validation step involved retrospectively classifying cases in the TURNS database to determine if classification influenced surgical technique and was associated with presumed stricture etiology.

RESULTS The final LSE classification system was found to have an interrater reliability of 0.79 (individual components 0.76, 0.70 and 0.93 respectfully). Retrospective classification of the 2162 TURNS strictures revealed the segment (S) to be strongly associated with urethroplasty type ($p = 0.0005$) and stricture etiology (E) ($p = 0.0005$).

CONCLUSION We developed and validated a novel, easy to use, urethral stricture classification system. The system's ability to aid in directing treatments, predict treatment outcomes, and facilitate collaborative research efforts will require further study. UROLOGY 143: 241−247, 2020. Published by Elsevier Inc.

Classification systems facilitate the organization of complex processes into logical units. The primary objectives of a medical classification system are to predict clinical outcomes, to aid in clinical communication, and facilitate research endeavors in a particular disease process. Urethral stricture disease (USD) is a complex condition with a poorly understood pathophysiology lacking a classification system able to accomplish these objectives.

The unifying feature of male USD is a narrowed urethral lumen. However, the average male urethra is nearly 20 cm long, is lined by three different types of epithelium, and receives blood supply from at least three different primary sources. Thus, while a diagnosis of USD may explain the presence of lower urinary tract symptoms in a patient, it lacks the precision needed to aid in operative planning, to appropriately counsel a patient on expected outcomes and possible complications, or to reliably compare surgical outcomes amongst surgeons and centers for research purposes and clinical trials.

The purpose of this current study was to develop, test, and then validate a classification system for USD. Our primary objectives when designing the system were 1) that it would be easy to use, 2) would be based on readily available clinical data, and 3) that the data utilized for classification were objective enough to allow for sufficiently high inter-rater reliability (i.e. a high likelihood that separate

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clinical observers would classify the stricture the same). Variables ultimately chosen for the system that fulfilled these objectives also had to be associated with clinical and surgical decision making and surgical outcomes, such that the system would be clinically relevant.

MATERIALS AND METHODS

Classification System Design and Definitions

Prior to classification system development, an extensive review of the literature was performed to identify candidate variables to be used that were both clinically useful and had been shown to independently affect surgical decision-making and surgical outcomes.[1-3] The three variables ultimately chosen for inclusion were stricture length (L), stricture segment/location (S), and stricture etiology (E) — the LSE urethral stricture classification system. Other variables that were considered but ultimately not chosen for primary classification, included prior number of endoscopic procedures,[4] history of tobacco use,[5] body mass index,[6] and uroflowmetry data.[7,8] Each of these variables had been associated directly or indirectly with surgical outcomes, but alone did not add sufficient anatomic detail that would alter operative technique in most cases.

Each of the LSE variables were subdivided as demonstrated in Figure 1. The rationale for the L subdivision was surgically based[2,9,10]: strictures less than 2 cm (in the bulbar urethra) in length (L1) are generally amenable to excisional repairs; strictures between 2 and 7 cm (L2) can be repaired with a single substitution graft; strictures greater than 7 cm (L3) will often require two sources of graft material (i.e. bilateral buccal harvest) or a fasciocutaneous tissue flap.

The S variable was divided into bulbar (S1) and penile (S2) segments as depicted in Figure 2 and with representative (properly performed) retrograde urethrogram (RUG) images in Appendix 1. Within the S1 division, subdivision was again based on generally accepted urethroplasty practices: S1a strictures can involve only proximal and mid- portions of the bulbar urethra, which is the most mobile urethral segment and amenable to longer excisional repairs.[11] The proximal urethra also has

TURNS LSE Anterior Urethral Stricture Classification System

L – **L**ength*	
1	≤ 2cm
2	> 2cm & ≤ 7cm
3	> 7 cm
S – Urethra **S**egment**	
1	**Bulbar Urethra**
1a	Bulbar Urethral Stricture without Distal Bulbar Urethra involvement.
1b	Bulbar Urethral Stricture Involving the Distal Bulbar Urethra.
2	**Penile Urethra**
2a	Stricture involving both bulbar and penile urethral segments without involvement of the fossa navicularis and/or urethral meatus.
2b	Stricture isolated to the penile urethra without fossa navicularis or meatal involvement.
2c	Stricture isolated to the penile urethra with fossa navicularis and/or meatal involvement.
2d	Stricture isolated to the fossa navicularis and/or urethral meatus.
3	Stricture involving the meatus/fossa, penile urethra and bulbar urethra (i.e. pan-urethral stricture).
S – Modifiers	
x	Portion(s) of the Stricture with Obliterated Lumen (e.g. S1ax, S2ax)
m	Separate strictures involving two or more distinct areas of the anterior urethra (managed with separate urethroplasty techniques). (e.g. Sm1a and Sm2d)
p	Extension of stricture into posterior urethra (non-PFUDD; e.g. S1ap), or isolated non-PFUDD posterior urethral stricture (e.g. Sp)
E – **E**tiology ***	
1	External Trauma (e.g. known straddle injury)
2	Idiopathic/Unknown Etiology
3	Iatrogenic
3a	Internal Trauma (e.g. post TURP/TURBT stricture)
3b	Recurrent Urethral Stricture in Prior Urethroplasty Segment (including penetrating injury healing with stricture +/ - prior repair; excluding hypospadias repairs (E5))
3c	Radiation Induced Urethral Stricture
4	Infectious/Inflammatory (e.g. post-gonococcal)
5	Stricture in Segment of Prior Hypospadias Repair
6	Lichen Sclerosus

* Total length of the diseased urethra being managed with a single urethroplasty technique. If an m modifier is utilized, two L variable values will be listed.

** If multiple strictures are radiographically isolated but are managed with a single technique, classify as a single stricture. If the strictures are managed separately (e.g. anastomotic repair for bulbar stricture, onlay for penile repair) then the m modifier should be utilized

*** If multiple etiologies suspected/known, stage with highest numbered etiology.

Figure 1. LSE Anterior Urethral Stricture Classification System.

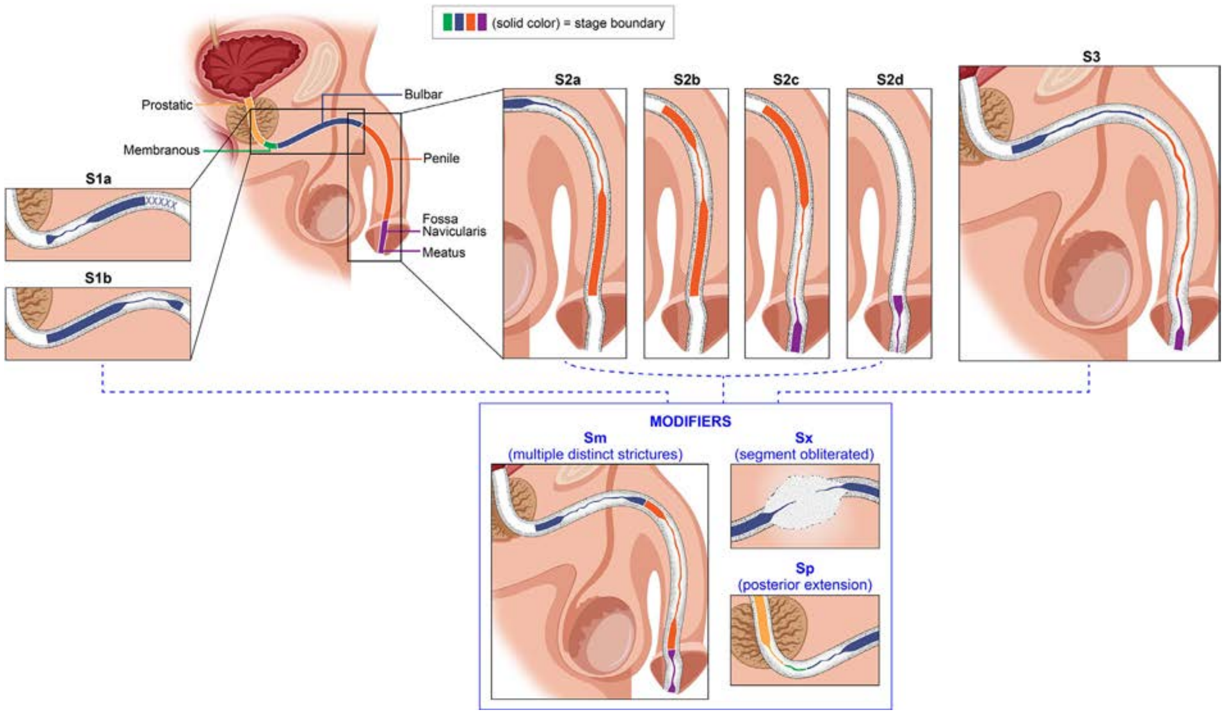

Figure 2. LSE classification segment (S) variables with modifiers. (Color version available online.)

the most robust blood supply and is thus supportive of grafts placed ventrally, laterally and/or dorsally on the urethra.[12] S1b strictures are also confined to the bulbar urethra but must also involve a portion of the distal bulbar urethra, which relative to the proximal bulb, has thinner spongiosal tissue, and is often less supportive of ventral grafts.[13] In addition, as the bulbar urethra transitions into the penile urethra, it becomes less mobile and thus less amenable to excisional repairs.

Any stricture involving a segment of the penile and/or fossa navicularis/meatal urethra was categorized as an S2 stricture. The S2 division is then further subdivided by location based primarily on the anatomic and histologic differences noted within the urethra as one moves proximally to distally. S2a strictures are penile urethral strictures that extend into the bulbar urethra (or vice versa) but spare the fossa navicularis and meatus. S2b strictures are isolated to the penile urethra and spare the fossa navicularis/meatus and bulbar urethra. S2c strictures involve both penile and fossa navicularis/meatal segments. S2d strictures are isolated to the fossa navicularis/meatus.[14] Lastly, an S3 stricture is a contiguous stricture, or a series of smaller strictures located close enough to one another such that they are managed with a single surgical technique (e.g. FCF or lateral buccal/Kulkarni onlay),[15] that involves all three segments of the urethra — bulbar, penile and fossa/meatus — frequently termed a "pan-urethral" stricture.

The E component was divided from E1 to E6, with higher E numbers roughly correlating with the clinical predictability of the urethral tissue within and surrounding the urethral stricture during urethroplasty. For example, a traumatic straddle injury (E1) to the bulbar urethra often results in a 1-2 cm segment of strictured/distracted urethra that rarely evolves or expands once the healing from the acute injury has subsided (i.e. static strictures). These strictures, though sometimes surgically challenging, have an established, uncontroversial method of repair (transecting excision and primary anastomosis) with excellent reported surgical outcomes. Conversely, strictures associated with lichen sclerosus (LS) (E6) are heterogeneous, lack an agreed upon method of repair and, unlike the traumatic stricture, can evolve and increase in size and severity with time (i.e. dynamic strictures). E2 strictures are idiopathic (i.e. unknown etiology) and, unfortunately, remain the most common type of stricture.[16,17] E3 strictures are iatrogenic strictures which we ultimately subcategorized into three groups: E3a strictures are the result of an intraurethral insult, such as post-TURP;[18] E3b strictures are strictures that arise in a previously reconstructed urethral segment (i.e. recurrent urethral strictures, excluding hypospadias strictures which are described below);[8,19] E3c strictures are associated with pelvic radiation.[20] E4 strictures are those associated with a known urethritis (i.e. infectious etiology), an etiology with mostly historical significance, but which may become more common now as antimicrobial resistance to Neisseria Gonorrhea infections grows.[21,22] E5 strictures are those that arise in a segment of urethra that had previously been constructed for congenital hypospadias.[23]

LSE Modifiers

The final components added to the classification system were the modifiers. The posterior (p) modifier is to be used when the (non-pelvic fracture distraction defect, non-bladder neck contracture) urethral stricture extends into the membranous and/or prostatic urethra. These types of strictures are common with radiation injuries (E3c) and after trans-urethral prostatic surgery (E3a) — but in general, can be managed with anterior urethral stricture repair principles. The multiple (m) modifier is used when a urethra has two or more distinct, clinically significant strictures that are managed with separate surgical techniques.[24] For example, a patient may have a 1 cm meatal/fossa navicularis stricture (S2d) and a 4 cm proximal bulbar stricture (S1a), both caused by TURP injury (E3a), managed with an extended meatotomy and ventral buccal graft, respectively. The bulbar stricture would thus be staged L2Sm1aE3c and the fossa component L1Sm2dE3c. The obliterative (x) modifier is used when a portion of the stricture has no lumen, which in general means that at least a portion of the stricture will require excision. A 2 cm obliterative stricture in the proximal bulb secondary to straddle injury would thus be classified as L1Sx1aE1.

LSE Classification System Validation

In the first validation phase, twenty-two RUGs from twenty-two patients with USD, selected from a series of over 300 RUGs and representing each of the S segments of various lengths, were presented to twenty practicing reconstructive urologists and reconstructive urology fellows, along with a supporting clinical vignette, utilizing SurveyMonkey (Appendix 2). The goal of this first phase of validation was to ensure there was sufficient clarity in the classification definitions and figures. The survey responses were aggregated and analyzed in R 3.4.3 for interrater agreement using Cohen's Kappa analysis, which is a measure of interrater agreement based on the ability of different raters to classify subjects into one of several categories to that expected by chance, as well as Light's Kappa, which is a generalization of Cohen's Kappa for more than two raters on fully-crossed designs (the same set of raters for all images). The goal for this validation phase was for each component of the LSE classification system to have a kappa value of ≥ 0.7, meaning substantial to near perfect agreement amongst reviewers. When kappa values did not meet this threshold, the individual vignettes were reviewed by the group and necessary changes were made to the classification system to improve clarity. Twenty new vignettes were then created utilizing different RUGs and the same reviewers were again asked to classify the strictures. A total of three versions of classification system were tested in the above manner until the final version, presented in Figures 1 and 2, was unanimously agreed upon by the TURNS group at an in-person meeting dedicated to finalizing the classification system.

The second validation step involved utilizing the LSE classification system to retroactively classify the 2162 strictures found in the TURNS anterior urethral stricture database. Once classified, we determined if stricture location (S), and stricture length (L) within the individual S groups, were independent predictors of urethroplasty type and stricture etiology, using Fischer's Exact Test and the Cochran-Mantel-Haenszel tests respectively, with a p-value of <0.05 representing statistical significance.

RESULTS

The final kappa statistic for the overall LSE classification system was 0.79, indicating substantial agreement amongst the reviewers. The kappa statistics for individual LSE components at each validation stage is shown in Table 1.

The distribution of the 2162 urethral stricture classifications in the TURNS database is shown in by repair type in Appendices 3 and 4. S classification strongly predicted both presumed stricture etiology ($p = 0.0005$; Fig. 3A) and urethroplasty type ($p = 0.0005$; Fig 3B). Within each L classification, there was a dependence between the S variable and E variable ($p = 0.0008$) and the S variable and urethroplasty type ($p < 0.0001$) (Appendix 5).

DISCUSSION

There is a clear need for a classification system in USD. This study demonstrated that a system based on three elements readily obtained from the pre-operative RUG, patient history, and physical exam, had sufficiently high interrater agreement to reliably be used clinically by urologists familiar with urethral reconstruction. In addition, we found that the stricture classification was strongly associated with urethroplasty type and etiology. Importantly, the system was deemed intuitive and clinically useful by post-survey questionnaire.

While USD classification systems have been proposed previously, none to date are routinely used for clinical or research purposes. Most recently, a system to determine stricture "severity," called the UREThRAL stricture score, was developed and later revised and renamed the "U-score".[25,26] Under this system a urethral stricture is given a numerical score of 4-9, based on points allotted for various stricture parameters, including stricture length, stricture number, stricture location and stricture etiology. The stated purpose of the score was to predict for urethroplasty complexity and surgical outcomes — and the ability for the score to accomplish was later validated.[27] However, a given score does little to describe the stricture itself or provide insight into disease mechanism without breaking the score into its original parts. This is not unlike what is seen in renal cell carcinoma, where a nephrometry score may provide insight into the surgical complexity and risk of post-operative outcomes after kidney surgery, but remains an incomplete assessment of the disease process itself without the accompanying TNM stage.[28,29]

Classifying Urethral Strictures

Adoption of a urethral stricture classification system has the potential to organize a heterogeneous condition into discrete stricture cohorts that will improve our ability to study the disease process. It is accepted that the pathophysiology of USD is heterogeneous, yet our treatments rarely account for this. An exception to this might be LS, where recent advancements in our understanding of LS

Table 1. Kappa statistics (overall and component) for each developmental and validation step of the LSE classification system (kappa value of ≥ 0.6 = substantial agreement)

	Validation Step 1	Validation Step 2	Final Validation Step
Length (L)	0.71	0.72	0.76
Segment (S)	0.50	0.56	0.70
Etiology (E)	0.85	0.98	0.93
Overall	0.65	0.73	0.79

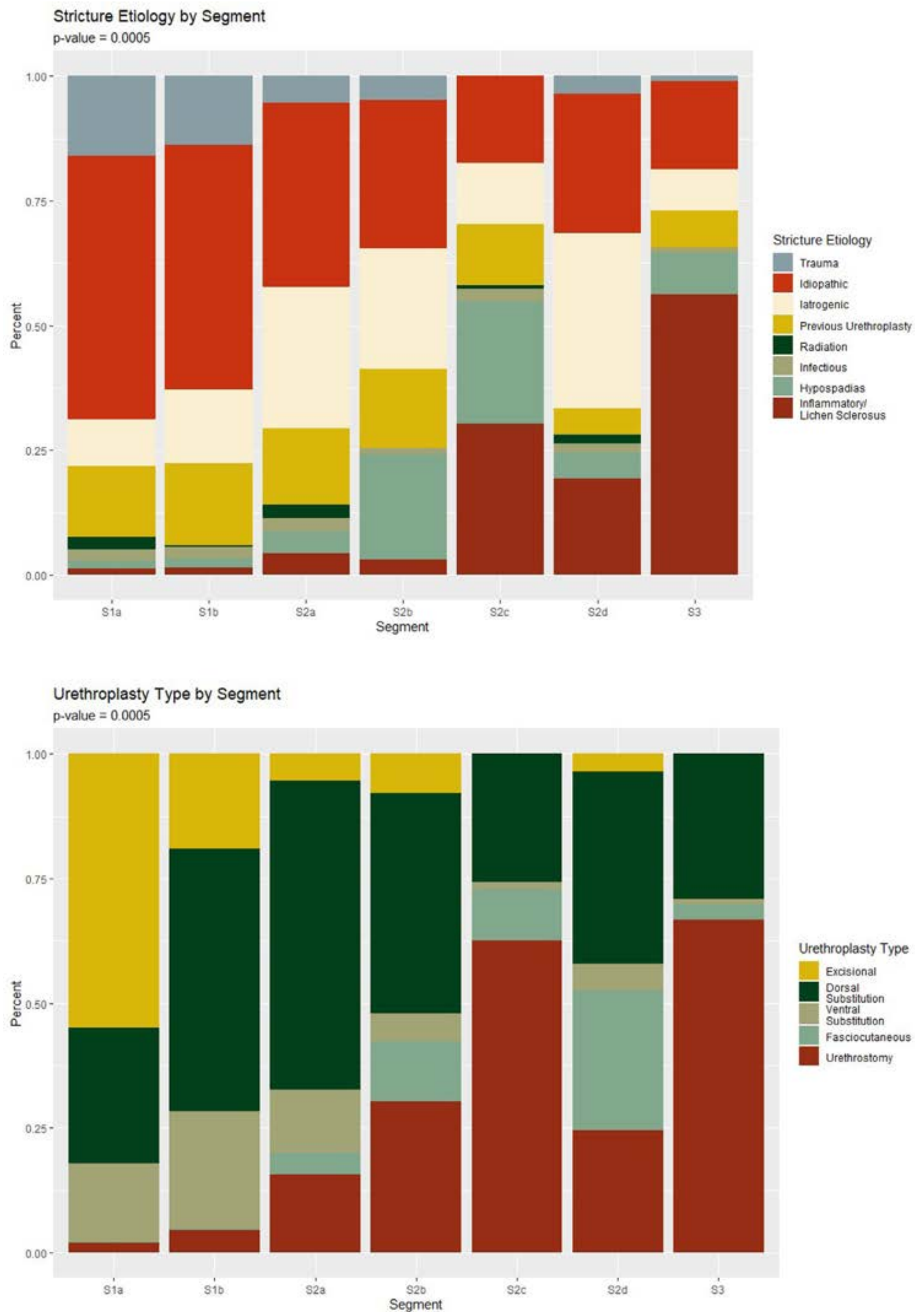

Figure 3. A: Distribution of stricture etiology (E) by stricture segment (S). (Color version available online.)
Figure 3 B: Distribution of urethroplasty type by stricture segment (S). (Color version available online.)

and its management have forced us to rethink how to best manage the "diseased urethra" — and furthermore, whether local, non-surgical therapies should be directed towards the chronic inflammatory process noted in a large percentage of urethral strictures, in lieu of surgery.[24,30] To answer these questions, however, a homogeneous population of patients must be studied (e.g. L2S2cE6 strictures), and multiple studies from multiple institutions must be performed to allow for meta-analyses. The classification system we present here was shown to be a reliable construct to facilitate this process.

Limitations

There are limitations to the study that deserve mentioning. First, the RUGs and clinical scenarios were selected from cases managed by a single reconstructive urologist that performs their own RUGs. RUGs performed by non-reconstructive urologists may not provide the detail necessary for accurate classification and furthermore, if an institution has multiple providers performing RUGs, variability may impact classification accuracy. Second, the kappa values were based on the "correct" interpretation of RUGs that were chosen in a non-random fashion by research team so to include the full complement of stricture types. Third, not all of these RUG studies included a complementary voiding cystourethrogram (VCUG), which can provide additional detail of the urethra proximal to the stricture that may have helped some observers with segment determination. However, the routine performance of the VCUG for USD is institutional dependent and is generally only helpful when the proximal extent of the stricture cannot be ascertained by standard RUG (e.g. obliterative strictures). If the surgeon cannot assess the proximal extent, a VCUG should be obtained but is not mandatory for accurate classification in most cases. Finally, while this system is meant to be used to classify all anterior strictures, not all anatomic strictures are functionally significant or bothersome. Similarly, many strictures lengths and locations "change" during urethroplasty relative to their pre-operative assessment. We expect that, similar to the TNM classification, the LSE classification will need to separate into clinical (c) (i.e. pre-intervention classification) and pathologic (p) (i.e. post-intervention classification) classifications as it becomes more widely utilized.

CONCLUSIONS

The LSE urethral stricture classification system was shown to be a reliable tool to describe urethral strictures amongst reconstructive urologists using patient history, physical exam and RUG images alone. The segment (S) classification was strongly associated with urethroplasty type and stricture etiology (E). We expect that widespread utilization will aid in clinical communication and facilitate collaborative research endeavors that will allow for needed advancement in management of this poorly understood disease process.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2020.03.072.

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EDITORIAL COMMENT

This manuscript provides an important contribution to the literature on urethral stricture disease. The need for a clinically usable and meaningful classification system for anterior urethral strictures is well-recognized, and the authors have thoughtfully selected key imaging, anatomic and disease-related factors to develop such a system. The critical importance and value of utilizing objective, descriptive classification systems has had a transformational impact on the utility of the published literature in urologic oncology, trauma, and other specialty areas. The need for such a system for stricture disease is no different. The system proposed here-in, the "LSE System", is based on the three elements of length of stricture (L), urethral segment involved by the stricture (S), and etiology (E), with various subclassifications and modifiers. It has been shown to be predictive of the type of urethroplasty needed for corrective reconstruction, and would be quite useful in comparing reported series and outcomes.

xWhile the generated numerical descriptions for the system proposed in this manuscript may be somewhat cumbersome ("L1Sm2dE3c", for example), the inter-rater variability was demonstrated to be acceptable among reconstructive urologists, and utilization would be a valuable means of grouping and describing strictures in the literature. It will be interesting to observe whether this system will come into common use by community urologists, considering its complexity, but nevertheless, even use by reconstructive urologists and in scholarly publications, has value. Community urologists who do not specialize in urethral reconstruction will appreciate the importance of considering the selected factors in assessing strictures and potentially in determining which stricture might best be referred for subspecialty care.

The authors describe the limitations of the proposed system in an appropriate manner. Overall I view the proposed classification of anterior urethral stricture as a well-structured system, adding meaningfully to the literature on anterior urethral stricture management.

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AUTHOR REPLY

To classify is to understand − and we hope the classification system we have presented here is another necessary step to better understand urethral stricture disease.

If we utilize oncology and the TNM staging as our guide, the next steps should be to utilize the LSE system to help us better describe and predict the surgical outcomes of various urethroplasty techniques. This knowledge should then help direct treatments.

Another natural extension will be the incorporation of histopathology in our treatment making decisions. Just as tumor grade dictates prognosis, so will stricture pathology − mostly likely by describing the type and extent of inflammation and fibrosis within and next to the stricture.[1,2]

Finally, we hope that by standardizing the classification of strictures, multi-institutional studies will become more commonplace, randomized controlled trials will be easier to perform (e.g. recruitment of L1S1a strictures only), and meta-analyses will be possible.

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