Prospective evaluation of flexible ureteroscopes with a novel evaluation tool

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Introduction: *Assess the function and handling in the clinical setting of three different types of reusable or disposable ureteroscopes using a novel, comprehensive flexible ureteroscope evaluation tool.*

Materials and methods: *Urologists used a fiberoptic (Olympus URF-P5/P6), digital reusable (Storz Flex Xc), or a new digital disposable ureteroscope (Boston Scientific LithoVue) during ureteroscopic laser lithotripsy. An investigator-designed evaluation tool was used to prospectively assess the performance and handling of the ureteroscopes related to user comfort, maneuverability, efficiency, and various mechanical qualities. After each procedure, surgeons involved in each case who used the ureteroscope completed the written evaluation of the ureteroscope he/she used independently of one another.*

Results: *We reviewed 79 evaluations that were completed after 34 surgical cases; residents and post-graduate MDs were involved in each case. On the characteristics evaluated, significant differences between ureteroscopes were noted. The Storz reusable digital ureteroscope received the highest ratings overall while the new LithoVue disposable ureteroscope generally scored lowest. Our evaluation tool demonstrated good internal consistency, suggesting reliable results. Ureteroscope maneuverability correlated most to overall satisfaction.*

Conclusion: *The clinical evaluation of flexible ureteroscopes for stone removal is critical in equipment purchase decision-making and in planning surgical approaches. We created a comprehensive evaluation tool to standardize and quantify the assessment of ureteroscopes used at our institution. Results revealed significant differences between ureteroscopes for several user and performance characteristics and good reliability of the evaluation tool itself.*

Key Words: equipment design, ureteroscopes, evaluation, urolithiasis, disposable equipment, technology

Introduction

The utilization of ureteroscopy for the management of kidney stones has increased dramatically in the last decade.[1-3] During this time, numerous advances in ureteroscopic technology have been made. Institutional purchasing decisions as well as decisions regarding approaches to individual surgical cases require a reproducible and quantitative evaluation process. Currently, no standardized method for the evaluation of flexible ureteroscopic technology exists. Previous evaluations of ureteroscopes have focused on the optical and mechanical qualities of ureteroscopes tested only in an *in vitro* setting.[4-8] Another in vitro study was recently reported evaluating flexible ureteroscopes in cadaveric kidneys.[9] While these studies provide important technical information, they do not provide a comprehensive evaluation methods of the ureteroscopes tested. Clinical outcomes of the disposable digital ureteroscope have recently been reported, but again, no evaluation method was offered to assess the urologists opinion of the flexible ureteroscope.[10] Moreover, with no standard tool by which to compare ureteroscopes during clinical use, the comparison of results between published

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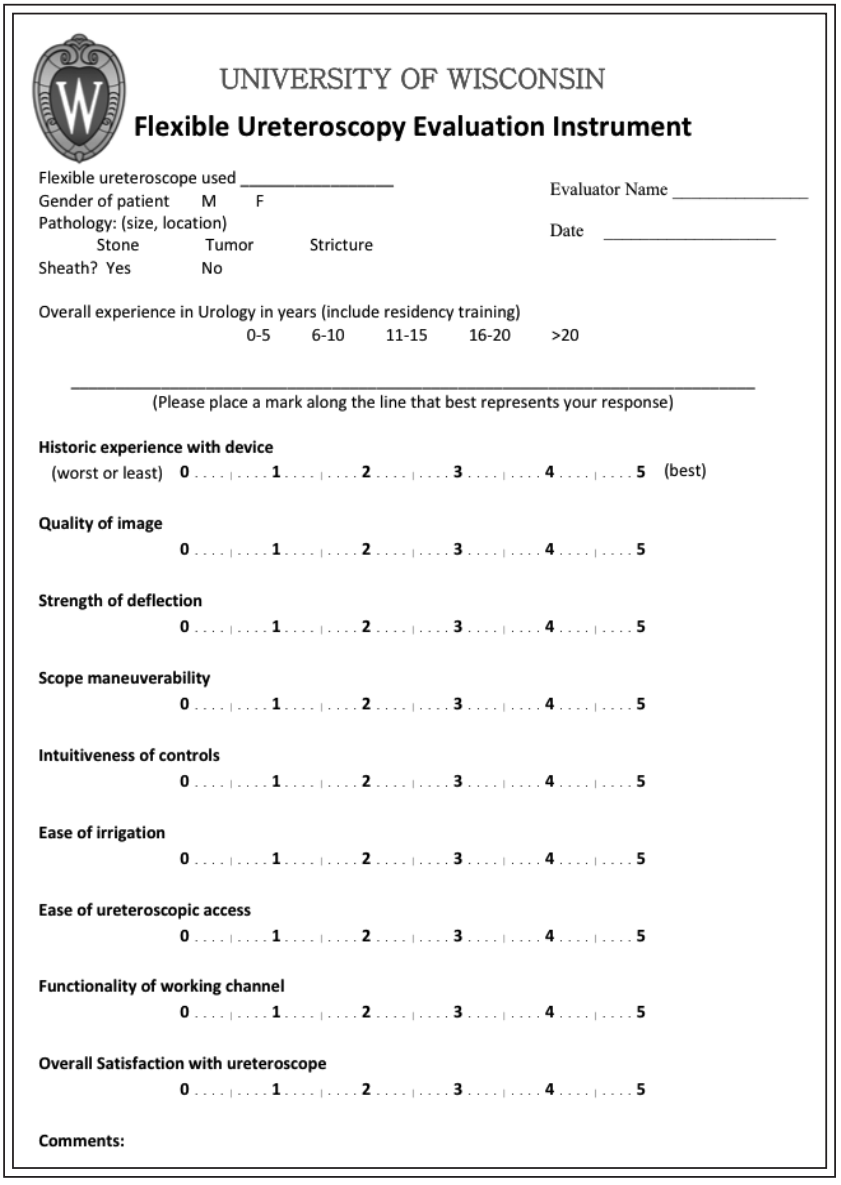
studies is limited. A standardized, validated tool for the evaluation of ureteroscopic technology would be useful in providing urologists and ureteroscope manufacturers information that could be used to improve surgical instrumentation. Thus, we developed and piloted an evaluation tool to be used by urologists to evaluate ureteroscopic technology.

The primary purpose of this study was to internally assess the internal consistency and reliability of an evaluation tool we designed for the comparison of flexible ureteroscopes. A secondary purpose was to assess the LithoVue disposable digital ureteroscope (Boston Scientific, Boston, MA, USA), a new disposable digital ureteroscope, and compare its performance and other qualities to ureteroscopes currently in use at our institution.

Materials and methods

Evaluation instrument development

We were unable to identify from the literature a standardized evaluation tool for assessing the performance of ureteroscopic surgical equipment. Thus, we iteratively constructed an evaluation tool in general accordance with classical test theory concepts for the creation of outcomes assessment tools.[11] After reviewing the literature, we defined our target outcomes by consulting with urologic surgeons experienced in ureteroscopic treatments for urolithiasis. Based on these inputs, we devised questions that reflected each of the target outcomes and once again consulted with urologists at our institution to confirm that the questions appropriately addressed items pertinent to assessing ureteroscope function and handling. Finally, we pilot-tested the questionnaire among urologists with various levels of training and experience at our institution. Based on feedback, minor revisions were made to the questionnaire. The final version consisted of eight questions assessing surgeon attitudes about: 1) functionality of the ureteroscope's working/irrigation channel, 2) instrument maneuverability, 3) comfort of use, and 4) image quality. An item for overall satisfaction was also included, Figure 1. The response option for each item was presented as an interval scale with 0.1 point increments ranging from 0 to 5 with 5 being the highest (most favorable or best) response possible.



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Flexible Ureteroscopy Evaluation Instrument

Flexible ureteroscope used _____

Gender of patient M F

Pathology: (size, location)

Stone Tumor Stricture

Sheath? Yes No

Evaluator Name _____

Date _____

Overall experience in Urology in years (include residency training)

0-5 6-10 11-15 16-20 >20

(Please place a mark along the line that best represents your response)

Historic experience with device

(worst or least) 0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | . . . . 5 (best)

Quality of image

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Strength of deflection

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Scope maneuverability

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Intuitiveness of controls

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Ease of irrigation

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Ease of ureteroscopic access

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Functionality of working channel

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Overall Satisfaction with ureteroscope

0 . . . . | . . . . 1 . . . . | . . . . 2 . . . . | . . . . 3 . . . . | . . . . 4 . . . . | 5

Comments:

Figure 1. Flexible ureteroscope evaluation tool. The evaluation tool developed and distributed to respondents is shown. It includes questions regarding the surgical case being performed and information about the respondent. The experience with the device is asked along with eight questions regarding the evaluation of the flexible ureteroscope. The modified Likert scale shown allows the urologist to place a mark anywhere along the continuum allowing for improved discrimination of responses.

TABLE 1. **Technical specifications of the flexible ureteroscopes evaluated. The two fiber optic Olympus ureteroscopes were evaluated as a single group**

Ureteroscope	Distal tip diameter (Fr)	Maximum tip diameter (Fr)	Upward deflection (degrees)	Downward deflection (degrees)	Working channel diameter (Fr)	Length (cm)
Olympus URF-P5	5.3	8.40	180	275	3.6	70
Olympus URF-P6	4.9	7.95	275	275	3.6	67
Storz Flex Xc	8.4	8.50	270	270	3.6	70
Boston Scientific LithoVue	7.7	9.50	270	270	3.6	65

Internal consistency

Evaluators' responses on the evaluation tool were tabulated and compared. Multivariate analyses were conducted in order to determine the statistical power of the results and to make comparisons between ureteroscopes. Pearson correlation coefficients were calculated to describe the linear relationship between items. Cronbach's alpha coefficients were calculated to assess the internal consistency of the questionnaire in an effort to extrapolate its reliability and potential generalizability in further ureteroscope evaluations.

Ureteroscopes and evaluation process

We prospectively evaluated a reusable flexible digital ureteroscope (Flex Xc, Karl Storz, Germany), two fiberoptic ureteroscopes (URF-P5 and URF-P6, Olympus Corporation of America, Center Valley, PA, USA), and the new LithoVue disposable digital ureteroscope (Boston Scientific, Marlborough, MA, USA). The two Olympic fiberoptic ureteroscopes were treated as a single group. Technical specifications of these ureteroscopes are compared, Table 1. Urologists participating in ureteroscope evaluations were two endourology fellowship-trained attending surgeons, one with > 20 years of post-fellowship experience and the other with 5 years of post-fellowship experience; and a current endourology fellow. In addition, six urology residents participated. Multiple operators were involved in each procedure (e.g., resident and attending urologist and/or fellow). Ureteroscope assignment was by instrument availability at the time of each case. In most cases, a single ureteroscope was used. Procedures for which the ureteroscopes were used involved treating upper urinary tract stones with the technique of dusting the stone using a holmium laser. It is common practice at our institution to examine all renal calyces under direct visualization; therefore, all surgeries included a complete flexible retrograde renoscopy. At the end of each ureteroscopy procedure, participants answered written, standardized questions about the handling and function of the ureteroscope they used; these evaluations were completed independently of one another at the end of each procedure. A priori estimations suggested that a minimum of 68 individual observations were required in order to detect significant differences in overall satisfaction between ureteroscopes ($p < 0.05$).

Results

Seventy-nine assessments were completed during 34 surgical cases. The number of cases with each ureteroscope is shown, Figure 2. Cases were conducted relatively similarly, but there were some notable variations. The LithoVue disposable digital ureteroscope was switched to one of the Olympus fiberoptic ureteroscopes during one case because of poor visualization caused by bleeding. Four patients had preoperative stents in cases involving the Olympus fiberoptic ureteroscopes compared to two patients in cases involving the Storz reusable

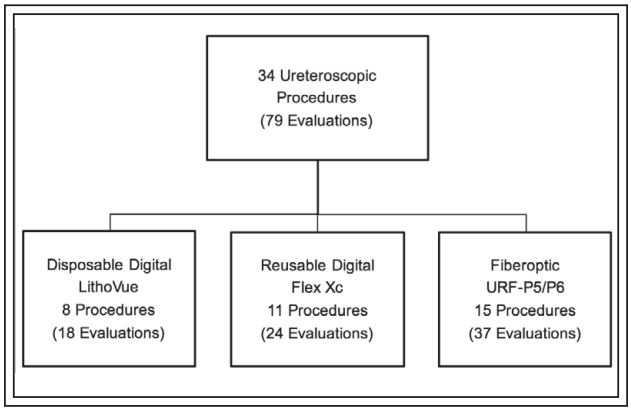

Figure 2. Clinical trial flow chart. The number of ureteroscopic procedures and evaluations completed are shown.

digital ureteroscope; no patients were pre-stented in cases involving the LithoVue disposable digital ureteroscope. Access sheaths were not used during any case with the Olympus fiberoptic ureteroscopes nor the LithoVue disposable digital ureteroscope. However, an access sheath was used in two cases involving the Storz reusable digital ureteroscope: in one case, it was used to dilate the ureteral orifice but did not remain in place during the procedure; it was used in the other case throughout the entire procedure.

Our instrument took < 1 minute on average to complete, and significant differences between the performances of the ureteroscopes were noted, Figure 3. Overall satisfaction with the Storz reusable digital ureteroscope was highest (4.6 ± 0.4 compared to 3.9 ± 0.5 and 2.9 ± 0.9 for the two Olympus fiberoptic ureteroscopes and the LithoVue disposable digital ureteroscope, respectively; $p < 0.01$). The LithoVue disposable digital ureteroscope was rated lowest for quality of image, strength of deflection, maneuverability, intuitiveness of controls, and ease of irrigation ($p < 0.05$ for all comparisons, Figure 3). The Storz reusable digital ureteroscope was not different for ease of ureteral access from the two Olympus fiberoptic ureteroscopes, Figure 3. The Storz reusable flexible digital ureteroscope was rated significantly higher than all other ureteroscopes evaluated for image quality, strength of deflection, maneuverability, intuitiveness of controls, ease of irrigation, and quality of the working channel ($p < 0.05$ for all comparisons; Figure 3).

Multivariate analysis revealed that level of user training significantly influenced the ratings of maneuverability, intuitiveness, and overall satisfaction, Table 2. In these categories, the postgraduate responders scored the ureteroscopes lower than residents. Mean differences in responses based on level of experience of the respondent are shown in Table 2.

Internal consistency of the ureteroscope evaluation tool was acceptable, evidenced by the relatively high Cronbach's alpha coefficient of 0.85. The inter-item correlation mean of the Pearson correlation coefficients was 0.46 with a range of 0.10 to 0.88, suggesting that the items measured different aspects of ureteroscope function, handling, and performance. The item that correlated most to overall satisfaction was maneuverability (Pearson correlation coefficient, 0.88).

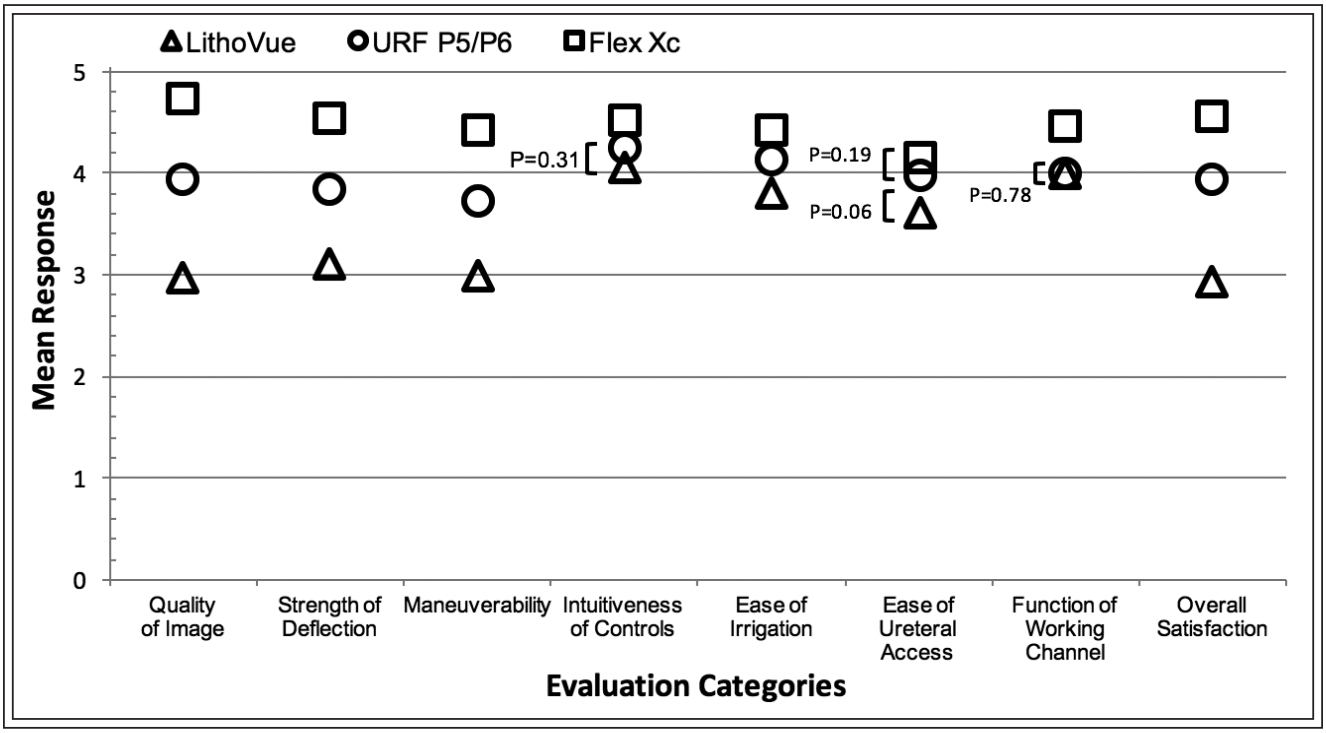

Figure 3. Mean user responses as reported on the ureteroscope evaluation tool. Differences between ureteroscopes for each evaluation item are statistically significant ($p \leq 0.03$; Student's t-test) unless otherwise noted. Data represent 79 completed evaluations (by 9 urologists and urology residents) from 34 ureteroscopic procedures.

TABLE 2. **Comparison of the difference in user responses according to level of user experience. Data shown represent the differences in scores per item between urology residents and urologists who had completed residency (i.e., urology resident scores minus post-graduate scores). P values are from multivariate analyses**

Evaluation category	Mean difference in response	SD	p value
Image quality	-0.088	0.13	0.507
Strength of deflection	0.225	0.15	0.133
Maneuverability of scope	0.315	0.13	0.019
Intuitiveness of controls	0.275	0.09	0.003
Ease of irrigation	-0.078	0.12	0.504
Ease of achieving ureteral access	0.133	0.15	0.368
Functionality (quality) of working channel	0.036	0.09	0.684
Overall satisfaction	0.284	0.14	0.046

Discussion

Using an evaluation tool we developed, which included characteristics related to user comfort and functionality in specific areas, Table 2, we evaluated the new LithoVue disposable digital ureteroscope and compared its performance and function to other ureteroscopes currently used at our institution: the Storz reusable flexible digital ureteroscope and two Olympus fiberoptic ureteroscopes. Evaluations were completed by urologists and residents of varying levels of experience. The results of this prospective clinical trial revealed that the Storz reusable digital ureteroscope was ranked highest (best) in all categories, Figure 3.

Using our evaluation tool, the image quality of the Storz reusable digital ureteroscope was rated better than the other ureteroscopes tested. Written comments provided by participants after the procedures suggested that use of the LithoVue disposable digital ureteroscope was associated with more screen interference. Comments indicated that while the image obtained with the LithoVue disposable digital ureteroscope was quite sharp prior to treatment, notable image interference was encountered during laser lithotripsy, impairing visualization of the stone target(s) and making fragmentation more challenging. This might be contrary to expected results regarding image quality and might suggest that the LithoVue was handled differently than the other ureteroscopes in this study. However, measures are in place at our institution to keep the laser fiber tip of the holmium laser at a safe and relatively uniform distance from the tip of the ureteroscope in all our cases, in accordance with safe practice.[12]

With respect to handling, the shaft of the LithoVue disposable digital ureteroscope was found by our evaluators to be more difficult to rotate compared to both the Olympus fiberoptic and the Storz reusable digital ureteroscopes. In addition, user comments stated that the deflection lever felt stiffer with this ureteroscope. The LithoVue has excellent flexion of 270 degrees in both directions *in vitro*. However, we noticed a somewhat more limited mobility clinically possibly due to anatomical variations. These qualities likely explain the lower scores in flexibility and maneuverability.

Other in vitro assessments of ureteroscope performance have been reported but have not aimed to standardize user feedback in a comprehensive evaluation. Our study was conducted in the clinical setting using a new comprehensive evaluation tool. This tool was developed according to classical test theory, an accepted psychometric paradigm used in the development of outcome measures.[11] Our evaluation tool was administered easily and was quickly completed. According to classical test theory, we assessed our evaluation tool for internal consistency and reliability, extrapolating its potential utility in the standardized evaluation of ureteroscopes by urologists. The use of Cronbach's alpha, a statistical procedure to objectively measure reliability and the first step in assessing the validity of an evaluation tool, revealed that we appropriately assessed the characteristics being measured (Cronbach's alpha coefficient, 0.85). The inter-item correlation mean of the Pearson correlation coefficients between specific items on the evaluation tool was 0.46 (range, 0.10-0.88), and this strongly suggests that different constructs/characteristics were measured.

Interestingly, the item that correlated most to the overall satisfaction of the ureteroscopes evaluated was maneuverability. Future planned multi-institutional studies using this evaluation tool will evaluate whether maneuverability is a feature valued as highly by other urologists and whether, as in our study, it contributes significantly to users' overall satisfaction.

The evaluation tool was able to discriminate between resident urologists in training versus graduates. Urologists with more experience scored the ureteroscopes lower in the categories of maneuverability, intuitiveness, and overall satisfaction. Therefore, our tool allows for the distinction of experience at our institution. Another potential application for our evaluation tool is to monitor the changes in ratings over time as the user gains more experience with the ureteroscope.

Limitations of our study included its single institution nature, which may not have accounted for variability in surgical technique and experience. We also recognize that the evaluation scores are subjective and may differ between users and institutions. New technology feels different and user experience may certainly bias opinions. Another limitation was the lack of ureteroscope randomization and blinding. Randomization was not possible due to the fact that the LithoVue disposable digital ureteroscope was available to us only on specific days; and it was logistically impossible to blind each operator to the ureteroscope he/she used. In an effort to control for this, the use of the ureteroscopes was varied among all surgical cases and among all users as much as possible. Limitations of the evaluation tool we created included its inability to take into account the durability and maintenance costs of ureteroscopes, which may play a role in ureteroscope purchasing decisions.[13] However, because short term durability and equipment failures are not measurable when surgical equipment is new, initial performance characteristics may take priority when deciding on new equipment purchases, especially given the unknown long-term durability and maintenance costs of new technology. Nonetheless, future versions of this evaluation tool may include questions related to cost and durability. The primary aim of this study was to evaluate ureteroscopic characteristics related to user acceptability. As such, another potential limitation was that we did not compare and report surgical outcomes related to the ureteroscopes we evaluated. Future studies may expand the comparison of ureteroscopes to include surgical outcomes.

The standardized evaluation of ureteroscopes (and potentially other surgical instruments used in urinary stone procedures) across institutions and among multiple users would be valuable. Such evaluations could result in critical information to drive the development of new technology that is both more effective and user-friendly. Our results revealed some advantages to reusable ureteroscopes compared to the new LithoVue disposable ureteroscope. Specific characteristics were identified that could be improved upon as or before this new ureteroscope is promoted for broader use by urologists. Further clinical trials are needed to continue to assess the quality of new ureteroscopic technology.

Conclusion

We developed and tested a novel evaluation tool that was used by urologists to compare the performance of flexible ureteroscopes during surgical procedures. Overall, our multi-user evaluation of three different types of ureteroscopes showed relative advantages of reusable digital or fiberoptic versus a new disposable digital ureteroscope with respect to function and user comfort. Maneuverability, which was associated most with the overall satisfaction of ureteroscopes by our users, should be further assessed (as should other ureteroscope characteristics) for its relative importance to other urologists. The evaluation tool we created was determined to be highly reliable, suggesting a relatively low error of variance. Nonetheless, prior to its broader release, future assessments of this evaluation tool are needed to confirm its validity and generalizability in the assessment of ureteroscopes, which may ultimately lead to the identification of ureteroscopic instrument features and characteristics of greatest significance and importance to urologists.

Disclosure

Drs. Stephen Y. Nakada and John Roger Bell are consultants for Boston Scientific. Dr. Kristina L. Penniston is a consultant for Retrophin. Dr. Sarah L. Best has no disclosures. □

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