

# *In Vitro* Evaluation of Single-Use Digital Flexible Ureteroscopes: A Practical Comparison for a Patient-Centered Approach

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## Abstract

**Objective:** To compare the manufacturing and *in vitro* performance characteristics of two single-use flexible ureteroscopes with a permanent optical flexible ureteroscope.

**Materials and Methods:** Two single-use flexible ureteroscopes, LithoVue (Boston Scientific) and Pusen (1st generation; Zhuhai Pusen Medical Technology Company Limited, China), were tested and compared with a permanent Flex-X<sup>2</sup> ureteroscope (Karl Storz, Germany) in terms of technical characteristics, optics, deflection mechanism, and additional parameters which could potentially affect surgical technique.

**Results:** Pusen was the lightest ureteroscope while the LithoVue had the longest working length. LithoVue had a higher resolution power than the other two ureteroscopes at all distances tested ( $p < 0.001$ ). Pusen showed higher resolution than Flex-X<sup>2</sup> ( $p < 0.01$ ). Field of view was wider for LithoVue (87°), followed by Flex-X<sup>2</sup> (85°) and Pusen (75°). Color representation was superior for Flex-X<sup>2</sup> than LithoVue and then Pusen. LithoVue outperformed Pusen and Flex-X<sup>2</sup> for all settings with instruments in terms of deflection loss ( $p < 0.01$ ). Pusen had the highest irrigation flow (52 mL/min) with an empty working channel ( $p < 0.01$ ). LithoVue and Pusen showed similar flow rates with a 200  $\mu\text{m}$  (21 mL/min) and 365  $\mu\text{m}$  laser fiber (7 mL/min) and 1.3F basket (18 mL/min), being superior to Flex-X<sup>2</sup> ( $p < 0.01$ ). With the 1.9F basket, LithoVue had superior flow rate (7 mL/min) than Pusen (3.5 mL/min) and Flex-X<sup>2</sup> (4 mL/min;  $p = 0.01$ ).

**Conclusion:** LithoVue outperformed the other ureteroscopes in terms of optical resolution, field of view, deflection capacity, and irrigation flow with larger instruments. Pusen is the lighter scope and showed better results in terms of irrigation when no instruments are in place. Flex-X<sup>2</sup> was superior in terms of color representation.

**Keywords:** ureteroscopy, instrumentation, urolithiasis

## Introduction

STONE DISEASE IS A major clinical and economic burden for healthcare systems worldwide.<sup>1</sup> Studies from developed and emerging countries show a trend toward increased use of less invasive techniques.<sup>2-4</sup> In the last decades, retrograde ureterorenoscopy has become a first-line option for management of renal calculi with low morbidity and high success rates.<sup>5,6</sup> However, the cost of flexible ureteroscopy has posed a deterrent to widespread global implementation. Disposable accessories are usually required and their expense can be substantial. In addition, reusable flexible ureteroscopes with advanced digital imaging are more expensive without gaining in longevity.<sup>7-9</sup> The risk of cross infection and the

expenditures for attaining and repairing flexible ureteroscopes in high-volume stone disease centers are the main drivers toward an increased use of single-use flexible ureteroscopes.<sup>7-11</sup>

The first single-use disposable flexible ureteroscope was the LithoVue (Boston Scientific). Initial laboratory testing and use in clinical practice validated its safety and high effectiveness profile which were comparable to contemporary reusable ureteroscopes.<sup>12,13</sup> Hence, the concept has gained popularity, and other single-use flexible scopes have been introduced in the market. The Pusen (Zhuhai Pusen Medical Technology Company Limited, China) has been recently released in Latin America and holds the promise of having the same performance profile of LithoVue while reducing commercial price.

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The purpose of this study was to systematically compare the manufacturing and *in vitro* performance characteristics of two single-use flexible ureteroscopes (LithoVue and Pusen) with a permanent optical flexible ureteroscope to critically evaluate specific advantages and disadvantages of each device in different scenarios, allowing a patient-centered approach for the urologist who seek a standard of care flexible ureteroscopy.

## Materials and Methods

We compared three types of flexible ureteroscopes available for commercial use in Latin America in terms of technical characteristics, optics, deflection mechanism, and additional parameters, which could potentially affect surgical technique and clinical outcomes. Two single-use flexible ureteroscopes, LithoVue (two scopes; Boston Scientific) and Pusen (first generation, two scopes; Zhuhai Pusen Medical Technology Company Limited), were tested and compared with a permanent Flex-X<sup>2</sup> ureteroscope (one scope; Karl Storz, Germany). No permanent digital flexible scope from Storz or other companies was available for bench testing or commercial use. Each scope tested was in new condition (no prior use), including the permanent one. Tests were performed having the specific manufacturing technicians in the room so that any engineering abnormality could be pointed out.

### Technical specifications

For each scope, video tower details, total ureteroscope weight, total working length, optical system, illumination, tip and shaft diameter, working channel characteristics, and deflection mechanism were appraised.

### Optical characteristics

The three flexible ureteroscopes were assessed *in vitro* for image resolution, field of view, and color representation. Tests were performed in a dark room, and no saline immersion was used since available models for optical tests cannot be placed under water. For each criterion, two independent observers who were blinded to the identity of the scope evaluated pre-recorded images. For the LithoVue and Pusen, their respective dedicated high-resolution monitors were used. For the Flex-X<sup>2</sup>, a Storz tower with high-definition camera and monitor and recording system (Karl Storz Image 1 HD Camera System with H3 and Xenon 300 Light Source) was used during all trials. To avoid bias of knowing the scope optical system used, specific and objective scales were used during all trials.

We evaluated image resolution using a 1951 US Air Force Test Pattern Card (Edmund Optics, Barrington, NJ) at a distance of 10, 20, and 50 mm with each flexible ureteroscope. The USAF 1951 resolution target uses a repeating series of parallel bars decreasing in size. System resolution is defined as the highest group and element in which the three bars can still be distinguished (Fig. 1A). Resolution was defined as the imaging system's ability to distinguish object detail and the test target measure resolution in terms of line pairs per millimeter.

To evaluate field of view, the scopes were placed over the 0° horizontal plane of a protractor. A sharp object placed over the outer round-shaped line of the protractor was moved from the lateral to medial ureteroscope field of view until it could

be seen on the video. This first outer point in which the object could be seen on screen was noted (Fig. 2A, B).

Color representation was evaluated using a Gretag-Macbeth Color Checker Target (Edmund Optics), and the ureteroscopes were tested 10, 20, and 50 mm away from the object (Fig. 3A). Three reviewers graded the color representation from 0 to 2 (0—no similarity; 1—little similarity; 2—great similarity).

### Deflection and irrigation flow

For the three scopes, we initially assessed loop diameter of the end-working portion of the scope in a complete deflected position with no instrument in the working channel.

Each flexible ureteroscope was tested with an empty channel followed by placement of different instruments to determine the extent to which they impact ureteroscope deflection and irrigation flow. A 200  $\mu$ m ball tip single-use laser fiber (Flexiva™; Boston Scientific), a 365  $\mu$ m flat tip single-use laser fiber (AccuTrac™; Boston Scientific), a 1.3F wire basket (OptiFlex™; Boston Scientific), and a 1.9F wire basket (ZeroTip™; Boston Scientific) were consecutively tested. Each device was advanced through the working channel of the flexible ureteroscope in a straight position until their tip protruded from the end of the scope. Measurements from three digital images of the maximum deflection in each direction were averaged for final comparisons.

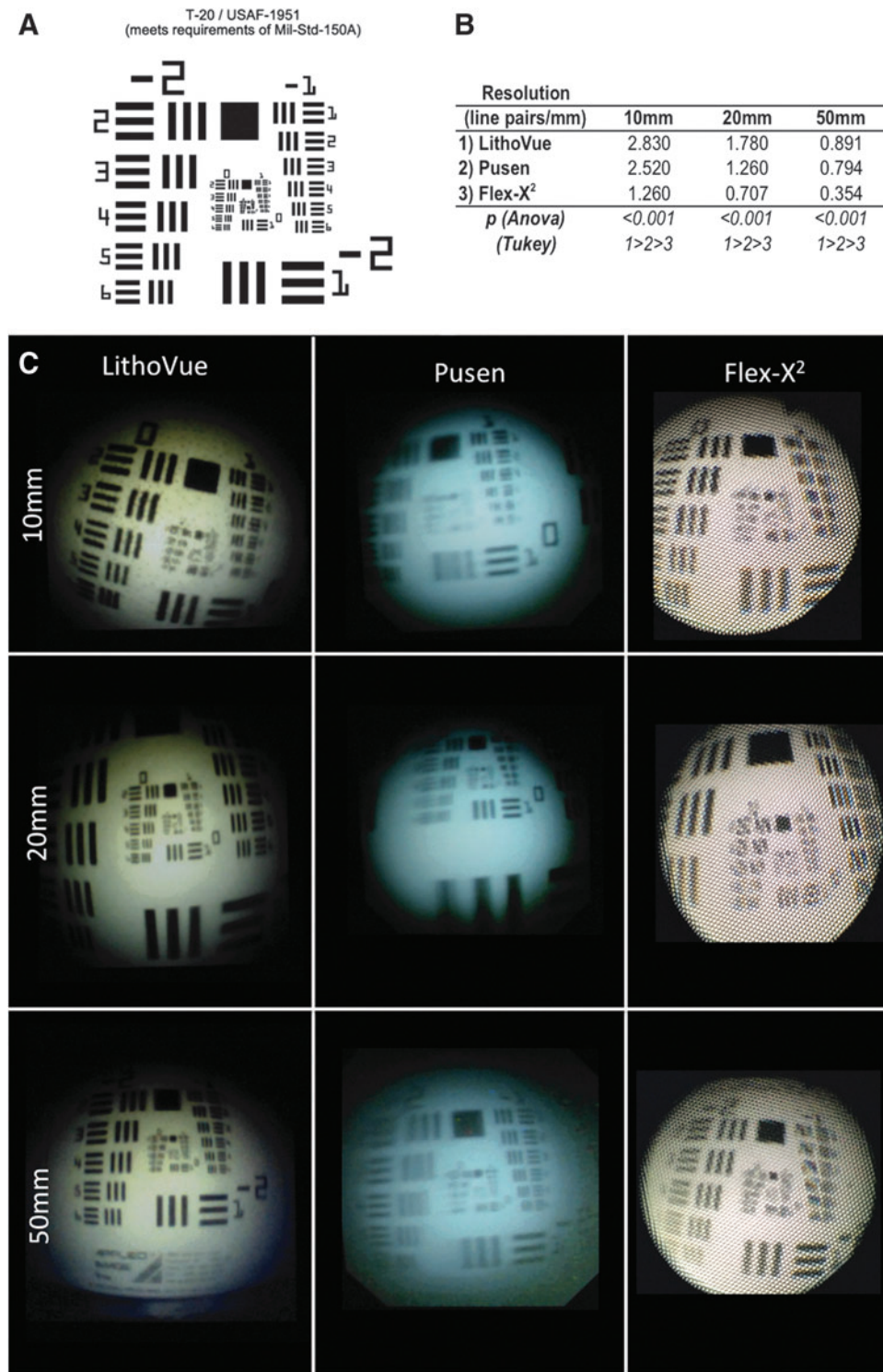
Irrigation flow rate was measured using standard saline at a height of 100 cm by connecting it to the irrigation channel of each flexible ureteroscope. Three trials were performed with an empty channel and then with the instruments described previously. For each setting, the system was allowed to equilibrate for 1 min before flow measurement was recorded.

### Ureteroscope performance and safety evaluation

The ease of deploying and retracting each flexible ureteroscope through a 11F/13F and a 13F/15F ureteral access sheath (Navigator™; Boston Scientific) was graded on a scale from 0 to 4 (0=no friction, 1=minor friction, 2=noticeable friction, 3=severe friction, 4=unable to deploy) with the sheath placed on an artificial model for flexible ureteroscopy practice. Furthermore, the scopes were tested with no instruments in the working channel to appreciate if all calices of the artificial model could be reached, including a difficult anterior calix in the lower pole of the right kidney (Fig. 4).

For evaluating the safeness of laser fiber positioning during lithotripsy to avoid back-burn of the tip of the scope, we introduced the 200  $\mu$ m laser fiber (Flexiva; Boston Scientific) through the working channel of the scope until the ball tip began to appear on the respective monitor and then measured the distance from the fiber to the ureteroscope tip over a digital ruler. The same experiment was performed advancing the laser fiber until the protective green outer layer of the fiber was seen on screen (Fig. 5).

At last, the laser fiber was retrieved and it was reintroduced with the ureteroscope in the complete deflected position. This was performed initially with the ball tip in place. In a second trial for each scope, following manufacture specification, the same test was performed after the laser fiber was cleaved sharply with a dedicated scissor. The ease of deploying the laser fiber was graded on a scale from 0 to 4 (0=no friction, 1=minor friction, 2=noticeable friction, 3=severe friction, 4=unable to deploy).



**FIG. 1.** Image resolution comparison between the three flexible ureteroscopes; (A) 1951 US Air Force Test Pattern Card used for all trials; (B) results of image resolution testing; (C) image representation of 10, 20, and 50 mm trials for the three scopes.

*Statistical analysis*

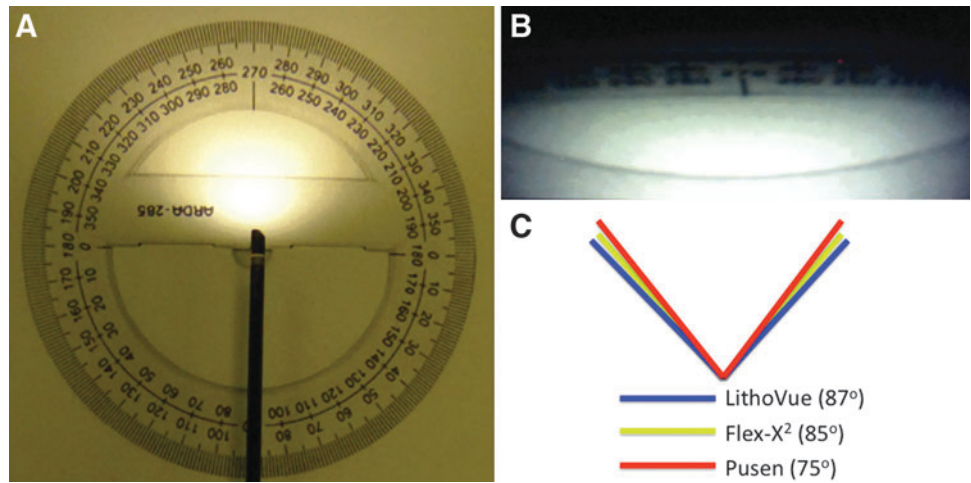
Statistical analysis was performed with SPSS Version 20 (SPSS, Inc., Chicago, IL). Results are expressed as mean and standard deviation. Analysis of variance was used for multiple comparisons. Tukey’s test for inequality assuming unequal variance with Bonferroni’s adjustment for multiple comparisons was used to determine significant differences for pair-wise comparisons among devices. The level of significance was set at  $p < 0.05$ .

**Results**

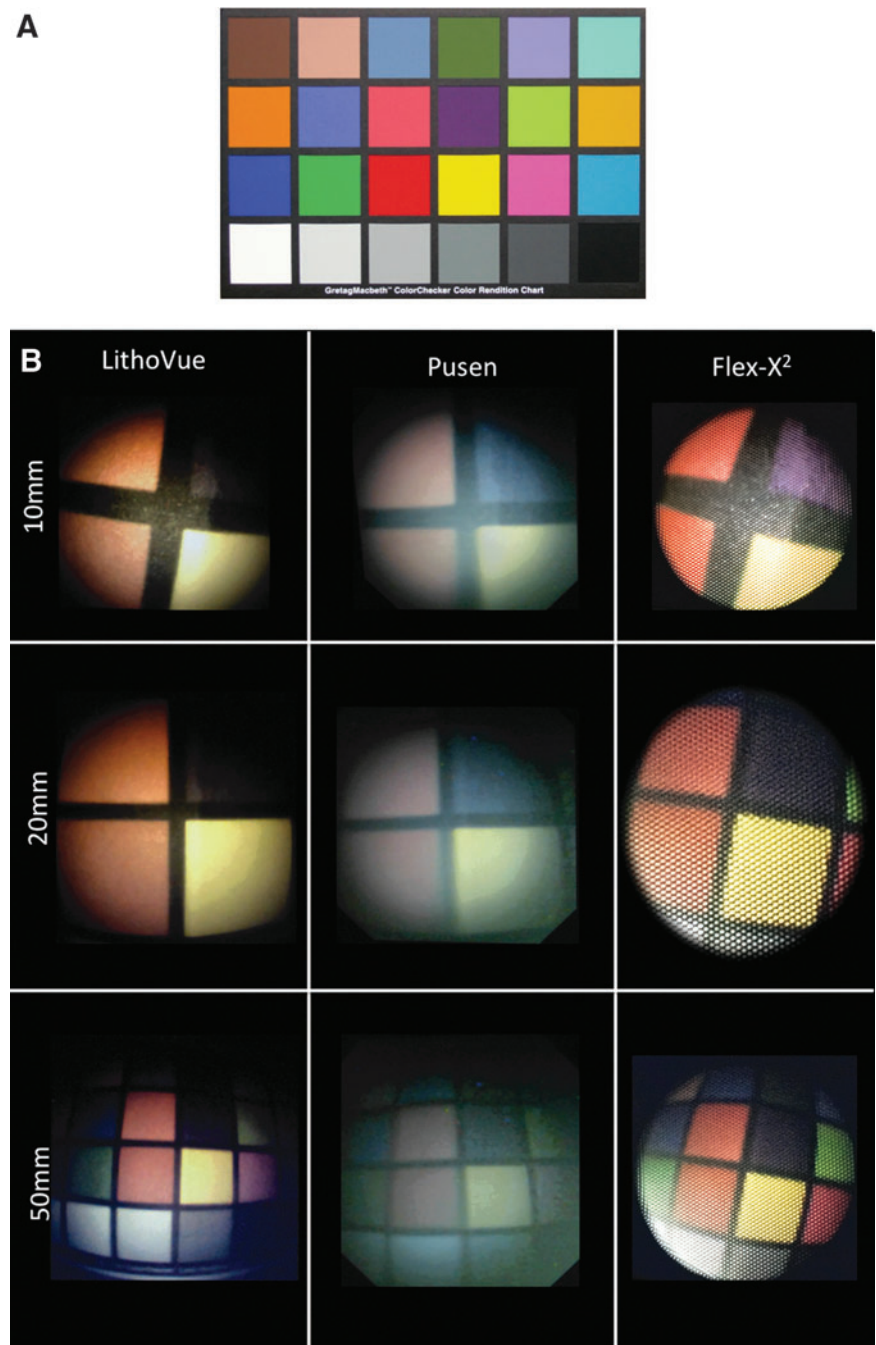
*Technical evaluation*

The Pusen was the lightest ureteroscope, while the LithoVue had the longest working length. The characteristics of the tested ureteroscopes are shown in Table 1. All ureteroscopes were similar in terms of dual deflection, although the handle control for its adjustment is in a dorsal position on Pusen and the scope should be used with the hand in a horizontal

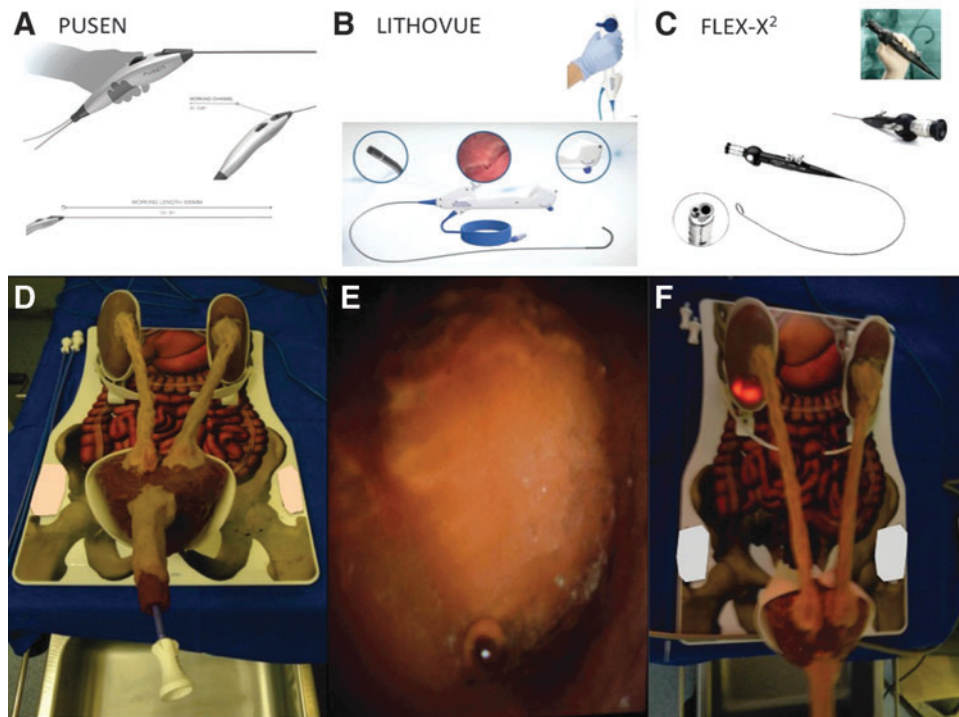
**FIG. 2.** Field of view evaluation among the three flexible ureteroscopes; (A) outer view of ureteroscope tip placement of the 0° horizontal line of a protractor; (B) endoscopic view of ureteroscope testing; (C) schematic representation of field of view of the three ureteroscopes tested.



**FIG. 3.** Color representation comparison between three flexible ureteroscopes; (A) Gretag-Macbeth Color Checker Target used for all trials; (B) image representation of 10, 20, and 50 mm trials for the three scopes.



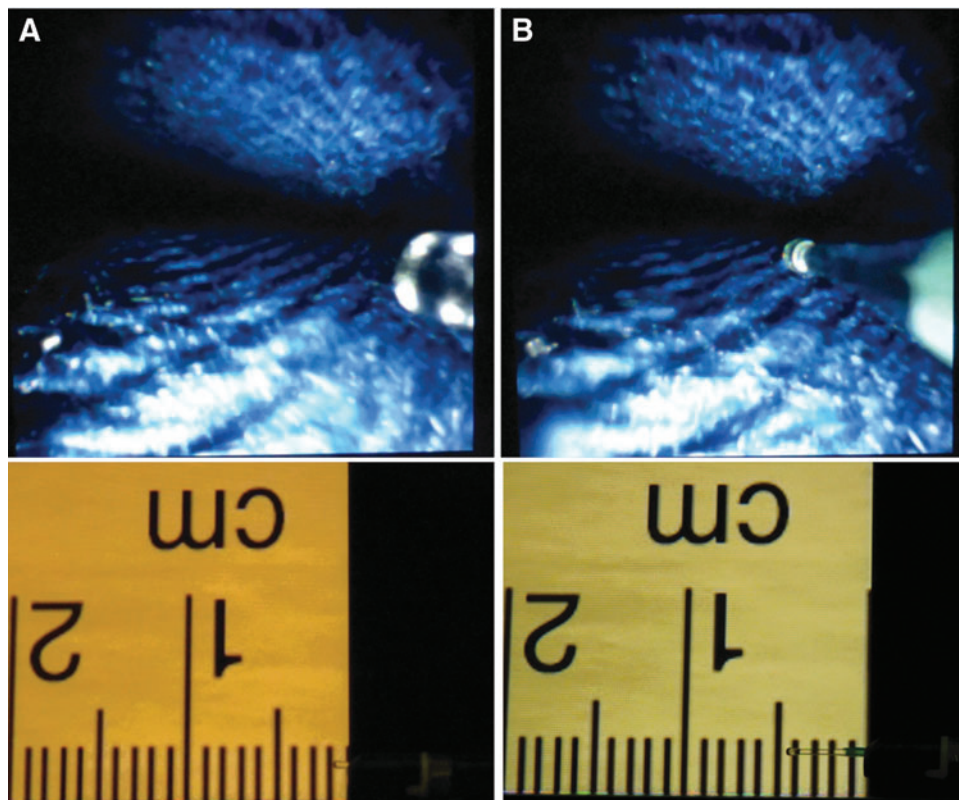




**FIG. 4.** Exemplification of the three ureteroscopes used; (A) Pusen; (B) LithoVue; (C) Flex-X<sup>2</sup>; collecting system model for flexible ureteroscopy practice; (D) ureteral access sheath passed through the right ureter; (E) endoscopic view of a bubble in an anterior calix in the lower pole; (F) exterior view of translucent illumination of the flexible ureteroscope placed in the same anterior calix.

orientation (Fig. 5). The LithoVue and Flex-X<sup>2</sup> have a standard position of the deflection lever control and are handled in the regular vertical orientation. All scopes have single 3.6F diameter working channels. For both single-use scopes the working channel is located at the four o'clock position, while for the Flex-X<sup>2</sup> it is positioned at eight o'clock. The back

entrance for the working channel is a T-port in the opposite position of the deflection handle control in LithoVue and Flex-X<sup>2</sup>. Conversely, in Pusen it is located in the same side of the deflection lever control, and no back connection of a fiber lock is possible since the working channel has an inner built antireflux mechanism (Fig. 5).



**FIG. 5.** Safety test of laser fiber positioning during lithotripsy; (A) identification of the ball tip of the laser fiber; (B) identification of the green outer protection layer of the laser fiber.

TABLE 1. FLEXIBLE URETEROSCOPES' TECHNICAL PARAMETERS

	<i>LithoVue</i>	<i>Pusen</i>	<i>Flex-X<sup>2</sup></i>
Ureteroscope weight	182 g	91 g	339 g
Monitor weight	6850 g	4350 g	—
Total working length	680 mm	630 mm	670 mm
Optical system	Digital (CMOS)	Digital (CMOS)	Fiber optic
Direction of view	0°	0°	0°
Illumination	LED light	Optical fiber	Optical fiber
Scope use	Single use	Single use	Reusable
Tip diameter	7.7F	9.0F	7.5F
Shaft diameter	9.5F	9.0F	7.5F
Working channel diameter	3.6F	3.6F	3.6F
Working channel tip position	4 o'clock	4 o'clock	8 o'clock
Working channel back position	Dorsal	Dorsal	Dorsal
Deflection type	Dual deflection	Dual deflection	Dual deflection
Deflection handle control	Ventral	Dorsal	Ventral

CMOS = complementary metal-oxide semiconductor.

### Optical performance

LithoVue had a higher resolution power than the other two ureteroscopes at all distances tested ( $p < 0.001$ ). LithoVue had a resolution of 2.83, 1.78, and 0.89 line pairs per millimeter when tested 10, 20, and 50 mm away from the target, respectively. Pusen was inferior to LithoVue but it showed significantly higher resolution than Flex-X<sup>2</sup> for all distances ( $p < 0.01$ ) (Fig. 1).

Field of view was wider for LithoVue (87°), followed closely by Flex-X<sup>2</sup> (85°) and Pusen (75°) (Fig. 2C). There was no significant statistic difference between LithoVue and Flex-X<sup>2</sup> and both were superior to Pusen ( $p < 0.01$ ).

Color representation was considered superior for Flex-X<sup>2</sup> compared to the digital ureteroscopes at 10, 20, and 50 mm distances (average grade 1.5). LithoVue provided better color (average grade 1) representation at all distances than Pusen (average grade 0.5).

### Impact of instrumentation on ureteroscope functionality

LithoVue had the smallest loop diameter (17 mm, radius of deflection 8.5 mm), being significantly tighter than Pusen (21 mm) and the Flex-X<sup>2</sup> (23 mm) ( $p < 0.01$ ), which were not significantly different between them ( $p$  nonsignificant) (Fig. 6A).

Baseline deflection with an empty working channel was superior for LithoVue (272°) and Flex-X<sup>2</sup> (270°) compared to Pusen (250°) ( $p < 0.01$ ). LithoVue outperformed Pusen and Flex-X<sup>2</sup> for all other settings in terms of deflection loss (Fig. 6B).

Pusen was the scope with highest irrigation flow (52 mL/min) with an empty working channel compared to LithoVue and Flex-X<sup>2</sup> (42 mL/min for both;  $p < 0.01$ ). LithoVue and Pusen showed similar flow rates with a 200  $\mu$ m laser fiber (21 mL/min), 365  $\mu$ m laser fiber (7 mL/min), and 1.3F basket (18 mL/min), both being superior to Flex-X<sup>2</sup> for those settings (11, 4, and 7 mL/min, respectively;  $p < 0.01$ ) (Fig. 6C). With the 1.9F basket, LithoVue showed a superior flow rate (7 mL/min) compared to Pusen (3.5 mL/min) and Flex-X<sup>2</sup> (4 mL/min) ( $p = 0.01$ ). Importantly, after the first laser fiber trial, minor back leak of saline from the working channel could be seen on Pusen.

### Safety and maneuverability analysis

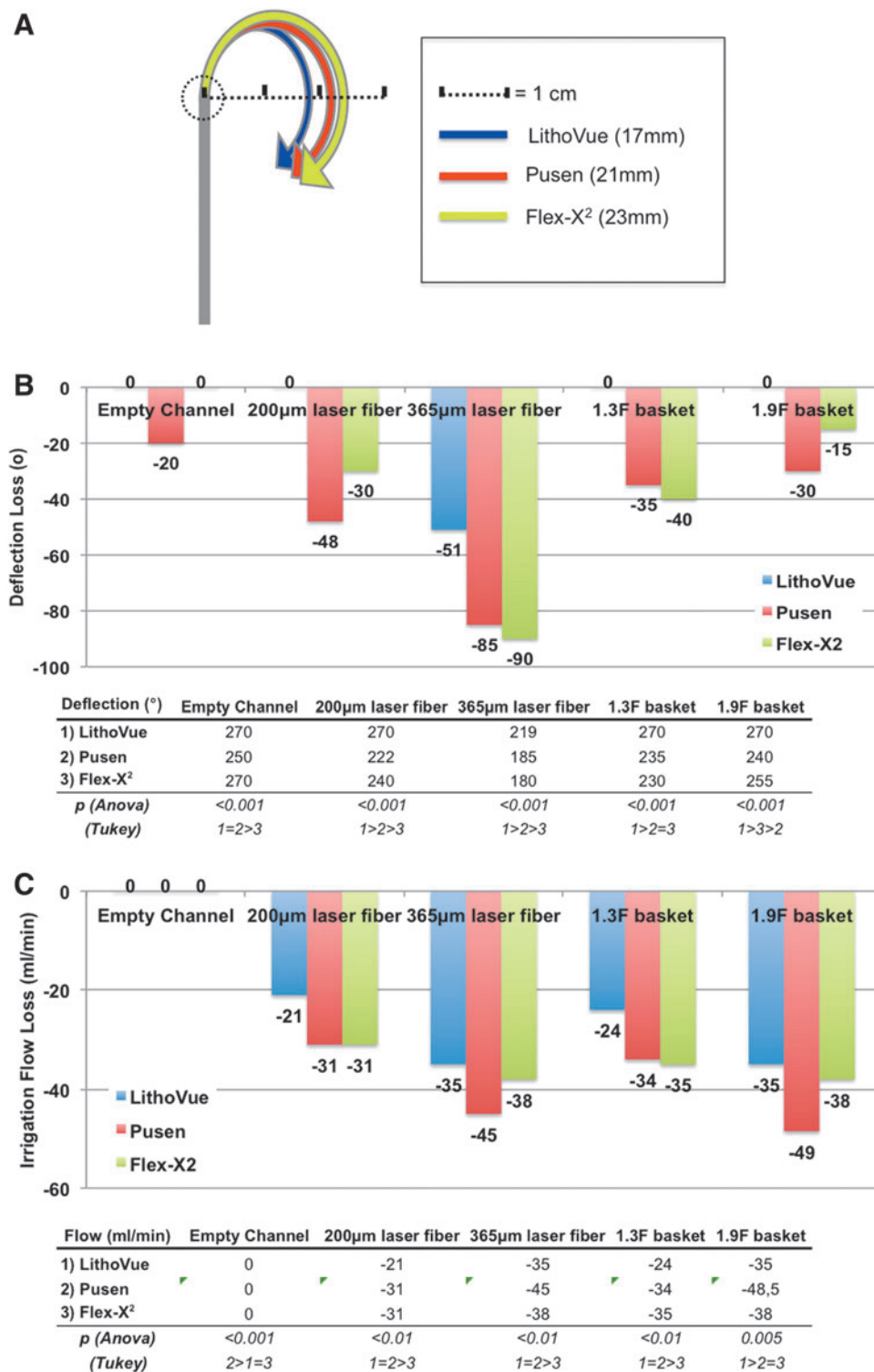
The LithoVue and Flex-X<sup>2</sup> showed no friction (grade 0) during kidney access through both 11F/13F and 13F/15F ureteral access sheaths. The same was noted for Pusen when a 13F/15F ureteral access sheath was used. However, for the 11F/13F sheath, Pusen showed minor friction (grade 1), which seemed to be caused by the stiffness of the long working shaft. All scopes could easily reach all calices of the kidney model, even the acute angled lower pole (Fig. 4).

Although the scopes had different fields of view during optical testing trials, the laser safety test (distance of advancement of the fiber till visualized) was comparable between them: the distance between the ball tip from the tip of the scope was 1 mm for the three scopes, and the distance from the laser fiber green protection shelter from the tip of the scope was 4.5 mm for all scopes (Fig. 5).

The intact ball tip laser fiber was effectively passed through the working channel of LithoVue and Pusen in the complete deflected position with minor friction (grade 1). With the cleaved fiber, the same could be accomplished for both scopes although noticeable friction (grade 2) was noted. For the Flex-X<sup>2</sup>, the laser fiber could not be completely advanced and the test was classified as failure to deploy (grade 4) for both the ball tip and the cleaved flat tip laser fiber.

### Discussion

The evaluation of specific features of the new single-use digital flexible ureteroscopes is crucial to predict whether their performance is comparable to existing reusable devices. The comparison between the single-use digital with permanent digital ureteroscopes could not be done since this last scope is not available in our nation. This is the first study to analyze Pusen and LithoVue in a comprehensive and standardized manner. By knowing the particulars of each flexible ureteroscope, the surgeon might optimize a patient-centered approach, increasing the chance of success while preserving safety. Several hypothetical situations might be addressed, for example, the physician might prefer a lighter scope for longer cases. Pusen is half the weight of LithoVue, although both may be considered light compared to reusable scopes. For instances in which the ureteral sheath fails to reach the



**FIG. 6.** Ureteroscope functionality evaluation; (A) loop diameter of the final ureteroscope working portion; (B) impact of instrumentation on ureteroscope deflection; (C) impact of instrumentation on ureteroscope irrigation flow.

upper ureter, a flexible ureteroscope with a longer working length might be more effective. LithoVue is 5 cm longer than Pusen and 1 cm longer than the Flex-X<sup>2</sup>. In terms of maneuverability, the handle control for deflection of Pusen requires surgeons to train in an unusual position for the dominant hand. All surgeons were more comfortable with standard scopes (LithoVue and Flex-X<sup>2</sup>) since they were trained in that manner. LithoVue was even easier to handle since it is much lighter than the permanent one. We did not include these data since

it is completely subjective, and if surgeons trained with the other handling technique performed the trials results would be probably different.

The entrance of the working channel is close to this handle control, and extra care should be taken when using a laser fiber while moving the scope, since no fiber lock mechanism is available for this model. Conversely, because of the stiffer shaft of Pusen, it could also be used as a substitute for the standard semirigid ureteroscope. In addition, although it is

not our practice, for surgeons who perform upper urinary tract stone dusting without an access sheath, Pusen might be of great interest since it can be used as a semirigid and flexible ureteroscope, possibly reducing operative time.

Complete stone-free status remains the ultimate outcome surgeons seek when performing flexible ureteroscopy for stone removal, regardless of stone composition. It is intuitive that adequate irrigation in combination with good optics is essential to allow efficient lithotripsy and to warrant complete stone fragment removal in a fast and secure manner. If one or the other is compromised, the final surgical result is suboptimal. LithoVue has a higher resolution and larger field of view. Conversely, Flex-X<sup>2</sup> was the scope with better color representation.

In terms of irrigation, Pusen had the best results when no instruments were used through the working channel. This was probably a consequence of the stiffer shaft of Pusen that prevents bending and therefore avoids compression of the inner diameter of the working channel. No difference was seen between Pusen and LithoVue when small-caliber instruments were in place. Conversely, with larger instruments, for example, the 1.9F basket, LithoVue outperformed Pusen, probably because of the back leak from the working channel entrance seen for this scope.

The LithoVue scope deflection did not deteriorate even with larger instruments, and only the 375  $\mu\text{m}$  laser fiber offered resistance for ureteroscope deflection. This is in accordance with previous clinical and *in vitro* studies.<sup>12–14</sup> By having the tightest loop diameter (radius of deflection), the LithoVue may offer greater dexterity to access lower pole stones. A lower pole location is a common indication for intrarenal flexible ureteroscopy as shockwave lithotripsy offers poor results.<sup>15</sup> This is especially true if an acute and long infundibulum-pelvic angle is present and if stone fragmentation has to be done *in situ*, with significant risk for scope damage.<sup>16</sup> Although both Pusen and LithoVue allowed passage of a 200  $\mu\text{m}$  laser fiber in the complete deflected position, we do not recommend this maneuver to be done routinely and the Pusen achieved only 222° deflection in that setting compared to 270° for the LithoVue.

Study limitations are present. The scopes were tested in a clear endoscopic environment. The impact of blood or stone debris on image quality deserves further study. The durability of the scopes was not tested. While the ability to reach all calices was tested, multiple users were not timed to evaluate the ease of access. Further clinical testing along with cost analysis modeling for utilization in low-volume and high-volume settings will further define the utility and potential impact of single-use scopes.

## Conclusion

LithoVue, Pusen, and Flex-X<sup>2</sup> have distinguishable baseline physical and optical characteristics. LithoVue outperformed the other ureteroscopes in terms of optical resolution, field of view, deflection capacity, and irrigation flow with larger instruments. Pusen is the lighter scope and showed better results in terms of irrigation when no instruments are in place. Flex-X<sup>2</sup> was superior in terms of color representation. By knowing the specifics of each flexible scope, a patient-centered approach might be optimized by the surgeon.

## Author Disclosure Statement

No competing financial interests exist.

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