Original Article

Characteristics of current digital single-use flexible ureteroscopes versus their reusable counterparts: an *in-vitro* comparative analysis

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Background: Single-use flexible ureterorenoscopes (fURSs) have been recently introduced aiming to offer solutions to the sterilization, fragility and cost issues of the reusable fURSs. In order to be a viable alternative, the single-use scopes must prove similar capabilities when compared to their reusable counterparts. The goal of our *in-vitro* study was to compare the current reusable and single-use digital fURSs regarding their deflection, irrigation and vision characteristics.

Methods: We compared *in-vitro* 4 single-use fURSs—LithoVue™ (Boston Scientific, Marlborough, Massachusetts, USA), Uscope™ (Zhuhai Pusen Medical Technology Co. Ltd., Zhuhai, Guangdong Province, China), NeoFlex™ (NeoScope Inc, San Jose, California, USA) and ShaoGang™ (YouCare Technology Co. Ltd., Wuhan, China) versus 4 reusable fURSs—FLEX-X[c] (Karl Storz SE & Co KG, Tuttlingen, Germany), URF-V2 (Olympus, Shinjuku, Tokyo, Japan), COBRA vision and BOA vision (Richard Wolf GmbH, Knittlingen, Germany). Deflection and irrigation abilities were evaluated with different instruments inserted through the working channel: laser fibres (200/273/365 µm), retrieval baskets (1.5/1.9/2.2 Fr), guide wires [polytetrafluoroethylene (PTFE) 0.038 inch, nitinol 0.035 inch] and a biopsy forceps. A scoring system was designed to compare the deflection impairment. Saline at different heights (40/80 cm) was used for irrigation. The flow was measured with the tip of the fURS initially straight and then fully deflected. The vision characteristics were evaluated (field of view, depth of field, image resolution, distortion and colour representation) using specific target models.

Results: Overall, the single-use fURSs had superior *in-vitro* deflection abilities than the reusable fURSs, in most settings. The highest score was achieved by NeoFlex™ and the lowest by ShaoGang™. PTFE guide wire had most impact on deflection for all fURSs. The 200 µm laser fibre had the lowest impact on deflection for the single-use fURSs. The 1.5 Fr basket caused the least deflection impairment on reusable fURSs. At the end of the tests, deflection loss was noted in most of the single-use fURSs, while none of the reusable fURSs presented deflection impairment. ShaoGang™ had the highest irrigation flow. Increasing the size of the instruments occupying the working channel led to decrease of irrigation flow in all fURSs. The impact of maximal deflection on irrigation flow was very low for all fURSs. When instruments were occupying the working channel, the single-use fURSs had slightly better *in-vitro* irrigation flow than the reusable fURSs.

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The field of view was comparable for all fURSs, with LithoVue™ showing a slight advantage. Depth of field and colour reproducibility were almost similar for all fURSs. ShaoGang™ and Uscope™ had the lowest resolution. FLEX X^c had the highest image distortion while LithoVue™ had the lowest. Partial field of view impairment was not for Uscope™ and ShaoGang™.

Conclusions: *In-vitro*, there are differences in technical characteristics of fURSs. It appears that single-use fURSs deflect better than their reusable counterparts. Irrespective of deflection, the irrigation flow of the single-use fURSs was slightly superior to the flow of the reusable fURSs. Overall, reusable fURSs had better vision characteristics than single-use fURSs. Further *in-vivo* studies might be necessary to confirm these findings.

Keywords: Single-use; reusable; digital flexible ureteroscopes

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Introduction

Flexible ureteroscopy is considered to be less invasive than percutaneous nephrolithotomy (1,2) and more successful than extracorporeal shock-wave lithotripsy (3). Over the last two decades, there has been a substantial widening of its indications, not just for treating larger stones but also in certain high risk and difficult patient groups such as in pregnancy, obesity and paediatrics (4-6). Technological progress has led to the downsizing of the scope shaft and miniaturization of digital cameras with improved view and access into the kidney. Worldwide incidence of kidney stone disease has also increased leading to higher rates of intervention including ureteroscopic treatment of stones (7-9).

After the introduction of digital cameras, the development of single-use flexible ureterorenoscopes (fURSs) might be the most significant step in endourology. The obvious clinical advantage of treating each patient with new and completely sterile fURS is undisputable. Currently, the on-going discussion on single-use fURSs mainly focuses on technical capabilities and cost-effectiveness. While the cost of single-use fURSs lies with the initial purchase price, the cost of the reusable fURSs includes costs due to on-going repair, maintenance and sterilization on top of the initial acquisition price. The ability of the single-use fURSs to be cost-effective and technically comparable with the reusable fURSs might lead to a much 'democratic' access to this efficient and minimally invasive treatment method.

Our aim was to compare *in-vitro* the main characteristics of the currently available digital single-use fURSs against their reusable counterparts, focusing on deflection, irrigation and vision characteristics.

Methods

We compared *in-vitro* 4 single-use fURSs—LithoVue™ (Boston Scientific, Marlborough, Massachusetts, USA), Uscope™ (Zhuhai Pusen Medical Technology Co. Ltd., Zhuhai, Guangdong Province, China), NeoFlex™ (NeoScope Inc, San Jose, California, USA) and ShaoGang™ (YouCare Technology Co. Ltd., Wuhan, China) versus 4 reusable fURSs—FLEX-X^c (Karl Storz SE & Co KG, Tuttlingen, Germany), URF-V2 (Olympus, Shinjuku, Tokyo, Japan), COBRA vision and BOA vision (Richard Wolf GmbH, Knittlingen, Germany). To get as close as possible to real working conditions, all single-use fURSs were new while all reusable scopes were pre-used but checked before investigation to ensure full functionality.

Before starting the tests, an evaluation of the physical characteristics of the single-use scopes (weight, length, type of connectors, size/shape of image processors, etc.) was performed. Some subjective impressions of the evaluators regarding the single-use fURSs were noted. This was done only on single-use fURSs since these characteristics of the reusable fURSs are well known.

Description of physical characteristics and subjective assessment of the single-use fURSs

LithoVue™ is a single-use digital complementary metal-oxide semiconductor (CMOS), light emitting diode (LED) lit fURS, with a 9.5 Fr 680 mm length shaft 270º bi-directional deflection and 3.6 Fr working channel (*Figure 1*). Instruments emerge at 3 o'clock on endoscopic view (*Figure 2*). The model we tested had European type deflection, but the

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fURS	Shaft size (Fr)	Shaft length (mm)	Working channel (Fr)	Deflection	Camera sensor type	Light type	Cable length (cm)	Connector type	Weight including cable (g)
LithoVue	9.5	680	3.6	Dual, 270°	CMOS	LED	253	Round 8 pins	276
Uscope	9.5	650	3.6	Dual, 270°	CMOS	LED	302	Flat, special	220
NeoFlex	9	680	3.6	Dual, >270°	CMOS	LED	180	USB	119
ShaoGang	9	645	4.2	Dual, 270°	CMOS	External	205	Round 8 pins	151

Figure 1 Physical characteristics, single-use flexible ureterorenoscope (fURSs).

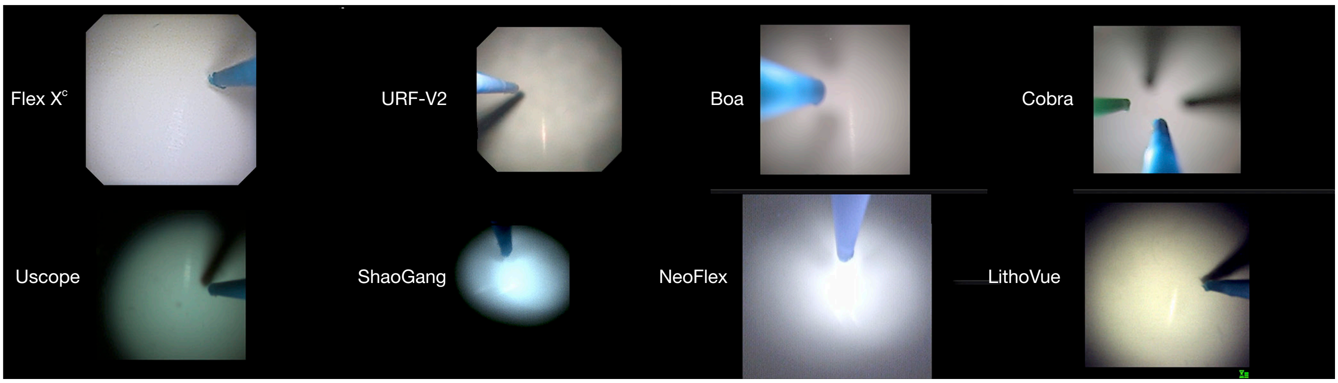

Figure 2 Endoscopic view 'exit point' position of instruments inserted through the working channel, all flexible ureterorenoscope (fURSs).

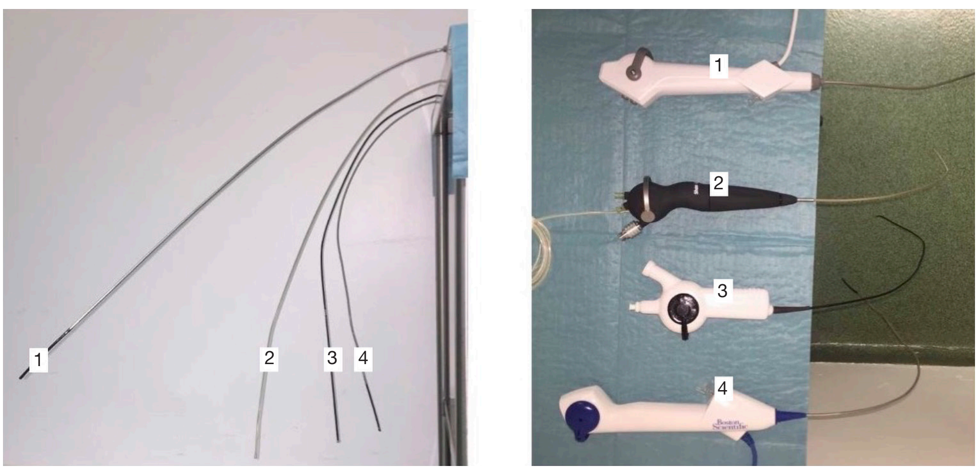

Figure 3 Visual assessment of shaft rigidity, single-use flexible ureterorenoscope (fURSs). 1, Uscope; 2, ShaoGang; 3, NeoFlex; 4, LithoVue.

manufacturer produces both types. It has the less rigid shaft compared to the other single-use fURSs (*Figure 3*). The attached transmission cable is 255 cm long and ends with a circular 8 pins connector (*Figure 4*). The weight (cable added) is 276 g. The image processor has a built-in monitor and can also record videos or capture screenshots. Overall, the subjective feeling is of a robust, trust-worthy fURS, confirming the objective test results.

Uscope™ is a single-use LED lit, CMOS digital fURS. The model we tested (UE3022) has a 9.5 Fr 650 mm length shaft, a standard 3.6 Fr working channel and 270º bi-directional deflection, American type (*Figure 1*). Manufacturer

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LithoVue Uscope NeoFlex ShaoGang

Figure 4 Connector types, single-use flexible ureterorenoscope (fURSs).

LithoVue Uscope NeoFlex ShaoGang

Figure 5 The tip of the single-use flexible ureterorenoscope (fURSs) after completion of all tests.

NeoFlex ShaoGang

Figure 6 Image processing units, NeoFlex and ShaoGang.

produced both deflection types. Instruments emerge at 3 o'clock on endoscopic view (*Figure 2*). The shaft seems to have the highest rigidity compared to the other single-use fURSs (*Figure 3*). The attached cable is long (302 cm) and uses a special connector (*Figure 4*) to plug into the image processor unit, which has an integrated monitor and allows image recording. Together with the cable, the fURS weights 220 g. The subjective feeling was that the fURS is well enough built, still the quality of materials is not homogenous. The black outer layer of the end part of the shaft seems easy to scratch and peel off (*Figure 5*).

NeoFlex™ is a single-use LED lit, CMOS digital fURS. The shaft is 9 Fr 680 mm length, with a 3.6 Fr working channel. The tested fURS has 370° deflection downward and 318° upward, American type (*Figure 1*). When deflected, the tip of the fURS goes laterally from the shaft. Instruments emerge at 12 o'clock on endoscopic view (*Figure 2*). The metal cover of the tip capsule has sharp edges (*Figure 5*). NeoFlex™ is the lightest of all single-use fURSs (119 g, weight measured including the cable). The image processor is small, light and compact and can also work as a recorder. It has a secure digital (SD) slot, allowing photo and video captures to be transferred on a standard SD card. Image from video processor can be viewed on any available screen via High-Definition Multimedia Interface (HDMI) connectors (*Figure 6*). Subjectively, the fURS seems to have good manoeuvrability and image illumination but some parts might require improvements. We liked the idea of having a mini universal serial bus (USB) 2.0 connection on the fURS's handle (*Figure 4*).

ShaoGang™ is a single-use digital CMOS fURS with dual 270° deflection, European type. The model we tested

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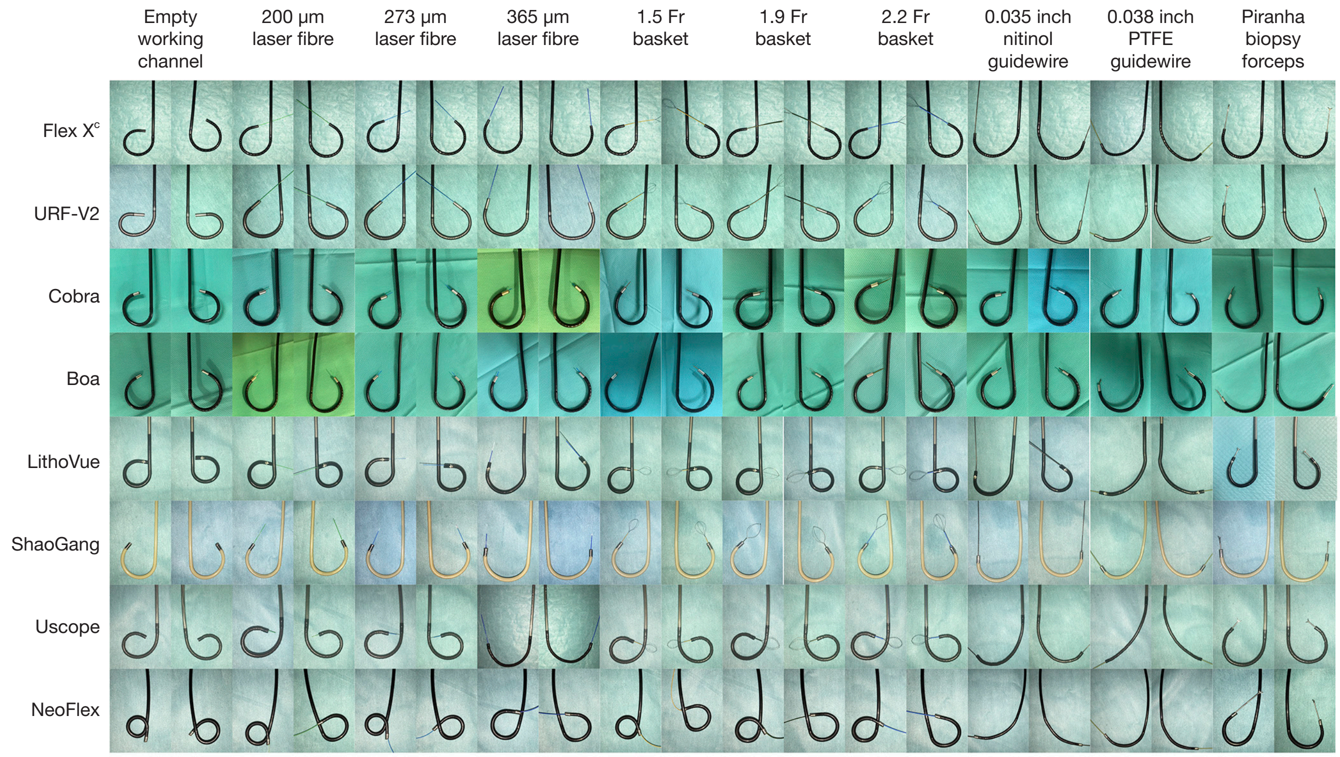

Figure 7 Deflection with the working channel empty and with different instruments inserted through the working channel, all flexible ureterorenoscope (fURSs).

has no LED technology and the light is transmitted through optic fibre, two bundles positioned laterally on the tip of the fURS (left and right) between the camera and the working channel (*Figure 5*). Therefore, a standard auxiliary light source is required. The shaft is 9 Fr, 645 mm length (including the 20 mm fixed metal tube emerging from the handle). It has a large 4.2 Fr working channel (*Figure 1*). Instruments emerge at 12 o'clock on endoscopic view (*Figure 2*). The fURS has an integrated 205 cm length cable, with an 8 pins round connector (*Figure 4*). Even adding the cable, the fURS is very light, weighing just 151 g. The video processor is bulky and heavy and has no recording facilities. The video output of the image processor is standard HDMI (*Figure 6*). The fURS has a round-shaped deflection control lever on the handle. Subjectively, the force needed to apply on the lever to achieve deflection was greater compared to the other fURSs.

Deflection

The deflection capabilities of all fURSs were assessed in ten different settings, starting with the working channel empty and then with the channel occupied by various instruments: laser fibres (200/273/365 µm), retrieval baskets (1.5/1.9/2.2 Fr), guide wires (0.038 inch PTFE coated, 0.035 inch nitinol with hydrophilic coating—Terumo Glidewire®) and a biopsy forceps (Piranha®). Maximal deflection was recorded in both directions in all the settings (*Figure 7*). Using a protractor, the deflection angles were calculated. Cumulative deflection values were obtained for each fURS by summing all the deflection degrees in each setting. We used these values to create a scoring system to compare all fURSs. At the end of all the tests, deflection with an empty working channel was evaluated again for each fURS.

Irrigation flow

The irrigation flow is of utmost importance for proper visibility during flexible ureteroscopy. Saline at different heights (40/80 cm) was used for irrigation through the T-flow™ dual port gravity line (Rocamed SAM, Monaco). The manual pump was not used. The flow was measured with the tip of the fURS at zero and maximal deflection, initially with an empty working channel and then with

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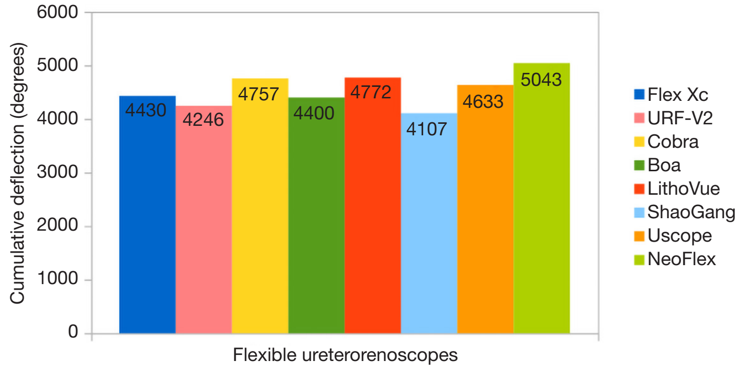

Figure 8 Deflection ranking chart, all flexible ureterorenoscope (fURSs).

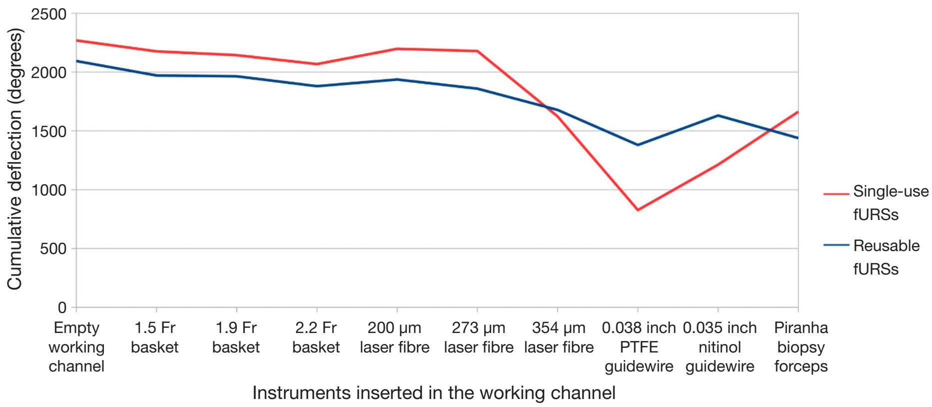

Figure 9 Cumulative deflection, single-use *vs.* reusable flexible ureterorenoscope (fURSs).

different instruments occupying the channel (similar to deflection assessment). Measurements were repeated three times. The median value was finally used.

Vision

Both single-use and reusable fURSs were assessed for vision capabilities. The field of view was evaluated using a multi-frequency grid target model and the depth of field using an Edmund Optics Depth of Field test target model. The image resolution evaluation was completed using a 1951 United States Air Force (USAF) Test Pattern model and the distortion was measured with a grid distortion target model. Colour representation was assessed using a Gretag Macbeth Colour Checker model. On the endoscopic view, the exit point of the instruments was noted.

Results

Deflection

Comparing *in-vitro* cumulative deflection, the highest score was obtained by NeoFlex™ (5,043°) and the lowest by ShaoGang™ (4,107°) (*Figure 8*). The 200 µm laser fibre had the least impact on deflection (2,198°) for the single-use fURSs, and the 1.5 Fr retrieval basket (1,971°) for the reusable fURSs. The PTFE coated guide wire determined the highest impairment on deflection for all fURSs (*Figure 9*). In almost all settings the disposable fURSs had better deflection than their reusable counterparts. Still, when larger calibre or more rigid instruments were inserted through the working channel (365 µm laser fibre or guide wires—both PTFE or nitinol) reusable fURSs were able to achieve superior deflection compared to the single-

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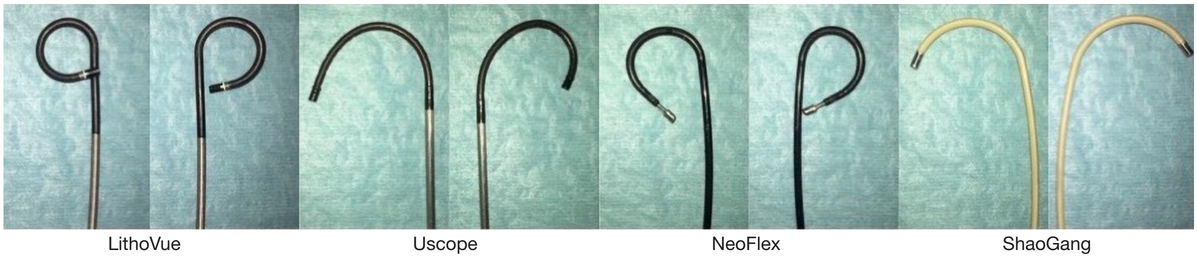

Figure 10 Deflection impairment after tests completion, all single-use flexible ureterorenoscope (fURSs).

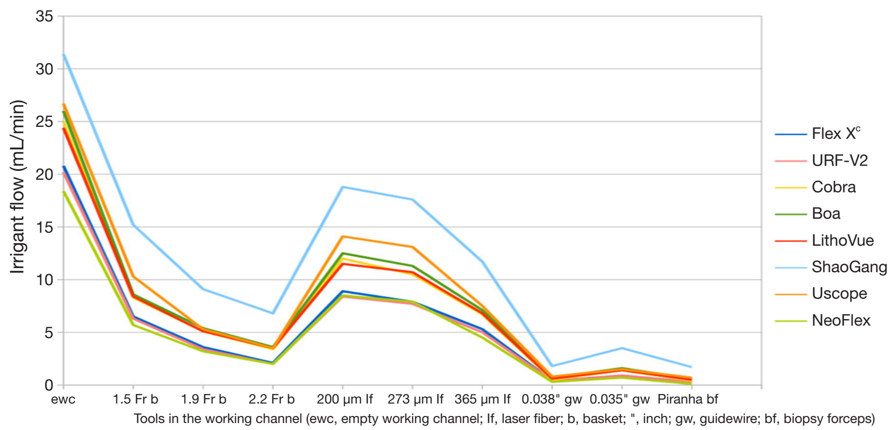

Figure 11 Irrigation flow impairment, all flexible ureterorenoscope (fURSs) (no deflection, saline height 40 cm).

use fURSs (*Figure 9*). At the end of the tests, almost all of the single-use fURSs had some deflection loss, with ShaoGang™ showing the most impaired deflection. NeoFlex™ had its tip metal capsule detached from the shaft (*Figure 10*). None of the reusable fURSs had deflection impairments after tests completion.

Irrigation flow

Having a 4.2 Fr working channel, ShaoGang™'s irrigation flow was superior to all the other fURSs. Also, considering that COBRA has two channels, 3.6 and 2.4 Fr, its irrigation flow was not impaired when separate channels were used for instruments and for irrigation. Increasing the size of the instruments occupying the working channel led to decrease of the irrigation flow in all fURSs (*Figure 11*). The 200 μm laser fibre caused the lowest impairment of the irrigation flow on all furs. On the opposite side, Piranha biopsy forceps inserted through the working channel had the highest impact on the irrigation flow of both disposable and reusable fURSs. When COBRA was evaluated, the irrigation line was connected to the 3.6 Fr channel. If instruments were inserted through the 2.4 Fr channel, no irrigation flow impairment was noted. Subsequent impairment of the irrigation flow was observed when instruments occupied the larger channel. The impact of maximal deflection on irrigation flow was very low for all fURSs (*Figure 12*). Overall, when instruments were occupying the working channel, single-use fURSs had slightly better *in-vitro* irrigation flow than the reusable fURSs (*Figure 12*).

Vision

In-vitro field of view was comparable for all fURSs, LithoVue™ showing a slight advantage. Resolution was similar for most fURSs, ShaoGang™ and Uscope™ having the lowest resolution while NeoFlex™, COBRA and BOA the highest in our tests. Depth of field values were homogenous for all fURSs. FLEX X^c had the highest image distortion while LithoVue™ had the lowest (*Figure 13*). Colour reproducibility was comparable for all fURSs, with a small advantage favouring the reusable fURSs (*Figure 14*). Two of the single-use fURSs had partial vision impairment.

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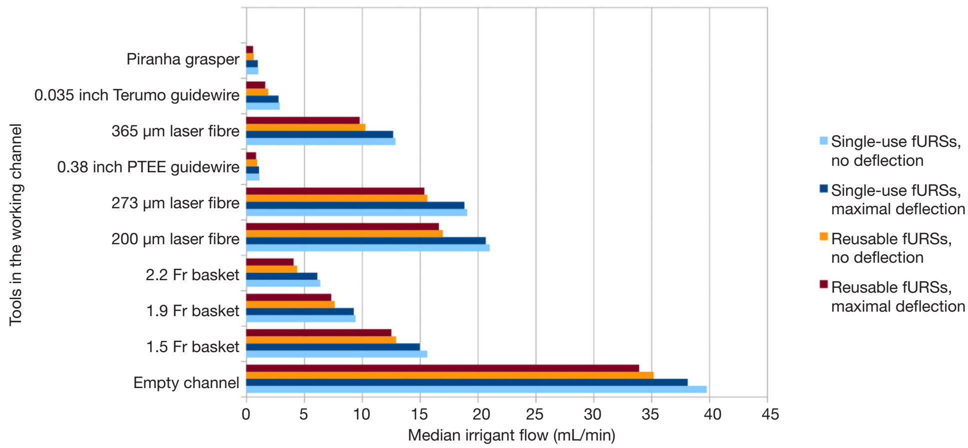

Figure 12 Median irrigation flow, single-use *vs.* reusable flexible ureterorenoscope (fURSs) (no deflection & maximal deflection, saline height 80 cm).

	Field of view (mm) at 10 mm	Resolution (lines/mm) at 10 mm	Depth of field (mm)	Distortion (%)	Instruments through working channel appear at (o'clock)
Litho Vue	15.5	7.13	4.5	3.8	3
Uscope	9.5	6.35	4	8.4	3
NeoFlex	11	10.1	5.5	14.5	12
ShaoGang	10	6.35	4.5	11.4	12
URF-V2	8.5	8.98	5.5	16.3	9
Flex X^c	10.5	8	6	22.6	3
Cobra vision	8	10.1	6	12.5	9 and 6
Boa vision	9	10.1	6	15.7	9

Figure 13 Vision characteristics, all flexible ureterorenoscope (fURSs).

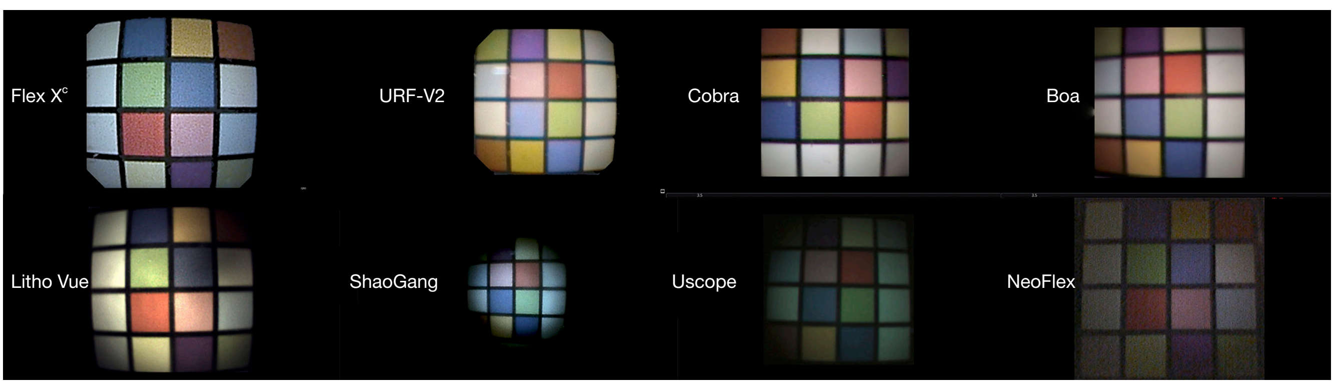

Figure 14 Colour reproducibility, all flexible ureterorenoscope (fURSs).

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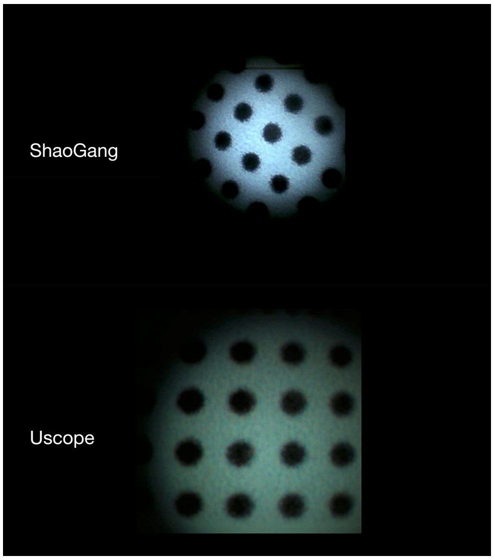

Figure 15 Partial vision impairment, Uscope and ShaoGang.

On Uscope™'s endoscopic image, some corners were dark. Poor illumination on the back of the image was noted, depending on the distance to the target. ShaoGang™'s image had dark corners, despite of good illumination in the centre of the field, irrespective of the distance from the target (*Figure 15*). These problems were not noted for the other two single-use fURSs or for any of the reusable fURSs. On the endoscopic view, the exit point of the instruments was different for most fURSs (*Figure 2*).

Discussion

Since its introduction more than 30 years ago, flexible ureteroscopy has changed the management of urolithiasis and is now safer and more efficient (10,11). Technological advancements have allowed continuous evolution of the fURSs, which have improved constantly their calibre, weight, deflection, irrigation and optic capabilities (12,13). The introduction of charged couple device (CCD) chip, more than 14 years ago, was a great improvement providing better quality digital images. Details on various aspects of ureteroscopic treatment including intra-renal pressure, temperature changes and the safe distance concept with laser use have been studied, helping us to better understand the subtle aspects of the procedure (14-16). Diverse accessories were created, from irrigation enhancing devices (16,17) to robotic platforms (18,19), in order to improve the outcomes of flexible ureteroscopy. Currently, a multitude of fURSs are available, both fibre-optic and digital. While reusable fURSs have been in use for a long time, there has possibly been a paradigm shift with the development of single-use fURSs. Up to now, the two most commonly used single-use fURSs have been LithoVue™ and Uscope™.

LithoVue™'s emerge was probably a landmark in the evolution of the single-use fURSs and brought them in the same league with the long-established reusable fURSs. For the first time, a single-use fURS had similar calibre, deflection, irrigation, optics and abilities to reach difficult calyces compared to its reusable counterparts (20-22). LithoVue™ has been thoroughly studied *in-vitro* and is largely accepted as having at least similar capabilities compared to the digital reusable fURSs, or even better abilities when matched against the fibre-optic fURSs (23,24).

In-vitro findings were confirmed in a live porcine model (25).

In the first study on fresh human cadavers, comparing LithoVue™ with two reusable fURSs, one fibre-optic (URF-P5, Olympus, Tokyo, Japan) and one digital (URF-V, Olympus, Tokyo, Japan), Proietti *et al.* showed that LithoVue™ was comparable to the reusable fURSs regarding visibility and manoeuvrability inside the urinary tract (26).

Recent clinical studies have confirmed the *in-vitro* and *ex-vivo* findings. Doizi *et al.* conducted an interesting prospective cohort study in eight European reference hospitals concluding that LithoVue™ has good image quality, active deflection and manoeuvrability (27). Usawachintachit *et al.* organized a prospective case control study comparing LithoVue™ to a reusable fiber-optic fURS (URF-P6, Olympus, Tokyo, Japan) and proved that the single-use fURS has a low rate of scope failure comparable to reusable fURSs. Interestingly, they found that LithoVue™ use shortens procedure duration (28).

Following the promising path opened by LithoVue™, a multitude of single-use fURSs have been developed and are available nowadays. Several manufacturers are developing new single-use fURSs and related devices, although they might not have the same functionality as the established reusable fURSs.

Emiliani *et al.* previously evaluated Uscope™ on ten patients (29). Although standard ureteroscopy was possible, the image quality, deflection and manoeuvrability decreased during the procedures. The image quality was considered good, but it was not as clear for structures farther away. The manufacturer has recently presented the next generation of fURSs, which might resolve some of these issues.

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NeoFlex™ was *in-vitro* compared with LithoVue™ and a previous fibre-optic version of ShaoGang™ by Tom *et al*. (30). The single-use fURSs were also matched against 2 reusable fURSs (FLEX-X[c] and COBRA). NeoFlex was noted to have a sharp resolution. Its deflection and irrigation characteristics were similar to the reusable fURSs. Nevertheless, NeoFlex™ had the greatest decrease in upward deflection after the introduction of instruments in the working channel.

To our knowledge, we were the first to test *in-vitro* the ShaoGang™'s digital version with CMOS chip on the tip and dual deflection. The impressive 4.2 Fr working channel (similar to the previous model) assured the ShaoGang™'s supremacy on irrigation flow tests, but combined to the digital camera led to an increase on shaft calibre to 9 Fr (the previous version was 8 Fr). Deflection was satisfactory, but after tests completion ShaoGang™ had the highest deflection loss. This may result in a lower ability to maintain proper deflection in complicated cases. Vision characteristics were comparable to the other digital fURSs but partial vision impairment was noted, which may lead to longer operative time. The lack of LED technology and subsequently the need for a light cable and a standard auxiliary light source may have an impact on surgeon's comfort during longer procedures. These hypotheses need further evaluation and clinical confirmation.

The exit point of the instruments on the endoscopic view is a characteristic, which may be important to consider when choosing the instrument. Ideally, multiple choices should be available, allowing the surgeon to adapt to each case requirement. From this perspective, COBRA has the advantage of allowing two different positions for emerging tools.

Arguably, active deflection when guide wires are inserted through the working channel is rarely needed during surgery. Large calibre laser fibres are not frequently used, as well. However, the superior deflection ability of the reusable fURSs when thicker or more rigid instruments occupy the working channel might be the result of a more robust building quality.

Based on the results of our *in-vitro* study, it is tempting to think that the better vision characteristics of the reusable fURSs might not be decisive in common urolithiasis treatment. It does not seem completely un-appropriate to assume that, from the vision capabilities perspective, the single-use fURSs would be suited for the majority of the patients. However, it would be reasonable to consider using a digital reusable fURS rather than a single-use or a fibre-optic fURS when enhanced vision might be required (e.g., diagnosis and treatment of upper urinary tract tumours), if options are available. *In-vivo* verification of these assumptions is needed.

The multiple flaws noted on most of the single-use fURSs (except LithoVue™) after test completion, mainly on deflection abilities, raise a question on the durability of these emerging devices. In our study there was no control on the forces applied on the fURSs, therefore we cannot conclude based on the impairments noted at the end of the tests. Still, no deflection loss or other defects were noted on the reusable fURSs, therefore it might be reasonable to question the ability of some of the single-use fURSs to maintain their characteristics at least until the end of a more difficult case. Further proper durability tests might be useful.

Strengths and limitations

To our knowledge, this is the first *in-vitro* study to cross-compare 4 digital reusable and 4 digital single-use fURSs *in-vitro*, in similar conditions, for their deflection, irrigation flow and vision capabilities. We systematically used different instruments in the fURSs to study their effect on these parameters. The experiments were also repeated for consistency. However, these were not tested in real clinical situations and the costs were not compared.

Conclusions

In-vitro, there are multiple differences in technical characteristics of the evaluated fURSs. When deflection was compared, it appeared that single-use fURSs deflected better than their reusable counterparts. Still, when thicker or more rigid instruments were inserted through the working channel, reusable fURSs had superior deflection abilities. Irrespective of deflection or working channel being free or occupied with various instruments, the irrigation flow of the single-use fURSs was slightly better than the flow of the reusable fURSs. Evaluating vision, the reusable fURSs had overall superior characteristics compared to the single-use fURSs. Several flaws of the single-use fURSs were noted at the end of tests, while no impairments were observed on the reusable fURSs. Further *in-vivo* studies might be necessary to confirm these findings.

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None.

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Footnote

Conflicts of Interest: Prof. Olivier Traxer is consultant for Coloplast, Boston Scientific, Olympus, Rocamed, EMS and IPG; Mr Oliver Wiseman is consultant for Boston Scientific, Coloplast and EMS; the other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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