Asian Journal of Urology 10 (2023) 64–69

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/ajur

Original Article

Single-use flexible ureteroscopes: Comparative *in vitro* analysis of four scopes

Abhijit Patil, Shashank Agrawal, Rohan Batra, Abhishek Singh, Arvind Ganpule*, Ravindra Sabnis, Mahesh Desai

Department of Urology, Muljibhai Patel Urological Hospital, Nadiad, India

Received 26 July 2020; received in revised form 22 March 2021; accepted 23 August 2021
Available online 22 February 2022

KEYWORDS
Single-use;
Disposable;
Flexible ureteroscopes;
In vitro;
Pusen;
LithoVue;
Indoscope

Abstract *Objective:* Single-use flexible ureteroscopes (fURSs) have recently been introduced by different companies. Goal of this *in-vitro* study was to compare four fURSs.
Methods: We performed *in vitro* analysis of Uscope 7.5 Fr and Uscope 9.5 Fr (Pusen Ltd., Zhuhai, China), LithoVue 9.5 Fr (LithoVue™, Boston Scientific, MA, USA), and Indoscope 9.5 Fr (Bioradmedisys™, Pune, India). Optical characteristics (image resolution, color representation, and luminosity) were compared at various distances of 10 mm, 20 mm, and 50 mm. Deflection and irrigation were evaluated with and without accessories.
Results: Color perception was comparable for all scopes at 10 mm ($p<0.05$), while Lithovue 9.5 Fr was comparable with Indoscope 9.5 Fr at the distances of 20 mm and 50 mm. Both scopes were statistically better than both Uscopes at the distances of 20 mm and 50 mm. Image resolution powers were comparable amongst all fURSs at the distances of 10 mm and 20 mm (3.56 line pairs per millimeter [lp/mm]). However, Indoscope (3.56 lp/mm) was superior to LithoVue and Uscope scopes (3.17 lp/mm) at the distance of 50 mm. Luminosity at the distance of 10 mm was comparable for LithoVue and Uscope 9.5 Fr. However, at the distances of 20 mm and 50 mm, LithoVue had the highest luminosity while Uscope 7.5 Fr had the lowest one. Indoscope had lower luminosity than other 9.5 Fr scopes at all distances. With empty working channel and 200 μm laser fiber, Indoscope had the maximum deflection (285°). With basket, Uscope 7.5 Fr had the maximum loss of deflection (30°) while Indoscope had no deflection loss. With empty working channel, all scopes had comparable irrigation flow rates in both deflected and undeflected state. Similarly, with 200 μm laser or basket, irrigation flow rates were comparable in all scopes.
Conclusion: Color representation was equivalent for Indoscope and LithoVue, while being better than Uscope 7.5 Fr and Uscope 9.5 Fr. Image resolution was comparable in all scopes at the distances of 10 mm and 20 mm. Beyond the distance of 10 mm, luminosity of LithoVue was the highest and that of Uscope 7.5 Fr was the lowest. Deflection loss was the minimum with

* Corresponding author.
E-mail address: doctorarvind1@gmail.com (A. Ganpule).
Peer review under responsibility of Tongji University.

https://doi.org/10.1016/j.ajur.2022.02.001

Indoscope and the maximum with 7.5 Fr Uscope. Under all scenarios, irrigation flow rates were comparable in all scopes.

1. Introduction

Incidence of nephrolithiasis has increased worldwide and it inherits a major and economic burden for healthcare systems [1,2]. Flexible ureteroscopy which is less invasive than percutaneous nephrolithotomy is becoming an important part of armamentarium of treatment of nephrolithiasis [3,4]. Single-use flexible ureteroscopes (fURSs) are becoming an effective alternative to conventional reusable fURSs for various reasons. In clinical setting disposable single-use fURSs have shown equivalent result to reusable fURSs in management of renal calculi including lower pole calculi [5].

The first single-use disposable fURS used in clinical practice was the LithoVue™ (Boston Scientific, Marlborough, MA, USA). Studies had found its performance similar to conventional reusable fURSs [5,6]. With these outcomes, many more companies have introduced single-use fURSs. The Uscope UE3022a, single-use digital disposable 9.5 Fr fURS developed by Pusen™ (Zhuhai Pusen Medical Technology Co, Ltd., Zhuhai, China) was the next single-use fURS to be introduced [7—11].

Two single-use digital fURSs—Indoscope (9.5 Fr and 7.5 Fr) (Bioradmedisys™, Pune, India) and 7.5 Fr Uscope PU3033A (Pusen™, Zhuhai Pusen Medical Technology Co, Ltd., Zhuhai, China) have been recently developed. Our objective was to systematically compare the *in vitro* performance characteristics of these four single-use fURSs: Indoscope 9.5 Fr, LithoVue 9.5 Fr, Uscope 9.5 Fr, and Uscope 7.5 Fr.

2. Materials and methods

This was an *in vitro* study comparing four single-use fURSs—Indoscope 9.5 Fr, Uscope 9.5 Fr, LithoVue 9.5 Fr, and Uscope 7.5 Fr. Each scope was tested in a brand new unused condition. For each fURS, working length, outer shaft diameter, exit positioning of accessory (laser or basket) through working channel, optical characteristics, deflective mechanism, and irrigation flow rate were evaluated. Working channel length was measured by inserting the laser fiber until the laser tip was flush with distal end of fURS. The distance between distal tip of fiber and the point of exit from the proximal portion of fURS was taken as working channel length.

2.1. Optical characteristic

All fURSs were assessed *in-vitro* for color representation, image resolution, and luminosity. Image resolution of all the scopes was assessed on the scope monitor by three experienced endourologists (experience of more than 10 years), who were not part of study and blinded to the make of scope. Image resolution was defined as the highest group and element in which the three-repeating series of parallel bars can be distinguished and was determined by viewing a 1951 U.S. Air Force Test Pattern Card (Edmund Optics, Barrington, NJ, USA) at the distances of 10 mm, 20 mm, and 50 mm with each fURS. It was recorded in line pairs per millimeter (lp/mm). The mean of three readings was considered for evaluation.

Assessment of color representation was done with Gretag Macbeth Color Checker Target (Edmund Optics, NJ, USA) and the fURSs were tested at 10 mm, 20 mm, and 50 mm away from the target. The correct representation of color was graded as (0-no resemblance, 1-slight resemblance, 2-near complete resemblance) by 10 endourologists who were blinded to the make of the scope. The luminosity of the scopes was evaluated at the distances of 10 mm, 20 mm, and 50 mm by using HTC Instrument LX-101A Light Meter Luxmeter (High Tech Computer Corporation, New Taipei, Taiwan, China) in a dark room. The mean of three readings was considered for evaluation.

2.2. Deflection

The deflective capabilities of all fURSs were evaluated in different settings. To assess the impact of different instrument on scope deflection, 200 μm laser fiber and 1.9 Fr basket were advanced through the working channel of fURSs in a straight position until they protruded out the distal tip by 10 mm followed by maximum deflection on either side. The angle of deflection of scope tip relative to shaft was measured using a protractor on the captured image. At end of all these deflective tests, deflection with an empty working channel was evaluated for each fURS. The mean of three readings was considered for evaluation.

2.3. Irrigation flow rate

Irrigation flow rate was assessed by attaching normal saline attached to manual pump at 100 mL/min and the flow rate was measured with the tip of the fURS at undeflected and maximal deflective state, initially with an empty working channel and then with different accessories (200 μm laser fiber and 1.9 Fr basket). In each condition, measurement was recorded after allowing the system to equilibrate for 1 min. Measurements in each setting were repeated thrice and the mean value was finally used.

3. Results

3.1. Optical performance

Image resolution power was comparable amongst all the ureteroscopes at the distances of 10 mm and 20 mm (3.56

lp/mm). However, Indoscope (3.56 lp/mm) was superior to LithoVue (3.17 lp/mm) and Uscope scopes (3.17 lp/mm) at 50-mm distance. Uscope 7.5 Fr had equivalent image resolution to LithoVue and Uscope 9.5 Fr fURS (Fig. 1).

Color perception was comparable for all scopes at 10 mm ($p<0.05$), while Lithovue 9.5 Fr was comparable with Indoscope 9.5 Fr at the distances of 20 mm and 50 mm, and these scopes were statistically better than Uscopes at the distances of 20 mm and 50 mm ($p<0.05$) (Fig. 2).

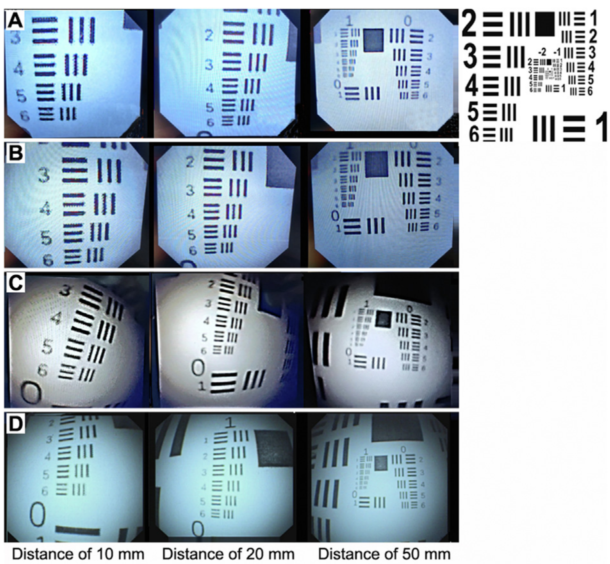

Figure 1 Image resolution of each scope using 1951 U.S. Air Force Test Pattern Card at the distances of 10 mm, 20 mm, and 50 mm. (A) Uscope 9.5 Fr; (B) Uscope 7.5 Fr; (C) LithoVue 9.5 Fr; (D) Indoscope 9.5 Fr.

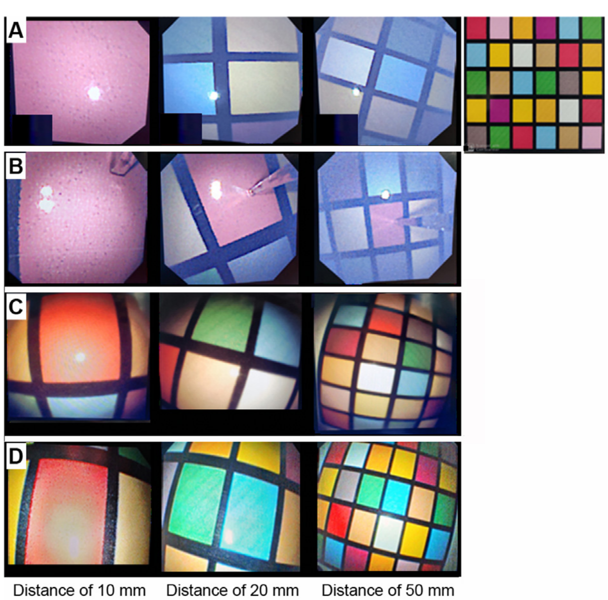

Figure 2 Color reproducibility using Gretag Macbeth color checker target kept at the distances of 10 mm, 20 mm, and 50 mm. (A) Uscope 9.5 Fr; (B) Uscope 7.5 Fr; (C) LithoVue 9.5 Fr; (D) Indoscope 9.5 Fr.

At the distance of 10 mm, the luminosities of Uscope 9.5 Fr and LithoVue 9.5 Fr were statistically comparable ($p=0.147$) and better than Indoscope 9.5 Fr ($p<0.05$) followed by Uscope 7.5 Fr ($p<0.05$). At the distance of 20 mm, LithoVue 9.5 Fr scope had the highest luminosity and was statistically significant ($p<0.05$) than other three scopes. Similarly, at distance of 50 mm LithoVue had significantly better luminosity amongst all scopes while Uscope 7.5 Fr scope had the lowest luminosity at all distances.

3.2. Deflection

With empty working channel and with 200 μm laser fiber Indoscope had the maximum deflection (285°) among other three scopes ($p<0.05$). With basket inside working channel, Uscope 7.5 Fr had significantly more loss of deflection than the other three scopes ($p<0.05$) (Fig. 3).

3.3. Irrigation flow rate

With empty working channel, all scopes had comparable irrigation flow rate in both deflected and without deflected state. Similarly, when working channel was occupied with either 200 μm laser or basket, the irrigation flow rate was comparable in all the scopes (Fig. 4).

4. Discussion

Since its introduction in 1964 by Marshall fURS has undergone several design improvements [12,13]. Technological advancement in tip deflection, improved optic capabilities, availability of small instruments passable via narrow working channel, fluid irrigation, and miniaturization of scope has made fURS an efficient and safe armamentarium in management of renal calculi [14,15]. Introduction of "chip at tip" technology is a major technological improvement which provides better image quality when compared with conventional fiber-optic ureteroscope and decreases operative time by 20% [16].

Limitations associated with reusable fURSs in form of high maintenance cost, infection transmission, sterilization challenges, expensive repairing, and prone to wear and tear after repeated use have paved way for search of alternative scope which can mitigate these problems. In *in vitro* settings, fURSs have shown to be more cost effective

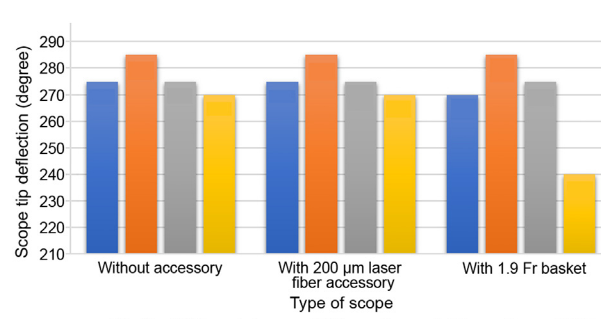

Figure 3 Deflection with working channel empty, with 200 μm laser fiber, and 1.9 Fr basket through the working channel of single-use digital flexible ureteroscopes.

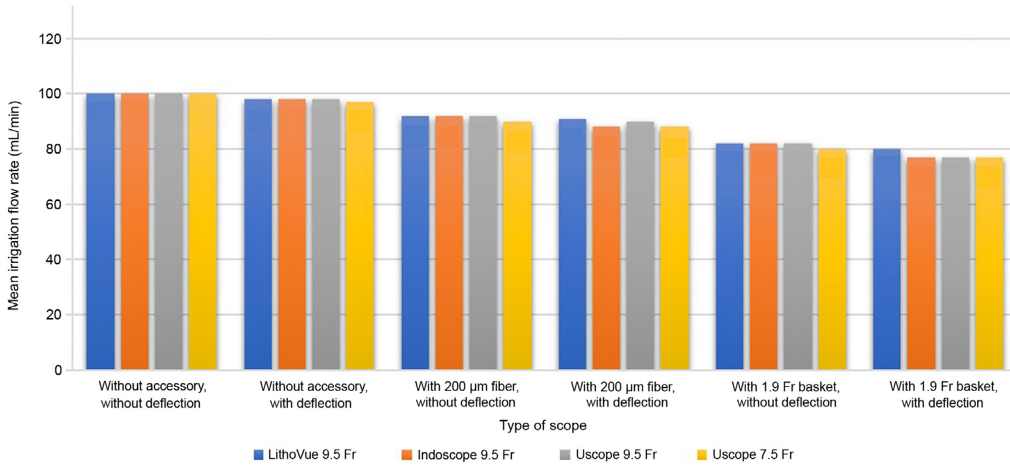

Figure 4 Mean irrigation flow rate in four single-use digital flexible ureteroscopes (scopes with and without deflection in various scenarios with irrigation pump of 100 mL/min).

alternative with regards to deflection mechanism, irrigation flow even with instruments, and field of vision optics than reusable flexible ureteroscope [9,17].

Acknowledging the details of each single-use fURS will enable the surgeon to follow a patient centered approach and to choose an effective single-use fURS among the various brands in the market. Comparison between two single-use digital fURSs—LithoVue and Uscope 9.5 Fr is available in recent literature [11]. To the best of our knowledge, this is the first *in vitro* study to analyze and compare characteristics of four single-use fURSs. Also, this is the first study to include Uscope 7.5 Fr and Indoscope *in vitro* comparative study.

The physical characteristics of the four scopes are as described in Table 1. LithoVue scope has longest working length (680 mm) with all scopes having similar working channel of 3.6 Fr, except Indoscope which has 3.3 Fr working channel. The Uscope 7.5 Fr has the smallest outer diameter with similar working channel.

The ultimate goal of any laser lithotripsy by fURSs is to achieve complete stone clearance in the least possible time. This can be achieved by sharp vision and good irrigation capacity of the scope. This combination ensures clear vision during lasing leading to better and fast stone clearance with minimal complications. The horizons of fURSs are increasing from management of kidney stones to diagnosis and treatment of upper urinary tract urothelial cancer [18]. The color perception of a scope is of utmost importance for correct treatment of cancer as well as to assess crystalline structure of stone [19]. The color perception of Indoscope and LithoVue was comparable at all distances. However, color perception of these to scopes was significantly better than Uscope 9.5 Fr and 7.5 Fr scopes especially at the distances of 20 mm and 50 mm.

Sharpness of image is important during laser lithotripsy and urinary tract urothelial cancer management. This can be assessed by image resolution. Optical image resolution was comparable for all the scopes at the distances of 10 mm and 20 mm. Image resolution at the distance of 50 mm was better for Indoscope followed by LithoVue, followed by Uscope 9.5 Fr which is equal with Uscope 7.5 Fr. The luminosity of fURS plays a pivotal role for better visibility, especially if there is intraoperative bleeding. The luminosity at 10 mm was comparable for LithoVue and Uscope 9.5 Fr, but at 20 mm and 50 mm, LithoVue had the highest luminosity while Uscope 7.5 Fr had the lowest one. Indoscope had lower luminosity than the remaining 9.5 Fr scopes at all distances, but this could be attributed to built-in auto-light adjustment feature in the scope to avoid glaring. In reality, only luminosity at 1—3 cm is of clinical relevance because the viewing distance in pelvi-calyceal system in not more than 3 cm.

The problem in fURSs for lower pole calculus especially with long and thin infundibulum, calyceal diverticulum, and complex stone is accessibility to the stone [20]. The fear of reusable scope damage was deterrent for such procedures.

Table 1 Physical characteristics of the scopes.

Variable	Uscope 7.5 Fr	Uscope 9.5 Fr	LithoVue 9.5 Fr	Indoscope 9.5 Fr
Shaft size, Fr	7.5	9.5	9.5	9
Total working length, mm	650	650	680	670
Working channel, Fr	3.6	3.6	3.6	3.3
Camera sensor type	CMOS	CMOS	CMOS	CMOS
Connector type	Flat	Flat	Round eight pins	Round with two cables
Endoscopic exit point (working channel tip position)	3 o'clock	3 o'clock	3 o'clock	9 o'clock
Deflection type	Dual deflection	Dual deflection	Dual deflection	Dual deflection

CMOS, complementary metal-oxide semiconductor.

Single-use fURSs may change the scenario. Thus, deflection of such scopes with accessories is of utmost importance especially in scenarios where relocation of stone to a favorable calyx is not possible. In terms of deflection, Indoscope had maximum deflection (285°) among all the scopes and did not have deflection loss with any accessory. LithoVue and Uscope 9.5 Fr had comparable deflection (275°) with no accessory and with 200 μm fiber. With basket, Uscope 9.5 Fr maintained deflection (285°), while LithoVue lost 5° (270°). Amongst all scopes, Uscope 7.5 Fr had the least deflection (270°) without accessory and with 200 μm fiber but had the least deflection (240°) with basket ($p<0.05$). In concordance with existing *in vitro* and *in vivo* studies, only five degrees of deflection loss were seen in LithoVue when accessory was placed inside working channel [6,21]. However, this may not be much of clinical relevance.

All the scopes had comparable irrigation flow rate with or without any accessory in both deflected and undeflected condition. It was interesting to know that the irrigation flow in Uscope 7.5 Fr scope was also comparable with remaining 9.5 Fr scopes. This was due to almost similar working channel sizes (3.6 Fr in all scopes except 3.3 Fr in Indoscope).

The criticism of digital flexible ureteroscopes has always been need for larger ureteral access sheath due to its larger diameter size. Bach et al. [22] compared safety of smaller size fiberoptic and larger size digital scopes in their study and concluded that there is increased need for ureteral access sheath in the digital arm and in two cases it led to distal ureteral injury. Thus, although the digital scopes have upper hand of better vision and durability, they come with the cost of increased morbidity. We evaluated 7.5 Fr single-use digital scope with the larger diameter 9.5 Fr counterparts. The optical parameters of Uscope 7.5 Fr were comparable with Uscope 9.5 Fr. The deflection without any accessory was comparable with all the 9.5 Fr scopes, although there was greater loss of deflection especially with 1.9 Fr basket. The clinical implication of this needs to be evaluated. Though the diameter of 7.5 Fr is less than that of 9.5 Fr scopes, the working channel size is similar leading to equivalent irrigation flow rate. With comparable characteristics, the decrease in the size of scope may lead to decrease in size of ureteral access sheath, leading to decrease in morbidity.

The LithoVue scope needs a propriety monitor and processor, while both the Uscopes and Indoscope can be attached to any existing monitor using a manufacture specific processing unit (Fig. 5). The lock-in period for these single-use fURSs is 4 h for LithoVue and both Uscopes, and 21 h for Indoscope. The location of working channel with respect to the tip is important for location of laser fiber exit. The laser fibers exit at 3 o'clock in LithoVue and both the Uscopes, while at 9 o'clock in Indoscope. The weight of Lithovue, both the Uscopes and Indoscope is 276 g, 220 g, and 280 g, respectively [17,23].

We acknowledge that all the tests were performed *in vitro*, and these results may differ in clinical setting where blood and stone dusts or fragments will have impact on irrigation and optic characteristics of scopes. However, this study highlights the different characteristics of 9.5 Fr Indoscope and 7.5 Fr slimmest available digital scope and may help clinicians in selecting the right scope. Clinical studies with multiple users are required for further extrapolation of these *in vitro* findings in clinical settings.

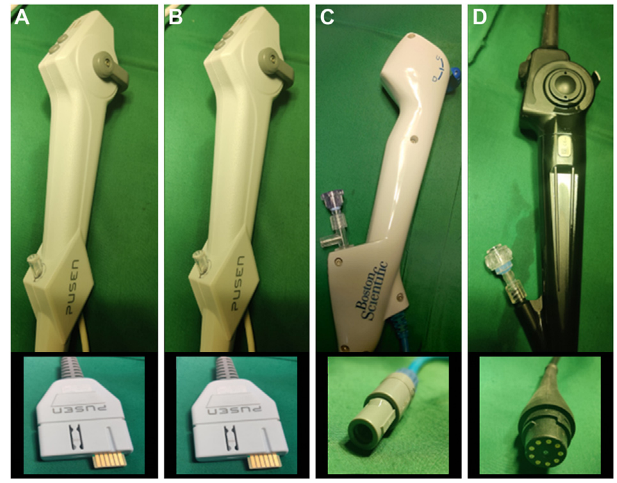

Figure 5 Visual assessment of handle and connector type of single-use digital flexible ureteroscopes. (A) Uscope 9.5 Fr; (B) Uscope 7.5 Fr; (C) LithoVue 9.5 Fr; (D) Indoscope 9.5 Fr.

5. Conclusion

The color representation is equivalent in Indoscope and LithoVue, while being better than Uscope 9.5 Fr and 7.5 Fr scopes at the distances of 20 mm and 50 mm. The image resolution was comparable in all scopes at the distances of 10 mm and 20 mm. At the distances of 20 mm and 50 mm, luminosity of LithoVue is the highest and that of Uscope 7.5 Fr is the lowest. The deflection loss is minimum with Indoscope and is maximum with Uscope 7.5 Fr. The irrigation flow rate is comparable in all scopes in all scenarios.

Author contributions

Study concept and design: Abhijit Patil, Shashank Agrawal, Ravindra Sabnis.
Data acquisition: Abhijit Patil, Rohan Batra, Shashank Agrawal.
Data analysis: Abhijit Patil, Rohan Batra, Shashank Agrawal.
Drafting of manuscript: Abhijit Patil, Shashank Agrawal, Arvind Ganpule, Ravindra Sabnis.
Critical revision of the manuscript: Abhishek Singh, Arvind Ganpule, Ravindra Sabnis, Mahesh Desai.

Conflicts of interest

The authors declare no conflict of interest.

References

[1] Rukin NJ, Siddiqui ZA, Chedgy EC, Somani BK. Trends in upper tract stone disease in England: evidence from the hospital episodes statistics database. Urol Int 2017;98:391–6.

[2] Saigal CS, Joyce G, Timilsina AR; Urologic Diseases in America Project. Direct and indirect costs of nephrolithiasis in an employed population: opportunity for disease management? Kidney Int 2005;68:1808—14.
[3] Koyuncu H, Yencilek F, Kalkan M, Bastug Y, Yencilek E, Ozdemir AT. Intrarenal surgery *vs.* percutaneous nephrolithotomy in the management of lower pole stones greater than 2 cm. Int Braz J Urol 2015;41:245—51.
[4] Assimos D, Krambeck A, Miller NL, Monga M, Murad MH, Nelson CP, et al. Surgical management of stones: American urological Association/Endourological Society guideline, PART I. J Urol 2016;196:1153—60.
[5] Proietti S, Dragos L, Molina W, Doizi S, Giusti G, Traxer O. Comparison of new single-use digital flexible ureteroscope versus nondisposable fiber optic and digital ureteroscope in a cadaveric model. J Endourol 2016;30:655—9.
[6] Usawachintachit M, Isaacson DS, Taguchi K, Tzou DT, Hsi RS, Sherer BA, et al. A prospective case-control study comparing LithoVue, a single-use, flexible disposable ureteroscope, with flexible, reusable fiber-optic ureteroscopes. J Endourol 2017;31:468—75.
[7] Winship B, Wollin D, Carlos E, Li J, Preminger GM, Lipkin ME. Avoiding a lemon: performance consistency of single-use ureteroscopes. J Endourol 2019;33:127—31.
[8] Salvadó JA, Olivares R, Cabello JM, Cabello R, Moreno S, Pfeifer J, et al. Retrograde intrarenal surgery using the single-use flexible ureteroscope Uscope 3022 (Pusen^{TM}): evaluation of clinical results. Cent Eur J Urol 2018;71:202—7.
[9] Marchini GS, Batagello CA, Monga M, Torricelli FCM, Vicentini FC, Danilovic A, et al. *In vitro* evaluation of single-use digital flexible ureteroscopes: a practical comparison for a patient-centered approach. J Endourol 2018;32:184—91.
[10] Emiliani E, Mercadé A, Millan F, Sánchez-Martín F, Konstantinidis CA, Angerri O. First clinical evaluation of the new single-use flexible and semirigid Pusen ureteroscopes. Cent Eur J Urol 2018;71:208—13.
[11] Kam J, Yuminaga Y, Beattie K, Ling KY, Arianayagam M, Canagasingham B, et al. Single use versus reusable digital flexible ureteroscopes: a prospective comparative study. Int J Urol 2019;26:999—1005.
[12] Rajamahanty S, Grasso M. Flexible ureteroscopy update: indications, instrumentation and technical advances. Indian J Urol 2008;24:532—7.
[13] De La Rosette J, Denstedt J, Geavlete P, Keeley F, Matsuda T, Pearle M, et al. The clinical research office of the endourological society ureteroscopy global study: indications, complications, and outcomes in 11 885 patients. J Endourol 2014;28:131—9.
[14] Bagley DH, Huffman JL, Lyon ES. Flexible ureteropyeloscopy: diagnosis and treatment in the upper urinary tract. J Urol 1987;138:280—5.
[15] Proietti S, Somani B, Sofer M, Pietropaolo A, Rosso M, Saitta G, et al. The "body mass index" of flexible ureteroscopes. J Endourol 2017;31:1090—5.
[16] Somani BK, Al-Qahtani SM, de Medina SDG, Traxer O. Outcomes of flexible ureterorenoscopy and laser fragmentation for renal stones: comparison between digital and conventional ureteroscope. Urology 2013;82:1017—9.
[17] Dragos LB, Somani BK, Keller EX, De Coninck VM, Herrero MR-M, Kamphuis GM, et al. Characteristics of current digital single-use flexible ureteroscopes versus their reusable counterparts: an *in vitro* comparative analysis. Transl Androl Urol 2019;8(Suppl 4):S359—70. https://doi.org/10.21037/tau.2019.09.17.
[18] Audenet F, Traxer O, Yates DR, Cussenot O, Rouprêt M. Potential role of photodynamic techniques combined with new generation flexible ureterorenoscopes and molecular markers for the management of urothelial carcinoma of the upper urinary tract. BJU Int 2012;109:608—13.
[19] Mandalapu RS, Remzi M, de Reijke TM, Margulis V, Palou J, Kapoor A, et al. Update of the ICUD-SIU consultation on upper tract urothelial carcinoma 2016: treatment of low-risk upper tract urothelial carcinoma. World J Urol 2017;35:355—65.
[20] Shah HN. Retrograde intrarenal surgery for lower pole renal calculi smaller than one centimeter. Indian J Urol 2008;24:544—50.
[21] Dale J, Kaplan AG, Radvak D, Shin R, Ackerman A, Chen T, et al. Evaluation of a novel single-use flexible ureteroscope. J Endourol 2017;35:903—7.
[22] Bach C, Nesar S, Kumar P, Goyal A, Kachrilas S, Papatsoris A, et al. The new digital flexible ureteroscopes: "size does matter"—increased ureteric access sheath use. Urol Int 2012;89:408—11.
[23] From internet, https://bioradmedisys.com/medical-devices/urologydisposableproducts/13991-2/. [Accessed 23 June 2020].