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UROLITHIASIS

A clinical evaluation of the new digital single-use flexible ureteroscope (UscopePU3022): an international prospective multicentered study

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Introduction We assessed the clinical performance of a new digital single-use flexible ureteroscope (UscopePU3022).

Material and methods A prospective cohort study was carried out across 11 centers (July–Oct. 2017). The UscopePU3022 was assessed regarding ease of insertion; deflection, image quality, maneuverability and overall performance using either a visual analog* or Likert scale.

Results A total of 56 procedures were performed in 11 centers (16 surgeons) with the indication being renal stones in 83%. The median score for ease of scope insertion was 10 (3–10). Intraoperative maneuverability was rated as 'good' in 38% and 'very good' in 52%. Visual quality was rated as 'poor or bad' in 18%, 'fair' in 37% and 'good or very good' in 43%. Two scopes failed intraoperatively (4%). Preoperative and postoperative median upward and downward deflection was 270 degrees. Compared to standard flexible ureteroscopy (f-URS) maneuverability was rated as 'equivalent' in 30% and 'better' in 60%; visual quality was 'worse' in 38% and 'equivalent or better' in 62%; limb fatigue scores were 'better' in 86%; and overall performance was 'worse' in 55% and 'equivalent or better' in 45%.

Conclusions UscopeTM3022 performed well with regards to maneuverability, deflection and limb fatigue and appears to be at least non-inferior to standard f-URS with regards to these parameters. Poor image quality is a concern for UscopePU3022 with it receiving a low overall performance rating when compared to standard f-URS. Despite this it scored highly when investigators were asked if they would use it in their practice if it was cost-effective to do so.

Key Words: digital ‹› flexible ureteroscope ‹› disposable ‹› single-use

INTRODUCTION

Over the past 30 years there has been considerable technological advancements in flexible ureteroscopy (f-URS), resulting in its widespread use in the diagnosis and treatment of upper urinary tract disease, mainly urolithiasis [1, 2]. F-URS has now surpassed external shockwave lithotripsy as the most common treatment modality for the management of renal stones with high success rates and low morbidity [3, 4]. There are a wide range of fiber optic and digital reusable flexible ureteroscopes used in current practice, but despite technological advancements there remains major concerns about their durability, potential risk of cross- contamination and significant costs associated with sterilization and repair [5–8]. For these reasons, as well as delays in reuseable f-URS repairs resulting in lack of scope availability, single-use f-URS have been introduced in some countries in an attempt to offer a reliable, clinically non-inferior, user friendly and cost-effective alternative [9].

A number of single-use f-URS are now available for commercial use (Polyscope™, SemiflexM, FlexorVue™, Neoflex™, Lithovue™, and UscopePU3022) but there remains limited robust data available assessing their technological design and clinical performance [9, 10]. Lithovue™ (Boston Scientific, USA) is the first digital single-use f-URS with initial laboratory and clinical performance studies confirming its performance and safety profile to be at least equivalent to the standard reusable scopes [11, 12, 13]. The UscopePU3022 digital single-use f-URS (Zhuhai Pusen Medical Technology Company Limited, China) has recently been introduced as a potential competitor to Lithovue™ with the promise of delivering equivalent clinical performance, but at a reduced cost. UscopePU3022 was evaluated for the first time in vivo by Marchini et al. [14] who compared it and Lithovue to the reusable Flex-X2 (Karl Storz,Germany) standard scope. They reported UscopePU3022 to be lighter and have higher irrigation rates (without instruments) compared to the other ureteroscopes, but Lithovue™ performed better overall in terms of optical resolution, field of view and deflection. Salvado and colleagues have recently published the first clinical evaluation of UscopePU3022 reporting stone free rates up to 95% in 71 patients with a mean stone size of 11.4 mm [15].

The purpose of this study was to perform a preliminary clinical evaluation of UscopePU3022 performance with regards to visual quality, maneuverability, deflection, limb fatigue and overall performance in the diagnosis and treatment of upper tract disease.

MATERIAL AND METHODS

Study design and patient participation

A prospective cohort study was carried out across 11 international tertiary hospitals (Austria, Denmark, France, Germany, Italy, the Netherlands, Sweden and two centers within Spain and the United Kingdom) between July and October 2017. All consecutive patients (17 years or older) underwent a flexible ureteroscopy (UscopePU3022) performed by an expert endourologist for the treatment of a urinary stone or the suspected diagnosis of a tumor in the upper tract. All patients provided informed consent for the procedure. Using a structured proforma (see appendix) preoperative data was collected on patient demographics (age and gender), indication (diagnostic or treatment), tumor or stone characteristics (number, size, location, density) and prior placement of a ureteric stent, and clinical and performance data on the ureteroscope was collected prospectively.

UscopePU3022

UscopePU3022 is a single-use digital flexible ureteroscope (Zhuhai Pusen Medical Technology Co, Ltd.Zhuhai, China) with a 650 mm working length, 9Fr distal tip (9.5Fr maximum insertion diameter), a 3.6Fr working channel for irrigation and insertion of instruments. It weighs 147 grams and can deflect 270 degrees in the upward and downward direction. At the distal tip it has a complementary metal oxide semiconductor (CMOS) which provides a 00 line of vision, 3–50 mm visible range, a 1200 field of view and has no lock-out time. UscopePU3022 can be connected to own 'plug and play' monitor (UTV 100) or to a standard theater stack monitor via a HDMI connection. The UTV 100 monitor can store intraoperative photos and videos. Two former versions include the Uscope UE3011 and UE5011. http://www.aquilantendoscopy.com/assets/aquilantendoscopy/Products/brochures/90501/PUSEN_Fully_Flexible_Single_Use_Ureteroscope_-_PU3022.pdf

Performance measures

The UscopePU3022 was assessed across a range of measures using a standard proforma (see appendix). Intraoperative data was collected on the ease of insertion using a visual analog scale (VAS, 1 = difficult and 10 = easy), use of a guide wire, use of an access sheath (size, type, success), laser characteristics (laser fiber type and size, frequency, energy and laser time), use of a basket (type and size) and breakage/failure of scope. Intraoperative scope image

quality, maneuverability and overall performance was assessed using a visual analog scale (12 = poor, 3–4 = bad, 5–6 = satisfactory, 7–8 = good, 9–10 = very good). A Likert scale (none, occasional not bothersome, occasional bothersome and frequently bothersome) was used to assess laser interference. Pre- and postoperative data was collected on maximal scope deflection (upward and downward) by two independent urologists experienced in endourology. Deflection angle was measured between the tangents to the active deflection segment and the deflected tip with a protractor using a photograph taken at the start and the end of the procedure while completely deflected in both directions. No data was recorded on stone free rates and postoperative complications.
The experts at each center were also asked to rate the performance of the UscopePU3022 compared to the standard reusable ureteroscopes (fiber optic and/or digital) used at each institution (Supplementary Table 1), using a visual analog scale (1–4 = worse, 5–6 = equivalent and 7–10 = better) with regards to image quality, maneuverability, wrist and thumb fatigue and overall performance. The institutions were also asked if they would use UscopePU3022 in their clinical practice if costs compared to your current scope were equivalent or better using a visual analog scale (1 = absolutely not; 10 = definitely).

Table 1. *Baseline demographics*

Characteristics	Total
Number of patients	56
Gender (M: F ratio)	31: 25
Age (years)	57 (17–84)
Indication for ureteroscopy, n (%)	
Stone disease	54 (96)
Diagnostic	2 (4)
Stone location, n (%)*+	
Kidney	45 (83)
Upper-pole	7
Mid-pole	3
Lower-pole	22
Pelvis	13
Ureter	9 (17)
Upper	5
Middle	3
Lower	1
No. of stones, n (%)+	
Single	33 (59)
Multiple	22 (39)
Stone size (mm), n (%)+	
<10	21 (38)
10–20	29 (52)
>20	1 (2)
Stone density (Hounsfield units)+	900 (380–1410)
Preoperative stenting, n (%)	24 (44)

*One patient's stone had passed spontaneously.
+Missing data: location (n = 2), no. of stone (n = 1): stone size (n = 5)

Statistical analysis

Data are presented as the median and range for continuous variables, and the number and percentage for categorical variables. The Wilcoxon rank sum test was used to compare repeated measures. χ^2 test was used to compare the difference between categorical data. All tests were two-sided, with statistical significance set at $p < 0.05$. All analyses were performed using IBM SPSS for Windows, version 22.

RESULTS

There were 56 UscopePU3022 flexible ureteroscopies performed in 11 centers. The median age of patients was 57 years (17–84), 31 (55%) were male and 54 (96%) were performed for the treatment of urinary stones. Stones were located in the kidney in 45/54 (80%) and in the ureter in 9/54 (20%) with 24/54 (44%) being stented preoperatively. The median stone size and density was 10 mm (5–25) and 900 (380–1410) Hounsfield units, respectively (Table 1). One procedure was abandoned because the ureter was too tight to insert the UscopePU3022 safely and in another the stone had already passed spontaneously.
The median score for ease of scope insertion was 10 (2–10) with 16/56 (28%) being passed over a guide wire alone and 40/56 (72%) using an access sheath (10/12Fr in 70%, 11/13 Fr in 28% and 12/14 in 2%). Laser lithotripsy was performed in 47/54 (87%) of the stone procedures using a 200-272um fiber in 89% (42/47) of cases. The median laser time, energy used, and frequency was 10 minutes (1–60), 0.9 Joules (0.4–1.5) and 15 Hertz (3–70), respectively. A stone basket was used in 30/54 (55%) of stone procedures (1.7Fr in 17%, 1.9Fr in 47% and 2.2Fr in 37%). An upper tract diagnostic procedure was performed in two cases (4%) (Table 2).
The UscopePU3022 median intraoperative maneuverability score was 9/10 (3–10) of which 38% were rated as 'good' and 52% as 'very good'. The median visual quality score was 6/10 (1–10) of which 18% were rated as 'poor' (9%) or 'bad' (9%), 37% as 'fair' and 43% as 'good' (13%) or 'very good' (30%). The median overall performance score was 7/10 (4–10) of which 14% were rated as 'poor', 23% as 'fair' and 61% as 'good' (48%) or 'very good' (13%). Laser interference was reported as bothersome in 33% and not bothersome in 67%. The UscopePU3022 UTV 100 monitor was utilized in 45% of procedures, whereas the standard stack monitor was used in 48% with most investigators reporting a better view with their standard monitor (Table 3). Two UscopePU3022

Table 2. *Intra-operative procedure characteristics*

Intra-operative characteristics	Median (range)
Ease of insertion, median (Range)*	10 (2–10)
PUSEN insertion, n (%)	
Guide wire alone	16 (28)
Access sheath	40 (72)
Type of guide wire, n (%)	16 (28)
Sensor	10
Terumo	4
PTFE	2
Ureteral access sheath, n (%)	40 (70)
10/12	28
11/13	11
12/14	1
Laser characteristics in stone procedures (n = 54)	
Laser used, n (%)	47 (87)
Laser type	
200–272	42
365	5
Frequency (Hertz)	15 (3–70)
Energy (Joules)	0.9 (0.4–1.5)
Laser time (minutes)	10 (1-60)
Basket characteristics in stone procedures (n = 54)	
Use of basket, n (%)	30 (55)
Basket size (Fr)	
1.7	5
1.9	14
2.2	11

* Visual Analog Scale, 1 = difficult insertion and 10 = easy insertion

Table 3. *UscopePU3022 clinical performance measures*

Clinical performance measures	Visual analogue scale (1–10)	
Maneuverability, median (range)*	9 (3–10)	
Grouped VAS scores, n (%)		
Very good	29 (52)	
Good	21 (38)	
Fair	4 (7)	
Poor	2 (4)	
Bad	0 (0)	
Visual quality, median (range)*	6 (1–10)	
Grouped VAS scores, n (%)		
Very good	17 (30)	
Good	7 (13)	
Fair	19 (34)	
Poor	5 (9)	
Bad	5 (9)	
Overall performance satisfaction, median (range)*	7 (4–10)	
Grouped VAS scores, n (%)		
Very good	7 (13)	
Good	27 (48)	
Fair	13 (23)	
Poor	8 (14)	
Bad	0 (0)	
Deflection pre- and postoperative, median (range)*		
Preop		
Upward	270°	[a]P = 0.05
Downward	270°	[a]P = 0.04
Postop		
Upward	270° (260–270)	
Downward	270° (30–270)	
Laser interference (Likert scale)		
None	27 (48)	
Occasional not bothered	4 (7)	
Occasional bothersome	15 (27)	
Frequently bothersome	3 (6)	
Monitor used, n (%)		
PUSEN	25 (45)	
Standard stack	27 (48)	
Both	2 (4)	
Scope failure, n (%)[+]	2 (4)	

Data presented with median (range) for each parameter
VAS = Visual Analog Scale
Missing data: visual quality (n = 3), overall performance (n = 1), monitor used (n = 2), laser interference (n = 7), deflection (n = 6), visual quality pre- and postoperatively (n = 27).
* Visual Analog Scale: bad = 1–2, poor = 3–4, fair = 5–6, good = 7–8 and very good = 9–10.
a Wilcoxon rank sum test comparing preop to postop deflection
[+] Scope failure due to failure of hand piece (n = 1) and poor views (n = 1)

procedures were terminated due to failure of scope deflection in one case and spontaneous loss of vision in another. Both these cases were subsequently successfully completed with the standard f-URS at that center. Preoperative and postoperative median upward and downward deflections were 2700 and 2700, respectively.

UscopePU3022 performance was compared to the standard f-FURS (fiber optic and/or digital) at each center (Table 4). The median maneuverability score when compared to standard f-URS was 8/10 (4–10) of which 30% were rated as 'equivalent' and 60% as 'better'. Median visual quality score was 5/10 (2–10) with 38% rating it as 'worse', 23% as 'equivalent' and 39% as 'better' than their standard f-URS. Median thumb and wrist fatigue scores were 10/10 (5–10) of which 84% and 87%, respectively, rated UscopePU3022 to be 'better' than their standard f-URS (Table 4). Investigators commonly reported UscopePU3022 to be much lighter than their standard f-URS. The median overall score on UscopePU3022 performance when comparing to standard f-URS was 4/10 (2–10) with 55% reporting it as 'worse', 16% as 'equivalent' and 29% as 'better'. When asked if they would use UscopePU3022 in their daily practice if the cost was equivalent or less, the median score was 7/10 (2–10).

Sub-group (n = 25) analysis of UscopePU3022 performance measures in centers who only used a fiber optic (n = 10) or a digital reuseable scope as standard (n = 15) showed that there was no statistical difference in the UscopePU3022 rating for maneuverability, visual quality and overall performance. There was a trend towards UscopePU3022 vision rating being better when compared to the reuseable fiber optic than reusable digital over f-URS. (Supplementary Table 2).

Table 4. *Rated UscopePU3022 performance compared to standard reusable ureteroscope*

Comparative performance measures	
Maneuverability	8 (4–10)
Grouped VAS scores, n (%)	
Better	36 (64)
Equivalent	17 (30)
Worse	3 (6)
Visual quality	5 (2–10)
Grouped VAS scores, n (%)	
Better	22 (39)
Equivalent	13 (23)
Worse	21 (38)
Wrist fatigue	10 (5–10)
Grouped VAS scores, n (%)	
Better	49 (87)
Equivalent	7 (13)
Worse	0 (0)
Thumb fatigue	10 (5-10)
Grouped VAS scores, n (%)	
Better	47 (84)
Equivalent	9 (16)
Worse	0 (0)
Overall UscopePU3022 performance	4 (2–10)
Grouped VAS scores, n (%)	
Better	16 (29)
Equivalent	9 (16)
Worse	31 (55)
Would you use UscopePU3022 in your clinical practice if costing was equivalent or better?	7 (2–10)

VAS – Visual Analog Scale
Data presented with median (range) for each parameter
Grouped VAS scores: 1–4 = worse, 5–6 = equivalent and 7–10 = better

DISCUSSION

Single-use digital flexible ureteroscopes have the potential to be a cost-effective alternative to standard reuseable f-URS and help address the major concerns regarding their durability and risk of cross-infection. Disposable f-URS are expected to be non-inferior to standard reusable scopes and should have the following properties: ergonomic, high quality image, optimal maneuverability and torque to access the entire collecting system, good irrigation flow with instruments inside the working channel (requires a 3.6Fr channel) and adequate bidirectional active deflection (270:270 degrees) [9, 11, 16]. Before disposable f-URS are considered as a viable alternate to standard reusable f-FURS, it is imperative they undergo comprehensive evaluation regarding their technological design, clinical efficacy and cost-effectiveness.

First generation fiber optic reuseable scopes such as SemiflexM and Polyscope™ underwent their initial evaluation as early as 2009. The original model of SemiflexM was a semi disposable scope consisting of a reusable eye piece attached to a straight handle with a lateral deflection lever, a 6.3fr shaft and 3.3F working channel. An in vitro study by Bolyu et al. 10 reported SemiflexM to have a comparable field of view (720) and the highest active defection (300/265 degrees) compared to six standard reusable scopes, but experienced the highest loss in deflection with a working instrument (up to 39%) and had significantly lower flow rates. The second generation SemiflexM is completely disposable, has improved 900 field of view, a 3.4 Fr working channel and an increased shaft diameter of 8.3 Fr. To our knowledge, no laboratory or clinical evaluations have been published on its performance.

Polyscope™ is another semi-disposable f-URS introduced in 2010 with a reusable fiber optic core, disposable 8Fr outer sheath, a syringe-like handle for 2650 unidirectional active deflection and a 3.6Fr working channel. Bader et al. performed an in vitro and clinical assessment of the Polyscope™ [17]. They measured its maximal active deflection to be 2600 which reduced by 1000 when inserting a 3Fr basket and reported a 50% loss in flow rate using a 220 um laser fiber. The field of view (960) and image quality were reported as comparable to standard f-URS. During clinical evaluation they described it as being easy to insert over a guide wire or through an access sheath, a 89.5% stone free rates in 40 laser lithotripsy procedures (mean stone size 1 cm), a mean op time of 26 minutes and no intra-operative complications. The scope failure rate was 12.5% (5/40). Gu et al. reported a primary stone free rate of 89.5% in 86 patients (median stone size 1.23 cm) with nine patients requiring secondary procedures [18]. Giusti and colleague's initial clinical experience with the Polyscope™ reported the maneuverability or quality of vision was not appropriate to perform a satisfactory procedure [19]. Despite the SemiflexM and Polyscope™ being available on the market for the last ten years neither have been able to match the performance of current standard reusable f-URS and despite them being a cheaper alternative, they have not been integrated in current clinical practice.

The introduction of LithoVue™ to the commercial market in 2015 has been a major step towards single-use f-URS becoming the next standard of care. LithoVue™ is the first single-use digital f-URS (EMA and FDA approved) which provides a 850 field of view, 2700 bidirectional active defection, a 3.6 Fr working channel, a 9.5 Fr shaft, a 7.7 Fr distal tip, measures 68cm in length and has a 4 hour usage time per scope. In the laboratory setting Prioetti et al. [11] compared LithoVue™ to a fiber optic (URF-V) and digital (URF-P5) reusable f-URS in four cadaveric models. They reported it to be comparable across a wide range of parameters, including: ureteral

access, maneuverability, image quality, navigation time to reach the calyces and deflection with or without a 1.9 Fr basket or 275 um laser fiber. A further study in a live porcine model by Wiseman et al. [20] compared LithoVue™ to a standard fiber optic reusable f-URS and reported excellent image quality, maneuverability and navigation in a complex calyceal system. The first clinical evaluation of Lithovue was performed by Doizi et al. [12] as part of a multicentric European feasibility study which assessed its preoperative and postoperative performance with regards to image quality, maneuverability and overall performance in 40 patients (5 per institution) treating renal stones in 92% of cases. Preoperative image quality and maneuverability were rated as 'good' or 'very good' in 95% of patients with no statistical differences in these measures when assessed postoperatively. At final evaluation the median bidirectional active deflection was 2700 before and after use with only one scope not maintaining this at the end. The overall performance satisfaction was 'acceptable' in 12.5%, 'good' in 17.5% and 'very good' in 70%. The scope failure rate was 5% (2/40) with one breaking after forced deflection and the other having spontaneous loss of vision.

LithoVue™ is the first single-use digital scope to be extensively evaluated in the laboratory and clinical setting with initial data showing it to be equivalent to standard reuseable f-URS. Although its commercial use is growing internationally its widespread use has been limited due to its current cost with a recent cost-benefit analysis by Martin et al. favoring reuseable scopes compared to Lithovue™ in high volume centers (>99 f-URS per year) [21]. The UscopePU3022 is a new single-use digital f-URS which has promised equivalent clinical performance to Lithovue™ and standard f-URS, but delivered at a more affordable cost.

This study reports on the initial clinical experience of the UscopePU3022 by international experts working in high volume centers. UscopePU3022 performed very well intraoperatively with regards to maneuverability and active deflection. There were mixed reviews regarding intraoperative image quality with 52% rating UscopePU3022 as 'fair' to 'bad' and 48% rating it as 'good' or 'very good'. The investigator's main complaint was that the image was too dark, especially at the periphery, which was even more pronounced when navigating the renal pelvis. In fact, one procedure was abandoned due to poor views without any report of bleeding. Interestingly, the authors reported better image quality when using their own standard monitor stack compared to using the Uscope UTV 100 monitor. Despite the reported issues with image quality, 61% of investigators rated their satisfaction with UscopePU3022 overall performance as 'good' or 'very good'. The UscopePU3022 intraoperative failure rate was 4% (2/56) which is comparable to the initial evaluation of LithoVue™ (5%) [12]. The reasons for failure were also similar with one due to loss of vision and the other due to active deflection failure.

Supplementary table 1. *Summary of standard flexible ureteroscopes used at each center*

	Standard reusable scope	Fiber optic or digital
Austria	Wolf Cobra vision	Digital
Denmark	Olympus URF-P2 and Storz Flex X^2/X^c	Fiber optic and digital
France	Olympus URF-P2 and Storz Flex X^c	Fiber optic and digital
Germany	Stortz Flex X^2/X^c	Fiber optic and digital
Italy	Stortz Flex X^2/X^c	Fiber optic and digital
Spain (Santiago de Compostela)	Olympus URF-P5	Fiber optic
Spain (Barcelona)	Stortz Flex X^c	Digital
Netherlands	Olympus URF-P2 and Storz Flex X^c	Fiber optic and digital
Sweden	Storz Flex X^c	Digital
UK (Cambridge)	Stortz Flex X^2	Fiber optic
UK (Oxford)	Olympus URF-P2 and Stortz Flex X^2/X^c	Fiber optic and digital

Supplementary table 2. *Sub-group analysis (n = 25) comparing UscopePU3022 rated performance to centers who used either a fiber optic or digital standard reusable ureteroscope*

Comparative performance measures	Standard scope		
	Fiber optic n = 10	Digital n = 15	P-value
UscopePU3022 maneuverability Grouped VAS scores, n (%)			[a]P = 0.62
Better	5 (50)	5 (33)	
Equivalent	4 (40)	9 (60)	
Worse	1 (10)	1 (7)	
UscopePU3022 visual quality Grouped VAS scores, n (%)			[a]P = 0.55
Better	4 (40)	3 (20)	
Equivalent	1 (10)	2 (13)	
Worse	5 (50)	10 (67)	
Overall UscopePU3022 performance Grouped VAS scores, n (%)			[a]P = 0.93
Better	4 (40)	5 (33)	
Equivalent	1 (10)	2 (13)	
Worse	5 (50)	8 (54)	

Centers which used both a reusable fiber optic and a digital f-URS as standard were excluded (n = 31)
VAS = Visual Analog Scale
Grouped VAS scores: 1–4 = worse, 5–6 = equivalent and 7–10 = better
[a]χ^2 test assessing for a difference in the UscopePU3022 performance rating when compared to reuseable fiber optic and reusable digital

This study also rated the UscopePU3022 clinical performance compared to the standard f-URS (see supplementary Table 1) used at each center. UscopePU3022 performed very well with regards to maneuverability and limb fatigue, with these being reported as 'equivalent' or 'better' in 94% and 100% of cases, respectively. Once again image quality had a varied rating with 38% rating it as 'worse' and 62% as 'equivalent' or 'better'. The UscopePU3022 overall clinical performance when compared to the standard f-URS was rated as 'worse' in 55% of cases. However, when the investigators were asked if they would use UscopePU3022 in their clinical practice, if it was cost equivalent or more cost effective, it received high scores.

Our study has several limitations. Although we are the first study to compare Uscope™ 3022 to standard f-URS we did not perform specific head-to-head comparisons as the type of standard scope varied from center to center. This study, however, should be considered as the preliminary evaluation in this respect. The small number of procedures are also a limiting factor but are similar in frequency to the initial evaluations of alternate single-use f-URS available in the market [10, 11, 18]. We also did not measure the stone free rate or postoperative complications which are important parameters to be assessed in future studies.

CONCLUSIONS

UscopePU3022 is a new single-use flexible ureteroscope, which on testing performed well with regards to maneuverability, deflection and limb fatigue and appears to be at least non-inferior to standard flexible ureteroscopy (f-URS) with regards to these parameters. Poor intraoperative image quality is a significant concern for UscopePU3022 and overall most investigators rated it as worse than standard f-URS. Despite this UscopePU3022 scored highly when investigators were asked if they would use it in their practice and if it was cost-effective to do so. Further research is required to assess its surgical outcomes and cost-effectiveness.

CONFLICTS OF INTEREST

Johnston TJ: None.
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USCOPE ASSESSMENT PUSEN

Date of procedure:
Operator:
Location:
Patient information:
Patient age:
Patient gender:
Indication for FURS:
Location of stone
Ureter :
Number of stones:
Size of largest stone (if applicable: measure largest diameter on axial image):
HU of largest stone:
Was the patient prestented?
Vision preop (use image provided to assess quality)
Please capture digital image of picture supplied and send after case with this proforma
Deflection preop:
Please take photo prior to use in this case showing maximal deflection in both directions (We will measure actual deflection from the images)

Up deflection:.....degrees
Down deflection:.....degrees

Insertion of the device:
Over wire alone:

If Yes, please state wire type:

Ease of insertion (1: difficult, 10 easy)

1	2	3	4	5	6	7	8	9	10

Comment .....
Access Sheath
Was insertion of an access sheath attempted (even if failed)?
Size of access sheath attempted .....
Type (brand) of access sheath attempted .....
Was the access sheath inserted successfully? Yes/No
Procedural details
Was a laser fibre used: Yes If Yes, size of fibre:
Laser settings: Frequency Energy
Lazing time:

Total energy……

Was there any interference of the image when using the laser?

none, occasional not bothersome, occasional bothersome or frequently bothersome

Use of basket: If Yes, then Size:

Manoeuvrability during the procedure

1: poor / difficult, 10: excellent, easy

1	2	3	4	5	6	7	8	9	10

Comment: ……

Quality of Vision during the procedure

1: poor, 10 very good

1	2	3	4	5	6	7	8	9	10

What viewing monitor did you use during the case?

Comment:

Postprocedure details

Vision postop / at end of procedure

Please capture digital image of picture supplied and email back with this form.

Deflection postop/ at end of procedure:

Please take photo after use in this case showing maximal deflection in both directions (We will measure actual deflection from the images)

Up deflection:…….…… degrees

Down deflection:…… degrees

Did the scope fail during the procedure?

Comment: ……

Overall assessment

How would you rate the UScope overall?

1: poor, 10: very good

1	2	3	4	5	6	7	8	9	10

What flexible ureteroscope do you usually use?

How would you rate the UScope vision compared to the flexi scope you usually use?

1–4 = worse, 5–6 = equivalent and 7–10 = better

1	2	3	4	5	6	7	8	9	10

How would you rate the UScope manoeuvrability compared to the flexi scope you normally use?

1–4 = worse, 5–6 = equivalent and 7–10 = better

1	2	3	4	5	6	7	8	9	10

How would you rate wrist fatigue with the UScope, compared to the flexi scope you usually use?

1–4 = worse, 5–6 = equivalent and–7-10 = better

1	2	3	4	5	6	7	8	9	10

How would you rate thumb fatigue with the UScope compared to the flexi scope you usually use?

1–4 = worse, 5–6 = equivalent and 7–10 = better

1	2	3	4	5	6	7	8	9	10

Overall, how does this scope rate compared to the flexi scope which you normally use?

1–4 = worse, 5–6 = equivalent and 7–10 = better

1	2	3	4	5	6	7	8	9	10

Would you be willing to use this scope regularly if costing compared to your current scope were equivalent or better?

1: Absolutely not, 10: definitely

1	2	3	4	5	6	7	8	9	10

Any other comments:

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