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Single-use disposable digital flexible ureteroscopes: an *ex vivo* assessment and cost analysis

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Objective

To assess and measure the capability of a single-use disposable digital flexible ureteroscope, the LithoVue™ (Boston Scientific, Marlborough, MA, USA), and to assess if there is a benefit to switching to single-use scopes.

Patients and Methods

The LithoVue was compared to two commonly used reusable flexible ureteroscopes (Olympus URF-V [Olympus, Tokyo, Japan] and Karl Storz Flex-X^c [Karl Storz & Co. KG, Tuttlingen, Germany]) *ex vivo*. An analysis of reusable ureteroscope usage was performed to evaluate damage, durability, and maintenance costs. This was then compared to the projected costs of using single-use disposable scopes.

Results

Flexion, deflection and irrigation flow of the LithoVue was equivalent, if not better than the reusable flexible ureteroscopes. An analysis of 234 procedures with seven new Olympus URF-V scopes, revealed 15 scope damages. Staghorn stones and lower pole/mid-zone stones were significant risk factors for damage ($P = 0.014$). Once damage occurred it was likely to occur again. Total repair costs were $162 628 (Australian dollars) (£92 411 in Great British pounds), the mean cost per case was $695 (£395). Factoring in the purchase cost, cleaning and repair costs, the cumulative cost of 28 reusable flexible ureteroscopy procedures was ~$50 000 (£28 412). If the LithoVue was priced at $1 200 (£682), switching to a single-use scope would cost ~$35 000 (£19 888).

Conclusion

The LithoVue is analogous to reusable flexible ureteroscopes in regard to standard technical metrics. Depending on its purchase cost it may also represent a cost saving for hospitals when compared to the cumulative costs of maintaining reusable scopes. Additionally, urologist may consider using the scope in cases in which reusable scope damage is anticipated.

Keywords

flexible ureteroscope, disposable flexible ureteroscope, single use instrument, urolithiasis, LithoVue, cost analysis

Introduction

The miniaturisation of endourological instruments and improvements in laser lithotripsy have revolutionised the approach to renal stones [1,2]. Flexible ureteroscopy (fURS) is increasingly used as a first-line treatment and it is not surprising that in some countries it exceeds all other modalities by up to 30% [3]. fURS has become popular with urologists, as it is easy to learn, is associated with high stone-free rates, and is acceptable to patients [4–6].

The initial purchase cost of reusable fURS instruments, combined with cleaning is significant. Furthermore, these instruments are delicate and can be easily damaged, and repair costs can be substantial [7,8]. There is also the recognised issue of ureteroscope degradation over time, which can cause inconsistent performance [9]. It is these issues of durability, degradation and repair cost that are limiting the use and uptake of fURS in some countries [10,11].

As an alternative to reusable fURS scopes, a single-use digital scope has been developed, the LithoVue™ (Boston Scientific, Marlborough, MA, USA). The advantages of a single-use scope is that it will eliminate the inconsistent performance of reusable scopes, whilst also avoiding the expensive reprocessing and repair costs [7–9,12].

The objective of the present study was to evaluate the new LithoVue single-use fURS scope, and assess if it could be an alternative to reusable scopes. The LithoVue was compared *ex vivo* to two commonly used reusable fURS scopes in terms of manoeuvrability and functionality. The cost of maintaining a reusable fURS scope was determined and compared to the cost of using the LithoVue, to assess if there would be an economic benefit of using single-use over reusable scopes.

Methods

fURS Scope Assessment

The LithoVue, URF-V (Olympus, Tokyo, Japan) and Flex-X^c (Karl Storz & Co. KG, Tuttlingen, Germany) were examined *ex vivo*. Flexion and deflection was measured with an empty working channel, then with various instruments in the working channel (hydrophilic guidewire, polytetrafluoroethylene (PTFE)-nitinol guidewire, 200-µm laser fibre, 1.9-F nitinol basket, and 3-F biopsy forceps). Irrigation flow was determined by connecting the instruments to a 1-L bag of 0.9% saline at 100 cm, then with a pressure bag set at a pressure of 250 mmHg. Flow rate (mL/s) was measured with an empty working channel, and with instruments in the working channel.

Cost Analysis

An analysis of consecutive fURSs over a 30-month period was performed. The start of this dataset coincided with the acquisition of seven new reusable URF-V scopes. Only procedures that involved laser lithotripsy of renal stones were included in the analysis. Data extracted included patient characteristics (age, sex), stone details (side, size, number, position in collecting system, staghorn or partial staghorn stone), operative details, and scope damage. All instruments were sterilised using the STERIS SYSTEM E1® (STERIS, Mentor, OH, USA).

Scope Damage

Damage reports were obtained from the supplier (Olympus). Expenses are reported in Australian dollars ($) and Great British Pounds (£). Minor repairs accounted for <5% of the cost and were excluded from the analysis. Damage was considered major when the repair cost was >$10 000 (£5 680). Data extracted on damaged and undamaged scopes were compared to identify risk factors for damage. Finally, three patients with renal stones were consented for treatment with the LithoVue. Movement, ergonomics, visibility, image quality, and treatment outcome, were objectively and subjectively assessed.

Statistical Analysis

The graphical representation of the observed cost of our reuseable fURS scopes was generated by assuming an initial purchase cost of $26 372 (£14 985) and fixed cleaning costs of $26.20 (£14.90) per case for URF-V fURS. At each repair time point, the cost was divided by the number of scopes that had performed that number of cases. In this way, we averaged the repair costs as if they were happening for a single scope, which allowed comparison to the fixed cost estimates for disposable scopes. Two prices for the single-use scope were used because at the time of analysis the manufacturer had not released the sale price of the instrument. Comparisons between cases with and without major damage were performed with either Student's *t*-test or Fisher's exact test. Tests were two-sided with statistical significance set at 0.05. Analysis was performed using Stata Statistical Software version 12.0SE (StataCorp., College Station, TX, USA).

Results

Comparison of fURSs

With an empty working channel, the LithoVue had a similar range of movement to the URF-V and Flex-X^c. Flexion of the scopes was: LithoVue 285°, URF-V 180°, and Flex-X^c 283°. Deflection of the scopes was: LithoVue 286°, URF-V 270°, and Flex-X^c 219°. The range of movement of all the scopes is summarised in Table 1. At a height of 100 cm, irrigation flow through the LithoVue was greater than the URF-V and the Flex-X^c, at 0.53 mL/s vs 0.43 mL/s vs 0.46 mL/s, respectively. This was maintained with different instruments in the channel and when a pressure bag was applied, flow rates are summarised in Table 2. Figure 1 shows the flexion and deflection of the LithoVue with an empty channel, and with a laser fibre and stone basket in the working channel.

Risk Factors for Scope Damage

In all, 234 renal stone procedures were performed with seven new Olympus URF-V scopes (designated A–G) over a 30-month period. In all, 178 patients (77.3%) were completely stone free, whilst 51 (22.7%) patients required further treatment. A total of 15 major scope damages occurred during the period. Patient age, sex, operation side, number of stones, stone size and operator experience was not associated with damage. Staghorn stones and stones in the lower pole calyx or mid-zone calyx were statistically significant risk factors for scope damage ($P = 0.016$ and $P = 0.074$, respectively). The risk factors for scope damage are shown in Table 3.

Type of Damage and Durability

The total number of procedures performed per scope varied from 58 (scope A) to 20 (scope G). In all, 34 separate different types of damage were reported during the 15 episodes of scope repair. The commonest type of scope damage reported was bending-tube leakage, which occurred in six of the seven scopes (B, C, D, E, F and G), which

Table 1 Range of movement of fURS scopes.

	LithoVue	Olympus URF-V	Stortz Flex Xc
Flexion			
Clear channel	285°	180°	283°
Hydrophilic guidewire	247° (−13.3%)	165° (−8.4%)	238° (−15.9%)
PTFE-Nitinol guidewire	228° (−20%)	134° (−25.6%)	192° (−32.2%)
200 μm laser fiber	277° (−2.8%)	180° (−0%)	262° (−7.4%)
1.9 Fr stone basket	270° (−5.3%)	175° (−2.8%)	254° (−10.2%)
3 Fr Biopsy forceps	142° (−50.1%)	112° (−37.8%)	164° (−42.1%)
Deflection			
Clear channel	286°	270°	219°
Hydrophilic guidewire	251° (−12.2%)	236° (−14.2%)	171° (−21.9%)
PTFE-Nitinol guidewire	233° (−14%)	195° (−29.1%)	140° (−36.1%)
200 μm laser fiber	270° (−5.6%)	254° (−7.7%)	193° (−11.9%)
1.9 Fr stone basket	260° (−9.1%)	256° (−6.9%)	185° (−15.5%)
3 Fr Biopsy forceps	130° (−54.6%)	170° (−38.2%)	113° (−48.4%)

Fr, French; μm, micrometre; PTFE, polytetrafluoroethylen.

Table 2 Irrigation flow in different fURS scopes.

	LithoVue	Olympus URF-V	Stortz Flex Xc
Specifications			
Length (mm)	680	670	700
Distal end diameter (Fr)	7.7	8.3	8.5
Working channel (Fr)	3.6	3.6	3.6
Light source	Integrated	External	Integrated
Flow rate 100 cm H_2O (mL/s)			
Empty channel	0.53	0.43	0.46
200 μm laser fiber	0.25	0.189	0.187
1.9 Fr stone basket	0.155	0.125	0.104
Flow rate 250 mmHg (mL/s)			
Empty channel	1.2	1.111	1.31
200 μm laser fiber	0.699	0.421	0.78
1.9 Fr stone basket	0.378	0.233	0.373

Fr, French; μm, micrometre; ml/s, millilitres/second; PTFE, polytetrafluoroethylen.

occurred 17 times. One scope (E) had the bending-tube rubber repaired on four different occasions. The mean number of uses of a new Olympus URF-V scope before damage occurred was 11 cases. After repair the mean number of uses before damage occurred again was 19. Data on the number of scope uses and damage is summarised in Table 4.

Cost Analysis of Reusable fURS

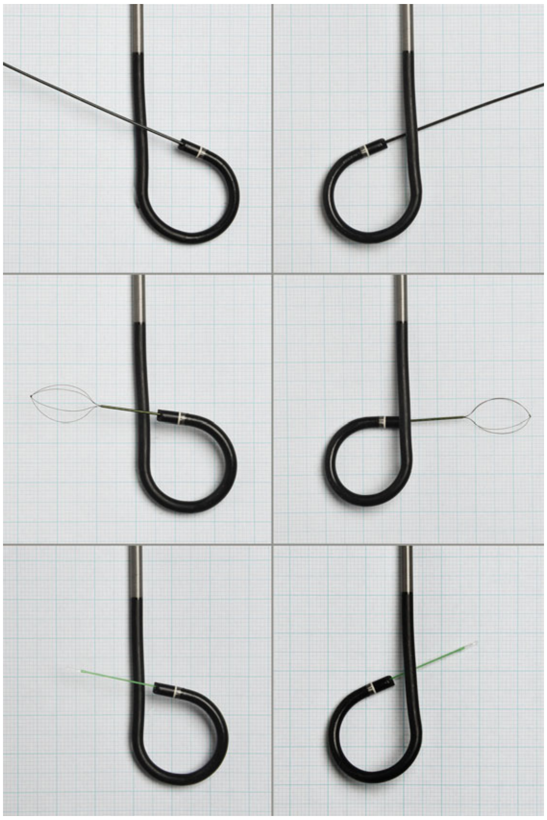
The total repair cost for the seven new scopes over the study period was \$162 628 (£92 411). The mean cost per case (repair cost only) was \$695 (£395). This varied from \$361 (£205) for scope A to \$1 179 (£670) for scope E. This does not include initial purchase cost, processing costs, cleaning and other indirect costs such as transport and staff time used in arranging service and repair. So the actual cost per case is higher. Scope repair costs and scope cost per case are summarised in Table 4.

The cost analysis of using the URF-V compared to the single-use LithoVue is shown in Fig. 2. The cumulative cost of 28 procedures for the reusable scope was ~\$50 000 (£28 412). If the single-use disposable LithoVue is priced at \$2 500 (£1 420), then it would cost ~\$72 000 (£40 913) for 28 procedures. This would make using the reusable scopes more economical. If the single-use disposable scope is priced at \$1 200 (£682), then the cost for 28 procedures would be \$35 000 (£19 888). This would represent a considerable cost saving and suggest that switching to the single-use scope would make sense from an economic point of view.

In vivo Assessment of the LithoVue

The LithoVue was used in three patients for the treatment of renal calculi. The mean number of stones was 1.5 and the mean stone size was 9 mm. Two stones were located in the mid-zone and one was located in the lower pole and was re-positioned. No patient was stented preoperatively, and an access sheath was used in all cases. Complete stone fragmentation and clearance was achieved in all cases. There were no scope damages. Subjective assessment of ergonomics, movement and image quality by performing complete pyeloscopy, stone extraction and laser lithotripsy proved the

Fig. 1 Manoeuvrability of the LithoVue scope. (a) Flexion and deflection with a hydrophilic guidewire in the working channel. (b) Flexion and deflection with a 1.9-F stone basket. (c) Flexion and deflection with 200-μm laser fibre.



LithoVue to be an excellent scope. LithoVue image quality is shown in Fig. 3.

Discussion

The design and functionality of flexible ureteroscopes has improved significantly over the past 20 years. The modifications to device diameter, flexion, deflection and imaging have made fURS the first-line treatment for renal stones in some countries [13–15]. Despite this, the initial purchase cost, maintenance cost, performance degradation and poor durability remain significant issues associated with both fibre optic and digital reusable scope use [10,11,16].

In the present study, we found that reusable scope damage was a common occurrence, with major damage occurring after a mean of 11 cases. Similarly, Martin et al. [17], reported an average of 12.5 cases until damage occurred. These findings were also confirmed by several other authors [10,18]. In addition to this, we noted that once a scope was damaged its durability was compromised, with the same damage occurring multiple times. This finding has also been reported in the literature [12,19]. To avoid the initial high purchase costs, poor durability and repair costs associated reusable scopes; the single-use scope was developed.

Table 3 Risk factors for reusable fURS scope damage.

	Damage, *N* (%)	No damage, *N* (%)	*P* value
Total	15	219	
Age, mean (range)	50 (26–79)	55 (20–88)	0.2
Sex			
Male	9 (7)	137 (93)	>0.9
Female	6 (6)	82 (94)	
Side			
Left	12 (9)	121 (91)	0.10
Right	3 (3)	96 (97)	
Staghorn calculus			
Yes	3 (33)	6 (67)	0.014
No	12 (5)	213 (95)	
Non-staghorn calculi			
Lower pole			
Yes	11 (8)	120 (92)	0.016
No	1 (1)	93 (99)	
Mid zone			
Yes	0 (0)	49 (100)	0.074
No	12 (7)	164 (93)	
Upper pole			
Yes	0 (0)	32 (100)	0.2
No	12 (6)	181 (94)	
Pelvis/ureter			
Yes	1 (2)	50 (98)	0.3
No	11 (6)	163 (94)	
No. of stones, mean (range)	1.7 (1–3)	1.6 (0–5)	0.8
Stone size (mm), mean (range)	12.2 (5–33)	9.6 (1–42)	0.14
Operator			
Consultant/fellow	7 (7)	89 (93)	0.8
Registrar	8 (6)	130 (94)	

Mm, millimetre; N, number.

We found the LithoVue to be functionally comparable to two of the most commonly used reusable scopes. With a clear working channel and a variety of different instruments in the channel, the LithoVue had equivalent, if not superior flexion and deflection to the Olympus URF-V and Karl Storz Flex-X^c. Irrigation flow was also similar. Analogous findings were also reported in a recent study examining the LithoVue in human cadavers [11]. With the equivalence of the LithoVue to reusable scopes established, the only remaining issue regarding its introduction is the financial viability of single-use vs reusable fURS scopes [7–9].

To assess this, we performed an analysis of reusable fURS scope usage at our institution. The initial purchase cost, cleaning overheads and repair expenses per case were calculated and compared to projected costs of purchasing and using a single-use scope instead. The mean cost per case for repairs alone was $695 (£395). These costs did not include purchase cost and cleaning, so the final cost is higher per case. These findings are similar to repair rates reported in the literature, so we feel accurately represent the cost per case for reusable scopes [18].

Table 4 Reusable scope damage and costs per case.

Scope	A	B	C	D	E	F	G	N, mean (range)
Total procedures	58	43	32	29	29	21	20	234
No. of repairs	2	2	2	2	3	2	2	15
No. of cases until first damage	29	18	5	17	4	3	1	11 (1–29)
First damage	a, b	c, d	c, d, e	c, d	b, c, d, e	d, f	d	–
No. of cases until second damage	29	20	23	12	18	16	13	19 (12–29)
Second damage	a	a, d	d	a	a, c, d, f	d, f	E	–
No. of cases until third damage	–	–	–	–	3	–	–	–
Third damage	–	–	–	–	d, e	–	–	–
Procedures/damage ratio	29	22.5	16	14.5	9.7	10.5	10	16.3 (9.7–29)
Repair costs, $ (£)	20 930 (11 977)	20 930 (11 977)	20 930 (11 977)	22 741 (13 014)	34 179 (19 559)	21 707 (12 422)	21 211 (12 138)	162 628 (92 411)
Cost per case, $ (£)	361 (205)	465 (266)	654 (375)	784 (448)	1 179 (670)	1 034 (591)	1 061 (607)	695 (395)

a = Insertion tube leak; b = Failed electrical safety test; c = Angulation malfunction; d = Bending tube leak; e = Biopsy channel leaking; f = ETO connector leak; $, Australian dollar; £, Great British pound.

Fig. 2 Cumulative cost of repair and/or acquiring equipment. The red line is the observed cost of the reusable scope [assuming that the cost of the reusable scope is of $26 372.30 (£15 092)], a cleaning cost of $26.23 (£15.01) per use, and that the repair costs are averaged over the number of available fURSs. The dark blue line is if disposable scope unit costs $2 500 (£1 420) per case, the light blue line is if it costs $1 200 (£682).

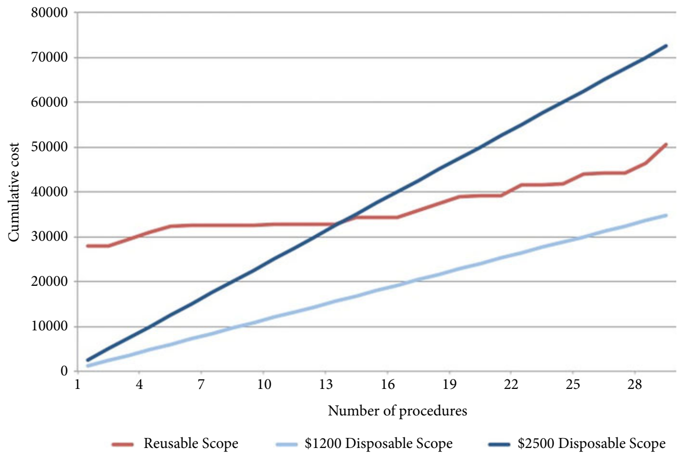
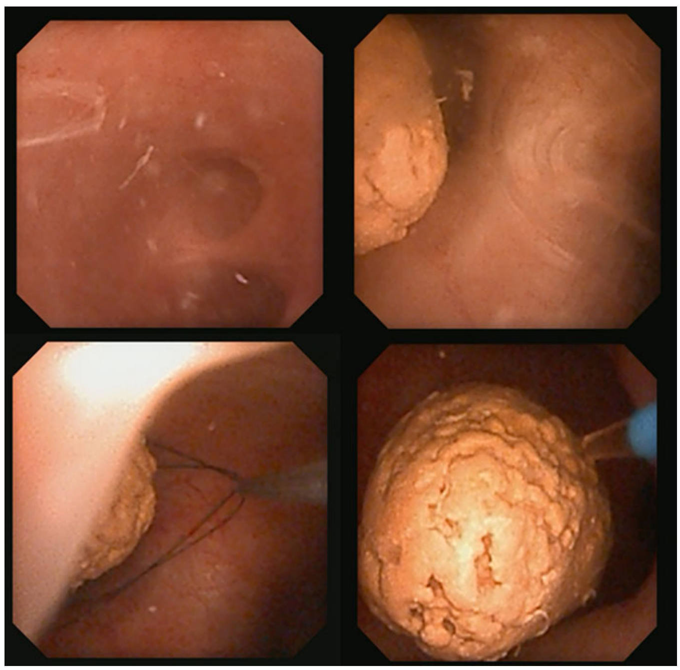


Fig. 3 LithoVue Image quality and laser lithotripsy. Pyelopscopy, stone identification, re-positioning with basket, and laser lithotripsy.



If the initial purchase cost of a new reusable digital fURS scope is ~$26 372 (£15 092) and cleaning costs fixed at $26.23 (£15.01) per case. Then the approximate cost of 28 fURS procedures is ~$50 000 (£28 412), when the repair costs are averaged over the number of available scopes. If the LithoVue is priced at $1 200 (£682), 28 procedures would cost ~$35 000 (£19 888) and using a single-use scope would make financial sense. However, if the LithoVue was priced at $2 500 (£1 420) then it would cost more than repairing reusable scopes and would not make financial sense.

An additional outcome of the present study was that we identified risk factors for reusable fURS scope damage. We found that staghorn stones and stones located in the lower pole to be significant risk factors for scope damage. Instead of switching to only single-use fURS scopes, the LithoVue could be held in reserve for cases in which damage is anticipated. Thus, the risk of reusable scope damage would be eliminated, reducing the cost of maintaining a reusable scope and decrease the average cost per case. Performance degradation is a well-recognised drawback of reusable fURS scopes. Overtime there can be a loss of flexion and deflection, and in the case of fibre optic instruments image quality. This loss of functionality could affect the outcome of stone surgery. The fact that the LithoVue would never be affected by performance degradation is an additional advantage of single-use scopes over reusable ones.

Limitations of the present study include, that we only compared the single-use LithoVue to reusable digital fURS scopes *ex vivo* and to a reusable digital scope for the financial comparison. Fibre optic fURS scopes are less expensive to purchase than digital scopes and can be more durable. It is possible that the single-use disposable digital scope may not be cheaper than a reusable fibre optic scope. However, digital fURS scopes, both single-use and reusable, have significant advantages over fibre optic scopes. Particularly with regard to movement and image quality [20]. An additional limitation was that we only used the LithoVue in a small number of patients and thus it was not possible to draw any conclusions on its durability. However, it is worth noting that if a single-use scope broke during a case, it would still be cheaper to use more than one single-use scope than repairing a reusable digital scope. Ultimately, individual urology departments will have to look at their own reusable scopes and determine their repair and maintenance costs to determine if there is an economic benefit to switching to the single-use fURS scopes.

Conclusion

The single-use disposable digital fURS scope, the LithoVue, is comparable *ex vivo* to two of the most popularly used reusable scopes available. The main advantage of a single-use scope is that it will have no maintenance or repair costs. Depending on the purchase cost, it may be more economical to use a single-use scope than purchasing and maintaining reusable scopes. If not, urologists may wish to use the single-use scope for cases in which reusable scope damage may occur, in particular in cases with lower pole and staghorn stones.

Author Roles

Derek B. Hennessey and Grzegorz L. Fojecki created the report concept and wrote the initial manuscript. Derek B. Hennessey, Grzegorz L. Fojecki and Damien Bolton performed data collection. Nathan P. Papa assisted with statistics. All authors refined the final manuscript, and agree to be accountable for all aspects of the work.

Conflict of Interest

Damien Bolton should be listed as a member of a clinical medical advisory board 2015-2017.

References

1 **Lee MC, Bariol SV**. Evolution of stone management in Australia. *BJU Int* 2011; 108 (Suppl. 2): 29–33

2 **Heers H, Turney BW**. Trends in urological stone disease: a 5-year update of Hospital Episode statistics. *BJU Int* 2016; 118: 785–9

3 **Ordon M, Urbach D, Mamdani M, Saskin R, Honey RJ, Pace KT**. A population based study of the changing demographics of patients undergoing definitive treatment for kidney stone disease. *J Urol* 2015; 193: 869–74

4 **Mi Y, Ren K, Pan H et al.** Flexible ureterorenoscopy (F-URS) with holmium laser versus extracorporeal shock wave lithotripsy (ESWL) for treatment of renal stone <2 cm: a meta-analysis. *Urolithiasis* 2016; 44: 353–65

5 **Javanmard B, Razaghi MR, Ansari Jafari A, Mazloomfard MM**. Flexible ureterorenoscopy versus extracorporeal shock wave lithotripsy for the treatment of renal pelvis stones of 10-20 mm in obese patients. *J Lasers Med Sci* 2015; 6: 162–6

6 **Ganesamoni R, Mishra S, Kumar A et al.** Role of active mentoring during flexible ureteroscopy training. *J Endourol* 2012; 26: 1346–9

7 **Shah K, Monga M, Knudsen B**. Prospective randomized trial comparing 2 flexible digital ureteroscopes: ACMI/Olympus Invisio DUR-D and Olympus URF-V. *Urology* 2015; 85: 1267–71

8 **Knudsen B, Miyaoka R, Shah K et al.** Durability of the next-generation flexible fiberoptic ureteroscopes: a randomized prospective multi-institutional clinical trial. *Urology* 2010; 75: 534–8

9 **Mues AC, Teichman JM, Knudsen BE**. Evaluation of 24 holmium: YAG laser optical fibers for flexible ureteroscopy. *J Urol* 2009; 182: 348–54

10 **Monga M, Best S, Venkatesh R et al.** Durability of flexible ureteroscopes: a randomized, prospective study. *J Urol* 2006; 176: 137–41

11 **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

12 **Carey RI, Martin CJ, Knego JR**. Prospective evaluation of refurbished flexible ureteroscope durability seen in a large public tertiary care center with multiple surgeons. *Urology* 2014; 84: 42–5

13 **Marshall VF**. Fiber optics in urology. *J Urol* 1964; 91: 110–4

14 **Giusti G, Proietti S, Peschechera R et al.** Sky is no limit for ureteroscopy: extending the indications and special circumstances. *World J Urol* 2015; 33: 257–73

15 **Somani BK, Al-Qahtani SM, de Medina SD, Traxer O**. Outcomes of flexible ureterorenoscopy and laser fragmentation for renal stones: comparison between digital and conventional ureteroscope. *Urology* 2013; 82: 1017–9

16 **Gridley CM, Knudsen BE**. Digital ureteroscopes: technology update. *Res Rep Urol* 2017; 9: 19–25

17 **Martin CJ, McAdams SB, Abdul-Muhsin H et al.** The economic implications of a reusable flexible digital ureteroscope: a cost-benefit analysis. *J Urol* 2017; 197: 730–5

18 **Kramolowsky E, McDowell Z, Moore B, Booth B, Wood N.** Cost Analysis of flexible ureteroscope repairs: evaluation of 655 procedures in a community-based practice. *J Endourol* 2016; 30: 254–6

19 **User HM, Hua V, Blunt LW, Wambi C, Gonzalez CM, Nadler RB.** Performance and durability of leading flexible ureteroscopes. *J Endourol* 2004; 18: 735–8

20 **Zilberman DE, Lipkin ME, Ferrandino MN et al.** The digital flexible ureteroscope: in vitro assessment of optical characteristics. *J Endourol* 2011; 25: 519–22

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Abbreviations: fURS, flexible ureteroscopy; PTFE, polytetrafluoroethylene.