Single-Use versus Conventional Reusable Flexible Ureteroscopes – An Evaluation of the Functional Parameters

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Abstract

Introduction and Objectives. The purpose of single-use flexible ureteroscopes (su-fURS) was to overcome the main limitations of conventional reusable ureteroscopes in terms of maneuverability and of the maintenance. We aimed to perform a systematic literature review on available su-fURS performance versus conventional reusable fURS with a focus on clinical data.

Materials and Methods. A systematic research using electronic database Pubmed was performed for studies evaluating single-use fURS and reusable fURS in the setting of urinary tract stone disease. Prospective assessments and case series studies were included. The goal of this review was to provide an overview of these single use and disposable flexible ureteroscopes and to examine and compare their capabilities (deflection, irrigation, optical properties).

Results. We found 11 studies which met our inclusion criteria, where it was compared the single use fURS with reusable fURS. The studies about single-use ureteroscopes included data on LithoVue (Boston Scientific), The Uscope UE3022 (Pusen, Zhuhai, China), NeoFlex-Flexible, (Neoscope Inc San Jose, CA), 23 YC-FR-A (Shaogang). Reusable ureteroscopes studies included data about three models, two digital (Karl Storz Flex-XC and Olympus URF-Vo) and one fiber optic (Wolf-Cobra). There were not significant statistical differences concerning stone-free rate, procedure duration, functional capabilities between single-use fURS and reusable fURS.

Conclusions. Single-use fURS demonstrate a comparable efficacy with reusable fURS in resolving renal lithiasis.

Key-words: single use, reusable, flexible ureteroscope, lithiasis.

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Introduction and objectives

Flexible ureteroscopes evolved from the first generation of analogues devices which had a limited degree of deflection to most recent digital technologies, which provide an increased flexibility and fiability. Technical limitations regarding visibility and access have now improved. Flexible URS can now treat renal calculi regardless of the calyx groups. Until recently, reusable ureteroscopes were the only tools available to perform ureteroscopy [1].

The durability of reusable digital ureteroscopes, superior to that of fiberoptic models, continues to be a challenge [2-4]. Increased number of surgeries can determine damages such as deflection loss and degradation of scope performance for subsequent procedures [5]. Finally, an important concern for the use of reusable flexible ureteroscopes is sterility [5,6]. A study from Ofstead et al. showed that even when reusable ureteroscopes had been cleaned manually and sterilized by hydrogen peroxide gas, contamination (by bacteria, adenosine triphosphate, hemoglobin and/or protein) appeared in some of the tested scopes [6].

However, in recent years, single-use flexible URS (su-fURS) and semi-rigid ureteroscopes have been developed as an alternative to reusable scopes. To date, more than 10 models of su-fURS are available on the market, with different characteristics and performance. Some of these devices have top-level features, almost catching up with those observed in reusable flexible ureteroscopes. Current commercially available devices are the LithoVue (Boston Scientific, Massachusetts, USA), Uscope (Zhuhai Pusen Medical Technology Co, Ltd., Zhuhai, China), NeoFlex (Neoscope Inc, California, USA), and Shaogang or YC-FR-A (YouCare Tech, Wuhan, China), to name a few.

The aim of this review is to analyze single-use fURS with conventional reusable fURS concerning their functional capabilities.

Materials and methods

A systematic research using Pubmed electronic database was performed for studies evaluating single-use and reusable fURS in the setting of urinary tract stone disease. The keywords included to attain relevant studies were: "single use flexible ureteroscopy versus reusable ureteroscopy". Eleven manuscripts published between 2013 and 2021 were reviewed and if it was not clear from the abstract whether the paper might contain relevant data, full paper was assessed [Figure 1]. The references cited in all full-text articles were also assessed for additional relevant or associated articles. Non-English articles were excluded from the analysis. With the consensus of the co-authors, the relevant studies were then selected and screened, and the data were extracted and analyzed. We aimed to answer pre-defined questions:

1) Are the stone free and complication rates different between single-use and reusable flexible ureteroscopes?

2) Is the operative time different between single-use and reusable flexible ureteroscopes?

3) What is the difference between the functional capabilities of the endoscope?

The Preferred Reporting Items for Systematic Reviews and Meta-analysis flowchart was used to report the numbers of papers identified and included or excluded at each stage. We then performed a narrative review of relevant findings.

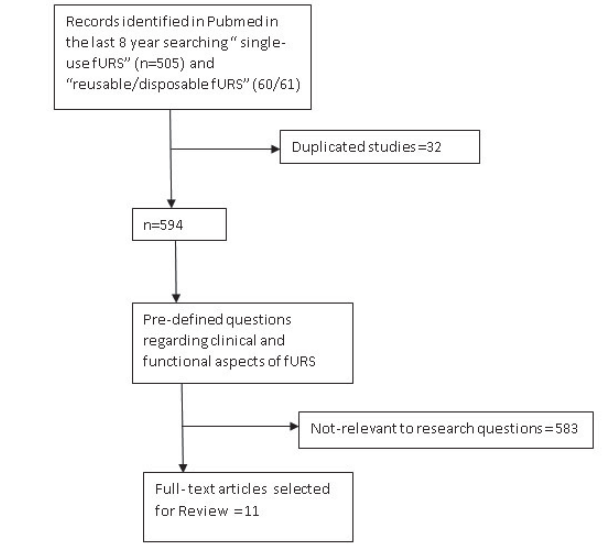


Figure 1. The criteria for selection of the studied articles

Results

Operative Time

Shiyong Qi et al. prospectively compared clinical outcomes of the the single-use digital fURS (ZebraScope) with Olympus digital reusable fURS. The primary endpoint was the 1-month postsurgical stone-free rate (SFR). The study included 126 patients, 63 in each group. The 1-month SFR was 77.78% for the ZebraScope group and 68.25% for the URF-V group (two-sided 95% confidence interval [CI]: -5.95 to 25.01). The conclusion of the study was that there was no difference between

the two groups in the operative time (p = 0.687) [7]. Also, Kam et al. study included 141 patients for stone treatment where it was compared LithoVue and PU3022A (Pusen) with reusable digital URF-V2 (Olympus). They found no differences in operative time [8]. In the same time, Usawachintachit et al., the overall mean procedure duration was 10.4 minutes shorter for LithoVue than with fiberoptic URF-P6 (64.5 vs. 54.1 min; p < 0.05). This difference broadened to 13 minutes and remained statistically significant in cases performed for stone removal (70.3 vs. 57.3 min; p < 0.05). This was translated in shortened operating room duration in stone removal cases with LithoVueTM (104.3 vs. 89.8 min, respectively; p < 0.05) [9].

Functional capabilities: mechanical, irrigation and optical properties

Our studies concerning single use ureteroscopes included data about: LithoVue (Boston Scientific), The Uscope UE3022 (Pusen, Zhuhai, China), NeoFlex-Flexible, (Neoscope Inc San Jose, CA), 23 YC-FR-A (Shaogang), while those about reusable ureteroscopes included data about three models: two digital (Karl Storz Flex-XC and Olympus URF-Vo) and one fiber optic (Wolf-Cobra).

The ability of a flexible ureteroscope to deflect is critical for intrarenal procedures as it is necessary for access and navigation of the renal pelvis, calyces, and diverticula [10]. It is especially important when attempting treatment of lower pole calculi as the lower pole of the kidney has been noted to be more challenging to access.

The study of Scotland et al. tested two single use ureterorenoscopes (the LithoVue and Uscope) versus one reusable digital ureterorenoscope Flex-XC (Storz). The results showed that deflection of the LithoVue and Uscope devices compared favorably to the reusable scope both with the working channel empty and in use. LithoVue and Uscope were comparable to the Flex- XC reusable scope with respect to image distortion. The LithoVue demonstrated superior deflection and irrigation flow while the Uscope showed better color representation and field of view. The Flex- XC had the best image resolution. In vivo, all scopes were able to access the upper, mid and lower poles with equal ease. Visibility was comparable among the scopes on access to the collecting system and while performing laser lithotripsy and basket extraction of stones [11].

The study of Dragos et al compared four disposables flexible ureteroscopes (LithoVue, Uscope, NeoFlex and Shaogang) with reusable flexible ureteroscopes in an in vitro study. Most of the single-use flexible ureteroscopes demonstrated overall superiority in their deflection capabilities; it is only with the guidewires and 365 µm laser fibers where the reusable ureteroscopes had greater deflection capabilities than the single-use ureteroscopes. When compared within the single-use flexible ureteroscope group, the cumulative degrees of deflection (sum of all deflection angles when working channel was occupied) were greatest with the NeoFlex followed by the LithoVue, then Uscope and Shaogang [12]. Also, an ex-vivo study conducted by Hennessey et al. that compared the deflection capabilities of the LithoVue against two reusable ureteroscopes: URF-V (Olympus, Tokyo, Japan) and Flex-XC (Karl Storz &Co. KG, Tuttlingen, Germany), showed similar results [13]. In another study, Davis et al. evaluated in vitro characteristics of LithoVue, Polyscope and SemiFlex founding similar mechanical, optical and irrigation properties to conventional fiber optic reusable flexible ureteroscopes [14].

However, Tom et al. compared the Shaogang and NeoFlex single use devices to the digital Flex-Xc and the fiberoptic Cobra flexible ureteroscope and found a superior flow rate with the Shaogang ureteroscope. The authors performed bench testing of the irrigation flow rate of the LithoVue and Uscope as compared to the Flex-Xc reusable digital ureteroscope and found superior flow rates for the LithoVue both with an empty working channel and with a 273 µm laser fiber [15].

Anyway, Kam et al. concluded that the URF-V2 group had better visibility scores than both the single-use scopes and higher maneuverability scores when compared with the PU3022A. The LithoVue had higher visibility and maneuverability scores when compared with the PU3022A [8].

Stone free rates and post-operative complications

Giorgio Bozzini et al. compared reusable flexible ureteroscope with digital technology (FLEX Xc, KARL STORZ SE & Co. KG, Tuttlingen, Germany) and disposable flexible ureteroscopes also endowed with digital technology (US31B-12, Innovex Anqing Medical Instrument CO. LTD, Shanghai, China) in terms of efficacy and safety for patients undergoing Retrograde Intrarenal Surgery. A total of 180 patients were included in the study. Ninety patients were treated with RIRS with reusable flexible ureteroscope (group A) and the other 90 patients with RIRS with disposable flexible ureteroscope (group B). The Stone Free Rates (SFRs) were not significantly different between the 2 groups

(86.6% and 90.0% for group A and group B, respectively, p = 0.11), while the overall complication rate in group A was 8.8% whilst in group B it was 3.3% (p ≤ 0.05). In particular, group A exhibited a greater number of major complications (Clavien score IIIaV). The overall postoperative infection rate was 16.6% in group A and 3.3% in group B (p ≤ 0.05) [16]. Also, Somani et al. published a study comparing reusable digital versus fiber optic flexible ureteroscopes and the results were similar in terms of accessibility to the entire collecting system and stone-free rates (SFRs). Complication rate was similar between the two modalities [17]. However, in another study Mager et al. prospectively compared 68 consecutive procedures using reusable flexible ureterorenoscopes (Flex-X2S/Flex-XC, Karl Storz) with 68 consecutive procedures utilizing single-use digital flexible ureterorenoscopes (LithoVue). Patients had same stone burden and demographic characteristics. The authors found non-significant different SFR (82% vs. 85%; p = 0.8) and complication rates (7% vs. 17%; p = 0.06) with reusable and single use scopes, respectively, but as a paradox, there was mentioned one febrile urinary tract infection (UTI) case occurring in the single-use group and none in the reusable scope cohort [18].

Shiyong Qi et al. prospective study concluded that single-use digital fURSs are an effective and safe alternative to reusable URF-V [7].

Meanwhile, Usawachintachit et al. performed a prospective case-control study where LithoVue was compared to Olympus fiberoptic URF-P6. A total of 116 cases were performed with single-use scope and 65 cases with reusable scopes. The number of patients with no fragments, insignificant residual fragments (≤ 2 mm) and significant fragments (> 2 mm) was 60.0%, 12.5%, 27.5% for LithoVue, and 44.7%, 13.2%, 42.1% for URF-P6 (p = 0.36). In this study, there were obtained better outcomes for the single-use scope [9] [Table 1].

Table 1. Single use and reusable fURS operative, post-operative and technical parameters.

	Reusable fURS (Type)	**Single Use fURS (Type)**	
Stone Free Rates	86.6% (FlexXc)	90% (US31-B-12)	Giorgio Bozzini et al.
	68.25% (Olympus URF-V)	77.78% (ZebraScope)	Shiyong Qi. et al.
	44.7% (Olympus URF-P6	60% (LithoVue)	Usawachintachit et al.
	82% (Flex-Xc| Flex-X2S	85% (LithoVue)	Mager et al.
Operative Time	64.3min	64.1min	Shiyong Qi. et al.
	64.5 min	54.1 min	Usawachintachit et al.
	76.2 min.	76.8 min.	Mager et al.
	72.3 min. (URF-V2)	86.1 min. (LithoVue)	Kam et.al
Ureteroscope Deflection with an Empty Working Channel	2850 (Flex-Xc)	2950 (LithoVue) 2900 (Uscope UE3022)	Scotland et. al
	2190 (Flex-Xc)	2860 (LithoVue)	Hennessey et al.
		2700 (LithoVue) 1800 (PolyScope) 3000 / 2650 down / up (SemiFlex)	Davis et. al
	2630 (Flex-Xc)	2760 (LithoVue) 2260 (NeoFlex)	Tom et.al
Visibility score	4.2 (URF-V2)	4.8 (LithoVue)	Kam et.al
Maneuverability score	4.7 (URF-V2)	4.9 (LithoVue)	Kam et.al

Conclusions

Single-use fURS demonstrates comparable efficacy with reusable fURS in treating renal calculi. The disposable scopes are particularly useful in treating difficult to access calculi since there is less concern for ureteroscope damage. Further studies on clinical efficacy are needed to determine whether single-use fURS will reliably replace its reusable counterpart.

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