First experience with HugeMed single-use flexible ureteroscope

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ABSTRACT

Disposable flexible ureteroscopes have been developed in recent years as an alternative to reusable ureteroscopes. More than 10 types of such instruments are known up to now. Our aim was to analyze the effectiveness and safety of the HugeMed HU30S (7.5 Ch) disposable flexible ureteroscope. Between June 2022 and February 2023, a number of 54 flexible ureteroscopies were performed with HugeMed: HU30S (Tip 7.5Fr., shaft 7.5F, working channel 3.6F, deflection 285/2850, field of view 120). Stone size: between 0.8-2.6 cm. (4 cases with multiple lithiasis). In two patients there were horseshoe kidneys. As for the distribution of stones, there were 8 (13.8%) in the renal pelvis, 10 (17.2%) in the upper calyx, 13 (22.4%) in the middle calyx and 27 (46.5%) in the lower calyx. In 21 cases (38.9%) the access sheath was used and in 33 cases (61.1%) it was not necessary to use the ureteral access sheath. Also, due to the small size of the ureteroscope and its flexibility, it was not necessary to relocate the stones to be processed. In all cases the stones were fragmented with the Holmium laser using the dusting method. In 45 patients (83.3%) the JJ tube was fitted postoperatively for one month. The state of stone free after one month was 88.9%. In 6 patients, a second session of total fragmentation of the residual stones was needed. Visibility was optimal and we described no lesions of the ureteric mucosa when we withdrew the ureteroscope. Intrarenal maneuverability was very good. The patients were discharged 24 hours after the intervention. Clavien I and II complications occurred in 6 patients

This new flexible single-use ureteroscope is very efficient and safe offering us easy access and maneuverability as well as very good visibility. The diameter of 7.5Fr. offers the advantage of a true minimally invasive maneuver with the possibility of performing the No Touch Technique.

Keywords: renal stones, single-use, reusable, flexible ureteroscopy, HugeMed

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Introduction

The use of flexible ureteroscopy (fURS) in treating a number of upper urinary tract diseases, primarily urolithiasis, has increased due to considerable technological and scientific developments in recent years. Major technological advances in flexible ureteroscopes have occurred since Marshall initially described fURS in 1964, and as a result, the clinical use of these devices is currently quite simple, with a high rate of success and minimal associated morbidity. Following the creation of fiberotic light-bundles, passive or active endoscope tip-deflection mechanisms, and the addition of an irrigation working-channel that permitted its use as a therapeutic instrument, fURS underwent a considerable improvement in last decades [1,2]. Technology has continued to advance and innovate with the aim of creating the best tiny diameter endoscopes possible, with enhanced picture quality, manoeuvrability, and long-lasting durability.

The first single-use ureteroscope (PolyscopeTM) was introduced by Lumenis in 2011 and used a reusable fiberoptic bundle that could be linked to disposable flexible catheters. This was the most current development in ureteroscope technology. The model's low effectiveness, particularly for lower pole stones because of its restricted deflection capabilities, prevented it from being extensively used [3,4]. The first digital single-use ureteroscope was made available by Boston Scientific in January 2016 with the LithoVueTM [5]. With the advent of innovative single-use instruments, flexible ureteroscopy and retrograde intra renal surgery (RIRS) were transformed.

Single use (SU) flexible ureteroscopes, often known as "disposable" ureteroscopes, are another innovation that has recently been commercially available. Their idea was largely inspired by attempts to do away with the need for maintenance, the accompanying costs, and concerns with durability such deflection loss after repeated uses [6,7]. Since then, they have drawn more attention, and a growing corpus of research—in the form of benchtop and clinical studies—is now available. It can be difficult for physicians to make an assessment and determine whether reality matches expectations given the rapid spread of experimental research at the moment because their function in clinical practise does not yet get any recommendations from worldwide guidelines.

One of the last flexible ureteroscopes to appear on the endourology market is the one from HugeMed with a very good visualization and high maneuverability, at an affordable price, representing until now a good tool in the armamentarium of any urologist in the upper urinary tract approach. In this paper, we present the experience of the Urology Clinic at St John's Clinical Emergency Hospital, Bucharest and Sanador Hospital Bucharest with this new flexible single-use tool in the treatment of kidney stones.

Materials and method

Between June 2022 and February 2023, a total number of 54 flexible ureteroscopies were performed with the HugeMed HU30S ureteroscope (7.5 Ch) at both urological centers: St John's Clinical Emergency Hospital, Bucharest and Sanador Hospital Bucharest. All cases included in the study were consecutive cases, depending on the availability of the disposable instrument. All cases were represented by minimally invasive endoscopic treatment of renal lithiasis.

Considering technical characteristics, the HugeMed 7.5F flexible ureteroscope has 720P imaging with the ability to automatically adjust its image size with separate GAIN (casting) adjustments on R G B colors, has a 285 degree deflection and has no electronic viewing limitation of the working capacity (HugeMed: HU30S: Tip 7.5Fr., shaft 7.5F, working channel 3.6F, deflection 285/2850, field of view 120). Concerning the laser settings for dusting we used low energy: 0.5J, high frequency: 50 Hz, for pop-corning we used high energy: >1 J, medium frequency: 10-50 Hz, and for fragmenting high energy: >1 J , low frequency: <10 Hz. We analyzed the efficiency of the procedures and the rate of complications. The technical characteristics of this instrument are presented graphically in Figure 1, and the laser settings are represented in Table I.

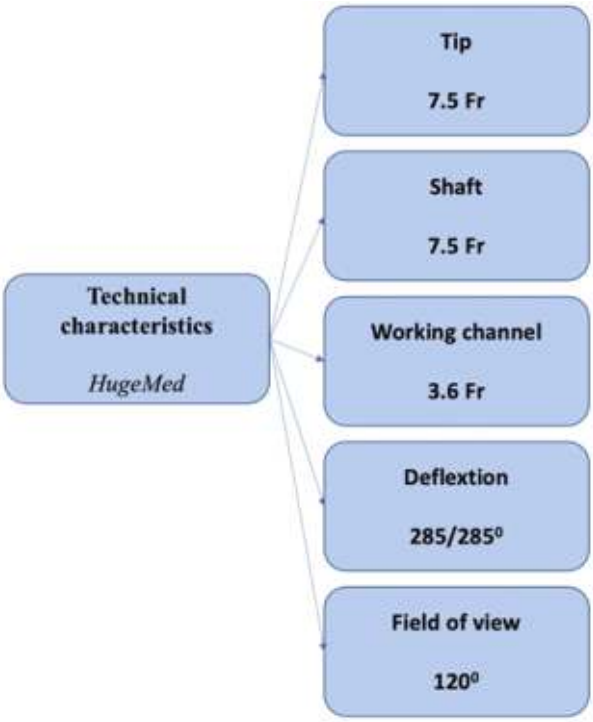


Figure 1. Technical characteristics of HugeMed single-use flexible ureteroscopes

Settings	*Energy*	*Frequency*
Dusting	0.5 J	50 Hz
Pop-corn	> 1 J	10-50 Hz
Fragmenting	> 1 J	< 10 Hz

Table I. Laser settings used in stone laser lithotripsy

Results

The demographic characteristics of the patients were represented by 32 female patients and 22 male patients, in all cases the ages of the patients were between 23 and 62 years.

The stone sizes were between 0.8-2.6 cm. (4 cases with multiple lithiasis). In two patients there were horseshoe kidneys. As for the distribution of stones, there were 8 (13.8%) located in the renal pelvis, 10 stones (17.2%) located in the upper calyx, 13 stones (22.4%) located in the middle calyx and 27 stones (46.5%) located in the lower calyx. Demographic characteristics of patients and stone location are represented in Table II. The high flexibility of this ureteroscope is represented in Figure 2 and 3.

Criteria	*Number (No.)*	*Percentage (%)*
Total female patients	**32**	**(59.25%)**
Female 20-30 years	4	(12.5%)
Female 30-40 years	9	(28.12%)
Female 40-50 years	12	(37.5%)
Female 50-60 years	6	(18.75%)
Female 60-70 years	1	(3.12%)
Total male patients	**22**	**(40.74%)**
Male 20-30 years	1	(4.54%)
Male 30-40 years	4	(18.18%)
Male 40-50 years	9	(40.9%)
Male 50-60 years	5	(22.72%)
Male 60-70 years	3	(13.63%)
Renal pelvis stones	8	(13.8%)
Upper calyx stones	10	(17.2%)
Middle calyx stones	13	(22.4%)
Lower calyx stones	27	(46.5%)

Table II. Demographic characteristics of patients included in the study and stone location



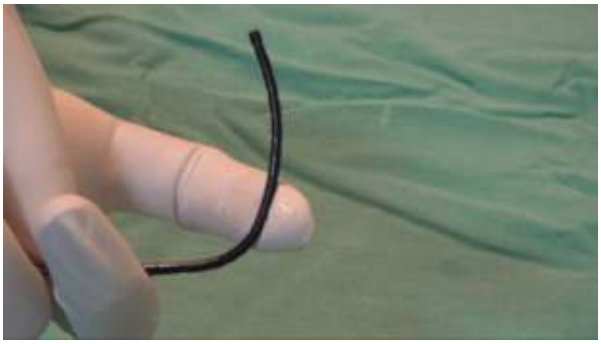
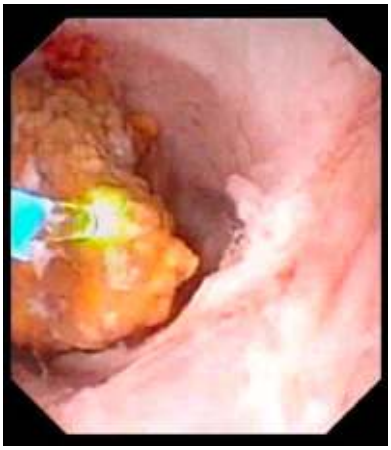


Figure 2 and 3. The high flexibility of the ureteroscope is represented ex-vivo through passive deflection.

Due to the reduced diameter ureteroscope, it was not necessary to present the patients. In 21 cases (38.9%) the access sheath was used and in 33 cases (61.1%) it was not necessary to use the ureteral access sheath, performing the so called "no-touch" technique. Also, due to the small size of the ureteroscope and its flexibility, it was not necessary to relocate the stones to be processed.

In all cases the stones were fragmented with the Holmium laser using various setting in order to complete desintegrade the stones. In 45 patients (83.3%) the JJ tube was fitted postoperatively for one month. The state of stone free (residual fragments under 3 mm.) after one month was 88.9%. The high visibility of renal stone and the observation of the stone-free status postoperatively is represented in Figures 4 and 5.





Figures 4 and 5. The high resolution of the image inside renal pelvis for good visualization of the stone and checking for residual fragments post-fragmentation

In 6 patients, a second session of total fragmentation of the outstanding stones was needed. Visibility was optimal and we described no lesions of the ureteric mucosa when we withdrew the ureteroscope. Intrarenal maneuverability was excellent. The patients were discharged 24 hours after the intervention. In 6 patients Clavien I and II complications were encountered.

Discussions

The first commercially produced single-use flexible ureteroscope (LithoVueTM) was released into clinical use by Boston Scientific in 2015. The following model, the Uscope® UE3011 S, was presented by Pusen (Zhuhai Pusen Medical Technology Co., Ltd., Zhuhai, China), and within a year, numerous other businesses had produced alternative models [8]. Prior to this, attempts had been made to incorporate SU equipment into the ureteroscope using experimental designs and what was referred to as "semi-disposable" technology. To date, more than 10 types of flexible instruments are available on the market for approaching the upper urinary tract [9].

Only three randomised controlled trials (RCTs) comparing single-use and reusable flexible ureteroscopes have been conducted to date. The first involved 126 patients in a trial by Qi et al. No significant differences were detected in the stone-free rate (SFR) at one month, surgery time, hospital stay, or complications in this investigation, therefore according to the authors, single-use flexible ureteroscope is not inferior [10]. When using the PU3022A, a different recent study from China revealed no differences in patient outcomes; nevertheless, image quality was considered to be better than the reusable ureteroscope. Given that the latter model is fiber-optic as opposed to digital, the latter may be assumed. In addition to these recent studies, a number of cohort studies have been published that demonstrate the non-inferiority of single-use models for outcomes like hospital stay or stone-free rate [11,12]. These data from the recently published literature comparing the performance between single-use and reusable flexible ureteroscopes are similar to the data obtained in our clinic. For the treatment of kidney stones, Somani et al.'s study evaluated the clinical outcomes of fiberoptic and digital reusable flexible ureteroscopes. Fiberoptic and digital ureteroscopes had stone-free rates of 86% and 88%, respectively, and 1% and 0.9%, respectively, for complications. Digital flexible ureteroscopes greatly reduced the length of the procedure (44 min vs. 54 min) [13].

Longchao Li et al. published a study in 2021 that found no significant difference in perioperative problems between the two groups. Perioperative complications were also classified using the Clavien-Dindo classification method in the investigations by Kam et al. and Usawachintachit et al. There was no statistically significant difference between the two groups in terms of acute renal damage, stent migration or urinary tract infections [14-16]. We also had similar results in the present work to those presented in other similar studies, in terms of Clavien Dindo I and II complications, represented by mild hematuria, fever or chills in the first 24 hours postoperatively or postoperative pain. Overall, we had similar results to the currently existing studies, considering single-use flexible ureteroscopy a current and reliable tool in the treatment of urinary lithiasis of the upper tract.

Conclusions

We consider disposable flexible ureteroscopy probably the future of flexible ureteroscopy for many reasons. When compared to fiberoptic ureteroscopes, single-use flexible ureteroscopes are lighter and have a higher image quality. There is no conclusive evidence that using single-use flexible ureteroscopes results in a higher stone-free rate or fewer problems. Depending on the local context, each institution must conduct an analysis of costs and benefits before deciding whether or not to employ such devices.

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