Urologia Internationalis

Research Article

Urol Int 2024;108:367–375
DOI: 10.1159/000538760

Received: October 27, 2023
Accepted: April 3, 2024
Published online: April 10, 2024

In vitro Comparison of the Mechanical and Optical Characteristics of 5 Disposable Flexible Ureteroscopes

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Keywords
Disposable · Flexible ureteroscopes · Reusable · Single-use ureteroscopes · Ureteroscopy

Abstract
Introduction: Disposable (single-use) flexible ureteroscopes are alternatives to reusable ureteroscopes. With their superior surgical efficacy and safety in the presence of upper urinary calculi, disposable ureteroscopes aim to overcome the main limitations of conventional reusable ureteroscopes. However, studies on the performance of the most recently developed models of single-use flexible ureteroscopes are scarce. This study aimed to compare the in vitro performance of several recently introduced, single-use, flexible ureteroscopes. ***Methods:*** Five disposable flexible ureteroscopes were tested in vitro to evaluate their mechanical and optical characteristics. To this end, their degrees of deflection, irrigation flow rates, and image qualities were investigated. The models examined were Innovex US31-B12, OTU-100RR, Redpine RP-U-C12, Sciavita SUV-2A-B, and Seplou URS3016E. Their performance was also compared with that of a reusable flexible ureteroscope, Olympus URV-F. ***Results:*** The OTU device had the highest degrees of deflection and the smallest loop diameter of the disposable ureteroscopes. The single-use ureteroscopes had identical image resolutions at a distance of 1 cm. The Innovex and Redpine devices had the best color representation. ***Conclusions:*** Of the tested disposable ureteroscopes, the OTU device had the best mechanical attributes, given its small loop diameter, high deflection angles, and low irrigation flow loss. As to their optical properties, the resolutions of all 5 single-use models were identical at an image distance of 1 cm.

Introduction

Nephrolithiasis is common throughout the world. Its reported incidence has ranged from 7 to 13% in North America, 5–9% in Europe, and 1–5% in Asia [1].

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Flexible ureteroscopy is the mainstream treatment for renal calculi and ureteral calculi [2]. Single-use (disposable) flexible ureteroscopes aim to overcome the main limitations of conventional reusable ureteroscopes in terms of purchase and maintenance costs, breakages, and reprocessing [3].

Many studies have demonstrated that single-use digital flexible ureteroscopes are an alternative to reusable flexible ureteroscopes because of their superior surgical efficacy and safety in the presence of upper urinary calculi [4–9]. Numerous brands and models of single-use ureteroscopes have been developed and applied in clinical practice. Some recently launched single-use ureteroscopes are Innovex US31-B12, OTU-100RR, Redpine RP-U-C12, Sciavita SUV-2A-B, and Seplou URS3016E. However, research studies comparing the efficacy, safety profiles, and cost-effectiveness of these newer models are scarce.

This current investigation was designed to compare the in vitro performance of several recently introduced, single-use, flexible ureteroscopes. Their degrees of deflection, irrigation flow rates, and image qualities were evaluated. Their performance was also compared with that of a reusable flexible ureteroscope.

Material and Methods

The 5 disposable flexible ureteroscopes investigated in this study were Innovex US31-B12, OTU-100RR, Redpine RP-U-C12, Sciavita SUV-2A-B, and Seplou URS3016E. All 5 tested disposable ureteroscopes were new and had never been used. Their performance was compared with that of Olympus URV-F, a reusable ureteroscope used by our institute. We compared the 6 ureteroscopes in terms of their mechanical characteristics (irrigation flow rate and deflection angle) and image quality (resolution and color representation).

Deflection and Irrigation Flow

We assessed each ureteroscope's degree of deflection and loop diameter using a protractor in 3 working-channel conditions. They were (1) with an empty working channel, (2) using a 267 μm holmium laser fiber (Lumenis Slimline 200), and (3) using a 1.9 Fr tipless nitinol basket (Boston Scientific Zero Tip). The aim was to evaluate each instrument's upward and downward deflection angle and deflection angle loss. "Loop diameter" was defined as the size of the widest horizontal diameter attained in the completely deflected position.

We subsequently compared the irrigation flow of each ureteroscope by using a pressure-regulated irrigation system (Uromat E.A.S.I., Karl Storz, Tuttlingen, Germany). The inflow pressure was set at 200 mm Hg. The maximal flow was limited to 250 mL/min. As with the deflection angle assessment, we assessed the irrigation flow with an empty working channel and various accessories (a 267 μm holmium laser fiber and a 1.9 Fr tipless nitinol basket). The irrigation flow was measured with the Uromat irrigation system and reported in mL/min.

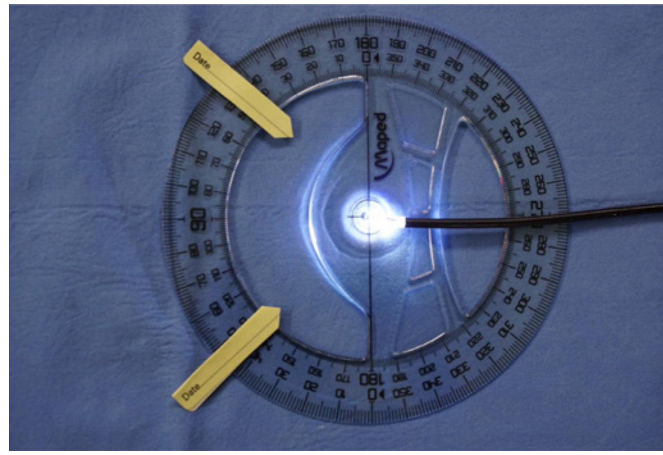

Fig. 1. Measuring the visual field.

Visual Field

We measured the visual field of each ureteroscope with a protractor fitted with 2 sharp-angle markers (Fig. 1). The measurements were made 3 cm from the tip of the ureteroscope and were reported in degrees. Initially, we placed the ureteroscope tip at a zero-degree horizontal plane. We then slowly moved each marker along the protractor from the midline of the ureteroscope to the left and right sides of the scope until each marker was no longer visualized on the monitor. The last positions at which the markers were observed on the left and right sides were noted, and the angle of the visual field was determined.

Optical Characteristics

We assessed the resolution of each ureteroscope with a 1951 US Air Force Test Pattern Card (Edmund Optics, Barrington, NJ, USA). The tests were performed in air and normal saline at working distances of 1 cm, 2 cm, and 3 cm from the card. Numbers on the horizontal line of the card represent a group, while numbers on the vertical line represent elements. The resolutions were recorded in line pairs per millimeter (lp/mm) and calculated with the following formula:

$$\text{Resolution (lp/mm)} = 2^{\text{Group} + (\text{element} - 1)/6}$$

As to color grading, we used the GretagMacbeth ColorChecker Chart. The measurements were made at a distance of 1 cm from the chart and with 2 sets of color panels. The color quality was graded blindly by 6 reviewers (5 urology residents and 1 fellow). The color representations were graded with "0" signifying "no similarity," "1" denoting "little similarity," and "2" indicating "a great similarity." The 6 reviewers' scores for each ureteroscope were averaged and reported between 0 and 2.

Table 1. Comparison of mechanical properties

Ureteroscope	Olympus	Innovex	OTU	Redpine	Sciavita	Seplou
Model	URF-V	US31-B12	OTU-100RR	RP-U-C12	SUV-2A-B	URS3016E
Weight	428 g	105 g	115 g	97 g	129 g	107 g
Total working length	670 mm	670 mm	670 mm	670 mm	680 mm	650 mm
Optical system	CCD	CMOS	CMOS	CMOS	CMOS	CMOS
Working-tip position	9 o'clock	8 o'clock	8 o'clock	8 o'clock	8 o'clock	8 o'clock
U/D deflection (°)	180/275	275/275	275/275	275/275	285/285	275/275
Tip diameter	8.4 Fr	9.3 Fr	7.4 Fr	9.12 Fr	8.1 Fr	7.2 Fr
Shaft diameter	9.9 Fr	8.7 Fr	8.6 Fr	9.6 Fr	8.4 Fr	9.0 Fr
Working-channel diameter	3.6 Fr	3.6 Fr	3.6 Fr	3.6 Fr	3.6 Fr	3.6 Fr

CCD, charge-coupled device; CMOS, complementary metal-oxide semiconductor; U/D, upward and downward deflection.

Results

Mechanical Characteristics

The mechanical specifications of the tested ureteroscopes are detailed in Table 1. All 5 disposable ureteroscope optical systems were based on a complementary metal-oxide semiconductor. The OTU device had the smallest loop diameter (1.6 cm in the empty channel, 267 μm holmium laser fiber, and a 1.9 Fr tipless nitinol basket), as shown in Table 2. A comparison of the loop diameters is illustrated in Figure 2.

The OTU device outperformed the 4 other disposable ureteroscopes and the 1 reusable ureteroscope. The upward and downward deflection angles are detailed in Table 3. In the evaluations of the disposable ureteroscopes with an empty working channel, the upward and downward deflection angles of the Innovex, OTU, and Sciavita devices reached their respective specifications. However, only the upward deflection angle of the Seplou device met its specification, and neither the upward nor downward deflection angle of the Redpine device matched the manufacturer's specification. Evaluations were then made of the deflection angle losses of each device when the working channel was filled with a 1.9 Fr tipless basket or a holmium laser fiber (Fig. 3a, b). When the basket was used, Innovex had the least upward deflection angle loss, while OTU had the least downward deflection angle loss. As to the laser fiber, Innovex had both the smallest upward and downward deflection angle losses.

The irrigation flow rates of the 5 disposable ureteroscopes in the empty channel were comparable, with all rates higher than that of the reusable Olympus device. Filling the working channel with a basket or a laser fiber decreased the irrigation flow rates (Table 4; Fig. 4).

Optical Characteristics

Of the single-use ureteroscopes, the Redpine device had the most expansive field of view (88°). The viewing field sizes of the other single-use devices were 85° (Sciavita), 83° (Seplou and OTU), and 80° (Innovex).

At a distance of 1 cm from the test pattern card, the disposable ureteroscopes had identical image resolutions in air (3.56 lp/mm; Table 5; Fig. 5). The corresponding value for the reusable Olympus device was 3.17 lp/mm. At a distance of 2 cm, however, the Innovex device gave the best resolution (3.56 lp/mm). At 3 cm, the Innovex and Sciavita devices had the best resolution (2.83 lp/mm each).

Concerning the tests in normal saline, the reusable device and all single-use ureteroscopes had the same resolutions (3.56 lp/mm) 1 cm from the test pattern card. At 2 cm, the Innovex, OTU, and Sciavita devices gave the best resolution (3.56 lp/mm), while at 3 cm, the Innovex and OTU devices had the best resolution (3.17 lp/mm; Table 5). Regarding color grading, the Innovex and Redpine devices produced the best color grading, with an average score of 1.6 (Fig. 6).

Discussion

As a result of technological advancements and refinements over several decades, there is now widespread use of flexible ureteroscopy. Its high efficacy and low morbidity in treating renal stones up to 20 mm in diameter have made it a treatment of choice for managing renal calculi [10, 11].

However, reusable flexible ureteroscopes have several limitations: a high cost of purchase, a risk of cross-infections, high sterilization and maintenance costs,

Table 2. Comparison of loop diameters

Ureteroscope	Empty working channel, cm	With 267 µm holmium laser fiber, cm	With 1.9 Fr tipless nitinol basket, cm
Olympus	1.60	2.05	1.65
Innovex	2.10	2.20	2.10
OTU	1.60	1.60	1.60
Redpine	2.35	2.75	2.50
Sciavita	2.45	2.60	2.50
Seplou	2.20	2.40	2.30

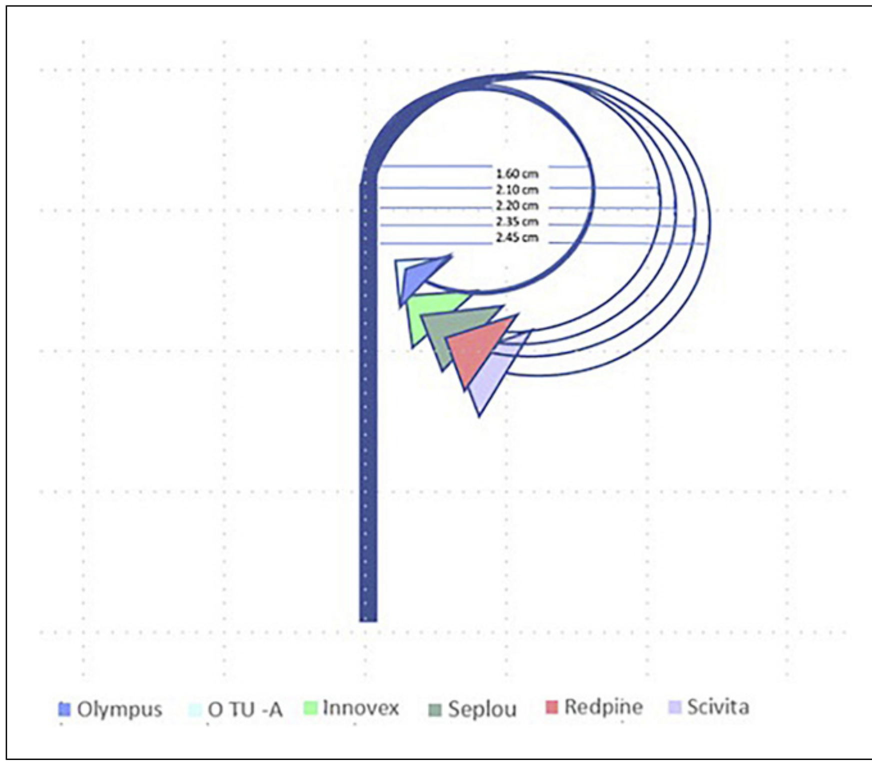

Fig. 2. Loop diameters.

Table 3. Comparison of the upward and downward deflection angles

Ureteroscope	Empty working channel (°) (U/D)	With 267 µm holmium laser fiber (°) (U/D)	With 1.9 Fr tipless nitinol basket (°) (U/D)
Olympus	180/280	164/200	178/269
Innovex	285/286	281/265	283/279
OTU	307/283	297/262	297/281
Redpine	249/226	224/186	232/205
Sciavita	294/298	260/261	285/283
Seplou	286/266	255/245	276/264

U/D, upward and downward deflection.

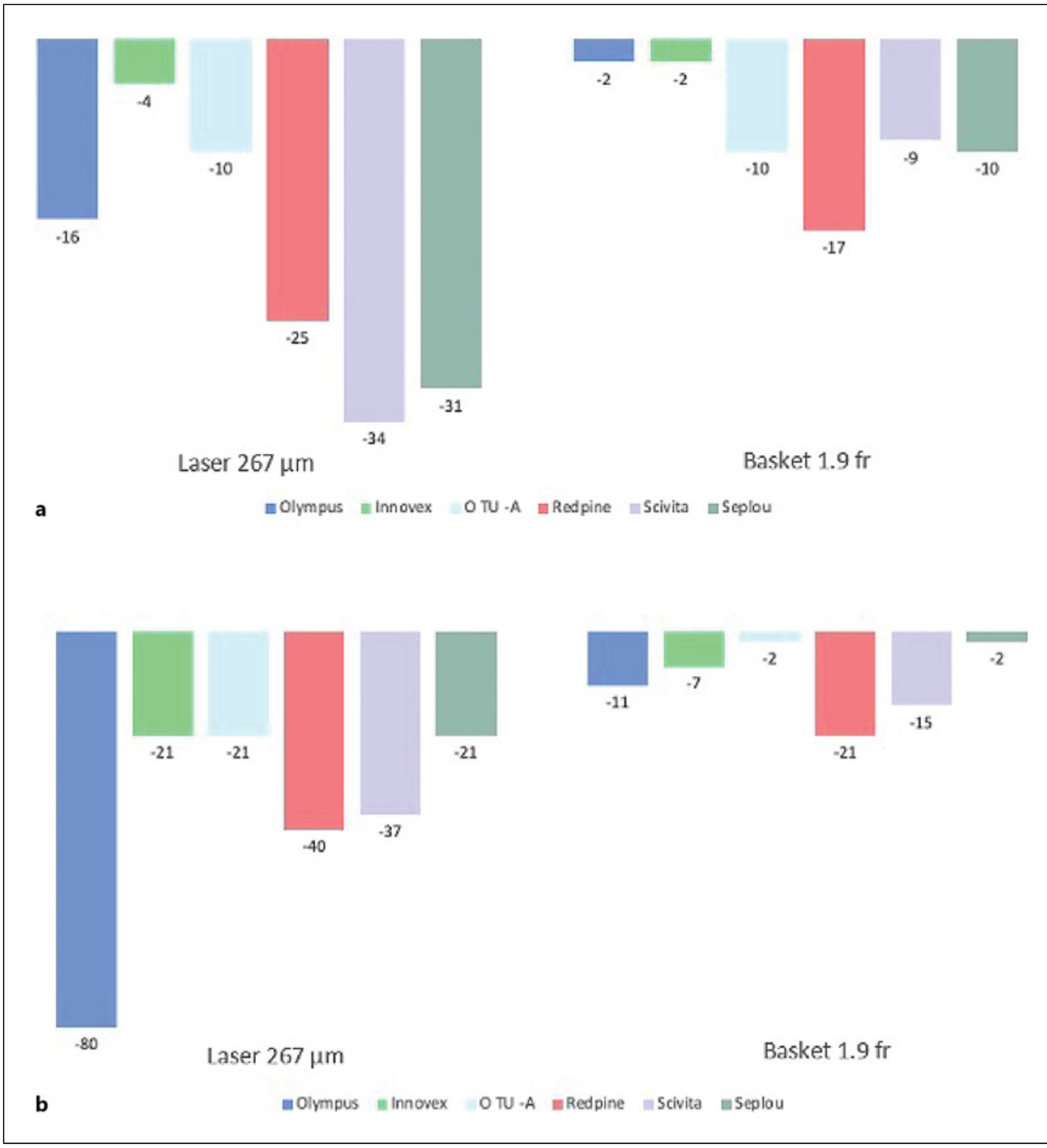

Fig. 3. a, **b** Upward deflection angle losses and downward deflection angle losses.

Table 4. Comparison of irrigation flow rates

Ureteroscope	Empty working channel, mL/min	With 267 µm holmium laser fiber, mL/min	With 1.9 Fr tipless nitinol basket, mL/min
Olympus	80	40	20
Innovex	100	60	30
OTU	110	70	30
Redpine	100	60	20
Sciavita	100	50	20
Seplou	110	60	30

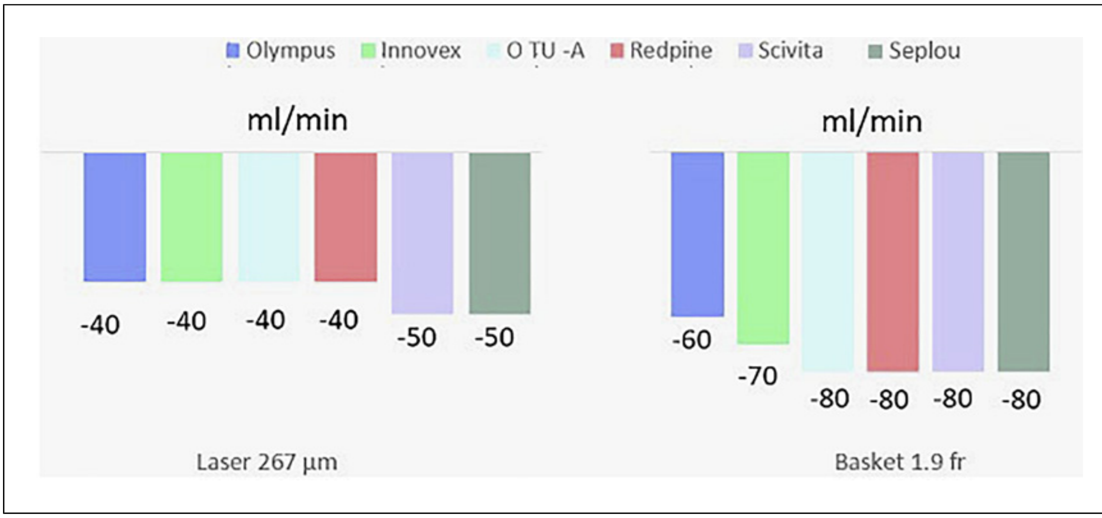

Fig. 4. Irrigation flow losses.

Table 5. Comparison of resolution in air and normal saline

Ureteroscope	1 cm, lp/mm		2 cm, lp/mm		3 cm, lp/mm	
	air	saline	air	saline	air	saline
Olympus	3.17	3.56	2.24	3.17	2.00	2.52
Innovex	3.56	3.56	3.56	3.56	2.83	3.17
OTU	3.56	3.56	3.17	3.56	2.24	3.17
Redpine	3.56	3.56	2.83	2.83	2.24	2.52
Sciavita	3.56	3.56	3.17	3.56	2.83	2.83
Seplou	3.56	3.56	2.83	2.83	2.52	2.52

lp/mm, line pairs per millimeter.

and limited durability [7, 12]. Thus, single-use flexible ureteroscopes were introduced as an alternative. Disposable ureteroscopes were designed to mitigate the problems associated with reusable ureteroscopes [13].

The first commercially available, disposable, digital, flexible ureteroscope for accessing the upper urinary tract and treating nephrolithiasis was LithoVue (Boston Scientific, Marlborough, MA, USA) [4]. Since its launch in late 2015, a few studies have demonstrated that the LithoVue scope and subsequent single-use ureteroscopes have comparable or superior efficacy to reusable ureteroscopes [8, 14, 15].

The present study compared the in vitro mechanical and optical properties of 5 single-use flexible ureteroscopes and 1 reusable ureteroscope. The specifications of the 6 tested ureteroscopes are summarized in Table 1. All of the disposable ureteroscopes were lighter than the reusable ureteroscope. The Redpine device was the lightest, weighing 97 g (including its safety guide wire). Of the disposable ureteroscopes, Sciavita had the most extended working length (680 mm), and Seplou had the shortest (650 mm). The upward and downward deflection angles of the single-use ureteroscopes were comparable. Most of the disposable ureteroscopes' tip diameters were smaller than their shaft diameters. The exception was the Innovex device: its 9.3 Fr tip diameter was wider than its 8.7 Fr shaft diameter due to having 2 LED bulbs embedded in its tip.

All disposable ureteroscopes had a working-tip position at 8 o'clock, which facilitates laser lithotripsy. Doizi et al. [10] stated that laser lithotripsy in the right kidney at the 3 o'clock working-channel position is better for ablating stones, while the 9 o'clock working-channel position is advised for left renal stones.

The highest performance and safety profiles achievable when using flexible ureteroscopes for intrarenal surgery depends on their mechanical and optical attributes. The mechanical factors are irrigation flow and ureteroscope flexibility. The optical aspects are image resolution, color representation, and visual field.

The irrigation flow rates and flexibilities of ureteroscopes vary markedly. Given the variations in device stiffness and diameters [16], we included a 267 µm holmium laser fiber and a 1.9 Fr tipless nitinol basket in our mechanical attribute testing.

Small loop diameters facilitate the treatment of urothelial lesions, and calculi can be treated in the most minimally invasive manner [17]. Flexible ureteroscopes with small loop diameters are also easier to use and cause less trauma to normal tissues than larger diameter flexible

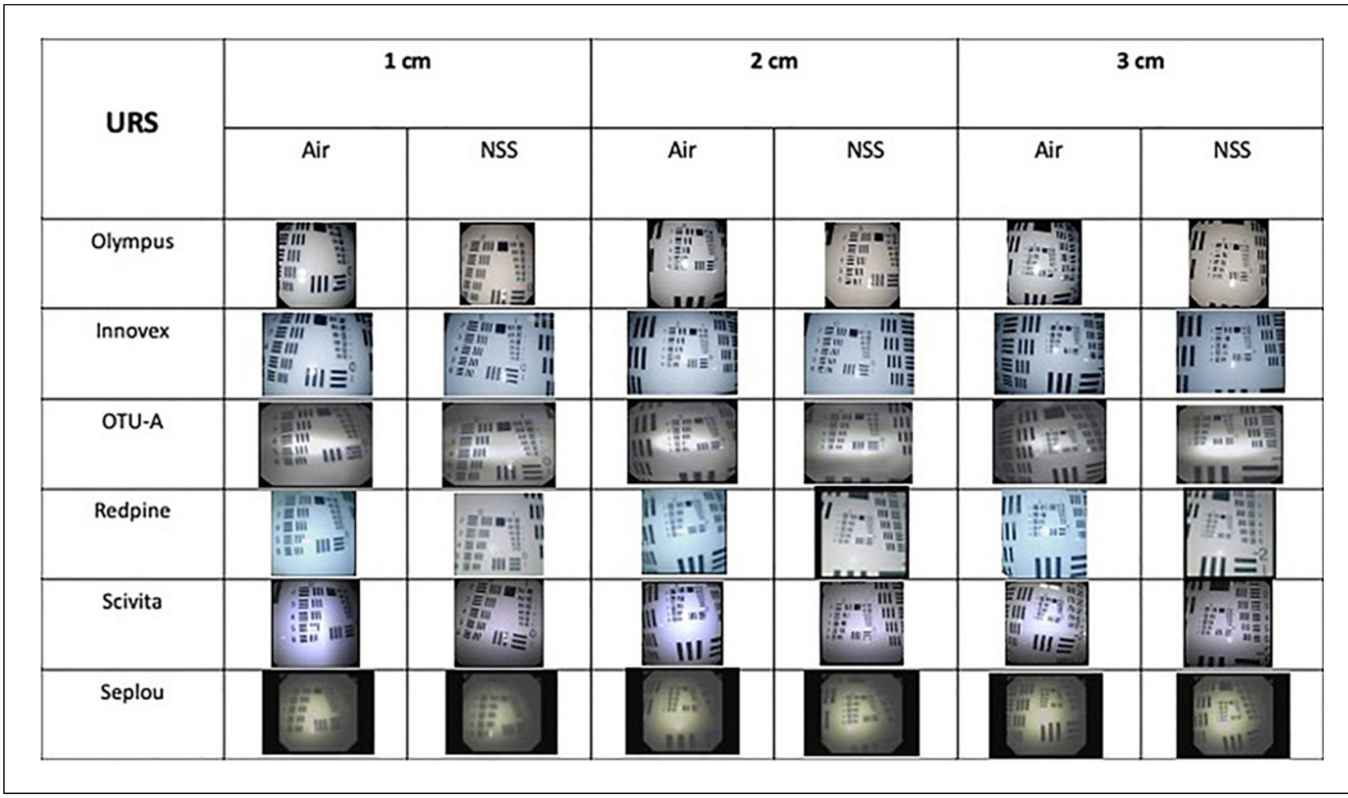

Fig. 5. Image resolutions.

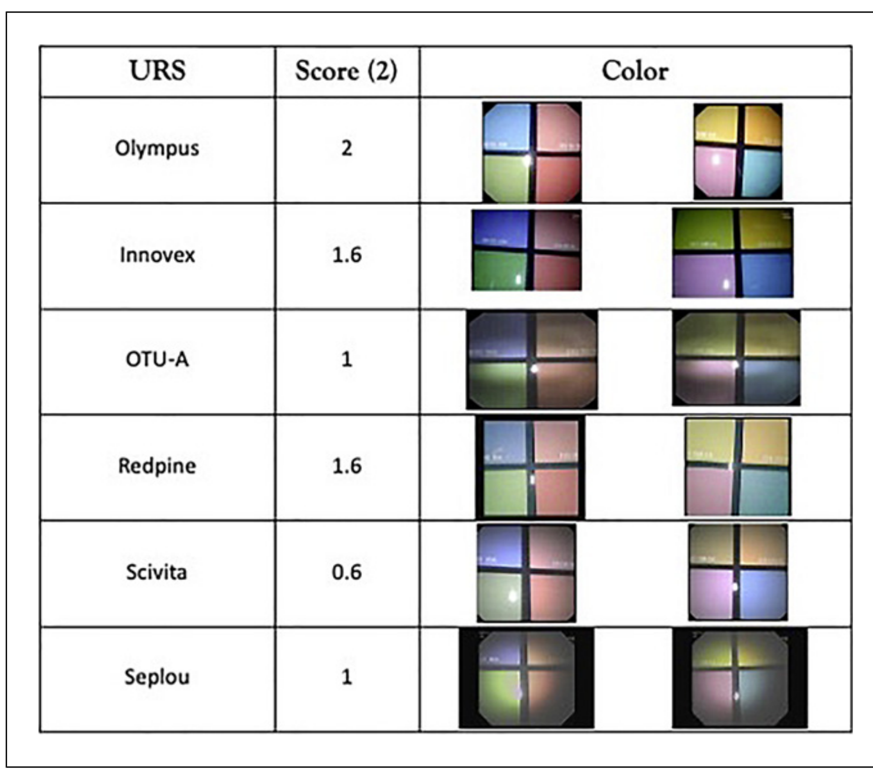

Fig. 6. Color grading.

ureteroscopes. However, the downside of small-diameter devices is that they are more fragile than those with large diameters. Of our tested disposable ureteroscopes, the OTU device had the smallest loop diameter (1.6 cm). Hence, this device requires the least space for a full deflection.

Regarding the deflection angles, the degrees of deflection revealed by manufacturers and reported by this study were generally comparable. The exception was the Redpine device: its deflection angle was slightly lower than the angle described in the manufacturer's specifications.

Concerning the irrigation flow rates, the OTU and Seplou devices had the highest rates in the empty channel (110 mL/min each). In the case of the Seplou ureteroscope, the rate is probably attributable to the device having the shortest working length of the 5 tested disposable ureteroscopes. The irrigation flow losses of the disposable devices were comparable. The working channel of the reusable device may have some effects on its surface after several procedures that caused the irrigation flow rates lower than the disposable device [18].

In addition to a device's lithotripsy efficacy, its image resolution is crucial for success in upper urothelial cancer diagnosis and treatment. Presumably, a high image resolution not only facilitates stone breakage, resulting in a shorter operation time, but also enhances the identification of any lesions. The resolutions of all of the single-use flexible ureteroscopes were identical at a 1-cm distance (3.56 lp/mm). We assumed that this distance represents the typical working distance during intrarenal surgery. At the 2- and 3-cm distances, the Innovex device had slightly higher resolutions (3.56 lp/mm and 2.83 lp/mm, respectively). The resolutions of the disposable devices in air were slightly worse than those achieved in normal saline. This difference can be explained by the hypothesis that objects in water appear larger than those in air by an optical magnification factor of 4/3. Objects in water appear beyond their optical distance and are slightly enlarged in linear size but not in accordance with the size-distance invariance [19].

The color capabilities of an ureteroscope are critical for correct cancer treatment and the assessment of a stone's crystalline structure [20]. From our study, the Innovex and Redpine devices had the best color representations.

In addition to their mechanical and optical characteristics, other factors must be considered when comparing single-use flexible ureteroscopes. Such factors include, for example, any unique features of a device, its durability, its purchase and operating costs, and its performance during in vivo testing. None of these were evaluated in the current work. To overcome this limitation, further in vivo testing of disposable ureteroscopes using a comparative study design is needed.

Of our tested ureteroscopes, the OTU device had the best mechanical attributes, given its small loop diameter, high deflection angles, and low irrigation flow loss. As to their optical properties, all 5 single-use models had identical resolutions at an image distance of 1 cm. Because this was an in vitro study, further in vivo testing of performance coupled with an assessment of cost-effectiveness and safety would benefit ureteroscope selection.

Conclusions

Of the tested disposable ureteroscopes, the OTU device had the best mechanical attributes, given its small loop diameter, high deflection angles, and low irrigation flow loss. As to their optical properties, the resolutions of all 5 single-use models were identical at an image distance of 1 cm.

Acknowledgments

The authors would like to thank Ms. Jitsiri Chaiyatho and the coordinators at Siriraj Hospital for their important contributions to this study.

Statement of Ethics

According to the study was an in vitro experiment without human and animal involvement; therefore, no approval from the Ethics Committee of the institution required.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

The authors have received no external funding.

Author Contributions

Phromprathum P.: data collection or management, data analysis, and manuscript writing/editing. Srinualnad S., Leewansangtong S., Taweemonkongsap T., Phinthusophon K., Jitpraphai S., Ramart P., Woranisarakul V., Suk-ouichai C., Mankongsrisuk T., Hansomwong T., and Jongjitaree K.: data collection or management. Chotikawanich E.: protocol/project development, data collection or management, data analysis, and manuscript writing/editing.

Data Availability Statement

The data that support the findings of this study are not publicly available due to privacy reasons but are available from the corresponding author upon reasonable request.

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