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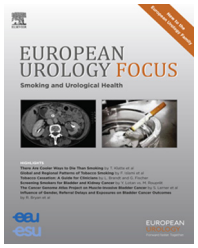

Endo-urology

Durability of Flexible Ureteroscopes: A Prospective Evaluation of Longevity, the Factors that Affect it, and Damage Mechanisms

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Abstract

Background: Flexible ureteroscopy is an established treatment modality for evaluating and treating abnormalities in the upper urinary tract. Reusable ureteroscope (USC) durability is a significant concern.
Objective: To evaluate the durability of the latest generation of digital and fiber optic reusable flexible USCs and the factors affecting it.
Design, setting, participants: Six new flexible USCs from Olympus and Karl Storz were included. The primary endpoint for each USC was its first repair. Data on patient and treatment characteristics, accessory device use, ureteroscopy time, image quality, USC handling, disinfection cycles, type of damage, and deflection loss were collected prospectively.
Intervention: Ureteroscopy.
Outcome measurements and statistical analysis: USC durability was measured as the total number of uses and ureteroscopy time before repair. USC handling and image quality were scored. After every procedure, maximal ventral and dorsal USC deflection were documented on digital images.
Results and limitations: A total of 198 procedures were performed. The median number of procedures was 27 (IQR 16–48; 14 h) for the six USCs overall, 27 (IQR 20–56; 14 h) for the digital USCs, and 24 (range 10–37; 14 h) for the fiber optic USCs. Image quality remained high throughout the study for all six USCs. USC handling and the range of deflection remained good under incremental use. Damage to the distal part of the shaft and shaft coating was the most frequent reason for repair, and was related to intraoperative manual forcing. A limitation of this study is its single-center design.
Conclusions: The durability of the latest reusable flexible USCs in the current study was limited to 27 uses (14 h). Damage to the flexible shaft was the most important limitation to the durability of the USCs evaluated. Prevention of intraoperative manual forcing of flexible USCs maximizes their overall durability.
Patient summary: Current flexible ureteroscopes proved to be durable. Shaft vulnerability was the most important limiting factor affecting durability.

☆ This study is registered at ClinicalTrials.gov under the study ID number NL201501.
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1. Introduction

Flexible ureteroscopy is widely performed for diagnostic and therapeutic purposes in the upper urinary tract. Technological advances and miniaturization for ureteroscopes (USCs) have improved the maneuverability and image quality of flexible USCs. However, reusable flexible USCs are still fragile instruments. The USC durability reported varies widely from three to 159 procedures [1–7]. The purchase and maintenance of high-quality flexible USCs remain costly [8–10]. Maximizing the durability of reusable USCs is essential to restrict the costs of flexible ureteroscopy.

The aim of this study was to evaluate the durability of the latest models of digital and fiber optic reusable, flexible USCs that have not yet been evaluated. Factors that may affect USC durability were also assessed. These outcomes will contribute to maximization of USC durability and thereby reduce costs. The scope of the study did not include comparison of USC durability by type or brand.

2. Materials and methods

2.1. Study objective

The study objective was to evaluate the overall durability of four digital and two fiber optic reusable, flexible USCs until a first repair was required. Factors that may affect durability were also assessed.

2.2. Study organization

Six new flexible reusable USCs were included: two digital Karl Storz Flex-Xc USCs (KS1 and KS2), one fiber optic Karl Storz Flex-X2 USC (KS3), two digital Olympus URF-V2 USCs (OL1 and OL2), and one fiber optic Olympus P6 USC (OL3). USC-specific parameters, ureteroscopy time, treatment data, and patient characteristics were prospectively collected for every procedure. The primary endpoint for each USC was first repair. Ureteroscopy procedures included urinary stone treatment, diagnostic and therapeutic procedures for upper tract urothelial carcinoma (UTUC), and other indications. Digital USCs were used as the standard of care for UTUC and diagnostic procedures owing to the superior image quality. The USCs studied were utilized as much as possible, depending on availability at the operating theatres. The USC availability was conditional on the logistics of the disinfection process. All USCs were disinfected according to a high-level disinfection protocol (Supplementary material).

All procedures were carried out in a single academic referral center and were almost exclusively performed by three urologists who are specialized in endourology. A standardized working method was maintained. Accessory devices were inserted into a straightened USC when possible. Stones in the lower pole were repositioned into the upper pole for fragmentation when possible.

2.3. Study parameters

Preoperative data registration included general patient characteristics, computed tomography–based stone size and density measurements, presence of a double-J stent, and the presence of anatomic deviations or renal anomalies, which included duplicate ureters, horseshoe kidney, ectopic kidney, malrotated kidney, reimplanted ureters, ileal conduit urinary diversions, and neobladders.

Before starting the procedure, the surgeon inspected the USC for external damage. The handling and deflection were qualitatively evaluated as easy, medium, or difficult. The same evaluations were performed during and at the end of the procedure. The surgeon rated the image quality on a Likert scale from 0 (very low) to 5 (very high) at the beginning, during, and at the end of each procedure.

The duration of the procedure was defined as the time from first introduction of the USC into the urethral meatus or ureteral access sheath (UAS) until final extraction. The number and method of USC introductions into the ureteral orifice, the use and type of UAS, the number of USC passages through the UAS, and the number of passages of accessory devices through the working channel were reported. After each procedure, the surgeon rated the amount of manual forcing and USC friction experienced on a Likert scale (never, incidentally, regularly, continuously). After every procedure, photographs of the USC shaft were taken to assess the maximal ventral and dorsal deflection.

For the disinfection process, the total number of disinfection cycles per USC, incorrect cleaning, incorrect packaging, and damage after disinfection were registered. The disinfection shelf life was 2 wk according to the protocol of the Department of Microbiology and Hygiene.

2.4. Analyses

Data processing was performed with SPSS v.24.0 (IBM, Armonk, NY, USA). Maximum deflection angles in the dorsal and ventral plane were derived from pictures captured after every procedure using Adobe Illustrator CS6 (Fig. 1). We hypothesized that the deflection angles decrease gradually over time and after certain procedures there is greater decrease (eg, when the USC is burdened more than average). Data on deflection loss for all six USCs were used to design a model that illustrates the overall durability of the deflection systems tested. The model describes the average deflection loss with increasing number of procedures. For all procedures, the averages for the dorsal and ventral deflection angles were calculated. The average deflection angles for a specific procedure number were calculated using the data available for all USCs. Linear regression analysis was used to create a model describing the relation between the number of procedures and the associated deflection loss.

3. Results

3.1. Indications and patient characteristics

From December 2015 to February 2017, a total of 198 procedures were performed with the six flexible USCs until their first repair. The indications for ureteroscopy and patient characteristics for each USC are presented in Table 1. Of the cases, 105 (53%) involved stone treatment, 58 (29%) UTUC follow-up and treatment, and 35 (18%) other diagnostic evaluations or treatments. The median stone burden was 58 mm^2 (interquartile range [IQR] 27–119). Of the 213 stones treated in 102 procedures, 44 (21%) were located in the ureter and 169 (79%) in the kidney. Of the 169 kidney stones, 69 (41%) were located in the lower pole. Fifty tumors were treated in 24 procedures for UTUC. Eight of these 50 tumors (16%) were located in the ureter and 42 (84%) in the kidney, including eight (16%) in the lower pole.

The prevalence of a deviant anatomy was 7.1%. A preoperative double-J stent was present in 43 cases (22%).

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