



Are Flexible Ureteroscopes (FURS) Equivalent in Deflection when an Anatomical Deformation is Applied? an Ex Vivo Comparative Study of 10 FURS

Rawad Abou Zahr^{1,2}, Bogdan Buhas¹, Jean Baptiste Beauval¹, Guillaume Ploussard¹, Ambroise Salin¹, Christophe Almeras^{1*}

¹Department of Urology UROSUD, La Croix du Sud Hospital, Quint Fonsegrives, France

²Department of Urology, Sainte Anne Saint Rémi Hospital, CHIREC group, Brussels, Belgium

***Corresponding author:** Christophe Almeras, Department of Urology UROSUD, La Croix du Sud Hospital, Quint Fonsegrives, France

Citation: Zahr RA, Buhas B, Beauval JB, Ploussard G, Salin A, et al. (2025) Are Flexible Ureteroscopes (FURS) Equivalent in Deflection when an Anatomical Deformation is Applied? an Ex Vivo Comparative Study of 10 FURS. J Surg 10: 11382 DOI: 10.29011/2575-9760.011382

Received Date: 09 July 2025; **Accepted Date:** 14 July 2025; **Published Date:** 16 July 2025

Abstract

Background/Objectives: Flexible Ureteroscopy (FURS) has become indispensable in endoscopic urological practice. The aim of the study was to determine if FURS were equivalent in terms of deflection when put in anatomical conditions.

Methods : A comparative ex vivo study was conducted on 10 different flexible ureteroscopes. Deflection was assessed both before and after the introduction of a 272 μ m laser fiber and a 1.5 Fr Nitinol stone basket. Measurements were taken under manufacturer settings and under reproduced anatomical constraints, applied using a 12–14 Fr Access Sheath (AS), respecting a ratio FURS/AS<0,75. Deflection angles were measured using AutoCAD 2022[®]. Additional parameters recorded for comparison included handle weight, working (mobile) length, circular diameter, deflection height at 180°, tip-to-shaft distance at full deflection, and maximum reach from the deflection point.

Results: The FURS tested were not equivalent in terms of deflection under reproduced anatomical constraints. A significant deflection loss was found between the FURS tested with a range of +11°/-75° that can be affected by the insertion of a device (basket/ laser fiber) into the working channel. According to the endoscopes employed, we observed two different bending shapes (round or deported) with very heterogenous characteristics that may change the ability to reach calyceal locations, particularly the more complex ones.

Conclusions: This study demonstrates significant variability in deflection stability and quality, particularly under anatomical constraints. These differences are critical considerations for preoperative device selection to optimize procedural success and also evaluate the reliability of the new devices that are appearing on the market.

Keywords: Anatomical Conditions; Bending; Comparative; Deflection; Flexible Ureterscopy; Urinary Stones

Abbreviations: FURS: Flexible Ureterscopy; AS: Access Sheath; ESWL: Extracorporeal Shockwave Lithotripsy; PCNL: Per Cutaneous nephrolithotomy; SuFURS: Single Use FURS; ReFURS: Reusablefurs; RAC: Reproduced Anatomical Constraints

Introduction

Urolithiasis is one of the most frequent pathologies affecting the urinary tract. Incidence of urinary stones is constantly increasing in industrialized countries and their prevalence in France and is estimated at 10% in the general population. Renal colic represents 1 to 2% of the reasons for consultation in emergency departments [1]. The treatment of urinary stones is based on parameters such as number, size (and nowadays volume), composition, and location [2]. Owing to its stone-free rates reaching up to 90% [3,4], its minimally invasive nature and the thriving technical improvements of the devices (LASERS, baskets, access sheaths, vision quality [5,6], miniaturization, suction), Flexible Retrograde Ureterscopy (FURS) is seeing a steady increase in its clinical indications in the treatment of renal stones to the detriment of other techniques (ESWL, PCNL) and despite a primary higher cost [7,8] that could be nevertheless balanced by its cost effectiveness [9]. Ureterscopes, whether reusable or single-use are commercialized based on their vision quality as well as their deflection ability. The commercial information given by the companies concerning each ureterscope is measured in straight industrial conditions. The introduction of a LASER fiber or a basket in the working channel alters the bending quality of FURS [10-13] and a deflection loss may also be observed during difficult procedures with deformation of the shaft [14] secondary to sharp angles. The aim of our study was to compare the deflection angles of various commercially available ureterscopes and to quantify the deflection loss following the introduction of a laser fiber and a stone basket, both under standard manufacturer conditions and simulated anatomical constraints. The secondary endpoint was to compare the industrial characteristics (tip-shaft caliber, working channel, handle weight). This information is essential for endourologists to make informed decisions when selecting a flexible ureterscope (FURS), taking into account both economic and operative factors [15]. It is particularly relevant given the increased risk of treatment failure in cases involving complex lower pole anatomy (such as a steep infundibulopelvic angle ($<30^\circ$), a long (>30 mm) or narrow (<5 mm) infundibulum [16,17]) as well as in anatomically challenging scenarios like horseshoe kidney, pelvic kidney, or urinary diversions.

Materials and Methods

Eight single use FURS (suFURS) and 2 reusable FURS (reFURS) were tested and compared ex vivo (Table 1). All the devices were

brand new. Deflection for each ureterscope was measured both before and after the introduction of a 272 μ m laser fiber (Rocamed[®]) and a 1.5 Fr Nitinol stone basket (Stonewrapper[®], Asept InMed), under both the manufacturer's standard (straight) conditions and Reproduced Anatomical Constraints (RAC).

RAC were simulated on a resin platform by applying targeted curvatures-mimicking the typical angulation and torsion of the human ureter-using controlled bends on a 12-14 Fr Coloplast[®] access sheath, respecting an endoscope/access sheath ratio $< 0,75$ according to Fang's publication [18].

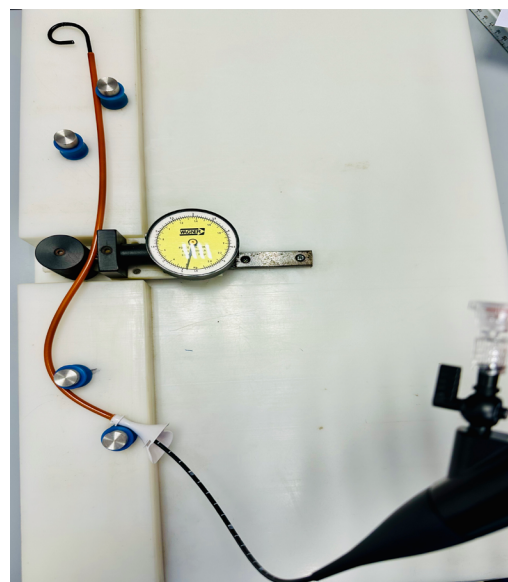


Figure 1: Ex vivo simulation model of anatomical constraints

Pictures were taken in each different situation from the same angle on graph paper. The pictures were then integrated in AutoCad 2022[®], which is a program used to create and design precise 2D and 3D models in architectural design. The deflection angles were then measured, and deflection loss was calculated based on the initial deflection measured in industrial or RAC. The measures were taken twice in each different condition to limit a bias of evaluation and a third measure was taken in case of unequal results. Other parameters measured for comparison were handle weight, Mobile Length (ML), Circular Diameter (CD), height at 180° of deflection (H180), tip-shaft distance in full deflection (T-SD) and Maximum Reach from Deflection Point (MR) (Figure 2). The measures of the mobile part of the ureterscope (ML, CD, H180, T-SD and MR) represent the ability of reaching extreme low locations and acute angles in an active way.

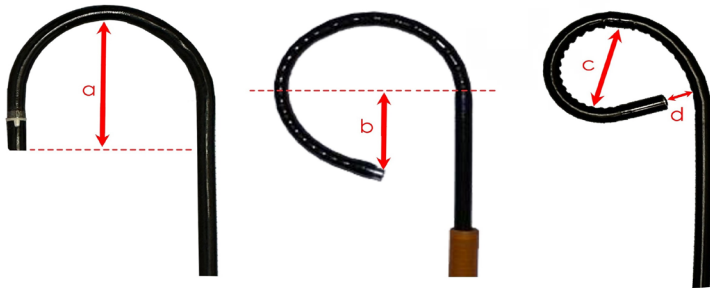


Figure 2: The different parameters measured of the mobile part of FURS.

a. Height at 180° vision; b. maximum reach from deflection point; c. circular diameter; d. Tip-shaft in full deflection

Results

Findings and measurements are presented in Table 1.

Manufacturer Specifications	Flexible Scope Name	Flex XCL [®]	LithoVue [™]	NeoScope [®] 9Fr	NeoScope [®] 7.5Fr	PU3022A [®]	PU3033A [®]	EU-Scope [™]	Wlscope [®]	Flex X.C [®]	Flex X2S [®]
	Company	Storz	Boston Scientifics	Seegen	Seegen	Pusen	Pusen	Innovex	OTU medical	Storz	Storz
	Type	Digital SU	Digital SU	Digital SU	Digital SU	Digital SU	Digital SU	Digital SU	Digital SU	Digital ReU	Fiber optic ReU
	Shaft (Fr)	9	9,5	9	7,5	9,2	7,5	8,7	8,6	8,5	7,5
	Tip (Fr)	9	7,7	9	7,5	9,2	7,5	9,3	7,4	8,5	7,5
	Working length (cm)	70	68	75	75	65	65	65	67	70	67
	Working channel (Fr)	3,5	3,6	3,6	3,6		3,6	3,6	3,6	3,6	3,6
	Visual field (°)	105	-	110	110	90	120	120	100	105	88
	Deflection down/up (°)	270/270	270/270	275/275	275/275	270/270	270/270	275/275	275/275	270/270	270/270
	Depoited	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
DD measured in manufacturer's conditions (°)											
		+ 30	+ 14	+ 4	+ 5	-26	-13	0	+ 30	-9	-23
DD under RAC		-8	-21	-4	-8	-64	-24	-8	-1	+5	-15
DD with laser fiber		-17	-37	0	-2	-33	-13	-15	-8	+11	-15
DD with fiber + RAC		-29	-33	-20	-12	-71	-34	-4	0	+4	-33
DD with Stonewrapper®		-26	-20	-1	0	-36	-5	-12	-3	+6	-14
DD with Stonewrapper® + RAC		-33	-31	-14	-12	-75	-37	-14	-3	+5	-34
Handle weight (g)		44,2	165	93	102	138	111	96	115	380	320
Mobile length (mm)		70	58	72	75	65	71	66	55	65	67
Circular diameter (mm)		25	20	25	23	30	27	22	15	27	27
Height at 180° vision (mm)		34	28	34	34	28	20	23	26	30	28
Tip-shaft in full deflection (mm)		4	0	3	1	11	15	5	-3	10	7
Maximum reach from deflection point (mm)		17	20	20	18	5	6	20	15	13	16

Table 1: Characteristics of 8 single use and 2 reusable uretero-renoscopes.

URS: uretero-renoscope; SU: single use; ReU: reusable; DD: Deflexion difference in comparison with déflexion in manufacturer's conditions ; RAC: reproduced anatomic constraints

An illustration of loss in deflection when a laser fiber and a stone basket is introduced is shown in our Figure 3.

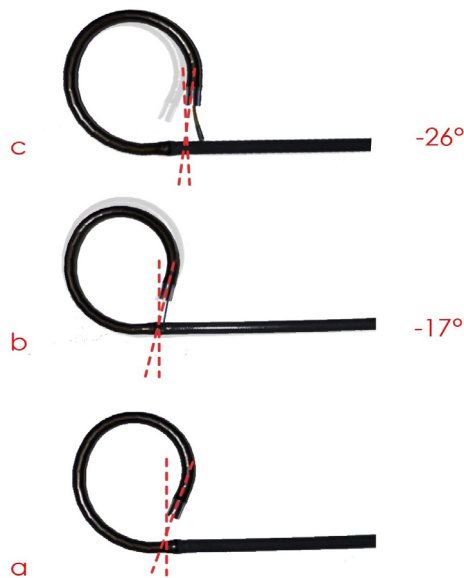


Figure 3: Example of deflection loss.

A. in manufacturer's conditions; b. upon introducing a laser fiber; c. upon introducing a stone basket Two ureterscopes had a bend with a round shape instead of a deported deflection bend Figure 4.

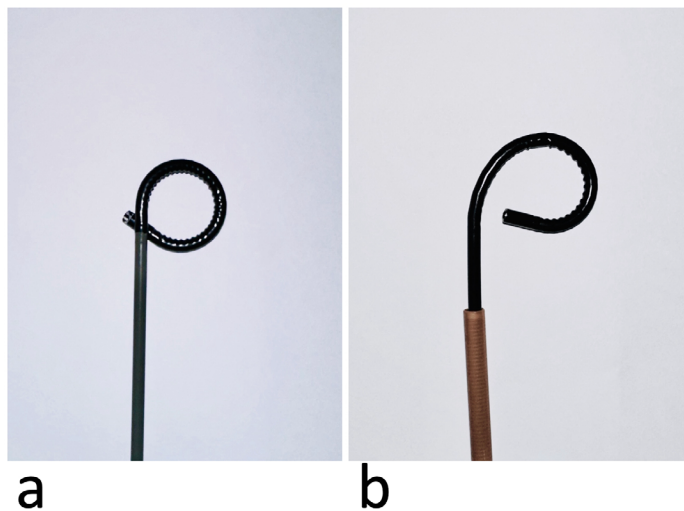


Figure 4: Different bending shapes a: round deflection; b: deported deflection

Primary Endpoint

A loss of deflection was observed when anatomical constraints were applied, which further increased following the insertion of a disposable instrument, such as a laser fiber or stone basket. We observed a substantial variation in deflection loss among the

ureterscopes included in our study, ranging from an increase of 11° to a decrease of 75°.

Secondary Endpoints

We also noted a difference in caliber between the tip and the shaft in two FURS, the Lithoview® and the EU-Scope™. All the FURS had the same working channel diameter of 3.6 Fr except for the Flex XC1 with a working channel of 3.5 Fr. Regarding other measures that were also compared, we noted a big range in the handle weight from 44g to 380g, and a difference up to 20 mm in Mobile Length (ML), 15 mm in Circular Diameter (CD) (measure (c) in Figure 2), 14 mm in height at 180° (H180) (measure (a) in Figure 2), between -3 and 15 mm of tip-shaft distance (T-SD) (measure (d) in Figure 2) and 15 mm (5-20 mm) in Maximum Reach at Deflection Point (MR) (measure (b) in Figure 2).

Discussion

Flexible ureterscopes, whether reusable or single-use are commercialized based on their vision and illuminance quality [19,21], on their caliber, but also on their deflection ability. The deflection can be altered by the insertion of a disposable (LASER fiber or basket) in the working channel [10,13] (Figure 3), but also during difficult procedures with the deformation of the shaft [14] secondary to sharp angulation and deflection. In our comprehensive comparative analysis of 10 flexible ureterscopes, we identified significant variability in deflection and bending characteristics particularly when anatomical constraints were simulated, and that was aggravated when an instrument (laser fiber or a stone basket) was inserted. While image quality, cost, and shaft caliber are often the primary concerns for urologists when selecting a Flexible Ureterscope (FURS), this study highlights significant differences not only in their ability to maintain deflection but also in the design and features of the shaft's mobile segment. These factors can greatly influence maneuverability and effectiveness in accessing and treating urinary stones. The measurements depicted in Figure 2 hold relevance within a clinical context: measurement (a) and (b) represent the depth that can be reached with the FURS, while (c) and (d) represent relevant measures in specific circumstances like stones in lateral and particularly medial calyces. Urologists have to get the knowledge of those features before choosing a ureterscope, and should not only rely on the image quality nor the shaft's caliber. Our study highlighted the two different bending shapes that are developed: round or deported. As the deported shape seems to be more fit for anatomy, a reverse vision may occur in some devices with excessive deflection on round bending shape (negative d values), that may mislead the urologist's navigation in the upper tract. With the use of a Holmium laser, an excessive bending with a small curved diameter increases the risk of fiber breakage [22]. It is important to interpret the measurements from our study

comprehensively, considering all parameters together to optimize preoperative planning based on factors such as stone location, steep infundibulopelvic angle, or narrow infundibulum. An interesting finding was that reFURS were not inferior in terms of deflection compared to suFURS nor in diameter size where the fiber optic scope Flex X2S® measured 7.5 Fr as well. Surprisingly, our results revealed a significant difference in deflection loss (from 0 to 75° (Table 1) due to the application of anatomical constraints among the different flexible ureterscopes. The information provided by the manufacturers appears to be insufficient, as it is based solely on measures in straight industrial conditions. This deflection loss may be related to insufficient deflection-holding strength, which could compromise in vivo performance. Maintaining strong deflection ability has become increasingly important due to the trend toward miniaturization, which can sometimes come at the expense of durability, as well as the recent use of flexible and navigable access sheaths with suction that increases resistance on the shaft's mobile segment [23]. Our study acknowledges several limitations that may impact the findings and conclusions. First it was an ex vivo study without irrigation flow (it could increase the adherence between the endoscope and the access sheath), second the experimental setup designed to simulate anatomical constraints may not fully capture the complexity and variability of human anatomy. The reproducibility of anatomical constraints poses a challenge, as slight variations in the experimental conditions could affect the accuracy of our findings. This study assessed mainly the physical properties of 10 FURS without considering the passive deflection that could occur in-vivo.

However, we can reasonably extrapolate that if a loss of deflection in simulated conditions is observed, it should increase with an additional applied deformation by passive deflection. Additionally, the selection of scopes and focusing on a specific set from available models, may limit the generalizability of our results to all ureterscopes on the market. Especially with the exponential evolution in the development of suFURS with shafts < 7Fr, and additional channels designed for suction. These limitations underline the necessity for cautious interpretation of the results and suggest the need for further research to validate our conclusions in a broader clinical context. Evaluating the deflection performance of Flexible Ureterscopes (FURS) and their ability to maintain deflection under anatomical constraints is essential for comparing the various models available on the market. If many studies already assessed the deflection and the impact of a tool (laser fiber/basket) insertion in the working channel [11,13,19,20,24], only one highlighted the positive role of a straight shaft on the quality of deflection [14]. This is to date the first study comparing 10 FURS in terms of deflection that reveals a significant disparity in stability and quality of deflection particularly when the shaft of the endoscope is subjected to anatomical constraints.

Conclusions

Technical considerations play a crucial role in the selection and utilization of FURS for the treatment of upper urinary tract stones. This ex vivo comparison of 10 disposable and reusable flexible ureterscopes demonstrates significant variability in deflection stability and quality, particularly under anatomical constraints. These differences are critical considerations for preoperative device selection to optimize procedural success and also evaluate the reliability of the new devices that are appearing on the market.

Patents

Author Contributions: Conceptualization, R Abou Zahr and C Almeras.; methodology, R abou Zahr and C Almeras.; software, R Abou Zahr; validation, JB Beauval, G Ploussard and A Salin; formal analysis, R Abou Zahr and B Buhas.; investigation, R Abou Zahr, B Buhas and C Almeras.; data curation, R Abou Zahr; writing—original draft R. Abou Zahr; writing—review and editing, C. Almeras; visualization, JB Beauval, G Ploussard and A Salin; supervision C Almeras

Funding: This research received no external funding

Institutional Review Board Statement: Not applicable

Informed Consent Statement: Not applicable

Data Availability Statement: The data used to support the findings of this report is included within the article and is owned by the corresponding author.

Acknowledgments: The authors take full responsibility for the content of this publication.

Conflicts of Interest: The authors do not report any conflict of interest.

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Citation: Zahr RA, Buhas B, Beauval JB, Ploussard G, Salin A, et al. (2025) Are Flexible Ureteroscopes (FURS) Equivalent in Deflection when an Anatomical Deformation is Applied? an Ex Vivo Comparative Study of 10 FURS. *J Surg* 10: 11382 DOI: 10.29011/2575-9760.011382

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