A Feasibility Study on Clinical Utility, Efficacy and Limitations of 2 Types of Flexible and Navigable Suction Ureteral Access Sheaths in Retrograde Intrarenal Surgery for Renal Stones

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OBJECTIVE To evaluate stone-free rate, device maneuverability, and complications after retrograde intrarenal surgery (RIRS) using 2 different sizes of flexible and navigable suction ureteral access sheaths (FANS).

METHODS A retrospective analysis was performed for patients who underwent RIRS for renal stones of any size, number, and location between November 2021 and October 2022. Group 1 had FANS of 12 French. Group 2 had FANS of 10 French. Both sheaths have a Y-shaped suction channel. Tip of 10 French FANS has 20% more flexibility. Lithotripsy was achieved using either thulium fiber or high-power holmium lasers. A 5-point Likert scale was used to assess the performance of each sheath.

RESULTS There were 16 patients in Group 1 and 15 patients in Group 2. Baseline demographics and stone parameters were similar. Four patients in Group 2 had the same session bilateral RIRS. Sheath insertion was successful in all renal units but one. Ten French FANS had a higher percentage of excellent scores for ease of use, manipulation, and visibility. Neither of the sheaths had an average or difficult rating for all evaluation scales. A fornix rupture requiring prolonged stenting occurred in group 2. All patients were discharged within 24 hours of surgery. One patient in each group visited the emergency department (analgesic treatment). There were no infectious complications. At 3 months, a computed tomography scan showed that the absence of residual fragments > 2 mm was significantly higher in Group 2 (94.7% vs 68.8%, P = 0.01).

CONCLUSION The 10 Fr FANS showed a higher stone-free rate. There was no infectious complication using both sheaths. UROLOGY 178: 173–179, 2023.

With the advent of high-power lasers in Retrograde Intrarenal Surgery (RIRS),[1] dusting as a modality is as effective as fragmentation alone and perhaps may become the preferred modality of lithotripsy and stone clearance.[2] To simultaneously improve dust aspiration and fragment removal, newer suction ureteral access sheath (SUAS)[3], direct in scope suction technique,[4] steerable post lithotripsy aspiration catheters,[5] and table tilting maneuvers[6,7] are some of the novel proposed modalities to improve single stage stone-free rate (SFR), minimize infectious complications and prevent reintervention.[8] The aforementioned techniques deploy suction and vacuum effects to remove the dust and fragments that are generated by lasering techniques.[3–5,9] However, there are strengths and limitations to each and hence there is continuous research and innovation ongoing on how to maximize RIRS outcomes using suction technology.[10] Recently, Chen et al compared a flexible vacuum-assisted ureteral access sheath (UAS) with traditional UAS in an ex-

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vivo porcine RIRS kidney model to evaluate the change in intrarenal pressure in the flexible vacuum-assisted-UAS at different irrigation fluid velocities and the capability to clean stones.[11] The authors found that flexible vacuum-assisted-UAS was able to keep intrarenal pressure below 10 cm H_2O at 30, 50, and 80 mL/minutes of irrigation fluid velocities, whilst intrarenal pressure (IRP) increased steadily from 26 to 99 cm H_2O in traditional UAS. In addition, flexible vacuum-assisted UAS was able to provide 70% complete stone-free status as compared to 100% of the residual fragments (RF) in traditional UAS.

To the best of our knowledge, clinical studies on flexible SUAS are currently lacking. We aimed to perform a feasibility study to assess the clinical outcomes of RIRS using a flexible and navigable suction ureteral access sheath (FANS).

MATERIALS AND METHODS

Patients

Anonymized data were retrospectively analyzed for patients who underwent RIRS using FANS in 2 centers between November 2021 and October 2022. Inclusion criteria were adult patients with renal stones of any size, number, and in any location within the pelvicalyceal system (PCS), and planned for RIRS using either of the 2 FANS. Bilateral procedures were included. The following preoperative variables were collected: demographics, symptoms at presentation, stone number, size and location, and stone density measured with Hounsfield units on computed tomography (CT) scan. Stone size was assessed as the largest diameter. Intraoperative and postoperative data were also collected.

All patients were planned for a day surgery (defined as less than 24 hours of hospital stay, with overnight observation where feasible) unless required otherwise as per surgeon discretion. Complications were evaluated within 30 days from RIRS. Postoperative follow-up was performed 3 months after surgery to assess for RF. Stone-free status was defined as the absence of a single RF > 2 mm on unenhanced CT scan[12] and was assessed per renal unit. The study was approved by the local ethics board (AINU12/2022).

Study Outcomes

The primary study aim was to evaluate SFR after RIRS comparing the 2 different sizes of FANS. Secondary outcomes were evaluation of ease, maneuverability, intraoperative visibility mechanical failures, ureteroscope and sheath damage, and 3-month complications.

Description of FANS

All procedures were performed using either Elephant II first or second-generation FANS (Zhejiang YiGao Medical Technology Co., Ltd, Hangzhou, China). First-generation Elephant II FANS have an inner diameter of 12 French and vary in length from 40 to 50 cm (length from the dilator tip to the end of the dilator mark) (Fig. 1A). Second-generation Elephant II FANS has an inner diameter of 10 or 12 French, varies in length from 40 to 55 cm (Fig. 1B). A Y-shaped suction channel arises at the end of the dilatator mark. Both UAS are made is of a mixture of Pebax, PolyVinyl, Propylene, Teflon, and silicone materials. The unique property of these sheaths is that their proximal 10 cm is flexible, soft, and can be actively and passively flexed (akin to a scope tip) and navigated into the desired calyx along with the flexible ureteroscope. The difference between generation 1 and 2 FANS is that the tip of the second generation FANS is 20% more flexible with an improved water sealing cap, an improved pressure control module that eliminates the need to use the thumb for intermittent suction, and a new clear indicator line designed and marked for the ureteroscope retrieval point near the Y connector.

Description of the Procedure

One consultant per each center performed all the procedures. Use of either sheath was as per availability in the operation theater and at the surgeons' discretion. RIRS was done as per the standardized description.[13] The steps were standardized into (1) positioning the patient in lithotomy position, (2) cystoscopy, placement of a guidewire (Sensor, Boston Scientific, Marlborough, MA or Soloplus, BD, Franklin Lakes, NJ) in the PCS, (3) on table retrograde pyelogram to delineate upper urinary tract anatomy and semirigid ureteroscopy to assess ureteral permeability, (4) insertion of FANS in the ureter by railroading over the guidewire under fluoroscopy and removal of the guidewire, (5) ensuring the tip of the sheath is placed across the ureteropelvic junction, and (6) deploying an 8 Fr disposable scope (Innovex, Innova Medical Equipment Co., Shanghai, China) in a 12 Fr sheath and 7.5 Fr disposable scope (Uscope, Pusen Medical, Guangdong, China) for a 10 Fr sheath. Irrigation was provided using the attached TRAXER-FLOW Dual Port Gravity Line (Rocamed, Southborough, Massachusetts). After an initial diagnostic check, the sheath was tested for both active (with scope in situ, Fig. 2A) and passive deflection (without the scope, Fig. 2B) to the desired calyx of choice before commencing lithotripsy. Lithotripsy was carried out using either a Thulium fiber laser (TFL) (Urolase SP 60W, IPG Photonics, Oxford, MA) or Holmium laser (Lumenis PULSE 120H,Boston Scientific, Marlborough, MA) with a 200-micron laser fiber in all cases. The primary modality was dusting and popcorning was deployed when needed. The laser setting was 0.4 J and 40 Hz for the Holmium laser and 0.2-0.4 J and 200-400 Hz for TFL. No stone was relocated as FANS were able to suck out the dust and fragments in situ. Suction was applied by connecting the Y junction at the distal end of the sheath (Fig. 1) with tubing to either a wall-mounted or portable vacuum machine. The initial pressure was set to 0.02 MPa (as recommended by the manufacturer) and increased in a stepwise fashion as was deemed necessary intraoperatively by maintaining an appropriate irrigation flow rate to allow for proper perfusion of the PCS. Vacuum was applied and dust was aspirated by suction either during active laser lithotripsy or post-lithotripsy. Further, fragments could directly be aspirated via the sheath by withdrawing the scope to the Y junction mimicking the Venturi effect based on the Bernoulli principle as has been proven in suction-guided percutaneous nephrolithotomy.[14] An option to attach a stone collecting chamber to the suction tubing is also available.

Postprocedure, on-table visual inspection of the PCS and entire ureter along with a retrograde pyelogram was done to document the assessment of SFR as well as the presence of any collecting system injury. Immediately after the procedure, the ureteroscope and sheath used were physically inspected and documented for any signs of tip damage. The need for postoperative stenting was left to the surgeon's discretion. Surgical

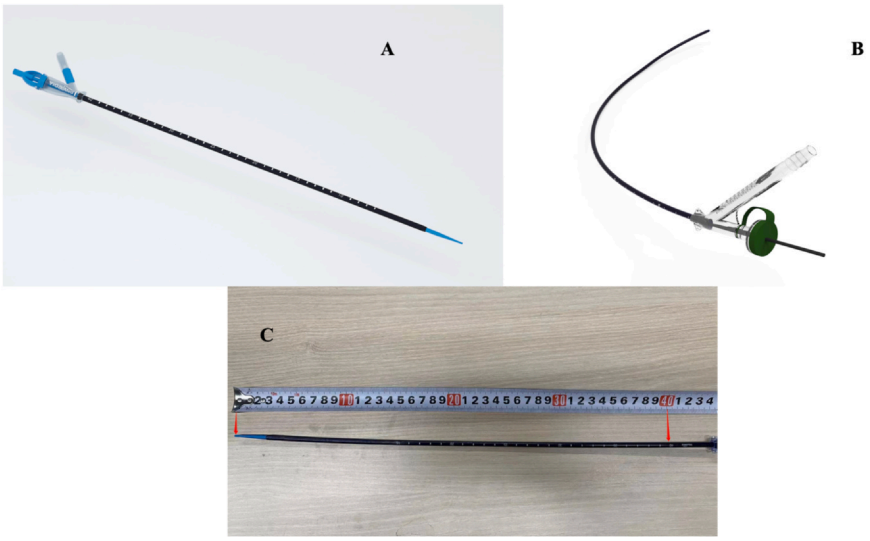

Figure 1. **(A)** First generation Elephant II sheath (12 French). **(B)** Second generation Elephant II sheath (10 French). **(C)** Length of first generation Elephant II from the dilator tip to the end of dilator mark (40 cm). (Color version available online.)

time was considered from insertion of the cystoscope to insertion of the stent.

Statistical Analysis

Using a 5-point Likert scale, data was gathered by the surgeon's evaluation of the performance of each sheath used in ease, maneuverability, and intraoperative visibility whilst using the sheath during lithotripsy. Continuous variables are presented as median and 25th-75th percentiles. Categorical variables are reported as absolute frequency and percentage. Patients were divided into 2 groups according to FANS size. Group 1 had 12 Fr and Group 2 had 10 Fr sheath. The Mann-Whitney *U*-test was used to assess the difference between the 2 groups for continuous variables, whereas the chi-square test for categorical ones. Statistical significance was set at a 2-tailed *P*-value < 0.05. Statistical tests were conducted using the SPSS software package version 25.0 (IBM Corp., Armonk, NY).

RESULTS

Table 1 shows baseline demographic and intraoperative parameters. Thirty-one patients were included. There were 16 patients in Group 1 and 15 patients in Group 2. Four patients in Group 2 had the same session bilateral RIRS (35 renal units in total). Age, gender, comorbidity, prior stone treatments, reasons for presentation, lower pole pelvic-caliceal angle $< 90°$, and stone parameters were similar between the 2 groups. A significantly larger number of renal units were presented in Group 2 (52.6% vs 12.5%, $P = 0.013$). This was because all 4 of the patients with bilateral stones were pre-stented bilaterally. Two patients in both groups had elective pre-stenting for a staged procedure. No significant difference was noted in total surgical time.

With regards to the Likert score, the 10 Fr FANS had a higher percentage of excellent scores for ease of use, manipulation, and visibility. Neither of the sheaths had an average or difficult rating for all evaluation scales. Sheath insertion was successful in all renal units but 1. All remaining procedures

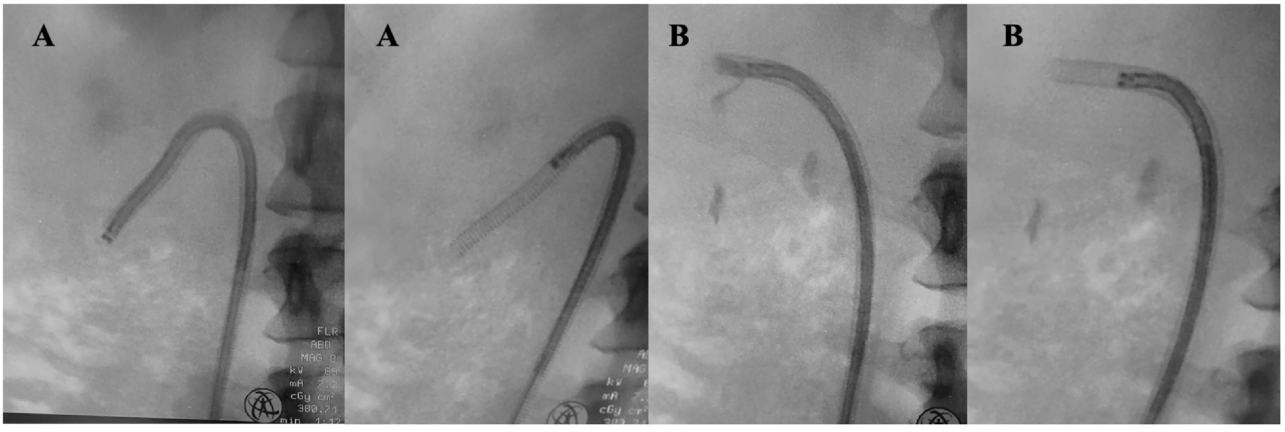

Figure 2. **(A)** Fluoroscopic view of active deflection of Elephant II sheath (with scope in situ) before lithotripsy. **(B)** Fluoroscopic view of passive deflection of Elephant II sheath (without scope in situ) before lithotripsy.

Table 1. Patient baseline and intraoperative characteristics.

	Group 1 (12 French) (N = 16; Renal Unit=16)	Group 2 (10 French) (N = 15; Renal Unit=19)	*P*-value
Age, median (25th-75th percentile)	39.5 (33.25-53.50)	55 (32.0-67.0)	0.136
Male, n (%)	11(68.7)	10 (66.7)	0.474
Comorbidity	0	2 (13.3)	0.527
Heart disease	2 (12.5)	3 (13.3)	
Diabetes	2 (12.5)	1 (6.7)	
Hypertension			
Kidney Right side§, n (%)	10 (62.5)	10 (52.6)	0.557
ASA score, n (%)	12 (75)	11 (73.4)	0.251
1	4 (25)	2 (13.3)	
2	0	2 (13.3)	
3			
Positive urine culture, n (%)	1 (6.3)	5 (33.3)	0.100
Previous SWL, n (%)	3 (18.8)	0	**0.048**
Previous RIRS, n (%)	1 (6.3)	2 (13.3)	0.377
Previous PCNL, n (%)	1 (6.3)	0	0.269
Pre-stented§, n (%)	2 (12.5)	10 (52.6)	**0.013**
Reason for prestenting§, n (%)	1 (6.3)	4 (26.7)	0.097
Pain	0	4 (26.7)	
Sepsis	2 (12.5)	2 (13.3)	
Elective	0	0	
Failed RIRS			
Lower Pole Pelvic-Caliceal angle < 90§, n (%)	2 (12.5)	7 (36.8)	0.101
Multiple Stones§, n (%)	12 (75)	15 (79)	0.782
Past stone surgery, n (%)	3 (18.8)	4 (26.7)	0.558
Stone size in mm§, median (25th-75th percentile)	21 (17.0-24.25)	19 (12.0-22.0)	0.182
HU§, median (25th-75th percentile)	984 (725.0-1039.75)	1050 (970.0-1200)	0.057
Bilateral RIRS, n	0	4	
Surgical time, minutes, median (25th-75th percentile)	63 (52.0-74.5)	76 (63.0-85.25)	0.092
Maneuverability into all calyces§, n (%)	14 (87.5)	16 (84.2)	0.782
Successful sheath insertion§, n (%)	16 (100)	18 (94.7)	0.891
Subjective evaluation of surgeon (ease of using Suction UAS	6 (37.5)	10 (52.6)	0.567
procedure)§, n (%)	9 (56.3)	7 (36.8)	
Excellent	1 (6.3)	2 (10.6)	
Very good	0	0	
Good	0	0	
Average			
Difficult			
Manipulation§, n (%)	5 (31.3)	8 (44.4)	0.728
Excellent	9 (56.3)	8 (44.4)	
Very good	2 (12.5)	3 (11.2)	
Good	0	0	
Average	0	0	
Difficult			
Visibility§, n (%)	11 (68.8)	16 (84.2)	0.147
Excellent	5 (31.3)	3 (15.8)	
Very good	0	0	
Good	0	0	
Average	0	0	
Difficult			
Sheath damage due to lasering§, n (%)	1 (12.5)	0	0.122

ASA, American Society of Anaesthesiologists; HU, Hounsfield units; RIRS, retrograde intrarenal surgery; SWL, shock-wave lithotripsy
§ Data calculated from all renal units.
Bold value stands for statistical significance.

were successfully completed with no necessity to remove or replace the sheath with a standard UAS. The tip of one of the 12 Fr FANS was found damaged due to laser burn but it was easy to remove and did not affect the case.

Table 2 shows postoperative outcomes. 18 of the 31 patients who were observed overnight had only a ureteric catheter placed instead of a double J stent and the catheter was removed before discharge. There was a fornix rupture requiring prolonged stenting (Clavien Grade 2) in Group 2. All patients were discharged within 24 hours of surgery with no readmission. One patient in each group visited the emergency department and both had outpatient analgesic treatment for pain (Clavien grade 1).

At 3-month follow-up, the SFR of renal units was significantly higher in Group 2 (94.7% vs 68.8%, $P = 0.01$). No

Table 2. Postoperative outcomes.

	Group 1 (12 French) (N = 16; Renal Unit=16)	Group 2 (10 French) (N = 15; Renal Unit=19)	p
Emergency visit, n (%)	1 (6.3)	1 (5.3)	0.282
Fever, n (%)	0	0	
Sepsis, n (%)	0	0	
Transient hematuria, n (%)	0	0	
Blood transfusion, n (%)	0	0	
Arterio-venous fistula, n (%)	0	0	
Urinary fistula, n (%)	0	0	
Complications causing the abandonment of the procedure, n (%)	0	0	
Fornix rupture§, n (%)	0	1 (5.3)	0.339
Pelvis perforation, n (%)	0	0	
Ureteral perforation, n (%)	0	0	
Ureteral avulsion, n (%)	0	0	
SFR*§, n (%)	11 (68.8)	18 (94.7)	**0.01**
RF > 4 mm, n (%)	0	0	
Multiple RF§ ≤ 2 mm at 3-month, n (%)	11 (68.8)	1 (5.3)	**0.001**
Site of single§ RF, n (%)			**0.019**
Lower pole	2 (12.5)	1 (5.3)	
Middle pole	3 (18.8)	0	
Upper pole	0	0	

RF, residual fragments; SFR, stone-free rate.
*single RF > 2 mm. § data calculated from all renal units.
Bold value stands for statistical significance.

patient had RF larger than 4 mm. The presence of multiple RF ≤ 2 mm was significantly higher in Group 1 (68.0% vs 5.3%, $P = 0.001$).

DISCUSSION

The efficacy of endourological interventions including RIRS is determined by their ability to provide a high if not 100% single-stage SFR[15] and safety lies in preventing any infective and iatrogenic injuries during the procedure.[8,16,17] UAS usage has been a boon and a bane for RIRS with recent studies confirming that UAS lowers IRP and intrarenal temperature by increasing irrigation outflow during RIRS.[18,19] Data on the impact of a UAS on SFR, postoperative pain, and risk of infectious complications was inconclusive. Importantly, the research highlighted that the use of TFL and high-power Holmium laser, smaller UAS, using digital ureteroscopes and devices with integrated pressure-measuring and aspiration technology could help to increase SFR and decrease pressure and temperature-related complications.

In our study with the use of both FANS, there were no intra or postoperative complications reported, either septic or traumatic in nature except for a fornix rupture requiring prolonged stenting. Our findings validate other studies which have used SUAS[20–22] and have shown better outcomes than non-SUAS. By adding suction, the post-RIRS systemic inflammatory response is decreased[23,24] as low IRP and intrarenal temperature prevent the harm caused by pyelovenous and pyelolymphatic reflux.[25] This finding was confirmed by our zero infectious complication rate, despite this resulting from a small cohort.

Quhal et al proposed that suctioning could help remove debris and fragments during laser lithotripsy and reduce IRP and, at the same time, allow for increased irrigation flow, potentially decreasing operation time and infectious complications.[9] This helps to minimize complications, maximize the outcomes of RIRS, and patient discharge on the same day. Indeed, our study confirms these findings with all patients discharged home within 24 hours. By adding suction, we were able to have good vision as simultaneously the dust, created was being aspirated, preventing the snow globe effect often seen and allowing visualization of the remaining stone for a focused laser lithotripsy.[9]

FANS sheath is different from the older generation of SUAS and unique in several aspects. Firstly, unlike the older sheaths, its salient advantage is that the proximal 10 cm of the tip is flexible and navigable into the desired calyx both by active and passive deflection especially if there is a dilated system. This was not possible with any other prior known UAS with and without suction. Yet, the second unique feature of FANS is that suction works in the UAS even with the tip bent in all calyces, including the lower pole and we did not find any mechanical failure problem or in the suctioning ability. Finally, unlike the other traditional SUAS, an added advantage of FANS was that by trapping the stone in the UAS, the retropulsion of stone fragments could be avoided and even in situ laser lithotripsy (ie, within the sheath) could be done with simultaneously aspirating the dust particles. This completely negate the need for a basket deployment for either stone repositioning from the lower pole or fragment extraction.

In our observation, the 10 Fr FANS fared superiorly to 12 Fr especially when the infundibulum-pelvic angle was more acute.[26] Even in cases with acute infundibulum-pelvic angles, there was no reported failure to do so with either sheath. Whilst we do see that the commonest occurrence of RF is in the lower and middle poles, even those were < 2 mm. All lower pole fragments could be removed, resulting in an on-table complete clearance with a possibility of 100% SFR that was then ascertained by CT the following day. We could speculate that the suction mechanism also worked better in the 10 Fr FANS which had a 7.5 Fr slim scope allowing for the fragments to easily back into the sheath at active suctioning. This could be related to a better flow rate considering the bigger 7.5/10 Fr ratio of Endoscope-Sheath Diameter versus the 8/12 Fr combination (0.75 vs 0.66) which plays a very crucial role in IRP and flow rate.[27]

Our series had large, multiple, and bilateral stones in all locations. The ability to aspirate dust, and navigate the flexible tip while simultaneously suctioning fragments has a 3-fold advantage as reflected in our results of high single-stage SFR which was confirmed by post-operative CT scan. This innovative modality could help to improve the success of RIRS as was proposed in our recent study on RIRS with suction.[4]

Whilst this is the first-ever clinical use, we feel that FANS may contribute to shortening the operative time, even in the case of same-session bilateral surgery.[28] Despite the large stone burden in our series, the median surgical time was 63 minutes for Group 1 and 76 minutes for Group 2 respectively. The difference was mainly due to 4 patients requiring bilateral procedures in the latter. Although surgeons were highly experienced in RIRS with a dedicated fellowship training in endourology, we acknowledge that there is a two-case learning curve to successfully manipulate the sheath and scope. FANS is not only a novel concept but one where the surgeon has to play a dynamic role in both navigating the sheath to the desired calyx as well as intermittently withdrawing the scope in the sheath to the Y junction when fragments need to be aspirated. We do recommend that until sufficient experience is gained this is preferably done under fluoroscopic guidance.

Whilst there are limitations to our study of note being not randomized, it is an evaluation where all steps of RIRS were done exactly as it is advocated in the current standard of practice.[13] Since the only variable is the FANS, our promising results with this device make it a very strong contender for routine use. The significant finding that we were able to deploy both sheaths in all patients irrespective of presenting status,[29] with no device failure and no infective complications despite using a smaller UAS are reasonably enough to adopt this in practice. Its success in bilateral RIRS procedures could mean that the same session bilateral endoscopic surgery by RIRS is indeed ready for prime time. A larger, multicenter study where surgeons with variable levels of expertise are the only way to certify the findings of our study.

CONCLUSION

In our feasibility study, we found that the 10 Fr FANS with a 7.5 Fr ureteroscope combination showed higher SFR than 12 Fr/8 Fr combination. No patient had any infectious complications. FANS have the potential to minimize the need for accessories and additional interventions, making this a potential game changer if replicated in future studies.

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Declaration of Competing Interest

Olivier Traxer is a consultant for Coloplast, Rocamed, EMS, Boston Scientific, and IPG. Ben Hall Chew is a consultant for Boston Scientific and The ureteral Stent Company. The remaining authors declare no conflict of interest.

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