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Prospective, Real-World Evaluation of CVAC 2.0 In-Scope Aspiration System Compared with Flexible and Navigable Ureteral Access Sheath for High-Volume Stone Disease

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Abstract

Purpose: To compare stone clearance, stone-free status, and complications between patients undergoing ureteroscopy for renal stones using either Flexible and Navigable Ureteral Access Sheath (FANS) or the CVAC 2.0 system.
Materials and Methods: A prospective study was completed on patients undergoing flexible ureteroscopy for renal stones at a single institution from March 2024 to December 2024. Subject demographics, intra-op data, volumetric and single-dimension stone clearance on non-contrast CT, and complications were compared. Stone-free rates (SFRs) using standardized cutoffs were compared. Pearson correlation analysis was performed to assess the relationship between preoperative stone volume and postoperative stone burden. Subanalysis was performed for patients with preoperative stone burden >1.5 cm.
Results: A total of 123 cases (CVAC 2.0-36, FANS-87) were included, with 64 eligible for volumetric analysis. Preoperative stone volume was larger in the CVAC group *vs* FANS (1075 mm^3 *vs* 397 mm^3; $p < 0.001$). Absolute stone clearance was greater in the CVAC group (1016 mm^3 *vs* 392 mm^3; $p < 0.001$), whereas residual stone volume (4.1 mm^3 *vs* 15.0 mm^3; $p = 0.55$) and SFRs (90% *vs* 81%; $p = 0.48$) were similar. In individuals with >1.5 cm preoperative stone burden, relative stone clearance was greater with CVAC 2.0 (98.9% *vs* 95.1%; $p = 0.026$). Pearson correlation analysis revealed positive linear relationship between preoperative stone volume and residual stone volume for FANS, but not for CVAC 2.0.
Conclusions: In this comparative study of FANS and CVAC 2.0, over 95% stone clearance was observed in both groups despite large initial stone burdens. In contrast to FANS, residual stone volumes with CVAC 2.0 did not increase significantly with increasing preoperative stone volumes.

Keywords: ureteroscopy, suction, nephrolithiasis, stone volume

Introduction

A myriad of new technologies have been developed to introduce stone fragment evacuation to ureteroscopy. Flexible And Navigable Ureteral Access Sheaths (FANSs) offer passive suction to evacuate dust during laser ablation and also allow for evacuation of fragments by withdrawing the ureteroscope to the end of the sheath.[1] FANS has been shown to yield improved stone-free rates (SFRs) compared with traditional flexible ureteroscopy (fURS) in several comparative studies, including randomized trials.[2–5] FANS also reduces intrarenal pressure with associated decreased infectious complications.[2,4] Despite this, studies have demonstrated lower SFR with the FANS system for larger stone volumes >1500 mm^3.[6]

Steerable ureteroscopic renal evacuation (SURE) is an alternative strategy to FANS that utilizes built-in irrigation and aspiration channels within a single device. The first generation CVAC® System (Calyxo, Pleasanton, CA) consisted of a radiographically directed dual lumen catheter capable of fragment aspiration, which was shown to achieve effective stone clearance for large stone volumes.[7,8] A recently published randomized control trial reported that the SURE system achieved a noninferior SFR compared with conventional ureteroscopy with superior stone clearance.[7] The second generation of this technology (CVAC 2.0®, Calyxo) includes separate, simultaneously acting aspiration and irrigation channels built into a 11.9F digital ureteroscope for visualization of real-time aspiration. There are no published data available regarding the safety and efficacy of this novel system.

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Data in progress for this study were previously presented at the American Urologic Association Annual Meeting (2025, Las Vegas, NV), and published abstract is found at https://doi.org/10.1097/01.JU.0001110072.52045.9d.04.

In this study, we prospectively compared the safety and efficacy of FANS (ClearPetra®, Wellead, Guangzhou, China) and CVAC 2.0 in treating renal stone burden from March 2024 to December 2024. We sought to compare volumetric stone clearance, SFR, and 30-day complication rates in FANS *vs* CVAC 2.0 augmented ureteroscopy. We hypothesized that CVAC 2.0 would achieve improved stone clearance compared with FANS with similar safety outcomes.

Patients and Methods

This was a prospective, nonrandomized study performed at a single tertiary care center from March 2024 to December 2024 after obtaining institutional review board approval for creation of a CVAC and FANS research registry (IRB #24-007550). Selection of CVAC 2.0/FANS for each individual case was determined by surgeon preference. All procedures were performed by two fellowship-trained endourologists. Follow-up imaging was requested 1–3 months after fURS unless a planned staged procedure was to be performed.

Adults undergoing ureteroscopy using either device for renal stones of any diameter with or without associated ureteral stones were eligible. Safety data were analyzed for the entire cohort. If a sheath was not able to be passed, the patient was excluded from analysis. For inclusion into analysis for stone clearance and SFR outcomes, patients were required to have a pre- and postoperative CT scan with ≤3.75 mm slices. Patients undergoing planned staged procedures, those with significant nephrocalcinosis, and those without complete CT imaging were excluded from SFR/stone clearance analysis. Patients excluded from volumetric analysis were included in safety analysis to assess infection rates and complications regardless of whether postoperative cross-sectional imaging was obtained.

Baseline and operative characteristics

We gathered baseline and intraoperative characteristics for all patients. Cumulative stone diameter was assessed on preoperative CT scan by determining maximal single-dimension diameter of each individual ipsilateral renal stone using bone windows. The combined diameter of all ipsilateral stones was used to calculate the cumulative stone diameter. Preoperative ureteral stones were only included in preoperative measurements if they were pushed up into the kidney (and not completely treated in the ureter). Preoperative stone volume was measured using Quantitative Stone Analysis Software (QSAS) (Mayo Clinic, Rochester, MN).[9,10] Investigator review of QSAS stone segmentation was performed to screen for and subtract any artifact.

Laser choice (Holmium/Thulium Fiber Laser) was up to surgeon preference and was recorded along with total laser energy and operative time. Intraoperative complications and device-related complications were assessed. The ureter was inspected at time of procedure termination with injuries graded on Traxer scale.[11]

Imaging and outcomes

Postoperative CT abdomen/pelvis was obtained within 3 months of index operation in patients otherwise eligible for volumetric analysis ($N = 75$) with 19 receiving ultrasound and thus excluded. Postoperative stone outcomes included single-dimension outcomes (cumulative residual diameter, diameter of largest single residual fragment) and volumetric outcomes (cumulative residual volume). As with the recent SURE randomized trial, we defined relative stone clearance as the proportion of preoperative stone volume cleared (Supplementary Fig. S1).[7] SFR was defined according to criteria utilized in the ASPIRE trial (Table 1) with SFR-4 defined as patients meeting Grade A, B, or C status (≤4 mm fragments or no residual fragments present). We performed a planned subanalysis of individuals with >1.5 cm preoperative cumulative stone burden for our primary outcome variables.

Surgical technique

Regardless of device, ureteral evaluation with a semi-rigid ureteroscope (8.5F, Storz) was attempted before access sheath insertion. In CVAC 2.0 cases, we attempted to place a 12/14F ureteral access sheath up to the proximal ureter. The CVAC 2.0 scope allows for passive removal of small fragments during lithotripsy through a distinct aspiration channel. Once fragments were small enough for removal, the laser bridge of the scope was removed and fragments aspirated using the 7F working channel. In the FANS group, we exclusively utilized the 11/13F ClearPetra sheath (Wellead, Guangzhou, China) and a Dornier® Axis (8.5F) flexible ureteroscope. Lithotripsy strategy and laser choice (Supplementary Appendix A) were determined by surgeon preference. In both groups, initial irrigation was provided via a ThermedX® system set to 150 mm Hg, and wall suction was set to 150 mm Hg.

Statistical methods

Comparisons between groups were performed using Wilcoxon tests for continuous variables and Fisher's exact tests for categorical variables. Pearson correlation analysis assessed for the interaction between preoperative stone volume and postoperative residual stone volume as well as relative stone clearance.[7] Stratified multivariable linear regression was performed to assess for the impact of preoperative stone volume on residual stone volume. Statistical analyses were performed using R version 4.4.1 (Vienna, Austria).

Results

From March 2024 to December 2024, 123 patients underwent ureteroscopy with CVAC 2.0 ($N = 36$) or ClearPetra FANS ($N = 87$). Demographic variables and comorbidities were similar between groups. A 12/14F sheath was able to be placed in all included CVAC cases. Patients treated with CVAC 2.0 were more likely to have been prestented before index ureteroscopy and had a significantly larger preoperative stone volume (1021 mm^3 *vs* 392 mm^3, $p < 0.001$). Lower pole stone burden >1.5 cm and primary stone composition did not differ between groups (Supplementary Table S1). Concordantly, 7 CVAC cases (19.4%) required planned second-stage ureteroscopy compared with 6 FANS cases (6.9%, $p = 0.05$; Supplementary Appendix B).

Table 1. Comparison of Volumetric (1A), Stone Free (1B), and Operative Data (1C) for Patients Undergoing Ureteroscopy with CVAC 2.0 or Flexible and Navigable Ureteral Access Sheath

	CVAC 2.0 (N = *21*)	*Flexible and navigable ureteral access sheath (FANS)* (N = *43*)	p-*Value*
A. Volumetric data			
Preoperative volume (mm^3)	1075 (845–1481)	397 (133–583)	<0.001
Postoperative volume (mm^3)	4.1 (1.3–6.1)	15 (1.0–33.5)	0.55
Postoperative cumulative stone diameter (mm)	2.9 (0.9–6.1)	3.4 (0–6.25)	0.92
Absolute stone volume reduction (mm^3)	1016 (734–1414)	392 (132–528)	<0.001
Relative stone clearance (% stone volume reduction)	98.8 (95.7–99.6)	96.0 (86.9–99.8)	0.24
B. Stone-free data			
Stone-free grade[a]	*N* = 21	*N* = 43	
Grade A (no residual fragments)	4 (19)	12 (28)	0.54
Grade B (≤2.0 mm fragments)	8 (38)	22 (51)	0.42
Grade C (2.1 to ≤4.0 mm fragments)	19 (90)	35 (81)	0.48
Not stone free	2 (10)	8 (19)	
C. Operative data			
Operative time (minutes)	102 (73–130)	74 (58–115)	0.24
Laser energy (kJ)	6.8 (5.2–15.9)	3.1 (1.0–7.6)	<0.001
Laser type			0.014
Holmium	9 (25.7)	6 (7.5)	
Thulium	26 (74.3)	74 (92.5)	

Analysis includes individuals with eligible pre- and post-op CTs. All continuous variables expressed as median (IQR), whereas categorical variables expressed as *N* (%). Wilcoxon ranked sum test was used for continuous variable comparisons and Fisher's exact test for categorical variables.

[a]Stone Free Grading as per Endourology Society guidelines. Grade (A) no stone fragments, totally stone free. Grade B—inclusive of any patients meeting A criteria PLUS patients with residual stones ≤2.0 mm. Grade C—Patients meeting A or B criteria plus individuals with 2.1 to ≤4.0 mm stones. Grade C and SFR-4 are equivalent in referring to absence of residual fragments >4.0 mm.

IQR = interquartile range; SFR = stone-free rate.

Volumetric and Stone-Free Data

Sixty-four patients (*N* = 21 CVAC, *N* = 43 FANS) were eligible for volumetric analysis with available cross-sectional imaging (Table 1A). Despite higher preoperative stone burden, residual stone volume was similar between CVAC 2.0 (4.1 mm^3, interquartile range [IQR] 1.3–6.1) and FANS groups (15 mm^3, IQR 1.0–33.5; $p = 0.55$). Absolute stone volume reduction was greater in the CVAC 2.0 group (1016 mm^3 *vs* 392 mm^3; $p < 0.001$). Among patients treated with CVAC, 98.9% of stone burden was cleared compared with 96% in patients treated with FANS ($p = 0.24$). SFRs by stone-free grading criteria are shown in Table 1B. Notably, SFR-C or better was achieved in 90% of patients treated with CVAC 2.0 *vs* 81% of patients in the FANS group. Laser energy was greater in the CVAC 2.0 group, and the holmium laser was more commonly used (Table 1C).

On subanalysis of individuals with >1.5 cm stone burden (*N* = 41; Table 2), preoperative stone volume remained significantly higher in the CVAC 2.0 group (1079 mm^3 *vs* 490 mm^3; $p < 0.001$). Cumulative residual stone volume was minimal (<5 mm^3) and was similar between groups with absolute stone volume reduction being greater with CVAC (1049.5 mm^3 *vs* 467.2 mm^3; $p < 0.001$). Relative stone clearance was greater in the CVAC 2.0 group (98.9% *vs* 95.1%; $p = 0.026$) despite similar operative time.

Pearson correlation analysis revealed that with FANS, there was a significant positive linear association between preoperative stone volume and residual stone volume ($R = 0.51$, $p = 0.005$). In contrast, there was no significant association between preoperative stone volume and residual stone volume with CVAC 2.0 (Fig. 1A). Relative stone clearance did not correlate with preoperative stone volume for CVAC 2.0 or FANS (Table 1B).

Multivariable linear regression for residual stone volume

Analysis of eligible (*N* = 64) patients for the combined cohort showed that neither device type nor preoperative volume was independently predictive of postoperative residual stone volume (Table 3). With FANS, for every 10 mm^3 increase in preoperative volume, there was a 1 mm^3 increase in residual stone volume ($\beta = 0.10$, $p < 0.001$). There was no significant association between pre-op volume and residual volume for CVAC 2.0.

Complications

Safety outcomes and complications did not differ significantly between groups (Supplementary Table S2). There was a total of 10 device-related complications all related to sheath/scope ureteral injuries (*N* = 1/36 CVAC 2.0, *N* = 9/87 FANS; $p = 0.28$), of which 5 were Traxer Grade I. Thirty-day infectious complication was rare and did not differ according to device type (CVAC 8%, FANS 3%; $p = 0.10$). All ureteral injuries were managed with stenting alone.

Discussion

In this study, we found that stone fragment aspiration with the CVAC 2.0 ureteroscope achieved clearance of over 98% of preoperative stone burden, despite high initial stone

Table 2. Comparison of Volumetric (2A), Stone Free (2B), and Operative Data (2C) for Patients Undergoing Ureteroscopy with CVAC 2.0 or Flexible and Navigable Ureteral Access Sheath with Preoperative Cumulative Stone Diameter >1.5 cm

	CVAC 2.0 (N = *20*)	*Flexible and navigable ureteral access sheath (FANS)* (N = *21*)	p-*Value*
A. Volumetric data			
Preoperative volume (mm^3)	1079 (863–1529)	490 (375–879)	<0.001*
Postoperative volume (mm^3)	14.5 (3.5–70.0)	23.0 (11–125)	0.33
Postoperative cumulative stone diameter (mm)	3.5 (1.2–6.2)	5.6 (3.1–11.7)	0.18
Absolute stone volume reduction (mm^3)	1049.5 (790.3–1469)	467.2 (301.0–641.0)	<0.001*
Relative stone clearance (% Stone volume reduction)	98.9 (94.9–99.7)	95.1 (95.6–98.4)	0.026*
B. Stone-free data			
Stone-free grade[a]			
Grade A (no residual fragments)	4 (20)	3 (14)	0.70
Grade B (≤2.0 mm fragments)	7 (35)	8 (38)	1.0
Grade C (2.1 to ≤4.0 mm fragments)	18 (90)	13 (62)	0.067
Not stone free	2 (10)	8 (38)	
C. Operative data			
Operative time (minutes)	110 (81–131)	110 (70–140)	0.79
Laser energy (kJ)	7.0 (5.4–16.2)	3.8 (1.8–10.3)	0.07
Laser type			0.047*
Holmium	5 (25)	0 (0)	
Thulium	15 (75)	20 (100)	

Analysis includes individuals with eligible pre- and post-op CTs. All continuous variables expressed as median (IQR), whereas categorical variables expressed as *N* (%). Wilcoxon ranked sum test was used for continuous variable comparisons and Fisher's exact test for categorical variables.

[a]Stone-Free Grading as per Endourology Society guidelines. Grade (A) no stone fragments, totally stone free. Grade B—inclusive of any patients meeting A criteria PLUS patients with residual stones ≤2.0 mm. Grade C—Patients meeting A or B criteria plus individuals with 2.1 to ≤4.0 mm stones. Grade C and SFR-4 are equivalent in referring to absence of residual fragments >4.0 mm.

*denotes statistical significant values.

burden of >1000 mm^3. Residual stone volumes and SFR after a single-session ureteroscopy were similar between FANS and CVAC despite patients treated with CVAC 2.0 having higher initial stone volumes. Although residual stone burden increased with large preoperative stone burden for FANS, residual stone volume was independent of preoperative stone volume for CVAC 2.0. To our knowledge, we are the first to present comparative data with CVAC 2.0 and FANS, highlighting effective stone clearance for both modalities with an advantage for CVAC 2.0 in the context of larger stone burdens.

Given existing evidence suggesting that both conventional ureteroscopy and FANS may decrease in efficacy for larger stone burdens, we sought to assess the efficacy of CVAC 2.0 in this role. Subanalysis of individuals with >1.5 cm of preoperative stone burden found that absolute stone clearance was greater with CVAC 2.0 (although starting volume was higher as well). Relative stone clearance was also higher with CVAC 2.0 (98.9% *vs* 95.1%) in this group. Furthermore, linear regression analysis revealed that when using FANS, as preoperative stone burden increased, so did residual stone volume. This finding is similar to a recent, multi-institutional FANS study by Gauhar and coworkers who found that preoperative stone volumes >1500 mm^3 were associated with 50% reduced odds of Grade A SFR.[6] Especially with preoperative stone volumes >500 mm^3, we observed greater variability in residual stone volumes after URS with FANS (Fig. 1).

In contrast, we found no significant association between increasing pre-op stone volume and residual stone volume after URS with CVAC 2.0. This parallels recent findings of the ASPIRE randomized trial in which the radiographically steered aspiration catheter predecessor of the CVAC 2.0 scope was used. Matlaga and associates found a median residual volume of 11.7 mm^3 (with preoperative volume of 490 mm^3) after ureteroscopy with this device and found no association between preoperative volume and residual volume ($r = 0.24$; $p = 0.11$).[7] Collectively, although we observed overall similar SFR with FANS and CVAC 2.0, we observed that CVAC 2.0 achieved high stone clearance independent of preoperative volume. This provides intriguing evidence that CVAC 2.0 may represent size-indeterminant treatment option effective in stone clearance for patients with larger stone burdens that may not be ideal candidates for percutaneous intervention.

We did observe SFR-Grade A that was lower than some multicenter single-arm studies on FANS. For instance, in their multicenter trial of 394 patients, the observed Grade A SFR was 57.4% (CT slice thickness not reported) compared with 28% with FANS and 19% with CVAC 2.0 in our cohort.[6] The majority of postoperative CT scans were obtained at our center, with ultrathin slices (0.6 mm) available and used for automated stone segmentation with QSAS and manual postoperative residual fragment measurements. Use of thinner slices likely increased detection of smaller fragments that could have been otherwise missed. Future studies should report postoperative imaging slice parameters and attempt to standardize these protocols.

Residual fragments >4.0 mm have been consistently associated with an increased risk of stone-related complications.[12–15]

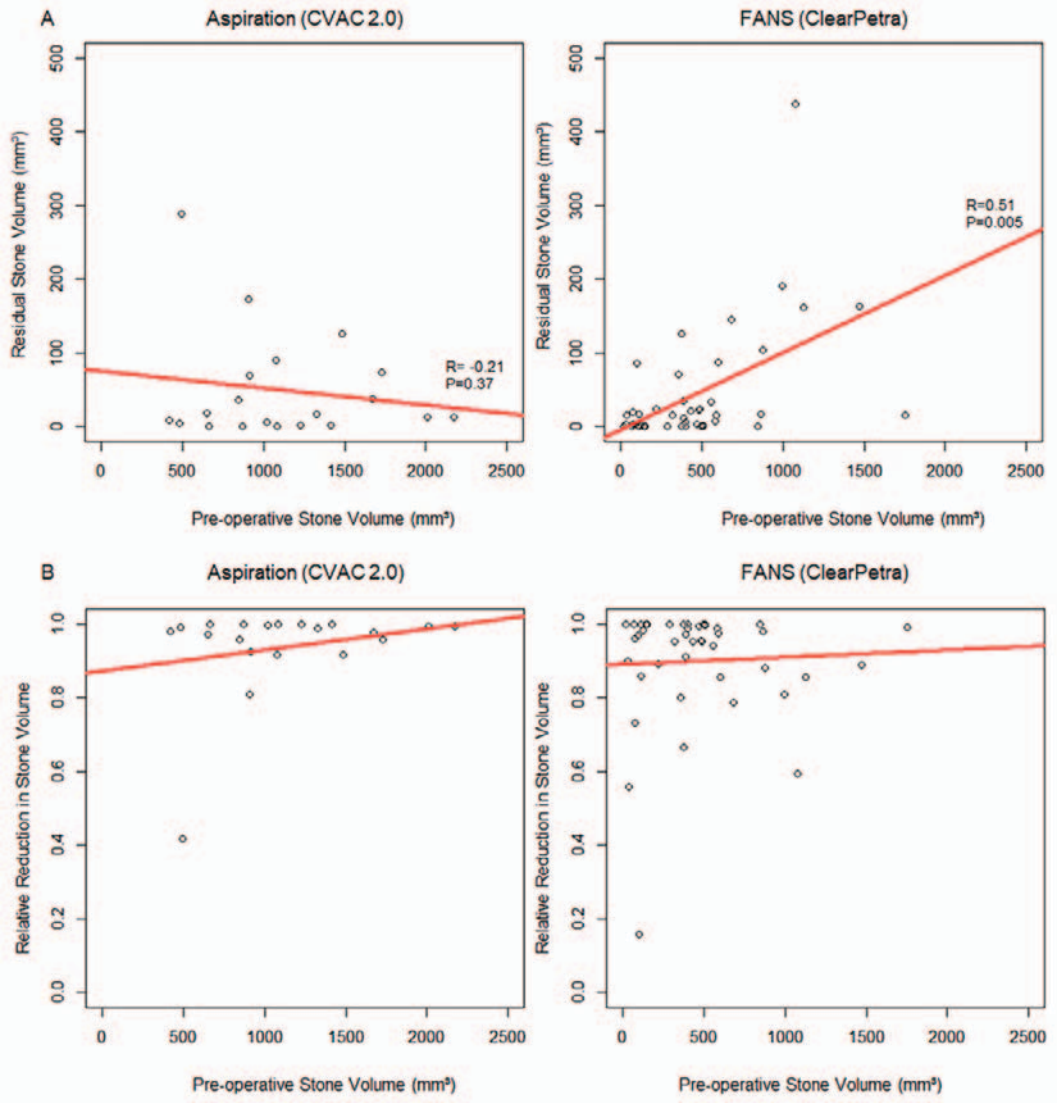

FIG. 1. Pearson correlation analysis of preoperative stone volume (mm^3) *vs* residual stone volume (**A**) and Relative Reduction in Stone Volume (**B**) for CVAC 2.0 and ClearPetra FANS. R denotes Pearson correlation coefficient. FANS = Flexible and Navigable Ureteral Access Sheath.

We observed that in patients with >1.5 cm preoperative stone burden, 90% of those treated with CVAC 2.0 and 62% of those treated with FANS were free of residual fragments >4 mm. It is important to note, however, that absolute SFR (zero residual fragments) was lower in this group (20%-CVAC, 14%-FANS). Percutaneous approaches remain guideline recommended for stone burdens >2 cm because of superior SFRs compared with ureteroscopy, with ongoing trials aimed at comparing PCNL to FANS for these large stone burdens.

Table 3. Multivariable Linear Regression for Associations with Residual Stone Volume After Ureteroscopy with CVAC 2.0 or Flexible and Navigable Ureteral Access Sheath

	Beta coefficient	*Standard error*	p-*Value*
Model 1—Combined patient population ($N = 64$)			
Preoperative volume (mm^3)	0.03	0.02	0.12
Device type (ref: CP)			
CVAC	−20.51	25.34	0.42
Model 2—CVAC 2.0 ($N = 21$)			
Preoperative volume (mm^3)	−0.02	0.02	0.37
Model 3—FANS ($N = 43$)			
Preoperative volume (mm^3)	0.10	0.03	<0.001

FANS = Flexible and Navigable Ureteral Access Sheath.

However, use of dichotomous cutoffs that rely on single dimension measurements have been criticized given absence of standardization and consensus from different guidelines.[16] There is a concern that single-dimension measurements fail to capture true complexity of residual stone burden. For example, a patient having either a 3 × 1 × 0.5 mm (0.79 mm^3) fragment or a 4 × 3.5 × 3.5 mm (25.66 mm^3) fragment would meet SFR-Grade C criteria, despite significant difference in volume. Furthermore, studies have suggested that ureteral stone volume outperforms maximal diameter in predicting likelihood of trial of passage.[9] In this study, we demonstrate similar residual volumes after URS with CVAC 2.0 or FANS, albeit with CVAC 2.0 having higher preoperative volumes. Further work will endeavor to

determine the significance of residual stone volume on risk of subsequent stone events, but future studies should ideally include both dichotomous SFR cutoffs and residual stone volumes as a continuous variable.

Infectious complications were rare (CVAC 2.0-8%, FANS-3%) despite nearly one-fourth of our population having positive pre-op cultures. Although not a statistically significant difference, we observed 1 ureteral injury in CVAC cases (2.8%) and 9 with FANS (10.3%; 5 being Traxer I). A prior multicenter study reported a 3.5% rate of ureteral injury.[17] However, it is worth noting that in our cohort, CVAC patients were more likely to be prestented (50% *vs* 29%), contributing to a lower injury risk. Given the unique functionality of FANS to advance past the ureteropelvic junction, further studies should determine intervenable factors that impact risk of ureteral injury.

There are important limitations of this study to consider. This was a nonrandomized study, which does introduce a risk of bias, and preoperative stone volumes were significantly higher for the CVAC 2.0 group. We performed a planned subanalysis controlling for stone size >1.5 cm and performed stratified linear regression to assess for the interaction between preoperative stone volume, device, and SFR. Furthermore, patients requiring staged procedures were not included in volumetric analysis because of absence of interval imaging between first/second procedures, but were included for our safety analysis. We did not standardize laser lithotripsy strategies/settings as this was intended as an initial, real-world experience aimed at being broadly applicable to different lithotripsy approaches. Future randomized studies are needed to more directly compare the relative efficacy of CVAC and FANS for specific laser settings/lithotripsy approaches. This study aims at informing appropriate statistical power analysis for future studies.

The decision-making between utilizing FANS and in-scope aspiration currently remains up to surgeon preference. Although we demonstrate here a potential advantage for CVAC 2.0 in larger stones, further work is needed to clarify factors that may impact the comparative effectiveness of these devices such as stone composition and location in the collecting system. Future cost analysis is also necessary. Furthermore, potential limitations of the CVAC 2.0 scope such as risk of outflow channel clogging and relatively lower resolution of the scope image require further study. For instance, the impact of stone composition or HU on risk of clogging is unknown and warrants further investigation.

Conclusions

In this prospective study, we compared stone clearance and safety outcomes between the novel CVAC 2.0 ureteroscope, which allows for simultaneous irrigation and fragment aspiration through distinct channels, and FANS. We found that CVAC 2.0 yields excellent stone clearance and SFR similar to FANS, despite higher preoperative stone burden. In contrast to FANS, residual stone volumes with CVAC 2.0 did not increase significantly with increasing preoperative stone volumes, highlighting the potential for this device in the management of large volume stone burdens.

Authors' Contributions

J.J.S.C.: Writing, data analysis, and data collection. C.C.B.: Writing, data collection, and data analysis. V.S.E.: Data collection and editing. M.R.H.: Supervision and editing. K.L.S.: Data analysis, conceptualization, editing, and supervision.

Author Disclosure Statement

None of the authors has any relevant conflicts for this article.

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Supplementary Material

Supplementary Data

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Abbreviations Used

CT = computed tomography
F = French
FANS = Flexible and Navigable Ureteral Access Sheath
fURS = flexible ureteroscopy
HU = Hounsfield units
IQR = interquartile range
SFR = stone-free rate
SURE = steerable ureteroscopic renal evacuation
UAS = ureteral access sheath
vs = versus