Case Series

Increased efficacy in lower pole stone management with a novel flexible and navigable suction ureteral access sheath with flexible ureteroscopic lithotripsy: a case series

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Background: The flexible and navigable suction ureteral access sheath (FANS-UAS) is regarded as a complement to flexible ureteroscopy in retrograde intrarenal surgery. Management of lower pole stones (LPS) is challenging due to the difficulty of anatomical access to the inferior renal calyx.

Case Description: The novel FANS-UAS (11/13.5 Fr; 40/50 cm length; 7 cm navigable tip length; 180° angulation) from Well Lead Medical (Guangzhou, China) has been commercially-available in July 2024 and first-used in The University of Hong Kong-Shenzhen Hospital. This case series included five candidates (three males; mean age 37.8±15.1 years) with LPS (max. diameter 7–10.5 mm) undergoing FANS-UAS with flexible ureteroscopic lithotripsy. Success rate of FANS-UAS catheterization was 80% as a male patient displayed poor ureter elasticity intraoperatively and the operation had to be completed with a 10/12 Fr tip-flexible UAS and stone basket. LPS, including those with an infundibulopelvic angle <30°, could be easily navigated and removed with insignificant to no residual stones remaining. No stone basket was used. Grade I and II ureteric injuries occurred in two separate patients that were resolved upon four weeks of ureteral stenting. No significant intra- and post-operative complication was observed. The mean total operative duration was 66.5±22.6 minutes. Computed tomography scans were conducted at day one post-operation. Among the cases with successful FANS-UAS insertion, the absolute and relative stone free rate, defined as complete absence and absence of residual fragments <2 mm, was 75% and 100%, respectively. All patients remained stone-free at one-month follow-up with no adverse events.

Conclusions: Early outcomes of the novel 11/13.5 Fr FANS-UAS applied successfully on four patients demonstrate its feasibility, safety, and efficiency in removing LPS. However, improvements in design may be necessitated in the future. For the meantime, prolonged follow-up and larger patient samples are necessitated to further elucidate its outcomes and prognosis.

Keywords: Flexible ureteroscopy; lithotripsy; retrograde intrarenal surgery; vacuum; case series

Submitted Oct 07, 2024. Accepted for publication Dec 29, 2024. Published online Jan 20, 2025.
doi: 10.21037/tau-24-388
View this article at: https://dx.doi.org/10.21037/tau-24-388

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Introduction

The increasing prevalence of urolithiasis poses a clinical and economical challenge to the healthcare system (1). Factors including race, nutritional intake, a sedentary lifestyle, and lack of physical exercise contributed to this phenomenon over the past few decades in both developed and developing countries (2). The increase in demand for stone surgery is expected. Retrograde intrarenal procedures (RIRS) are preferred over open or percutaneous operations given its minimal invasiveness (3). In order to improve the clinical outcomes of RIRS, products such as endoscopes, endovision systems, and relevant consumables and accessories have undergone constant innovative development, to the extent that it occupied the largest market share among Urology Surgical Instruments in 2024 (4).

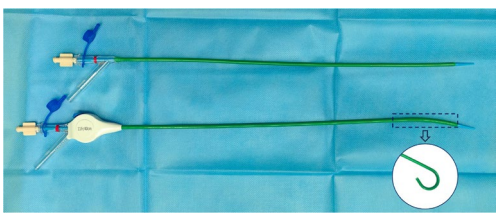

Figure 1 The conventional Well Lead ureteral access sheath compared to the flexible and navigable suction ureteral access sheath with its bendable tip (circle).

Highlight box

Key findings

- The novel 11/13.5 Fr flexible and navigable suction ureteral access sheath (FANS-UAS) is a feasible, safe, and efficient complement for lower pole stone (LPS) removal when combined with flexible ureteroscopic lithotripsy.

What is known and what is new?

- Early European multicenter reports the promising role of FANS-UAS in upper urinary tract stone management.
- The 11/13.5 Fr FANS-UAS is favorable for the management of LPS but successful catheterization also depends on ureter diameter and elasticity. For this case series of five patients with four successful cases, the absolute and relative stone free rate, defined as complete absence and absence of residual fragments <2 mm, was 75% and 100%, respectively.

What is the implication, and what should change now?

- Further FANS-UAS observational studies with longer follow-up and comparison with other UAS are required to elucidate its outcomes. Design improvements, including enabling bidirectional deflection and smaller shaft diameters may increase its application in retrograde intrarenal surgery.

Ureteral access sheaths (UASs) are one of the crucial equipment in RIRS. Early studies raised concerns towards the mandatory use of UAS due to risks of urinary tract infection (UTI) and sepsis (5). More evidence has revealed UASs' ability to improve vision by establishing continuous irrigation outflow, lower intrarenal pressure (IRP) upon forced irrigation, and potentially reduce operating time (6). The European Association of Urology (EAU) has yet provided a clear recommendation for UAS during typical ureteroscopy procedures but recently deemed flexible and navigable suction (FANS) UAS a potential game-changer in RIRS (7,8). The multicenter prospective cohort found high single-stage stone free status rate, negligible serious adverse event, and reintervention rates for stones in all locations with the use of FANS-UAS.

Lower pole stones (LPS) account for approximately 35% of renal stones (9). Access to the inferior renal calyx and elimination of *in situ* fragments render LPS management difficult (10). In RIRS, improved flexible ureteroscopes (FURS) allows for significant active and passive deflection to reach LPS. With the commercial-availability of FANS-UAS launched in China, our high-volume tertiary institute was granted the privilege to use the first five products manufactured. After thorough surgical planning, it was decided that the device was to be used with FURS specifically for patients with LPS in order to determine its safety, efficacy, and efficiency. This study documents the five cases of LPS with other concomitant diagnosis. We present this case series in accordance with the AME Case Series reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-24-388/rc).

Case presentation

Study population

During July 2024, the Well Lead Medical Co., Ltd. launched its first commercially available FANS-UAS (11/13.5 Fr; 40/50 cm length; 7 cm navigable tip length; 180° angulation) in China (*Figure 1*). The first five products were supplied to The University of Hong Kong-Shenzhen Hospital Urology Department. Clinical characteristics of the five treated patients primarily diagnosed with LPS were highlighted below. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with

the Helsinki Declaration (as revised in 2013). Publication of this case series and accompanying images was waived from patient consent according to The University of Hong Kong-Shenzhen Hospital ethics committee.

Surgical technique

The operation was conducted with reference to video instructions previously reported by Yue *et al.* (11). Under general anesthesia, the patient was placed in lithotomy position. A disposable digital FURS (7.5 Fr; HU30S; Shenzhen HugeMed Medical Technical Development Co., Ltd., Shenzhen, China) was introduced under direct vision to evaluate the bladder and ureteral orifices. Under FURS guidance, a 0.035" guidewire was inserted to the target ureter before further advancement of FURS, followed by the insertion of the 11/13.5 Fr FANS-UAS. Once the FANS-UAS was in place, the FURS was adjusted to push any ureteric stone into the kidney. Stones were pulverized with holmium, laser lithotripsy (SlimLine SIS^2 200 µm Laser Fiber; VersaPulse®, Boston Scientific, MA, USA). Fragments were aspired under vacuum assistance until no residual stone was observed. Finally, a Marflow double-J stent (5/6 Fr; APR Medtech Ltd., Oxfordshire, UK) prior guidewire withdrawal and a 16 Fr Foley catheter was retained.

Postoperative treatment and early follow-up

Patients routinely underwent removal of the Foley catheter and plain computed tomography (CT) scan one-day post-operation to evaluate stone clearance. Patients with concomitant UTI were prescribed with two-week oral antibiotics upon discharge. Another follow-up CT was conducted at 2–4 weeks post-operation to reevaluate the upper urinary tract and stone status prior double-J stent removal. Pre- and post-operative CT results can be found in *Figures 2,3*, respectively.

Case 1

A 45-year-old man with recurrent intermittent hematuria for a year was admitted for staged stone removal. He was previously diagnosed with bilateral renal stones and a left ureteric stone at a local hospital but conservative treatment failed. Preoperative CT revealed a right ureteric stone (7 mm × 7 mm × 7 mm), a right ureteropelvic junction stone (12 mm × 9 mm × 8 mm), mild pelvicalyceal dilation, multiple bilateral renal stones [right LPS diameter: 5 mm × 4 mm × 3 mm, infundibulopelvic angle (IPA): 46°, total stone volume (TSV): 1,153.4 mm^3; left renal stone diameter: 14 mm × 10 mm × 8 mm, max. density: 914 Hounsfield units (HU), TSV: 1,393 mm^3], and left renal atrophy. Biochemicals were unremarkable. Elective right stone removal was prioritized to preserve renal function. Total operative time was 89 minutes and complete stone clearance (CSC) was achieved. No intra-/post-operative complication was observed. The double-J stent was removed after CT review at two weeks showed no abnormalities. He made an unremarkable recovery and proceeded with elective left stone removal after a month. CT review at day 2 post-operation confirmed bilateral CSC.

Case 2

A 59-year-old woman was referred to our department after being diagnosed with a right LPS (12 mm × 8 mm × 7 mm; max. density: 1,744 HU; IPA: 52°; TSV: 352.6 mm^3) that was responsible for her persistent right lumbar pain, nausea and vomiting for a week. She had a history of total thyroidectomy. She underwent elective stone removal with no intra-/post-operative complication. The total operative time was 51 minutes. Plain CT on the first postoperative day showed a few <2 mm residual stones. She remained asymptomatic and the double-J stent was removed after two weeks after CT showed no abnormalities.

Case 3

A 38-year-old female experienced an acute onset of fever, left lumbar pain, and nausea for two days. She consulted our outpatient clinic. Ultrasound found a left ureteric and renal stone with moderate edema of the left kidney. Urinalysis suggested UTI and she was given oral antibiotics without being admitted. She returned to the emergency department the following day as her max. body temperature reached 40 ℃ and was admitted to the urology department. Stronger antibiotics and analgesics were administered. Biochemicals revealed elevated white blood cell count (16.54×10^9/L), C-reactive protein (210.9 mg/L), and procalcitonin (PCT) (1.31 ng/mL). Urgent decompression with double-J stenting was performed. Preoperative CT found two LPS measuring 6 mm × 5 mm × 5 mm and 5 mm × 5 mm × 4 mm with max. density of 1,397 HU. The IPA was 40° and TSV 131.2 mm^3. Once infection was controlled, she underwent elective left stone removal. Initial insertion of the FANS-

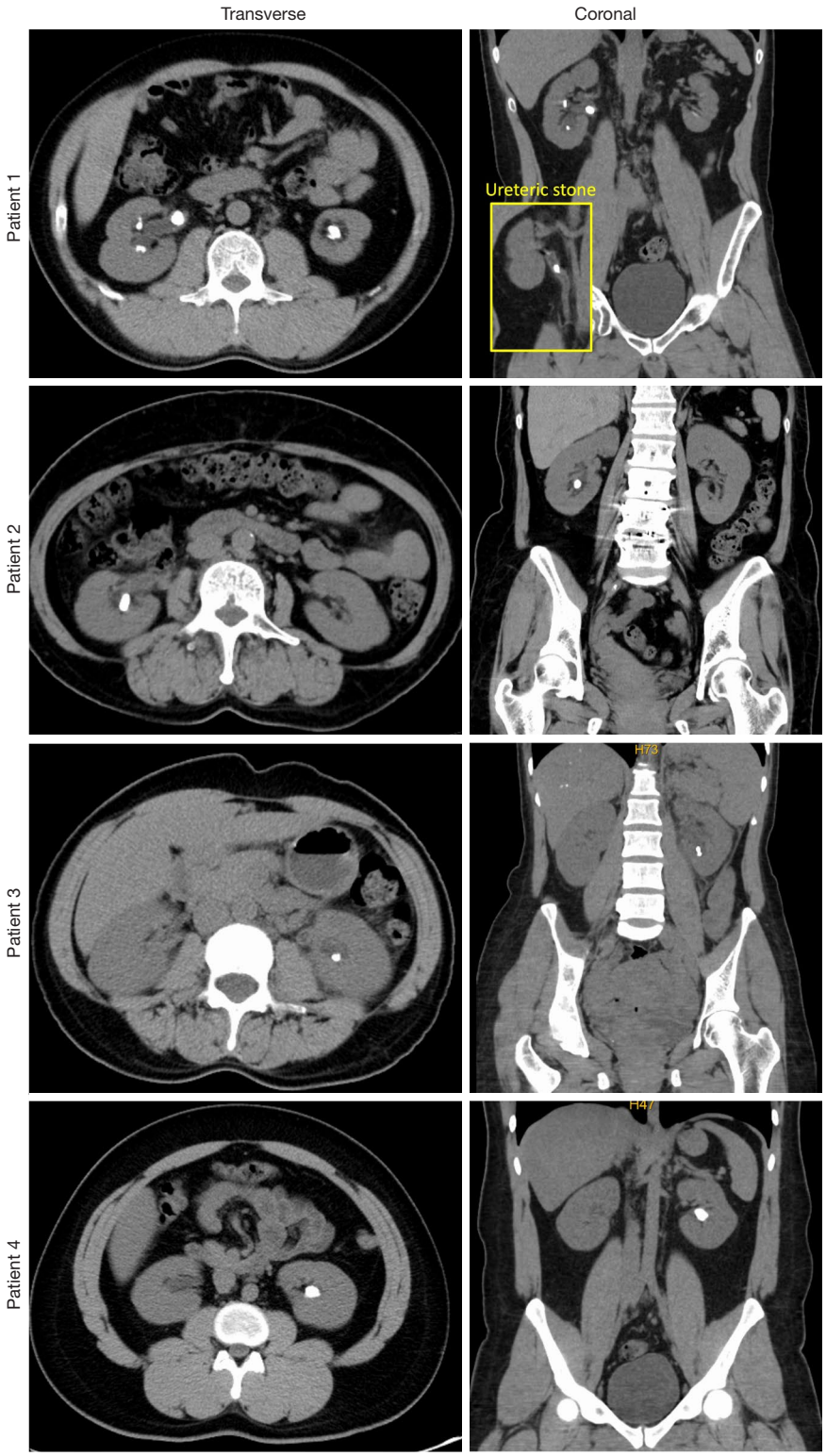

Figure 2 Preoperative computed tomography scans in transverse (left column) and coronal (right column) planes for patients 1 to 4 that have successfully undergone stone removal procedures using the flexible and navigable suction ureteral access sheath. Lower pole stones can be seen. The ureteric stones for patient 1 are included in yellow boxes for reference.

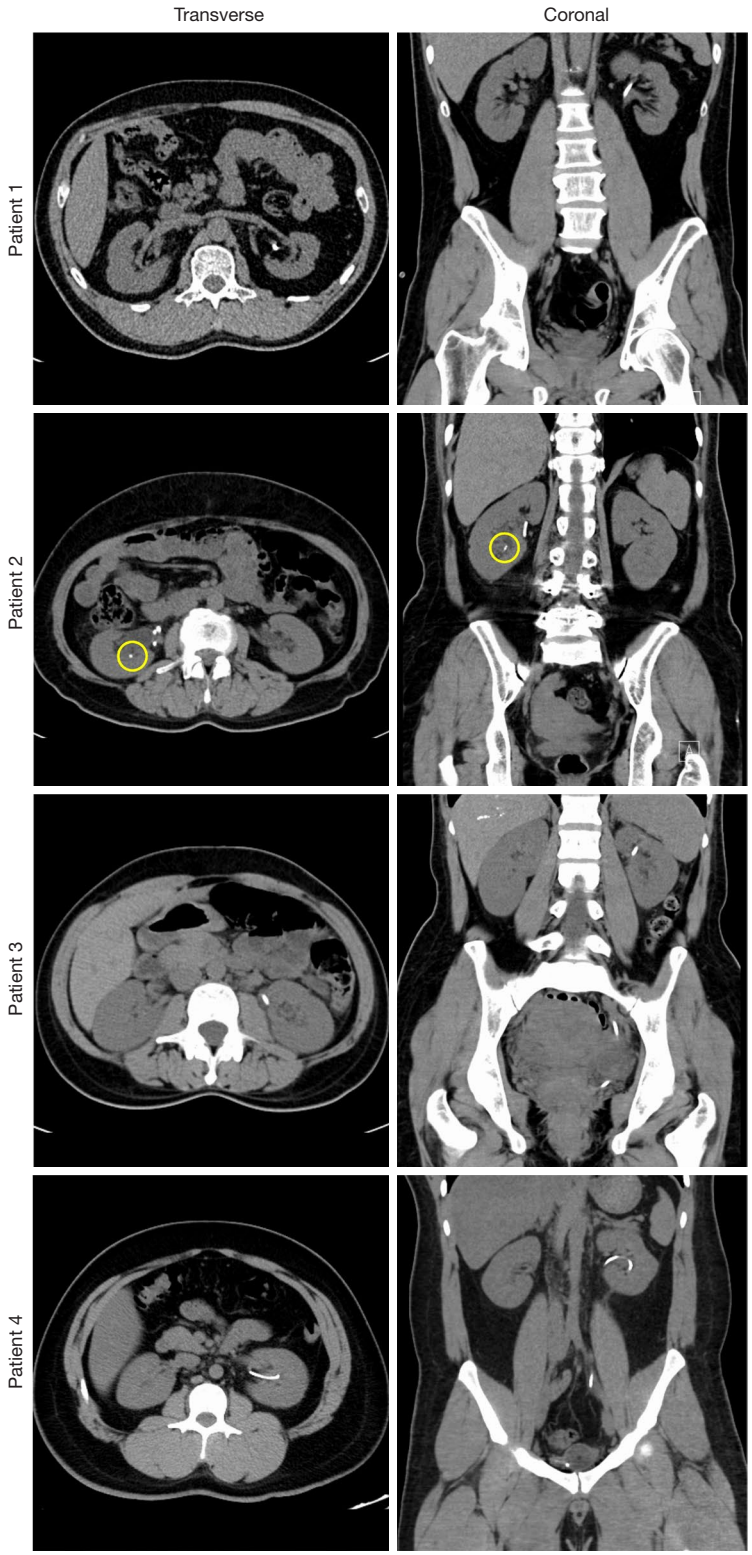

Figure 3 Postoperative computed tomography scans in transverse (left column) and coronal (right column) planes for patients 1 to 4 that have successfully undergone stone removal procedures using the flexible and navigable suction ureteral access sheath. Patient 2 was the only case with residual stones (yellow circles).

UAS was difficult due to stricture of the upper segment of the left ureter, which was dilated using angioplasty (18 Fr × 6 cm; UroMax Ultra^{TM} high pressure balloon catheter; M0062251280; Boston Scientific, MA, USA). Grade I ureteric injury was detected with no major complication. The total operative time was 40 minutes. CSC was achieved and she was discharged with oral tamsulosin. CT review at one-month post-operation showed satisfactory recovery and the double-J stent was removed.

Case 4

A 24-year-old male with a nine-month history of bilateral renal stones underwent right ureteroscopic lithotripsy with a tip-flexible UAS to remove the large cast stone (30 mm × 25 mm) that partially occupied the lower pole. Stone composition analysis returned as L-cystine and he was prescribed with urine alkalizing agents upon discharge. The initially insignificant and asymptomatic left stone grew obvious in size (14 mm × 13 mm × 12 mm; IPA: 55°, TSV: 1,145.8 mm^3; max. density: 787 HU) after six months post-operation, while the right kidney remained stone-free. He was admitted for left stone removal. Grade II ureteric injury was detected with no major complication. The total operative time was 96 minutes. CSC was achieved and he was to continue taking urine alkalizing agents. He declined undergoing genetic testing for cystinuria. CT review at one-month post-operation showed that bilateral kidneys remained stone-free and the double-J stent was removed.

Case 5

A 47-year-old male was diagnosed with a right LPS (7 mm × 6 mm × 5 mm; max. density: 1,214 HU; IPA: 53°), a left renal stone (5 mm × 4 mm × 4 mm), and a left upper ureteric stone (12 mm × 10 mm × 8 mm; TSV: 655.8 mm^3) with mild hydronephrosis. Attempts to insert the FANS-UAS into either ureter failed due to poor ureteral elasticity. Intraoperatively, left ureteroscopy observed significant mucosal edema around the ureteric stone. The stone was carefully pushed into the kidney under low pressure irrigation. Therefore, a 10/12 Fr tip-flexible UAS was used instead to complete the procedure. Stones were retrieved using a stone basket. CT review found no residual stone. The double-J stent was removed four weeks post-operation.

Discussion

Our initial experience with the Well Lead FANS-UAS combined with flexible ureteroscopic lithotripsy showed satisfactory stone clearance rates for LPS, achieving a 100% relative stone clearance rate (defined as absence residual fragments <2 mm) at 2–4 weeks of follow-up. Despite the small patient sample, results showed the promising role of FANS-UAS in stone removal, including LPS, by demonstrating both safety, efficacy, and efficiency in all procedures.

This study aimed to demonstrate the efficacy of FANS-UAS especially for the removal of LPS, which was considered anatomically challenging throughout literature. FURS, UAS, and laser fibers can be regarded as the inseparable in RIRS. The design of FANS-UAS greatly improves the overall maneuverability. The Well Lead model, for example, has a navigable tip that is 7 cm in length and can bend 180°, forming a near circle 3 cm in diameter, allowing it to reach the lower renal calyx. The catheter can be anchored at site to proceed with stone fragment aspiration by deflecting the navigable tip without adjusting catheter position. This feature is favorable for relatively larger LPS as it can effectively reduce operative duration. When paired with flexible scopes, even LPS at an IPA <30° can be reached.

UAS with larger shaft diameters (i.e., 12/14 Fr) are not considered as it increases the risk of high-grade ureteral injuries upon use (6). Despite successful cases using a 11/13.5 Fr FANS-UAS, patients from cases 3 and 4 were found to have grades I and II iatrogenic ureteral injuries, respectively. Therefore, both ureteral stent removal was scheduled later than other patients. The combination with a 7.5 Fr disposable scope maintained a ratio of ureteroscope-sheath diameter (RUSD) at either 0.75 or 0.63, which was within the recommended value to maintain a safe IRP (12). The low IRP enabled a larger irrigation flow and higher irrigation pressure, which can clear surgical vision and enhance navigation of the target LPS that would be aspired under vacuum assistance (13).

The success rate of FANS-UAS insertion was 80%. For case 5, the patient was deemed an unsuitable candidate for FANS-UAS intraoperatively due to poor ureter elasticity. Further attempts to insert the instrument could lead to preventable ureteral injuries. A study found that UAS size,

the male gender, and small stone diameter were significant predictive factors for ureteral injury (14). Unlike the patient in case 3, balloon dilatation was not considered due to poor elasticity throughout the ureter lumen bilaterally. Should balloon dilatation be performed, it would have to be conducted near the entire length of the ureter. However, despite balloon dilatation being one of the most common endoluminal treatment modalities for ureteric stricture, it has not gained widespread acceptance due to high-risk of stricture recurrence (15). Another solution would be pre-stenting the ureter for 2–4 weeks prior staged stone removal, which may result in patient dissatisfaction. Therefore, a 10/12 Fr UAS was used to complete the procedure.

Other than the above limitation of the 11/13.5 Fr FANS-UAS, another disadvantage includes to the use of a built-in steel wire support that adds approximately 1 Fr to the inner diameter, thereby increasing the difference between inner and outer diameters. The 13.5 Fr outer was equivalent to a 14 Fr catheter that contributed to failed catheterization (approximately 10–20% failure rate). Currently, the tip could only be turned in a single direction, which would limit its applicability for the management of complicated upper calyx stones.

Urolithiasis is a multifactorial and multistep metabolic disease (16). All patients, except the young cystinuria patient from case 4, had calcium oxalate stones. Cystinuria patients have a higher risk of recurrent stone episodes and require more interventions, resulting a worser health-related quality of life when compared to non-cystine stone formers (17). This patient initially did not agree to undergo bilateral stone retrieval as his left renal stone was asymptomatic and insignificant. However, the stone grew obvious in size after seven postoperative months. With the right renal cast stone completely removed using a tip-flexible UAS and showing no sign of recurrence at the given period of time, the patient realized the importance of stone clearance and finally decided to undergo stone retrieval. Regardless of stone type, it was found that the incidence of stone relapse at mid-term was proven lower after the removal of small, asymptomatic stones than non-removal (18,19). Therefore, FANS-UAS could be a viable early management solution for diagnosed LPS, which is often regarded as asymptomatic stones that can be passed out naturally without intervention. This is especially important for patients with cystinuria.

The limitations of this study include its retrospective nature as well as the small size and heterogenous presentation of stones of the cohort. Therefore, results from this case series may overestimate the benefits of the FANS-UAS and procedure. Nonetheless, FANS-UAS, as determined by the large prospective multi-center cohort, is a promising complement to RIRS. Similarly, larger patient sample and a prospective randomized trial ought to be conducted among patients with upper urinary tract stones, and with better effort to eliminate heterogenous factors to focus on stones perhaps based on location and size. For now, we believe that FANS-UAS is a valuable tool for removal of LPS of intermediate size.

Conclusions

The novel 11/13.5Fr FANS-UAS with FURS is safe, efficient, and effective in removing LPS. Prolonged follow-up and larger patient samples are necessitated to further elucidate its outcomes and long-term prognosis.

Acknowledgments

None.

Footnote

Reporting Checklist: The authors have completed the AME Case Series reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-24-388/rc

Peer Review File: Available at https://tau.amegroups.com/article/view/10.21037/tau-24-388/prf

Funding: None.

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-24-388/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Publication of this case series and accompanying images was waived from patient consent according to

The University of Hong Kong-Shenzhen Hospital ethics committee.

References

1. Stamatelou K, Goldfarb DS. Epidemiology of Kidney Stones. Healthcare (Basel) 2023;11:424.
2. Al-Shawi MM, Aljama NA, Aljedani R, et al. The Role of Radiological Imaging in the Diagnosis and Treatment of Urolithiasis: A Narrative Review. Cureus 2022;14:e33041.
3. Zeng G, Traxer O, Zhong W, et al. International Alliance of Urolithiasis guideline on retrograde intrarenal surgery. BJU Int 2023;131:153-64.
4. Reports, B. G. (2024, June 28). [2024-2030] urology surgical instruments market demand, growth. LinkedIn. Available online: https://www.linkedin.com/pulse/2024-2030-urology-surgical-instruments-market-mhk3f/
5. Villa L, Dioni P, Candela L, et al. Understanding the Role of Ureteral Access Sheath in Preventing Post-Operative Infectious Complications in Stone Patients Treated with Ureteroscopy and Ho:YAG Laser Lithotripsy: Results from a Tertiary Care Referral Center. J Clin Med 2023;12:1457.
6. De Coninck V, Somani B, Sener ET, et al. Ureteral Access Sheaths and Its Use in the Future: A Comprehensive Update Based on a Literature Review. J Clin Med 2022;11:5128.
7. Türk C, Petřík A, Sarica K, et al. EAU Guidelines on Interventional Treatment for Urolithiasis. Eur Urol 2016;69:475-82.
8. Gauhar V, Traxer O, Castellani D, et al. Could Use of a Flexible and Navigable Suction Ureteral Access Sheath Be a Potential Game-changer in Retrograde Intrarenal Surgery? Outcomes at 30 Days from a Large, Prospective, Multicenter, Real-world Study by the European Association of Urology Urolithiasis Section. Eur Urol Focus 2024;S2405-4569(24)00073-7.
9. McClinton S, Starr K, Thomas R, et al. The clinical and cost effectiveness of surgical interventions for stones in the lower pole of the kidney: the percutaneous nephrolithotomy, flexible ureterorenoscopy and extracorporeal shockwave lithotripsy for lower pole kidney stones randomised controlled trial (PUrE RCT) protocol. Trials 2020;21:479.
10. Mazzucchi E, Berto FCG, Denstedt J, et al. Treatment of renal lower pole stones: an update. Int Braz J Urol 2022;48:165-74.
11. Yue G, Dou S, Cai C, et al. A Novel Distal Active Flexible Vacuum-assisted Ureteric Access Sheath in Retrograde Intrarenal Surgery. Urology 2023;179:204-5.
12. Ostergar A, Wong D, Shiang A, et al. Intrarenal Pressure with Vacuum-Assisted Ureteral Access Sheaths Using an In Situ Cadaveric Porcine Model. J Endourol 2023;37:353-7.
13. Shi J, Huang T, Song B, et al. The optimal ratio of endoscope-sheath diameter with negative-pressure ureteral access sheath: an in vitro research. World J Urol 2024;42:122.
14. Taguchi M, Yasuda K, Kinoshita H. Evaluation of ureteral injuries caused by ureteral access sheath insertion during ureteroscopic lithotripsy. Int J Urol 2023;30:554-8.
15. Wang B, Gao W, Yang K, et al. Analysis of the Efficacy and Risk Factors for Failure of Balloon Dilation for Benign Ureteral Stricture. J Clin Med 2023;12:1655.
16. Xu Z, Yao X, Duan C, et al. Metabolic changes in kidney stone disease. Front Immunol 2023;14:1142207.
17. Servais A, Thomas K, Dello Strologo L, et al. Cystinuria: clinical practice recommendation. Kidney Int 2021;99:48-58.
18. Sorensen MD, Harper JD, Borofsky MS, et al. Removal of Small, Asymptomatic Kidney Stones and Incidence of Relapse. N Engl J Med 2022;387:506-13.
19. Brain E, Geraghty RM, Lovegrove CE, et al. Natural History of Post-Treatment Kidney Stone Fragments: A Systematic Review and Meta-Analysis. J Urol 2021;206:526-38.

Cite this article as: Xiong L, Kwan KJS, Xu X, Wei GG, Wen XY, Yuan JB. Increased efficacy in lower pole stone management with a novel flexible and navigable suction ureteral access sheath with flexible ureteroscopic lithotripsy: a case series. Transl Androl Urol 2025;14(1):158-165. doi: 10.21037/tau-24-388