World Journal of Urology (2025) 43:644
https://doi.org/10.1007/s00345-025-06024-2

RESEARCH

Head-to-head comparison of novel suction technologies in endourology: suction mini-PCNL versus flexible ureteroscopy using flexible and navigable suction ureteral access sheaths for renal stone management. An EAU-endourology, propensity score-matched analysis of 1372 patients

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Received: 25 July 2025 / Accepted: 17 October 2025

Abstract

Background To compare the two suction technologies, namely suction mini-percutaneous nephrolithotomy (SM-PCNL) and flexible ureteroscopy using flexible and navigable suction ureteral access sheaths (FANS) for renal stone management.

Methods Propensity-matched pair analysis was conducted on prospectively collected data from two global registries. The Suction mini-PCNL registry (STUMPS) included 30 centers across 21 countries, and the Flexible and Navigable Suction Access Sheath in Ureteroscopy registry (FANS) involved 25 centers across 20 countries. Each group included 686 patients after matching for age, sex, Guy's stone score, and stone volume. The primary outcome was the stone-free rate (SFR), assessed by 30-day non-contrast CT scan, categorized as Grade A (100% clearance or zero residual fragment, ZRF), Grade B (single ≤ 4 mm residual fragment), or Grade C (any fragment > 4 mm or multiple fragments).

Results In the matched cohort, immediate ZRF was significantly higher in SM-PCNL (85.7% vs. 60.1%, $p < 0.001$), and reinterventions were fewer (0.9% vs. 4.4%, $p < 0.001$). FANS demonstrated significantly superior recovery profiles with lower postoperative pain scores (VAS 1.0 vs. 2.0, $p < 0.001$), shorter hospital stays (1.0 vs. 2.0 days, $p < 0.001$), and reduced need for basket extraction (9.5% vs. 24.5%, $p < 0.001$). Operative time difference of 6 min, favoring SM-PCNL was noted (46 vs. 40 min, $p < 0.001$). Complication rates were low and comparable: fever managed by observation (2.1% FANS vs. 3.2% SM-PCNL, $p = 0.29$) or antibiotics (3.1% FANS vs. 6.0% SM-PCNL, $p = 0.08$), blood transfusion (0.1% FANS vs. 0.3% SM-PCNL, $p > 0.99$). No sepsis case was reported for both modalities. Multivariable analysis identified SM-PCNL as a significant independent predictor of Grade A stone-free status (OR 4.06, 95% CI 3.06–5.43, $p < 0.001$). Notably higher stone complexity GSS 2 and 3 had significantly better predictive odds of lower SFR than stone volume. Stone volume was a predictor of any complications (OR 1.16, 95% CI 1.03–1.30, $p = 0.01$).

Conclusions Both techniques are safe and effective; SM-PCNL is better for achieving 100% stone clearance, especially in GSS 2 and 3 cases. FANS offers faster recovery and lower postoperative pain scores. The Guy's stone score is useful to predict 100% SFR for both modalities. Even though the proposed re-intervention rate was higher in FANS, as ours is only a 30-day follow-up study, the true reintervention rate and outcomes are lacking.

Keywords Kidney stones · Percutaneous nephrolithotripsy · Flexible ureteroscopy · Suction · Vacuum

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Published online: 29 October 2025

Introduction

Nephrolithiasis affects up to 10% of the global population, with rising incidences due to dietary and environmental factors [1]. Over the past three decades, kidney stone disease (KSD) treatment has evolved from open surgery to minimally invasive techniques like percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS). A tailored approach is preferred based on stone size, location, patient anatomy, and clinical case complexity, such as congenital kidney anomalies and obesity [2–4]. Standard PCNL remains preferred for large or complex stones [5], with mini-PCNL reducing morbidity whilst maintaining high clearance rates [6, 7]. Suction integration in PCNL helps improve visibility, fragment evacuation, reduce operative time, hospital stays, and complications [8]. Technological advancements in RIRS include miniaturized scopes and flexible suction ureteral access sheaths, enhancing irrigation-aspiration techniques that are capable of reducing infection risk and improving fragment extraction [9, 10]. The use of mini-PCNL (M-PCNL) and FANS in stones 2–3 cm has shown that the latter is non-inferior to Mini-PCNL [11]. The study compared outcomes using the largest stone diameter and M-PCNL with M-PCNL sheaths of 18fr only with FANS, paving the way for using FANS in larger stone burdens. However, to our knowledge, there is no head-to-head comparison of two modalities, namely suction M-PCNL (SM-PCNL) and RIRS using FANS, both incorporating suction-aspiration for any renal stone burden, objectively assessed using the Guy's stone score (GSS) [12] and stone volume (SV) as two parameters for stone burden and complexity. The primary aim of this study is to report which of these are better able to achieve a 100% stone-free rate (SFR) and 30-day morbidity due to the same.

Methods

The Suction Technology Utility in Mini-PCNL Study (STUMPS) registry included patients diagnosed exclusively with kidney stones who were prospectively recruited from 30 medical centers across 21 countries between March and November 2024. For this study, only adult patients aged 18 years or older, with only kidney stones, and those with data reporting stone burden using the GSS and SV were included. The original details of all patients in this database were already published [13]. Patients under 18 years of age, with concurrent ureteral stones and a lack of data on both GSS and SV were excluded. GSS was calculated by the treating urologist.

In the global multicenter FANS study, patients were prospectively enrolled between August 1, 2023, to August 30, 2024, involving 25 medical centers in 20 Countries, all of whom participated in the STUMPS registry. Eligible participants were adults aged 18 years or older who successfully underwent RIRS with FANS using 10/12 Fr or 11/13 Fr sheaths for any stone burden, recorded using SV calculated and GSS. Pediatric patients and those with ureteral stones or patients who had incomplete data records were excluded. Institutional board review approval was obtained by the leading center (Asian Institute of Nephro-Urology, AINU #01/2024) for STUMPS and FANS (AINU-EC/28/2023) study. Inclusion criteria adapted from the global FANS study published earlier [14] included adult patients with normal renal anatomy who were deemed suitable to undergo RIRS using FANS-UAS for single or multiple renal stones in any location within the collecting system. Exclusion criteria included pediatric patients, anatomical renal abnormalities, concomitant lithotripsy for ureteral stone, and patients who lacked. Stone burden was reported using GSS and SV in these patients from the pre op NCCT scans. Baseline and operative characteristics were collected from electronic medical records. All patients had a non-contrast CT scan performed 6weeks before surgery to assess stone burden and renal complexity, and SFR was evaluated at 30 days after the procedure. SV (for the largest stone in cases of multiplicity) was calculated using the ellipsoid formula (length*width*depth*π*0.167) and GSS was reported for all patients as per the original classification Surgeons performed suction mini-(SM)PCNL or RIRS procedures according to their standard clinical practices The choice of energy source, FANS-specific characteristics (sheath size, pre-stenting, and exit strategy), and PCNL-specific characteristics (patient positioning, puncture method, tract dilation method, exit strategy) were at the respective surgeons' discretion based on their experience and available resources.

The following FANS were employed: Clearpetra (Welllead Medical, Panyu, Guangzhou, China), Negative Pressure Ureteral Access Sheath (Innovex Medical, Shanghai, China), Elephant second generation (Zhejiang YiGao Medical Technology, Hangzhou, China), Suction UAS (SEPLOU, Beijing, China), Disposable Ureteral Guide Sheath (ZSR Biomedical Technology, Dongguan, Guangdong China China). For SM-PCNL, Clearpetra (Welllead Medical, Panyu, Guangzhou, China) and Shah sheath were used.

All positive preoperative cultures were treated as per the hospital's antibiogram. Anticoagulants or antiplatelets were stopped 3 days prior for all patients and restarted postoperatively at the surgeon's discretion. All patients received on-table single-dose antibiotic prophylaxis as per local practices, irrespective of prior treatment. Negative urine culture was not mandatory. Pain was evaluated by the treating surgeon on the first postoperative day using a 10-point visual analog scale (VAS), with 1 representing the lowest level of pain [15]. No standardized pain protocol was employed and this was left to each participant center according to each case and local practice. All patients were followed up for 30 days. Complications were graded according to the Clavien classification [16]. The definition of sepsis adhered to the guidelines outlined in the Third International Consensus Definitions (sepsis-3) by the presence of at least two clinical criteria that constitute the quick SOFA score. Readmissions within 30 days for re-intervention or reported complications were documented. Stone-free status, as assessed by a non-contrasted CT scan, was categorized into one of the following categories:

- - *Grade A*: 100% stone-free, indicating zero residual fragments (ZRF),
- - *Grade B*: single RF measuring up to 4 mm in maximum diameter.
- - *Grade C*: single RF > 4 mm in maximum diameter, or multiple RF of any size.

Operative time was defined as the interval between the start of cystoscopy and the completion of the procedure (i.e., stent placement, ureteral catheter placement, or no drainage). Ureteroscopy time was defined as the duration from the insertion of the ureteral access sheath (UAS) to its removal. Laser lithotripsy time refers to the actual time spent using the laser for stone fragmentation, as recorded in the operative report or device log. Sheath accessibility to the renal collecting system was assessed intraoperatively in both the FANS and SM-PCNL groups to ensure effective access for stone extraction of the target calix or in case of fragments migration.

Statistical analysis

Continuous variables are described using median and interquartile range, while categorical variables are described using absolute numbers and percentages. To visualize the similarities and differences between both study arms, patient demographics, peri-operative parameters, and 30-day outcomes were compared between the groups using the χ2 test for categorical parameters and the Mann-Whitney U test for continuous variables. Propensity score matching (PSM) was used to reduce confounding in the statistical comparisons. Propensity scores were calculated using a logistic regression model, and one-to-one nearest-neighbor matching for age, sex, GSS, and SV. To ensure optimal matching of covariates, the caliper width was started at 0.2 [17, 18], with the target of absolute standardized mean difference (ASMD) for all covariates of < 0.1 [18] being achieved at this starting caliper width. All statistical comparisons were then repeated for the PSM cohort, like the overall cohort.

Finally, two multivariable logistic regression analyses were performed in the matched population to evaluate factors associated with Grade A stone-free status and all complications. These predictors are described using odds ratios (OR), 95% CI, and p-values. All statistical tests were performed using R Statistical language, version 4.3.0 (R Foundation for Statistical Computing, Vienna, Austria), with $p < 0.05$ indicating statistical significance.

Results

Table 1 shows that the unmatched cohort comprised 1,963 patients: 704 patients who underwent FANS (Group 1) and 1,259 patients who underwent SM-PCNL (Group 2). In the unmatched population, patients in both groups had similar median ages (50 years) but differed significantly in gender distribution (55.0% male in Group 1 vs. 40.2% male in Group 2, ASMD 0.30). The groups also showed significant differences in GSS distribution, with FANS patients having higher proportions of GSS 3 stones (13.8% vs. 8.4%, ASMD 0.25) and SM-PCNL patients having more GSS 1 stones (61.2% vs. 57.0%). SV was significantly larger in Group 2 (median 1.6 cm^3 vs. 1.4 cm^3, ASMD 0.31), and stone location patterns differed substantially between groups (ASMD 0.37). There were no GSS 4 in Group 1.

After propensity score matching, 686 patients were included in each group and successfully matched with excellent covariate balance (ASMD < 0.1 for all matched variables; Table 1). The energy source for lithotripsy after matching is presented in Fig. 1. The matched cohort demonstrated similar baseline characteristics between groups, with median ages of 50 years in Group 1 and 49 years in Group 2, comparable gender distribution (54.4% vs. 55.4% male), and well-balanced GSC, except GSS4 which was missing in FANS and only 1 patient noted in SM-PCNL group, and SVs. In the matched population, significant differences were observed in procedural parameters and outcomes between the groups (Table 2). Total operation time was longer for FANS procedures (median 46 min [IQR 37–61] vs. 40 min [IQR 27–66], $p < 0.001$). The need for basket extraction was significantly lower in Group 1 (9.5% vs. 24.5%, $p < 0.001$), while sheath accessibility to all intrarenal collecting system was comparable between groups (89.1% vs. 87.2%, $p = 0.34$).

Postoperative pain scores were significantly lower in Group 1 (median 1.0 [IQR 1.0–2.0] vs. 2.0 [IQR 1.0–3.0], $p < 0.001$). Regarding complications, there was no case of sepsis requiring intensive care unit admission (Clavien 4). The complication rate was low in both groups with a similar

Table 1 Baseline characteristics of unmatched and matched cohort

	Unmatched			Matched		
	FANS (*n* = 704)	SM-PCNL (*n* = 1259)	ASMD	FANS (*n* = 686)	SM-PCNL (*n* = 686)	ASMD
Age, years, median [IQR]	50 [36, 61]	50 [39, 60]	0.02	50 [36, 61]	49 [38, 60]	< 0.01
Male gender, n (%)	387 (55.0)	506 (40.2)	**0.30**	373 (54.4)	380 (55.4)	0.02
ASA score, n (%)			**0.11**			**0.14**
1	368 (52.3)	692 (55.0)		360 (52.5)	373 (54.4)	
2	274 (38.9)	459 (36.4)		270 (39.3)	247 (36.0)	
3	62 (8.8)	103 (8.2)		56 (8.2)	61 (8.9)	
4	0	5 (0.4)		0 (0.0)	5 (0.7)	
BMI, kg/m^2, median [IQR]	26.0 [24.8, 29.4]	26.0 [23.0, 29.0]	0.08	26.0 [24.8, 29.4]	26.0 [23.0, 29.0]	**0.19**
First time stone former, n (%)	502 (71.3)	974 (77.4)	**0.14**	495 (72.2)	518 (75.5)	0.08
Right side stone, n (%)	284 (40.3)	614 (48.8)	**0.17**	272 (39.7)	336 (49.0)	**0.19**
Guy's stone score, n (%)			**0.25**			0.08
1	401 (57.0)	770 (61.2)		395 (57.6)	402 (58.6)	
2	206 (29.2)	365 (29.0)		200 (29.2)	206 (30.1)	
3	97 (13.8)	106 (8.4)		91 (13.3)	77 (11.2)	
4	0	18 (1.4)		0 (0.0)	1 (0.1)	
Hounsfield units, median [IQR]	1100 [976, 1220]	1191 [936, 1366]	**0.25**	1100 [967, 1215]	1200 [942, 1354]	**0.27**
Stone volume, cm^3, median [IQR]	1.4 [0.8, 2.1]	1.6 [0.9, 3.1]	**0.31**	1.4 [0.8, 2.1]	1.4 [0.8, 2.1]	0.03
Stone location, n (%)			**0.37**			**0.38**
Multiple	25 (3.6)	0 (0.0)		25 (3.6)	0 (0.0)	
Upper pole	167 (23.7)	197 (15.6)		163 (23.8)	110 (16.1)	
Middle pole/pelvis	309 (43.9)	574 (45.6)		297 (43.3)	300 (43.7)	
Lower pole	203 (28.8)	488 (38.8)		201 (29.3)	276 (40.2)	

Bold values indicates that the results are statistically significant

FANS Flexible and navigable suction ureteral sheath, *SM-PCNL* suction mini-percutaneous nephrolithotripsy, *BMI* body mass index, *ASMD* absolute standardized mean difference, *IQR* interquartile range

incidence of blood transfusion (Clavien 2: 0.1% in Group 1 vs. 0.3% in Group 2, $p > 0.99$), postoperative fever (>38° C) managed by observation without antibiotics (Clavien 1: 0.1% in Group 1 vs. 0.3% in Group 2, $p > 0.99$), postoperative fever (>38 °C) managed with more than 48 h of antibiotics (Clavien 2: 2.1% in Group 1 vs. 3.2% in Group 2, $p = 0.29$),

Hospital stay duration was significantly shorter for FANS procedures (median 1.0 day [IQR 0.0–1.0] vs. 2.0 days [IQR 2.0–3.0], $p < 0.001$). Readmission rates within 72 h were comparable between groups (1.7% vs. 1.2%, $p = 0.50$), but.

30-day CT scan demonstrated a significant advantage for ZRF for Group 2. Grade A stone-free status was achieved in 85.7% of SM-PCNL patients compared to 60.1% of FANS patients. A significantly higher planned reintervention for RF(s) after 30 days in Group 1 (4.4% vs. 0.9%, $p < 0.001$) was noted.

The multivariate analysis demonstrates that SM-PCNL (OR 4.06 95% CI 3.06–5.43, $p < 0.001$) was the only factor associated with higher odds of being grade A stone-free (Table 3). Higher GSS were associated with lower odds of ZRF (GSS 2: OR 0.60, 95% CI 0.44–0.81, $p = 0.001$; GSS 3: OR 0.36, 95% CI 0.24–0.56, $p < 0.001$). For complications, only SV emerged as a significant predictor of increased odds (OR 1.16, 95% CI 1.03–1.30, $p = 0.01$).

Discussion

Recent technological innovations in both PCNL and RIRS, such as suction and vacuum devices, have emerged as a potential game changer in the management of renal stones [14, 19]. The foundational research from the global STUMPS and FANS registries proved that these technologies are feasible, safe, and have promising outcomes across various patient groups [13, 14]. A recent RCT [11] comparing non-suction M-PCNL with FANS also demonstrated that for stone diameters of 2–3 cm, FANS is non-inferior. There were no SM-PCNL cases, nor did it use the GSS to represent stone complexity. The excellent RCT was only done in high-volume centres with highly experienced surgeons in a well-protocolised environment, and thus excellent non-inferiority outcomes were demonstrated.

To the best of our knowledge, our prospective, multicenter comparative study represents the first head-to-head analysis comparing SM-PCNL and RIRS using FANS with a primary aim to achieve 100% stone-free status, assessing

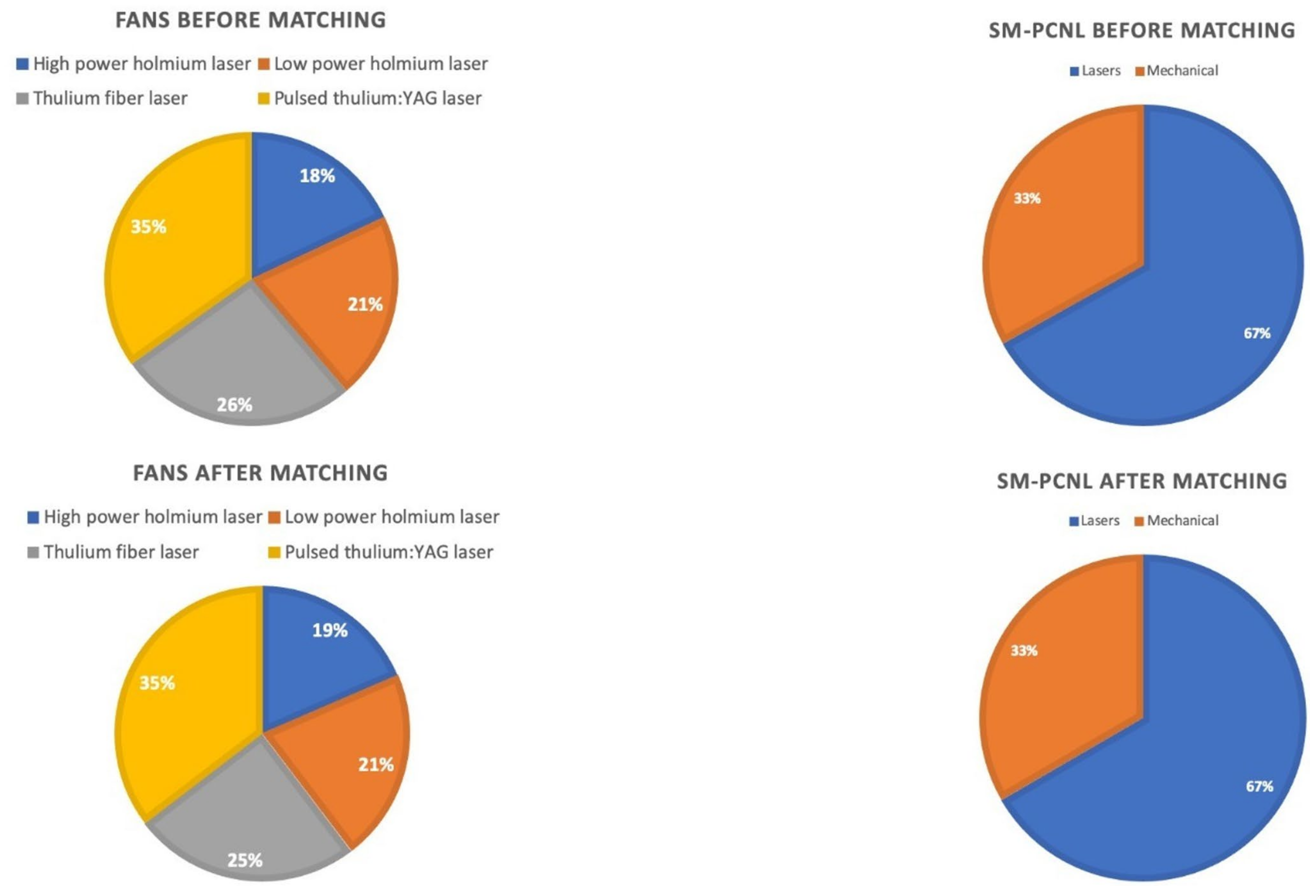

Fig. 1 Energy sources for lithotripsy in unmatched and matched cohort

GSS and SV to represent the stone burden in a real-world practice using any device for either FANS or SM-PCNL [20]. As SV is better adopted in endourological management of KSD, 100% SFS or ZRF assessed at 30 days with an NCCT is considered the best measure for a successful intervention and is proposed as a better benchmark in KSD intervention [21]. Our findings demonstrate that SM-PCNL was significantly more effective in achieving complete stone clearance, whereas FANS offered advantages in terms of postoperative recovery and morbidity. Notably, both techniques were associated with low complication rates, confirming their overall safety in appropriately selected patients.

The superior 100% stone-free rate observed with SM-PCNL (85.7% vs. 60.1%) aligns with existing literature supporting the efficacy of miniaturized PCNL approaches. Previous studies have shown that mini-PCNL maintains comparable SFRs to standard PCNL while reducing morbidity [22, 23]. Even in the RCT [11], it was observed that the FANS group had a non-inferior immediate SFR (84% vs. 85%; 95% CI) and a significantly longer operative time of 29 min. We found that in our study, in the PSM group, the difference was 6 min more for Group 1 (Table 2, $p < 0.001$).

Multivariable regression analysis confirmed SM-PCNL as an independent predictor of ZRF (OR 4.06). Further, GSS 2 and 3 were independently associated with lower odds of achieving a Grade A SFS. These findings reinforce the prognostic utility of the GSS system, previously validated as a complexity-based risk stratification tool [12], and reinforce the importance of stone complexity scoring in treatment selection and outcome prediction. The planned higher reintervention rate following FANS (4.4% vs. 0.9%) must be balanced against the reduced morbidity and faster recovery associated with this approach, and a lack of longer follow-up limits our ability to actually report the true re-intervention. It has been reported that whilst an NCCT scan is the best way to predict and report RF, often the timing of the same is debatable, and that a 30-day NCCT scan may unnecessarily lead to increased re-intervention [24]. As a consequence, the choice between SM-PCNL and FANS should be carefully individualized based on patient factors, stone characteristics, and treatment priorities, but GSS should be considered instead of just SV or diameter if these two interventions are to be compared. SM-PCNL may be preferred when complete stone clearance is paramount, particularly for complex stones or patients. FANS may be

Table 2 Procedural and postoperative characteristics in unmatched and matched cohort

	Unmatched			Matched		
	FANS (*n*=704)	SM-PCNL (*n*=1259)	p	FANS (*n*=686)	SM-PCNL (*n*=686)	p
Total operation time, minutes, median [IQR]	46 [37, 60]	41 [29, 65]	**<0.001**	46 [37, 61]	40 [27, 66]	**<0.001**
Basket required for stone extraction, n (%)	66 (9.4)	295 (23.4)	**<0.001**	65 (9.5)	168 (24.5)	**<0.001**
Sheath able to access all of the renal collecting system, n (%)	627 (89.1)	990 (87.5)	0.36	611 (89.1)	567 (87.2)	0.34
Intraoperative stone-free status			**<0.001**			**<0.001**
100% clear	395 (56.1)	1082 (85.9)		388 (56.6)	591 (86.2)	
Only dust remains	237 (33.7)	156 (12.4)		226 (32.9)	83 (12.1)	
Fragments remain	72 (10.2)	21 (1.7)		72 (10.5)	12 (1.7)	
Collecting system injury requiring stent, n (%)	5 (0.7)	17 (1.4)	0.28	5 (0.7)	10 (1.5)	0.30
Postoperative fever (>38° C) managed by observation without antibiotics (Clavien grade 1), n (%)	14 (2.1)	32 (2.5)	0.62	14 (2.1)	22 (3.2)	0.29
Postoperative fever (>38 °C) managed with antibiotics in the ward (Clavien 2), n (%)	9 (2.9)	73 (5.8)	0.06	9 (3.1)	41 (6.0)	0.08
Blood transfusion (Clavien 2), n (%)	1 (0.1)	15 (1.2)	**0.03**	1 (0.1)	2 (0.3)	>0.99
Bleeding requiring multiple bladder washouts/irrigations (Clavien grade 2), n (%)	0	4 (0.3)	0.33	0	4 (0.6)	0.13
Postoperative pain score, median [IQR]	1.0 [1.0, 2.0]	2.0 [1.0, 3.0]	**<0.001**	1.0 [1.0, 2.0]	2.0 [1.0, 3.0]	**<0.001**
Stone-free status on 30-day CT scan, n (%)	420 (59.6)	1066 (84.7)	**<0.001**	412 (60.1)	588 (85.7)	**<0.001**
Grade A: zero RF	275 (39.1)	160 (12.7)		265 (38.6)	83 (12.1)	
Grade B: single RF≤4 mm	9 (1.3)	33 (2.6)		9 (1.3)	15 (2.2)	
Grade C: single RF>4 mm/multiple RF of any size						
Hospital stay, days, median [IQR]	0.0 [0.0, 1.0]	2.0 [2.0, 3.0]	**<0.001**	1.0 [0.0, 1.0]	2.0 [2.0, 3.0]	**<0.001**
Readmission for any reason within 72 h, n (%)	14 (2.0)	17 (1.4)	0.37	12 (1.7)	8 (1.2)	0.50
Reintervention for RF(s) after 30 days, n (%)	30 (4.3)	15 (1.2)	**<0.001**	30 (4.4)	6 (0.9)	**<0.001**

Bold values indicates that the results are statistically significant

RF residual fragment, *FANS* Flexible and navigable suction ureteral sheath, *SM-PCNL* suction mini-percutaneous nephrolithotrispy, *IQR* interquartile range

Table 3 Multivariable regression analysis of factors affecting grade A stone-free status and overall complications

	Grade A stone-free status		All complications	
	OR (95%CI)	p	OR (95%CI)	p
Suction mini-PCNL (reference FANS)	4.06 (3.06–5.43)	**<0.001**	0.71 (0.49–1.04)	0.08
Stone volume	0.94 (0.85–1.03)	0.18	1.16 (1.03–1.30)	**0.01**
Guys' stone score (reference 1)				
2	0.60 (0.44–0.81)	**0.001**	1.15 (0.74–1.76)	0.53
3	0.36 (0.24–0.56)	**<0.001**	1.64 (0.94–2.79)	0.07
Hounsfield units	1.01 (0.98 -1.04)	0.31	1.15 (0.74–1.76)	0.64

Bold values indicates that the results are statistically significant

FANS Flexible and navigable suction ureteral sheath, *PCNL* percutaneous nephrolithotrispy

more appropriate for patients prioritizing rapid recovery, those with comorbidities increasing surgical risk, or when the retrograde approach offers better access to specific stone locations. Even though counselling for a second stage possibility, especially in GSS2 and 3 cases, must be done, caution may be exercised to consider the modality of re-treatment. Notably, the FANS study also reported that even in normal kidneys with a median SV of 1.2 cm^3, grade A SFS was achieved in 57.8% cases, yet the actual reintervention was only seen in 11 patients. Again, a larger stone burden (SV 3000 mm3 and above) was significantly associated with reduced 100% SFR and contributed to re-intervention.

While FANS demonstrated lower SFR compared to SM-PCNL in our study, the 60.1% Grade A stone-free rate, even with complex stones (GSS 2 and GSS 3), represents a significant improvement over traditional RIRS approaches. Recent international multicenter randomized trials have demonstrated that suction ureteral access sheaths achieve superior stone-free rates compared to traditional sheaths in RIRS, supporting the value of this technology. Cacciatore et al. found that the absence of fragments larger than 3 mm 30 days after RIRS was 95% in the FANS group as compared with only 67% in the standard non-suction sheath [25]. More recently, a meta-analysis reiterated that FANS provided superior stone clearance and reduced complications compared to non-suction sheaths [26].

Beyond efficacy, the procedural and recovery profiles varied significantly between techniques. The FANS group needed fewer basket extractions (9.5% vs. 24.5%), showing that FANS efficiently evacuates fragments without the need for active retrieval. This could potentially reduce the costs of accessories [27]. Conversely, SM-PCNL required more manual basket retrieval despite active suction, likely due to stone migration or the need to clear large fragments.

Operative time difference of 6 min favoring SM-PCNL (46 vs. 40 min)aligns with previous comparative studies showing that RIRS usually involves longer operative times, particularly in cases of multiple or lower pole stones, due to complex deflection angles and limited outflow capacity [28, 29]. Whilst it was only 6 min, we are unable to quantify what might have been the exact reasons for the same. Likely, it is multifactorial influenced by the surgeon's experience, moving the FANS sheaths to various parts of the kidney for inspection, especially into the lower pole or complex anatomy, and final exit strategy deployed. Yet this is significantly less than the 29-minute difference reported by Zeng et al. [11]. Interestingly, in the RCT [11], the mean Operative Time (OT) in the M-PCNL group was 59 min, whilst in our study, OT for SM-PCNL was 40 min. Perhaps SM-PCNL can facilitate stone evacuation much faster and may be a better choice than M-PCNL alone when considering bigger stone burdens, and reiterates previous studies [30].

Additionally, SM-PCNL has been shown to reduce OT and intrarenal pressure (IRP), which may facilitate clearer vision and faster stone clearance [8]. We acknowledge that our study lacks IRP data to make deductions on which suction modality has a better IRP safety profile. It has, however, been postulated and well proven in studies that novel non-invasive monitoring techniques for IRP are available and have better SFR and complication outcomes in SM-PCNL and FANS [31–33].

Interestingly, mild intraoperative bleeding was more frequently reported in the FANS group (5.7% vs. 2.2%). While this did not obscure vision or affect procedural safety, it may reflect differences in intrarenal pressure dynamics and fluid handling between the two techniques. Prior studies have shown that mini-PCNL typically maintains lower IRP values, reducing the risk of pyelovenous backflow and infection-related complications [34]. Conversely, fURS may generate transient IRP peaks exceeding 100–400 cm H_2O unless actively controlled [34]. FANS technology, which incorporates suction, may help modulate IRP depending on the sheath design and irrigation settings. Maintaining IRP below 30 cm H_2O is generally considered a critical safety threshold [34].

Regarding postoperative recovery, our findings demonstrated that patients treated with FANS reported significantly lower postoperative pain (median VAS 1.0 vs. 2.0) and shorter hospital stays (1 vs. 2 days), which represent important quality-of-life advantages. These findings align with the minimally invasive nature of retrograde approaches and the reduced tissue trauma compared to percutaneous procedures. These are consistent with the literature supporting FANS as a minimally invasive profile and outpatient feasibility, as previously indicated [11, 14, 35, 36].

Finally, in the multivariate model, SV emerged as an independent predictor of complications (OR 1.16), in line with previous literature linking increased stone burden with greater perioperative risk [37]. Larger SVs have been linked to longer operative times, increased bleeding, higher intrarenal pressure, and greater risk of postoperative infection or need for transfusion [38–40]. In particular, stone size has been shown to correlate with higher Clavien–Dindo complication grades following PCNL [7]. These findings highlight the importance of preoperative risk stratification in patients with complex stones and may support using SM-PCNL over FANS for its superior evacuation efficiency, particularly in those patients having large and complex stones. Increasingly, with the wider adoption of FANS, it's likely that more studies will evaluate SM-PCNL with FANS, GSS, and SV as significant predictors of ZRF and complications, respectively (Table 3). These may be the better variables to consider, as seen in our MVA.

Our study is not devoid of limitations. The non-randomized design, despite propensity score matching, may introduce selection bias. Nevertheless, both registries are prospective, large, and multicenter international, depicting a real-world practice. While this geographic and institutional diversity enhances generalizability, it inevitably introduces heterogeneity in terms of surgeon expertise, procedural technique, instrumentation, and perioperative care pathways. Although PSM was used to adjust for key confounders, unmeasured variables, such as surgical experience, center volume, and local protocols, may have influenced the outcomes. Moreover, the observational and non-randomized nature of the study prevents us from establishing causal relationships. Notably, the lack of detailed intraoperative data, like irrigation pressures and laser settings, limits understanding of the mechanisms driving outcome differences between the two techniques. Importantly, patient-reported outcomes such as quality of life, return to normal activities, or satisfaction were not collected, and these factors are increasingly valued in comparative surgical studies. This is undoubtedly a further study limitation. Additionally, follow-up was limited to 30 days; therefore, the actual re-interventions performed and their findings are unavailable. Even though functional renal outcomes and long-term anatomical outcomes in different GSS groups are missing, it's well proven that using FANS in normal kidneys is anatomically and physiologically safe in adults [41, 42].

The use of GSS as a matching covariate between PCNL and RIRS groups may be inappropriate, as GSS was originally developed and validated specifically for PCNL procedures and reflects complexity factors unique to PCNL that do not translate to equivalent complexity in RIRS. However, GSS is a reasonable surrogate marker to standardize comparisons across groups in the absence of a universally accepted scoring system for RIRS as demonstrated by recent comparative studies which showed that GSS predict surgical results in RIRS as well, with SFRs decreasing and complications increasing as GSS increased for both procedures [43, 44]. Nevertheless, the significant baseline imbalance in lower calyceal stone distribution between groups (29.3% vs. 40.2%) represents another potential bias, as lower pole stones are traditionally considered more challenging for RIRS due to unfavorable ureteroscope angles and gravity-dependent drainage. Conversely, a recent study of RIRS with FANS comparing patients with lower pole stones versus other locations showed that the SFR of lower pole stones is comparable to non-lower pole locations, suggesting that the imbalance in lower pole stones might not have significantly biased our findings [45].

Finally, as this was a comparative study where the STUMPS registry had used 4 mm as a cutoff, this was also applied to FANS patients for statistical analysis. Perhaps if we used 2 mm as a cutoff threshold for RF, the outcome reporting may have been different. As highlighted by Zeng et al. [11], future randomized trials with standardized protocols and long-term follow-up are needed to refine the comparative roles of these suction modalities to enable a patient-tailored approach, also considering cost-effectiveness.

Conclusion

Although both techniques are safe and effective, SM-PCNL is better for achieving 100% stone clearance or ZRF, especially in GSS 2 and 3 cases. FANS offers faster recovery and lower postoperative pain scores. The GSS is useful to predict 100% SFR for both modalities. Even though the proposed re-intervention rate was higher in FANS, as ours is only a 30-day follow-up study, the true re-intervention rate and outcomes are lacking. As zero sepsis and absence of major complications make both modalities safe, surgeons should individualize treatment based on counselling and their expertise.

Author contributions Conception and design: Vineet Gauhar, Angelo Cormio, Daniele Castellani. Acquisition of data: Steffi Kar-Kei Yuen, Nariman Gadzhiev, Jaisukh Kalathia, Amish Mehta, Vigen Malkhasyan, Nitesh Kumar, Edgar Beltrán-Suárez, Abhay Mahaja, Karl Tan, Kremena Petkova, Kazumi Taguchi, Mohamed Amine Lakmichi, Yiloren Tanidir, Marcos Cepeda, Alexey Martov, Zelimkhan Tokhtiyev, Lazaros Tzelves, Andreas Skolarikos, Mahmoud Laymon, Esteban Acuña, Wissam Kamal, Heng Chin Tiong, Leonardo Gomes Lopes, Dmitriy Gorelov. Statistics: Khi Yung Fong. Drafting of the manuscript: Angelo Cormio, Vineet Gauhar, Daniele Castellani. Critical revision for important intellectual content: Bhaskar K. Somani, Thomas R. W. Herrmann. Supervision: Vineet Gauhar. All authors approved of the final version of the manuscript for submission.

Funding The authors did not receive support from any organization for the submitted work.

Data availability Data is available on request from the corresponding author.

Declarations

Conflict of interest The authors declare no conflict of interest.

Human rights Institutional board review approval was obtained by the leading center for STUMPS (Asian Institute of Nephro-Urology, AINU #01/2024) and FANS (AINU-EC/28/2023) study. The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

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