BJU Int 2021; **127:** 307–310 doi:10.1111/bju.15291

BJUI
BJU International

Research Communication

Robot-assisted fluoroscopy-guided renal puncture for endoscopic combined intrarenal surgery: a pilot single-centre clinical trial

The development of new and improved endoscopic devices has led to percutaneous nephrolithotomy (PCNL) being widely used to treat large renal stones [1]. Although this technique provides a high stone-free rate (SFR), it is also associated with various complications, e.g. bleeding, urosepsis, and thoracic/abdominal injuries, which are mainly related to renal access. Thus, even during endoscopic combined intrarenal surgery (ECIRS), renal access and especially papillary puncture should be guided using ultrasonography (US) or fluoroscopy, which requires a fair amount of training to master [2]. A new strategy involves electromagnetic guidance through a ureteroscope to achieve retrograde puncture of the renal papilla [3]. These techniques can allow even inexperienced surgeons to achieve proper renal access, although manual adjustment of the puncture remains a challenging step.

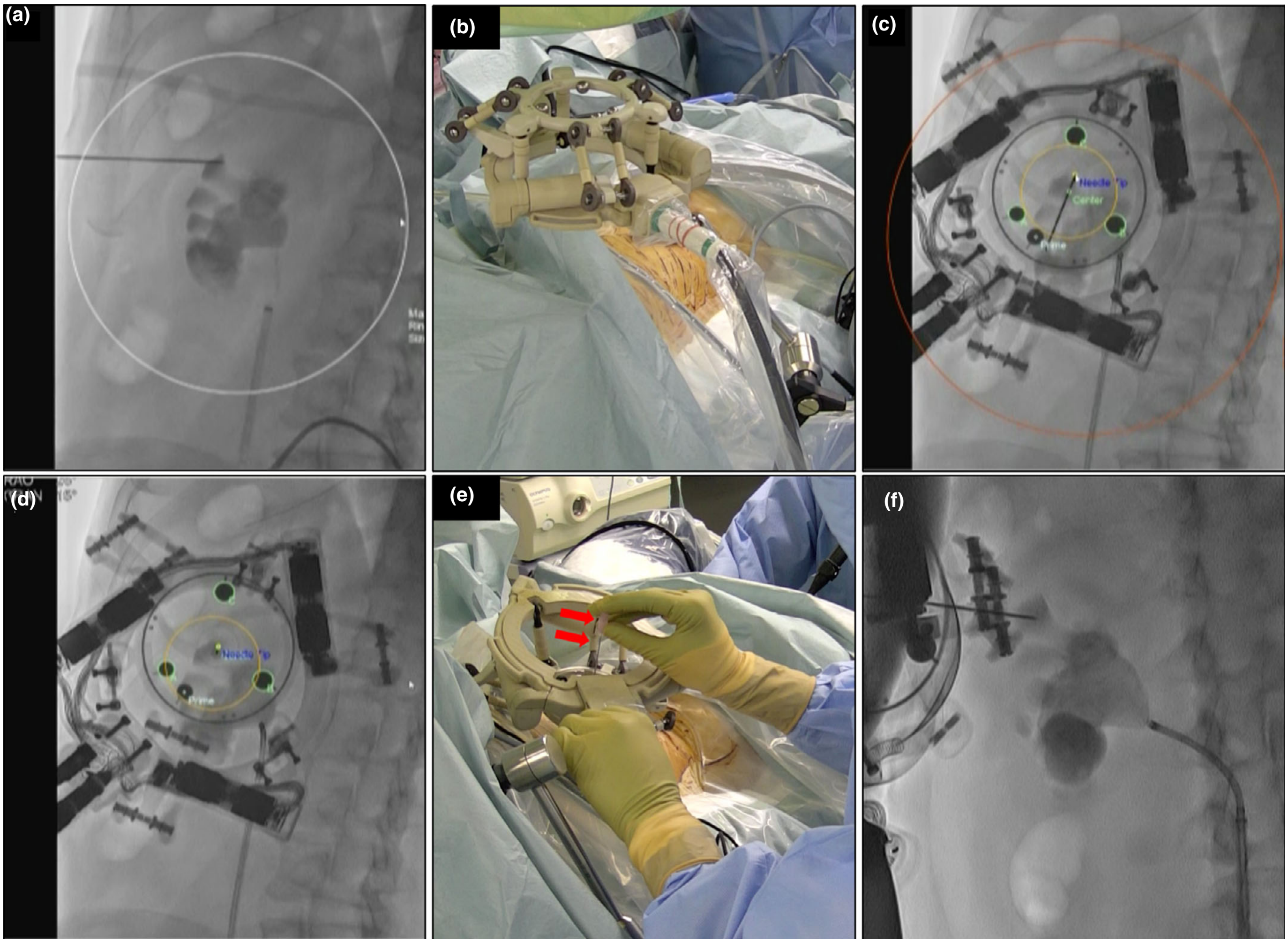
Robotic percutaneous access to the kidney was first introduced in 2002 [4] and an automated needle target with X-ray (ANT-X) has been developed for navigating renal puncture during PCNL [5]. The software uses artificial intelligence to determine the optimal trajectory for needle puncture using a single-shot fluoroscopic image and a calculation of the distances between the robot-arm markers and the needle tip location on the patient's skin. We have evaluated the safety and efficacy of ANT-X for renal puncture in a bench-top study using a phantom kidney model and subsequently during ECIRS [6]. Based on the preliminary results indicating that the ANT-X process was potentially useful, we designed a pilot study to investigate the clinical safety and feasibility of robot-assisted fluoroscopy-guided (RAF)-ECIRS.

The present single-centre single-arm pilot study was conducted at the Nagoya City University Hospital between January 2020 and June 2020. The study protocol was approved by the Institutional Review Board (#2019A002) and registered in the Japan Registry of Clinical Trials (#jRCTs042190074). All subjects provided informed consent prior to enrolment. We recruited patients who were aged 16–80 years, had large renal stones (diameter >15 mm), and had requested miniaturised ECIRS. We excluded patients if they were pregnant women, had an active UTI, were undergoing anti-platelet/coagulation therapy, or general anaesthesia was considered difficult by the anaesthesiologists. The primary endpoints were SFR at 3 months after the procedure and the rate of successful renal puncture. The secondary endpoints included the renal puncture time, fluoroscopy time, total operation time, and perioperative complications. The SFR was calculated as the number of cases with no residual fragments that were >3 mm, based on CT findings.

All RAF-ECIRS procedures were performed by a single surgeon (K.T.) who had never performed a procedure that involved fluoroscopy-guided renal access. During the procedures, the patients were positioned in the prone split-leg position under general anaesthesia. A flexible ureteroscope was inserted through a ureteric access sheath and the contrast medium was injected from the ureteroscope to fluoroscopically visualise the renal collecting system. The surgeon then initiated the PCNL by mounting the robot-arm on the patient and marking the needle tip point on the patient's skin based on the fluoroscopic image of the renal collecting system. The software determined the optimal trajectory for calyx puncture using the fluoroscopic image and the needle was inserted into the targeted calyx from the tilted C-arm view. The insertion was also guided by fluoroscopy and ureteroscopy if possible. The details of RAF renal access are illustrated in Fig. 1. The rest of the procedure was continued using a 16.5/17.5-F percutaneous tract with a 12-F nephroscope (Karl Storz, Tuttlingen, Germany) and pneumatic lithotripter.

Despite the coronavirus pandemic, we enrolled 19 patients during the 6-month study period, including 14 men and five women. The mean age was 55 years and the mean body mass index (BMI) was 24.18 kg/m^2. Seven cases involved staghorn stones and 14 did not involve hydronephrosis. Table 1A and B summarises the renal puncture parameters and the surgical outcomes between the RAF-ECIRS arm and a historical cohort of patients from our institutional database that underwent US-guided ECIRS between January 2016 and December 2019. The historical cohort was matched 2:1 according to age, sex, BMI, preoperative hydronephrosis, and stone burden/density. The RAF-ECIRS arm had median values of one needle insertion attempt, 3.6 min for total needle insertion time, 10 s for needle alignment time, and 1.2 min for irradiation time during renal access. Successful renal access was achieved from the lower calyces in 10 cases, the middle calyces in six cases, and the upper calyces in three cases. The learning curve for renal puncture during RAF-ECIRS was evaluated based on a comparison to the first 10

Fig. 1 Surgical technique of RAF percutaneous access. (**a**) The needle insertion point on the patient's skin was determined by fluoroscopy. (**b**) The robot-arm of the ANT-X was mounted over the patient. (**c, d**) The software view of the ANT-X integrated with a fluoroscopic image. The needle tip was selected for the adjustment. (**c**) After the puncture trajectory alignment completion, the needle formed a 'bull's eye' aiming for the renal calyx. (**d**) The needle was inserted by the surgeon through the needle holder with the robot-arm, **e**: external view (red arrows = 18-G needle) and (**f**) fluoroscopic view.



cases, which revealed that the last nine cases had significantly lower median values for total needle insertion time (2.8 vs 8.5 min, $P = 0.006$) and irradiation time during renal access (0.9 vs 3.1 min, $P = 0.002$). We also compared the outcomes between the RAF-ECIRS arm and the historical US-guided ECIRS cohort, which generally revealed no significant differences in operation time, fluoroscopy time, and SFR. One exception was a significant difference in the change in the estimated GFR (eGFR).

To the best of our knowledge, the present study is the first experience with RAF-ECIRS using the ANT-X device. The trajectory toward the targeted renal calyx was calculated via artificial intelligence, which facilitated prompt renal access using the 'bull's eye' technique, even for a surgeon that had no previous experience with fluoroscopy-guided renal puncture. The outcomes for renal puncture during ECIRS seem reasonable, based on median values of one needle insertion attempt and 3.6 min for a successful needle insertion, which included device set-up. More importantly, a comparison of the RAF-ECIRS arm and the matched historical US-guided ECIRS cohort revealed no significant differences in terms of surgical outcomes, including the SFR, operation time, fluoroscopy time, and complication rate. Nevertheless, the RAF-ECIRS group had a significant decrease in the eGFR, which suggests that there is room to improve this technique. There are no clear data regarding whether fluoroscopy-guided or US-guided PCNL is preferable [7], and it would be useful to both clinicians and patients to have an alternative modality. Our present results suggest that RAF-ECIRS using ANT-X is feasible for treating large renal stones in clinical practice. We also observed that the learning curve

Table 1A) Renal puncture details and surgical outcomes for RAF-ECIRS.

a) Details of renal puncture in each case of RAF-ECIRS

Case number	Needle insertion attempts, *n*	Needle insertion time, min*		Needle alignment time, s†	Radiation time, min‡	Calyx location (diameter, mm)			
		Average	Total	Final attempt	Total	1st attempt	2nd attempt	3rd attempt	4th attempt
1	1	3.1	3.1	25	1.6	Lower (10)			
2	1	7.6	7.6	23	2.9	Lower (12)			
3	4	13.4	53.7	14	14.4	Upper (5)	Upper (5)	Lower (8)	Lower (10)
4	1	4.4	4.4	10	1.2	Middle (8)			
5	2	5.1	10.1	23	4.4	Lower (8)	Lower (8)		
6	1	3.4	3.4	12	1.1	Lower (8)			
7	4	4.7	18.6	9	3.9	Upper (5)	Middle (10)	Middle (8)	Middle (10)
8	2	4.7	9.4	9	4.1	Lower (6)	Middle (10)		
9	1	4.1	4.1	10	1.4	Lower (12)			
10	2	6.6	13.2	11	3.2	Middle (10)	Middle (10)		
11	1	3.4	3.4	9	1	Lower (18)			
12	1	1.6	1.6	10	0.9	Middle (8)			
13	1	2.6	2.6	8	0.6	Lower (20)			
14	1	3.1	3.1	9	1.2	lower (12)			
15	1	3.6	3.6	10	0.9	Lower (12)			
16	2	5.2	10.3	14	3.2	Middle (12)	Middle (10)		
17	1	2.6	2.6	9	0.9	Upper (12)			
18	1	2.7	2.7	20	0.9	Upper (9)			
19	1	2.8	2.8	8	0.5	Upper (15)			

Characteristic	RAF-ECIRS (*n* = 19)	US-guided ECIRS (*n* = 38)§	*P*
Age, years, mean (SD)	55.0 (12.2)	55.6 (14.7)	0.872
Sex, male:female, *n* (%)	14 (73.7):5 (26.3)	29 (76.3):9 (23.7)	1.000
BMI, kg/m^2, mean (SD)	24.18 (3.43)	24.42 (4.63)	0.839
Presence of staghorn stone, *n* (%)	7 (36.8)	12 (31.6)	0.769
Stone burden, mm, median (IQR)	42.0 (28.5–50.5)	38.5 (29.3–44.8)	0.594
Stone density, HU, median (IQR)	1198 (1131–1407)	1271 (989–1377)	0.352
Hydronephrosis, *n* (%)	14 (73.7)	25 (65.8)	0.135
None	1 (5.3)	8 (21.1)	
Mild	3 (15.8)	1 (2.6)	
Moderate	1 (5.3)	4 (10.5)	
Severe			
Operation time, min, median (IQR)	112.0 (76.0–139.5)	122.5 (99.5–152.3)	0.365
Fluoroscopy time, min, median (IQR)	11.0 (8.1–17.8)	12.0 (8.9–18.8)	0.477
Stone-free outcome, *n* (%)	11 (61.1)	18 (47.4)	0.399
Decrease in haemoglobin, g/L, median (IQR)	10.0 (4.0–18.0)	9.0 (4.3–16.7)	0.939
Decrease in eGFR, mL/min/1.73 m^2, median (IQR)	4.80 (0.35–11.80)	–0.50 (–4.75 to 3.60)	0.011
Clavien–Dindo classification of postoperative complications, *n* (%)	11 (57.9)	23 (60.5)	0.857
Grade 0	4 (21.1)	6 (15.8)	
Grade I	4 (21.1)	9 (23.7)	
Grade II			

Time from robot-arm placement on the patient to confirmation of urine efflux and/or guidewire insertion. †Time from the start of the software trajectory calculation to successful needle alignment. ‡Time from robot placement to confirmation of nephroscope insertion into the renal collecting system. §Propensity score matching (1:2) was performed according to age, sex, BMI, stone burden, stone density, and preoperative hydronephrosis grade.

may be relatively short for RAF-ECIRS using ANT-X, as we detected substantial improvements after the first 10 cases in terms of needle insertion attempts, needle insertion time, and irradiation time during needle insertion. Thus, this technique may facilitate accurate renal puncture and safe PCNL or ECIRS, even for inexperienced surgeons or trainees.

The present study has some limitations. First, the pilot nature of the study resulted in a small sample size and limited power of the statistical analyses. Second, the RAC-ECIRS arm was not compared to a group that underwent conventional manual fluoroscopy-guided renal access. Third, the single-centre nature of the study suggests that different results might be observed at other centres or when performing PCNL.

We developed a new RAF-ECIRS technique for treating large renal stones, which appears to be a safe and effective procedure when combined with ANT-X, similar to the US-guided ECIRS technique.

Acknowledgements

This work was funded by the Grants-in-Aid for Scientific Research, Japan Society for the Promotion of Science (20K21658) and a research grant from the Casio Science Promotion Foundation. We also thank NDR Medical Technology for the use of the ANT-X device, as well as our radiology staff and medical engineers for their assistance. In addition, we would like to thank Editage (www.editage.com) for English language editing.

Conflicts of Interest

None declared.

Kazumi Taguchi, Shuzo Hamamoto, Taiki Kato, Shoichiro Iwatsuki, Toshiki Etani, Atsushi Okada and Takahiro Yasui

Department of Nephro-urology, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan

References

1 **Axelsson TA, Cracco C, Desai M et al.** Consultation on kidney stones, Copenhagen lithotripsy in percutaneous nephrolithotomy. *World J Urol* 2020 [online ahead of print]. DOI: https://doi.org/10.1007/s00345-020-03383-w

2 **Veys R, Verpoort P, Van Haute C, Wang ZT, Chi T, Tailly T.** Thiel-embalmed cadavers as a novel training model for ultrasound-guided supine endoscopic combined intrarenal surgery. *BJU Int* 2020; 125: 579–85

3 **Lima E, Rodrigues PL, Mota P et al.** Ureteroscopy-assisted percutaneous kidney access made easy: first clinical experience with a novel navigation system using electromagnetic guidance (IDEAL Stage 1). *Eur Urol* 2017; 72: 610–6

4 **Su LM, Stoianovici D, Jarrett TW et al.** Robotic percutaneous access to the kidney: comparison with standard manual access. *J Endourol* 2002; 16: 471–5

5 **Oo MM, Gandhi HR, Chong KT et al.** Automated needle targeting with X-ray (ANT-X) – robot-assisted device for percutaneous nephrolithotomy (PCNL) with its first successful use in human. *J Endourol* 2018 [online ahead of print]. DOI: https://doi.org/10.1089/end.2018.0003

6 **Taguchi K, Hamamoto S, Okada A et al.** Robot-assisted fluoroscopy versus ultrasound-guided renal access for nephrolithotomy: a phantom model benchtop study. *J Endourol* 2019; 33: 987–94

7 **Corrales M, Doizi S, Barghouthy Y, Kamkoum H, Somani BK, Traxer O.** Ultrasound or fluoroscopy for percutaneous nephrolithotomy access, is there really a difference? A review of literature. *J Endourol* 2020 [online ahead of print]. DOI: https://doi.org/10.1089/end.2020.0672

Correspondence: Kazumi Taguchi, Department of Nephro-urology, Nagoya City University Graduate School of Medical Sciences, Kawasumi 1, Mizuho-cho, Mizuho-ku, Nagoya 4678601, Japan.

e-mail: ktaguchi@med.nagoya-cu.ac.jp

Abbreviations: ANT-X, automated needle target with X-ray; BMI, body mass index; ECIRS, endoscopic combined intrarenal surgery; eGFR, estimated glomerular filtration rate; HU, Hounsfield unit; PCNL, percutaneous nephrolithotomy; RAF, robot-assisted fluoroscopy-guide; SFR, stone-free rate; US, ultrasonography.