Evaluation of flexible ureteroscope with an omni-directional bending tip, using a JOYSTICK unit (URF-Y0016): an ex-vivo study

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ORIGINAL ARTICLE

Evaluation of flexible ureteroscope with an omni-directional bending tip, using a JOYSTICK unit (URF-Y0016): an ex-vivo study

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Abstract

Purpose To compare the range of reach of our newly designed omni-directional ureteroscope (URF-Y0016), compared to the commonly used URF-P6, FlexX2s, and LithoVue™ scopes, in the upper, middle, and lower calyces in an ex-vivo pyelocaliceal model.

Methods We fabricated a three-dimensional pyelocaliceal model of the upper, middle, and lower pole calyces using urethane and acrylic resin. The inner surface of the dome of each calyx was engraved with reference lines along eight directions, set at 10° of latitude from the top to the base of the dome, and at angles of 0–90°, to precisely determine the range of reach of each scope. The main feature of the URF-Y0016 scope is the omni-directional bending of the tip of the flexible ureteroscope, with the control of these four directions integrated into a handgun-type control unit with a joystick. The range of reach within each calyx was measured by four expert surgeons.

Results The URF-Y0016 scope provided a greater range of reach along all directions in the lower pole calyx compared to URF-P6, FlexX2s, and LithoVue™ scopes ($p < 0.001$), particularly along the anterior–posterior direction in the lower lobe calyx. However, the URF-Y0016 scope did not influence the improvement of reach range in the upper and middle pole calyx compared to URF-P6, FlexX2s, and LithoVue™ scopes ($p = 0.08$, $p = 0.296$).

Conclusion The novel design of the URF-Y0016 could improve treatment outcomes for calyceal stones in the lower pole in practice.

Keywords New technology of fURS · Omni-directional bending · Joystick handle · Lower pole access

Abbreviations

SWL	Extracorporeal shockwave lithotripsy
PCNL	Percutaneous nephrolithotomy
RIRS	Retrograde intrarenal surgery
EAU	European Association of Urology
SFR	Stone-free rate
IPA	Infundibulopelvic angle
IL	Infundibular length
IW	Infundibular width
CPH	Caliceal pelvic height
TURBT	Transurethral bladder tumor resection
TURP	Transurethral prostate resection

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Introduction

Technological developments, including the introduction of endoscopes, holmium laser, and basket forceps, have provided more appropriate and less invasive treatment options, including the use of extracorporeal shockwave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL), and retrograde intrarenal surgery (RIRS) for the treatment of urolithiasis. In particular, RIRS using a flexible ureteroscopy has dramatically advanced kidney stone surgery. The European Association of Urology (EAU) guidelines recommend RIRS as a versatile and an appropriate treatment option for all locations of kidney stone and for all stone size [1]. However, patients with lower pole stones are 2.25 times more likely to have residual stones after RIRS, compared to patients with stones in other locations [2]. The treatment of lower pole stones using RIRS is technically difficult due to the restricted range accessible in the lower pole calyx when using a retrograde ureteral access with a flexible ureteroscope having

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two-directional tip deflection. To address this limitation, we developed a novel flexible ureteroscope that uses a joystick unit (URF-Y0016) to provide omni-directional bending of the tip. Our aim in this study was to evaluate the usefulness of the URF-Y0016 flexible ureteroscope for the treatment of lower pole stones.

Materials and methods

Specifications of the URF-Y0016 flexible ureteroscope

The URF-Y0016 (Olympus, Japan) provides omni-directional bending of the tip of the flexible ureteroscope, with the control of these four directions integrated into a handgun-type control unit with a joystick (Fig. 1a). Other features of the URF-Y0016 ureteroscope include a micromini C-MOS optical sensor; an 8.4 Fr outer diameter of the insertion tube; a working length of 670 mm; and a 3.6 Fr working channel, located at the 9:00 o'clock position. Furthermore, the scope includes a range of angulation range from 275° (up) to 275° (down), as well as 100° each to the right and left (Fig. 1b–d). The diameter of curvature at full deflection in up-down and right-left is 24 mm and 23 mm, respectively.

The 3-dimensional pyelocaliceal model used

A 3-dimensional (3D) pyelocaliceal model was used to evaluate the range of each ureteroscope. The model was fabricated using urethane and acrylic resin. The model included the upper, middle, and lower pole calyces, as well as the ureteral portion located on the opposite side of the upper calyx. Based on a previous study [3], the model included an infundibulopelvic angle of 40°, an infundibular length of 15 mm in each calyx, and a 10-mm infundibular width in the lower calyx. A 20-mm dome radius was also constructed in each calyx to ensure sufficient movable range for the flexible ureteroscope (Fig. 2a). The inner surface of the dome of each calyx was engraved with reference lines along eight directions, set at 10° of latitude from the top to the base of the dome, and at angles of 0–90°, to precisely determine the range of reach of the flexible ureteroscope (Fig. 2b, c).

Evaluation of the URF-Y0016

We compared the accessible range of the URF-Y0016 to the URF-P6 (Olympus, Japan), FlexX2s (Karl Storz, Germany), and LithoVue™ (Boston Scientific, US) which are commonly used in practice and characterized by 22 mm, 33 mm, and 28 mm in the diameter of curvature at full deflection of up-down, using our 3D pyelocaliceal model immersed in

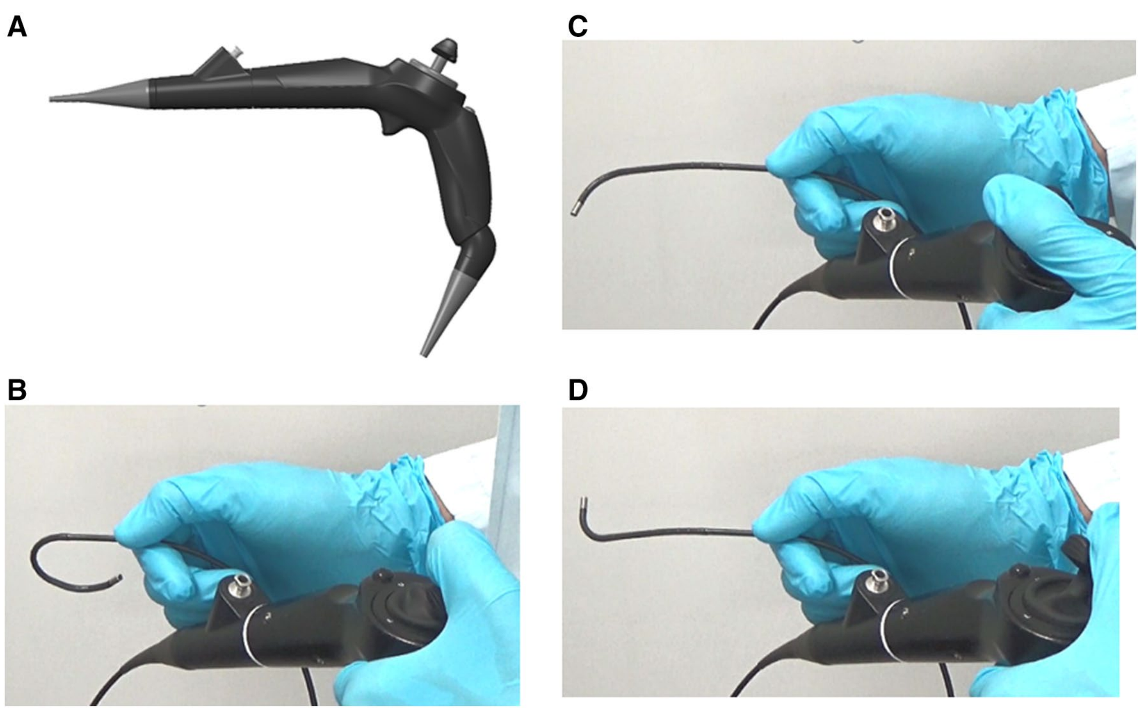

Fig. 1 **a**–**d** Armamentarium of novel flexible ureteroscope with JOYSTICK unit (URF-Y0016). The image of control unit of handgun type with joystick (**a**), down deflection with joystick (**b**), left side deflection with joystick (**c**), right side deflection with joystick (**d**)

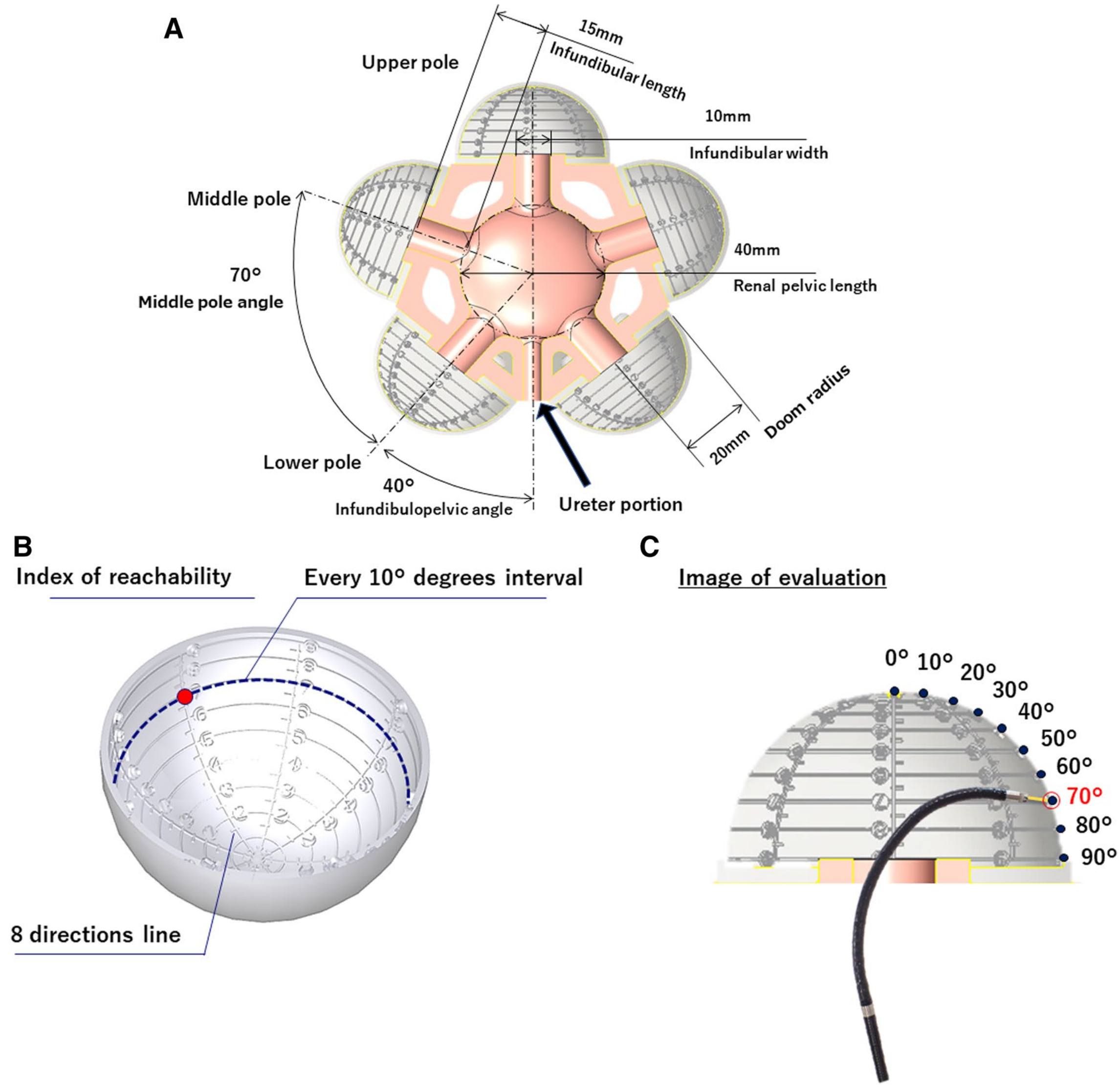

Fig. 2 **a**–**c** Three-dimensional pyelocaliceal model. The schema of details in pyelocaliceal model (**a**), the index of reachability inside of calyx dome in model including eight directions line and every 10° interval line (**b**), imaging schema to evaluate the reachability of flexible ureteroscope

water as an ex-vivo model [4]. Four surgeons, expert in urolithiasis procedures, evaluated the accessible range of both scopes along the eight directions, in the upper, middle, and lower calyx. Measurements with each scope were repeated twice. For all measurement, the flexible ureteroscope being evaluated was inserted via the ureteral portion of the 3D pyelocaliceal model. Basket forceps (Flex-Catch NT 1.9 Fr, Olympus) were inserted through the working channel of each scope and fixed to the tip of the scope. The index of reachability for each scope was determined by the furthest point contacted along all eight directions, which, together, provided the full range of reach of each scope in each calyx (Fig. 3a), which we compared among the four scopes. An analogue clock diagram was used to simply depict the full range of reach for each scope. The direction in these diagrams was classified as 1 through 8, with directions 1 and 5 along the anterior and posterior direction, respectively, in each calyx (Fig. 3b).

Statistical analysis

All collected data were analyzed using SPSS (version 21, IBM Corp., Armonk, NY, USA). An analysis of variance (ANOVA), with a Bonferroni correction for two-way factorial ANOVA, was used to evaluate the reach angle along with all eight directions among the URF-Y0016, URF-P6, FlexX2s, and LithoVue™ scopes in each calyx. A two-sided p value of < 0.05 was considered statistically significant.

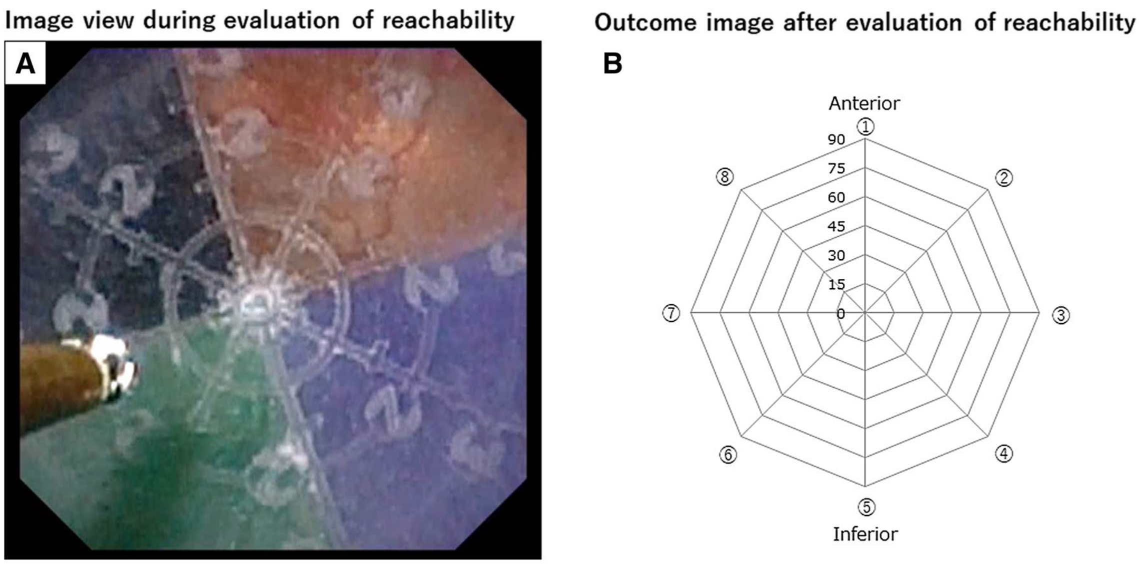

Fig. 3 **a**–**c** Evaluation methods of reachability. Image view during the evaluation of reachability (**a**), outcome image after evaluation of reachability (**b**)

Results

Compared to the URF-P6, FlexX2s, and LithoVue™, the URF-Y0016 had a significantly greater range of reach in the lower pole calyx of the 3D pyelocaliceal model ($p < 0.001$), but with no difference in the upper ($p = 0.08$) and middle ($p = 0.296$) pole calyx (Fig. 4). In the lower pole calyx, the URF-Y0016 provided a greater angle of reach in all directions compared to the URF-P6, FlexX2s, and LithoVue™, In particular, the URF-Y0016 quite significantly increased the reach angle along the 12:00 and 1:30 o'clock directions (anterior) and 4:30, 6:00 and 7:30 o'clock direction (posterior) in the lower pole calyx compared to the URF-P6, FlexX2s, and LithoVue™ ($p < 0.0001$) (Table 1). The accessible range among URF-P6, FlexX2s, and LithoVue™ is not significant difference in the lower, middle, and upper pole calyx, respectively ($p = 0.867$, $p = 0.945$, $p = 0.740$).

Discussion

We developed a novel flexible ureteroscope, the URF-Y0016, which provided omni-directional bending using a joystick unit. In this study, we demonstrated that the URF-Y0016 provided a significantly greater range of reach in the lower pole calyx of the 3D pyelocaliceal model than the URF-P6, FlexX2s, and LithoVue™ scopes which is commonly used.

The RIRS provides a sufficiently high stone-free rate (SFR) of 79–83% for kidney stones 10–15 mm in size, with a SFR of 73–90% for stones > 20 mm in size [5, 6]. RIRS has

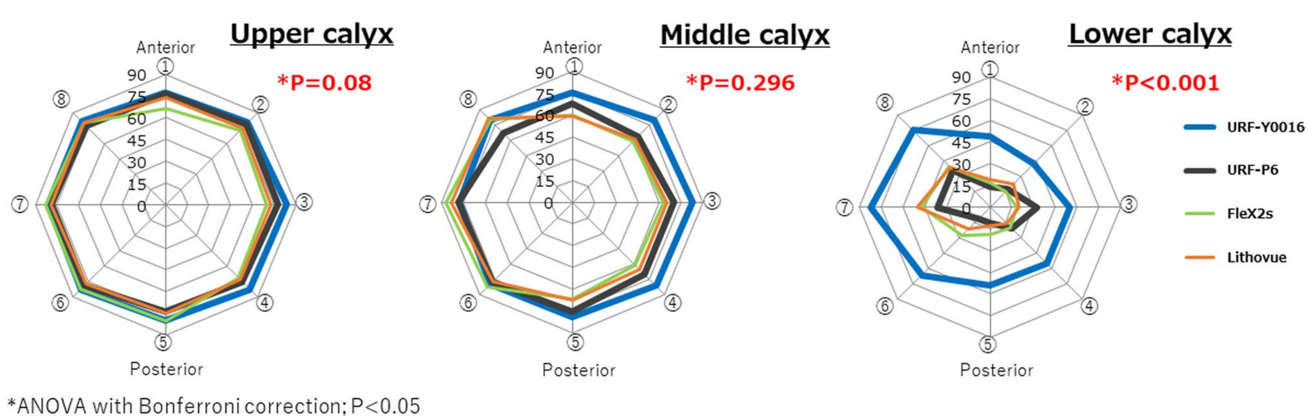

Fig. 4 Reachability range in upper, middle, and lower calyx

Table 1 Reachable angle among four types flexible URSin lower calyx according to eight directions

Direction no	Clock position	Mean accessible angle; URF-Y0016, degree (SD)	Mean accessible angle; URF-P6, degree (SD)	Mean accessible angle; FlexX2s, degree (SD)	Mean accessible angle; LithoVue, degree (SD)	*p* value*
1	12:00	48.7 (8.5)	13.7 (2.5)	16.2 (2.5)	18.7 (2.5)	< 0.0001**
2	1:30	42.5 (6.5)	17.5 (5.0)	15 (0)	22.5 (2.8)	< 0.0001**
3	3:00	55 (5.8)	32.5 (13.2)	18.7 (2.5)	20 (8.1)	0.0006
4	4:30	55 (12.2)	21.2 (7.5)	20 (0)	16.2 (2.5)	< 0.0001**
5	6:00	53.7 (7.5)	11.2 (2.5)	18.7 (2.5)	12.5 (2.8)	< 0.0001**
6	7:30	66.2 (2.5)	11.2 (8.5)	27.5 (2.8)	21.2 (2.5)	< 0.0001**
7	9:00	82.5 (5.0)	36.2 (17.0)	47.5 (6.4)	50 (0)	0.0004
8	10:30	75 (4.1)	36.2 (21.4)	40 (0)	38.7 (2.5)	0.0032

*ANOVA with Bonferroni correction; $p < 0.05$

**ANOVA with Bonferroni correction; $p < 0.0001$

become an alternative modality even if in pediatric patients with kidney stones 1–2 cm in size [7]. However, the efficiency of RIRS in the lower pole calyx is lower than that of PCNL due to a difficult access owing to various anatomical difference (SFR 71.2% for RIRS versus 91.2% for PCNL) [8]. Tonyali et al. reported that patients with lower pole stones are 2.25 times more likely to have residual stones after RIRS compared to patients treated for stones in other locations [2].

The pelvicalyceal anatomy dictates the success of surgery, with the anatomy of the lower pole being specifically related to treatment outcome for lower pole kidney stones [9, 10]. Inoue et al. identified an infundibulopelvic angle (IPA) < 30° as a significant negative risk factor for achievement of a stone-free status after RIRS, although infundibular length (IL), infundibular width (IW), and caliceal pelvic height (CPH) were not identified significant factors [3]. In their systematic review, Kalim and colleagues also reported that a steep IPA (< 30°) was a significant predictor of surgical failure in patients treated for isolated lower pole stones using RIRS [9]. In addition, Jung et al. [11] found that location of a stone in the lower-anterior minor calyx also negatively influenced the stone-free status after RIRS, with stones in this location being more difficult to remove than those in the lower-posterior minor calyx. Therefore, the treatment of stones in the lower pole calyx using a flexible ureteroscope with the usual two directions of tip deflection may be impractical, owing to the difficulty in accessing the required range of the lower pole calyx, due to the local anatomy and the limited functionality currently available ureteroscopes. It is for these reasons that PCNL is still considered as the standard option for the treatment of kidney stones in the lower pole, including for cases in which the anatomy makes it difficult to reach the stone and in cases of failed RIRS [12]. However, PCNL does carry disadvantages, including a higher volume of blood loss, complication rate, postoperative pain, and longer hospitalization, compared to RIRS [13]. It is for these reasons that we developed our novel flexible URF-Y0016 ureteroscope with omni-directional bending, using joystick unit, providing accessibility to the upper, middle, and lower lobe calyces during RIRS. In present this study, we demonstrated that URF-Y0016 provided a significantly greater range of reachability than the URF-P6, FlexX2s, and LitoVue scopes, particularly along the anterior–posterior direction of the lower pole calyx.

The ergonomic design of flexible ureteroscopes has recently been increasingly considered, owing to the discomfort and fatigue reported by surgeons, during or after procedures [14]. Various factors contribute to this reported discomfort and fatigue, including ureteroscopic manipulation, surgeon positioning (sitting or standing), weight of the ureteroscope, and the need for wearing a lead apron. Current new robotic flexible ureteroscope has been improved the surgeon ergonomics. Saglam et al. reported robotic flexible ureteroscope was a significant advantage regarding surgeon ergonomics than reusable flexible ureteroscope [15, 16]. In our study, we modified the grip handle of the URF-Y0016, opting for a handgun controller design with a joystick unit, as found in other devices used for transurethral bladder tumor resection (TURBT) and transurethral prostate resection (TURP). The shaft of the flexible ureteroscope is straight, providing easy 'back and forth' manipulation of the scope with one hand. As such, it is possible for the surgeon to perform the procedure in a sitting position. Overall, our design may be expected to decrease the ergonomic burden of the procedure, which is important considering the need to wear a lead apron to protect against radiation exposure.

The limitations of our study need to be acknowledged. The present study was performed to evaluate the functionality of URF-Y0016, compared to the commonly used URF-P6 scope, using a 3D pyelocaliceal ex-vivo model. However, the efficiency of the URF-Y0016 scope in clinical practice is not evaluated yet. Therefore, we are planning in the near future to evaluate the benefit and safety of the URF-Y0016 in clinical practice. Secondary, although we did not assess about ergonomics for surgeon's comfort in this present study, we are undergoing the comparison to ergonomics such as hand pain, arm pain, wrist stiffness and so on in another study. Therefore, we will report about it after trial. Despite these limitations, we still expect that the URF-Y0016 will improve the treatment of lower pole stones, leading to an increase in SFR for these cases, as well as for all other locations of calyceal stones.

Conclusion

We developed the URF-Y0016 as a novel flexible ureteroscope, providing omni-directional bending of the tip with an ergonomically-designed controller. The URF-Y0016 provides greater access to the lower pole calyx, particularly along the anterior–posterior direction. This increased reachability, compared to the commonly used URF-P6, FlexX2s, and LithoVue scopes, could improve treatment outcomes for calyceal stones in the lower pole in practice.

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Author's contribution TI: protocol/project development, data collection, data analysis, manuscript writing. SO: protocol/project development. SH: protocol/project development. HM: data collection. JM: data collection. MT: data collection. HF: protocol/project development. MF: protocol/project development. TM: protocol/project development. KN: protocol/project development.

Compliance with ethical standards

Conflict of interest Olympus funded, and lent the equipment for this study.

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