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Effectiveness of a newly-developed training module using 3D printing for the navigation during retrograde intrarenal surgery

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Purpose: This study aimed to evaluate the feasibility of the newly-developed three-dimensional (3D) printed training module for navigation during retrograde intrarenal surgery.

Materials and Methods: Two specialists provided orientation to all trainees. The 3D printing model consisted of eight calyces in each kidney. One navigation time started from the moment when the endoscope entered the ureter. After navigation was completed, the navigation time was recorded. The goal was to perform ten navigation times for each side, starting from the right or the left side at random. After the experiment, all trainees were asked to fill out a questionnaire.

Results: The average training period of all 17 trainees was 3.05±1.80 years. Eleven trainees (64.7%) had the experience of assisting surgery for <100 cases, and six trainees (35.3%) had the experience of assisting surgery for 100 to 500 cases. Nine trainees (52.9%) began training from the right, and eight trainees (47.1%) started from the left. The average navigation time of 308 trials was 153.4±92.6 seconds. The maximum and minimum navigation times were 354.3±177.2 seconds and 80.1±25.6 seconds. The mean navigation time of the first and the last trials of all trainees significantly decreased from 251.4±108.0 seconds to 93.9±33.2 seconds. The average reduction in navigation time was 201.3±133.3 seconds. Almost all trainees were satisfied with the training.

Conclusions: The newly-developed 3D printing navigation training module seems to be adequate to improve surgical skills of flexible ureteroscopy.

Keywords: Education; Endoscopy; Navigation training module; Renal calculi; Three-dimensional printing

INTRODUCTION

Flexible ureteroscopy (fURS) has become popular in the last several decades [1]. Indications for retrograde intrarenal surgery (RIRS) have extended from small calyceal stones to difficult cases such as large stones, stones in lower pole, or in kidneys with anatomical abnormalities. Recent technological advance has supported this evolution while increasing the complexity of procedures [1,2].

RIRS can be a complicated procedure to achieve successful outcomes. The steep learning curve will make beginners stop the surgery if they are not familiar with the RIRS

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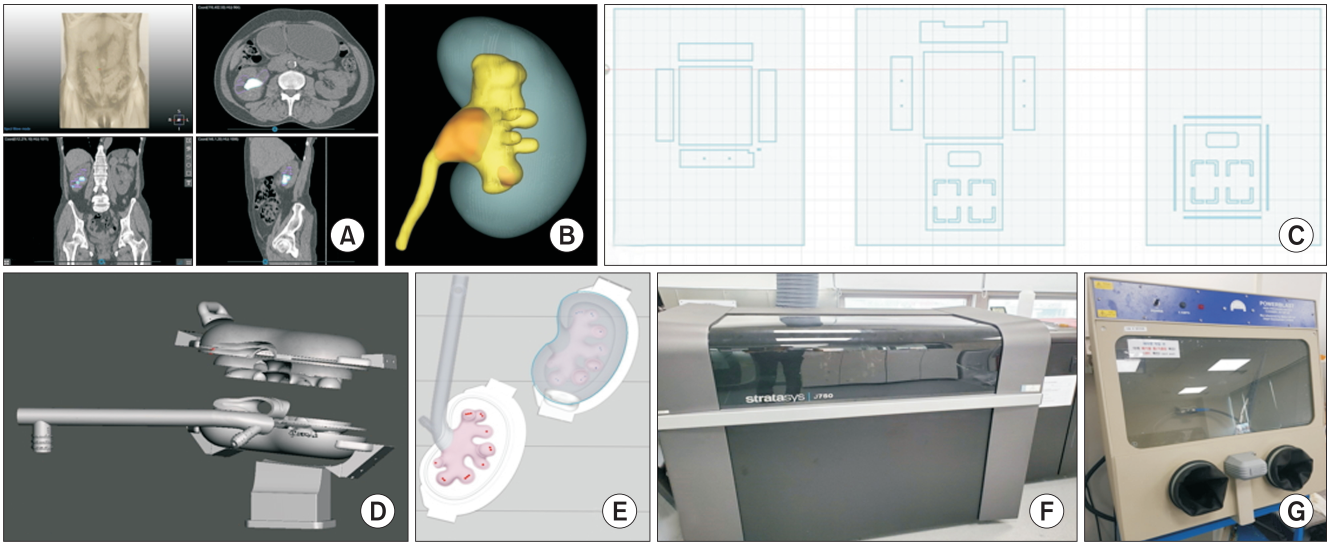


Fig. 1. Retrograde intrarenal surgery navigation training module. (A) MEDIP software (Medical IP, Seoul, Korea), a reconstruction and rendering program for segmentation. (B) Visual printing software. Once a web address of a rendered object was uploaded to server, it was sent to the authors. (C) Fusion360 (AUTODESK, San Francisco, CA, USA) acryl design. (D) GrabCAD (Stratasys, Eden prairie, MN, USA) image. (E) Output file (stl) uploaded on the slicing program (GrabCAD). (F) Three-dimensional (3D) printing performed with a Polyjet printer J750 (Stratasys). (G) Water spray machine to remove supporters remaining on the printout immediately after 3D printing.

technique. Successful endourological procedures for diagnosing and treating urolithiasis require accumulated practical experience and training [3].

There are some artificial training modules for ureteroscopy for beginners. Although they all seem to work well, they have shown different advantages and disadvantages according to their speculations [4-6]. The initial and essential step in RIRS surgery seems to be the navigation of all calyces, especially checking the location of the entrance into all calyces when urologists put fURS inside the caliceal system. Therefore, training modules have to mimic the renal anatomy as identically as possible. Three-dimensional (3D) technology allows us to make this happen as previous investigations have shown that surgical guide is the most popular medical application of 3D printing in orthopedics, neurosurgery, dental surgery, spine surgery, and maxillofacial surgery [7]. Results are promising to reduce operative time [8-10].

The objective of the present study was to devise a new module for practical ureteroscopy training. This study evaluated the feasibility of using a newly developed 3D printed handy module to train RIRS navigation for urologists who were not fully exposed to RIRS as operators.

MATERIALS AND METHODS

After receiving the written informed consent, the enhanced computed tomography urography images without patient identifier were used for 3D printing. This study was approved by the Institutional Review Board of Seoul National University Hospital (IRB No. E-2106-023-1224); it was done in strict accordance with the ethical guidelines of the Declaration of Helsinki. A total of seventeen, twelve residents and five young board-certified urologists with no experience of RIRS as operators joined this study. All the trainees showed consent to participate in this study and informed written consent was obtained from all individual participants included in the study.

1. Simulator production using 3D printing

The 3D printing simulator is manufactured through five processes, as shown in Fig. 1 and described in the Supplementary File. A detailed image of module is shown in Fig. 2.

2. Instructions and orientation education

Two expert endourologists provided the orientation training over the 10-minute session to all trainees. All trainees held fURS with their right hands since all of them were right-handed. The orientation training included the information as follows: 1) an explanation of the caliceal anatomy, locations of upper, mid, lower calyces, and their anterior and posterior branches of minor calyces; 2) six movement directions of the fURS including upward, downward, left-sided, right-sided, forward, and backward; 3) skills of thumbs' up and down motion and flexion and extension of the wrists with the help of left fingers (Fig. 3A, B); 4) differences in motion between right and left-sided kidneys; 5) 'the refer-

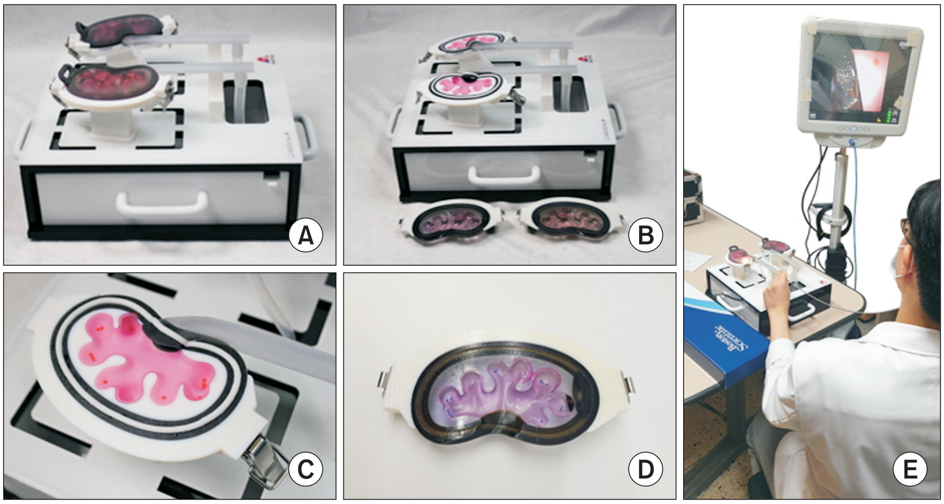
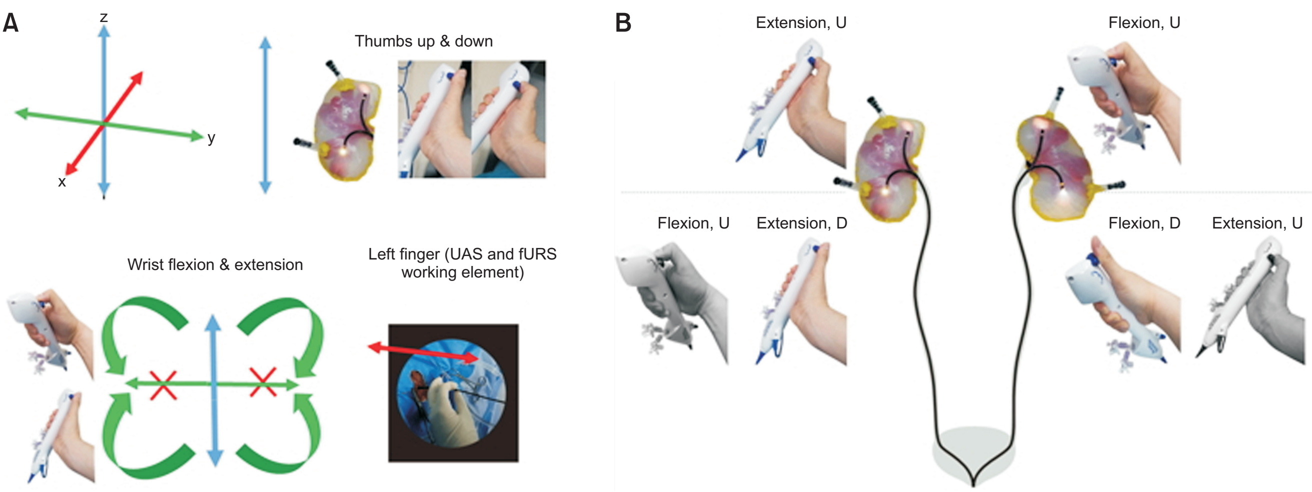


Fig. 2. Detailed image of three-dimensional printed retrograde intrarenal surgery (RIRS) training module. Fully assembled module (A) and module with its lids opened (B). The posterior aspect of the module has eight calyces with red dots (C), and the anterior aspect has the same number of calyces with blue dots (D). (E) RIRS training can be performed in the office conveniently without the need for burdensome devices.



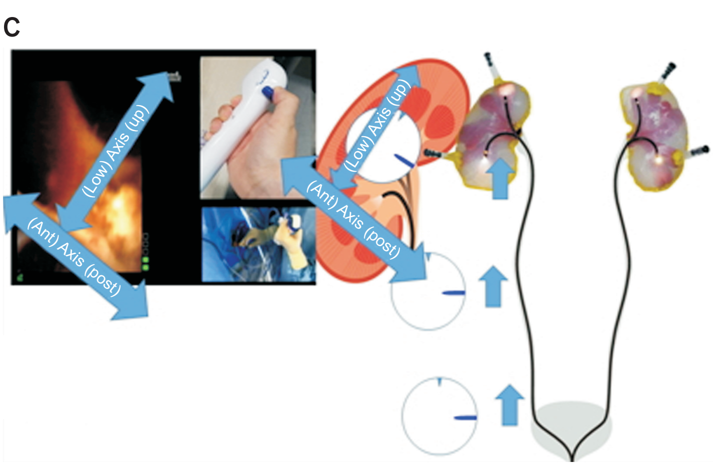


Fig. 3. Explanation materials of flexible ureteroscope (fURS). (A) Movement directions of fURS include: 1) upward, downward, left-sided, right-sided, forward, and downward directions; 2) Skills of thumbs' up and down motion; 3) Flexion and extension of wrists and the help of left fingers. (B) Skills of thumbs' up and down motion as well as flexion and extension of wrists to navigate caliceal structures. The explanation described differences in motion between right and left-sided kidneys. (C) The fURS needs to move from 12 to 7 o'clock from the upper pole to the lower pole. Differentiation of anterior (ant) and posterior (post) minor calyces is also necessary. The view at the reference point usually has the upper pole entrance in front and a mid-pole inlet at the lower part of the endoscopic screen. The inlet of the lower pole is normally identified if the fURS is not flexed. UAS, ureteral access sheath.

ence point', where the navigation starts, defined as the point when the fURS is located at the level of ureteropelvic junction where the scope can see the inlets of upper pole in front and mid calyces at lower screen at a time (Fig. 3C); 6) the direction from the upper to lower poles, it normally lies from 1 to 7 o'clock in the right-sided kidney and from 11 to 5 o'clock in the left-sided kidney; 7) the location of the inlet of the lower pole. When fURS is flexed, the inlet to the lower calyces can be identified. When the orientation was lost, the authors usually recommended returning to this reference point and then starting navigation again.

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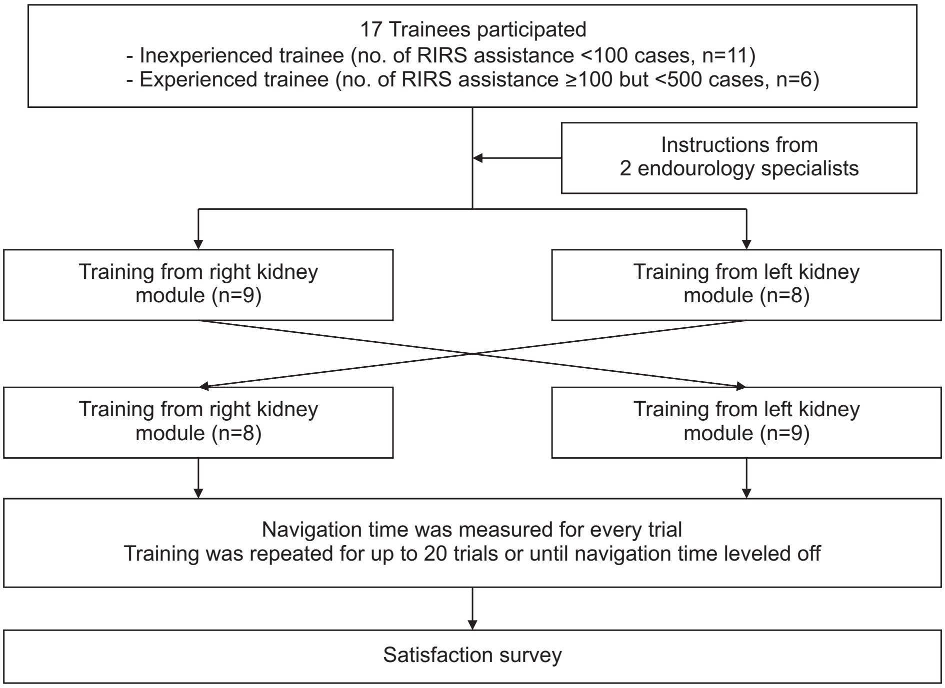

Fig. 4. Summary of study protocol. RIRS, retrograde intrarenal surgery.

3. RIRS navigating training protocol

Lithovue™ Single-Use Digital Flexible Ureteroscope (Boston Scientific, Marlborough, MA, USA) was used for training. The 3D printing model consisted of three minor calyces in the upper and lower poles and two in the mid calyx (i.e., eight calyces in a single kidney). Each calyx was marked with a red dot on the anterior side and a blue dot on the posterior side. Thus, there were a total of 16 points per kidney. Because upper pole calyces are located most dependently, the systematic navigation was performed in the following order: renal pelvis, lower anterior, lower posterior, mid anterior, mid posterior, upper anterior, and upper posterior calyx.

4. Evaluation parameters

The study protocol is summarized in Fig. 4. The navigation time was measured as the primary outcome, and the trainee's satisfaction was surveyed as the secondary outcome.

One navigation time was measured from the moment when the endoscope entered the ureter to the moment when navigation was completed. The goal was to perform ten navigation times for each side, starting from the right or the left side at random. Once trainees began from the right side, they performed it on the left side the next time (RL group). If trainees started from the left side, they performed it on the right side the next time (LR group).

The experiment was finished when the trainee completed 20 trials or specialists judged that the trainees' navigation time leveled off. All trainees completed their training on the same day. After the experiment, all trainees were asked to fill out the questionnaire with five degrees, which consisted of seven questions related to the usefulness of training.

5. Statistical analysis

All statistical analyses were performed using IBM-SPSS ver. 25.0. (IBM Corp., Armonk, NY, USA) and R statistical software version 3.5.3 (www.r-project.org). For categorical variables, results are expressed as numbers and percentages. Chi-squared test and Fisher's exact test were used for categorical variables. ANOVA and Student t-tests were used to compare continuous variables. The Wilcoxon signed-rank test was used to compare the first and the last trials. Statistical significance was considered when the bilateral p-value was less than 0.05.

RESULTS

1. Reduction of the navigation time

Seventeen trainees were included in this experiment. Eleven trainees had the experience of assisting RIRS for less than 100 cases and six trainees for 100 to 500 cases. Trainees' demographics are shown in Table 1.

The results of navigation training are summarized in Table 2. A total of 308 trials were performed (154 trials per side). Thirty-two trials (9.4%) were not performed because six and four of all trainees stopped their navigation training at the 8th and 9th trials showing minimum value of

Table 1. Trainee demographics

Criteria	Value
Total number of trainee	17
Years of training in urology	3.05±1.80
Case number of RIRS assist	
<100	11 (64.7)
100 to 500	6 (35.3)
Side of training begin	
Right	9 (52.9)
Left	8 (47.1)

Values are presented as number only, mean±standard deviation or number (%).
RIRS, retrograde intrarenal surgery.

Table 2. Results of navigation training

Category	Value	p-value
Total trial	308	-
Right side	154	
Left side	154	
Navigation time (s)		
Total	153.4±92.6	
Right side	149.5±85.3	0.498
Left side	157.2±99.5	
Maximum	354.3±177.2	-
Minimum	80.1±25.6	
First trial	251.4±108.0	<0.001*
Last trial	93.9±33.2	
Right to left group		
First trial	249.0±124.1	0.008*
Last trial	97.7±33.5	
Left to right group		
First trial	254.1±94.9	0.012*
Last trial	91.0±35.4	

Values are presented as number only or mean±standard deviation.
*Statistically significant p<0.05.

navigation time, respectively. The average navigation time was 153.4±92.6 seconds for all trials. It was 149.5±85.3 seconds for the right side and 157.2±99.5 seconds for the left side. There were no significant differences in navigation time between the right and left sides (p=0.498). The maximum and minimum navigation times were 354.3±177.2 seconds and 80.1±25.6 seconds, respectively. The mean navigation time of all trainees' first and last trials significantly decreased from 251.4±108.0 seconds to 93.9±33.2 seconds, respectively (p<0.001). The mean navigation time of the RL group decreased from 249.0±124.1 to 97.7±33.5 seconds (p=0.008) and that of the LR group decreased from 254.1±94.9 seconds to 91.0±35.4 seconds (p=0.012). The change in navigation time did not show any significant difference between RL and LR groups (p=0.283).

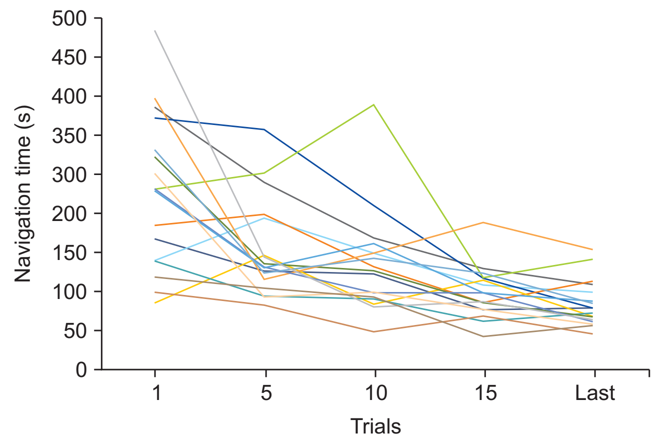

Fig. 5. Reduction curves for all trainees. Maximum and minimum navigation time were significantly decreased for all trainees.

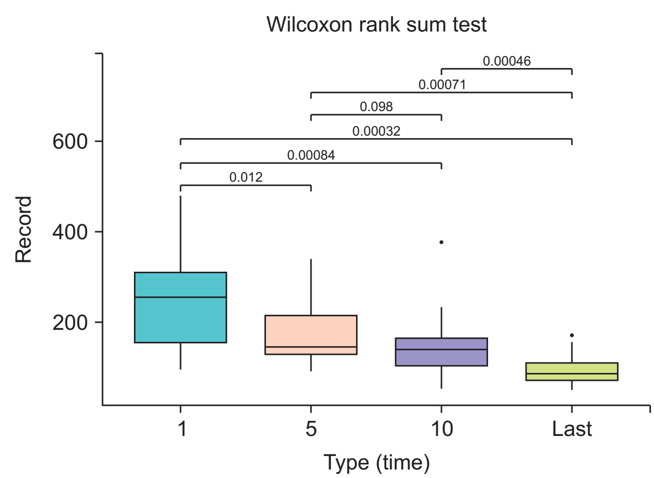

Fig. 6. Decrease in navigation time of trainees. The navigation time significantly reduced as the experience of trainees accumulated.

The average reduction in navigation time was 201.3±133.3 seconds. The maximum and minimum reduction of navigation time was 400 seconds and 45 seconds, respectively.

Reduction curves of all trainees are shown in Fig. 5. Regardless of the direction of RL and LR, improvement in the 2nd session was faster than in the 1st session. Similar patterns of improvement were observed in 15 of 17 trainees (88.2%) whose navigation time was transiently increased at the 4th to 6th trials while these trainees adapted to the movement of mirror image. In this situation, navigation time increased by more than 30 seconds for ten trainees (58.8%). However, it decreased again in the final trials. Wilcoxon rank sum test results are shown in Fig. 6 to show the navigation time across the 1st, 5th, 10th, and last trials. The navigation time significantly decreased from the 1st to the last trial (except for the 5th or the 10th trial).

Subgroup analysis comparing six experienced (number

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of RIRS assistance 100–500 cases) and eleven inexperienced (number of RIRS assistance <100 cases) trainees is presented in Table 3. The experienced group (177.0 s to 86.8 s, 51% reduction, p=0.028) and inexperienced group (292.0 s to 97.7 s, 67% reduction, p=0.003) showed reduced navigation time after completion of training. Note that the experienced group showed better performance in the first trial when compared with the inexperienced group (177.0 s vs. 292.0 s, p=0.037), but the difference between the two groups was diminished after training.

2. Satisfaction

Almost all trainees were satisfied with the training module for RIRS practice (Table 4). The average score of the questionnaire was 3.7±0.8 for the similarity to real kidney, 4.5±0.5 for the training efficacy to the upper calyx, 4.5±0.5 for the training efficacy to the mid calyx, 4.2±0.9 for the training efficacy to the lower calyx, 4.5±0.5 for the usefulness of red and blue dots, 4.6±0.5 for the usefulness for RIRS practice, and 4.7±0.5 for the commendableness of tests to other beginners.

DISCUSSION

1. The importance of navigation in fURS

When fURS enters the caliceal system, a complete understanding of caliceal anatomy is the essential step in RIRS. An initial fURS exam to identify typical caliceal structure gives operators tips to memorize the direction of approaching each calyx. It allows less traumatic procedures to be maintained even under hematuria situations. To remember the calyx with stone is essential to remove all stones and increase the success rate of the surgery. Any traumatic change in the case of pre-stenting or percutaneous procedures prior to main procedures should be evaluated before stone fragmentation.

Table 3. Subgroup analysis comparing experienced and inexperienced group

Navigation time (s)	First trial	Last trial	p-value
Experienced (n=6)	177.0±50.2	86.8±27.1	0.028*
Inexperienced (n=11)	292.0±110.7	97.7±36.7	0.003*
p-value	0.037*	0.733	

Values are presented as mean±standard deviation.
*Statistically significant p<0.05.

2. The importance of fURS module training

Due to the high price of fURS and accessories, it is hard to obtain all instruments for urologists in resource-poor regions. The increased risk of scope damage makes it the trainees challenging to have enough training opportunities. Because kidney anatomy and distribution of stones may be complicated, RIRS has shown a steep learning curve. Some cognitively specific motor skills are necessary for operators [5]. Suppose inexperienced operators encounter difficult situations such as mucosa damage with hematuria, impacted stones, or anatomical abnormalities. In that case, they tend to give up the removal of stones if they are unfamiliar with basic surgical techniques of handling instruments. Therefore, this 3D training module close to the real anatomy of kidneys can develop the trainee's skills with fURS and instrument accessories [11].

3. How to utilize the 3D printed fURS training modules

Some existing models do not look handy because they need accessory devices, such as the system for the virtual module, fURS surgical tower, irrigation tower, water bag, water-proof drape, bucket for water. If the module is an animal or cadaver, the preparation becomes more complicated than a bench-top module. Therefore, RIRS training was only available in a workshop that secured a lot of equipment. In addition, when irrigation fluid is connected separately, the surrounding area around modules can often be flooded. However, the newly-developed module of the current study has its own irrigation circulating system. Therefore, separate

Table 4. Survey response for satisfaction

Question	Score
Were the insertion of endoscope and navigation similar to a real human kidney?	3.7±0.8
Was the navigation training for upper calyces useful?	4.5±0.5
Was the navigation training for middle calyces useful?	4.5±0.5
Was the navigation training for lower calyces useful?	4.2±0.9
Was the process to confirm the red and blue spots in calyces useful?	4.5±0.5
Do you think this training session using kidney model improved your skill?	4.6±0.5
Are you willing to recommend this training session to your colleagues?	4.7±0.5

Values are presented as mean±standard deviation.

irrigation systems would no longer be necessary.

To date, several simulation models have been developed. Simulators can be categorized according to how much they are close to real anatomy. Some simulators are never biological, making the equipment inexpensive and portable. Some others are closer to a realistic environment to provide satisfactory simulations, although they are expensive and disposable [4].

Benchtop models allow instruments to engage in modules. They are portable, reusable, and inexpensive. Although they are widely used, they are less realistic than biological models [4]. Virtual reality models have advantages such as reusability, easy data collection, easy setup, and immediate feedback. However, there are expensive and difficult to maintain due to costs. Animal models and cadavers can provide high-fidelty models, but high price, special facilities, no reusability, and ethical concerns are their main disadvantages [4].

Several advanced fURS models have been developed in the last decade. Villa et al. [12] presented the Key-Box, a portable bench model composed of boxes with an anatomical variation. It is efficient, low cost, and reusable for training scope manipulation and use of guidewire, access sheath, or basket. A similar model would be the 3D printed one published by Orecchia et al. [13]. Six of the 3D printed models are equipped with different anatomical pelvicalyceal systems so that simulation can be performed in different situations. This was connected to the URS part-task trainer (Cook Medical, Bloomington, IN, USA) to create an environment similar to the actual RIRS.

The resistance can be problematic, especially at the ureterovesical junction level and the calyces' inlet during the caliceal navigation. Since this module aimed to focus on pelvicalyceal navigation procedure, we came up with some methods to reduce resistance. First, we designed a straight ureter to mimic the situation of the presence of a ureteral access sheath. Second, the inner diameter of the ureter was designed wide enough (24 Fr) for the endoscope to move freely. Third, the infundibulopelvic angle might fight against the upper part of the fURS when it is deflected for accessing the lower-anterior minor calyx. So the protruding length of the renal parenchyma between the midpole and the lower-pole calyces was shortened.

4. Advantages of the new 3D RIRS training modules

Although the essential element in RIRS surgery is the initial navigation of all calyces, there have been a few modules reflecting the anatomy of the renal caliceal system to practice. Most of the existing modules have focused on creating a kidney-like model and learning how to use devices for sales. The newly-developed training module in this article tried to help beginners to understand the real kidney structure using 3D printing techniques. Furthermore, systematic training to differentiate anterior and posterior minor calyces can be helpful by using markers inside calyces. And it should be noted that it has a compact but efficient self-circulation system, so for an environment similar to RIRS, there is no need to have additional equipment with the module. Another distinct advantage of this module is that the operator can print kidney replica by 3D printing before surgery, attach it to the module, and practice before surgery to shorten the operation time and improve the stone-free rate, especially in challenging cases. The module itself is semi-permanent, so it is reusable until being impaired.

Although there were significant differences in individual skills, almost all trainees' navigation time converged to 1 to 2 minutes in this training program. Since surgery is not a record game, having a short performance time is not unconditionally good. Therefore, a 'training success' can be considered when the navigation time at the time of the final trial or the average time of the last three performances is <3 minutes. If the navigation time is shortened to <1 minute, it can be regarded as an expert level with the training module.

The following hypotheses for the transient increase in the navigation time at the 4th to 6th trials can be made. First, trainees gained a proper understanding of training by the time they performed at the 4th trial as their skill level had increased. Second, their concentration could decrease, and their motivation could fall while mechanically completing a repetitive circuit. To perform training five times in a row with a break can be helpful.

5. Limitations of this study

This study has a few limitations. First, reduction of navigation time is the only parameter utilized to assess improvement. Other parameters like damage to the kidney or the instrument were not evaluated. Although it could not be explained as an objective indicator, we considered accurate navigation to make sure that the dot was clearly visible in the center of the screen during navigation. If not, the moderator controlled the trainee not to proceed to the next dot. Further studies are needed for validation of the other parameters. Second, the number of 10 trials might not be enough for some trainees. However, even with less than ten trials, most trainees' navigation time leveled off, considered meaningful and effective for training. Third, we designed a straight ureter to mimic the situation where the ureteral

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access sheath is in place. Also, the inner diameter of the ureter was designed wide enough (24 Fr) that the endoscope could move freely without resistance, and the trainee could focus on the pelvicalyceal navigation procedure. For that, our module is unsuitable for practice situations such as advancing fURS into the ureter with complex anatomy or inserting fURS without ureteral access sheath. Fourth, the number of participants was not big enough. In this study, 2 participants did not have RIRS experience at all, 9 participants had RIRS assistance experience in less than 100 cases, and six had RIRS assistance experience between 100 and 500 cases. Dividing participants into three groups (initial experience, inexperienced, and experienced) would have been better, but due to the lack of participants number in the initial experience group (n=2), statistical analysis between 3 groups was inadequate. Fifth, the endoscopic surgical tower has not yet been integrated into the module. Although a more convenient practice system can be built using a disposable endoscopic system, a reusable endoscopic system is recommended to save the cost of the training. Lastly, we did not perform the training for stone fragmentation or basketing technique. Navigation is the first and the essential step of RIRS as mentioned. Therefore, we first focused on showing our training module's strength in improving navigation skills for novices. As we confirmed efficacy in navigation, we are planning to conduct further trials, including stone fragmentation and basketing to strengthen our module's effectiveness.

CONCLUSIONS

The newly-developed 3D printing navigation training module seems to be effective in reducing navigation time. This will help improve RIRS skills for beginners.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Gyoohwan Jung and Sung Yong Cho. Data acquisition: Yongseok Kho and Gyoohwan Jung. Statistical analysis: Yongseok Kho, Hyun Sik Yoon, Dae Hyoung Park, Minh-Tung Do, and Gyoohwan Jung. Data analysis and interpretation: Yongseok Kho, Gyoohwan Jung, and Sung Yong Cho. Drafting of the manuscript: Gyoohwan Jung. Critical revision of the manuscript: Yongseok Kho, Hyun Sik Yoon, Dae Hyoung Park, Minh-Tung Do, and Sung Yong Cho. Obtaining funding: Sung Yong Cho. Administrative, technical, or material support: Sung Yong Cho. Supervision: Hyun Sik Yoon, Dae Hyoung Park, Minh-Tung Do, and Sung Yong Cho. Approval of the final manuscript: all authors.

SUPPLEMENTARY MATERIAL

Supplementary material can be found via https://doi.org/10.4111/icu.20220205.

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