Effectiveness of a Newly-Developed Training Module Using 3D Printing for The Navigation During Retrograde Intrarenal Surgery

Gyoohwan Jung
Seoul National University Bundang Hospital
Sung Yong Cho (kmoretry@daum.net)
Seoul National University Hospital

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Abstract

We evaluated feasibility of the newly-developed 3D printed training module for the navigation during retrograde intrarenal surgery. 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 into the ureter. After navigation was completed, the navigation time was recorded. The goal was to perform ten times of navigation 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. The average of training period of all 17 trainees was 3.05 ± 1.80 years. The average navigation time of 308 trials was 153.4 ± 92.6 sec. The maximum and minimum navigation time were 354.3 ± 177.2 sec and 80.1 ± 25.6 sec. The mean navigation time of the first and the last trials of all trainees significantly decreased from 251.4 ± 108.0 sec to 93.9 ± 33.2 sec. The average of reduction in navigation time was 201.3 ± 133.3 sec. Almost all trainees were satisfied with the training. The newly-developed 3D printing navigation training module seems to be effective.

Introduction

Flexible ureteroscopy (fURS) has become popular in the last several decades.[1] Indications for a 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 including diverticulum and duplicated ureters. 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 stope the surgery if they are not familiar with the RIRS technique. Successful endourological procedures for diagnosing and treating urolithiasis requires accumulated practical experience and training.[3]

There are some artificial training modules of ureteroscopy for beginners, including the Uro-Scopic trainer (Limbs & Things Ltd., Bristol, UK), the URO Mentor (Simbionix, Cleveland, OH), the Scope Trainer (Mediskills Ltd., Edinburgh, UK), cadavers, and porcine models. Although they all seem to work well, they have shown different advantages and disadvantages according to their speculations.[4–6]Most of them are not handy as they need various accessory devices. Although they tried to reflect anatomical characteristics of renal calyces, many urologists recently recognize that 3D printing technology can show more accurate anatomical features than others. The initial element in the RIRS surgery seems to be the navigation of all calyces. It means that the most essential step for RIRS is to check the location of the entrance into all calyces when urologists put the fURS inside a caliceal system. Therefore, training modules have to mimic the renal anatomy as identical as possible. 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 the newly developed 3D printed handy module to train RIRS navigation for a group of urologists who were not fully exposed to RIRS as operators.

Materials And Methods

The Computed Tomography (CT) images of the candidate for training module were used for 3D printing after receiving the written informed consent. No identifier was shown in the trainee, and all experimental protocols were approved and consent for volunteers was exempted by the institutional review board of the Seoul National University Hospital Biomedical Research Institute (IRB No. E-2106-023-1224) because only volunteers joined this education program among 32 residents and 14 board-certified urologists in the urology department of the authors' hospital. Therefore, only twelve residents and five young board-certified urologists with no experience of RIRS as operators joined this study. All methods were carried out in accordance with relevant guidelines and regulations.

Simulator production using 3D printing

As shown in Fig. 1, the 3D printing simulator was manufactured through five processes as described below:

(1) Segmenting

The basement of simulator's kidney anatomy was extracted by segmenting CT Digital Imaging and Communications in Medicine (DICOM) images using MEDIP (Medical IP, Seoul, Republic of Korea), a reconstruction and rendering program for segmentation, with STereoLithograph (STL) file extension (Fig. 1A).

Structures of renal major and minor calyces, renal pelvis, and ureters were primarily rendered through segmentation and transformed into a form suitable for training based on anatomical information. The authors in this article confirmed kidney structures several times through 'Visual printing'. This is an efficient real-time confirmation platform between urologists and Medical IP. Once a web address of a rendered object was uploaded to the server, it was sent to the authors (Fig. 1B). The authors could then annotate directly on the web page via text or drawing to give feedback using a smartphone or a computer.

(2) 3D Mesh modeling

After the anatomy was confirmed, an acrylic plate was designed equipped with a tubing line and a water tank for application of a water circulation system (Fig. 1C). Classification and Boolean operation were performed using a modeling program for no overlapping part of the designed STL file. We then extracted each STL file and uploaded it to GrabCAD (Stratasys 3D Printer Slicing program) (Fig. 1D).

For each STL file of each structure transferred to GrabCAD, the desired material and color transparency were independently selected. Then a transparent clear resin was used to the exterior so that the inside structure could be seen with naked eyes from the outside. In the case of calyces and pelvis, a pink translucent material (Vero clear plus Vero magenta v mixture) was used (Fig. 1E).

(3) 3D printing

After selecting all materials, 3D Printing was performed using a Polyjet printer J750 (Stratasys; 7665 commerce way Eden prairie, MN 55344, USA) as shown in Fig. 1F.

(4) Post-processing

The supporter on the printed material was removed. Locking rings were attached onto both sides to fasten anterior and posterior sides. The sling ring was then fixed with silicon on the bottom to prevent leakage while water circulated. A mold of sling ring was printed out of Acrylonitrile Butadiene Styrene copolymers using FlashForge, a Fused Deposition Modeling type printer (Fig. 1G). After that, fumigation was performed to remove the lattice-shaped hard support and smoothen the surface. After assembling the mold according to the position, a silicon of Shore A10 was injected and molded.

(5) Assembly

The completed module was fixed to a custom-made acrylic plate and connected to the tube line. The whole procedure was finished by connecting a water pump to the end of the inlet tube and installing it in a water tank.

(6) Design and the structure of the simulator

Because the module had its own water circulation and water-proof systems, it only needed an endoscopy system for RIRS training. The tank and kidneys were filled with water and circulated with an electronic pump to create similar environment to the real practice of RIRS. LithoVue™ (Boston Scientific, Marlborough, MA, USA) was used for experiments to reduce total volume of the training set as shown in Fig. 1H. The kidneys can be split into two anterior and posterior pieces and stone fragments can be put inside the calices. The training of stone fragmentation and basketing technique is available.

Instructions and orientation education

Two expert endourologists provided the orientation training over a 10-minute session to all trainees. This 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 are shown in Figs. 2(A) and 2(B); (4) differences in motion between right and left-sided kidneys; (5) 'the reference 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 as shown in Fig. 2(C); (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 to return to this reference point and then start navigation again.

RIRS navigating training protocol

The 3D printing model consisted of three minor calyces in 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 navigation should be performed from the renal pelvis followed by the lower anterior, lower posterior, mid anterior, mid posterior, upper anterior, and upper posterior calyx in order. Fragmented stones normally gather in the upper posterior and mid posterior calyces. The final dusting procedures can be performed in these two calyces efficiently.

Evaluation parameters

The navigation time was measured as the primary outcome, and the satisfaction of the trainee was surveyed as the secondary outcome.

One navigation time started from the moment when the endoscope entered into the ureter of the model. All 16 points were checked when the scope approached the inner side of calyces where laser emission and stone fragmentation were available in clinical situations. After navigation was completed, the navigation time was measured and recorded. Basically, the goal was to perform ten times of navigation 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 began from the left side, they performed it on the right side the next time (LR group).

The experiment was stopped when specialists judged that the trainee reached the plateau of no more time reduction three times or more or that the trainee’s technique was sufficiently completed by performing navigation smoothly without hesitation. The training for stone fragmentation and basketing technique is not performed for this study to simplify the protocol.

After the experiment, all trainees were asked to fill out a questionnaire. The questionnaire consisted of 7 questions related to the following: (1) similarity to real kidney, (2) training efficacy to the upper calyx, (3) training efficacy to the mid calyx, (4) training efficacy to the lower calyx, (5) the usefulness of red and blue dots, (6) usefulness for RIRS practice, and (7) commendableness of tests to other beginners. Each question was evaluated in five degrees (5: strongly agree, 4: agree, 3: neutral, 2: disagree, 1: strongly disagree).

Statistical analysis

All statistical analyses were performed using IBM-SPSS 25.0. (New York, NY; United States). For categorical variables, results are expressed as numbers and percentages. Chi-squared test and Fisher's exact test were used for categorical variables. Continuous variables are expressed as median values.

ANOVA and Student t-test were used to compare variables in two or more categories. The Wilcoxon signed rank test was used to compare the first and the last trials. Statistical significance was considered when a bilateral p-value was less than 0.05.

Results

Trainee demographics

All 17 trainees were included in this experiment. The training period in the urology department ranged from 0.66 years to 7 years, with an average of 3.05 ± 1.80 years. Eleven (64.7%) trainees had the experience of assisting RIRS for less than 100 cases and six (35.3%) trainees had the experience of assisting RIRS for 100 to 500 cases. None of the trainee experienced RIRS as the main surgeon. Nine (52.9%) trainees began training from the right and eight (47.1%) trainees started from the left.

Reduction of the navigation time

A total of 308 trials were performed (154 trials per side). Thirty-two (9.4%) trials were not performed because six and four of all trainees stopped their navigation training at the 8th and 9th trials showing a plateau of the navigation time, respectively. The average navigation time was 153.4 ± 92.6 sec for all trials. It was 149.5 ± 85.3 sec for the right side and 157.2 ± 99.5 sec for the left side. There were no significant differences in the navigation time between the right side and the left side ($P = 0.498$).

Reduction curves of all trainees are shown in Fig. 3. The maximum and minimum navigation time were 354.3 ± 177.2 sec and 80.1 ± 25.6 sec, respectively. The mean navigation time of the first and the last trials of all trainees significantly decreased from 251.4 ± 108.0 sec to 93.9 ± 33.2 sec, respectively ($P < 0.001$). The mean navigation time of the RL group decreased from 249.0 ± 124.1 to 97.7 ± 33.5 sec ($P = 0.008$) and that of the LR group decreased from 254.1 ± 94.9 sec to 91.0 ± 35.4 sec ($P = 0.012$). The change of navigation time did not show any significant difference between RL and LR groups ($P = 0.283$). The average of reduction in navigation time was 201.3 ± 133.3 sec. The maximum and minimum reduction of navigation time were 400 sec and 45 sec, respectively.

Regardless of the direction of RL and LR, the improvement in the 2nd session was faster than that in the 1st session. Similar patterns of improvement were observed in 15 (88.2%) of 17 trainees whose navigation time was transiently increased at the 4th – 6th trials while these trainees adapted to the movement of the mirror image. In this situation, the 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. 4 to show the navigation time across the 1st, 5th, 10th, and the last trials. The navigation time was significantly decreased from the 1st trial to the last trial (except for the 5th or the 10th trial).

Satisfaction

Almost all trainees were satisfied with the training module for RIRS practice. 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

The importance of navigation in fURS

When fURS enters the caliceal system, complete understanding of the caliceal anatomy is the most essential step in RIRS. The training module was designed to give us the opportunities to learn the next step of stone fragmentation with laser or basketing technique following navigation technique. However, the present study evaluated only navigation procedure to simplify the protocol. The residents and clinical fellows in the authors' hospital can learn the next step whenever they want to learn with the training modules.

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 a hematuria situation. 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.

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 the trainees difficult 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] If inexperienced operators encounter difficult situations such as mucosa damage with hematuria, impacted stones, or anatomical abnormalities, 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 real anatomy of kidneys can develop trainee's skills with fURS and instrument accessories.[11]

How to utilize the 3D printed fURS training modules

Some existing models do not look handy because they need some accessory devices, including a system for a virtual module, fURS surgical tower, irrigation tower, water bag, water-proof drape, a bucket for water, and so on. If the module is an animal or a cadaver, the preparation becomes more difficult than a bench-top module. Therefore, RIRS training was only available in a workshop that secured a lot of equipment. When irrigation fluid is connected separately, the surrounding area around modules can be often flooded. However, the newly-developed module of the current study has its own irrigation circulating system. Separate irrigation systems would be no longer 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 engaged 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 have the advantage of reproducibility and similarity to human kidneys. However, they have a high cost for living animals. In addition, they need special equipment and staffing with no reusability. Ethical concern can be another problem.[4] Cadavers can be one of the best options concerning the use of human kidneys. However, high price, difficulty in obtaining cadavers, and proper facilities would be their main disadvantages.[4]

Several advanced fURS models have been developed in the last decade. Villa et al. presented the Key-Box, a portable bench model composed of boxes with an anatomical variation.[12] It is efficient, low cost, and reusable for training scope manipulation and use of guidewire, access sheath, or basket. A most 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.

Advantages of the new 3D fURS training modules

Although the basic element in RIRS surgery is the initial navigation of all calyces, there have been a few modules reflecting the anatomy of renal caliceal system to practice. Most of 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 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 in relation to the module. Another distinct advantage of this module is that the operator can print a kidney replica by 3D printing before surgery, attach it to the module, and then practice before surgery to shorten the operation time and improve the stone-free rate especially in challenging cases.

Although there were significant differences in individual skills, almost all trainees’ navigation time converged to 1 to 2 min in this training program. Since surgery is not a record game, it is not unconditionally good to have a short performance time. 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, as the concept of a plateau, 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.

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 kidney or to 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, and if not, the moderator controlled the trainee not to proceed to the next dot. Further studies are needed for validation of the other parmaeters. Second, the number of 10 trials might not be enough for some trainees. However, even with less than ten trials, most of these trainees reached a plateau. Thus, the module could be considered as meaningful and effective for training. Another limitation is that the endoscopic surgical tower has not yet 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 for the training. Last thing is that the authors did not perform the training for stone fragmentation or basketing technique in this study to simply the training protocol.

Conclusion

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

Declarations

Acknowledgement

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Conflict of interest

The presenting authors claim no conflicts of interest.

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Figures

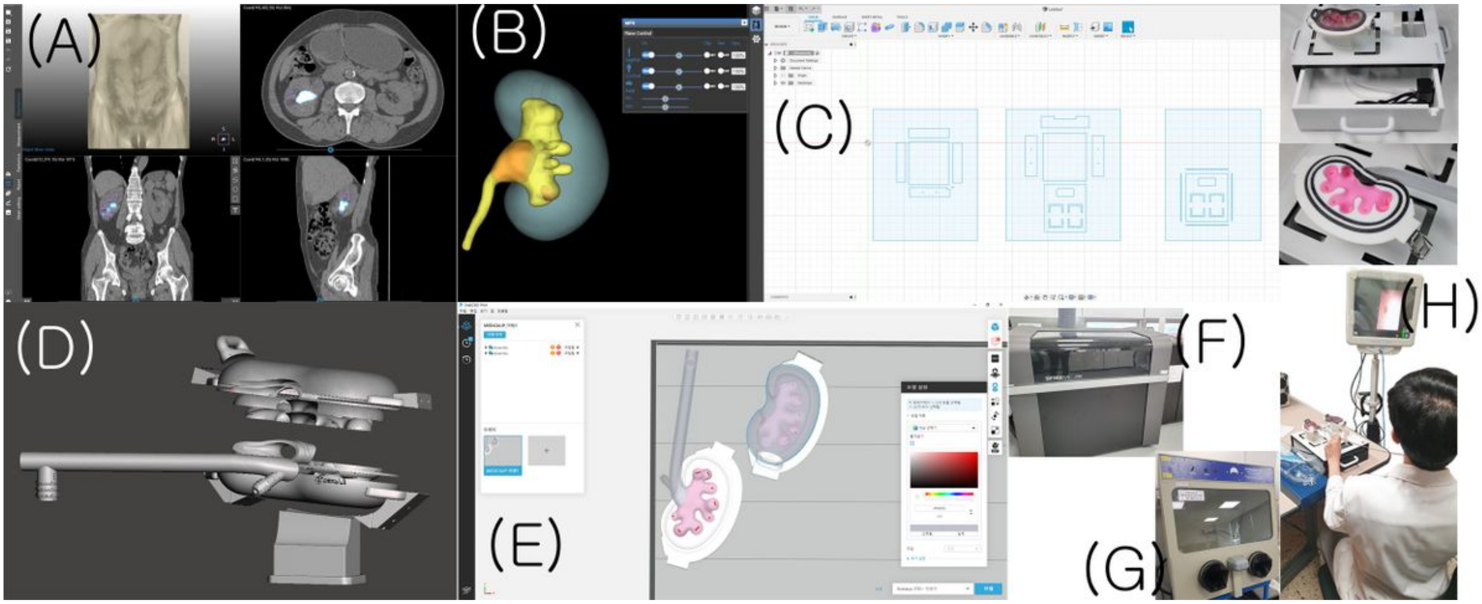

Figure 1

RIRS navigation training module. (A) MEDIP software, 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 acryl design, (D) GrabCAD image, (F) 3D Printing performed with a Polyjet printer J750, (G) Water spray machine to remove supporters remaining on the printout immediately after 3D printing, (H) Navigation training setting with the module, the Lithovue® scope, and the monitor.

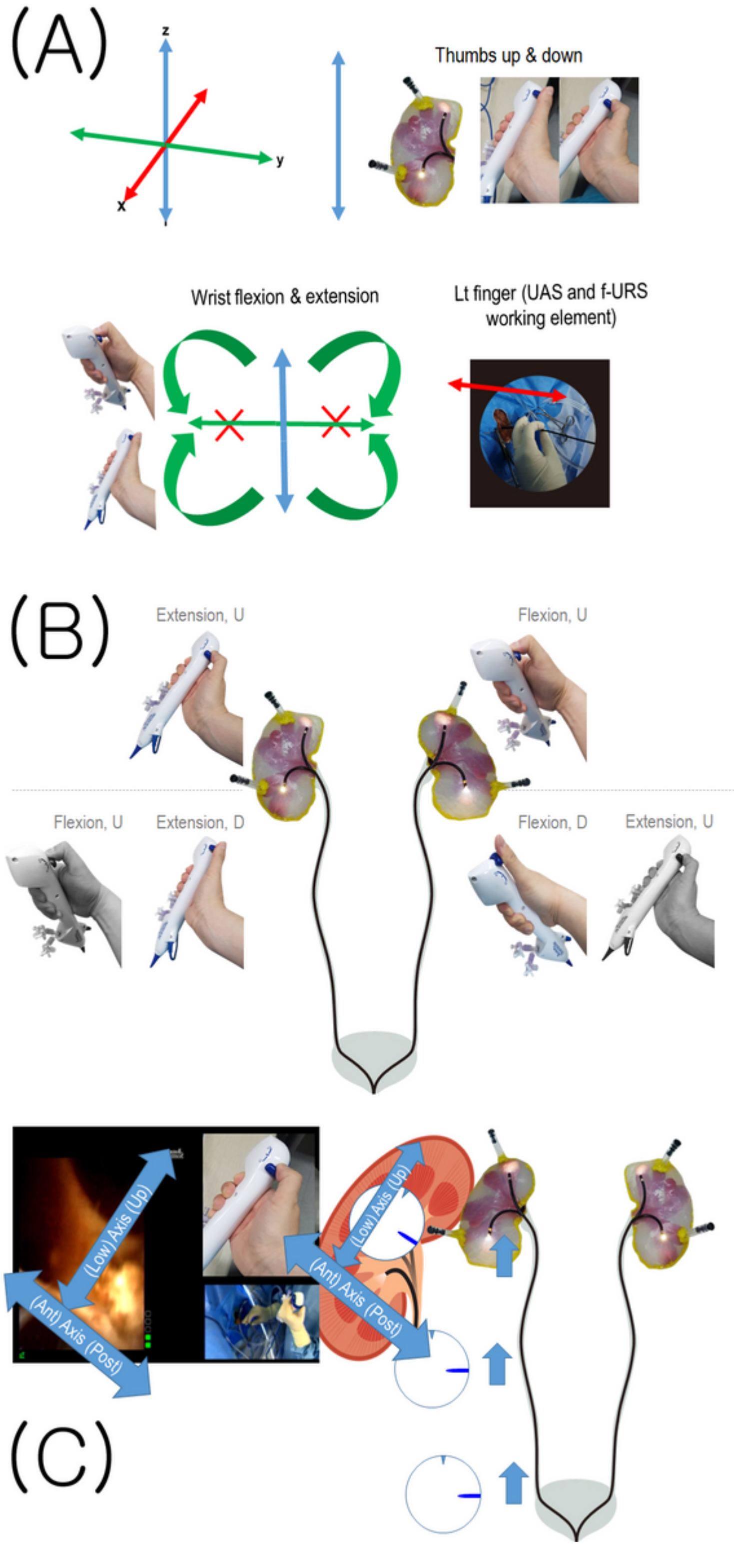

Figure 2

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 for the navigation of 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 and posterior minor calyces are also necessary. The view at the reference point usually has the upper pole entrance in front and 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.

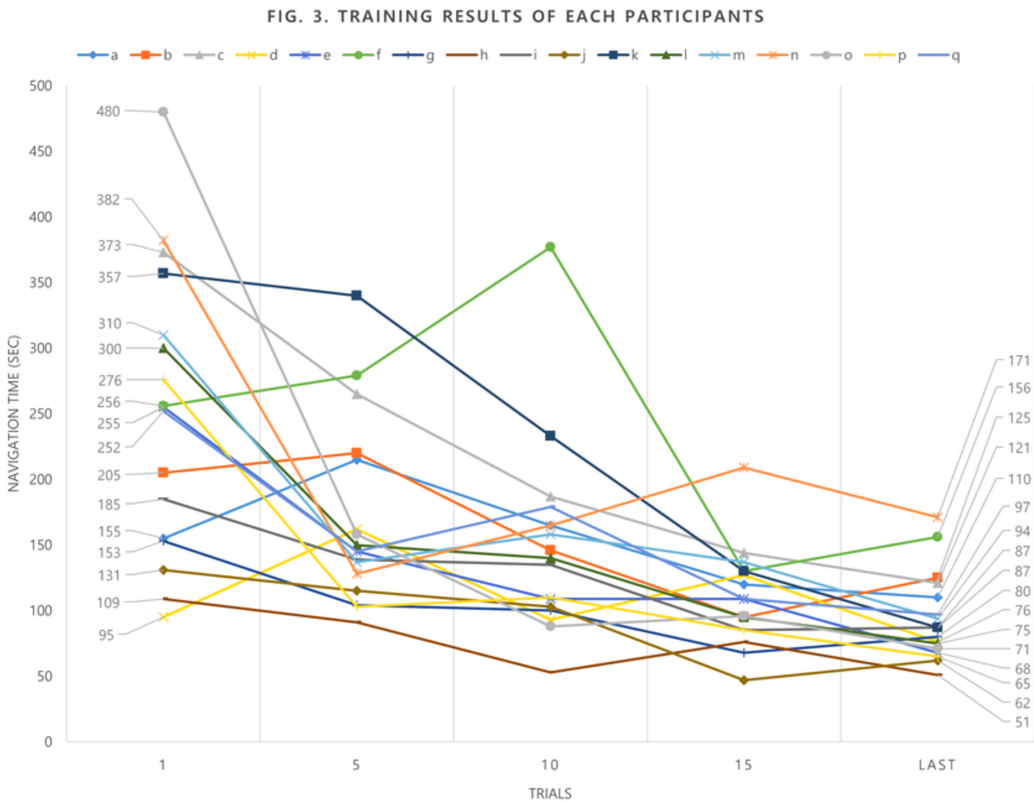

Figure 3

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

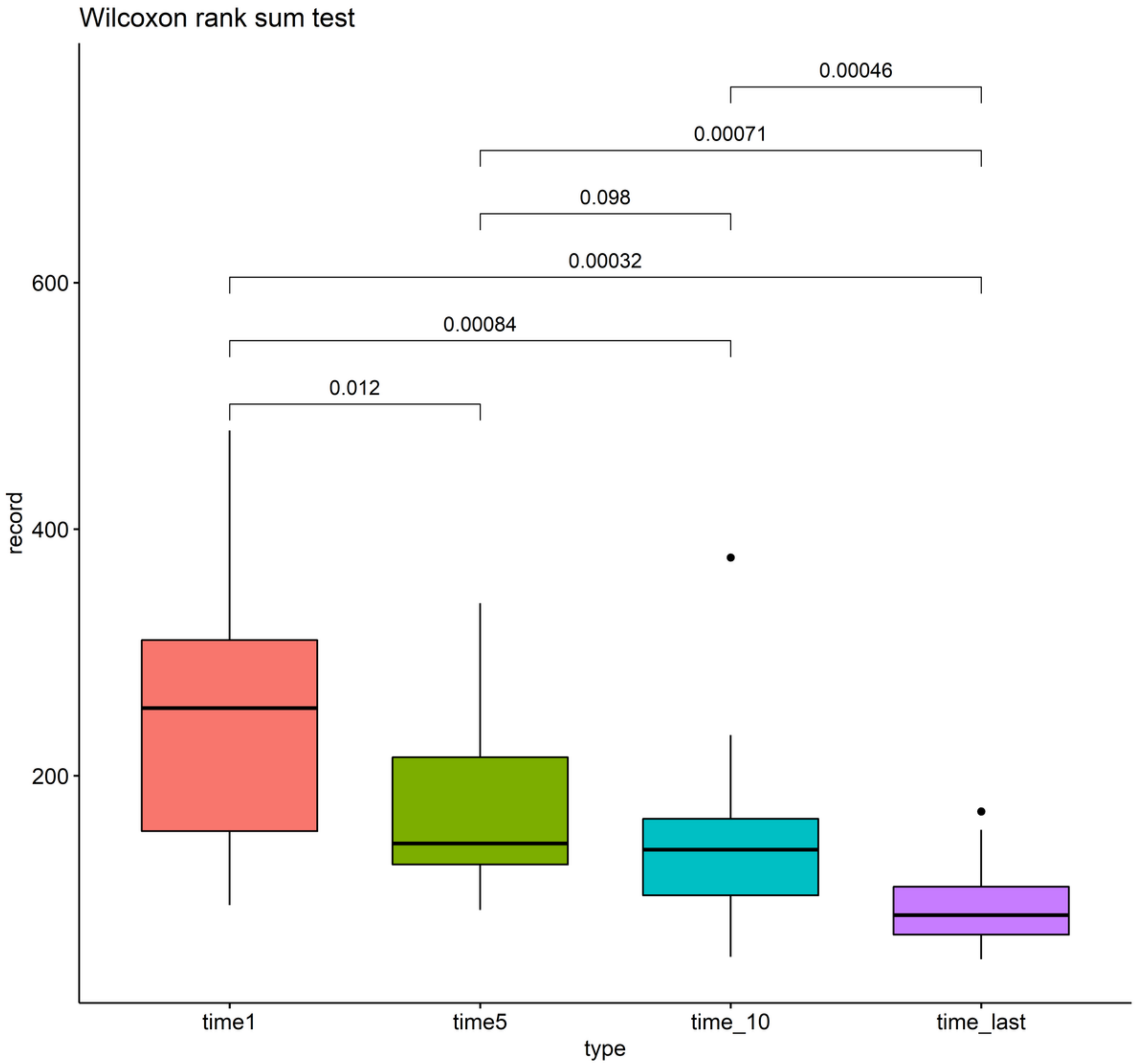

Figure 4

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