ORIGINAL PAPER

UROLITHIASIS

Endoflex – the first portable virtual simulator for flexible ureterorenoscopy (fURS): pilot study

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Citation: Talyshinskii A, Hameed ZBM, Ravinder PP, et al. Endoflex – the first portable virtual simulator for flexible ureterorenoscopy (fURS): pilot study. Cent European J Urol. 2024; 77: 486-493.

Article history
Submitted: Jan. 25, 2024
Accepted: Apr. 23, 2024
Published online: Sep. 23, 2024

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Introduction The market for virtual reality simulators designed to simulate retrograde intrarenal kidney stone (RIRS) surgery, utilising flexible ureteroscopes, is highly limited and dominated by a handful of simulators. The objective of our research is to carry out a pilot study and to provide a description of Endoflex, a transportable virtual flexible ureterorenoscopy simulator for kidney stone treatment.

Material and methods Seventeen novices were recruited, and each performed a virtual ureterorenoscopy with lithotripsy and lithoextraction. The cavity and location of the stone were determined randomly using the random.org portal. The same scenario was used after an educational week, to define changes in metrics. The time taken for the entire simulation, lasing time, fluoroscopic time, stone-free rate, novices' opinions regarding the usefulness of such a simulator in their training, and its impact on their motivation to continue learning endourological skills were evaluated. Three experienced endourologists were asked about the face and content validity.

Results There was a significant decrease in simulation time, activated laser time, and fluoroscopy time. The number of novices who fully cleared the pelvicalyceal system increased from 11 to 15 (out of 17). All participants found the Endoflex simulator to be useful for their education. The face and content validity estimated was 4 each for face and content validity.

Conclusions Endoflex is a promising VR-simulator that can be implemented in urological simulation-based training. However, further improvements are necessary for its full-fledged training of RIRS.

Key Words: urolithiasis ‹› RIRS ‹› fURS ‹› VR ‹› education

INTRODUCTION

Significant technological advances in flexible ureteroscopy (fURS) over the past few decades have enabled its pervasive application in the treatment of upper urinary tract disorders, most notably urolithiasis [1]. Current guidelines designate fURS as the primary treatment option for kidney stones measuring up to 2 cm in diameter, and even for larger stones when alternative interventions are contraindicated [2]. Nevertheless, the growth of this procedure is accompanied by challenges that prevent new trainees from attaining proficiency in it. These obstacles include the need to have simulation training prior to performing the procedure on patients, which will be ethical and ensure patient safety. The necessity to transition to simulation-based training (SBT) is underscored by this fact [3].

Notwithstanding the abundance of documented biological [4] and non-biological [5] simulation devices

doi: 10.5173/ceju.2024.34.R1

in the literature, their storage conditions, production time, cost, and/or reliance on fragile flexible ureterorenoscopes highlight the issues for simulators based on virtual reality (VR) technology. Such simulators would enable users to be fully immersed in an environment. Regrettably, the market for VR simulators designed to simulate retrograde intrarenal surgery (RIRS) utilising flexible ureteroscopes is very limited and dominated by a handful of simulators, the most well-known of which is the commercially available UroMentor [6]. An ample body of research exists concerning the efficacy of this method in fostering the development of retrograde endourological abilities. The requirement for large apparatus and its high price, however, restrict accessibility for all users. The objective of our research was therefore to provide a description of Endoflex, the transportable virtual flexible ureterorenoscopy (fURS) simulator for kidney stone treatment, and to carry out a pilot study.

MATERIAL AND METHODS

Endoflex simulator construction

The simulator comprises 2 fundamental elements: 1) a specialised controller designed to resemble flexible ureterorenoscopes; and 2) personal computer (PC) software functioning on the MS Windows operating system (OS).

Controller architecture

The controller is patented and (DM/228394, ARTVISION LLC, Moscow, Russia) presented as an elongated body featuring extensions at its distal and proximal ends, respectively, and a longitudinal recess in the central portion of the body (Figure 1). The size of controller is 22 × 3 × 3 cm. At the distal end, there is a USB port for the controller-computer connection. In terms of the feel and function, the lever affixed to the proximal end of the handle resembles that of a flexible ureterorenoscope (fURS). At first, the lever is positioned at a zero-degree angle perpendicular to the handle. However, after active deflection, it is subsequently shifted to the typical fURS position through a steel compression spring contained within the controller.

The housing contains a microcontroller electrically connected to an accelerometer, designed to measure the angle of rotation of the tool around the longitudinal axis from –180° to +180°. Also, on the microcontroller there is a magnetic encoder, opposite which a neodymium magnet is installed on the inside of the lever, which changes its position when the lever is shifted. The sensor sends information about the angle of rotation of the lever to the microcontroller. This information is then sent via USB to the computer. Moving the lever up and down by 90° equates to bending the virtual endoscope up and down by 270°. After calibrating the controller, the maximum error for all the above measurements is ±0.3°. In this model, the virtual endoscope had inverted deflection control (thumb lever down = tip up) resembling the European style of fURS. Working length, shaft diameter, and distal tip were set at 670 mm, 8.5 Fr, and 7.5 Fr, respectively. Also, the deflection angle and other parameters could be easily corrected, which made it possible to imitate different flexible instruments.

Software

The software was created in the Unity development environment in the C# programming language and is based on rigid and flexible body physics as well as procedural destructibility. Custom connections were used to model flexible elements. This approach was used to maximally imitate real ureteroscope behaviour. It allows the imitation of the active deflection of the tip controlled by the surgeon but also its passive bending when in contact with the urinary tract system.

The software consists of several preliminary windows before the actual procedural simulation. Firstly, this is the window for selecting a clinical scenario for training. It is necessary to select the laterality of the affected kidney, and then to select a specific pelvicalyceal distribution. Currently, the program database contains 5 cavities of different anatomy, corresponding to the variants according to the Sampaio classification. These were taken from computed tomography (CT urography) scans of 5 patients suffering from kidney stones, from a local database, after their informed consent. It is then necessary to select the stone according to its location. Each existing cavity has at least 4 stone location options. In each scenario, an existing stone is scaled and placed into different calyces using Blender software. The last pre-simulation window is for the tool calibration. It is necessary to place the controller in the sagittal plane with a deviation of 15–20° towards the user. Then it is necessary to check the accuracy of the lever by deflecting it, which can be seen on the slider opposite the corresponding item. The last step is to select the position of the working channel in the virtual ureteroscope in accordance with the dial. In all simulation cases the former was placed at 3 o'clock.

Two screens serve as the simulation window during training. The left screen displays virtual ureteroscopy, while the right screen corresponds to a simulated C-arm fluoroscopy. Simulation is started at the distal end of the virtual ureteral access sheath (UAS) (Figure 2). Management is carried out as follows: Rotation and deflection are performed as described above. Further movement options are actioned via the PC keyboard. Anteroposterior movement is carried out using the arrows on the keyboard. The appearance and disappearance of the laser are carried out by the L (laser) button, while the laser on/off is implemented by the F (fire) button. It should be clarified that currently, the laser operates only in the stone fragmentation mode without the ability to correct its energy and frequency (Figure 3). The appearance or disappearance of the basket is carried out by the B (basket) button, and its opening and closing by the num8 and num2 buttons, respectively (Figure 4). Lastly, the appearance or disappearance of the fluoroscopy window is carried out with the C button (C-arm).

The simulation window displays several indicators and metrics. The success bar on the top panel of the software displays the lithotripsy process. Before contact with the stone, it remains colourless, while when the stone is fragmented and removed, it is displayed with yellow and green colour, respectively. In the upper right corner, there is a tab with measured metrics:

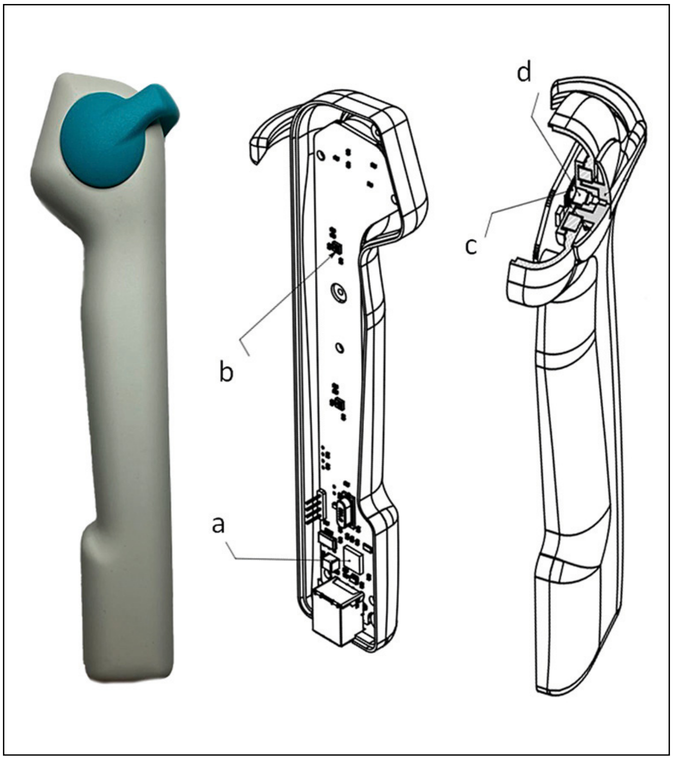


Figure 1. *External and schematic view of the controller: a – microcontroller; b – accelerometer; c – magnetic encoder; d – neodymium magnet.*

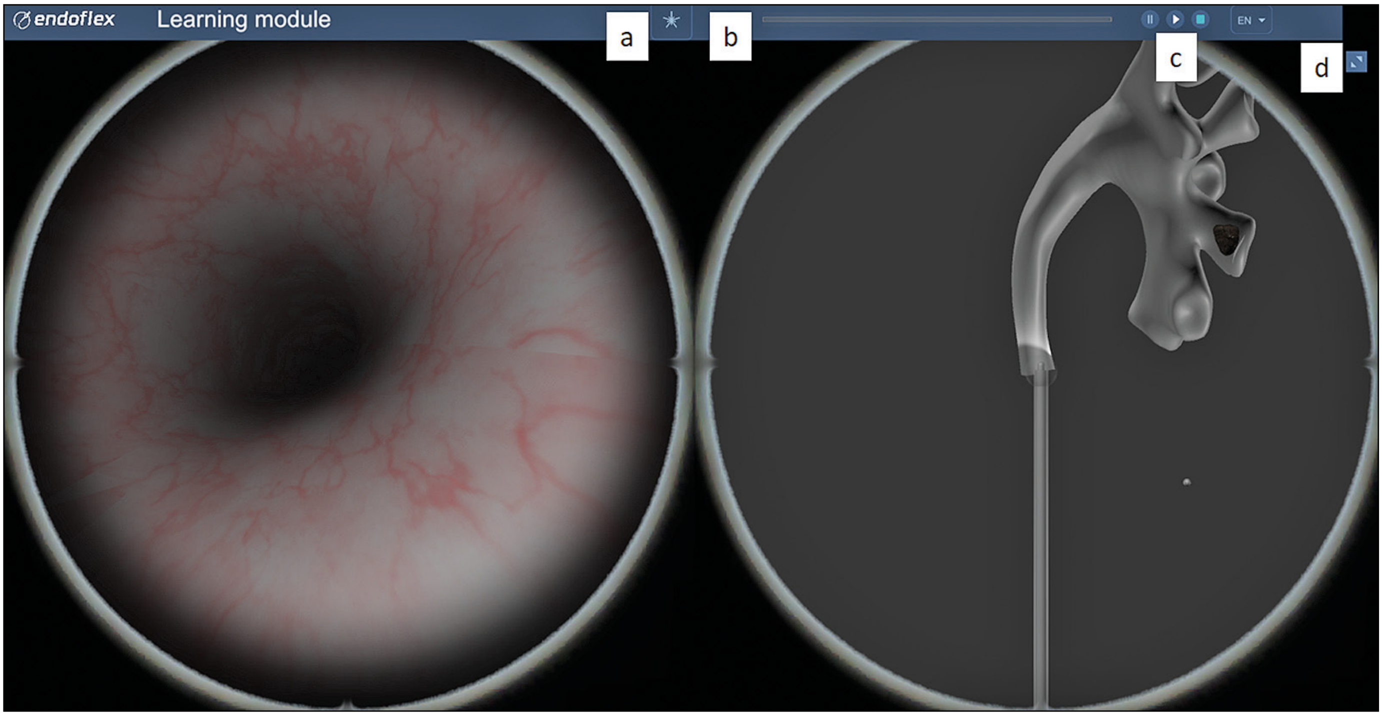


Figure 2. *Working window consisting of 2 screens: left – virtual endoscopic view, right – virtual C-arm. Simulation is started at the distal point of the virtual UAS; a – indicator of activated laser; b – success bar, which initially is grey and covered with yellow and green colours when the stone is fragmented and removed, respectively; c – button for the simulation pause and end; d – hidden real-time metrics.*

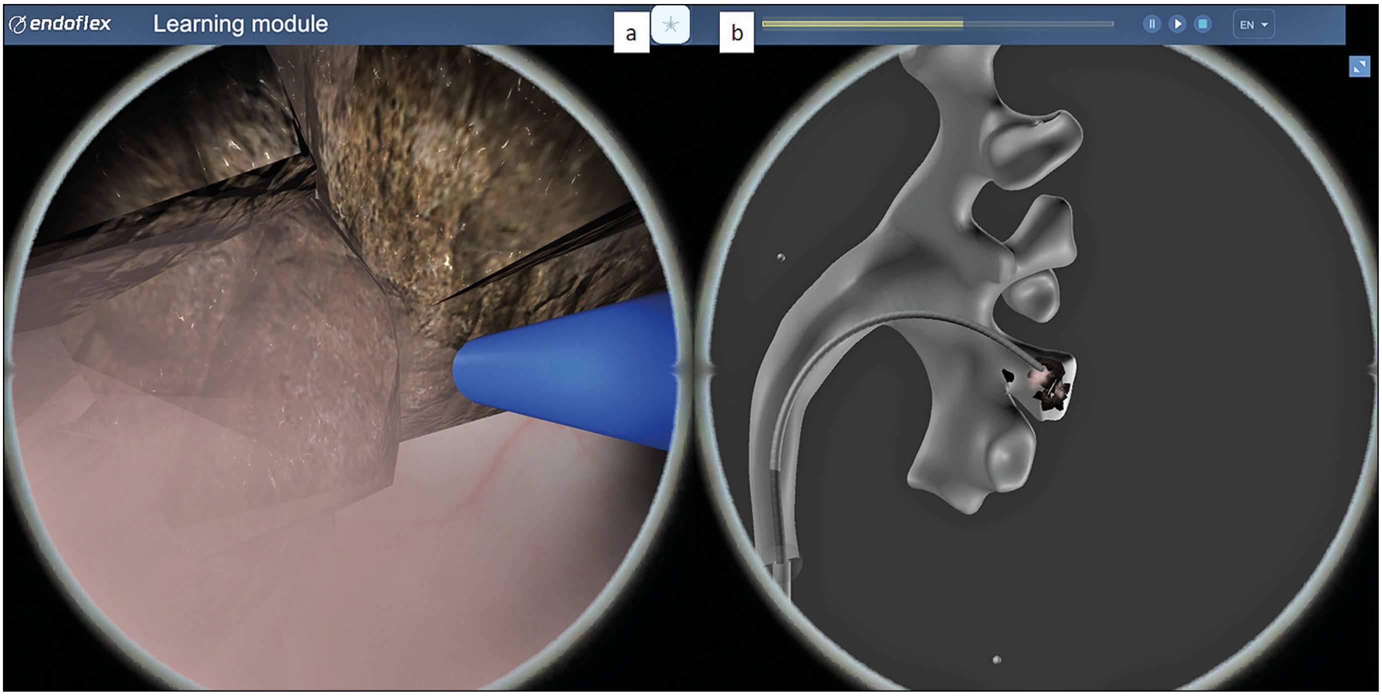
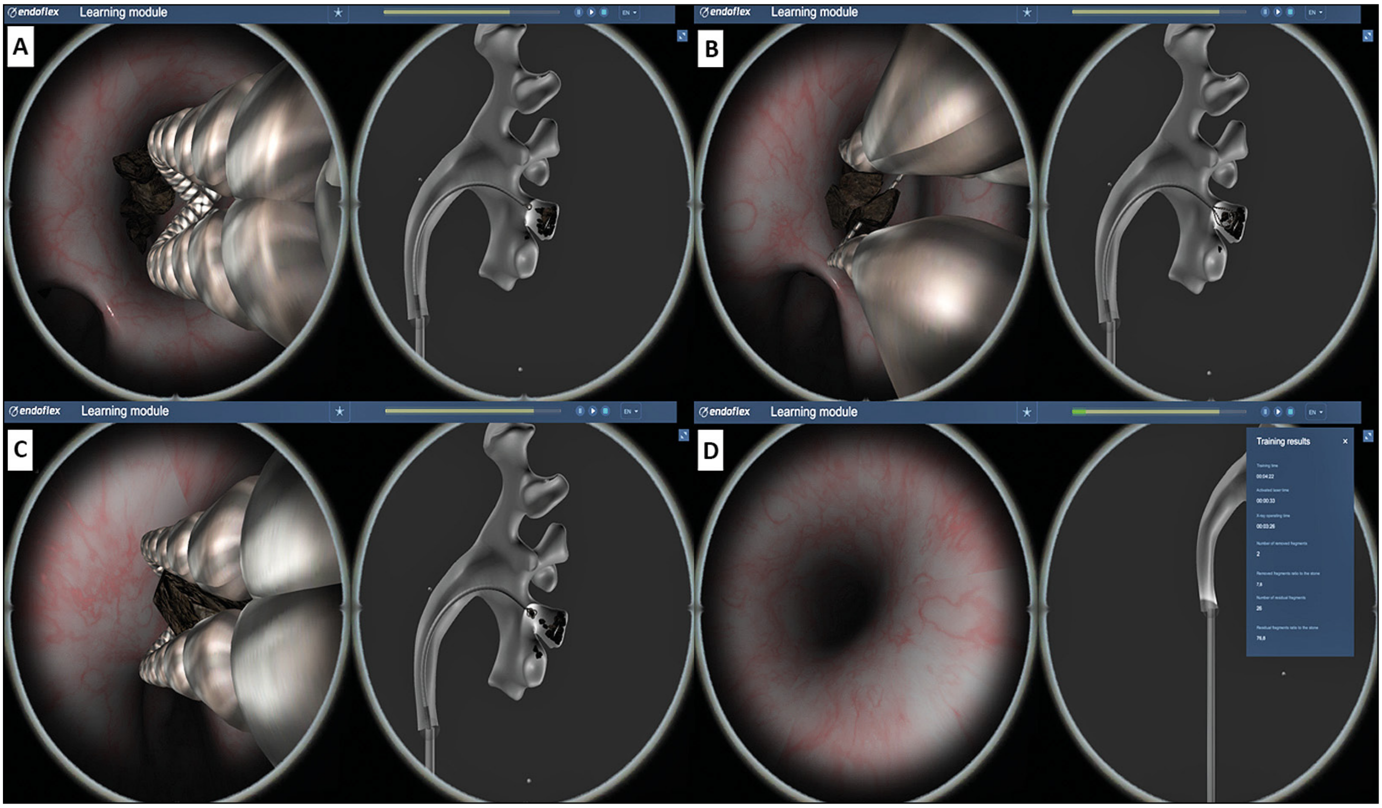


Figure 3. *Stone fragmentation after laser being introduced and activated via PC keyboard buttons L and F, respectively; a – lased is activated; b – success bar is half-covered with yellow because almost half of the stone is fragmented.*



Training results

Training time
00:04:22

Activated laser time
00:00:33

X-ray operating time
00:03:26

Number of removed fragments
2

Removed fragments ratio to the stone
7,8

Number of residual fragments
26

Residual fragments ratio to the stone
76,8

Figure 4. *Stone manipulation with basket:* **A)** *basket is introduced via PC keyboard button B;* **B)** *basket is dynamically opened via button num8;* **C)** *stone fragment is captured and basket is dynamically closed via button num2;* **D)** *endoscope is moved back via the Down Arrow button up to the distal point of UAS for fragment removal. The success bar is covered with green; performance metrics are opened.*

simulation time, laser active time, number of fragments removed, and stone-free status relating to the whole stone, as well as the number of fragments remaining after lithotripsy (Figure 4). With a dedicated controller in hand and managing the major functions via the keyboard on a personal computer, the user can simply delve into the process of executing a virtual RIRS of kidney stones (Figure 5).

Pre-education session

After ethical committee approval (EKC7072), 17 novices with no experience in performing fURS were recruited. Nine of them were final-year medical students, 5 were first-year residents, and 3 were second-year residents. To minimise their knowledge differences, all of them were provided with a lecture by a senior endourologist on pelvicalyceal system (PCS) anatomy, classification of kidney stones, indications for their removal, and fURS manipulations using a single-use LithoVue scope (Boston Scientific). The lecture lasted 2 hours and was delivered just before the practical part.

Education and post-educational analysis

After the lecture, each trainee was provided with a simulator workflow by the urologist, who also acted as their mentor (A.T.). Then, each novice performed a virtual ureterorenoscopy with lithotripsy and stone extraction. The cavity and location of the stones were determined randomly using the random.org portal. The same scenario was used after an educational week to define the change in metrics. The time of the entire simulation, lasing time, fluoroscopic time, and stone-free rates were evaluated.

After an initial assessment, each novice was provided with a free simulator, for use for one hour daily during a 7-day educational course. During free training, novices were able to use only 4 cavities of the PCS, to minimise the effect of overtraining on the same cavity and memorise them. At the end, each novice again performed the procedure on the initially defined scenario. The same metrics were checked and compared with their pre-educational session. It should be noted that all metrics were hidden from novices during simulation tasks.

In addition to the objective metrics, novices answered questions regarding their overall opinion regarding the usefulness of such a simulator in their training, its impact on their motivation to continue learning endourological skills, whether they would recommend it to other novices, and if they would agree to participate in further studies.

Also, opinions were taken from 3 dedicated endourologists with experience in more than 60 self-performed ureteroscopy cases regarding the similarity of virtual reconstruction with a real ureteroscopic picture during surgery (face validity) and the usefulness of integrating the Endoflex simulator into the training program of inexperienced trainees (content validity).

SPSS statistical software version 26.0 (IBM, Chicago, USA) was used for statistical analysis. Continuous data were presented as the mean and standard deviation (SD) or median and minimum and maximum value according to data distribution, which was assessed via the Kolmogorov-Smirnov test. The Wilcoxon test compared the results of novices before and after training. Nominal data were compared using the chi-square test. Validities as well as novice opinions were evaluated using a Likert scale (from 0 to 5). A significant difference was considered to be $p < 0.05$.

RESULTS

Novices' demographics as well as pre-study questions are presented in Table 1. Only 2 of them had experience in assisting for fURS; however, there were too few cases to be significant for distortion of results (3 and 4 cases, respectively). None of them had experience of VR-simulator use. Interestingly, all train-

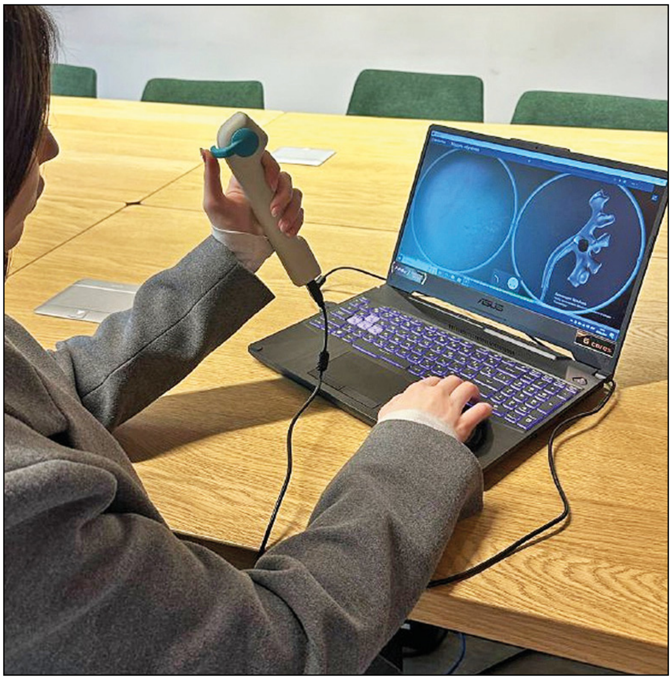


Figure 5. *The real simulation process. The user holds a specialised controller, moves the virtual flexible ureteroscope through the keyboard forward to the stone and ready to virtually activate the laser.*

ees were interested in console games, regardless of gender, and thought that the gamification approach should be integrated into their educational process. The results of the Endoflex curriculum are presented in Table 2. After one week of free simulator use, there was a significant decrease in simulation time (51.5 ±5.4 vs 41.7 ±4.7 min, p = 0.0002), activated laser time (13.8 ±2.9 vs 7.6 ±2.2, p ≤0.0001), and fluoroscopy time (121.4 ±32.8 vs 68.3 ±21.6, p ≤0.0001).

In terms of achieving a stone-free status, this increased from 11 to 15 novices who fully cleared the PCS from significant fragments, but the difference was not significant (p = 0.1058). All participants found the Endoflex simulator to be useful for their education and sufficient for increased motivation to further enhance their endourological skills. Moreover, all of them would recommend it to other junior trainees as well as participate in future studies related to the Endoflex simulator.

The experts described the simulator as having a high similarity to the real PCS appearance. While the appearance and basketing were considered realistic (4/5), due to a lack of manual selection of laser parameters and non-variable stone appearance, these were only considered mildly realistic. Moreover, the experts also mentioned the lack of physical accessories, and perhaps to reduce the dependence on the keyboard to activate the procedural steps, besides a lack of haptic feedback and error indicators. However, it was useful for novices (content validity = 4/5), especially if integrated into their endourological curriculum with different biological and non-biological simulators. Preliminary training with Endoflex may potentially better prepare them for real fURS use and make them less prone to damage (Table 3).

DISCUSSION

Flexible URS has become an important diagnostic and therapeutic modality for upper urinary tract diseases, especially for kidney stones. This popularity of fURS is the result of many years of technological advancements. However, there is an obvious paradigm shift in urological education over the last decade. This has certain benefits, such as increasing simulation exposure of surgical trainees while minimising the impact of untrained trainees on patients, thereby improving patient safety. According to a recent systematic review [7], the learning curve for urolithiasis surgery has been outlined as 60 cases for operative time and 56 cases for fragmentation efficacy. Simulation training would thus be beneficial and enhance this aspect of training.

Table 1. *Novices' demographics and pre-educational questionnaire*

Parameter	Number
Educational level Last-year student First-year resident Second-year resident	 9 5 3
Gender (male/female)	11/6
Dominant hand side (left/right)	4/13
Experience on self-performing fURS (yes/no)	0/17
Experience on assistance during fURS (yes, number of cases/no)	2 (3 and 4 cases)/15
Experience on virtual surgical simulators (yes/no)	0/17
Availability of virtual simulators in your department (yes/no)	0/17
Do you like to play console/mobile/PC games? (yes/no)	17/0
Should gamification be integrated to urological education? (yes/no)	17/0

fURS – flexible ureterorenoscopy

Table 2. *Endoflex curriculum results*

Metrics	Before	After	p-value
Simulation time [min]	51.5 ±5.4	41.7 ±4.7	**0.0002**
Activated laser time [min]	13.8 ±2.9	7.6 ±2.2	**<0.0001**
Fluoroscopy time [s]	121.4 ±32.8	68.3 ±21.6	**<0.0001**
Stone-free rate [%]	64.7 (11)	88.2 (15)	0.1058

Table 3. *Novices' post-educational opinions and experts' validation*

Novices' opinion	
Is the proposed simulator useful for your education? (yes/no)	17/0
Is your motivation to proceed with endourological education further increased after Endoflex use? (yes/no)	17/0
Would you recommend Endoflex to other novices? (yes/no)	17/0
Would you like to participate on further studies on Endoflex? (yes/no)	17/0
Experts' opinion	
Face validity	4/5
Content validity	4/5

Many simulators are available for fURS, divided into biological, non-biological, and VR, depending on the manufacturer [8]. Although physical trainers provide an appropriate haptic response, the overall effect of training novices is analogous to virtual analogues [9]. VR-based simulation has the advantage of unrestricted, repeatable mental skill acquisition in a stress-free setting, before their routine use in a clinical set-up [10]. Furthermore, the habits and hobbies of young professionals have changed noticeably. Although this was not the main goal of our research, as can be seen from the survey results, all beginners played console games and stated that such gamification should be integrated into routine simulation and education. This leads us to the idea that further development of various simulators, including those in endourology, should be guided in this direction, to combine interests and skills for more productive learning.

The above-mentioned concepts are the reason for the emergence and popularisation of the only virtual simulator available on the market, UroMentorTM (Simbionix, Cleveland, OH), which allows simulation of fURS performance, urinary stone fragmentation, and extraction. Chou et al. [11] investigated whether a model-based training format and an interactive virtual-reality simulator could provide equivalent teaching of basic ureteroscopy skills to an inexperienced medical student. They discovered that the medical students' skills and ability to perform a basic ureteroscopic stone-management procedure obtained through VR simulation was non-inferior to those gained through the use of a physical ureteroscopy training model. Aloosh et al. [12] found UroMentor useful for novice training and noted that the skills obtained on the simulator could be transferred to the operating room (OR). Another attractive feature of UroMentorTM is that cystoscopy skills can also be practiced, which is especially useful in developing endoscopic skills in general. Indeed, Zhang et al. [13] confirmed that UroMentorTM can improve urologists' ability to perform flexible cystoscopy and could be used as an effective training tool for trainees. Moreover, such simulators are an excellent solution not only for training, but also for assessing RIRS skills. Aloosh et al. [14] aimed to assess the flexible ureteroscopic stone extraction skills of urology postgraduate trainees (PGTs) in an objective structured clinical examination (OSCE), and they confirmed the feasibility of incorporating the UroMentor in OSCEs to assess the competency of urology PGTs in ureteroscopic stone extraction skill. However, its price of around $60,000, and the need to use large equipment makes this kind of simulator expensive and insufficiently available for training. This is an important fact that directly contributes to the availability of technology implementation, not just in clinical practice but also in routine training of novices, with the possibility of using it even at home. To simplify the architecture of the VR simulator of fURS for training of certain steps, Madera et al. [6] proposed a pulley-based haptic simulator device as a training tool for URS, allowing for continuous insertion into a virtual ureter. The device motor provides a resistive feedback force to familiarise users with the forces experienced during ureteroscopy. They conducted a preliminary evaluation study with 7 participants to compare subjective performance using the system, with visual and visual-haptic feedback. The addition of haptic feedback caused them to perform the task more slowly. However, it did not affect the task performance across many metrics.

While the above-mentioned VR analogues focus on the early stages of the procedure, one of the most important aspects to learn is navigation around the PCS. In our opinion, the current Endoflex simulator is the first portable simulator of its kind. To use it, the trainee needs to have only a personal computer and a controller, which makes it accessible even for home use. Movements of the dominant hand are calculated with a minimum error of ±0.3°, which is almost identical to the real instrument. This also allows practicing of fURS for an unlimited period, without extra cost, preparing for the real procedure. As can be seen from the results, there was a statistically significant improvement in all metrics except for the stone-free rate. The latter may be due to the small number of participants included, and the hypothesis should be tested again in the future with the inclusion of a larger number of novices and more details on laser settings.

However, there are a few disadvantages that need to be mentioned, such as the absence of the insertion channel for accessories for double-hand manipulation as well as a lack of haptic feedback with error indication. Accessory-based steps, such as stone fragmentation and extraction, are fully realised via a keyboard in our model. Moreover, the experts stated the necessity for manual selection of laser parameters to better imitate stone fragmentation. However, we have already implemented some of the solutions to the above-mentioned problems and are developing software improvements to all the identified shortcomings. Also, a disadvantage is the small number of participants and the lack specialised tools to measure fURS manipulations. Finally, the price of Endoflex is not yet determined, and the concept of its higher accessibility compared to other

VR simulators is only theoretical. We did not measure construct or predictive validity in this study. While our software was based on 5 PCS configurations based on 5 patients, in future we can individualise the fURS simulation to a specific patient anatomy, prior to performing the procedure.

CONCLUSIONS

Endoflex is a promising VR simulator that can already be implemented into urological simulation-based training. However, further improvements are necessary for its full-fledged training of RIRS.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The ethical approval was not required.

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