Three Dimensional Printing Technology Used to Create a High-Fidelity Ureteroscopy Simulator: Development and Validity Assessment (Rein-3D-Print-UroCCR-39)

Astrid Boulenger de Hauteclocque, Clément Michiels, Joffrey Sarrazin, Matthieu Faessel, Jocelyn Sabatier, Abderrahmane Khaddad, Gaëlle Margue, Nicolas Grenier, Frédéric Bos, Vincent Estrade, and Jean-Christophe Bernhard

OBJECTIVE To create and assess the validity of a high-fidelity, three dimensional (3D) printed, flexible ureteroscopy simulator resulting from a real case.

METHODS A patient's CT scan was segmented to obtain a 3D model in .stl format, including the urinary bladder, ureter and renal cavities. The file was printed and a kidney stone was introduced into the cavities. The simulated surgery consisted of monobloc stone extraction. Nineteen participants split into 3 groups according to their level (6 medical students, 7 residents and 6 urology fellows) performed the procedure twice at a 1-month interval. They were rated according to a global score and a task-specific score, based on an anonymized, timed video recording.

RESULTS Participants demonstrated a significant improvement between the 2 assessments, both on the global score (29.4 vs 21.9 points out of 35; $P < .001$) and the task-specific score (17.7 vs 14.7 points out of 20; $P < .001$) as well as procedure time (498.5 vs 700 seconds; $P = .001$). Medical students showed the greatest progress for the global score (+15.5 points (mean), $P = .001$) and the task-specific score (+6.5 points (mean), $P < .001$). 69.2% of participants considered the model as visually quite realistic or highly realistic and all of them judged it quite or extremely interesting for intern training purposes.

CONCLUSION Our 3D printed ureteroscopy simulator was able to enhance the progress of medical students who are new to endoscopy, whilst being valid and reasonably priced. It could become part of a training program in urology, in line with the latest recommendations for surgical education. UROLOGY 00: 1−6, 2023. © 2023 Elsevier Inc.

The Halstedian model[1] for surgical training, "see one, do one, teach one," is no longer adapted to the need for rigor in acquiring skills within the operating theatre. There is an urgent need to enhance learning programs for young surgeons by introducing new teaching media.

Abbreviations: *3D, three dimensional; CT-scan, computed tomography scan; GS, global score; OR, operating room; OSATS, objective structured assessment of technical skills; PT, procedure timing; TSS, task-specific score*

Financial Disclosure: *The authors declare that they have no relevant financial interests.*
Funding Support: This work was supported by the Région Nouvelle Aquitaine through European funds (Grant number 211110 FEDER 2016/121201 AQT) and French government through the France 2030 program (ANR-21-RHU5-0015).

From the Department of Urology, Bordeaux University Hospital, Bordeaux, France; the Department of Additive Fabrication Engineering, Bordeaux University Technological Institute, Gradignan, France; and the Department of Radiology, Bordeaux University Hospital, Bordeaux, France

Address correspondence to: Astrid Boulenger de Hauteclocque MD, Bordeaux University Hospital, place Amélie Raba-Léon, 33000 Bordeaux, France. E-mail: astrid.dehauteclocque@gmail.com

Submitted: November 21, 2022, accepted (with revisions): February 28, 2023

Simulation training has spread widely in the past years in all medical fields, especially surgery, due to the requirement for specific skills.

Over the last 30 years, ureteroscopy has become the main technique for removing renal calculi, overtaking shock wave lithotripsy.[2] It has thus become compulsory for newly-trained urologists to be familiar with this procedure.

Basic endo-urological surgery models are among the most commonly developed simulation devices for both cystoscopy and ureteroscopy.[3] These simulators are of different types: inanimate, animal, cadaveric or virtual-reality models. The more realistic they are, the greater the cost. High-fidelity models are usually unaffordable for institutions.

The evaluation of surgical simulators is usually based on McDougall's validity,[4] consisting of 5 subcategories : face, content, construct, concurrent, and predictive validities.

https://doi.org/10.1016/j.urology.2023.02.039
0090-4295

However, this definition appears to be out of date and needs to be replaced by a new taxonomy that sees validity as an ongoing process. This concept was first described by Noureldin et al[5,6] in 2018 calling for the collection of 5 types of evidence to acknowledge validity: content, response processes, internal structure, relation to other variables and consequences (Supplementary Figure 1).

The purpose of this study was to create a high-fidelity ureteroscopy simulator and assess its validity based on the new taxonomy.

MATERIALS AND METHODS

Flexible Ureteroscopy Simulator

The ureteroscopy model was created from a patient's whole urinary tract using a nephrogenic phase CT-scan. The patient had given informed consent as part of the UroCCR French kidney cancer database project, registered on Clinical Trials under the number NCT03293563. A three-dimensional (3D) model of the bladder, ureter and renal calyces of the left kidney was constructed using Synapse 3D software (Fujifilm) and then 3D-printed (J750 Polyjet printer, Stratasys) (Fig. 1). The model was built from Agilus30 soft-material from the printer's catalogue as its tensile strength (up to 310 N/mm2) was close to that of the human ureter, as estimated by Shilo et al[7] (457.52±33.74 N/mm2). A wedge was placed under the ureter to mimic the crossing iliac vessels and the whole device was placed in a box to prevent it from moving around during training (Fig. 1).

Apart from 2 single-use ureteroscopes donated by Boston Scientific, all the surgical instruments had been recovered from previous real procedures and were reused after decontamination. This made our simulation device additional-cost-free.

The items collected were as follows: 5 units of Lithovue single-use flexible ureteroscope (Boston Scientific), 3 units of Radiofocus 0.035" guide wire (Terumo), 2 units of Re-Trace 10-12CH ureteral access sheath (Coloplast) and 2 units of Dormia No-Tip 1.5CH nitinol basket (Coloplast).

Validity Assessment

Our study was designed to assess 4 of the 5 types of validity evidence as defined by Noureldin et al.[5]

- Content: by means of validated questionnaires previously used in flexible ureteroscopy simulation studies;
- Response processes: by ranking participants according to their urology level;
- Internal structure: consistency of the scoring system measured by Cronbach's alpha coefficient;
- Consequences: evaluation of whether there has been an improvement in the participants' performance between the 2 assessments.

Participants and Procedure

Participants with variable endoscopy experience were voluntarily enrolled in 3 groups according to level: medical students, residents and fellows. All participants received a standard training course on ureteroscopy based on a Powerpoint© document, presenting principles of ureteroscopy, operating tools, manipulation of the endoscope and a step-by-step explanation of the procedure they were about to perform.

They were asked to enter the bladder with the flexible ureteroscope, place the guide wire and the access sheath in the ureter up to the renal pelvis, explore all the renal calyces, remove one calculus placed by the evaluator before each attempt and, finally, remove the access sheath under visual control.

The medical students who had never seen an ureteroscope before were offered the chance to manipulate it for 1 minute before the procedure.

An assistant offered help during the procedure only if the participant asked for it. His role consisted in holding the guidewire, changing it to the stone-retrieval basket and manipulating the basket according to the participant's orders.

Participants performed a second, exact same procedure 1 month later.

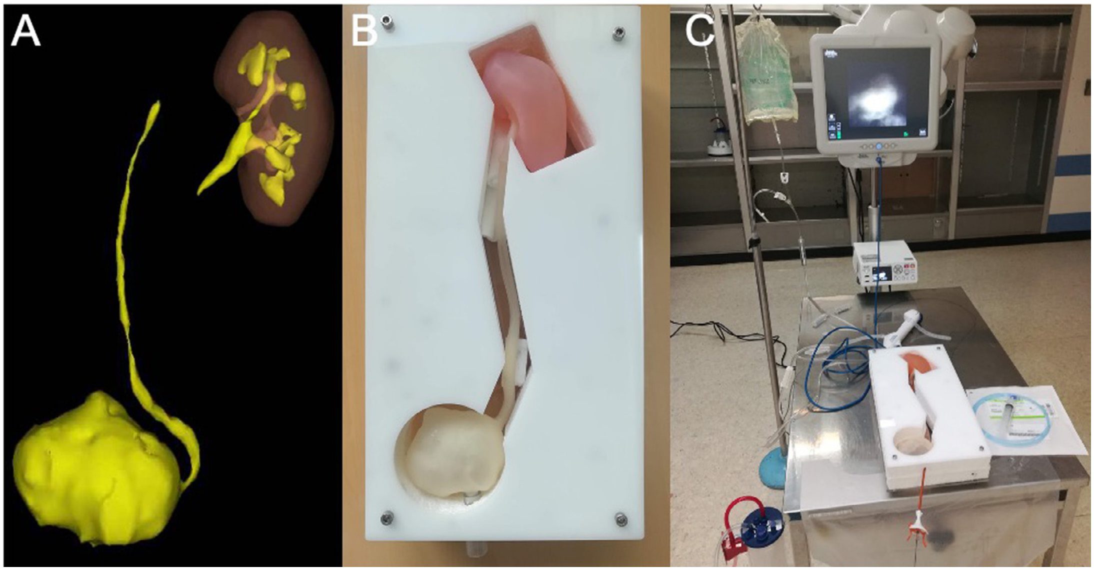

Figure 1. Our bench model for ureteroscopy simulation. (A). 3D model; (B). 3D printing inside its box; (C). Ready-to-use installation in the operating room (Color version available online.)

Table 1. Detailed items evaluated in the global score and the task-specific score

	Points
Global score*	
Respect for tissue	1-5
Time and motion	1-5
Instrument handling	1-5
Handling the endoscope	1-5
Procedure flow and forward planning	1-5
Use of assistants	1-5
Knowledge of the procedure	1-5
Total	35
Task-specific score	
Identification of the ureteric orifice	1-4
Slow, careful insertion into the ureteral sheath	1-4
Stone extraction by withdrawing scope and basket together and keeping the basket in view	1-4
Checking for emptiness of the renal calyxes	1-4
Ureteral sheath extraction under visual control	1-4
Total	20

* Ureteroscopic global rating scale, from Matsumoto ED, et al. A novel approach to endo-urological training: training at the Surgical Skills Center. J Urol. 2001[9]

Scoring

Scoring was done with 2 questionnaires based on the OSATS (objective structured assessment of technical skills) scoring system elaborated by Martin et al,[8] specially updated by Matsumoto et al[9] for the assessment of ureteroscopy simulators and validated in many studies. This consists of a global score (GS) to evaluate the level of important skills in ureteroscopy (7 skills scoring up to 5 points with a total score of 35) and a task-specific score (TSS) for the achievement of crucial steps (5 steps scoring up to 4 points each with a total score of 20) (Table 1).

The whole procedure, from ureteroscope insertion into the bladder to its final removal, was timed by the operator.

Each performance was recorded and scored on the video and each participant's identity and group were blinded.

Satisfaction data were evaluated using a 5-point Likert scale.

Statistical Analysis

Statistical analysis was performed with R software (RStudio v1.1.463 for Mac OS X). The global score, task-specific score and procedure time (PT) were compared for each assessment using paired t-tests with a significance level set at 0.05. Intergroup comparisons were made using Kruskal Wallis rank sum tests with Wilcoxon-Mann-Whitney test corrected by Bonferroni for Post-Hoc analysis with a significance level of 0.0167.

RESULTS

All participants performed the ureteroscopy procedure twice within 1 month.

We enrolled 19 participants, including 6 medical students, 7 interns and urology residents and 6 urology fellows. Their mean age was 27.3 years (±4.91) and 52.6% were women. Apart from 1 participant, none of the medical students had ever seen a ureteroscopy procedure before.

Demographics and data on endo-urology experience are shown in Table 2.

Validity

The internal structure assessment revealed excellent consistency for the global score (Cronbach's alpha = 0.97) and acceptable consistency for the task-specific score (alpha = 0.78).

Comparison Between the Two Assessments

The participants showed significant progress between the first evaluation and the second one as regards global score (mean ± SD 29.4 ± 4.4 vs 21.9 ± 9.8, $P < .001$), task-specific score (17.7 ± 1.6 vs 14.7 ± 3.5, $P < .001$) and procedure time (499 ± 194 vs 700 ± 263 seconds, $P = .001$) (Fig. 2).

The highest improvement was seen for medical students with an increase of 15.5 points (out of 35) on the global score (26.0 ± 5.59 vs 10.5 ± 0.55, $P = .001$) and 6.5 points (out of 20) on the task-specific score (16.8 ± 1.47 vs 10.3 ± 1.21, $P < .001$). Residents and fellows also improved their scores but without reaching significance.

Apart from this, a decrease in procedure time was only significant for residents (431 ± 137 vs 682 ± 296 seconds, $P = .019$).

Table 2. Demographics and endo-urology experience

	Total (n = 19)	Medical Students (n = 6)	Residents (n = 7)	Fellows (n = 6)
Age ±SD, yr	27.3 ± 4.91	22.5 ± 0.55	26.9 ± 3.72	32.5 ± 3.08
Male sex, no. (%)	9 (47.4)	3 (50)	3 (42.9)	3 (50)
Dominant hand, no. (%)				
Right hand	15 (78.9)	5 (63.3)	6 (85.7)	4 (66.7)
Left hand	3 (15.8)	1 (36.7)	1 (14.3)	1 (16.7)
Ambidextrous	1 (5.3)	0	0	1 (16.7)
Year of attendance, no. (%)				
First year	–	–	2 (28.6)	3 (50)
Second year	–	–	2 (28.6)	1 (16.7)
Third year	–	–	1 (14.2)	2 (33.3)
Fourth year	–	–	2 (28.6)	–
Number of ureteral stents previously placed [range]	205.6 [0;1000]	0 [0;0]	43.7 [6;100]	600 [100;1000]
Number of ureteroscopies previously observed [range]	129.1 [0;500]	0.67 [0;1]	57.0 [4;100]	341.7 [100;500]
Number of ureteroscopies previously performed [range]	44.7 [0;200]	0 [0;0]	20.0 [0;100]	118.3 [30;200]

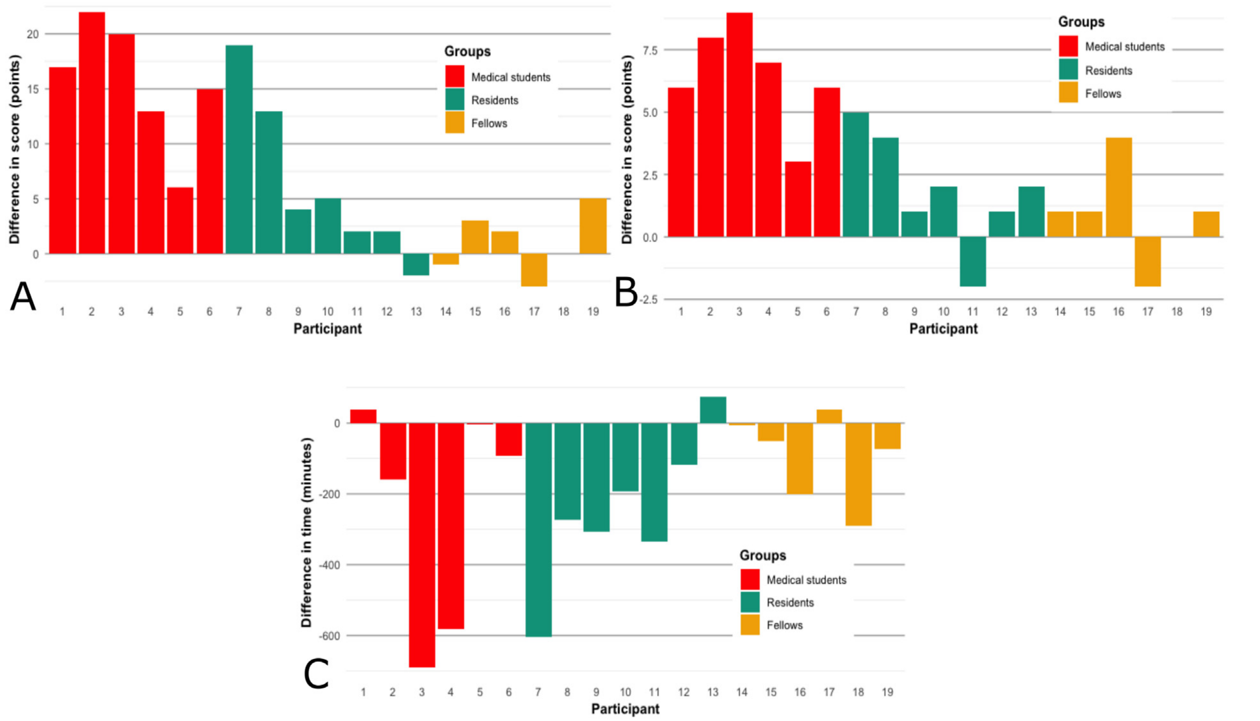

Figure 2. Modified parameters between the 2 assessments. (A). Modification of global score (GS); (B). Modification of task score (TS); (C). Modification of procedure timing (PT) (Color version available online.)

Inter-Group Analysis

Repeated Kruskal-Wallis rank sum tests indicated a statistical relationship between group level and performance on the first evaluation with respect to global score (P = .0028), task-specific score (P = .0023) and the time taken to complete the procedure (P = .0159).

Inter-groups tests showed that fellows performed statistically better than medical students on global rating score (31.0 ± 2.83 vs 10.5 ± 0.55, P = .0045) whereas the difference between medical students and residents on the one hand, and between residents and fellows on the other hand was not significant (P = .036 and P = .032 respectively).

Task-specific score grading also showed a difference between the groups. Fellows did better than medical students (17.3 ± 1.37 vs 10.3 ± 1.21, P = .0048) and so did residents (16.3 ± 2.29 vs 10.3 ± 1.21, P = .0033), although the difference between fellows and residents was not significant (P = .51).

The improvement in the medical students' and residents' performance on the second evaluation made the difference between groups disappear (P = .059 for GS and P = .102 for TSS).

At first, the procedure time was significantly longer for medical students compared to fellows (490 ± 79.5 vs 931 ± 141 seconds, P = .0022). No subsequent difference between groups was seen on the second procedure.

Specific Tasks

The "time and motion" evaluation (second item on GS) hierarchically differed between the groups on the first evaluation. The score ranged from 1 to 3 (over 5 points) for medical students, 1 to 5 for residents and 3 to 5 for fellows. On the second procedure, the range was 3 to 5 for all participants.

Satisfaction

Experienced participants (residents and fellows who had already seen more than 1 real ureteroscopy procedure) judged the appearance of the simulator. 69.6% of them judged visual realism as "total" or "moderate" and 39.5% judged the physical sensation of realism as "total" or "moderate."

Among the ureteroscopists under study, 100% of them thought the simulator would make a good training tool for urologists to be.

DISCUSSION

Our novel ureteroscopy simulator achieved the 4 faces of validity that we had to evaluate. Evidence of Content was achieved with scoring tools validated in previous studies [10-12]; evidence of Internal Structure was achieved with a good Cronbach coefficient for GS and TSS; Evidence of Response Processes was achieved with a fine distinction between experienced and novice ureteroscopists and evidence of Consequences was achieved with significant progress between the 2 assessments.

Medical students showed the best improvement on scores and time between the 2 procedures. Residents and fellows also improved their scores but without reaching significance. The simulator had an impact statistically significant between medical students vs residents and fellows, which concludes that the tool can be useful for first-year residents. But there were no differences between residents and fellows, which suggests that it will not have an additional impact on training. To determine this, it is necessary to conduct another study with a larger sample of residents who attend different years compared to fellows.

A surprising point was that in a very short period of time, participants showed a significant improvement in respect to time. We speculate that the reasons for that may be the effect of learning which was important with the device due to the simplicity of the case, so was the competitive spirit between subjects.

Endo-urology has boomed over the past 30 years with the tremendous promotion of ureteroscopy for the treatment of renal calculi. In France, in 2014, this procedure accounted for 76% of surgical lithiasis management whereas in 1985 it was only 4.4%.[13] It is therefore impossible to imagine a urology curriculum without ureteroscopy training. Inanimate physical models and virtual reality simulators have shown their utility for enhancing endo-urology skills in urology residents.[14,15] Bench models seem to be as effective as the far more expensive virtual reality simulators but the downside is that they are less convincing.[10]

We assumed that 3D technology would unite both cost-effectiveness and similarity to real life. Our model was constructed at a cost of 700€. All the endo-urologic tools had been recovered from previous operating room procedures with the benefit of training using real instruments at no additional cost. We noted an immersive effect with almost 70% of experienced endo-urologists judging the model to be visually realistic. The sensations inside were not so similar, probably due to the absence of ureteral peristalsis and difference in the properties of the material compared to a real ureter. Haptic feedback is known to be a weakness of virtual surgery but this has not stopped the development of the best-known robotic surgical systems and no complications due to the lack of haptic feedback have been reported.[16]

Exploration of the relationship between the fidelity of task simulators and the ability to properly train students has shown that low-fidelity simulation approaches are often sufficient.[17]

One point in our simulation procedure which differs from real-life ureteroscopy protocols is the omission of fluoroscopy. We voluntarily omitted its use as there is a trend to evaluate ureterorenoscopy "as low as reasonably achievable" (ALARA) to keep radiation exposure to a minimum level.[18] Publications have shown the feasibility of radiation-reduced protocols and their efficiency in managing lithiasis. Thus, considering this precautionary principle in training future urologists is warranted.

While the device we developed appears to be an effective tool for simulation training, it is important to note that programs that implement simulation require a structured program with a curriculum, technology, additional costs and trained staff. Such teaching programs need to be established for surgical education to evolve.

CONCLUSION

This study suggests the validity of our 3D printed ureteroscopy simulator and shows its ability to enhance the progress of novices to endoscopy whilst being easy-to-use and reasonably priced. It could be part of a training program in urology, in line with the latest recommendations in surgical education.

AUTHOR CONTRIBUTIONS

ABDH: Writing—original draft, Formal analysis, Methodology, Investigation, Visualization. CM: Conceptualization. JS: Resources, Methodology. MF: Resources. JS: Resources. AK: Investigation. GM: Investigation. NG: Resources. FB: Project administration, Resources. VE: Review, Supervision, Validation. JCB: Conceptualization, Review and Editing, Funding acquisition, Supervision, Validation.

ACKNOWLEDGMENTS

The authors wish to thank Teresa Sawyers, Medical Writer at the B.E.S.P.I.M, Nîmes University Hospital, France, for her help in editing the manuscript.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2023.02.039.

References

1. Reznick RK, MacRae H. Teaching surgical skills—changes in the wind. *N Engl J Med*. 2006;355:2664–2669. https://doi.org/10.1056/NEJMra054785.
2. Oberlin DT, Flum AS, Bachrach L, et al. Contemporary surgical trends in the management of upper tract calculi. *J Urol*. 2015;193:880–884. https://doi.org/10.1016/j.juro.2014.09.006.
3. Aydin A, Shafi AMA, Shamim Khan M, et al. Current status of simulation and training models in urological surgery: a systematic review. *J Urol*. 2016;196:312–320. https://doi.org/10.1016/j.juro.2016.01.131.
4. McDougall EM. Validation of Surgical Simulators. *J Endourol*. 2007;21:244–247. https://doi.org/10.1089/end.2007.9985.
5. Noureldin YA, Lee JY, McDougall EM, et al. Competency-based training and simulation: making a "Valid" argument. *J Endourol*. 2018;32:84–93. https://doi.org/10.1089/end.2017.0650.
6. Noureldin YA, Sweet RM. A call for a shift in theory and terminology for validation studies in urological education. *J Urol*. 2018;199:617–620. https://doi.org/10.1016/j.juro.2017.10.022.
7. Shilo Y, Pichamuthu JE, Averch TD, et al. Evaluation of the tensile strength of the human ureter—preliminary results. *J Endourol*. 2014;28:1470–1473. https://doi.org/10.1089/end.2014.0226.
8. Martin JA, Regehr G, Reznick R, et al. Objective structured assessment of technical skill (OSATS) for surgical residents. *Br J Surg*. 1997;84:273–278. https://doi.org/10.1046/j.1365-2168.1997.02502.x.
9. Matsumoto ED, Hamstra SJ, Radomski SB, et al. A novel approach to endourological training: training at the Surgical Skills Center. *J Urol*. 2001;166:1261–1266. https://doi.org/10.1016/s0022-5347(05)65749-7.
10. Chou DS, Abdelshehid C, Clayman RV, et al. Comparison of results of virtual-reality simulator and training model for basic ureteroscopy training. *J Endourol*. 2006;20:266–271. https://doi.org/10.1089/end.2006.20.266.
11. White MA, Dehaan AP, Stephens DD, et al. Validation of a high fidelity adult ureteroscopy and renoscopy simulator. *J Urol*. 2010;183:673–677. https://doi.org/10.1016/j.juro.2009.10.013.

12. Matsumoto ED, Pace KT, Honey RJD. Virtual reality ureteroscopy simulator as a valid tool for assessing endourological skills. *Int J Urol*. 2006;13:896–901. https://doi.org/10.1111/j.1442-2042.2006.01436.x.
13. Doizi S, Raynal G, Traxer O. Évolution du traitement chirurgical de la lithiase urinaire sur 30ans dans un centre hospitalo-universitaire. *Prog En Urol*. 2015;25:543–548. https://doi.org/10.1016/j.purol.2015.05.002.
14. Brehmer M, Swartz R. Training on bench models improves dexterity in ureteroscopy. *Eur Urol*. 2005;48:458–463. https://doi.org/10.1016/j.eururo.2005.04.031.
15. Brunckhorst O, Aydin A, Abboudi H, et al. Simulation-based ureteroscopy training: a systematic review. *J Surg Educ*. 2015;72:135–143. https://doi.org/10.1016/j.jsurg.2014.07.003.
16. Reiley CE, Akinbiyi T, Burschka D, et al. Effects of visual force feedback on robot-assisted surgical task performance. *J Thorac Cardiovasc Surg*. 2008;135:196–202. https://doi.org/10.1016/j.jtcvs.2007.08.043.
17. Talbot TB. Balancing physiology, anatomy and immersion: HOW much biological fidelity is necessary in a medical simulation? *Mil Med*. 2013;178(suppl_10):28–36. https://doi.org/10.7205/MILMED-D-13-00212.
18. Greene DJ, Tenggadjaja CF, Bowman RJ, et al. Comparison of a reduced radiation fluoroscopy protocol to conventional fluoroscopy during uncomplicated ureteroscopy. *Urology*. 2011;78:286–290. https://doi.org/10.1016/j.urology.2010.11.020.