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ARTICLE

Three-dimensionally printed non-biological simulator for percutaneous nephrolithotomy training

Stanislav Ali[a], Evgenii Sirota[a], Hussein Ali[a], Evgenii Bezrukov[a], Zhamshid Okhunov[b], Mikhail Bukatov[c], Alexandr Letunovskiy[c], Nikolai Grygoriev[d], Mark Taratkin[a], Stanislav Vovdenko[a], Andyshea Afyouni[b] and Yuri Alyaev[a]

[a]Institute for Urology and Reproductive Health, Sechenov University, Moscow, Russia; [b]Department of Urology, University of California, Irvine, Irvine, CA, USA; [c]LLC «VERITEL», Moscow, Russia; [d]European Medical Center, Moscow, Russia

ABSTRACT

Objective: We sought to improve the educational and pre-operative training on various stages of percutaneous nephrolithotomy (PCNL) under fluoroscopic and ultrasound guidance. We developed a three-dimensional (3D) printed simulator (3D-printed PCNL model) for urological trainees.
Methods: 40 s year urology residents were randomly assigned into two groups, completing PCNL surgical steps on a URO Mentor^{TM} surgical simulator (Group A) or on our new 3D-printed PCNL model (Group B). Following the training, both groups completed a standardized questionnaire (Likert scale from 0 to 10) which we used to asses the learning curve associated with PCNL training.
Results: The mean score of Group A was 65.2/80 while Group B was 76.1/80. Mann-Whitney U-test showed no significant difference between the groups ($U = 16$, $p < 0.05$).
Conclusion: The 3D-printed PCNL model developed is a novel and highly effective tool that can facilitate enhanced endourological education and personalized pre-operative planning for urolithiasis cases. According to the criteria tested, residents who used our 3D-printed PCNL models performed better under all metrics.

ABBREVIATIONS: 3D: Three Dimensional; CT: Computed Tomography; DICOM: Digital Imaging and Communications in Medicine; FDM: Fused Deposition Modeling; FS: Fluoroscopy; PCNL: Percutaneous Nephrolithotomy; PLA: Polylactide; STL: Standard Triangulation Language; US: Ultrasound; OR: Operation room

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Introduction

Epidemiological studies have shown the 1.7–14.8% prevalence of urolithiasis in the United States, though this statistic continues to increase each year [1]. Today, stone treatment, depending on the severity of the disease, typically comprises minimally invasive endoscopic surgical intervention. In the last two decades, percutaneous nephrolithotomy (PCNL) has become the standard of care to treat exceedingly large kidney stones. Like the overall rate of urolithiasis, the incidence of complex forms of urolithiasis, such as staghorn stones, high-density stones (>1000 HU), and stones in kidneys with abnormal anatomies, comprise roughly 45–60% of all urolithiasis cases [2]. Because of the increased incidence of complex forms of urolithiasis, the use of PCNL has become widespread given its improved stone-free rates over other modalities [3].

Obtaining initial renal access for PCNL not only requires the expertize and accuracy but also involves the use of state-of-the-art, modern urological equipment. Because of the lack of adequate training and resources available to develop thorough skills of this procedure, hands-on participation in the operating room (OR) is often the only method for residents and trainees of mastering PCNL surgical techniques. Schilling and colleagues provided evidence of this as they closely evaluated the PCNL learning curve and showed that beginners show significantly inferior results in operative times, complication rates, and stone free rates when compared to more experienced surgeons [4].

It is well known that establishing a precise percutaneous tract is the most crucial step to avoid major complications [5,6]. To minimize potential hemorrhagic complications, endourologists are required to not only get but proactively refine their surgical skills to facilitate the proper access and dilation of the tract. According to De la Rosette and colleagues, trainees can get a basic understanding of fundamental PCNL surgical skills after roughly 24 PCNLs [5]. Similarly, Tanriverdi and colleagues showed that surgeons need at least 60 operations to overcome the steep learning curve associated with achieving adequate percutaneous access and a minimum of 115 procedures to reach a consistent level of surgical performance [7,8].

Recently, several PCNL simulators have been introduced into clinical practice to help attenuate the steep learning

CONTACT Stanislav Ali nabilali095@gmail.com Institute for Urology and Reproductive Health, Sechenov University, Pirogovskaya str., 2, bldg. 4.4, Moscow, 119991, USA

curve associated with learning proper PCNL techniques [6,9]. In this study, we sought to assess the efficacy of a novel 3D-printed PCNL model in helping urology residents to improve their PCNL skills, specifically regarding their ability to establish accurately the percutaneous access under fluoroscopic and ultrasound guidance, dilate the tract, perform endoscopy and subsequent lithotripsy, and place nephrostomy tubes correctly. This study aims to compare our new 3D-printed PCNL model with the traditional URO Mentor^{TM} surgical simulator in a group of residents.

Materials and methods

General features

The study was approved by the Institutional Review Board. Computer tomography (CT) Digital Imaging and Communications in Medicine (DICOM) data was used to create various iterations of the 3D-printed PCNL model. The data was first converted to computer-aided design (CAD) files and two parts of the model were subsequently synthesized on a 3D printer (Modified FDM 3D printer RTN 1490-14RU, Moscow, Russia) silicone and polylactide (PLA). A first (constant) part is the human torso (Figure 1(a)). A distinctive feature of this part is a PLA bone (vertebral column Th11—L5-S1, ribs VIII-XII, the crest of the ilium) which can simulate a PCNL puncture site while also X-ray and US landmarks. A second (changeable) part of the training model is an individual kidney model with intrarenal vasculature (PLA) and hollow collecting systems (Figure 1(b)). Another feature of this pelvicalyceal system is the possibility to position an alabaster stone of any size and shape into it. To allow residents to better perceive a real PCNL case, the kidney model can also be inserted and variably positioned inside the torso model. We performed all simulations with either model in an OR equipped with both fluoroscope and X-ray. The pelvicalyceal system is leak tight, allowing for X-ray guided manipulations with contrast agents.

Synthesis of the 3D-printed PCNL model

***Step I*:** A patient with a kidney stone undergoes contrast enhanced CT (Toshiba Aquilion One 640 (Japan)) following a standard four-phase protocol

***Step II*:** DICOM data is converted to STL format, which is well-suited for subsequent 3D-printing

***Step III*:** The pelvicalyceal system is printed first using polylactide filament and FDM technology

***Step IV*:** The kidney model's silicone scaffold is made in two steps. First, the printed scaffold mold is placed in a container that is half-filled with silicone. After solidification of the silicone, the scaffold mold is coated with a release agent while the remaining volume is filled with additional silicone. After polymerization of the silicone, the scaffold mold is disassembled and the printed model of vascular and collecting systems is placed inside.

The silicone used has two components: Silicone Tool Decor 15 and a heat-resistant scaffolding silicone used for platinum molds and Shore score Hardness A 15 (extra soft) used to mimic the human tissues elasticity.

***Step V*:** The assembled scaffold mold with installed vascular and collecting systems is filled with a transparent liquid silicone composite that forms the body of the kidney.

***Step VI*:** A torso model can be synthesized using the same process.

Validation of the PCNL model

Forty second-year urology residents (PGY Level 3) were recruited in this study during a training course hosted at the Institute for Urology and Reproductive Health at Sechenov University . We used five 3D printed models in our training. After each session of 5 residents, the models had to be reassembled and repaired prior to further use. The study participants were randomly (the randomization was done using randomizer with permuted block algorithm) assigned to two different two groups with similar PCNL experience (-9 PCNLs performed on average (min 4, max 14), 15 nephrostomy tubes placed urgently on average (min 9, max 21)). All

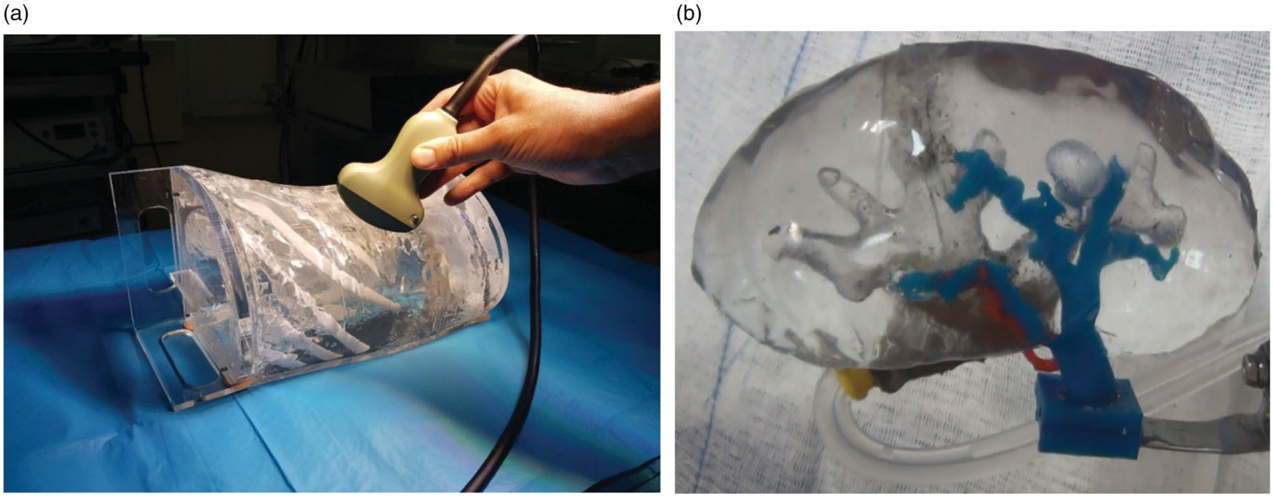

Figure 1. (a): Non-biological 3D printed human torso model. (b) Non-biological 3D kidney model, including renal vasculature and collecting systems.

Table 1. Questionnaire used to assess the performance of resident participants using either PCNL model.

Questionnaire	1–10
How do you rate the X-ray guided puncture of the pelvicalyceal system?	
How do you rate the realism of a guidewire placement?	
How do you rate the realism and visualization of a calyx for puncture?	
How can you describe the stone shape and its location?	
How do you rate the realism of nephrostomy tube placement?	
How do you rate the realism of kidney anatomy evaluation using X-ray imaging?	
How do you rate the realism of tissue model feed back?	
How do you rate the benefit of post-training errors discussion?	

resident participants were blinded to the training model they would use. Group A comprised trainees who completed the PCNL surgical steps on the URO Mentor^{TM} surgical simulator while Group B used our novel 3D-printed PCNL model. After the training tasks, both groups completed a self-administered questionnaire (Likert scale from 0 to 10) adapted from a study by Vernez and colleagues [10].

Residents who were included in the study were at least 2nd year residents with some previous experience in performing a PCNL or nephrostomy tube placement. Participants were excluded if they had some prior experience using either the URO Mentor^{TM} surgical simulator (Simbionix Ltd. Beit Golan, Israel) or our 3D-printed PCNL model.

Using either PCNL model, resident participants were asked to perform the following PCNL steps under fluoroscopy and ultrasound guidance:

1. Percutaneous renal access under X-ray guidance
2. Inserting a guidewire into the pelvicalyceal system
3. Nephrostomy tube placement
4. Group B performed additionally:
5. Tract dilation
6. Nephroscopy and Lithotripsy

Survey

The benefits of 3D-printed simulator during the real PCNL training of resident participants were tested using a questionnaire with Likert scale (1–10) previously used by Vernez and colleagues [10]. Specific questions are presented in Table 1. Training and supervision of residents were performed by experienced surgeons who have individually performed over 100 PCNL cases.

Statistical analysis

We performed data analysis using the SPSS statistical software version 22.0 (IBM, Chicago, USA). Group A was compared with Group B. In the absence of a normal distribution, non-parametric pair-group comparisons of quantitative variables were performed with a Mann-Whitney-U test. A Spearman rank correlation coefficient was used to analyze the correlation between the two models. A p-value of less than 0.05 was considered being statistically significant. We present all the data with standard errors of the mean.

Table 2. Results of the questionnaire for Groups A (URO Mentor^{TM}) and B (new 3D-printed PCNL model).

Skills tested	Group A	Group B	*p*
X-ray guided puncture of the pelvicalyceal system	7.30	8.10	0.16
Guidewire placement	6.60	9.00	$p < 0.001$
Identification of the correct calyx for a puncture	8.70	9.60	$p < 0.001$
Distinguishing of the stone shape and its location	9.90	9.85	$p < 0.001$
Nephrostomy tube placement	8.00	9.88	0.643
Kidney anatomy evaluation using X-ray imaging	8.60	9.85	$p < 0.001$
Tissue model feed back	8.40	9.96	$p < 0.001$
Post-training errors discussion	7.70	9.94	$p < 0.001$
Total	**65.20**	**76.18**	$p < 0.001$

Table 3. Performance of residents who attempted the additional tasks in Group B.

Skills tested	Group B
US-guided puncture of the pelvicalyceal system	8.9
Tract dilation	9.1
Lithotripsy Skill	9.6
Total	27.3

Results

All resident participants completed the questionnaire after the procedure with a 100% response rate. Table 2 shows the results of the survey. The total Likert score was 65.2/80 in Group A and 76.1/80 in Group B. Table 3 shows the results of the additional task assigned to Group B participants. The Mann-Whitney U-test showed a significant difference among the groups ($U = 16$, $p < 0.05$). In the first part of the training Groups A and B performed the X-ray guided puncture. The participants provided the best marks to the following indices: - X-ray guided puncture of the pelvicalyceal system (7.30 vs 8.10); Guidewire placement (6.60 vs 9.00); Identification of the correct calyx for a puncture (8.70 vs 9.60); Nephrostomy tube placement (8.00 vs 9.88); Kidney anatomy evaluation using X-ray imaging (8.60 vs 9.85); Tissue model feedback (8.40 vs 9.96); Post-training errors discussion (7.70 vs 9.94). After the main stage, group B completed an additional task with the following marks: US-guided puncture of the pelvicalyceal system (8.9), Tract dilation (9.1); Lithotripsy Skill (9.6). In group A, this skill was not evaluated because it was not available on the simulator used.

Discussion

At present, there are several types of simulators available which allow novice surgeons to practice percutaneous access for PCNL procedures [10]. Virtual simulators have recently been shown to have a beneficial role in preoperative patient counseling and planning for PCNLs [11,12]. While porcine models are similar in renal structure to that of humans, they do not fully reproduce the human anatomy of the calyceal system accurately to allow for a real understanding of a PCNL procedure [12,13].

With the rapid development of 3D-printing technology, there have been several models previously proposed for surgical training [14,15]. Using the non-biological 3D model, surgeons can better practice achieving percutaneous access and other key steps of PCNL surgical intervention and overcome

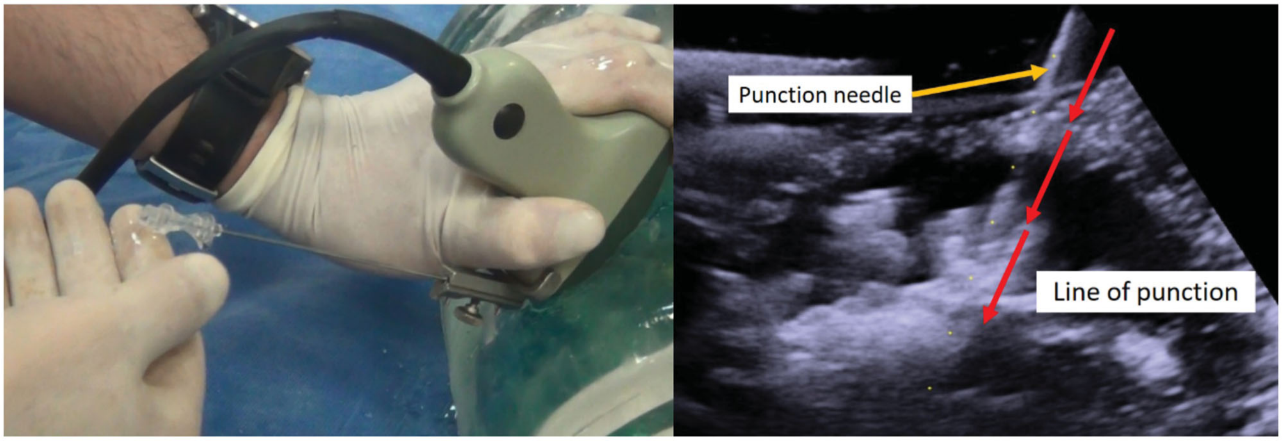

Figure 2. Ultrasound-guided renal access (A) Ultrasound-guided puncture. (B) Echogenic picture of nonbiological 3D printed kidney model and puncture needle.

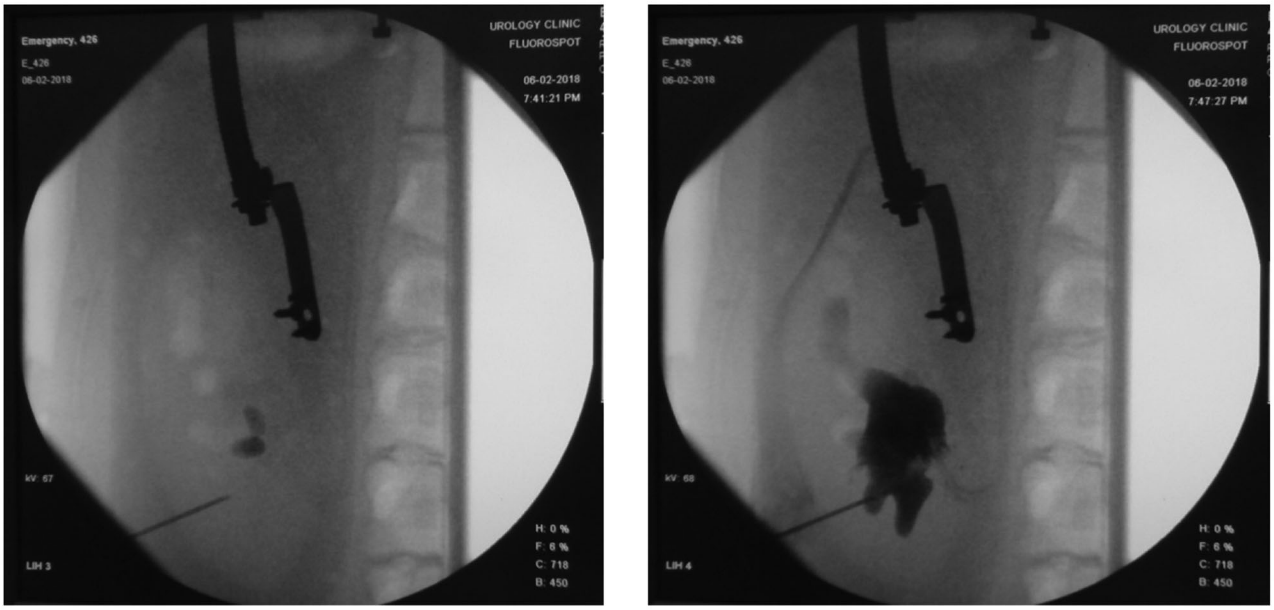

Figure 3. Renal collecting system anatomy under fluoroscopic guidance with and without contrast injected and.

a steep learning curve. The anatomy of our 3D printed models is based on individual clinical cases. Therefore, this distinct advantage allows the urologist to be prepared and expect possible intraoperative issues before the procedure. Several reported studies show that pre-operative 3D-printed models of the kidney collecting system help to achieve better PCNL outcomes [16,17].

One of the pioneer studies on anatomically accurate kidney model production using 3D-printing for PCNL simulation was provided by Bruyere and colleagues [17]. The authors used the rapid prototyping technology to produce the model of the lower calyx, which allowed them to simulate the movement of the kidney during respiration. However, unlike our model, the model in Bruyere's study was not anatomically identical to the pelvicalyceal system of the specific patient. Our 3D models can not only be beneficial for surgeons regarging improving their preoperative practices, but also for patients' understanding of their procedure and medical condition.

Turney and colleagues were the first who developed an anatomically accurate CT-based kidney model that had several important advantages: a high-fidelity representation of renal anatomy, low cost, and ability to use the model for preoperative navigation [18]. One drawback of the model, however,was the inability to perform procedure-specific training under ultrasound guidance, a key feature of real PCNL procedures that is commonly lacking from training for most novice urologists. In comparison, our model allows resident trainees to perform US-guided PCNL access (Figure 2).

One of the main advantages of the proposed model is the ability to reproduce all intraoperative stages of PCNL, including reusable percutaneous access sites (up to or exceeding five accesses) that can be visualized under either fluoroscopic and ultrasound control (Figure 3). Another advantage of our model is that the torso and kidney model are printed separately. Once the trainees are able to attempt percutaneous access on the kidney model several times, it is also possible to replace the kidney model inside the torso model. In this way, it is feasible to use our model to create an anatomically precise kidney model for each unique patient and thus better simulate intraoperative PCNL conditions. With this drastically improved model, PCNL training for residents could be significantly expedited and enhanced.

Validation of our model in this study showed that the resident participants favored the 3D-model across all aspects of their PCNL training compared to the URO Mentor^{TM} surgical simulator. Specifically, after performing practice tasks on the 3D-printed patient model, residents had a better understanding of kidney and stone anatomy, location of renal access, and overall comfort and understanding the procedure. In terms of surgical skills, residents reported that they felt they operated better when getting renal access under fluoroscopic and ultrasound visualization, dilating the tract, and performing laser lithotripsy. While the URO Mentor^{TM} is a validated tool for resident training, it does not provide real hands-on experience for specific surgical steps such as tract dilation, lithotripsy, guidewire placement, and stent placement.

There are several limitations to this study. First, the residents who took part in the study had different levels of exposure to PCNL procedures depending on the duration of their rotation on the Endourology service and the volume of PCNL procedures performed during that period. To minimize the variation in resident training, we selected only second-year trainees, who did not have previous experience with either simulator.Second, our 3D-printed model does not allow performing simultaneous ureteroscopy. We plan to modify the model to facilitate ureteroscopic access and practice endoscopic-guided PCNL, as this has been shown to improve renal access significantly and improve accuracy and outcomes [18–20]. Finally, our study did not assess the role of 3D-printed models in the clinical performance of the residents in the OR and in surgical outcomes. This study was the pilot to support the efficiency of our model. The primary outcome was to achieve at least the same efficacy as of Uromentor. On the second step we are planning to evaluate it's efficiency in training of residents with different skill level.

Conclusions

Based on the survey results, those residents who used the 3D-printed PCNL models showed better performance metrics when compared to the UroMentor regarding stenting, distinguishing stone shape and location, guidewire insertion, and X-ray guided puncture of the pelvicalyceal system. The proposed 3D printed simulator facilitates the enhanced endourological training practices which should promote the improved pre-operative planning to reduce the risk of endourological complications commonly associated with PCNLs. In this study, we show the decisive advantage of our novel 3D-printed PCNL model in its ability to reproduce all intraoperative stages of a routine PCNL, such as establishing percutaneous access, achieving proper tract dilation, inserting a guidewire under X-ray and US guidance, performing endoscopy and subsequent stone lithotripsy, and finally properly placing a nephrostomy tube.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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