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Original article

Development and Validation of a Novel Skills Training Model for PCNL, an ESUT project

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Abstract. *Background and aim:* The aim of this study is to validate a totally non biologic training model that combines the use of ultrasound and X ray to train Urologists and Residents in Urology in PerCutaneous NephroLithotripsy (PCNL). *Methods:* The training pathway was divided into three modules: Module 1, related to the acquisition of basic UltraSound (US) skill on the kidney; Module 2, consisting of correct Nephrostomy placement; and Module 3, in which a complete PCNL was performed on the model. Trainees practiced on the model first on Module 1, than in 2 and in 3. The pathway was repeated at least three times. Afterward, they rated the performance of the model and the improvement gained using a global rating score questionnaire. *Results:* A total of 150 Urologists took part in this study. Questionnaire outcomes on this training model showed a mean 4.21 (range 1-5) of positive outcome overall. Individual constructive validity showed statistical significance between the first and the last time that trainees practiced on the PCNL model among the three different modules. Statistical significance was also found between residents, fellows and experts scores. Trainees increased their skills during the training modules. *Conclusion:* This PCNL training model allows for the acquisition of technical knowledge and skills as US basic skill, Nephrostomy placement and entire PCNL procedure. Its structured use could allow a better and safer training pathway to increase the skill in performing a PCNL.

Key words: PCNL, training model, urology, validation.

Introduction

Learning how to make an entire percutaneous nephrolithotomy procedure (PCNL) from the US or X-ray guided puncture to the stone fragmentation through the dilatation process remains one of the most difficult aspects of endourological training (1). Converting the visual-spatial information provided by the fluoroscopic or US image into the psychomotor ability to make an accurate puncture is always a struggle for the trainee as it is how to make a perfect dilatation and a subsequent PCNL. Lots of surgeons have learnt their punctures on real patients. In the changed atmosphere of an actual operating theatre, the usual situation is of an extremely anxious trainee attempting a puncture under the supervision of an impatient trainer on an absolutely clueless patient. One way of circumventing this problem is to train on a simulator. In the past decade, simulator training has been accepted as an adjunct to surgical training (2). Available simulators are virtual reality models (VR), non-biological or animal models (3,4,5). VR models give a good vision and tactile feedback but are not worldwide accessible due to high costs. Cost control and tactile feedback in training models is an important concern in order to make them widely available and attached to reality. Animal models tend to be awkward and imply elaborate precautions and regulations. Keeping these considerations in mind, we have developed a simulator which can orient the trainee to depth and distance perception during the calyx puncture, the subsequent dilatation and the Amplatz sheath placement. It allows to perform a complete PCNL procedure from the nephroscope insertion, passing through the stone fragmentation with different devices (Laser, Ballistic or Ultrasonic or both) and the stone fragment retrieval. The aim of this study is to test and validate the PCNL model developed.

Materials and methods

We developed and patented a model to train Urologists in a complete PCNL procedure, from the US guided puncture of the calyx to the complete stones fragmentation and their retrieval (6) (fig. 1). The model has a reusable external part and a changeable kidney cartridge that inserted simulates different types of kidney stone conditions (fig. 2). It has been made to work either with Ultrasound or X Ray or combined calyx puncture procedure (fig. 3). Tactile feedback on

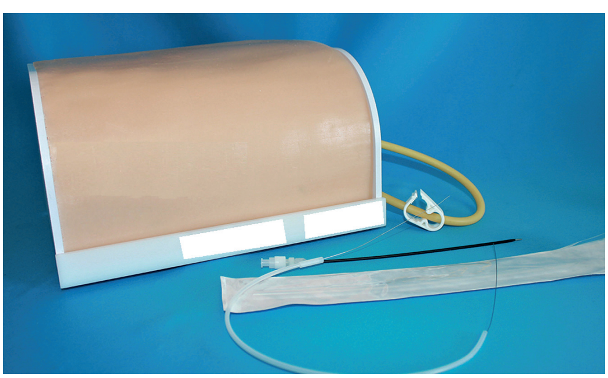

Fig. 1: The PCNL Boz Model

Fig. 2: Insertion of the reusable renal cartridge

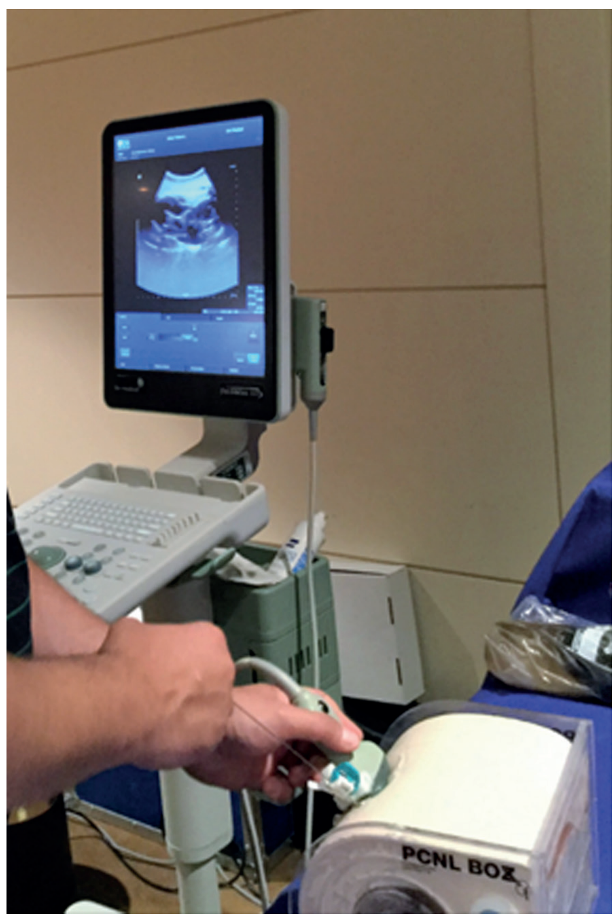

Fig. 3: Ultrasound guided puncture of the renal calyx

the outside skin allow to feel the landmarks such as the iliac crest of the hip, thoracic 11th and 12th ribs, and the thoracic and lumbar spinal cord (fig. 4). On the same hand, the Ultrasound visive feedback on the screen reveal a human-like appearance with the subcutaneous fat the muscular layer and the perirenal fat. Kidneys can be filled from outside with saline providing a hydronephrotic condition as well as fluid drip once a guide needle is placed (fig.5).

The entire PCNL procedure was divided into three modules to pursue the teaching aim of a step by step acquisition of increasing skills and to better adapt the model to the different aims and features of the trainees. To access the subsequent module it was compulsory to fulfill the previous one. Once a trainee was about to start the second and the third sequence of module the kidney cartridge was changed to face a different renal and stone situation.

The trainees were stratified according to their level of expertise: resident, fellow, and expert. Fellows were classified as expert when they performed more than 50 procedures as first operator. To appreciate the construct validity of our simulator, it was evaluated by anyone of this three categories.

Modules: Module **1** is related to the acquisition of basic Ultrasound (US) skill on the kidney. It is divided into four different tasks. 1) to see the kidney and to orientate the convex probe to obtain a US imagine on the longer ax of the kidney too. 2) to see the different calyx from the upper ones to the lower ones 3) to see and locate the stone inside the kidney. 4) to choose the right calyx to be punctured in order to access easily and safely the upper urinary tract for a correct PCNL procedure.

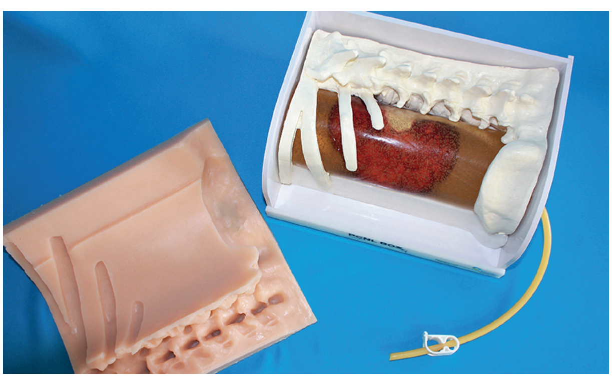

Fig. 4: Inner view of the bone landmarks

Module **2** consists of the correct puncture of the designated calyx. It is divided into four different tasks. 1) to find out the correct orientation of the needle. 2) to locate the correct place for the needle insertion. 3) to see on the US screen the needle while it is proceeding without losing its image. 4) to reach the chosen calyx and to place properly the guide wire.

Module **3**, in which a complete PCNL procedure is performed. It is divided into four tasks. 1) to dilatate the access to the calyx to allow the Amplatz sheath placement. 2) to insert the nephroscope and to locate the stones. 3) to fragment the stones. 4) to retrieve the stones fragment and place the nephrostomy once the renal pelvis has been completely cleared.

The PCNL model was used during the “Hands on Sessions” on PCNL during 6 different International Meetings in the Field of Urology and Urolthiasis since

Fig. 5: Obtaining an hydronephrotic kidney

2013. They took place in Milan (EULIS Masterclass, 2014), Athens (ESUT Meeting, 2016), Patras (ESUT Masterclass, 2017), Boston and San Diego (AUA annual Meeting 2016 and 2017) and Florence (IEA Masterclass, 2013).

Each module has its own PCNL model and its Tutor to teach the trainee how to reach the aim in the four different tasks and then rate him. Each task for any module was counted to be fulfilled by the trainees and the module was considered passed if the tasks were reached in a maximum overall time of 10 minutes (600 seconds). During the "hands on sessions" employed to validate the model a MyLab 25 Ultrasound device (EASAOTE, Firenze, Italy) and a BK 3000 (BK Peabody, MA USA) were used with a 3.5 Mhz Convex probe. A 18 Gauge needle was employed to puncture the renal calyx. Cook disposable materials (balloon dilatator, Amplatz sheath, guide wire, N Trap and N Gage stone extractors) were employed for the PCNL procedure. A Storz Nephroscope 21 Ch. with a Storz Tele Pack X and a EMS LithoClast Master were employed to locate and fragment the stones inside the model.

At the end of the three modules repeated three times, the trainees were asked to complete a questionnaire to rate the model from 6 different point of view: 1) reality of outfit anatomy, 2) US reality and tactile feedback of the puncture, 3) Dilatation process, 4) PCNL procedure, 5) Skill increase 6) Overall impression. Each point can be rated with 1 (lowest) to 5 (highest) points.

Data were analyzed using SPSS for Windows version 17.0 and compared using a Student's t-test and a p value <0.05 was considered for statistical significance.

Results

A total of 150 Urologists took part in this study. The simulator was evaluated by anyone of the participants: Experts (n=44), Fellows (***n***=34), and Residents (***n***=72). Results are summarized in Tables 1 and 2.

Table n. 1 summarizes the time-counted outcomes on the different three modules tasks stratified by the Level of Experience of the Participants that took part the different "Hands on Session" of the meetings in which the model was employed.

In any module and in any group the last time of practicing was faster than the first time.

All the participants were able to finish the three modules in the due time thus fulfilling all the tasks inside the different modules. Experts mean time was in all the modules lower than the other two groups. On the same hand Residents were slower than the others. In the first module, mainly focused on US skill, there were no significant differences in timing. The second

Table 1. Comparison of the Different Outcomes of the Simulator Modules According to the Level of Experience

	Tasks (mean value sec.)				Overall (mean value sec. ± SD)	Corrected p Values		
	1	**2**	**3**	**4**		**Resident vs Fellow**	**Resident vs Expert**	**Fellow vs Expert**
Module 1								
Residents	66	87	45	59	257 ± 72	0.13	0.06	0.11
Fellows	51	80	33	38	202 ± 44			
Experts	49	71	21	42	183 ± 23			
Module 2								
Residents	71	48	62	81	262 ± 89	0.02	0.03	0.04
Fellows	48	33	25	62	168 ± 51			
Experts	41	25	18	43	127 ± 45			
Module 3								
Residents	128	100	165	157	550 ± 43	0.46	0.04	0.04
Fellows	123	85	161	160	529 ± 41			
Experts	95	61	134	144	434 ± 85			

Table 2. Evaluation Score of the Simulator on a 5-Point Likert-type Scale according to the Level of Experience; Expert Surgeons (n = 44), Fellows (n = 34), and Residents (n = 72)

Criteria	Resident Mean (±SD)	Fellow Mean (±SD)	Expert Mean (±SD)	Global Mean (±SD)
Overall impression	4.24 ± 0.58	4.20 ± 0.47	4.11 ± 0.93	4.21 ± 0.70
Reality of outfit anatomy	3.59 ± 0.79	3.81 ± 0.73	3.85 ± 0.86	3.73 ± 0.89
US reality and tactile feedback of the puncture	3.66 ± 0.75	3.68 ± 0.71	3.85 ± 0.86	3.72 ± 0.79
Dilatation process	3.88 ± 0.77	3.50 ± 0.68	3.37 ± 1.19	3.54 ± 0.98
PCNL procedure	4.16 ± 0.88	3.90 ± 0.68	4.20 ± 0.79	4.10 ± 0.80
Skill increase	4.35 ± 0.69	3.31 ± 0.58	2.22 ± 1.04	3.32 ± 0.81

SD, standard deviation.

module, focused on renal calyx puncture, underlined differences with statistical evidence. The third module, from dilatation to stone fragment extraction, underlined the supremacy of the Experts group.

Table n. 2 reports evaluation scores for the Simulator on a 5-Point Likert-type Scale according to the Level of Experience.

All the participants had a good overall impression of the simulator as a teaching tool with a mean score of 4.21 (range 1-5) with the highest score for the Residents (4.24). Residents had a significantly higher score for the item "Skill increase" and "Dilatation process" than Fellows or Experts. The lowest-scored item was for "US reality and tactile feedback of the puncture" with a mean of 3.66, inversely correlated with the level of expertise. Experts gave significantly better scores for the items "Reality of outfit anatomy", "US reality and tactile feedback of the puncture" and "PCNL procedure" than Residents or Fellows. There was a significant difference among the 3 categories of surgeons for the item "Skill increase" with a score ranging from 2.22 to 4.35. The best overall score was for the "Skill increase" item with a mean of 4.35 rated by Residents, indicating that they would use the simulator in their own skills training and teaching programs. This rate came down in the other two groups.

Conclusion

A simulator is a device that can replace a real world system, in order to gain experience and to interact with the simulation with realistic auditory, visual or tactile clues (1-7). Simulation in the field of surgery has emerged in the last decade because of the necessity to change the traditional modality of learning and teaching surgery, and its efficiency which has been proved in medical education (8,9,10). The operating room as a primary teaching environment may not be desirable nowadays, and it also carries legal and ethical concerns, amplified by increasing pressures with respect to operating room efficiency. For Bridges et al., the teaching of surgical skills to residents in the operating room could double the operation time (10-11). This change has also been implemented due to the increased focus on safety of the patients, the need to incorporate technology into surgical training to parallel advancements in other industries, the increase in the number of surgical trainees, and the reduction in the duty hours for surgical trainees, implying drastic reduction in the amount of surgical cases that trainees perform. An ideal surgical simulator must allow a practice in a safe environment for the patient, and therefore support the transfer of learned techniques to the body of the patient. Surgical simulation is an important adjunct to surgical training as it fills the void between surgeons being trained in a technique and a surgeon achieving competency in that surgical procedure (12,13,14). These studies show a significant benefit of surgical simulation in developing the surgical skills of surgical trainees (15). However, they also have their limitations, owing to low number of participants varying from 10 to 50, variable evaluation standards, and a focus on short-term results, often with no follow-up evaluation. Our study was on six different international events, with 3 categories of participants (***n***=150), which were distributed evenly according to their level of expertise.

Since now there were two essential components of a PCNL procedure that a simulator was able to reproduce. The first is a tissue-like medium for the needle to go through and the second is a target representing the calyx (3). There were no model able to allow an entire PCNL procedure X-ray or US guided and this is one of the aspect that collocate. On the same hand VR models are able to train for a correct puncture but cannot allow to pursue a complete PCNL procedure (7).

There is no publication dealing with training and simulation about an entire PCNL, and only 9 articles for PCNL training model mainly ex vivo, biological and PC-VR based (1, 7, 16-21). This emphasizes the need to develop a training simulator for PCNL. The price of traditional surgical training is important, suggesting the necessity of news modern skill acquisition techniques. Traditionally, teaching was based on the used of animal and cadaveric models. However, these simulators are pricey and require the use of specialized apparatus. Our model is of lower cost than other options for PCNL. For example, the "LimbandThings" simulator costs US $ 1,195.04 and despite its reusability it is not able to represent anything that can be seen as attached to reality. The VR PercMentor is actually very good for X-ray guided renal puncture but does not allow to perform an entire PCNL and costs more than US $ 10,000. On the other hand acquiring an animal simulator for a skills laboratory costs approximately US $ 800 to $ 1200 with additional costs for veterinarian technician support staff and euthanasia, and the simulator is for one-time use only. Our model cost is currently US $ 1350 and it is a reusable one.

The other promising feature of this model is related to the possibility to have a different renal situation to face at any time without purchasing a new model. This is possible because of the renal cartridge that can be customized, as the trainees (or trainers) wish. This is to avoid that using always the same reusable model a Resident can be very well trained to do a correct procedure on the model (which is always the same) and not on the patients (that usually change from one to another).

The timing outcome (Tab. 1) in which the Expert group revealed a faster result underlines how this model is able to represent a real human-like situation in which the expertise previously gained play an important role. To be more precise the first module, related to the acquisition of basic US skill on the kidney, revealed no differences among the groups as this did not happen in the subsequent two modules. This can be easily explained with the US skill that is more easily to be obtained as the invasive procedures of an entire PCNL (from the puncture to the stone fragment retrieval) are not. To confirm the good outcome as a training model the time decreased in all the groups from the very first attempt to the third and last one. In our study, the participants had good overall impression of our simulator, with a mean score of 4.21 (Tab. 2). "Skill increase" item had a high rate from the Residents as they were facing each time the "real theatre clue" and the model was able to help in the solving problem process with the help of the Tutors too. On the other hand the lowest rate was from the Experts group as they were not able to find out new important skill to learn from this experience.

Concerning the results about the overall impression, realistic features, and Skill increase, and the fact that expert surgeons had a better impression on the PCNL procedure than Residents and Fellows, our model seems to present a correct construct validity as defined by the American College Of Surgeons Division: "construct validity describes the agreement between a theoretical concept and a specific assessment tool or procedure". The results of our analysis allowed for discrimination between fellows and experts and between residents and experts, but not always between fellows and residents. There was a significant difference between the timing and the evaluation of participants.

Many participants in our study underlined the reality of our simulator for the procedure, and it was correlated with level of expertise (Table 2). In any case, it is to be expected that this simulator, which could also be used to perform Retrograde IntraRenal Surgery, can be adapted for an entire Endoscopic Combined IntraRenal Surgery, will benefit from modifications for further refining the model and improving on its usability.

Surgeons and trainees, with the use of different types of simulated kidney stone conditions (large staghorn, upper and lower caliceal stones), can practice the removal of kidney stones also in an hydronephrotic kidney. We can summarize the positive features of this model with the chance to perform an entire PCNL procedure as a simulated operation using either ultrasound or fluoroscopy. The respect of the body landmarks with features life-like skin and subcutaneous tissue layers as well as built-in anatomical markers such as the iliac crest of the hip, thoracic 11th and 12th ribs, and a thoracic spine. It also provides many different orientations of the kidney and multi-surgical stone conditions via interchangeable kidney cartridges. Kidneys can be filled with water providing a hydronephrotic condition as well as fluid drip once a guide needle is placed. Trainees can improve their skills in the access to the kidney from multiple entry points, through the ureter or from the back. The trainer furnishes a clean operating environment and it is reusable for a lot of training sessions, allowing the elimination of cadavers or animals for training.

This model does have limitations. It does not replicate normal respiratory movements. We believe this feature to be unnecessary in a simulator. However, we have to underline that the absence of respiratory movements is a significant limitation of this model and the trainee will need to reorient to respiratory excursions once actual PCNL punctures are performed “in vivo”. The other limitation is that due to the fact that was employed and tested in meeting and the X-ray guided puncture was not this way tested. We do test it in the theatre ensuring its x-ray transparency using contrast from the ureter.

Our study demonstrates face validity of this training simulator for PCNL. The aim of our research was not to evaluate the residents and fellows; nevertheless, an additional study will evaluate the trainees on the simulator and if these skills, practiced on simulators, are transferable to the operating theater and whether the skills acquired through simulation are durable.

In conclusion, this PCNL training model allows for the acquisition of technical knowledge and skills as US basic skill, Nephrostomy placement and entire PCNL procedure. Its structured use could allow a better and safer training pathway to increase the skill in performing a PCNL. It shows promise as an educational tool. Surely there is a need to set up a proper validated curriculum to train (and to train the trainers) in PCNL procedure.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

References

1. Ghani KR, Andonian S, Bultitude M. Percutaneous nephrolithotomy: update, trends, and future durections. Eur Urol 2016;70: 382-96. Abdallah MM, Salem SM, Badreldin MR, Gamaleldin AA. The use of a biological model for comparing two techniques of fluoroscopy-guided percutaneous puncture: A randomised cross-over study. Arab J Urol 2013;11(1):79-84.
2. Aydin A, Shafi AM, Khan MS, Dasgupta P, Ahmed K. Current Status of Simulation and Training Models in Urological Surgery: A Systematic Review. J Urol 2016;196(2):312-20.
3. Häcker A, Wendt-Nordahl G, Honeck P, Michel MS, Alken P, Knoll T. A biological model to teach percutaneous nephrolithotomy technique with ultrasound- and fluoroscopy-guided access. J Endourol 2007;21:545–50.
4. Jutzi S, Imkamp F, Kuczyk MA, Walcher U, Nagele U, Herrmann TR. New *ex vivo* organ model for percutaneous renal surgery using a laparoendoscopic training box: The sandwich model. World J Urol 2014;32:783–9.
5. Redaelli A, Fiore B, Cipollini C, et al. Devices for surgical training. United States Patent Application 2015; 0037776.
6. Mishra S, Jagtap J, Sabnis RB, Desai MR. Training in percutaneous nephrolithotomy. Curr Opin Urol 2013;23(2):147-51.
7. Reznick RK, H. MacRaeTeaching surgical skills—changes in the wind N Engl J Med, 355 (25), pp. 2664-2669.
8. Seymour NE, A.G. Gallagher, S.A. Roman. Virtual reality training improves operating room performance: results of a randomized, double-blinded study. Ann Surg 2002; 236 (4), pp. 458-463.
9. Mayberry JC. Residency reform Halsted-style. J Am Coll Surg 2003; 197 (3) pp. 433-435.
10. Bridges M, D.L. Diamond. The financial impact of teaching surgical residents in the operating room. Am J Surg 1999; 177 (1), pp. 28-32.
11. Cooke DT, R. Jamshidi, J. Guitron, J. Karamichalis. The virtual surgeon: using medical simulation to train the modern surgical resident. Bull Am Coll Surg 2008; 93 (7), pp. 26-31.
12. Van Hove PD, G.J. Tuijthof, E.G. Verdaasdonk, L.P. Stassen, J. Dankelman. Objective assessment of technical surgical skills. Br J Surg 2010; 97 (7), pp. 972-987.

13. Lentz GM, L.S. Mandel, B.A. Goff. A six-year study of surgical teaching and skills evaluation for obstetric/gynecologic residents in porcine and inanimate surgical simulators. Am J Obstet Gynecol 2005; 193 (6), pp. 2056-2061.
14. DiMaggio PJ, A.L. Waer, T.J. Desmarais. The use of a lightly preserved cadaver and full thickness pig skin to teach technical skills on the surgery clerkship—a response to the economic pressures facing academic medicine today. Am J Surg 2010; 200 (1), pp. 162-166.
15. Sarmah P, Voss J, Ho A, Veneziano D, Somani B. Low vs. high fidelity: the importance of 'realism' in the simulation of a stone treatment procedure. Curr Opin Urol 2017;27(4):316-322.
16. Bruyère F, Leroux C, Brunereau L, Lermusiaux P. Rapid prototyping model for percutaneous nephrolithotomy training. J Endourol 2008;22(1):91-6.
17. Strohmaier WL, Giese A. Improved ex vivo training model for percutaneous renal surgery. Urol Res 2009;37(2):107-10.
18. Turney BW. A new model with an anatomically accurate human renal collecting system for training in fluoroscopy-guided percutaneous nephrolithotomy access. J Endourol 2014;28(3):360-3.
19. Sinha M, Krishnamoorthy V. Use of a vegetable model as a training tool for PCNL puncture. Indian J Urol 2015;31(2):156-9.
20. Atalay HA, Canat HL, Ülker V, Alkan İ, Özkuvanci Ü, Altunrende F. Impact of personalized three-dimensional -3D- printed pelvicalyceal system models on patient information in percutaneous nephrolithotripsy surgery: a pilot study. Int Braz J Urol 2017;43(3):470-475.
21. Maldonado-Alcaraz E, Gonzalez-Meza Garcia F, Serrano-Brambila EA. Evaluation of 2 inanimate models to improve percutaneous fluoroscopy-guided renal access time. Cir Cir 2010: 83:402-8

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