ORIGINAL RESEARCH

Design and Validation of a Non-biological 3D Printed Pelvocalyceal System (RIRS Box) for Simulation-based Training of Flexible Ureteroscopy: A Stage 2A Surgical Innovation Study

Rajiv H. Kalbit, MD; Enrique Ian S. Lorenzo, MD, FPUA; Juan Godofredo R. Bardelosa, MD, FPUA and Edgardo L. Reyes, MD, FPUA

Department of Urology, Jose R. Reyes Memorial Medical Center

In the field of Urology, flexible ureterorenoscopy (fURS) remains a challenging skill for junior residents to develop due to its steep learning curve. Hence, training models were incorporated into simulation-based training to allow for novice trainees to overcome the learning curve without potentially compromising patient outcomes and minimize complications.

Objective: To describe the design and test the validity of a non-biological three-dimensional (3D) model of the pelvocalyceal system as a tool for simulation-based training for flexible ureterorenoscopy

Methods: This was a prospective, quasi-experimental, surgical innovation research stage 2a study conducted in a tertiary government hospital. The retrograde intrarenal surgery (RIRS) box was composed of four siliconized pelvocalyceal systems which were 3D printed using computed tomography urograms of actual patients. Thirty-two urologists were asked to perform flexible ureteroscopy using the RIRS box and were given a questionnaire to assess face and content validity using the Likert scale.

Results: The RIRS Box training model showed good face and content validity. The 3D printed pelvocalyceal system was judged to have a close anatomical resemblance to an actual calyceal system. While performing fURS, the RIRS box provided similar pelvocalyceal visualization and instrument handling as in an actual procedure. Majority of participants considered the training model useful for training (75%) and believed that it may improve the RIRS technique (46.8%).

Conclusion: The RIRS Box training model may help urologists improve the manner in which they acquire technical knowledge and skills necessary in performing fURS.

Keywords: RIRS box, non-biological model, flexible ureteroscopy, 3D printed pelvocalyceal system

Introduction

Surgical education is rapidly changing. New procedures and technologies are emerging. As such, novel educational and training paradigms have become necessary to navigate the current trends and to meet the challenges of the 21st century. Since the traditional Halstedian model of apprenticeship has shortcomings in meeting the educational needs of the modern surgical trainee, simulation-based training (SBT) has emerged as a mainstay in the modern training curriculum.[1,2]

Over the last two decades, there has been an increase in the incidence of urinary stone disease, creating the need for more efficient surgical management. Flexible ureterorenoscopy (fURS) has gained widespread popularity for the treatment of stone disease. The advances in science and technology have improved the safety and utility of flexible ureteroscopy (fURS) but still carries a certain level of complexity.[3]

fURS remains a challenging skill to develop for junior residents due its steep learning curve. Training models were incorporated into SBT's to allow for novice trainees to overcome the learning curve associated with the procedure without compromising patient outcomes and at the same time, minimize complications.[3,4]

Several training models have been used to reduce the steep learning curve of fURS. These include virtual reality simulators (example: URO Mentor, Simbionix, Lod, Israel), low- fidelity non-biological models (example: K-box, Proges-Coloplast, Rosny-sous-Bois), high-fidelity non-biological models (example: Scope Trainer, Mediskills, Northampton, UK) animal models (example: porcine), and finally, human cadaver models.[5,6] Each model has it is advantages and disadvantages. Despite the availability of these models, there remains a need to develop an SBT model to suite the urologist's unique needs.

Present here is a design for a low-cost, non-biological model for fURS training, the retrograde intrarenal (RIRS) box, that may help novice endoscopists overcome their learning curve. The current study aims to determine the face and content validity of the RIRS box when used for SBT for fURS.

Methods

Research Design

This was a prospective, quasi-experimental, surgical innovation research, stage 2a conducted in a tertiary government hospital. A RIRS box was constructed composing of four siliconized pelvocalyceal systems. These systems were 3D-printed using the computed tomography urograms of actual patients. Urology consultants and residents were asked to perform flexible ureteroscopy using the RIRS box. They were then given a questionnaire to assess the face and content validity using the Likert scale. The questionnaire was based on a 5-point Likert scale, wherein 1 denoted strong disagreement with the statement and 5 denoted strong agreement. Thirty-two urologists were included in this study. The sample size was computed using a 5% level of significance and 90% power. The mean score of anatomical resemblance used was 5.56 (out of 7) based on the article of Inoue, et al.[6] The hypothesized mean was 5. It was assumed that the mean score on anatomical resemblance is higher than the hypothesized mean.

Development of 3D Pelvocalyceal System Model

The RIRS box measured 80cm x 40cm x 15cm (Length x Width x Height). It weighed 2 kg. Each box was composed of four anatomically different siliconized pelvocalyceal systems. The models were made using a 3D printer. The molds were based on CT urogram 3D reconstructions of the pelvocalyceal systems of actual patients.

Image Segmentation and Extraction of Pelvocalyceal System from CT Scan

CT urogram images were imported and opened in a PACS-DICOM viewer (RadiAnt DICOM viewer) (Figure 1A). These files were then exported and opened in an open-source software platform for medical image informatics, image processing and three-dimensional visualization, 3D slicer (http://www.slicer.org). They were then exported as Standard Triangulation Language (STL) files (Figure 1B). Finally, the STL files were imported to Meshmixer (Autodesk) to remove non-connecting contrast material and were then stitched to produce a single pelvocalyceal system structure.

3D Printing and Designing of the Mold

STL files were exported to an open-source 3D printing software (Ultimaker Cura) and were printed using a 3D printer (Anycubic Mega) which printed the models using Poly Lactic Acid (PLA) filament. A variety of collecting systems were printed (Figure 1C).

Each 3D printed pelvocalyceal system was placed in a molding box and were then used as molds for the silicone-based model systems. A two-part silicone rubber room temperature vulcanizing (RTV) mixture (composed of base silicone and CA30 curing agent) was poured into each mold. The molds were cured for 3 hours at room temperature.

RIRS Box

After taking out each 3D model from the mold, the mold was sealed and then connected to a rubber tubing which would function as the ureter (Figure 1D). Each complete pelvocalyceal system model was then placed in a plastic box, while ensuring that they are in an anatomically-correct position, and the box was sealed.

Flexible Ureteroscopy on the 3D Printed Pelvocalyceal System (RIRS box)

Twenty-eight urologists performed flexible ureteroscopy on a 3D printed model using AnQing EU-Scope flexible ureteroscope (Shanghai AnQing Medical Instrument Co. Ltd) for three to five minutes (Figure 2). Each one performed systematic intrarenal inspection of a calyceal system (Figures 2A & 2B).

Face and Content Validity

After performing fURS using the RIRS box, the participants were asked to answer a structured questionnaire. The measurement used a Likert scale (1= strongly disagree, 5 = strongly agree). The three questions measuring face validity asked about the anatomical resemblance of the model to a biological calyceal system, the quality of pyelocalyceal visualization, and the ease of instrument handling while doing the exercise. Three questions assessing content validity of the RIRS box asked about the participant's view on its usefulness for training,

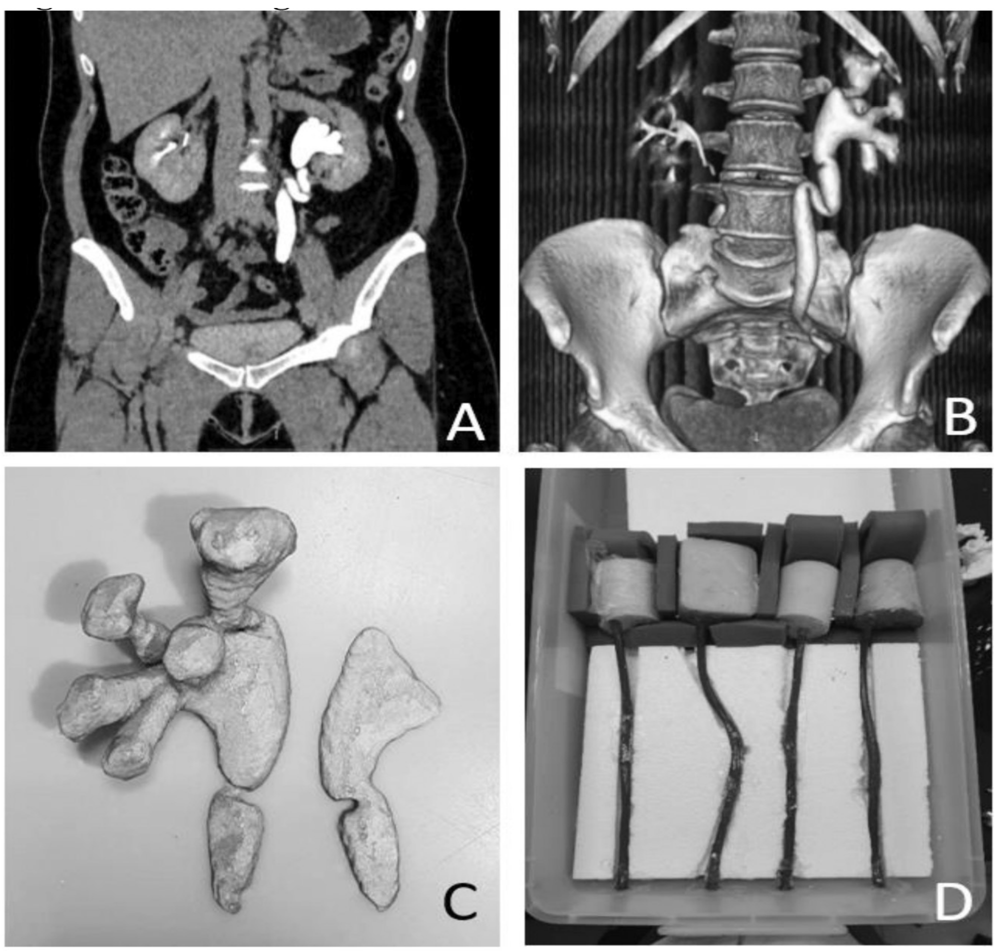

Figure 1. CT urogram and RIRS box.
A) CT urogram, B) 3D reconstruction for printing, C) Posterior view of 3D printed model, D) RIRS box

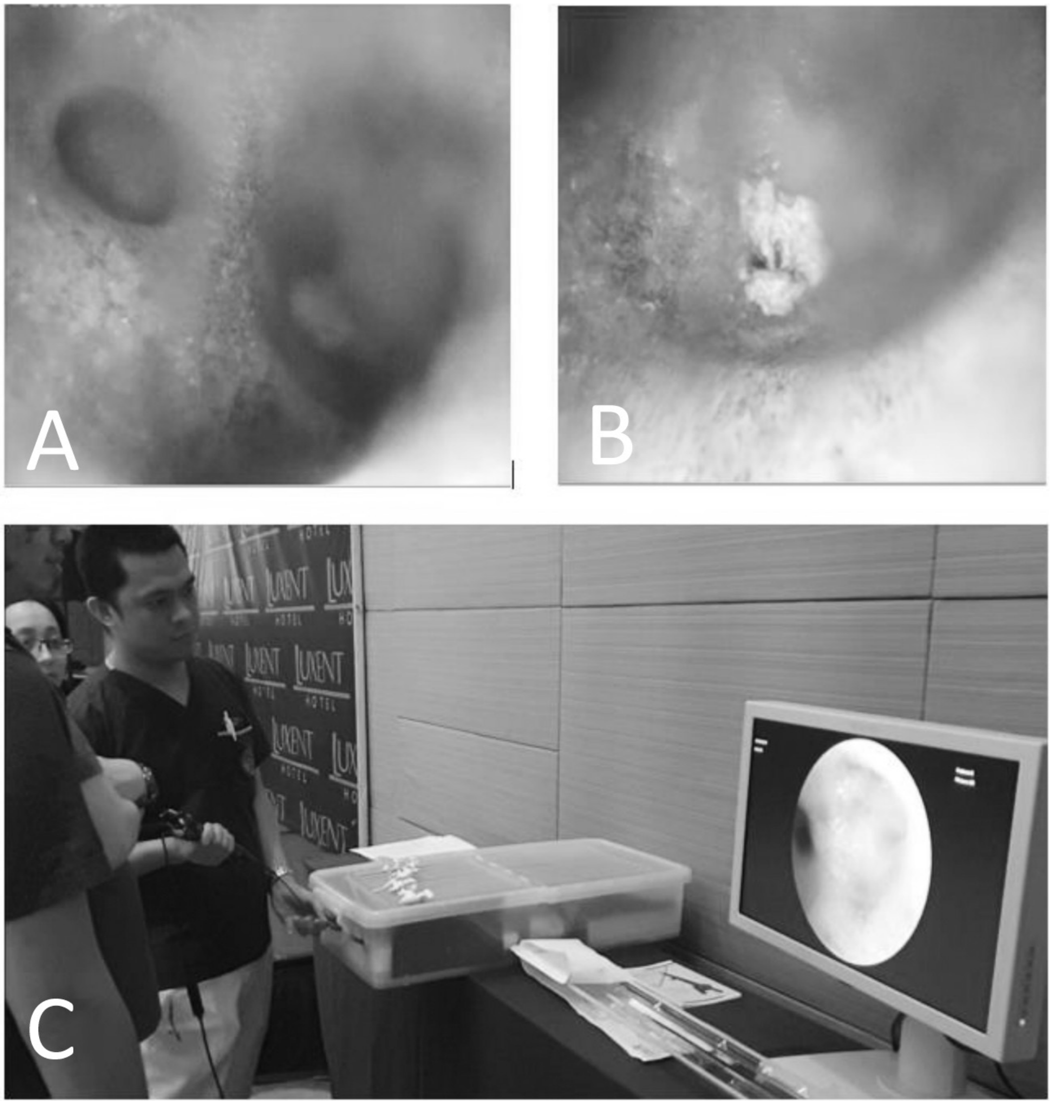

Figure 2. Ureteroscopic and external view of model.
A) Pelvocalyces visualization, B) Stone inside calyx, C) Resident doing ureteroscopy

degree of interest in using the simulator, and degree of improvement of fURS technique after the exercise.

Analysis

Descriptive statistics was used to summarize the general and clinical characteristics of the participants. Frequency and proportion were used for nominal variables, median and range for ordinal variables, and mean and standard deviation for interval variables. Missing variables were neither replaced nor estimated. STATA version 15.0 was used for data analysis.

Results

Among the participating urologists, 12 (37.5%) were consultants and 20 (62.5%) were residents (Table 1). Majority were male (84.38%), and right-handed (93.75%). Most of those surveyed (53.13%) have had limited prior exposure to advanced training in endourology. A large number of the participants ($\geq$ 40%) saw the RIRS box to be promising in terms of usefulness for training, were interest in utilizing it, and noted an improvement in technique in performing the RIRS after training sessions using this simulator tool. (Tables 2 & 3)

Table 1. Summary of participant demographics (n = 32).

	Frequency (%)
Level of training	
Consultant	12 (37.5)
Resident	20 (62.5)
Sex	
Male	27 (84.38)
Female	5 (15.63)
Handedness	
Right	30 (93.75)
Left	2 (6.25)
Prior flexible ureteroscopy (RIRS)	
None	17 (53.13)
<5 cases	6 (18.75)
5-10 cases	4 (12.5)
>10 cases	5 (15.63)

Table 2. Face validity evaluation of RIRS box.

	Overall scores	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
	Median (Range);			Frequency (%)		
Resemblance to actual pelvocalyceal system						
1) All participants	5 (4 - 5)	0	0	0	8 (25)	24 (75)
2) Group 1*	5 (4 - 5)	0	0	0	6 (40)	9 (60)
3) Group 2**	5 (4 - 5)	0	0	0	2 (12)	15 (88)
Quality of pelvocalyceal visualization						
1) All participants	5 (3 – 5)	0	0	3 (9.38)	8 (25)	21 (65.63)
2) Group 1*	4 (3 – 5)	0	0	2 (13.33)	7 (46.67)	6 (40)
3) Group 2**	5 (3 – 5)	0	0	1 (6)	1 (6)	15 (88)
Ease of instrument handling						
1) All participants	4 (3 – 5)	0	0	2 (6.25)	15 (46.88)	15 (46.88)
2) Group 1*	4 (3 – 5)	0	0	1 (6.67)	10 (66.67)	4 (26.67)
3) Group 2**	5 (3 – 5)	0	0	1 (6)	5 (29)	11 (65)

* Group 1 = Participants with extensive experience with RIRS
** Group 2 = Participants with limited clinical experience with RIRS

Discussion

Over the last two decades, minimally invasive urological procedures have steadily replaced open procedures. Unfortunately, due to their steep learning curves, minimally-invasive procedures require specialized training. The Halstedian concept of "See one, do one, teach one", adopted for the past decades has slowly given way to the concept of simulation-based training.[7,8]

The RIRS Box was developed as a high-fidelity bench model, made of an anatomically-accurate pelvocalyceal system. This training model should allow inexperienced urologists to become confident with their surgical instruments handling and technical skills before they perform ureterorenoscopy on actual patients.

Face validity measures, the extent to which an examination resembles the situation in the real world.[5] The current study showed that the use of the RIRS box was very similar to an actual fURS in terms of anatomical resemblance, quality of pelvocalyceal visualization, and ease of instrument handling. Participants who had prior experience with RIRS strongly agreed (80%) with the face validity of the RIRS box.

Content validity refers to the extent by which the intended content is being measured by an assessment exercise.[5] Participants of this study considered the training model to be useful for training (75%) and believed that it may improve the RIRS technique (46.8%). Participants who have had prior RIRS experience had the same comments. A similar study of Soria, et al. presented their own RIRS training model which was also a high-fidelity, non-biological model.[9] Blankstein, et al. evaluated the Cook ureteroscopy part-task model (Cook Medical, Bloomington, IN) and enlisted 15 residents and 5 endourology experts. Their study showed that the model was useful as a training device and demonstrated good face, content and construct validity.[10] A more recent study by Inoue, et al. about the Smart Simulator for flexible ureteroscopy training revealed a satisfactory face and content validity.[6] Notable in this study was the incorporation of movement of the kidney model which simulated the actual movement of an actual kidney as influenced by breathing. This allowed the accurate simulation of an actual RIRS. Such a feature is absent in our RIRS box.

In the Philippines, simulation-based training is still in its infancy. There is no structured simulation-based curriculum because of the high cost of developing, manufacturing or procuring the training model. This RIRS Box training model showed good face and content validity. It is the authors' belief that this training model will be of a great aid in starting a simulation-based training. This will ultimately help improve urologists acquire technical knowledge and skills in preparation for the time when they will handle actual patients.

This study has a number of limitations. Firstly, participants were mostly residents who had limited experience with RIRS. Measurement of face

Table 3. Content validity of RIRS box.

	Overall scores Median (Range);	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
		Frequency (%)				
Usefulness for training						
1) All participants	5 (4 - 5)	0	0	0	6 (18.75)	26 (81.25)
2) Group 1*	5 (4 - 5)	0	0	0	3 (20)	12 (80)
3) Group 2**	5 (4 - 5)	0	0	0	3 (17.6)	14 (82.4)
Interest to use the simulator						
1) All participants	5 (4 – 5)	0	0	0	3 (9.38)	29 (90.63)
2) Group 1*	5 (4 – 5)	0	0	0	1 (6.67)	14 (93.33)
3) Group 2**	5 (4 – 5)	0	0	0	2 (12)	15 (88)
Noted improvement of RIRS technique						
1) All participants	5 (4 – 5)	0	0	0	6 (18.75)	26 (81.24)
2) Group 1*	5 (4 – 5)	0	0	0	1 (6.67)	14 (93.33)
3) Group 2**	5 (4 – 5)	0	0	0	5 (30)	12 (70)

* Group 1 = Participants with extensive experience with RIRS
** Group 2 = Participants with limited clinical experience with RIRS

and content validity is more ideal if experienced endourologists were the ones assessing this training model. Secondly, the authors were unable to conduct a construct validity test. This could have been done using an objective structured assessment of technical skills (OSATS), which consists of a global rating scale as defined by Matsumoto et al.[11]

Conclusion

The RIRS Box training model may help improve the manner in which urologists acquire technical knowledge and skill necessary in performing fURS. Further studies that look into construct, concurrent, and predictive validity of non-biological training models for fURS are highly recommended.

References

1. Wilhelm DM, Ogan K, Roehrborn CG, Cadeddu JA, Pearle MS. Assessment of basic endoscopic performance using a virtual reality simulator. J Am Coll Surg 2002; 195: 675-81.
2. Botoca M, Bucuras V, Boiborean P. The learning curve in ureteroscopy for the treatment of ureteric stones. How many procedures are needed to achieve satisfactory skills? Eur Urol Supp 2003; 2: 138.
3. Blankstein U, Lantz AG, Honey JD, et al. Simulation-based flexible ureteroscopy training using a novel ureteroscopy part-task trainer. Can J Urol 2015; 9: 331-5.
4. Zendejas B, Cook DA, Bingener J, et al. Simulation-based mastery learning improves patient outcomes in laparoscopic inguinal hernia repair. Ann Surg 2011; 87: 502-11.
5. Brunckhorst O, Aydin A, Abboudi H, et al. Simulation-based ureteroscopy training: a systematic review. J Sur Education 2014; 72: 135-42.
6. Inoue T, et al. New advanced bench model for flexible ureteroscopic training: the Smart Simulator. J Endourol 2017; 32(1): 1-20. DOI: 10.1089/end.2017.0430.
7. Carter BN. The fruition of Halsted's concept of surgical training. Surgery 1952; 32: 518– 27.
8. Cloutier J, Traxer O. Do high-fidelity training models translate into better skill acquisition for an endourologist? Curr Opin Urol 2015; 25: 143-52.
9. Soria F, Morcillo E, Serrano A, et al. Development and validation of a novel skills training model for retrograde intrarenal surgery. J Endourol 2015; 29: 1276-81
10. Blankstein U, Lantz AG, RJ DAH, Pace KT, Ordon M, Lee JY. Simulation-based flexible ureteroscopy training using a novel ureteroscopy part-task trainer. Can Urol Assoc J 2015; 9: 331-5.
11. Matsumoto ED, Hamstra SJ, Radomski SB, et al. The effect of bench model fidelity on endourological skills: A randomized controlled study. J Urol 2002; 167: 1243-7.