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Validation of the Advanced Scope Trainer for Flexible Ureterorenoscopy Training

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Abstract

Objective

To validate the Advanced Scope Trainer (AST; Mediskills, Northampton, UK). The AST is a currently unvalidated simulator, developed for flexible ureterorenoscopy (fURS) training. This study aims to assess the face, content, construct and concurrent validity to assess the level of transferability of skills to the OR.

Materials and Methods

This prospective, observational and comparative study recruited novices (n=19) and trainees (n=34) with participants performing a diagnostic fURS, followed by removal of a lower pole stone, on the AST. 15 participants performed a fURS on fresh frozen cadavers to assess concurrent validity. Trainees were supervised by expert urologists (n=7) during each procedure. Performance was evaluated using the validated OSATS assessment. Face and content validity were demonstrated by anonymous surveys from participants and faculty.

Results

Face validity assessment revealed that trainees found the simulator was 76% realistic (3.8/5 on a Likert Scale). Laser Stone Fragmentation (4.11±0.85) and Manual stone extraction (4.03±0.85) were thought to be the most realistic components and guidewire insertion (3.14±1.35) the least. Participants also believed the simulator to be useful, giving transferrable skills to take into the OR, demonstrating content validity. Using an OSATS assessment, concurrent validity was demonstrated in 'respect for tissue' ($p=0.0105$) and 'time & motion' ($p=0.0196$). Construct validity was also demonstrated when comparing novices to trainees (mean OSATS 10.11±2.28 vs 23.89±5.38).

Conclusions

This study has demonstrated face, content, construct and concurrent validity of the AST for fURS training. Further evaluation is necessary to demonstrate construct A and predictive validity of skills gained using the model.

INTRODUCTION

Traditionally, surgery has been taught in an apprenticeship style with junior surgeons learning and practising on patients under the supervision of more senior and experienced surgeons [1, 2]. However, with working conditions as well as the nature of surgery itself ever-changing, this traditional form has come into question.

Minimally invasive procedures, in the modern era, have a steep learning curve and many models are being utilised to provide simulation training to postgraduate surgical trainees [3, 4]. The traditional method of 'see one, do one, teach one' is becoming more difficult to implement in an era of the 'Working-Time Directive' and increased time pressures on trainees therefore, simulators are being increasingly used.

Endourology is particularly suited for simulation training given its closed-cavity nature. Many of the simulators for ureterorenoscopy (URS) have already been validated [5, 6] including the initial Scope Trainer (Mediskills, Northampton, UK) [7]. This model was followed by the Advanced Scope Trainer (AST), which includes new features to better facilitate simulation training such as a clear acrylic cover, the ability to add renal calculi to the model and more realistic anatomical modelling. This bench-top model is currently not validated. This prospective study seeks to demonstrate face, content and concurrent validity of the updated model.

METHODS

Study design and participants

This prospective, observational and comparative study recruited 60 participants, comprising of 19 medical students, 34 urological trainees, who have performed less than 10 procedures, and 7 senior urologists of consultant/specialist level from where different training sessions were conducted (UK, Austria, Japan and China).

The Advanced Scope Trainer

This model is constructed from high tensile elastomeric silicone and comprises of a distensible bladder, realistic ureteric orifices, two ureters and two kidneys with renal pelvises and calyces encased in a clear acrylic casing. It has been designed to have one distorted ureter and one enlarged kidney with a small calyceal tumour to simulate pathology and more different anatomical variations. The model is set up to enable use either 'dry' or 'wet' with irrigation fluid. Prepared calculi can be inserted (and recharged following destruction via two external ports) for stone fragmentation, using holmium laser.

Study Process

All participants were given an induction with didactic lectures before training on the AST. Each participant was required to perform a diagnostic flexible ureterenoscopy (fURS) with systematic intrarenal inspection followed by laser fragmentation and/or basket extraction of calyceal stones on the model. Fourteen junior urologists further performed diagnostic fURS using fresh frozen cadavers, to demonstrate concurrent validity. After completion, participants were invited to a structured questionnaire, with demographic information as well as participant experience of the realism, acceptability and feasibility of the model.

Outcome measures

The outcome measures were face, content, construct and concurrent validity of the simulator (Supplementary Table). Each participant completed the two tasks and was then assessed by faculty members using the validated Objective Structured Assessment of Technical Skills (OSATS) tool in its respective domains [8-10]. Construct validity was assessed comparing the performance of novices and residents whilst concurrent validity was assessed comparing the performance on the AST and fresh frozen cadavers. Feasibility, acceptability, face and content validity were assessed using the mentioned quantitative surveys.

Statistical analysis

Statistical analysis was performed using GraphPad Prism 7.03 (La Jolla, CA, USA) and Microsoft Excel 2016 (Redmond, WA, USA). For the evaluation of concurrent validity, statistical differences between the intervention groups were analyzed using two-tailed Mann–Whitney U-tests with nonparametric data assumed. Statistical significance was assumed at a p-value of <0.05.

RESULTS

Demographics

The participants consisted of 19 novices (medical students), 34 junior urological residents and 7 senior specialists. The junior residents were mostly (n=14) in their third year of urology-specific postgraduate training, with 24% being in their first year of speciality training. They ranged in age between 24 and 50 years old (mean = 31.2).

Face and Content Validity

On a Likert scale (1='Least Useful', 5='Most Useful), most trainees believed the model was overall 76% realistic (3.8/5). Laser stone fragmentation (4.11 ± 0.85) and manual stone extraction (4.03 ± 0.85) were deemed to be the most realistic components and guidewire insertion (3.14 ± 1.35) the least (Figure 2). Trainees thought all the components of the tasks to be fairly realistic (meeting the acceptability threshold of 3/5). This was backed up by the expert senior urologists (n=7) considering most of the components to also be realistic.

The majority of participants rated the simulator to be a useful and productive training modality which gave them transferrable skills to take into the operating room (4.18 ± 0.62). Additionally, when asked if 'Simulation-based training and assessment is essential for patient safety', most strongly agreed (4.31 ± 0.67). When asked regarding how useful the AST was in teaching the components of a ureterenoscopy, once again Laser Stone Fragmentation (mean: 4.07 ± 0.88) and manual stone extraction (4.07 ± 0.83) were thought to be the components the AST was most useful at simulating and stent insertion (3.29 ± 1.13) the least (Figure 2).

Construct and Concurrent Validity

Statistical significance was demonstrated in all seven standardised OSATS domains ($p<0.0001$ in all). When considering the total score, construct validity was established with the medical students scoring on average 10.11 ± 2.28 whilst the trainee residents scored 23.89 ± 5.38 ($p<0.0001$) (Figure 3).

Regarding concurrent validity, statistical significance was demonstrated in respect for tissue (mean 3.53/5 vs 4.18, $p = 0.0105$), time & motion (3.13 vs 3.81, $p = 0.0196$) as well as instrument handling (3.07 vs 3.64, $p = 0.0285$) OSATS domains (Figure 3).

Educational value

On the qualitative fields of the survey, it was noted that a particular strength of the AST is its ability to enable simulation of fURS using the real instruments rather than simulated instruments. Additionally, the ability to practice laser fragmentation using it was applauded. However, a noted weakness was the frictions of the model and difficulty in ureteral orifice catheterisation therefore often requiring experts to insert the access sheath before trainees were able to continue with the task.

DISCUSSION

Over the past few decades, the field of surgical simulation and the quality of simulation models has expanded and improved to the point where it is becoming standard in surgical education and training. There is a great variety of procedural simulators and/or models available for urological procedures including for ureterenoscopy [5], transurethral resection and related laser procedures [6, 11-13], laparoscopy [6, 14] and robotic surgery [15, 16].

The current study employed a robust training and assessment approach to establish face, content, construct and concurrent validity of the AST, with 53 novices and junior urologists undertaking two tasks (diagnostic inspection and simulated urolithiasis). The participants received one-to-one mentoring throughout the tasks from faculty members (n=7).

The face validity questionnaire showed that the AST was realistic (3/5) at simulating all the assessed components of fURS. The instrumentation, laser fragmentation and stone extraction were all identical to those used in real procedures and these proved particularly favourable with candidates, being rated as 78%, 82% and 81% realistic respectively. Participants also found that the simulator was useful, demonstrating content validity and that most thought that simulation provided transferrable skills (4.18/5) and that it's essential for safety (4.31/5). Additionally, the present study found that the simulator was useful at simulating various components of fURS, especially laser stone fragmentation and stone extraction (81% and 81% realistic respectively). On evaluation of concurrent validity against fresh frozen cadaveric tissue, validity was established for the AST using OSATS, especially in non-simulator-specific skills such as time & motion and respect for tissue ($p<0.05$ for both) as well as in instrument handling with no significant differences in the other parameters between the AST and fresh frozen cadavers. Qualitative assessment revealed that stent insertion and ureteric access was difficult on the model, however this may be because one of the ureters is purposefully designed to be tortuous and 'S shaped' in order to simulate difficult anatomical variations; the lower ratings of usefulness and realism for these components of the procedure may be a reflection of this fact. Participants praised the ability to use and simulate real instruments as opposed to simulated instruments in virtual reality models.

Brehmer et al. [7, 17] evaluated the earlier Scope Trainer (Mediskills, Northampton, UK) and found there was no statistical difference between performance of a fURS task on patients and on the simulator as well as no difference between the scoring of senior and junior urologists. Additionally, they also concluded that participants found the simulator realistic and provided good practice prior to performing procedures on live patients. However, this study only assessed construct validity rather than face or content validity.

Several other models have also been developed and evaluated (Table 1) for fURS training. Soria et al. [18, 19] determined face, content and construct validity in a study comparing the

ETXY-Uro Adam (ProDelphus, Olinda, Brazil) and biological porcine tissue in the teaching of semi-rigid and flexible URS, ureteral orifice catheterisation and urethrocystoscopy. They demonstrated clear face, content and construct validity, with significant differences in performance between first and last sessions (increasing by 43.89%).

The Key-Box (K-Box) is another bench model which consists of a series of boxes with anatomical variations and is designed to practice the specific motions needed to control a flexible ureteroscope. It has demonstrated construct validity [20, 21] with a group of trainees who had been trained on the model, taking significantly less time to complete a set of tasks (manipulation and stone extraction), compared to a non-trained group. This is in addition to a statistically significant difference upon an OSATS assessment in all domains.

A similar model is the Cook URS Trainer (Cook Medical, Bloomington, IN, USA), which has three training components: renal calyces, complete KUB (kidney ureter bladder) and a tortuous ureter. Blankstein et al [22] demonstrated face, content and construct validity with it being rated as realistic (mean 4.20/5) and experts deemed it useful (mean 4.9/5). Construct validity was demonstrated with a marked improvement in overall procedure skills on a validated global rating scale (p=0.007). Both of the models only allow simulation of individual skills rather than an entire procedure, with the latter model having the possiblity of inserting stones to simulate stone extraction and lasering.. The K-box and Cook URS trainer have demonstrated validity with a Level of Recommendation (LoR) of 2 and 3, respectively as graded by a modified educational Oxford Centre for Evidence-Based Medicine level of evidence (LoE) and LoR classification system, as adapted by the European Association of Endoscopic Surgery [23].

The CREST KU/KUB Model (SimPORTAL, Minnesota, MN, USA) is a high-fidelity organosilicate bench model of the upper urinary tract derived from CT reconstructions of actual patients. Construct validity was demonstrated when Kishore et al [24] demonstrated a strong positive correlation coefficients (r) between performance and experience of more than 0.75 in 12/15 cognitive tasks (such as use of flexible ureteroscope, troubleshooting and use of access sheath) as well an *r* of greater than 0.95 in 5/5 psychomotor skills (Rigid cystoscope assembly, flexible ureteroscope navigation and guidewire insertion, identification of calices, lithotripsy, basketing, global psychomotor skills).

Argun et al [25] demonstrated similar results when they found an correlation between training year and total cognitive score on specified tasks (r=0.66 (0.39-0.82)) and between training year and total combined psychomotor scores (r=0.66 (0.35-0.84)). However, there was only a correlation of 0.48 (0.15-0.72) between level of URS experience and total cognitive score. Therefore the CREST KU/KUB Model demonstrated construct validity with a LoR of 2.

The only virtual reality simulator available for URS training is the URO-Mentor (Simbionix, Lod, Israel), which has been most thoroughly assessed and validated, demonstrating face, content, construct, concurrent and predictive validity [6] with a LoR of 2. A study by Dolmans et al [26] showed that over 25% of their participants rated the URO Mentor above the acceptability threshold for realism (3.5/5 Likert scale) and 82% for usefulness.

Surgical training using human cadavers has been a crucial part of training for minimally invasive surgery [27]. Ahmed et al [28] conducted a study reviewing the merits of cadaveric simulation and found that cadaveric simulation was vastly more preferred as a mode of training (mean 4.26/5) than other types such as live animals (3.33) and animal tissue (2.78).

More than 70% of participants rated it as useful (above 4/5) and proved to be useful for teaching anatomy, as well as operative skills useful for both open and endoscopic procedures in addition to enhancing confidence in performing operations.

To improve the current model, the present study recommends slightly less strongly-pathological anatomy to facilitate the training of more junior trainees as well as a more robust collecting system, as numerous participants complained of leakages and difficulty in maintaining water flow in the model.

The present study had a number of limitations. Intermediate participants varied in levels of experience in fURS and ideally face and content validity would include more experts (n=7) who are particularly proficient in fURS and therefore able to assess the realism and usefulness of the simulator. Furthermore, more data and a larger number of participants (both junior and senior urologists) is needed to come to a more reliable conclusion on the overall validity of the simulator. Finally, a learning curve study should be conducted to assess progress made using the simulator.

CONCLUSION

This study has demonstrated face, content, construct and concurrent validity of the Advanced Scope Trainer for fURS training despite reported limitations in ureteral orifice catheterisation. Further evaluation is necessary to compare its effectiveness against other available models and demonstrate the predictive validity of skills gained using the model.

REFERENCES

[1] Kerr B, O'Leary JP. The training of the surgeon: Dr. Halsted's greatest legacy. Am Surg. 1999 Nov: **65**:1101-2

[2] Reznick RK, MacRae H. Teaching surgical skills--changes in the wind. N Engl J Med. 2006 Dec: **355**:2664-9

[3] Aydin A, Raison N, Khan MS, Dasgupta P, Ahmed K. Simulation-based training and assessment in urological surgery. Nat Rev Urol. 2016 Sep: **13**:503-19

[4] Aydin A, Ahmed K, Shafi AM, Khan MS, Dasgupta P. The role of simulation in urological training - A quantitative study of practice and opinions. The surgeon : journal of the Royal Colleges of Surgeons of Edinburgh and Ireland. 2016 Dec: **14**:301-7

[5] Brunckhorst O, Aydin A, Abboudi H, et al. Simulation-based ureteroscopy training: a systematic review. Journal of surgical education. 2015 Jan-Feb: **72**:135-43

[6] Aydin A, Shafi AM, Shamim Khan M, Dasgupta P, Ahmed K. Current Status of Simulation and Training Models in Urological Surgery: A Systematic Review. J Urol. 2016 Aug: **196**:312-20

[7] Brehmer M, Tolley D. Validation of a bench model for endoscopic surgery in the upper urinary tract. European urology. 2002 Aug: **42**:175-9; discussion 80

[8] Anastakis DJ, Regehr G, Reznick RK, et al. Assessment of technical skills transfer from the bench training model to the human model. Am J Surg. 1999 Feb: **177**:167-70

[9] Faulkner H, Regehr G, Martin J, Reznick R. Validation of an objective structured assessment of technical skill for surgical residents. Acad Med. 1996 Dec: **71**:1363-5

[10] Martin JA, Regehr G, Reznick R, et al. Objective structured assessment of technical skill (OSATS) for surgical residents. Br J Surg. 1997 Feb: **84**:273-8

[11] Khan R, Aydin A, Khan MS, Dasgupta P, Ahmed K. Simulation-based training for prostate surgery. BJU Int. 2015 Oct: **116**:665-74

[12] Aydin A, Ahmed K, Brewin J, Khan MS, Dasgupta P, Aho T. Face and content validation of the prostatic hyperplasia model and holmium laser surgery simulator. Journal of surgical education. 2014 May-Jun: **71**:339-44

[13] Aydin A, Muir G, Graziano M, Khan M, Dasgupta P, Ahmed K. Validation of the GreenLightTM Simulator and development of a training curriculum for photoselective vaporisation of the prostate. BJU Int Journal Translated Name BJU International. 2015 01 Jun: **115**:994-1003

[14] Brewin J, Nedas T, Challacombe B, Elhage O, Keisu J, Dasgupta P. Face, content and construct validation of the first virtual reality laparoscopic nephrectomy simulator. BJU Int. 2010 Sep: **106**:850-4

[15] Abboudi H, Khan MS, Aboumarzouk O, et al. Current status of validation for robotic surgery simulators - a systematic review. BJU Int. 2013 Feb: **111**:194-205

[16] Fisher RA, Dasgupta P, Mottrie A, et al. An over-view of robot assisted surgery curricula and the status of their validation. International journal of surgery. 2015 Jan: **13**:115-23

[17] Brehmer M, Swartz R. Training on bench models improves dexterity in ureteroscopy. Eur Urol. 2005 Sep: **48**:458-63; discussion 63

[18] Soria F, Morcillo E, Sanz JL, Budia A, Serrano A, Sanchez-Margallo FM. Description and validation of realistic and structured endourology training model. American journal of clinical and experimental urology. 2014: **2**:258-65

[19] Soria F, Morcillo E, Serrano A, et al. Development and Validation of a Novel Skills Training Model for Retrograde Intrarenal Surgery. J Endourol. 2015 Nov: **29**:1276-81

[20] Villa L, Sener TE, Somani BK, et al. Initial content validation results of a new simulation model for flexible ureteroscopy: the Key-Box (K-BOX(R)). J Endourol. 2016 Nov 21:
[21] Proietti S, Dragos L, Buttice S, Gutierrez F, Traxer O. Ureteroscopic Skills with and without Roboflex Avicenna in a Training Model. J Endourol. 2015: **29**:A82-3
[22] 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 Sep-Oct: **9**:331-5
[23] Carter FJ, Schijven MP, Aggarwal R, et al. Consensus guidelines for validation of virtual reality surgical simulators. Surgical Endoscopy And Other Interventional Techniques. 2005: **19**:1523-32
[24] Kishore TA, Pedro RN, Monga M, Sweet RM. Assessment of validity of an OSATS for cystoscopic and ureteroscopic cognitive and psychomotor skills. J Endourol. 2008 Dec: **22**:2707-11
[25] Argun OB, Chrouser K, Chauhan S, et al. Multi-Institutional Validation of an OSATS for the Assessment of Cystoscopic and Ureteroscopic Skills. J Urol. 2015 Oct: **194**:1098-105
[26] Dolmans VE, Schout BM, de Beer NA, Bemelmans BL, Scherpbier AJ, Hendrikx AJ. The virtual reality endourologic simulator is realistic and useful for educational purposes. J Endourol. 2009 Jul: **23**:1175-81
[27] Patel HR, Linares A, Joseph JV. Robotic and laparoscopic surgery: cost and training. Surg Oncol. 2009 Sep: **18**:242-6
[28] Ahmed K, Aydin A, Dasgupta P, Khan MS, McCabe JE. A Novel Cadaveric Simulation Program in Urology. Journal of surgical education. 2015 Jul-Aug: **72**:556-65

FIGURES

Figure 1. The Advanced Scope Trainer (Mediskills, Northampton, UK) in use.

Figure 2. Assessment of face and content validity by a Likert score (1= 'Least useful', 5='Most Useful'). All components scored above an acceptability threshold of 3/5.

Figure 3. Assessment of construct and concurrent validity using an OSATS scale.

Table 1. The available fURS models and their validation status [6].

Name of Model (Institution / Manufacturer)	Study	Validation	LoE	LoR
Scope Trainer (Mediskills, Northampton, UK)	Brehmer (2002) [7]	Face, Content, Construct	2b	3
	Brehmer (2005) [17]	Construct	2c	
CREST KU/KUB Model (SimPORTAL, Minnesota, MN, USA)	Kishore (2008) [23]	Construct	2b	2
	Argun (2015) [24]	Construct	2b	
Cook URS Trainer (Cook Medical, Bloomington, IN, USA)	Blankstein (2015) [22]	Face, Content, Construct	2c	3
Key Box (K-Box; Porges-Coloplast, Rosny-sous-Bois, France)	Villa (2015) [20]	Construct	2a	2
	Proietti (2015) [21]	Construct	4	
ETXY Uro Adam (ProDelphus, Olinda, Brazil)	Soria (2015) [19]	Face, Content, Construct	2b	3
URO Mentor VR simulator (Simbionix, Lod, Israel)	Aydin (2016) [6]	Face, Content, Construct, Concurrent, Predictive	1a	2

Abbreviations: KUB- Kidney Ureter Bladder, LoE- Level of Evidence, LoR- Level of Recommendation.