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Development and validation of a novel and cost-effective animal tissue model for training TransUrethral Resection of the Prostate (TURP)

Sichuan Hou MD¹, Gillian Ross BSC², Iain Tait PhD FRCS², Paul Halliday FRCS³, Benjie Tang
MD²

¹Department of Urology, Qingdao Municipal Hospital, PO Box 266071, 5 Donghai Road
Middle, Qingdao, China

²Cuschieri Skills Centre, Ninewells Hospital and Medical School, University of Dundee,
Dundee DD1 9SY, UK

³Department of Urology, Ninewells Hospital and Medical School, Dundee DD1 9SY, UK

Correspondence to: Mr Benjie Tang

Cuschieri Skills Centre, Ninewells Hospital and Medical School, University of Dundee,
Dundee DD1 9SY, UK

Email: b.tang@dundee.ac.uk

Phone: +44 (0)1382 383411

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Conflict of interest: Dr Sichuan Hou, Ms Gillian Ross, Mr Iain Tait, Mr Paul Halliday, and Dr Benjie Tang have no conflicts of interest or financial ties to disclose.

Ethical standards: Ethical approval for the trainees to participate the study was obtained from local ethical committee and verbal consent was given by the trainees who participated the study. A clear announcement was made that the participation was purely voluntary based.

Authors' Contribution: All the authors contributed to the paper equally.

Abstract

Objectives: To develop and validate a new and cost-effective animal tissue training model for practicing resection skills of TransUrethral Resection of the Prostate (TURP).

Methods and Materials: A porcine kidney was prepared and restructured to simulate the relevant anatomy of the human prostate. The restructured prostate was connected to an artificial urethra and bladder. Face, content, and construct validity of the model was carried out using a five-point Likert scale questionnaire and comparison in task performance between participants and experts using Observational Clinical Human Reliability Analysis (OCHRA).

Results: 24 participants and 11 experts practiced TURP skills on this model from October 2014 to December 2015 were recruited. The mean score on specific feature of the anatomy and colour, sensation of texture and feeling of resection, conductivity of current, efficacy and safety of the model were 4.34 ± 0.37 , 4.51 ± 0.63 , 4.13 ± 0.53 , 4.35 ± 0.71 respectively by participants while they were 4.22 ± 0.23 , 4.30 ± 0.48 , 4.11 ± 0.62 , 4.56 ± 0.77 respectively by the experts on a scale of 1(unrealistic) to 5(very realistic). Participants committed more technical errors than the experts (11 vs 7, $p < 0.001$), produced more instruments movements (51 vs 33, $p < 0.001$), and required longer operating time (11.4 minutes vs 6.2minutes, $p < 0.001$).

Conclusions: A newly developed restructured animal tissue model for training TURP was reported. Validation study on the model demonstrates that this is a very realistic and effective model for skills training of TURP. Trainees committed more technical errors, more unproductive movements, and required longer operating time.

Introduction

Transurethral resections skills of the prostate (TURP) is one of the essential competencies for participants to master before completing urological training ⁽¹⁾. Like any endoscopic procedures, it requires trainees to perform hundreds of procedures to reach proficiency ⁽²⁾. However, the reduction of working hours introduced by the European Working Time Directive **has significantly reduced trainees' surgical training time ⁽³⁾ and the** developments in medical therapy **for benign prostatic hyperplasia** have resulted in fewer TURPs being performed ⁽⁴⁾, **these changes in surgical practice together** have resulted in the current trainees performing less TURPs ^(3,4). To find a solution to overcome these limitations, both participants and specialists have explored the use of simulation as a method of safe and effective urology training ^(5,6). A programme of simulation training for technical and non-technical skills has been implemented in a pioneering training centres ⁽⁷⁾.

Virtual reality simulators have been proven a valid method for training in TURP and a number of systems have been developed and used for this purpose ⁽⁸⁻¹¹⁾. The advantages of virtual reality simulators are that they are able to simulate prostates of different size, shape, and grade of difficulty. They can simulate bleeding during practice and also provide feedback by automatically measuring the performance ⁽⁹⁻¹¹⁾. However, these systems have a shortcoming in common in that they are very expensive and some of them do not have tactile feedback, or only have some unrealistic tactile feedback. Some virtual reality simulators have been proven to be in need of modification ⁽¹²⁾. In addition to this, a commercially available physical synthetic model has been developed and validated ⁽¹³⁾.

Animal training models have been widely used for surgical skills training in other endoscopic procedures ⁽¹⁴⁻¹⁷⁾. However, there is no existing animal prostate suitable for TURP training.

Human cadavers have been used for TURP training in some training centres and it has been demonstrated that it is feasible, acceptable, and high value for surgical training ^(18, 19).

However, this is a very precious resource and it is not always possible to get access to them ^(18,19). Therefore, it is worth exploring an effective alternative by designing a restructured animal tissue model to simulate prostates for training in TURP as having been developed in other surgical specialities ^(15, 20).

When designing and developing such a model the following factors can be considered ^(21,22).

1) The model may be as realistic as possible in order to simulate the anatomy and pathology involved in the procedure; 2) Skills learned on this model may be transferable to the operating theatre; 3) the final result of the performance can be made available for inspection and feedback; 4) it may have the ability to distinguish the experience of surgeons; 5) it may also be cost effective to produce and simple enough to be massively re-produced for a group of participants and routine use for practice.

A model developed has to be realistic, appropriate and effective as a teaching and training tool and it also should have ability to distinguish surgeons' experience. Thus, validation of reliability and effectiveness remains critical ⁽²³⁻²⁶⁾. The aim of this study was to describe the details of how to make such a training model for TURP and to conduct face, content, and construct validity of the model.

Methods and Materials

Design and preparation of the restructured animal tissue model of TURP

Porcine kidneys weighed from 50 grams to 70 grams were obtained. A restructured prostate made from a kidney of this size was similar to the size of an enlarged human prostate. These kidneys were collected from a local abattoir which was fully registered under the standard regulations stipulated by the meat industry and follows strict ethical guidelines. The porcine kidney could also be bought from the meat counter in the local supermarkets for one box of 6 for £2.90. The cost of making a complete model was about £80, which included labour and materials. **This porcine kidney prostate portion of the model was mounted in a reusable latex portion of the model.** Once the **latex portion of the model** being made it was used for many years.

Close supervision and instruction were provided by an experienced consultant urologist during the restructuring process. A piece of renal vessel was prepared and sutured onto the middle centre to simulate the verumontanum of the prostate (Figure 1A). Two light cuts were made on the back of the kidney to allow it to sit better on the base and a cable-tie was used to tie the two ends of the kidney loosely together to form the shape of three lobes of a prostate (Figure 1B, an endoscopic view of the model). A piece of tin foil was wrapped around the prostate model to enable the use of monopolar electrosurgery. The isolated system of electrosurgery was used, thus, there was no need for the grounding pad.

A mould designed with the relevant anatomy of the urethra and bladder was made. Liquid latex was poured into the pre-made mould and waited for 24 hours for setting. Once the liquid latex was set after 24 hours a model with urethra and bladder was ready to use. One

latex model could be used repeatedly for many years (Figure 2A). Two sutures were stitched on either site of the base of the latex bladder to simulate the ureteric orifices (Figure 2B). Sutures were better than the permanent mark pen as they were not washed off by water irrigation during the resection. The urethra was made for a resectoscope to be inserted easily and the external urethral orifice was water-tight. A kidney prostate was mounted in this enlarged section of the model (Figure 2A). The synthetic part of the model was water tight so that irrigation could be used during the exercise (Figure 2A, Figure 3A). A restructured prostate was mounted in the latex bladder and urethra, then, the complete set up for TURP training was ready to be used (Figure 3B).

Use of the animal tissue model for TURP course

Real resectoscopes (27050 E, Storz, Tübingen, Germany) and angled cutting loops were employed for the skills training. A standard electrosurgical generator (Pfizer, Valleylab, Force FX, Park Royal, London) was connected to the instrumentation for cutting and coagulation current (Figure 3A). The power setting was increased from 70 watts for cutting current while the level of power was set at 50 watts for coagulation. Irrigation and draining systems were also connected to the system.

A theoretical session with lectures and video demonstrations on TURP were given by expert urologists before the practical session. Each trainee had two prostate models to practice on during the course. The first TURP was practiced under close and constant supervision from a consultant urologist so they could give immediate feedback and correction to the trainee. A constant supervision was provided during the resection in addition to the video demonstration. The capsule of the kidney/prostate was the indication of a complete resection and it was not the resection of all tissue down to the latex. After the completion

of the first procedure, the trainee had a chance to perform the second TURP during which the performance was assessed by a different consultant urologist.

Face, Content and construct validity

A clear announcement of voluntary participation was made to the participation and consents were given by the trainees before the participating the study. Criteria for validity were defined based on the definition and recommendation which are commonly used for validity testing for endourologic models and simulators ^(23,24). Face validity relates to the degree of realism of the simulator in relation to the real anatomy and setup while content validity involves in the measurement of the appropriateness of the simulator as an effective training modality. Construct validity is to **test** whether the simulator has the ability to distinguish the inexperienced from the experienced surgeon ⁽²³⁾. Study design and data collection followed recommendations for reporting validation studies reported by Van Nortwick et al ⁽²⁴⁾.

A structured questionnaire was designed for face and content validity of the TURP model based on subjective assessment by both participants and expert. At the end of the course all participants and experts completed a structured questionnaire to assess the validity of the model for TURP training ^(21, 22). The evaluation on realism on: i) anatomy and colour, ii) sensation of texture and feeling of resection, iii) conductivity of electrosurgery, v) safety and efficacy were the end points used for assessment of the reconstructed TURP model. Questions such as ‘was the model useful in teaching TURP?’; ‘did you think the skills learned on the model is transferrable to the operating room?’; ‘did you feel more confident in performing TURP after having practiced on the model?’ were used for content validity.

For the construct validation, assessment of comparison of task performance of participants and experts were conducted. Since this was not a real life procedure and some important intraoperative complication, such as bleeding, couldn't be simulated in this model and there was on preoperative information and postoperative complication associated with the procedure, thus, the existing assessment tool, such as Global Rating System which was commonly used to assess performance in real life surgery, was not suitable for the assessment of performance on this TURP model. For the purpose to evaluate the quality of the endoscopic resection skills of the trainees, we used Observational Clinical Human Reliability Analysis (OCHRA) approach to assess the recorded full procedure on unedited video to measure the quality of the performance by assessment of technical errors, number of movement, and operating time.

It has been demonstrated that a recently developed and validated OCHRA ⁽²⁷⁻²⁹⁾ was a reliable approach to assess the endoscopic task performance recorded on videos in different specialities. Thus, both participants and experts procedures were video-recorded and coded anonymously and video-recorded participants were selected randomly. The videos were analysed blindly using the OCHRA by a surgeon and an expert of OCHRA (BT) and a consultant urologist (SH). Technical errors were defined by urologist and slight modification of OCHRA was made based on the published study by Tang et al ⁽²⁷⁾. The inter-reliability of the assessment from two assessors were tested. Technical errors, number of movement, and operating time were the endpoints used for the construct validation of the model.

Data collection and statistical analysis

Data was collected using a Likert scale (1= strongly disagree; 2 = disagree; 3 = neither agree nor disagree; 4 = agree; 5 = strongly agree) on a standardised anonymous questionnaire. Evaluation forms were completed by participants and experts, and analysis of the feedback was conducted. The interrater consistency of the OCHRA had been assessed by an expert of OCHRA (BT) and a consultant urologist (SH) and the interrater reliability was found to be 82%. The expert panel provided consultation throughout the study and checked the accuracy of the videotape analysis process. Excel (Microsoft office 2013) and Statistical Package for the Social Sciences version 16 were used for data collection and analysis. The number of technical error, number of movement, and operating time were used as endpoint parameters to measure the surgical performance in this study. It was predicted that the number of technical errors would be higher in the trainees' performance than the expert using the OCHRA assessment⁽²⁷⁻²⁹⁾, thus, no formal power calculation was performed; however, to identify trends in the data, Chi-square test of statistical significance were used with $p < 0.05$ considered to signify a statistically significant result.

Results

Demographics of participants and experts

24 course participants and 11 experts were recruited in this study from October 2014 to December 2015. 24 participants were in years 1-3 of urology training. There are 21 males and 3 females in the participant group while they were all males in the expert group. The expert group consisted of 11 certified consultant urologists in the UK and China, who were aged from 37 to 51. Experts were recruited also based on a voluntary base without any financial interest and other disclosure conflict. Participants in years 1-3 performed small number of TURP (<10 TURPs, median 3.6). The experts performed 120 to 600 cases of TURPs (median 360).

Outcome of face validity of the model

The overall mean satisfaction rate for the TURP training model given by the participants was 4.32 ± 0.55 on a scale of 1 (unrealistic/ poor) to 5 (very realistic/ useful) while the experts rated it as 4.61 ± 0.31 (Table 1).

Content validity

Both participants and experts agreed this was a very useful and effective model for training in TURP (4.55 ± 0.52 vs 4.63 ± 0.45) (Table 1). The trainees felt the skills learned on this model could be transferred into operating theatre. Both participants and expert expressed that this model should be used as a routine training model for TURP (4.70 ± 0.46 vs 4.81 ± 0.23).

Construct validity

11 participants attending courses in different time were randomly selected in order to reduce bias of the data. Consents were obtained for video recording their performance. 11 fully qualified consultant urologists who had performed more than 120 cases were invited to perform a TURP on the same model within the exact same set up. Participants required more number of instrument movement to perform the procedure compared with the expert (51 vs 33, $P < 0.001$) and consequently produced more unproductive movements of the instrument compared with the experts (11 vs 6, $p < 0.001$) (Figure 3). For the indicating parameter data, participants committed more technical errors than the experts (11 vs 7, $p < 0.001$). Participants required longer time (minutes) to complete the procedure than the experts (11 vs 7, $p < 0.001$).

Discussion

Despite all the merits of virtual reality simulators for endoscopic skills training in a number of surgical specialties including TURP ^(8-12, 22), animal tissue models were recently proven to be better and the preferred method for surgical trainees to learn technical skills in endoscopic surgery when a suitable organ or tissue can be found to exist in an animal ^(15,16). When suitable and realistic anatomy or organs cannot be found in nature, a restructured animal tissue model may become a valuable and effective resource. These kinds of models have been successfully developed and used in different endoscopic procedures such as laparoscopic salpingectomy and laparoscopic fundoplication in gynaecology and general surgery ^(20, 30). These types of models have been proven realistic, cost effective, and simple enough to be produced for use in laboratory based surgical training courses with a large number of surgical trainees ^(20, 30). The final results of the procedures could be assessed, feedback could be given to the trainees, and the exercise could be repeated ^(20,30).

The materials and methods used to develop such a TURP training model with restructured porcine kidney were described in detail in this paper. The key features that were considered when designing and developing this model were: realistic anatomy, effective simulation, repetitive practice, feedback on performance, simulator validity and cost ^(21, 22). We felt that demonstrating the details of the materials used and method applied to design and develop such a model could provide information for urologists and educators who wish to use such a model in a simulation programme ^(6, 7, 21).

Compared to synthetic models, animal models and virtual reality simulators, human cadavers remain the most realistic training model for many surgical procedures including TURP ^(18,19). Ahmed K et al has demonstrated a novel cadaveric simulation program in

urology while participants practice a list of urological procedures in a 3-day course. We would recommend that participants could practice on this restructured animal tissue TURP model to gain skills and experience up to intermediate level before participating in a cadaveric course in simulation-based training programme ⁽⁶⁾.

It is essential to validate a simulator to examine its fidelity, authenticity, and efficiency before it is widely employed for training purposes ^(8-13, 22-26, 31). Therefore, the face, content, and construct validation of this entire system of the TURP model was carried out. Experts commented that the texture and feeling of resection was very good but it was felt slightly different from real life as it was softer and there was no bleeding. However, the novice trainees marked this aspect higher than the experts. It might be that they had less experience in resecting real prostates and were more focused on the resection skills exercise. Both novice trainees and experts agreed that this was a very safe and effective way of training in TURP when electrosurgery was utilised during the exercise.

It also demonstrated that this model had the ability to discriminate level of skills and experience ^(8, 9, 12, 13, 22, 26, 31) by video analysing of the performance between participants and experts. OCHRA has been developed and validated in a wide range of surgical specialties, especially in endoscopic surgery over the last decade ⁽²⁷⁻²⁹⁾. The strength of the analysis carried out in this study was that video recordings were coded and analysed blindly by an OCHRA expert and an experienced consultant urologist. Trainees committed more technical errors as this procedure requires competence in eye-hand coordination, depth perception and manual dexterity, which a participant had to gain from repetitive exercise.

Compared with the other existing training models, the major advantages to use this model for TURP training were observed as following: 1) real animal tissue was used, thus, it was

more useful in appreciation of tissue plane, tissue handling, and haptic feedback during the exercise; 2) the relevant anatomy involved in the procedure was restructured as close as possible the real anatomy; 3) real electrosurgery, real equipment and instruments were utilised during the exercise; 4) final result of the procedure was checked; and 5) it was very cost effective ⁽²⁰⁾. It cost about £80 preparing such a model. Thus, the cost was minimal compared to other simulators ^(8-13, 20-22).

Despite the higher face validity scores from the novice trainees and experts, the major shortcoming of this model was that it did not simulate bleeding, which was an essential skills to learn for TURP. Therefore, the novice trainees were not able to practice managing intraoperative bleeding though the participants scored the content validity with a high scores. This might be that they had centred on practicing resection skills. In the future, further development to simulate intraoperative bleeding can be the next step to refine this model. There was also a lack of objective data to demonstrate whether skills learned on this model could be transferred to improved performance in the operating theatre (criterion validity). A further studies on criterion validity should be conducted if this model is to be used as an assessment tool of the trainees in the future.

Conclusions: A newly developed restructured animal tissue model for training TURP was reported. Validation study on the model demonstrates that this is a very realistic and effective model for skills training of TURP. Trainees committed more technical errors, more unproductive movements, and required longer operating time.

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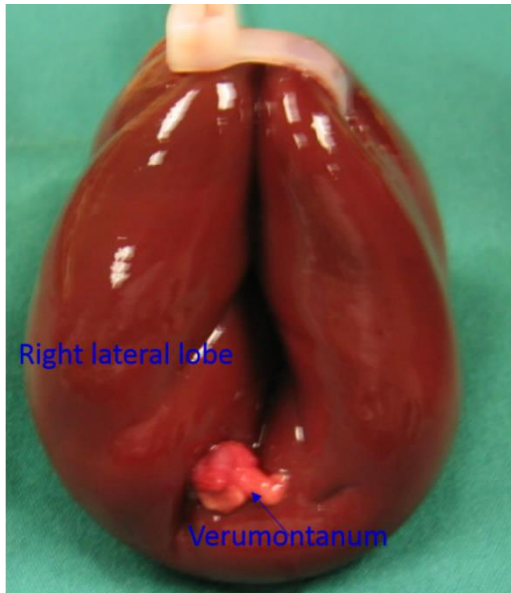
Figure legends:

Figure 1: Simulation of the verumontanum and the lobes of a prostate were developed by suturing a piece of tissue in the front of the folded kidney (Figure 1A). An endoscopic view of the restructured prostate model after the kidney has been mounted within the latex urethral and bladder model (Figure 1B).

Figure 2: A latex bladder and urethra with a water tight external urethral orifice (Figure 2A) was made in-house. Two ureteric orifices were simulated inside the latex bladder (Figure 2B).

Figure 3: A complete set up of TURP training model (Figure 3A) and the use of the model by trainees (Figure 3B).

Figure 4. Comparison task performance between participants and experts using OCHRA on the assessment of the restructured TURP model. Participants committed more technical errors, required more instruments movement, and required longer operating time than experts ($P < 0.001$).



A. Apex of the prostate

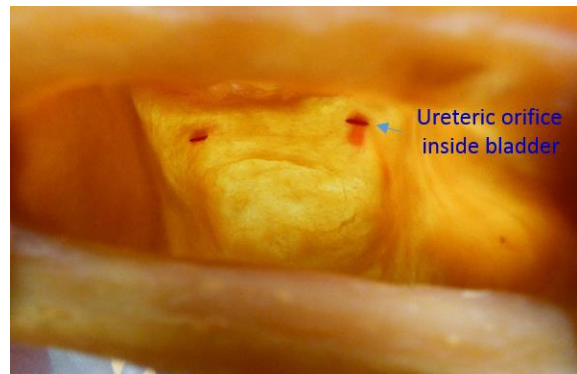
B. An endoscopic view of the restructured prostate

Figure 1: Simulation of the verumontanum and the lobes of a prostate were developed by suturing a piece of tissue in the front of the folded kidney A. An endoscopic view of the

restructured prostate model after the kidney has been mounted within the latex urethral and bladder model B.

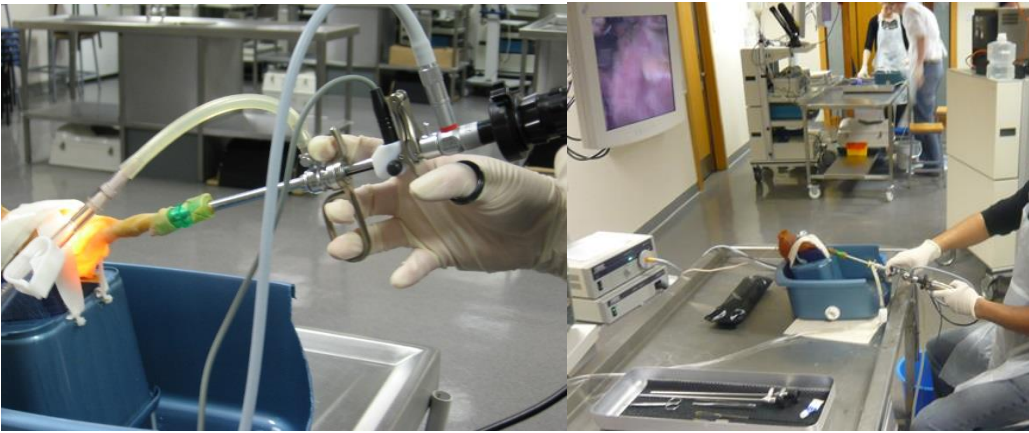


A



B

Figure 2: A latex bladder and urethra with a water tight external urethral orifice A was made in-house. Two ureteric orifices were simulated inside the latex bladder B.



A

B

Figure 3: A complete set up of TURP training model (Figure 3A) and the use of the model by trainees (Figure 3B).

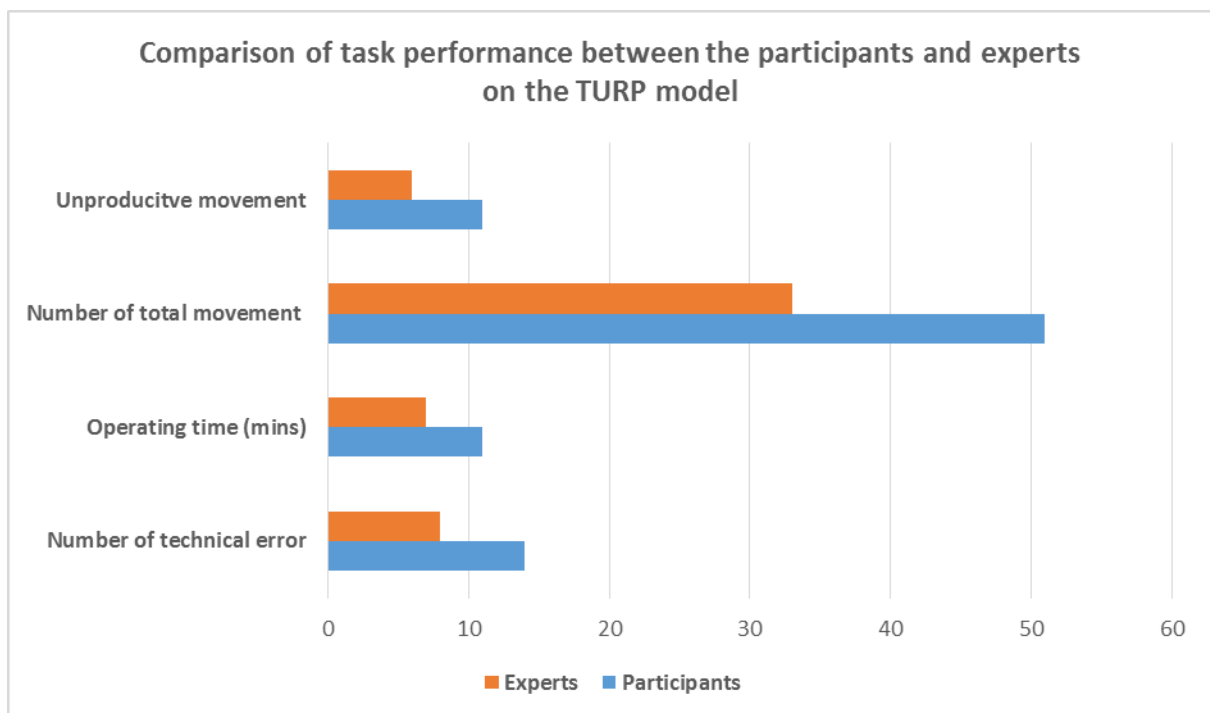


Figure 4. Comparison task performance between participants (n=11) and experts (n=11) using OCHRA on the restructured TURP model. Participants committed more technical errors, produced more number of instrument movement, and required longer operating time than experts (P<0.001).

Table 1. Results of face, content validity of the restructured animal tissue TURP models.

Face and content validity of realism and usefulness of the restructured animal tissue TURP model (1 not very realistic to 5 very realistic)		
	Scored by the participants (n =24) (Mean± SD)	Scored by the experts (n=11) (Mean± SD)
Anatomy and colour of the model	4.34 ± 0.37	4.22 ± 0.23
Sensation of texture and feeling of resection	4.51 ± 0.63	4.30 ± 0.48
Conductibility of electrosurgery	4.13 ± 0.54	4.11 ± 0.62
Efficacy and safety of skills exercise on the model	4.35 ± 0.71	4.56 ± 0.77
Overall satisfaction of the model	4.32 ± 0.55	4.61 ± 0.31
Are the equipment and instruments provided excellent for TURP training?	4.59 ± 0.76	4.63 ± 0.38
Is this a useful model for teaching TURP?	4.55 ± 0.52	4.63 ± 0.45
Did you gain transferrable skills to operating theatre from this model?	4.64 ± 0.43	4.54 ± 0.58
Do you feel more confident in performing TURP after having practiced on this model (for trainees)? Do you think this will help to improve trainee's confidence in performing TURP (for experts)?	4.22 ± 0.33	4.76 ± 0.66
Do you think this model can be used as a routine training model for TURP?	4.70 ± 0.46	4.81 ± 0.23