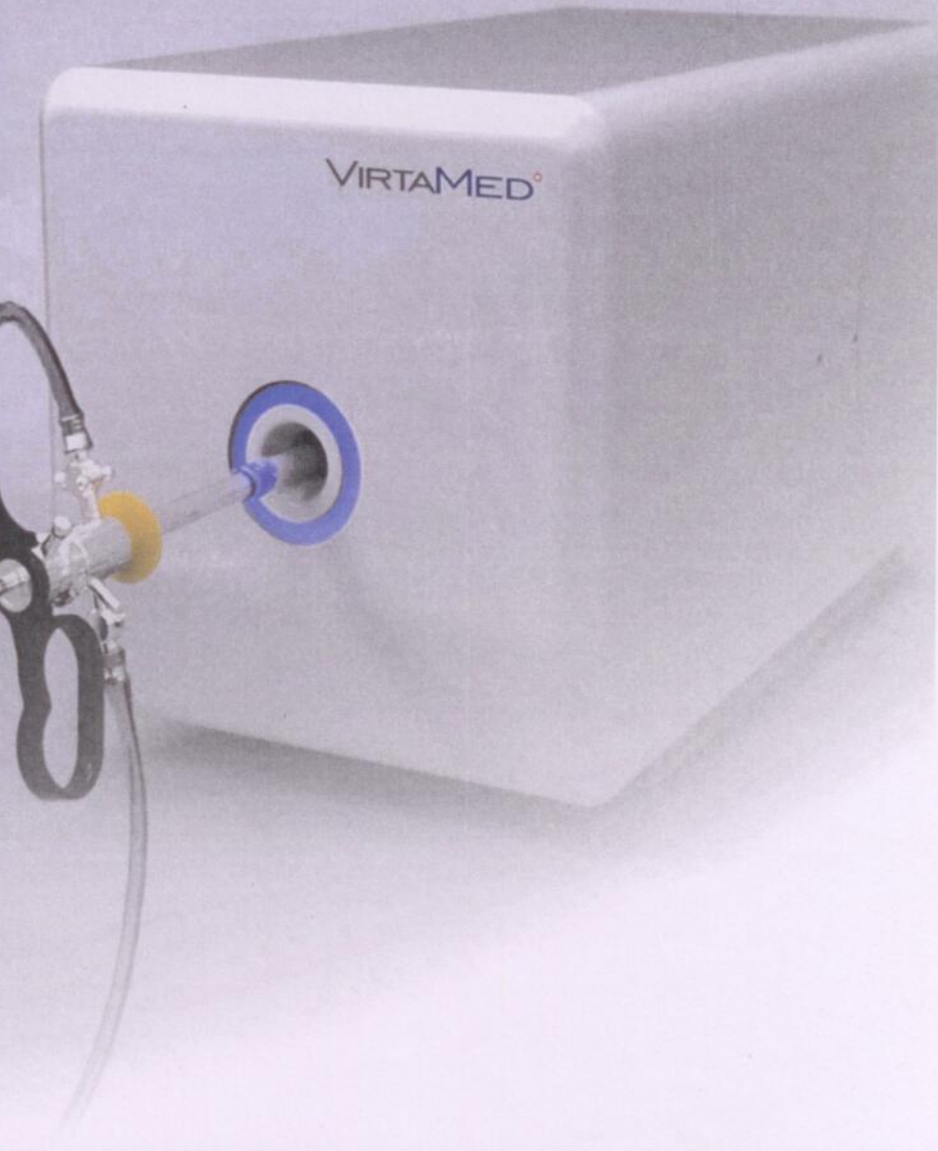


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SSC 5C (ELECTIVE) IN ACADEMIC & CLINICAL UROLOGY

**Department of Urology, Guy's and St. Thomas' NHS Foundation Trust,
King's Health Partners**

**Evaluation of a Novel Virtual Reality Simulator
for Holmium Laser Enucleation of the Prostate**

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INTRODUCTION

Transurethral resection of the prostate (TURP), and simple open prostatectomy (OP) are the traditional, commonly performed surgical interventions for management of benign prostatic hyperplasia (BPH). Over the past two decades, laser treatment modalities have also been introduced to overcome associated complications with TURP [1]. Amongst these, Holmium Laser Enucleation of the Prostate (HoLEP) has been the most thoroughly evaluated method as it is the only modality with level 1 evidence [2]. Although shown to be effective, it has been described as having a long and steep learning curve, with as many as 50 cases required to become proficient [3, 4]. Thus, more efficient training programmes must be devised in order to preserve patient safety during the learning phase.

Surgical model simulators have been used in training courses as a method to shorten the learning curve without endangering patients. However, before these surgical simulators can be used for training and assessment, they must undergo validation across various parameters, in order to assess their potential for clinical training [5, 6].

Recently, VirtaMed (Zurich, Switzerland) have developed the UroSim™ HoLEP virtual reality simulator, the subject of the present study. It has yet to be validated and assessed for its potential use in HoLEP training.

AIM AND RATIONALE OF STUDY

During the stay of my elective, we validated this simulator through scientific measures. We designed and ran a prospective, multi-institutional study to assess the face, content, and construct validity of this novel simulator, alongside the feasibility and acceptability of its use in training programs and curricula. We also evaluated the learning curves of novice participants to ensure repeated training session correlated with improved performance.

MATERIALS AND METHODS

SETTING

This prospective, observational, longitudinal, and comparative study was undertaken with participants recruited at a multi-institutional level, including from King's College London, Guy's and St. Thomas' NHS Foundation Trust, and other centres across the UK. More participants were recruited from outside the UK at the 107th French National Congress of Urology in Paris.

VIRTAMED™ HOLEP VIRTUAL REALITY SIMULATOR

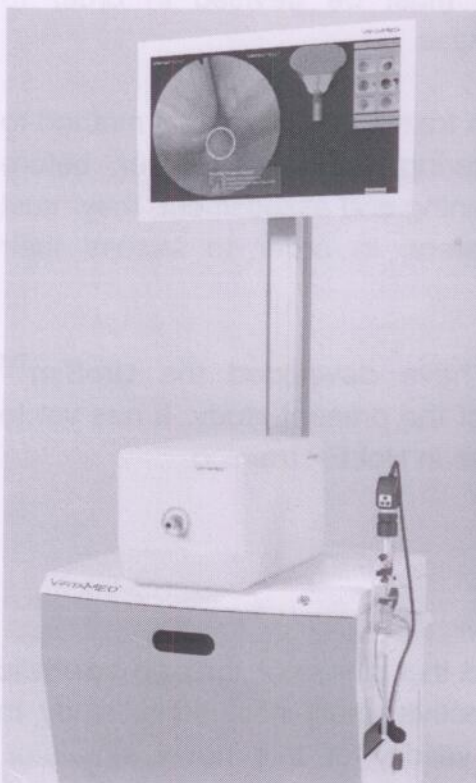


Figure 1: The VirtaMed UroSim™ simulator with SimBox™.

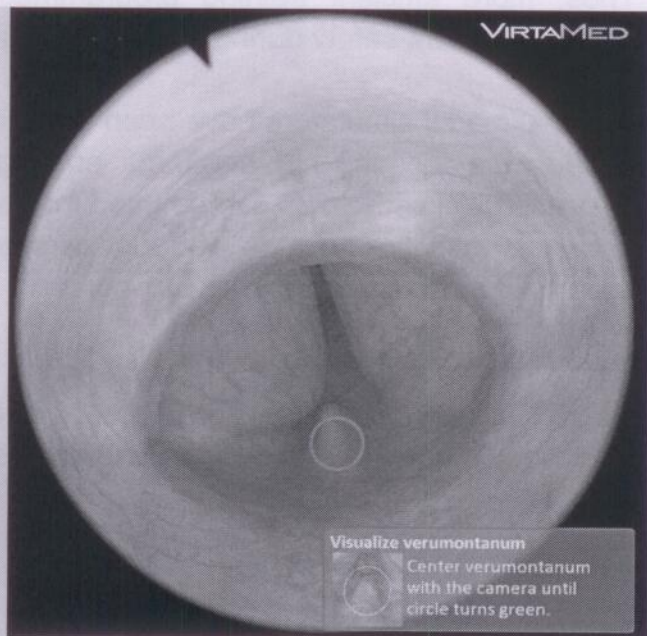


Figure 2: Visualisation exercise showing task given to visualise the verumontanum, augmented and highlighted with a red circle. This will only disappear when the operator has fully visualised the anatomy

The novel VirtaMed UroSim™ HoLEP simulator (Figure 1) utilises haptic feedback to recreate Holmium laser enucleation. It uses an adapted original Storz Resectoscope (Karl Storz, Germany) feeding into the VirtaMed SimBox™, which produces haptic feedback, recreating the resistance of the tissue to the scope. It was developed using videos of surgeries performed by experts at multiple institutions from around Europe, and from the existing VirtaMed TURPsim™ module, which has been face and construct validated by different groups [7, 8].

The simulator includes an anatomy visualization and cystoscopy module, and six operative cases with various degrees of prostatic hyperplasia, each with slightly different anatomical variations. The simulator also has the ability to augment the prostate with colour showing the ideal depth of enucleation, or to guide the operator to the relevant anatomy in the visualisation modules (Figure 2).

A performance evaluation report is provided at the end of every case on outcomes such as procedure time, percentage of prostate enucleated, enucleation efficiency, and also whether any safety parameters were breached, e.g. sphincter or verumontanum damage (Figure 3). This allows the trainee to self-evaluate their own performance and also allows mentors to highlight areas of improvement.

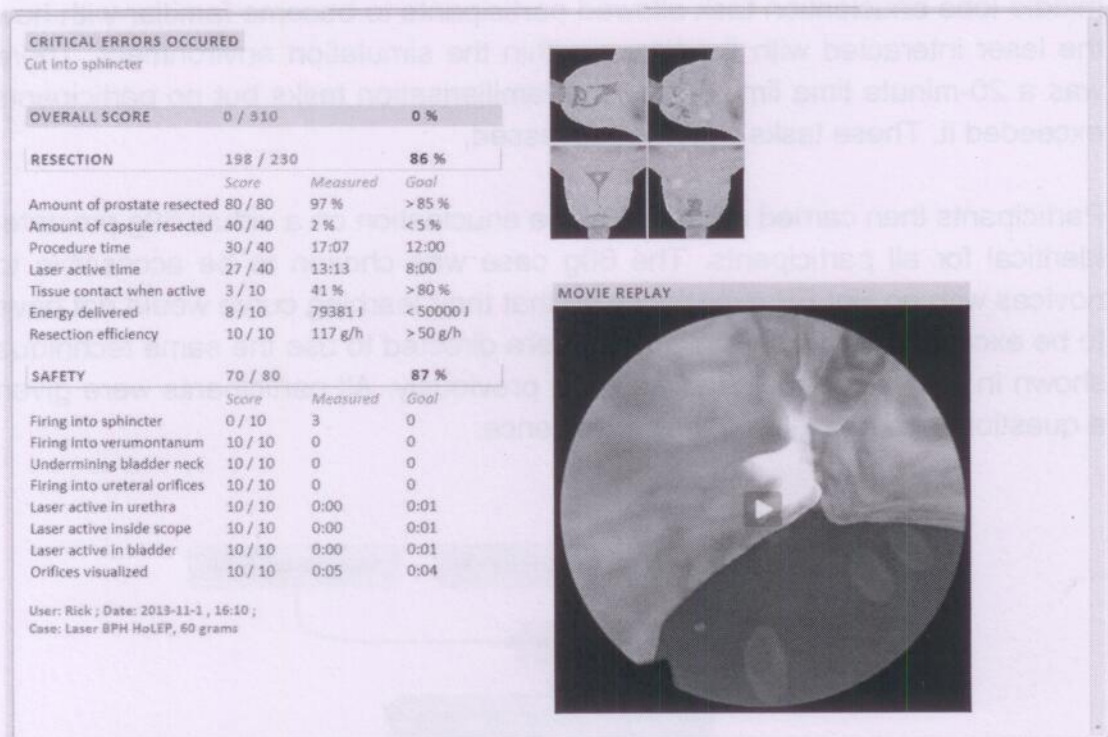


Figure 3: Performance evaluation report showing scores, safety parameters and statistics. It also provides a video to aid in mentorship and trainee feedback

STUDY DESIGN

The study recruited 42 participants in 3 groups: Those with no prior experience of HoLEP or other endourological procedures (Endourological Novices n=18), trainee or consultant urologists with no HoLEP experience but with significant other endourological experience (Intermediates: n=18), and consultant urologists with greater than 100 HoLEP procedures performed (HoLEP Experts: n=6). Medical students were used as novices as they were most likely to fit the novice criteria.

As shown in Figure 4, participants were divided into groups, all of which were given the same educational package before being exposed and introduced to the virtual reality simulation environment. This educational package consisted of didactic lectures on the significance of HoLEP surgery, correct use of instruments, laser safety, and HoLEP technique. Participants then viewed an instructional video outlining HoLEP technique and then viewed a video of a real HoLEP procedure carried out by an expert HoLEP surgeon.

Participants were then introduced and familiarized with the simulator environment. Two exercises were used to do this, a visualization/cystoscopy exercise, and a simple middle lobe enucleation task. The first of these directed participants to identify the relevant and important anatomical structures and to carry out a full cystoscopy, which should always be performed before any endourological procedure for safety reasons. The middle lobe enucleation task allowed participants to become familiar with how the laser interacted with the tissue within the simulation environment. There was a 20-minute time limit set for the familiarisation tasks but no participants exceeded it. These tasks were not assessed.

Participants then carried out a full 3-lobe enucleation on a virtual 60g prostate, identical for all participants. The 60g case was chosen to be accessible to novices with no HoLEP experience so that their learning curve would not have to be excessively steep. Participants were directed to use the same technique shown in the videos they had watched previously. All participants were given a questionnaire to evaluate their experience.

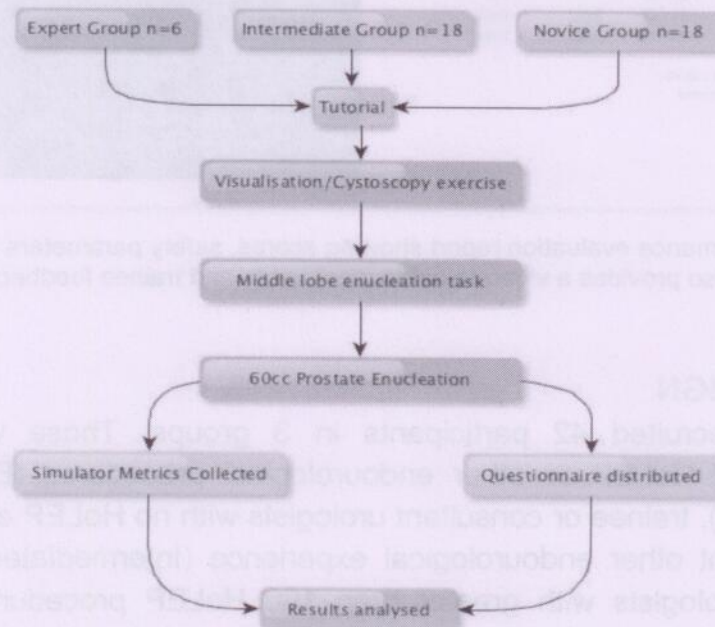


Figure 4: Flow diagram showing study progression

Learning Curve

After performing their first case as described above, a subgroup of the novice group (n=7) continued to do between 5 and 10 extra cases in order to assess their learning curve on the simulator. One participant was used as a pilot study in order to roughly assess how many cases were required to display a learning curve.

We compared results between novice, trainee and expert groups using the Mann-Whitney U statistical test. Efficiency, the outcome measure used in the vast majority of HLF, learning curve studies, showed a statistically significant difference between all three groups (Figure 3). Experts had a mean efficiency of 88.8%, trainees had 57.1% and novices had 34.9%. This difference in efficiency means the system has construct validity.



Figure 3: Construct validity parameters

Other performance outcomes measured did not give significant construct validity results. Although not significant, experts encountered a larger proportion of the prostatic capsule, indicating experts encircled to a slightly deeper level than trainees, and a much deeper level than novices. When considering the degree of damage to the bladder neck, Vasudevan and external sphincter, no trend was found.

RESULTS

86% of participants agreed that simulator-based assessment was essential for patient safety and 88% agreed that there was a role for a validated VR simulator for use in HoLEP training. 97% thought that simulation should be integrated into training programmes, 61% thought that the overall experience was similar to the real-life setting, 82% thought it feasible to incorporate simulation into training programmes, and 68% of non-experts reported that the simulation session had improved their skills.

We compared results between novices, trainees and expert groups using the Mann-Whitney U statistical test. Enucleation efficiency, the outcome measure used in the vast majority of HoLEP learning curve studies, showed a statistically significant difference between all three groups (Figure 5). Experts had a mean efficiency of 99.8g/h, Intermediates had 57.1g/h and novices had 24g/h. This difference in efficiency shows the system has construct validity.

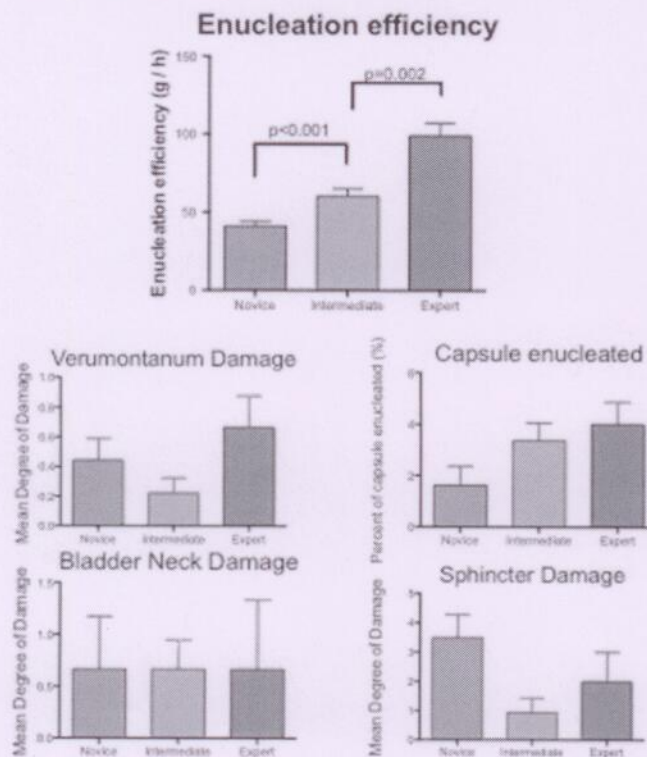


Figure 5: Construct validity parameters.

Other performance outcomes measured did not give significant construct validity results. Although not significant, experts enucleated a larger proportion of the prostatic capsule, indicating experts enucleated to a slightly deeper level than trainees, and a much deeper level than novices. When considering the degree of damage to the bladder neck, Verumontanum and external sphincter, no trend was found.

Analysis of the all learning curve data is shown in Figure 6, including up to trial 10, where only 1 novice was able to complete the trial due to time constraints. These results show a classic learning curve with a plateau after case 4 ($p=0.005$). However care should be taken in interpreting this as not all participants performed the same number of trials. A learning curve showing the first 5 cases of all participants is shown in figure 3.7 that again shows a plateau after trial number 4 ($p=0.001$).

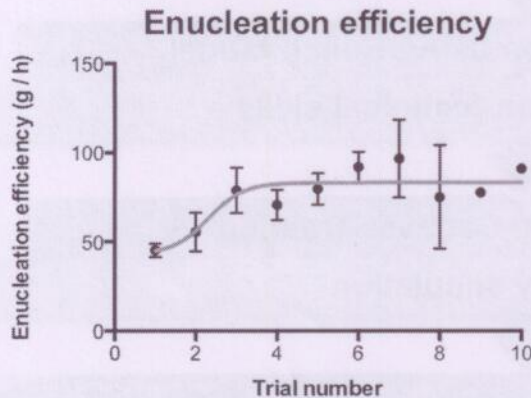


Figure 6: Integrated learning curves from all participants and all trials showing plateau after 4 to 5 cases. All participants completed first 5 trials. Remaining trials consist of incomplete data but continue the extrapolation of the plateau phase

Based on the results of our study and other available simulators, we came up with a recommended pathway for simulation-based HoLEP training. Utilisation of different simulation methods would allow trainees to learn and practice procedural steps and movements, and receive initial instruction and familiarisation with HoLEP in a virtual reality environment, before gaining experience with real operative equipment and laser safety protocols using the bench model. Trainees could then apply these skills alongside non-technical skills in a distributed simulation environment, and then in animal and human cadaver models, before transferring. This would provide the optimum simulation based curriculum in order to shorten the long learning curve associated with HoLEP, without endangering patient safety. Mentorship and Proctorship should be utilised as much as possible throughout, having shortened the learning curve in other urological procedures [9].

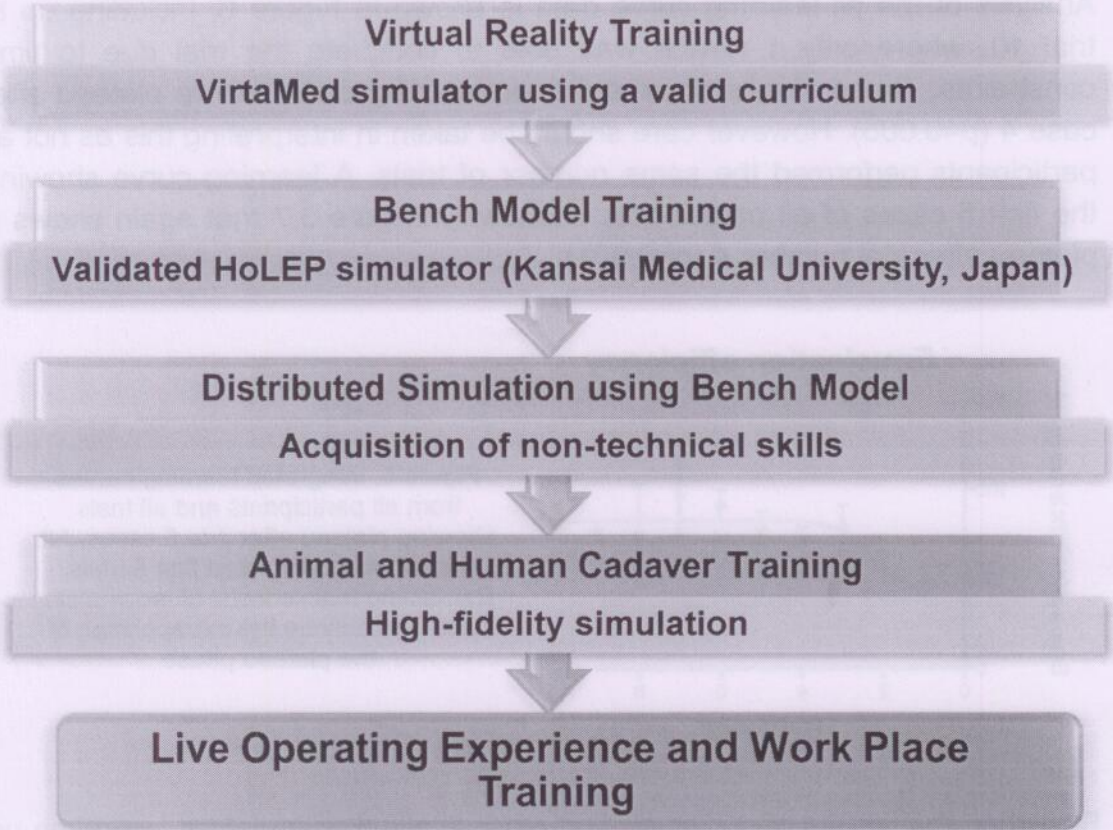


Figure 7: Recommended simulation-based HoLEP training

CONCLUSIONS

In summary, the VirtaMed UroSim™ HoLEP simulator has been shown to be a valid and useful tool in HoLEP training. This study demonstrates the face, content, and construct validity of the simulator. It has also been reported to be a feasible and acceptable model for training with a good education impact. Learning curve data for the simulator demonstrate good skill acquisition, and a plateau in the learning curve observed at 4-6 cases for the 60g prostate module. However, although having demonstrated this, the author does not recommend utilisation of the simulator in its current state for clinical training purposes due to design and durability issues. Nonetheless, after further development and study, its potential for use in training alongside other simulation methods in the near future is great.

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