Development and validation of a virtual reality transrectal ultrasound guided prostatic biopsy simulator

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Abstract

Objective: We present the design, reliability, face, content and construct validity testing of a virtual reality simulator for transrectal ultrasound (TRUS), which allows doctors-in-training to perform multiple different biopsy schemes.

Methods: This biopsy system design uses a regular “end-firing” TRUS probe. Movements of the probe are tracked with a micromagnetic sensor to dynamically slice through a phantom patient’s 3D prostate volume to provide real-time continuous TRUS views. 3D TRUS scans during prostate biopsy clinics were recorded. Intrinsic reliability was assessed by comparing the left side of the prostate to the right side of the prostate for each biopsy. A content and face validity questionnaire was administered to 26 doctors to assess the simulator. Construct validity was assessed by comparing notes from experts and novices with regards to the time taken and the accuracy of each biopsy.

Results: Imaging data from 50 patients were integrated into the simulator. The completed VR TRUS simulator uses real patient images, and is able to provide simulation for 50 cases, with a haptic interface that uses a standard TRUS probe and biopsy needle. Intrinsic reliability was successfully demonstrated by comparing results from the left and right sides of the prostate. Face and content validity respondents noted the realism of the simulator, and its appropriateness as a teaching model. The simulator was able to distinguish between experts and novices during construct validity testing.

Conclusions: A virtual reality TRUS simulator has successfully been created. It has promising face, content and construct validity results.

Résumé

Objectif : Nous présentons le plan, la fiabilité, la validité apparente, de contenu et conceptuelle d’un simulateur virtuel d’échographie transrectale permettant aux médecins en cours de formation d’exécuter de nombreux schémas différents de biopsie.

Méthodologie : Ce système de biopsie est muni d’une sonde à échographie transrectale habituelle à « émission verticale ». Les mouvements de la sonde sont suivis grâce à un capteur micromagnétique permettant pratiquer des incisions de façon dynamique dans un volume prostatique virtuel en 3 dimensions et de produire des images continues en temps réel. Les images en 3 dimensions obtenues pendant des stages de biopsie prostatique ont été enregistrées. La fiabilité intrinsèque a été évaluée en comparant le côté gauche et le côté droit de la prostate pour chaque biopsie. On a évalué le simulateur grâce à un questionnaire portant sur le contenu et la validité apparente rempli par 26 médecins. La validité conceptuelle a été évaluée en comparant les notes provenant d’experts et de débutants quant au temps requis pour effectuer les biopsies et à la précision de chaque biopsie.

Résultats : Les images provenant de 50 patients ont été intégrées au simulateur. Le simulateur d’échographie transrectale virtuelle utilise de vraies images de patients et peut fournir une simulation pour 50 cas, avec une interface haptique fondée sur une sonde d’échographie transrectale et une aiguille de biopsie standard. La fiabilité intrinsèque a été démontrée avec succès en comparant les résultats des côtés gauche et droit de la prostate. Les répondants des questionnaires de validité apparente et de contenu ont noté le réalisme du simulateur, et son adéquation en tant que modèle d’apprentissage. Le simulateur a été en mesure de faire la distinction entre les experts et les débutants pendant l’analyse de la validité conceptuelle.

Conclusions : Un simulateur virtuel d’échographie transrectale efficace a été créé. Il a généré des résultats prometteurs lors de tests de la validité apparente, de contenu et conceptuelle.

Introduction

The current gold standard and the most widely used method to diagnose prostate cancer is transrectal ultrasound (TRUS)-guided prostatic biopsy, which is commonly performed in Westernized high income countries. For instance, in Australia in 2008 a total of 26 146 TRUS guided biopsies of the prostate were performed.1

Transrectal ultrasound-guided prostatic biopsy does have well-documented complications. A recently published Japanese nationwide survey of more than 200 000 prostatic biopsies revealed that complications occurred frequently, with hematuria in 12%, hematochezia in 5.9%, hematospermia in 1.2%, fever in 1.1%, sepsis in 0.07%, voiding symptoms in 1.9%, urinary retention in 1.1% and prostatitis in 0.9%. Hospitalization to treat complications occurred in 0.69% of the entire cohort.2 Mortality rates at 120 days of 1.3% have also been noted in a cohort of 22 175 patients by Gallina and colleagues.3 Unfortunately, there...
are currently no good alternative diagnostic techniques to histologically diagnose and confirm the presence of prostate cancer, and so TRUS-guided prostatic biopsy will remain in widespread usage for the foreseeable future.

Numerous prostate biopsy schemes exist, with no universally agreed standard, although most authors suggest an extended biopsy scheme. Variations in core biopsy schemes can arise from the TRUS view chosen (axial vs. sagittal), the number of cores taken (commonly ranging from 10 to 20), and the anatomical location of the biopsies themselves (e.g., sextant vs. sextant plus alternate sites). Given the small but definite biopsy risks, sufficient training of urology and radiology residents is difficult given the great variation in procedural schemes. Current training methods for TRUS-guided prostatic biopsy are based on an apprenticeship approach, with trainees watching some procedures, and then performing the procedure under the guidance of a mentor; eventually the trainee will perform the procedure without supervision. The problem with this traditional approach to medical skills acquisition is that the patient is being exposed to the complete learning curve of the trainee. Some have argued that simulation-based training is imperative to further protect patients’ interests. Other reasons for using simulators include decreasing access to patients for training purposes, time constraints for teaching during procedures due to demands for greater efficiency and shorter working hours for residents; simulators can also be used as a tool to assess initial competence and subsequent recertification. Other industries, most notably the aviation industry, have long used simulators for this purpose, where both initial training and subsequent recertification can be performed safely without putting lives in danger.

To improve the training of TRUS-guided prostatic biopsy, we have developed and performed initial validation of a simulator for this procedure. The aim of this study was to perform intrinsic reliability testing (defined as the reproducibility or consistency of a test), to demonstrate face validity (defined as the opinion of novices with regards to realism), content validity (defined as the opinion of experts with regards to whether the simulator teaches what it is designed to teach), and finally to demonstrate construct validity (defined as the ability of the simulator to discriminate between experts and novices).

**Methods**

**Patient prostate image database**

3D TRUS prostate images of 50 patients were collected using a side-firing, biplane 2D TRUS probe attached to a rotational mover. All patients were scheduled for prostate biopsy for suspected prostate cancer. All 3D TRUS images were collected with approval from the local institutional ethics board.

**Prostate biopsy simulator design**

The TRUS-guided prostatic biopsy simulator was designed to improve the accuracy of prostatic ultrasound, specifically through the development of novel 3D ultrasound techniques. The development of the simulator has been a collaborative effort between imaging physicists, engineers, academic urologists and academic radiologists carried out at a dedicated imaging research facility (Robarts Research, London, Ontario, Canada) in conjunction with clinical departments at the University of Western Ontario. The design of the biopsy simulator incorporates a patient’s 3D TRUS prostate image into a mock pelvis allowing for multiple simulated biopsies to be performed using a standard end-fire TRUS probe. The database of patient TRUS images...
Virtual reality TRUS-guided prostatic biopsy simulator provides prostates of varied shape, size and pathology for biopsy training.

The hardware of the simulator is composed of a TRUS biopsy probe, a 3D magnetic tracking system, a mock pelvis and a biopsy activator foot pedal (Fig. 1). A standard clinical 2D TRUS probe is held and manipulated by the operator to perform a simulated biopsy within the mock pelvis (Fig. 2). The end-fire TRUS probes were used for our biopsy simulator; however, the simulator design allows for the use of a biplane side-fire TRUS probe, if preferred. A contoured polyoxymethylene plastic housing was manufactured to attach to an end-fire TRUS probe and contain a micro-magnetic tracking sensor (Fig. 3). The embedded magnetic sensor is 1.8 mm in diameter and allows for real-time monitoring of the TRUS probe position using a second-generation, Aurora magnetic tracking system (NDI, Waterloo, ON). The magnetic sensor can monitor the probe movement with 6 degrees of freedom (position: x, y, z and rotation: pitch, roll, yaw). The position of the magnetic sensor on the TRUS probe was calibrated with the TRUS image location, so that the position and orientation of the 2D TRUS image plane are known and can be monitored throughout the biopsy procedure.

The mock pelvis is a 6-sided (height × width × depth = 9.5 × 14.0 × 11.0 cm³) rectangular box, manufactured using polyoxymethylene plastic, with a single 3.1 cm diameter porthole. Large rubber bands were crossed over the hole to create a tight, elastic entry port, representative of an anus (Fig. 4). A dense elastic foam was embedded within the pelvis to create a pliable surface representative of a rectal wall. The elastic foam location within the mock pelvis is adjustable to allow for the simulated biopsy to be performed in left lateral decubitus or lithotomy positions. The patient’s 3D TRUS prostate image is virtually placed behind the foam rectal wall within the mock pelvis, such that simulated transrectal biopsies are performed by inserting the tracked TRUS probe through the anus to “image” the prostate across the mock rectal wall. It is important to note that no real TRUS imaging is performed during the simulated biopsy procedure. Instead, the tracked orientation and position of the TRUS probe within the mock pelvis is used by the simulator software to dynamically slice the 3D TRUS prostate image to provide cross-sectional TRUS images that replicate those seen in a biopsy procedure (Fig. 4).

The hardware inputs are received by the biopsy simulator software and were integrated on a standard PC (Pentium 4, 3.2 GHz, 1 GB RAM). The simulator user interface provides multiple biopsy training modes including evaluation tools. The 2D TRUS mode displays standard 2D TRUS images of a patient’s prostate as the operator manipulates the probe within the mock pelvis and is representative of the actual

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**Fig. 3.** Ultrasound probe with attached micro-magnetic tracking sensor.

**Fig. 4.** 2D TRUS views from simulator. (a) Mid-gland image displaying verumontanum. (b) Prostatic calcification in apex. (c) Right side peripheral zone hypoechoic lesion suspicious for prostate cancer.
biopsy procedure. Examples of anatomy and pathology from the prostate simulator are shown in Fig. 4. The 3D TRUS mode extends 2D TRUS by providing an anatomical reference of the TRUS image location relative to 3D models of the patient’s pelvic anatomy (Fig. 5). Patient-specific models of the prostate, bladder and urethra are reconstructed from the original 3D TRUS image, and the relative anatomical position of the TRUS image plane is displayed in real-time. The 3D TRUS mode user interface is an enhancement of a clinical 3D TRUS biopsy interface, and it allows the trainee to visualize the 3D TRUS probe location within the pelvis to aid with their orientation.

Multiple biopsy schemes can be designed and incorporated into both the 2D and 3D TRUS simulator modes (Fig. 5); however, the location of each biopsy target is not visible to the user under 2D TRUS. This allows trainees to learn biopsy schemes within the 3D TRUS mode, and then practice performing simulated schematic biopsy procedures under the 2D TRUS guidance. Activation of a foot pedal connected to the simulator software signals initiation of biopsy tissue collection and the location of the TRUS image along with the biopsy needle path are recorded simultaneously. Within the simulator, the accuracy of each biopsy is automatically calculated, based on the 3D distance of the schematic biopsy target from the biopsy needle line on the TRUS image, and the total time required to perform the biopsy is recorded. This information can be displayed to the trainee after each biopsy or summarized after completion of a full procedure.

Simulator evaluation

Intrinsic reliability of the simulator was assessed using the technique of split-halves, comparing the left side of the prostate with the right side of the prostate for 14 physicians with regards to time taken to complete a 12-core biopsy. The split-halves technique correlates the performance on one side of the prostate with the performance on the other side of the prostate.

To test, validate and gain further insight into possible improvements with the TRUS guided prostatic biopsy simulator, we developed a content and face validity questionnaire, which uses a Likert scale for evaluators of this new device (Appendix 1). This questionnaire sought to gain insights on the evaluators impressions of the simulator, in particular on the realism, the ease of use of the interface, the realism of the force feedback (haptics), the similarity of the images to a regular ultrasound machine, the range of motion of the ultrasound probe and whether the simulator would be useful for training urology and radiology residents on TRUS-guided biopsy of the prostate. The simulator was trialled and the questionnaire administered to 26 physicians (14 experts and 12 novices).

Construct validity was assessed by comparing experts and novices with regards to accuracy and time taken to perform a TRUS guided prostatic biopsy on the simulator. Simulated biopsies were performed on 3 separate prostate cases by 5 biopsy experts and a mixture of 9 radiology and urology resident trainees to evaluate the intrinsic reliability and construct validity of the biopsy simulator. The biopsies were performed in a targeted manner on 12 virtual biopsy targets that were arranged in a standard 12-core sextant scheme with medial and lateral targets defined for each region. This experiment used and expanded upon previously published work from our group, which compared simulated prostate biopsy accuracies using 2D ultrasound to 3D ultrasound systems, and involved only experts and radiology residents.

Prior to each simulated biopsy, a single, static 2D TRUS image of the virtual target was provided to the operator for review. It is important to note that the length of time for target review was not limited and was at the discretion of the biopsy operator for each virtual target. Following sufficient review, the operator performed a simulated biopsy under 2D TRUS guidance and attempted to sample the location of the virtual target, which was no longer displayed. When the operator was confident in the position of TRUS probe, then
the biopsy needle was fired to signify tissue collection. For each simulated biopsy, the simulator automatically recorded the total time for review and biopsy guidance along with the accuracy of the biopsy. Biopsy accuracy was defined and calculated within the simulator as the 3D Euclidean distance between the virtual target and the expected path of the biopsy needle on the TRUS image. Large values in biopsy accuracy suggest poor alignment or targeting of the biopsy needle and a decreased likelihood of sampling tissue surrounding the virtual target.

Statistical analysis was performed using SPSS (SPSS, Chicago, IL) and Stata (StataCorp LP, College Station, TX), utilizing parametric methods; statistical significance was defined as <0.05.

Results

All components of the software were developed and successfully integrated with the 3D magnetic tracking hardware and the biopsy activation foot pedal. Patient-specific 3D pelvic anatomy models were created for each 3D TRUS prostate image within the patient database, and each prostate was successfully incorporated with the simulator for training purposes.

Intrinsic reliability was assessed by comparing the left side with the right side of the prostate with regards to the time taken for each biopsy for the 14 physicians involved in the construct validity experiments. A total of 252 cores from the 14 physicians were used for this analysis. Mean time for the left side and right side was 62.4 seconds (95% CI 57.2-67.7 seconds) and 63.0 seconds (95% CI 58.4-67.6 seconds) respectively, with no statistically significant difference. Strong correlation was noted ($r = 0.83$) between the time taken for the two sides of the prostate, confirming the intrinsic reliability of the simulator.

The device was successfully assessed by both novice and expert physicians in the area of TRUS-guided biopsy of the prostate (Table 1). Physicians were equally divided between radiologists and urologists. The simulator was tested by academic and community urologists at a regional urological conference. Among these expert assessors, 93% found the simulation accurate, 100% found the interface easy to use, 100% agreed that the images on the simulator moved in a similar manner to a regular ultrasound machine, 64% regarded the haptics as lifelike, 93% rated the range of motion as realistic, and all felt that the simulator would be useful for training residents. For novice trainees, the pool of radiology and urology residents was used at the University of Western Ontario (London, Ontario, Canada) training program. Among these novice assessors, 67% found the simulation realistic, 100% found the interface easy to use, 83% rated the range of motion as realistic, 83% felt that the images on the simulator moved in a similar manner to a regular ultrasound machine, and 67% regarded the haptics as lifelike. All novices (100%) felt the simulator would be a useful tool in their training.

Construct validity was assessed by comparing 5 experts with 9 novices with regards to the time taken and accuracy for each biopsy (Table 2). This experiment used previously published work from our group, which assessed the accuracy of 5 experts using a 3-dimensional ultrasound system.17 We found differences between experts and novices using the simulator with regards to the time taken (34.7 seconds vs. 78.3 seconds, respectively); however the differences in accuracy of each biopsy between experts and residents (3.76 mm vs. 4.16 mm, respectively) did not reach statistical significance. The differences in accuracy were trending towards reaching statistical significance ($p = 0.16$), and we suspect that the difference could be confirmed with larger sample sizes. During construct validity testing, we also noted

<table>
<thead>
<tr>
<th>Table 1. Survey results</th>
<th>Strongly agree (%)</th>
<th>Agree (%)</th>
<th>Neither agree nor disagree (%)</th>
<th>Disagree (%)</th>
<th>Strongly disagree (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The TRUS biopsy simulator provides a realistic simulation of the actual procedure</td>
<td>10 (38%)</td>
<td>11 (42%)</td>
<td>5 (19%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The instrumentation/interface is easy to use</td>
<td>12 (46%)</td>
<td>14 (54%)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>The force feedback (haptics) was realistic</td>
<td>6 (23%)</td>
<td>11 (42%)</td>
<td>9 (35%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The images on the screen moved in a similar manner to a regular ultrasound machine</td>
<td>8 (31%)</td>
<td>16 (62%)</td>
<td>2 (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The ultrasound probe had a realistic range of motion</td>
<td>8 (31%)</td>
<td>15 (58%)</td>
<td>3 (12%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The TRUS biopsy simulator would be useful for training residents</td>
<td>19 (73%)</td>
<td>7 (27%)</td>
<td></td>
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TRUS: transrectal ultrasound.
significant improvements amongst residents in the time taken between the first prostate biopsied and the third prostate biopsied. As expected, such an improvement was not seen among experts (Fig. 6).

**Discussion**

We have successfully developed a TRUS-guided prostatic biopsy simulator, and initial content and face validity testings have shown encouraging results, with all testers finding the simulator to be realistic. Of note, force feedback (or haptics), which is often very difficult to replicate in the simulation environment, was realistic in this simulator. We have also demonstrated intrinsic reliability and construct validity for this simulator. Other future potential applications of this technology lie with the training and accreditation of newer minimally invasive procedures which use prostatic ultrasound to guide therapy, as these minimally invasive options become more widely accepted with sound guidelines underscoring their usage (e.g., prostate cryosurgery).

There are no comparable simulators for a TRUS-guided prostatic biopsy reported in the literature.12 There are, however, numerous other simulator devices which are being developed or are in usage, particularly in the fields of laparoscopy19,20 and endoscopy.21-25 Eventually, these simulators will hopefully be incorporated into both medical education and subsequently medical re-certification, with governments and universities around the world investing in the required infrastructure for simulation centres to improve patient safety and outcomes. All of these simulators require multiple forms of validation (e.g., predictive, content, face, concurrent) prior to being used,13 with early consensus panels noting the lack of rigorous validation prior to usage.26 Although we have now performed face, content and construct validity testing, our simulator warrants larger scale studies given the promising initial findings. These larger scale studies will need to demonstrate predictive validity (defined as the extent to which the simulator predicts future performance in the operating room), using an objective structured assessment of technical skills (OSATS) as the main outcome measure.13

Potential limitations, in particular, the lack of actually seeing the biopsy gun firing in real-time, were identified by the testers of the device. However, this is a minor limitation given the fact that we can accurately track the exact location of where the biopsy was taken using our software, and then show the trainee where the biopsy was taken from. Other limitations noted include the fact that we have only tested the simulator with a small sample size of 26 physicians. We do plan to do further research with the simulator to demonstrate predictive/transfer validity. Also, our simulator demonstrated similar biopsy accuracy between experts and residents; this is likely to be due to the small difference in accuracy between experts and residents, which will necessitate a much larger sample size than is available in any one training program. Conversely, our simulator found significant differences in the time taken for each biopsy, suggesting that residents are able to achieve similar levels of accuracy as experts, but take longer to achieve those results. Validation of surgical simulators prior to widespread usage is required, especially if they are to be used for recertification procedures. Similar to the aviation industry, it is not inconceivable that if the standard biopsy template or the technique change (e.g., usage of local anaesthesia), practicing physicians will have to demonstrate competence on a TRUS-guided prostatic biopsy simulator to continue practicing. Such procedures are commonplace in the aviation industry, where technology on planes and standard procedures are constantly being updated.

**Conclusion**

In the ideal world, all physicians would perform procedures on a simulator before performing the procedure under supervision on a patient. We believe that our TRUS-guided prostatic biopsy simulator could potentially be incorporated...
into training programs for radiology and urology residents. Furthermore, the simulator could also be used on a continuing basis for re-certification of practicing physicians (i.e., every 5 to 10 years). We believe that better training, along with continual improvement in the basic technology of ultrasound (e.g., 3D sonography) may lead to improved outcomes and safety for patients.

A virtual reality TRUS simulator has successfully been created; it has promising face, content and construct validity results. More predictive validity studies are needed to further develop this technology.

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Competing interests: None declared.

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References


Appendix 1. Content validity questionnaire: prostate biopsy simulator

Approximately how many transrectal ultrasound (TRUS) guided biopsies do you perform per year?
☐ Less than 20
☐ More than 20

1. The TRUS biopsy simulator provides a realistic simulation of the actual procedure
☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree

2. The instrumentation/interface is easy to use
☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree

3. The force feedback (haptics) was realistic
☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree

4. The images on the screen moved in a similar manner to a regular ultrasound machine
☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree

5. The ultrasound probe had a realistic range of motion
☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree

6. The TRUS biopsy simulator would be useful for training residents
☐ Strongly disagree
☐ Disagree
☐ Neither agree nor disagree
☐ Agree
☐ Strongly agree

Suggestions/Comments:


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