A virtual reality simulator combining a learning environment and clinical case database for image-guided prostate biopsy

Sonia-Yuki Selmi¹, Gaelle Fiard², Emmanuel Promayon¹, Lucile Vadcard³, Jocelyne Troccaz¹,²
¹ UJF-Grenoble 1 / CNRS / TIMC-IMAG UMR 5525, Grenoble, F-38041, France
² Grenoble University Hospital, Department of Urology, Grenoble, France
³ LSE, UPMF, Grenoble, France

Abstract

The recent availability of navigation systems for mapping and targeting of transrectal ultrasound (TRUS) guided prostate biopsies revealed new opportunities in training the clinician. This paper describes a simulator for TRUS guided prostate biopsy that offers similar information, enhanced by a complete learning environment. Various exercises have been developed in accordance with a didactical study identifying the training needs. A dedicated clinical case database fed by a prostate navigation system provides a large patient prostate image database that covers the main situations encountered during clinical practice. A haptic device is used to enable complete biopsy procedures or practice specific tasks. This paper also presents work in progress of the evaluation of such a simulator.

1. Introduction

Virtual reality surgical simulators, as educational tools, allow medical practitioners to perform complex procedures in a controlled environment and provide an independent evaluation system [1].

Prostate cancer is the second most common cancer worldwide for males [2]. Prostate biopsy procedures, performed to obtain and analyze tissue samples of the gland, are required for diagnosis confirmation. Conventional biopsies are performed under transrectal ultrasound (TRUS) guidance (see fig. 1) and the initial training, performed through an apprenticeship, can be challenging for the trainee, painful for the patient, and does not allow quantitative evaluation. Indeed, the exact position of the biopsy is not known.

1.1. Context

The quality of a prostate biopsy procedure is essential for the initial diagnosis and management of prostate cancer. Current teaching methods, based on apprenticeship without feedback on biopsy distribution and overall performance led to a low correlation between the presumed biopsy location and the final pathology of the prostatectomy specimen [3]. Previous work showed that a visual feedback about the real location of performed biopsy sessions allowed improvement of the biopsy distribution, even for an experienced operator [4].

Figure 1. Anatomy of the prostate and imaging by transrectal ultrasound

The prostate biopsy procedure is challenging for several reasons. First of all, it requires mental reconstruction of a three dimensional (3D) gland (almost spherical, 4 cm in diameter) based on two-dimensional (2D) TRUS images, and a good hand-eye coordination to regularly distribute biopsies in order to sample each part of the gland, as previous biopsies are not displayed on the US image. Secondly, tasks vary from randomized sampling to very precise targeting, which becomes necessary with the emergence of targeted biopsies on MRI suspicious areas. Also, the prostate moves and is deformed due to the ultrasound probe movements during a biopsy session. Moreover, patient anatomy varies and the gesture must be adapted to various prostate sizes. Finally, except the display of
the current 2D US image where a biopsy occurs, no visual feedback or evaluation of the biopsy location in the 3D prostate volume can be obtained from a conventional biopsy procedure. Besides, recent progress in Magnetic Resonance Imaging (MRI) has allowed the definition of suspicious areas inside the prostate prior to biopsy, and the performance of targeted biopsies on these areas. Targeting under US imaging an area detected on another imaging modality (i.e., MRI) can be performed using mental fusion or navigation systems, and there is a need for simulation of this specific task.

A recent report by the French Health Authorities (HAS) revealed an insufficient use and a lack of validated surgical simulators, although specifications and conditions of use have been well specified by a meta-analysis [5][1]. These conditions of use include a learning environment around the simulator, as a hyper-realistic simulator does not guarantee its educational interest [6]. Explanations and guidance of the trainee are necessary to take the full benefit of simulations and facilitate the transfer of the acquired skills to biopsy real patients. Besides, a balance between repetitive practice and experience of varying situations is essential for performance improvement.

1.2. State of the art

Different types of simulators have been developed to teach and improve technical and non-technical medical skills. Surgical simulators represent a small proportion of available simulators, and most of them are dedicated to laparoscopic skills [5]. In the field of urology, simulators of robotic, laparoscopic and endoscopic procedures have been described or commercialized [7][8]. Some of them have demonstrated reliability (reproducibility for the same user), face validity (realism of the simulator assessed by nonexperts), content validity (assessed by experts, the simulator teaches what it is supposed to teach) and construct validity (the simulator is able to discriminate between novices and experts), but not all showed a clinical benefit (i.e., the ability to transpose acquired skills in clinical practice)[9].

To our knowledge, mainly two devices were designed for the simulation of prostate biopsy procedures. Xang et al. [10] and Zeng et al. [11] developed 3D simulation models but used it to evaluate the efficiency of various biopsy schemes rather than for educational purposes. Chalasani et al. [12] reported the development and face, content and construct validation of a Virtual Reality TRUS guided prostate biopsy simulator, which allowed the performance of virtual conventional prostate biopsies with assistance, with a limited teaching environment.

This paper presents the design of a complete virtual reality learning environment for prostate biopsy teaching, practicing and evaluation, based on real patient cases and containing a set of exercises allowing for personalized learning paths. The next sections describe the simulator and the planned modalities of its validation.

2. Methods and tools

2.1. Training needs assessment

In order to obtain a real clinical benefit, a simulator has to help the students not only to learn the gesture, but also to learn and train on the prostatic biopsy procedure as a whole. In order to ensure this, the simulator has to integrate multiple functions: make the link between theory and practice, offer exercises which target different aspects of prostate biopsy, contain various patient cases and provide increasing difficulty for biopsy.

A didactical study was performed to evaluate the training needs [13]. Its purpose was to identify the activities of trainees and to analyze how reference situations can be transposed into a simulator. It allowed the development of specific exercises, taking into account individualized learning pathways.

A biopsy procedure requires understanding hand-eye coordination using both the 2D TRUS image and the virtual probe. The aim is to develop jointly skills and the good 3D mental representation they require. Pre-requisites include ultrasound image reading, prostate volume measurement and ability to determine the probability of finding a cancer based on clinical data (prostate specific antigen (PSA), prostate volume, digital rectal examination (DRE)).

In clinical practice, a 12-core biopsy protocol is usually performed, using an end-fire probe. The probe is held in one hand and the other hand is needed to fire the biopsy. The patient can be installed in either dorsal or lateral decubitus position, and biopsies can be performed using 2D axial or transversal US view.

The gland is divided in 12 areas usually called quadrants (see fig. 2) and clinicians take sample in each quadrant of the prostate in order to obtain well-distributed biopsy samples. Clinicians generally start to perform the biopsy on one side of the prostate (starting by the base or the apex) and take six samples. Then, they do the other side symmetrically. The order of biopsy depends on clinicians’ habits. Learners have to learn how to biopsy a target or a “quadrant” of the prostate. Performing biopsy with assistance (3D
representation of the US plane and the prostate) can help users build a 3D mental representation.

Figure 2. Prostate scheme and the twelve quadrants (transverse view)

2.2. Biopsym simulator

The Biopsym simulator is a complete learning environment for prostate biopsy. Based on a first version of the simulator [14][15], the second version presented here is connected to a clinical database where patient cases can be added (see 4.1.2) and provides a complete realistic virtual environment, where the previously identified relevant for learning conditions of a prostate biopsy procedure are replicated.

2.2.1. System architecture. The simulator (see fig. 3) is running on a laptop computer connected, on one hand, to a haptic interface Phantom Omni (Sensible Devices Inc., MA, USA) and, on another hand, to a CamiTK-based graphical user interface software [16]. CamiTK is an open-source modular framework, developed to prototype Computer Assisted Medical Interventions applications. CamiTK viewers are used for data insertion and biopsy feedback. The simulator also uses Insight and Registration Toolkit (ITK) and Visualization Toolkit (VTK) libraries for data processing and representations. The interface is developed with Qt, which allows an intuitive manipulation of the software.

We use the OpenHaptic™ library provided by Sensible Devices Inc. to handle communication with the Phantom. The low-level library gives access to the haptic device configuration, which allows the simulator, for instance, to get the device position and orientation. The high-level library is used for haptic rendering, in order to provide force effects.

2.2.2. Databases.

Medical data. Patient data are collected and anonymized from the UroStation ® system (Koelis, France). This system gives us access to a complete database containing 3D US prostate volumes, MRI exams, prostate meshes and image fusion information that enable the registration of all these data in a single reference system. All TRUS images are acquired during a prostate biopsy procedure on patients who are suspected of cancer. Ultrasound image is acquired from an end-fire 3D TRUS probe.

Each patient case in the database is composed of clinical information (PSA, prostate volume, DRE and age), an ultrasound image (including a targeted area), an MRI image (including a targeted area) and a prostate mesh. After a process of data anonymization, a dozen patient cases were integrated into the simulator to offer a good sample of what can be expected in clinical practice. The database is not limited and new cases can be easily added through an administrator access.

User data. The user database contains information about the simulator users and records their biopsy results and exercise results. It allows users to access their personal performance (score, minimum and maximum score, average time, cumulated time and so on…). The purpose of this part of the database is to provide the users an overview of their improvement and trace of the training process. Extraction of these data will also allow statistical analysis to facilitate the evaluation of the simulator itself. Both databases are managed by the open source relational database management system MySQL (Oracle, CA, USA).

2.2.3. Simulator usage. The haptic device is used, as a motion tracker, the device stylus representing the virtual US probe (see fig. 4). The Phantom device provides a constant force to replicate the tissue friction.

Figure 3. Simulator architecture

Figure 4. Omni Phantom device

1 See http://camitk.imag.fr
The 2D TRUS image plane is displayed in real-time in function of the virtual probe orientation. Guided by the 2D TRUS image plane, the users move the probe to perform the biopsy. As in a real biopsy procedure, the needle guide is fixed on the US probe, the virtual guide position is defined directly from the stylus position and orientation. The fixed guide position displays the potential trajectory of the needle on the 2D TRUS image plane. Learners have to use the laptop’s keyboard to adapt the needle length and take a sample. The buttons on the Phantom stylus are not used.

2.2.4. Exercises. According to the previously led didactical study, we implemented various exercises, which allow each to develop an aspect of the required skills.

Specific exercises. Seven exercises have already been implemented to target different aspects of the surgical gesture and help understand hand-eye coordination using both the two-dimensional (2D) TRUS image and the virtual probe.

The first two exercises test basic knowledge about US image reading by asking the user to select the different anatomical structures on the image.

The third exercise also evaluates the US image knowledge and corresponding 3D representation by asking the user to measure the prostate volume.

The fourth exercise tests more fundamental urology knowledge by asking the user an estimation of the probability of positive biopsies based on clinical data.

Three other exercises are dedicated to targeted biopsy. Learners have to biopsy a target or a specific “quadrant” of the prostate. The target is previously defined during data integration in the database. One target is placed on the ultrasound image and another one is placed on the MR image. The targets are then displayed in the virtual 3D representation using MR-US image registration.

Each of these three exercises is divided into two levels of increasing difficulty. In the easier level, users perform the biopsy with assistance; it means that, in addition to the usual 2D TRUS image, a 3D representation of the prostate with the current probe plane position is displayed (see fig. 5). The 3D representation displays the prostate mesh as well as the position of the TRUS image slice. This representation helps to build a correct visualization of the TRUS image relatively to the prostate (see fig. 6).

Each exercise provides the users with a score representing their performance.

Virtual biopsy procedure. Finally, the simulator offers the ability to perform an entire virtual biopsy procedure. This exercise requires all the skills acquired during the various specific exercises and completely mimics the actual procedure performed clinically on patients.

The simulator can be configured to perform the biopsy with the patient either in decubitus position or in lateral position. Moreover, the initial view can be either the axial view or the sagittal view. Finally, biopsy order is chosen by the user at the beginning of the simulation (with the choice of a procedure starting at the prostate left central base, left lateral base, right central base, or right lateral base).

To improve the realism and educational interest, learners have to complete a pre-operative checklist before beginning the procedure, based on the checklist used in clinical practice. The assistance of the 3D visualization can also be provided in this exercise.

3. Results

The simulator we developed provides a complete learning environment and allows users to be evaluated.

The current state of the simulator can be visualized at http://www.youtube.com/watch?v=FeTtc5d_kQc (virtual assisted biopsy procedure) and http://www.youtube.com/watch?v=q5qlJUPbVmE (exercise with targeted biopsy).
3.1. Performance assessment

Once the learners have completed their biopsies, they can access their results by visualizing sample positions relatively to the 3D image of the prostate in a CamiTK 3D interactive viewer (see fig. 7). This visualization offers a precise feedback about the biopsy. For each sample, learners can access to the following information: (1) sample location in the ultrasound image and prostate mesh (biopsy mapping) (2) sample position relatively to the targeted quadrant (3) sample length inside the targeted quadrant. The success rate (given as the percentage of the sample positions in their targeted quadrants) is given.

The simulator also provides the biopsy duration and the number of non-biopsied quadrants. This allows the score to also take into account the duration of the procedure relatively to a reference duration as well as a coverage rate.

Using this information, we can evaluate the quality of the biopsy. The biopsy results are also saved in the same reference frame as the patient images, mesh and biopsy location. CamiTK facilitates the analysis of the results in order to assess the impacts of the simulator on physician training. The scoring system could be defined as a combination of precision, missed area, and duration relatively to simulations performed by experts and in collaboration with educational scientists.

![Figure 7. Result visualization](image)

3.2. Evaluation

The first exploratory evaluation was performed to obtain feedback on the software and the haptic device from a first set of users, and to demonstrate face validity. Eight non-clinicians (PhD and Masters students, researchers in computer assisted medical interventions) performed a virtual biopsy session with the simulator and filled an evaluation questionnaire. Six of them thought the simulation was close to what they imagined; the other two did not give an opinion. All of them thought the simulator was easy to use and intuitive, and thought the scoring of the performance was important.

The next step consisted in the evaluation of the simulator by clinicians. Novices (medical students) and experts (trained urologists) looked through the various exercises and educational contents and performed virtual biopsies on the simulator. Experts validated the content and suggested improvements notably in the realism of the ultrasound probe. The basic scoring system used did not significantly discriminate between a limited sample (n=21) of novices and experts and will have to be improved and validated on a larger population.

4. Discussion

As mentioned before, our aim is to reach the exact level of realism that serves our training goals. Thereby, more realism could be achieved by including prostate deformations due to the probe. A model of prostate deformation under TRUS examination would have to be developed in order to compute in real-time the prostate movements and distortions. Whether this could improve the simulation realism would also have to be evaluated.

We chose to use the keyboard to fire the virtual needle to force the use of both hands, as it is the case during a real procedure.

The different exercises have been implemented. A decision-making system which can automatically provide the best exercise depending on previous results of a given user has been described [13]. It would provide the creation of personalized learning paths and also has to be implemented.

To evaluate the educational interest, an evaluation is scheduled in 2013 among a population of novices (medical students), in order to compare the learning of the prostate biopsy procedure with or without the use of the simulator.

5. Conclusion

In this paper, we have described a complete training simulator for TRUS prostate biopsy. In a realistic virtual environment, learners can perform the complete prostate biopsy procedure.

We have worked on didactical aspects of the simulator to analyze training needs and develop exercises targeting multiple tasks of the gesture.

A complete evaluation is scheduled to attest for the clinical interest of our simulator.

The development of this simulator meets the training needs for augmented-surgery systems such as the Urostation®, which provide access to new data,
especially the fusion between medical imaging modalities. Besides, virtual reality based simulators give the clinicians a first experience of robotic systems and computer-assisted medical systems.

The evaluation of the educational value of the simulator and the transfer of the acquired skills to an actual patient would conclude the validation of the simulator, with the aim of obtaining a reliable tool for initial training, evaluation and certification, for conventional randomized biopsies or targeted biopsies with assistance.

6. Acknowledgments

This work was supported by French state funds managed by the ANR within the Investissements d’Avenir programme (Labex CAMI) under reference ANR-11-LABX-0004, the Association Française d’Urologie - AstraZeneca (grant G.Fiard) and by INSERM CHRT (grant J.Troccaz). We want to thank Dr Pierre Mozer, from La Pitié Salpêtrière Hospital, Paris, for his strong involvement in the early versions of Biopsym and Koelis for giving us access to internal data structures of the Urostation®.

7. References


11. Copyright forms and reprint orders
A virtual reality simulator combining a learning environment and clinical case database for image-guided prostate biopsy

COMPLETE LIST OF AUTHORS:
Sonia-Yuki Selmi, Gaelle Fiard, Emmanuel Promayon, Lucile Vadcard, Jocelyne Trocza

IEEE PUBLICATION TITLE (Journal, Magazine, Conference, Book):
IEEE International Symposium on Computer-Based Medical Systems (CBMS 2013)

CONSENT AND RELEASE
1. The undersigned hereby assigns to The Institute of Electrical and Electronics Engineers, Incorporated (the “IEEE”) all rights under copyright that may exist in and to:
   (a) the above Work, including any revised or expanded derivative works submitted to the IEEE by the undersigned based on the Work; and (b) any associated written or multimedia components or other enhancements accompanying the Work.

2. In the event the undersigned makes a presentation based upon the Work at a conference hosted or sponsored in whole or in part by the IEEE, the undersigned, in consideration for his/her participation in the conference, hereby grants the IEEE the unlimited, worldwide, irrevocable permission to use, distribute, publish, license, exhibit, record, digitize, broadcast, reproduce and archive, in any format or medium, whether now known or hereafter developed:
   (a) his/her presentation and comments at the conference;
   (b) any written materials or multimedia files used in connection with his/her presentation; and
   (c) any recorded interviews of his/her (collectively, the “Presentation”). The permission granted includes the transcription and reproduction of the Presentation for inclusion in products sold or distributed by IEEE and live or recorded broadcast of the Presentation during or after the conference.

3. In connection with the permission granted in Section 2, the undersigned hereby grants IEEE the unlimited, worldwide, irrevocable right to use his/her name, picture, likeness, voice and biographical information as part of the advertisement, distribution and sale of products incorporating the Work or the Presentation, and releases IEEE from any claim based on right of privacy or publicity.

4. The undersigned hereby warrants that the Work and Presentation (collectively, the “Materials”) are original and that he/she is the author of the Materials. To the extent the Materials incorporate test passages, figures, data or other material from the works of others, the undersigned has obtained any necessary permissions. Where necessary, the undersigned has obtained all third party permissions and consents to grant the license above and has provided copies of such permissions and consents to IEEE.

☐ Please check this box if you do not wish to have video/audio recordings made of your conference presentation. See reverse side for Retained Rights/Terms and Conditions, and Author Responsibilities.

GENERAL TERMS
- The undersigned represents that he/she has the power and authority to make and execute this assignment.
- The undersigned agrees to indemnify and hold harmless the IEEE from any damage or expense that may arise in the event of a breach of any of the warranties set forth above.
- In the event the above work is not accepted and published by the IEEE or is withdrawn by the author(s) before acceptance by the IEEE, the foregoing copyright transfer shall become null and void and all materials embodying the Work submitted to the IEEE will be destroyed.
- For jointly authored Works, all joint authors should sign, or one of the authors should sign as authorized agent for the others.

(1) ___________________________ ___________________________ 02/21/2013
Author/Authorized Agent for Joint Authors Date

U.S. GOVERNMENT EMPLOYEE CERTIFICATION (WHERE APPLICABLE)
This will certify that all authors of the Work are U.S. government employees and prepared the Work on a subject within the scope of their official duties. As such, the Work is not subject to U.S. copyright protection.

(2) ___________________________ ___________________________
Authorized Signature Date

(Authors who are U.S. government employees should also sign signature line (1) above to enable the IEEE to claim and protect its copyright in international jurisdictions.)

CROWN COPYRIGHT CERTIFICATION (WHERE APPLICABLE)
This will certify that all authors of the Work are employees of the British or British Commonwealth Government and prepared the Work in connection with their official duties. As such, the Work is subject to Crown Copyright and is not assigned to the IEEE as set forth in the first sentence of the Copyright Transfer Section above. The undersigned acknowledges, however, that the IEEE has the right to publish, distribute and reprint the Work in all forms and media.

(3) ___________________________ ___________________________
Authorized Signature Date
IEEE COPYRIGHT FORM (continued)

RETAINED RIGHTS/TERMS AND CONDITIONS

General
1. Authors/employers retain all proprietary rights in any process, procedure, or article of manufacture described in the Work.
2. Authors/employers may reproduce or authorize others to reproduce the Work, material extracted verbatim from the Work, or derivative works for the author’s personal use or for company use, provided that the source and the IEEE copyright notice are indicated, the copies are not used in any way that implies IEEE endorsement of a product or service of any employer, and the copies themselves are not offered for sale.
3. In the case of a Work performed under a U.S. Government contract or grant, the IEEE recognizes that the U.S. Government has royalty-free permission to reproduce all or portions of the Work, and to authorize others to do so, for official U.S. Government purposes only, if the contract/grant so requires.
4. Although authors are permitted to re-use all or portions of the Work in other works, this does not include granting third-party requests for reprinting, republishing, or other types of re-use. The IEEE Intellectual Property Rights office must handle all such third-party requests.
5. Authors whose work was performed under a grant from a government funding agency are free to fulfill any deposit mandates from that funding agency.

Author Online Use
6. Personal Servers. Authors and/or their employers shall have the right to post the accepted version of IEEE-copyrighted articles on their own personal servers or the servers of their institutions or employers without permission from IEEE, provided that the posted version includes a prominently displayed IEEE copyright notice and, when published, a full citation to the original IEEE publication, including a link to the article abstract in IEEE Xplore. Authors shall not post the final, published versions of their papers.
7. Classroom or Internal Training Use. An author is expressly permitted to post any portion of the accepted version of his/her own IEEE-copyrighted articles on the author’s personal web site or the servers of the author’s institution or company in connection with the author’s teaching, training, or work responsibilities, provided that the appropriate copyright, credit, and reuse notices appear prominently with the posted material. Examples of permitted uses are lecture materials, course packs, e-reserves, conference presentations, or in-house training courses.
8. Electronic Preprints. Before submitting an article to an IEEE publication, authors frequently post their manuscripts to their own web site, their employer’s site, or to another server that invites constructive comment from colleagues. Upon submission of an article to IEEE, an author is required to transfer copyright in the article to IEEE, and the author must update any previously posted version of the article with a prominently displayed IEEE copyright notice. Upon publication of an article by the IEEE, the author must replace any previously posted electronic versions of the article with either (1) the full citation to the IEEE work with a Digital Object Identifier (DOI) or link to the article abstract in IEEE Xplore, or (2) the accepted version only (not the IEEE-published version), including the IEEE copyright notice and full citation, with a link to the final, published article in IEEE Xplore.

INFORMATION FOR AUTHORS

Author Responsibilities
The IEEE distributes its technical publications throughout the world and wants to ensure that the material submitted to its publications is properly usable to the readership of those publications. Authors must ensure that their Work meets the requirements as stated in section 8.2.1 of the IEEE P802 Operations Manual, including provisions covering originality, authorship, author responsibilities and author misconduct. More information on IEEE’s publishing policies may be found at http://www.ieee.org/publications_standards/publications/rights/pubtools_policies.html. Authors are advised especially of IEEE P802 Operations Manual section 8.2.1.B12: “It is the responsibility of the authors, not the IEEE, to determine whether disclosure of their material requires the prior consent of other parties and, if so, to obtain it.” Authors are also advised of IEEE P802 Operations Manual section 8.1.1B: “Statements and opinions given in work published by the IEEE are the expression of the authors.”

Author/Employer Rights
If you are employed and prepared the Work on a subject within the scope of your employment, the copyright in the Work belongs to your employer as a work-for-hire. In that case, the IEEE assumes that when you sign this Form, you are authorized to do so by your employer and that your employer has consented to the transfer of copyright, to the representation and warranty of publication rights, and to all other terms and conditions of this Form. If such authorization and consent has not been given to you, an authorized representative of your employer should sign this Form as the Author.

IEEE Copyright Ownership
It is the formal policy of the IEEE to own the copyrights to all copyrightable material in its technical publications and to the individual contributions contained therein, in order to protect the interests of the IEEE, its authors and their employers, and, at the same time, to facilitate the appropriate re-use of this material by others. The IEEE distributes its technical publications throughout the world and does so by various means such as hard copy, microfiche, microfilm, and electronic media. It also abstracts and may translate its publications, and articles contained therein, for inclusion in various compendiums, collective works, databases and similar publications.

THIS FORM MUST ACCOMPANY THE SUBMISSION OF THE AUTHOR’S MANUSCRIPT. Questions about the submission of the form or manuscript must be sent to the publication’s editor. Please direct all questions about IEEE copyright policy to:
IEEE Intellectual Property Rights Office, copyrights@ieee.org, +1-732-562-3966 (telephone)

8