Design and evaluation of an immersive ultrasound-guided locoregional anesthesia simulator

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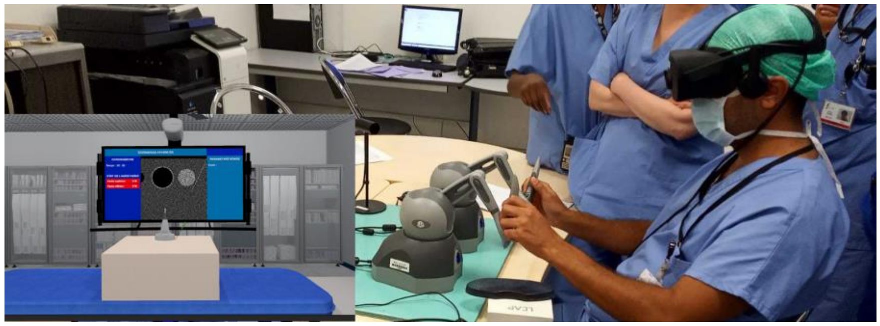

Figure 1: The user interface of the immersive ultrasound-guided locoregional anesthesia simulator. (Bottom left) The Virtual scene with the virtual instruments manipulated by the user and the ultrasound screen displays the ultrasound image.

Abstract

We present the design and evaluation of an immersive ultrasound-guided locoregional anesthesia simulator. A face and content validation study with eighteen anesthesiologists was conducted. The results show that the developed system is a promising tool suited for developing hand-eye coordination skills. On the other hand, the study raised some issues related to the fidelity of the haptic feedback. These findings support our design choices and suggest improvements before the validation of the simulator.

Keywords: Medical training, Immersive simulation, User-centered design, Simulator validity.

1 Introduction

During the last few years, medical training has evolved to increase patients' safety by including more simulation tools during the education curricula.

Anesthesiology is among medical specialties impacted by these changes. Locoregional anesthesia (LRA) is one of the anesthesiology techniques that aims to temporarily paralyze a peripheral motor block by blocking musculo-nervous conduction. It only concerns one part of the body, such as the leg or the arm. This technique permits to limit postoperative pain and facilitates patient rehabilitation. The recent evolutions of this technique recommend using ultrasound images to guide the needle insertion, leading to fewer complications and failures [1]. On the other hand, these new practices require mastering additional technical skills, which has created a strong demand for interns and experts training.

Virtual Reality (VR) technologies have demonstrated their effectiveness in medical training [2, 3, 4] and can be promising for training LRA operators. However, the development of such tools is often based on superficial visual characteristics, which have a limited impact on the acquisition of the target skills [5]. Therefore, rigorous design and evaluation methods are required to ensure that the virtual simulators capture the essential characteristics of the real-world environment and the task to be learned and generate realistic behaviors from learners [5]. For that, iterative user-centered design approaches have been successfully used to meet the needs of virtual simulators' users [6, 7].

This paper presents the design and evaluation of an immersive simulator for training ultrasound-guided LRA operators. The system design and evaluation were carried out in collaboration with field experts following a user-centered approach.

The objective of this work is twofold. On the one hand, it informs about the design process of a VR simulator for training technical, medical skills. On the other hand, it presents the evaluation results of the system's prototype to validate some of its aspects and guide the next steps of its development.

2 Related work

2.1 Validity of simulators

Validity is the extent to which a test, model, simulation, or other reproduction provides an accurate representation of its real-world counterpart [5]. The validation of a medical simulator requires five steps [8]:

1- Face validity: represents an anesthetic assessment based on the interface appearance and its differences with the real-world environment.
2- Content validity: evaluates the accuracy and relevance of the content offered by the simulator.
3- Construct validity: ensures that the simulator manages to differentiate the performance of a novice from that of an expert.
4- Concurrent validity: checks if the simulator is similar to its competitors in the field.
5- Predictive validity: verifies that the performances obtained on the simulator are similar to those obtained in the real-world situation.

Each of these validation steps verifies an essential aspect of the system. Therefore, the complete validation of a simulator is a slow and incremental process that requires extensive studies.

2.2 Locoregional anesthesia simulators

Medical simulators are designed to replicate a working medical environment such as an operating room. We present in the following a review of existing LRA training simulators. These systems will be separated into two main categories: physical simulators and virtual simulators.

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Physical simulators are synthetic models reproducing all or part of the anatomy. Their fidelity varies according to the training needs. Low-fidelity simulators, also called part-task trainers, are task-focused and aim to train basic technical and psychomotor skills, such as bimanual dexterity and hand-eye coordination [6]. The skills learned separately can then be combined to perform the complete procedure. For instance, the Blue Phantom Select (Blue Phantom) is used to practice basic LRA skills. This minimalist model consists of a block of soft silicone tissue containing small tubular structures representing vessels and nerves. It also has a fluid management system that mimics blood flow when vessels are punctured. Other non-commercial prototypes have also been proposed in the literature [9, 10].

These low-fidelity simulators generally have a low acquisition cost [11, 7]. However, they also have many disadvantages. First, their reusability is limited [6, 12, 7, 13]. They also include only a few scenarios difficult to customize for a particular case. Moreover, they do not provide objective measurements to assess learners' performance [14, 15]. Finally, they often lack tactile sensations and realistic haptic feedback [16]. These drawbacks have limited these systems' large-scale adoption, validation, and use [16, 17].

Virtual simulators simulate the medical environment through computer-generated 3D models and include physical interfaces to interact with these models. They have many advantages for medical training. Indeed, they allow for repeated training sessions with different scenarios, including progressive and personalized difficulty levels [18] or contextualized cues to help the learner throughout the simulation. They also provide the learners with objective measurements recorded automatically by the system [8, 15] to give appropriate feedback on their performance and learning curves [3]. However, they also have some drawbacks. Indeed, although it is currently relatively easy to obtain a realistic visual rendering, providing realistic haptic feedback is much more complex [19, 18]. Moreover, their acquisition cost is often very high, especially when including haptic interfaces [12]. Finally, although validation studies exist, very few simulators have been adopted as standard medical training tools [20, 7].

Several virtual systems have been proposed for training LRA skills. For instance, Bibin et al. [21] have developed SAILOR, a VR simulator for LRA incorporating realistic visual rendering, simple mouse interactions, and pseudo-haptic feedback when interacting with tissues. Ulrich et al. [22] have presented RASim, a virtual LRA simulator based on a 3D stereoscopic screen displaying the tools and the limb, and a haptic arm to manipulate the virtual needle. A similar interface was used by Grottke et al. [23] in their LRA simulator, which supports the generation of personalized scenarios using patients' specific data. Only preliminary subjective evaluations of these systems have been conducted [24]. In addition, they do not include ultrasound guidance which limits their use for LRA procedures that comply with current practices [25]. In this context, Vidal et al. [26] have proposed a virtual simulator to perform an ultrasound-guided puncture in interventional radiology. The user interface includes a stereoscopic screen displaying a 3D limb and two haptic arms to manipulate the virtual needle and the ultrasound probe. Face and content validation studies were conducted on the system [27] only with novices making it challenging to assess its validity. Alamilla-Daniel et al. [28] have recently proposed a virtual simulator for ultrasound-guided interarticular infiltration. The user interface comprises two haptic arms to control the ultrasound needle and probe and a simple computer screen for visualizing the virtual scene. No user study has been conducted to evaluate this system.

To summarize, physical simulators are affordable but have several disadvantages. Although virtual simulators offer an alternative to overcome some of these drawbacks, existing systems integrate user interfaces with a moderate level of fidelity. In addition, very few systems currently combine ultrasound with needle insertion, which is a strongly recommended practice for performing LRA currently. Finally, very few validity studies have been carried out on the proposed systems. Therefore, it seems necessary to us to go further by proposing a new virtual simulator for training ultrasound-guided LRA skills.

3 Design and Development of the System

3.1 Analysis of the procedure

The analysis of the LRA procedure was carried out by combining several approaches. First, we have visualized ten public educational videos showing expert anesthesiologists performing this procedure and explaining their practice by commenting on the videos. Second, we have consulted a reference document dedicated to teaching anesthesia interns how to perform different types of LRA, including the femoral nerve block [29]. Finally, we have observed three ultrasound-guided LRA procedures of the femoral nerve block (FNB) in the field, followed by interviews of the performing experts. Combining these approaches made it possible to carry out a hierarchical task analysis of the ultrasound-guided LRA procedure of the FNB, validated by the experts (Figure 2).

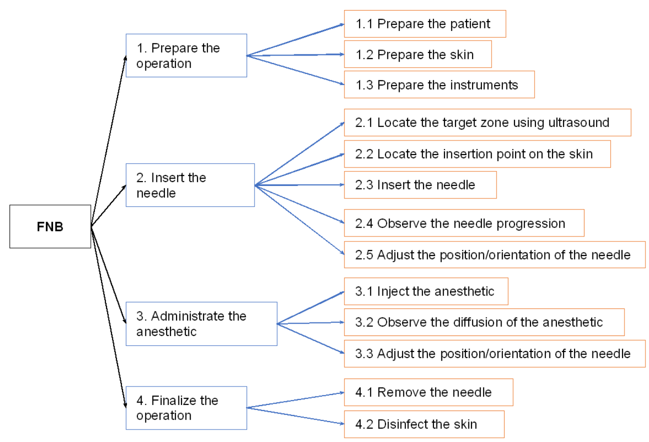

Figure 2: Hierarchical task analysis for the FNB (blue: the steps; red: the related tasks)

3.2 Analysis of skills

To define the ultrasound-guided LRA skills to be trained through our simulator, a focus group session was conducted with two expert anesthesiologists. During this session, the experts were asked to associate technical skills with the tasks identified during the hierarchical task analysis and give their opinion on the relevance of training them through the virtual simulator. Subsequently, the following technical skills for performing ultrasound-guided LRA were identified:

- Placing and orienting the ultrasound probe correctly to visualize the different anatomical structures (veins, arteries, nerves, bones, etc.),
- Locating and identifying these structures on the ultrasound image and planning the needle trajectory,
- Inserting and removing the needle according to an appropriate trajectory,
- Coordinating the movements of each of his hands (one to manipulate the probe, the other to insert the needle) while having his eyes focused on the ultrasound image,
- Injecting the anesthetics in the correct location.

Among these skills, hand-eye coordination was highlighted by experts to be an essential skill to acquire. It was therefore chosen to be the primary training objective of our simulator. The design process focused then on step 2 (insert the needle), step 3 (administer the anesthetics), and the associated subtasks (Figure 2).

3.3 System design

Two focus group sessions were carried out with the two experts to guide the system's design. The choices of the various components of the simulator are described and discussed hereafter.

The virtual simulator must have high interface fidelity for interactions directly related to learning the technical skills targeted by the simulator, as suggested by previous studies [7]. Based on our task analysis, the user must be able to perform the following interaction tasks on the simulator:

1- Visualizing the environment with the possibility of changing the viewpoint,
2- Handling the ultrasound probe,
3- Manipulating of the anesthesia needle,
4- Injecting of the anesthetic product.

Among these tasks, the visualization and the two manipulation tasks are directly related to hand-eye coordination. Therefore, our objective was to design high-fidelity interactions to perform them.

Therefore, two haptic arms were used for manipulating the needle (task 3) and the ultrasound probe (task 2). This allows the user to have a natural tool handling and perform movements over 6 degrees of freedom (DOF) to control instruments directly. They also provide force feedback related to the interaction of the instruments with the tissues. Indeed, several studies have shown the importance of this feedback for learning technical skills in medicine [30, 31, 32]. The haptic feedback on the ultrasound probe sliding on the skin is necessary to position the ultrasound probe correctly. In addition, the haptic feedback during the needle penetration inside the tissue is required to guide the movement.

A VR HMD is used to immerse users in the virtual environment that includes the patient body and the ultrasound screen (Figure 1). The HMD allows the user to change their point of view (task 1) naturally by moving their head. In addition, the real user's hands can be collocated with the virtual hands in the virtual environment. This is in line with previous studies suggesting that the co-localization of the user's hands and controlled tools positively impacts performance in VR manipulation tasks [33, 34, 35].

The virtual simulator can have moderate environment fidelity [7]. The anesthesiologists explained that they do not look at the patient's body during the needle insertion and that their attention is exclusively focused on the ultrasound screen. Therefore, similar to existing part-task physical simulators (ex. Blue Phantom), only a simplified knee of the virtual patient represented by a rectangular parallelepiped was included in the virtual scene (Figure 3). Indeed, this is the only body part with which the anesthetist interacts during the FNB. Nevertheless, this model contained three structures (Figure 3): the femoral nerve, the femoral artery, and the femoral vein to provide the realistic anatomical representation necessary for the realization of the procedure.

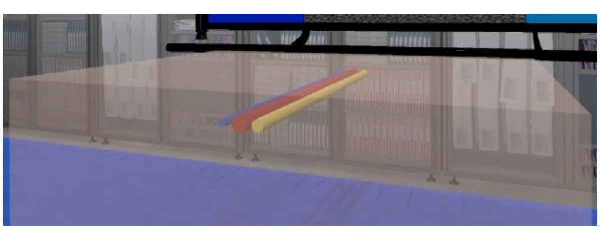

Figure 3: The rectangular parallelepiped (in transparency) representing the knee and containing three tubes representing the femoral nerve (on the right), the femoral artery (in the middle), and the femoral vein (on the left)

We did not include the user's virtual hands but only the instruments he handles, as suggested by previous studies [36, 37] and by the experts who explained that they do not look at their hands during the procedure. Finally, the virtual scene also included the instruments, an ultrasound screen, and a hospital bed (Figure 1).

The application was developed on the Unity 3D game engine. An Oculus Rift HMD was used for visualization and two Geomagic Touch haptic devices for manipulating the instruments. These devices have 6 DOF for position and 3 DOF for force feedback.

4 FACE AND CONTENT VALIDATION OF THE SYSTEM

A user study was carried out to validate the face and content of the simulator. A total of 18 anesthesiologists (11 males, 7 females; 17 right-handed) aged 32 to 69 years (44.16±11.28 years) participated in the study. All of them had minimal experience with VR and haptic devices. They were divided into two groups according to their level of expertise in performing ultrasound-guided LRA: 7 experts (including two females) and 11 beginners (including 5 females). The study was validated by the Research Ethics Committee (CER) of Université Paris Saclay.

The experimental procedure consisted of sessions of 20 min long on average per participant. Upon arrival, the participant had to read and sign the informed consent form and complete a demographics questionnaire. After that, the experimenter explained the study's objective and presented the simulator and how it works. The participant had to sit comfortably, put on the VR headset, grab the haptic interfaces, and freely test the system.

After this familiarization phase, the test of the simulator began. During this test, the participant was instructed to perform the needle insertion task guided by the ultrasound image to perform an LRA. To do this, he had to explore the interior of the virtual body and locate the femoral nerve while identifying the adjacent structures. Then he had to choose an entry point and insert the needle. Once he got close enough to the nerve, he had to inject the anesthetic and follow its spread around the nerve.

The test ended when the participant removed the needle from the virtual body. The participants were not required to finish this test because the main objective was to obtain subjective feedback on the appearance and content of the simulator. Immediately after the test, they successfully answered the face and content validity questionnaires. These questionnaires are inspired by recent studies on the validation of other VR simulators [13, 38, 39]. The face validation questionnaire is composed of 11 questions with a 5-point Likert scale, and the content validation questionnaire is composed of 6 questions and a 5-point Likert scale. Finally, the participants were allowed to make free comments on their experience with the system and the potential improvements of the prototype.

5 RESULTS

The answers to the face validation questionnaire are summarized in Figure 4. The scores were generally moderate to positive (37.66% of experts' answers and 31.40% of novices' answers have a score greater than 3).

The lowest scores were obtained for the question regarding the "realism of the needle haptic feedback." In contrast, the highest scores were obtained for the question on "the realism of the virtual environment" and "the realism of vein deformation".

The answers to the content validation questionnaire are summarized in Figure 5. The scores were generally positive (66.66% of experts' answers and 59.09% of novices' answers have a score above 3.

The lowest scores were obtained for the question regarding "the simulator being sufficient to train LRA." The other questions received higher average scores, with the highest scores for "the simulator being a promising training tool" and "the simulator adapted for developing hand-eye coordination skills."

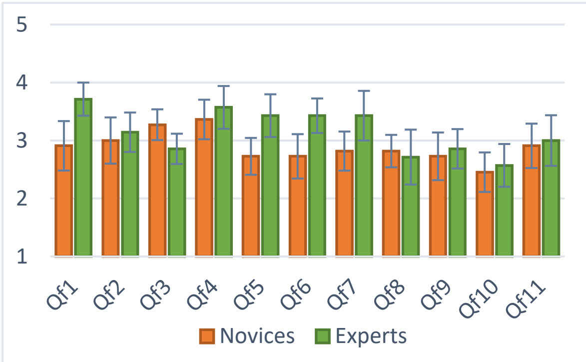

Figure 4: Answers to the face validation questionnaire (error bars represent the standard error)

Regarding the complimentary comments, several participants reported a lack of support of their arms when manipulating the haptic devices, which increased fatigue and decreased the accuracy of the movements. The experts also noted that the force amplitudes displayed during the lateral displacement of the probe on the skin were too low compared to the real world. Additionally, although the needle force feedback before and during skin penetration was satisfactory, several participants reported that the force amplitudes were too low once the needle had passed the skin surface, thus making the movements too fast and less accurate.

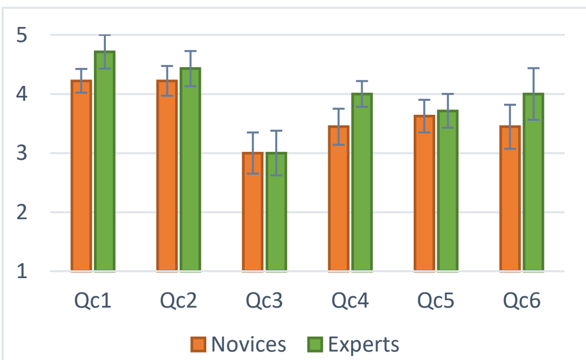

Figure 5: Answers to the content validation questionnaire (error bars represent the standard error)

6 Discussion and Future Works

The objective of our study was to evaluate the face and content validity of our system aimed to train hand-eye coordination skills for ultrasound-guided LRA. Although the face and content validity are usually evaluated by field experts [8], the participation of novices was helpful to obtain feedback from the potential future users of this system (the trainees).

Overall, the participants' feedback was positive. However, the haptic components generated some skepticism from the participants due to the lack of fidelity of the force feedback during needle insertion. A hardware limitation can justify this issue since the used haptic arm supports force feedback only on 3-DOF (on translation). Using a higher fidelity device with 6-DOF of force feedback could improve the haptic feedback fidelity but will considerably increase the simulator price. Additional studies will be necessary to validate this choice.

As suggested by the participants, the integration of armrests to support the user's arms during the procedure will also improve the system's ergonomics.

The involvement of field experts throughout the design process provided beneficial feedback for choosing the components of the system. Still, it did not allow us to identify all the issues of the prototype. The user study on the prototype permitted to offer a hands-on experience to other users of the system, which provided additional feedback to improve the system. For example, haptic sensations are difficult to describe verbally [7]. Allowing anesthesiologists to test the simulator permitted them to compare the force feedback returned by the system with those learned during their field experiences and to describe the relative differences more easily. This approach was very enriching and valuable for pointing out the problems related to the fidelity of the system interface and improving them during the following iterations.

The results of this study lead to the conclusion that the developed simulator is a promising training tool for developing hand-eye coordination skills. However, problems related to the fidelity of the interface and ergonomics have been identified. An improvement of these elements is necessary before validating the system.

Once these improvements have been operated, new evaluation studies will be carried out to validate the other aspects of the simulator: its ability to distinguish between novices and experts (construct validity), its similarity with current training standards (concurrent validity), and its ability to transfer the learned skills to the real world (predictive validity).

The system validation will provide the LRA operators with an alternative and will complement the current education methods while improving practices and ensuring patient safety.

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