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Design and evaluation of UltRASim: an immersive simulator for learning ultrasound-guided regional anesthesia basic skills

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Abstract

Virtual reality shows great promise as a technology for training healthcare professionals within a secure simulated environment. This work presents the design, development, and assessment of UltRASim: an immersive simulator for ultrasound-guided regional anesthesia. First, task and skills analyses were performed with domain experts to build the task model of the procedure and determine the simulator's learning objectives and design constraints. Then, a face and content validity study was conducted with eighteen anesthesiologists to assess the simulator's prototype. The responses to seven of eleven face validity questions were predominantly positive, indicating a favorable reception. The primary concerns pertained to the fidelity of haptic feedback during needle insertion. This suggests incorporating a higher fidelity haptic device in future design iterations. Conversely, responses to all six questions related to the content validity were predominantly positive. Participants found that the simulator held significant potential as a training tool, particularly for developing hand-eye coordination skills. These findings validate several design choices and highlight areas for improvement in subsequent iterations of UltRASim before its formal validation as a training tool.

Keywords: Immersive simulation, Medical training, Simulator fidelity, Haptic feedback, Ultrasound-guided regional anesthesia

1. Introduction

The training of healthcare personnel is a critical concern within the medical field, as it directly impacts patient safety. Traditionally, training has relied on a companionship model, which combines theoretical lessons with observations of experienced practitioners, followed by hands-on practice on patients, animals, or cadavers [1, 2]. However, this approach raises ethical and patient safety issues [3, 4, 5]. Recognizing this, the French High Authority for Health published a report [6] emphasizing the importance of "never the first time on a patient". This

led, in 2018, to significant reforms in medical studies in France, encouraging a shift towards innovative training methods that do not put patients at risk. This created an urgent need to develop simulation-based tools to support medical training.

One medical specialty significantly impacted by these reforms is anesthesiology. This field involves administering anesthesia to eliminate pain and motor reactions before surgical procedures. More precisely, regional anesthesia targets specific nerve blocks in a localized part of the body (such as the arms or legs), temporarily blocking the nerves' ability to transmit information. The advantage is that the patient can stay awake during surgical procedures and recover faster [7]. However, this approach requires complex technical skills due to the proximity of the target nerves to vital structures such as blood vessels, organs, and the nerves themselves. Hence, incorpo-

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Figure 1: The user interface of UltRASim including a head-mounted display with two tracking cameras to visualize the virtual scene and two haptic devices to control the virtual instruments. (Top left) The virtual scene as seen by the user with the virtual instruments manipulated by the user and the ultrasound screen displaying the ultrasound image.

rating simulation into regional anesthesia training seems natural and essential. Additionally, ultrasound for needle guidance in regional anesthesia has become increasingly prevalent, leading to a high demand for training in this imaging modality among interns and experienced practitioners [8]. Thus, training guidelines have been published to highlight the significant role of simulation in this specialty [9].

In this context, virtual reality (VR) emerges as a valuable tool for acquiring the technical skills necessary for ultrasound-guided regional anesthesia (UGRA). VR technology has already proven effective in medical training [10, 11, 12], as it immerses learners in realistic environments, enables the practice of various scenarios, and allows for repeated practice until skills are mastered—all while avoiding risks for real patients.

However, developing these tools is challenging and potentially expensive [13], with a need for more guidelines for their design. Additionally, their evaluation often confuses presentation with system functionality, relying heavily on superficial visual features that do not impact the acquisition of target skills [14]. Therefore, adopting these technologies for training requires a rigorous design and validation approach to demonstrate that the virtual simulation accurately captures the essential charac-

teristics of the real environment and the task to be learned while generating realistic behaviors from learners [14].

This work presents the design and evaluation of UltRASim: Ultrasound-guided Regionale Anesthesia immersive Simulator (Figure 1), aiming at learning basic UGRA skills [15]. The task and skills analysis and the system design were conducted in collaboration with expert anesthesiologists, following a user-centered approach guided by the concept of simulator fidelity.

The objective of this work is twofold. First, it informs about the UGRA practice, the learners' needs, and the design process of UltRASim. Second, it presents the results of evaluating the first prototype of the system, validating certain aspects, and guiding the next steps of its development. The contributions of this work are as follows:

- Presenting the task, skills analyses for the UGRA procedure, and the design requirements of UltRA-Sim,
- 2. Designing the simulator's components in collaboration with domain experts and following guidelines based on the concept of simulator fidelity,
- Evaluating the face and content validity of the simulator with experts and novices and extracting recommendations for future design iterations.

2. Related Work

2.1. Fidelity and validity of simulators

Fidelity and validity are fundamental for evaluating and adopting simulators as training tools. We present in the following a brief review of these two concepts.

2.1.1. Simulator validity

Validity refers to the degree to which a test, model, simulation, or other reproduction accurately represents its real-life counterpart [14]. For instance, a valid simulation effectively accurately represents the intended task, considering the specific learning objectives and the target population's characteristics. It is important to note that validity does not necessitate an exact replica of the real situation. Instead, the simulation should capture the essential characteristics of the task and the real environment. In the context of medical simulation, the validation process typically involves five steps [16]:

Face validity, an aesthetic validation based on the system appearance and its difference from the real device. Content validity, which assesses the accuracy and relevance of the content offered by the simulator. These two steps are carried out by experts based on a detailed system examination. Construct validity aims to ensure that the simulator differentiates novices' performance from that of experts. The concurrent validity verifies whether the simulator is equivalent to its competitors in the field. Finally, the predictive validity verifies that the performances obtained on the simulator are similar to those obtained in real situations. Each validation step verifies a critical aspect of the system. Therefore, the complete validation of a simulator is a slow and gradual process requiring numerous studies.

2.1.2. Simulator fidelity

It is commonly accepted that, to create simulators that enable the transfer of skills to the real world, a strong connection between the simulation environment and the actual environment is necessary [17]. This introduces the concept of simulator fidelity. Considering the training objectives of a simulator, fidelity can be defined as the similarity between the skills taught in a simulator and those used in the real-world [18]. Since introducing the term fidelity, many researchers have proposed different dimensions related to this concept to evaluate their simulators.

The variety of domains and presented simulators makes a classification that encompasses all the dimensions in the literature difficult. In addition, depending on the context, certain fidelity aspects may have more or less importance for the objectives and performance of a simulator. Finally, a consensus has yet to be found to determine the exact role of simulator fidelity in medical training and, more importantly, the role of each dimension in transferring skills to the real world [13].

In this context, we will refer to the model presented by Waller and Hunt [19], which differentiates between two aspects of fidelity: interface fidelity and environmental fidelity. *Interface fidelity* is defined as the degree to which the input and output interaction devices used in the simulator operate in the same way as if the learners were interacting with the real world. This dimension is central in transferring skills to the real world [20]. It is affected by the ease of interaction and the user's level of control over the system [17]. For example, effective interaction requires that any action by the operator in the virtual environment (VE) generates an instantaneous and consistent multimodal response from the system.

On the other hand, environment fidelity is related to the realism of the simulation [17]. It is defined as the degree of correspondence between the real world and the simulated environment [19]. This dimension depends on a subjective judgment of similarity between these two environments rather than a quantifiable correspondence between the values of the variables. It is affected by the quality of the system's visual, auditory, and haptic rendering. However, the realism of the environment should be a means to serve the specific educational objectives of the system and not a goal of its design [21]. Thus, environment fidelity should be used to positively affect interface fidelity [13].

Although these two dimensions can be used to guide VR simulator design, there currently needs to be more specific guidelines to achieve their appropriate levels for medical simulators. While it may seem intuitive that medical skills transfer is guaranteed when the real and simulated environments are indistinguishable, effective and efficient training can still be achieved with low-fidelity simulators [22, 23]. Moreover, high-fidelity simulators are currently relatively expensive. This raises several questions. For example, how low can fidelity levels be set? What elements should be included in a simulator, and

should all features have the same level of fidelity? Does lower fidelity in certain aspects impact learners' performance and ability to transfer skills to real-world scenarios?

The present work does not aim to provide definitive answers to these questions. Nevertheless, it will rely on the existing literature on fidelity to guide the design process and the selection of elements for our simulator. To achieve this, a user-centered design approach is employed, involving inputs from expert anesthetists in determining the features to be incorporated into the simulator and their corresponding fidelity levels. Furthermore, the evaluation of the simulator will adhere to the principles of validity and follow the validation steps mentioned above. The aim is to create and validate a system that better meets the practitioners' needs using an evidence-based methodology.

17 2.2. Simulators for medical training

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Medical simulators are designed to emulate various working environments, replicating specific aspects of a task or recreating an entire environment, such as an operating room. We will explore some of the existing literature on medical simulators, emphasizing those designed for UGRA. These simulators can be divided into two families: physical and virtual simulators.

2.2.1. Physical simulators

These simulators utilize mannequins and synthetic models that reproduce all or part of the anatomy. Their fidelity is variable according to the specific learning requirements.

High-fidelity simulators enable learners to practice entire procedures [24]. They often possess a high visual fidelity that can accurately mimic the human body in its entirety or certain aspects. Nonetheless, these simulators tend to be costly due to their intricate functionality, which limits their widespread utilization in training centers and teaching hospitals.

Low-fidelity simulators, known as part-task trainers, concentrate on specific tasks and aim to develop fundamental technical and psychomotor skills [25]. These skills are learned separately and later integrated to perform a complete procedure. An example of these systems is the Blue Phantom Select (Blue Phantom), utilized for acquiring basic UGRA technical skills. This simplified

model comprises a soft silicone tissue block containing small tubular structures representing vessels (veins, arteries, etc.) and nerves. Additionally, it features a fluid management system that replicates blood flow when vessels are punctured. However, to simulate UGRA, this model must be used with an external ultrasound system and a needle (not included). Similar commercial models such as NYSORA simulators (NYSORA) and the TruNerveBlock (TwinMedical) and non-commercial prototypes [26, 27] have been developed.

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Low-fidelity simulators are characterized by their low acquisition cost and offer a moderately realistic tactile and haptic experience [13, 28]. While this task-centered approach is appealing, the low-fidelity simulators have several limitations. First, their reusability is limited, leading to increased long-term training costs [25, 13, 29]. The repeated insertion of needles leaves visible marks on ultrasound images and alters the mechanical properties of the tissue, which can impede learners during subsequent practice sessions [30]. Additionally, these simulators offer limited scenarios and are challenging to customize for specific case studies. Furthermore, they lack objective measures to assess learners' performance, often relying on subjective evaluations by experts [31, 5]. Finally, a recent literature review reveals that physical UGRA simulators frequently lack tactile sensations and realistic haptic feedback [1]. These drawbacks have hampered the widespread adoption, validation, and utilization of such systems [1, 32].

2.2.2. Virtual simulators

Virtual simulators use computer-generated 3D models to recreate medical environments. They often integrate physical interfaces that enable real-time control of instruments. The system captures changes made to the 3D models and provides a suitable response to the user. Some systems incorporate haptic feedback, creating a sense of physical contact with 3D objects. This allows users to perceive the sensation of touching the 3D representation of the patient in addition to seeing it. Some simulators also combine virtual and physical elements to provide realistic tactile experiences [33]. Virtual simulators offer numerous advantages for medical training. They facilitate the multiplication and customization of training sessions and scenarios [24], allowing for progressive difficulty levels. Contextualized cues can be incorporated to

assist learners throughout the process, and stress elements can be introduced as learners gain competence [34]. Furthermore, virtual simulators enable objective evaluation of performance by automatically measuring various parameters [16, 5]. This allows for tailored feedback to learners regarding their performance and enables them to track their learning curves over time [11].

However, these technologies also have some draw-backs. While obtaining a high visual fidelity rendering is currently reasonably achievable, getting a realistic haptic rendering is far more complex [4, 24]. Additionally, the acquisition cost of these simulators is often notably high, particularly when haptic interfaces are involved [29]. However, this cost can be amortized over the long run as these systems are more reusable than physical simulators. Lastly, despite the existence of validation studies, only a few simulators have been widely embraced as standard tools for medical training [35, 13].

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Like their physical counterparts, virtual simulators can be divided into two categories: partial and full simulators. We will focus on partial virtual simulators that train needle insertion skills, particularly in regional anesthesia. Two aspects will be mainly discussed: the validity studies of these systems and the fidelity of their user interfaces. Needle insertion is a common medical procedure that involves inserting a needle into the patient's body with or without the aid of an imaging system (e.g., MRI, CT scan, or ultrasound) to reach a target area (a tumor or an organ) and collect a sample or perform a treatment (biopsy, anesthesia). These procedures require good hand-eye coordination, three-dimensional spatial abilities, and haptic perception skills [36]. Several virtual simulators for needle insertion training have been proposed [37, 38, 30, 39]. The reader can refer to two recent literature reviews on this topic [40, 41].

Several virtual systems have been explicitly proposed for regional anesthesia training. For example, Bibin et al. [42] developed SAILOR, a virtual simulator for regional anesthesia. The simulator incorporates realistic visual rendering, simple interactions using the mouse to manipulate the needle, and a pseudo-haptic effect when interacting with tissues. Ulrich et al. [43] presented RASim, a regional anesthesia virtual simulator based on a 3D stereoscopic screen displaying the tools and the concerned limb and a haptic arm allowing manipulation of the virtual needle. Grottke et al. [44] utilized a comparable interface in

their regional anesthesia simulator, featuring the creation of personalized scenarios by using patient-specific data. These systems have only undergone preliminary subjective evaluations, and no studies have been published regarding their validity [45]. In addition, the previous systems used external monitors where the 3D scene is shifted from the user's action space. This could impact the acquisition of hand-eye coordination skills during task performance. Indeed, some studies showed that indirect vision with translational misalignment between the motor space and the visual space has a negative impact on hand-eye coordination [46, 47, 48]. Other studies showed that colocalization of hands and tools controlled by the user improves manipulation task performance in VR [49, 50, 51]. Finally, these systems do not include a simulation of ultrasound to guide the needle insertion, which limits their use to train procedures complying with the recommendations of scientific societies of anesthesiology [9].

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In contrast, there have been limited VR systems designed explicitly for training ultrasound-guided needle insertion procedures [45, 52] Vidal et al. [53]. introduced a VR simulator to facilitate ultrasound-guided punctures in interventional radiology. The user interface features a stereoscopic monitor displaying a 3D view of the targeted limb and two haptic arms for manipulating the virtual needle and the ultrasound probe. Face and content validity studies were conducted [54]. However, the evaluations were limited to novice users, limiting the comprehensive assessment of its validity. Alamilla-Daniel et al. [55] proposed a VR simulator for ultrasound-guided interarticular infiltration, comprising two haptic arms to control the probe and the needle and a basic computer monitor for visualizing the VE. However, a user study has yet to be conducted to evaluate this system. Recently, Chuan et al. [56] have designed an immersive simulator for UGRA. The user interface includes an HMD for the visualization of the 3D scene. In addition, the system comes with a lowfidelity user interface since it uses Hand-held controllers to manipulate the needle and the ultrasound probe, and no haptic feedback is included. The system was evaluated for construct validity and could differentiate the performance of novices and experts.

The previous review demonstrates that partial simulators, whether physical or virtual, are more suitable than full simulators for learning basic technical skills. Physical simulators are affordable but come with several lim-

itations. While virtual simulators provide an interesting alternative to overcome some of these limitations, existing systems incorporate interfaces with low to moderate levels of fidelity. Moreover, very few systems combine ultrasound with needle insertion, which is highly recommended for regional anesthesia procedures and is currently considered the standard of care for peripheral nerve blocks [57]. Finally, only a limited number of validation studies have been conducted on these systems. Therefore, it appears necessary to go beyond the existing solutions by introducing a new VR simulator for UGRA. The proposed 11 approach incorporates the concept of interface fidelity to 12 overcome the existing systems' limitations and follows a 13 rigorous evaluation process to validate the different sys-14 tem components progressively. 15

In the following, we present the design process of our system, starting from the task and skills analysis and concluding with the system evaluation by domain experts.

9 3. Task and skills analysis

3.1. Task analysis

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3.1.1. Analysis method

To follow user-centered design principles, the first step 22 was to build the task model. Task analysis provides a better understanding of how users move from goals to tasks 24 and then actions. Thus, this analysis aims to highlight all the tasks performed to understand better how the whole 26 procedure is performed and how it should be simulated. 27 This analysis divides the procedure into steps, tasks, and sub-tasks. The combination of all the steps achieves the main objective of the procedure. Steps only occur once. 30 Tasks are actions that are combined to achieve the goal of 31 the step. They can occur several times during the same step. Tasks are made up of sub-tasks, more defined. Sub-33 tasks can appear multiple times within a single task and can be decomposed into more basic actions. Steps, tasks, 35 sub-tasks, and actions are hierarchical. Tree diagrams can therefore represent their order and structure. Thus, 37 a hierarchical decomposition tree describing the Hierarchical Task Analysis (HTA) of the UGRA procedure at 39 these different levels of detail was generated using the mental mapping software Xmind (XMIND LTD, version 22.09.3168).

The task model was produced using data from the literature, educational videos, and macroscopic observations carried out in the field. First, ten public videos with a total duration of 49 min were viewed. These videos show the performance of UGRA of the sciatic nerve and the femoral nerve. The analysis of these videos provided a first insight into UGRA and helped identify the basic steps the practitioner must follow to perform it.

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The second step involved referring to a specific document designed for interns, which provided detailed instructions for performing UGRA procedures, specifically targeting the sciatic nerve, femoral nerve, and brachial plexus [58]. The information provided in this document complemented and enhanced the notes taken from the videos.

Finally, a total of 42 cases performed by expert anesthesiologists were observed. A thinking-aloud method [59] was used to have details on the tasks performed. Once all the data was grouped, the task model was generated using Xmind.

3.1.2. Validation method

The first validation step took place during the weekly meeting of the partner anesthesia department. This meeting brought together ten expert anesthesiologists. During this one-hour validation session, the diagram was displayed on a large screen to the anesthesiologists, who were encouraged to provide unrestricted feedback on the model's alignment with their practice. As a result, this real-time feedback enabled the comparison of practices between experts, highlighting the value of this approach in generating a universal model for UGRA procedures.

Following this first validation phase, modifications were made to the task model based on experts' feedback. Most of these changes were related to terminology adjustments. The final validation was done remotely due to the busy schedule of the anesthesiologists. For that purpose, the diagram was sent by email accompanied by an online demographics and validation questionnaire, allowing to specify the profile of the respondents as well as their opinion on the validity of the model.

3.1.3. Results

Among the ten anesthesiologists present during the first validation session, only eight responded to the final validation questionnaire (six men and two women, with

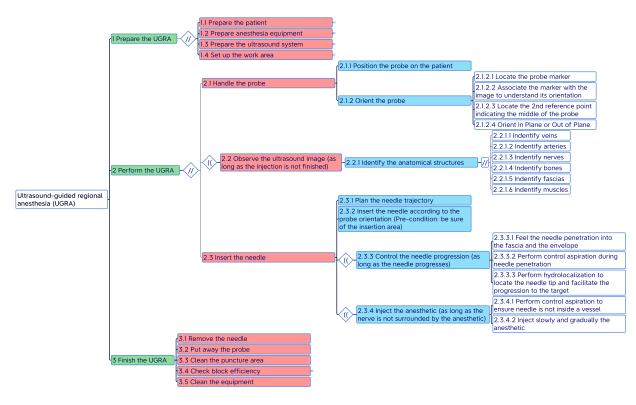


Figure 2: The task model of UGRA at the step (green), task (pink), sub-task (blue), and action (white) levels. Sub-tasks and actions are exposed only for step 2 (pointed out as the most relevant for the system design). The "//" symbol indicates parallel tasks while the "((" symbol indicates iterative tasks (loops).

13.12± 8.33 for the average number of years of practice and 675±353 cases of UGRA achieved on average). The hierarchical decomposition of the UGRA procedure is presented in (Figure 2). All the involved expert practitioners validated it.

Among the various UGRA procedures, we decided, in consultation with expert anesthesiologists, to focus the simulator's design on the femoral nerve block (FNB) scenario. FNB involves injecting an anesthetic agent around the femoral nerve to provide analgesia to the anterior aspect of the thigh, knee, and proximal tibia. FNB can be used for postoperative anesthesia or analgesia in various lower limb surgeries, ranging from femoral neck fracture fixation to total knee replacement. Hereafter, we describe the FNB using our task model.

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The FNB consists of three main steps broken down into tasks, sub-tasks, and actions. The first step is to prepare the UGRA by positioning the patient and preparing the area to be anesthetized while ensuring compliance with hygiene rules. This step also includes preparing the equipment to be used. The equipment comprises an ultrasound scanner with a 5-10 MHz frequency linear probe, a 22gauge, and a 5-centimeter needle. The second step is to perform the UGRA. It includes manipulating the probe on the surface of the patient's skin to observe and locate anatomical structures while inserting the needle. The structures to be identified include the artery, which is characterized by slight pulsations, and the femoral vein, which collapses under the pressure applied by the probe on the skin. The nerve is located just to the right of the artery and appears as a bright oval-shaped hyperechoic structure. Once located, the anesthesiologist inserts the needle (the target depth is between 2 and 4 centimeters in an adult) in the ultrasound plane (In-plane approach). In this approach, the entire needle is visible on the ultrasound as a straight line. An out-of-plane approach, where the needle is represented on the ultrasound as a single white dot, is also possible. When the needle reaches the nerve junction point, the practitioner can inject the anesthetic and observe its distribution around the nerve. When applied to the nerve tissue, this substance can block nerve conduction. It should be noted that the needle must be inserted above and below the nerve without touching it to avoid causing damage. The last step is to finish the UGRA by removing the needle and probe and cleaning the puncture area and the equipment.

3.2. Skills analysis

3.2.1. Analysis method

This step aimed to identify the skills required to perform UGRA. Once identified, the skills can be associated with the task needed to perform the procedure and then classified according to the relevance of their learning through the simulator. This can permit us to choose those to be targeted by the simulator and define the learning objectives of the system. For that purpose, a review of the literature was first carried out. After that, a focus group was organized with the same eight experts who participated in the validation session. During this two-hour session, the anesthesiologists had to associate the skills with the tasks previously identified and assess the importance of acquiring them through the immersive simulator.

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3.2.2. Results

According to the recommendations of the American Society of Regional Anesthesia and Pain Medicine and the European Society Of Regional Anaesthesia and Pain Therapy Joint Committee, [9], the skills needed to master the UGRA can be divided into four groups: (1) understanding the ultrasound bases and handling the equipment, (2) optimization of the ultrasound image, (3) interpretation of the ultrasound image and, (4) introduction of the needle and injection of the anesthetic solution. During the focus-group session, the experts pointed out that the skills related to step 2 (Perform the UGRA) are the most difficult to acquire and require the most extended learning curve. Thus, we have focused only on this step, the related tasks, sub-tasks, and the associated skills. Subsequently, only the last three skill groups were incorporated into the next phase, which consists of associating the subtasks with the skills. The results are presented in Table 1.

The experts then classified the skills according to their complexity and, thus, the relevance of their learning using the simulator. *Coordination of hand and eye movements* was considered the most complex to acquire. It is required while performing the three parallel tasks: 2.1 Handling the probe, 2.2 Observing the ultrasound image, and 2.3 Inserting the needle. Consequently, this skill was chosen as the primary training objective of our simulator. The remaining skills were judged necessary. They were classified as secondary training objectives of the simulator. The subsequent design process focused on those skills

and their associated sub-tasks from step 2 (perform the UGRA).

3 4. Design of the simulator

4.1. Design method

To guide the design of the system components, two dedicated focus group sessions (of two-hours each) were organized with two experts among those participating in the primary sessions. The recommendations from the literature also guided the design choices. In the following, we describe the various simulator components' choices and their fidelity levels.

4.2. Design choices

4.2.1. Interaction techniques and user interface

The initial decisions revolve around selecting interaction techniques and interfaces to be incorporated into the simulator. To simulate the chosen UGRA tasks (i.e., tasks and sub-tasks of Step 2), the system must enable users to perform the following interactive tasks (sub-task numbers are extracted from Table 1):

- 1. Visualize the VE from different perspectives (to observe the ultrasound screen, the needle, and the probe): required to perform all the sub-tasks of step 2,
- 2. Manipulate the ultrasound probe: required to perform sub-tasks 2.1.1, 2.1.2, 2.3.2, and 2.3.3,
- 3. Manipulate the anesthesia needle: required to perform sub-tasks 2.3.2 and 2.3.3,
- 4. Inject the anesthetic: required to perform sub-task 2.3.4.
- 5. Change the ultrasound image scale (zoom-in/zoom-out): this is achieved in the "prepare the ultrasound system" task related to step 1 (Figure 2) but is a prerequisite to perform sub-tasks 2.2.1 and 2.3.1.

As mentioned above, the VR simulator should prioritize a high level of fidelity for interactions that directly contribute to the acquisition of the primary learning objectives [13]. Consequently, we have attributed a high degree of interface fidelity to the first three interaction tasks directly related to the defined primary skill "Coordinated eye and hand movements" associated with orienting the

probe (sub-task 2.1.2) and controlling the needle progression (sub-task 2.3.3). On the other hand, interaction tasks 4 and 5 were deemed less critical for developing this skill. Therefore, lower-fidelity interactions, involving clicks on physical buttons were used to accomplish them.

Thus, two haptic arms were chosen to manipulate the probe and the needle, one per instrument. Using haptic arms allows the user to have a natural grip and to manipulate the instruments over 6 degrees of freedom (DoF). The generated movements are closer to the real situation than joysticks or a mouse, for instance. Haptic arms also provide force feedback related to the interaction of the instruments with the tissue. Indeed, several studies have stressed the importance of this feedback for learning technical skills in medicine [60, 61, 62].

4.2.2. Haptic and visual rendering

To ensure a realistic and effective user experience, as well as the acquisition of the skills of group 2, the haptic feedback on the ultrasound probe must allow the user to smoothly slide it on the skin surface to achieve proper positioning and select the appropriate approach (in-plane or out-of-plane). The probe pressure on the skin must also generate vein deformation.

Realistic haptic feedback during needle penetration into the body is crucial to acquiring needle manipulation skills. Once the skin's surface is punctured, the needle moves in one direction, allowing slight adjustments through small rotations around the insertion point (yaw and pitch). The user also needs to feel the needle passing through various tissue layers.

For visual rendering, a VR headset was chosen to immerse the user in the VE, which includes the patient and the ultrasound screen. This setup enables the user's virtual hands to align perfectly with their real hands following the recommendations derived from the literature [46, 47, 49, 50, 51] to support the acquisition of hand-eye coordination skills. Experts advise learners to position the ultrasound screen in front of themselves, ensuring that the needle, probe, and screen remain within their visual field. Using a monitor instead of a headset would have created a discrepancy between the user's real hands and the virtual instruments displayed. Furthermore, the VR headset allows users to naturally change their point of view (interaction task 1) simply by moving their heads.

4.2.3. Content of the virtual environment

As per the recommendations in the literature [10, 13], the level of environment fidelity can be moderate. Furthermore, the anesthesiologists commented that, during needle insertion, they focus mainly on the ultrasound screen and do not look at the patient's body. Hence, like partial physical simulators, the virtual scene included only a cuboid representing a patient's knee, the primary working area during the FNB. However, this representation needed to have three essential structures: the femoral nerve, the femoral artery, and the femoral vein to ensure a realistic anatomical simulation, thus helping to practice the third skills group (image interpretation).

In addition, no user's virtual hands were included, as suggested in the literature [63, 64]. Instead, we simulated the instruments (needle and probe) they manipulate. Experts' feedback supported this choice, as they admitted not focusing on their hands during needle insertion.

Lastly, to create a more immersive experience, the virtual scene incorporated a hospital bed on which the cuboid was placed, along with a 3D model of an ultrasound screen. Ambient operating room sound was also added as background noise in the simulation.

5. Simulator Development

5.1. Virtual Environment

The simulator was running on a laptop with an Intel Core i7 processor at 2.2GHz, 16GB of RAM, and an Nvidia GeForce GTX 1070Ti graphics card with 8GB of RAM. We used an Oculus Rift headset with a resolution of 1080x1200 per eye at 90 Hz and two tracking cameras to visualize the 3D scene (Figure 3).

We used Unity 3D (2019.4.2f1) with the SteamVR plugin to develop the system prototype. The virtual scene consisted of a cuboid containing three cylinders representing the femoral nerve, artery, and vein, respectively (Figure 4). We positioned an ultrasound screen in front of the user (Figure 1). Additionally, realistic 3D models of an ultrasound probe and an anesthesia needle were integrated into the scene (Figure 1).

To simulate the ultrasound image, we used an orthographic camera linked to the virtual probe's movements, positioned to capture the interior of the cuboid perpendicularly to the probe (Figure 4). We used shaders to configure the visual rendering and obtain a 2D cross-section of



Figure 3: The virtual scene with the cuboid laying on the hospital bed

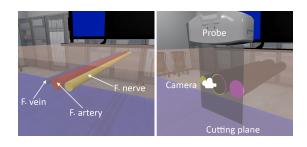


Figure 4: The cuboid (in transparency) included three tubes representing the anatomical structures. An orthographic camera and a cutting plane at the position of the probe were used to render the ultrasound image.

the intersected 3D objects (Figure 4). The resulting image was transformed into a grayscale. Finally, we applied dynamic Perlin noise [65] to the texture to achieve an appearance resembling that visualized on an ultrasound system. The image allowed visualization of the three anatomical structures and the needle (Figure 1).

5.2. Haptic interactions and rendering

We used two Geomagic Touch haptic arms (3D Systems Inc.) with the Kirurobo open-source plugin¹ for instrument manipulation. These arms enable movements in 6 DoF (translation and rotation along x-y-z axes) and provide force feedback in 3 DoF (translation along x-y-z axes). Each device has a 160 width x 120 height x 70 depth mm workspace. We used the two buttons of the left haptic arm to adjust the scale of the ultrasound image. We also used one of the buttons on the right arm to trigger the anesthetic injection.

¹https://github.com/kirurobo/ManagedPhantom

The ultrasound probe must maintain continuous contact with the skin surface and exert pressure during movement.

- To achieve this, we have implemented two forces: friction
- 4 force and Hooke's force.

The friction force is generated as the probe slides across the skin surface and is calculated as follows:

$$\begin{cases}
0 & \delta \leq d_i \\
\lambda \delta^n + \mu \dot{\delta} \delta^n & d_i < \delta \leq d_j \\
0 & \delta > d_i
\end{cases} \tag{1}$$

Here, λ represents the unknown contact stiffness, μ denotes the unknown damping coefficient, n is the unknown Hertzian compliance coefficient, d_i (the bottom) and d_j (the top) denote the positions of the tissue surface, and $\delta(t)$ represents the skin's local deformation:

$$\delta(t) = x - x_t \tag{2}$$

Where x_t represents the initial vertical position of the skin and x is the current position.

Hooke's force is generated when the probe applies pressure to the skin and can be expressed as:

$$f_h = -kx \tag{3}$$

Where k is the skin stiffness, and x is the penetration vector.

The value of Hooke's force is also used to deform the femoral vein under the pressure of the probe on the skin.

In contrast to the probe, the needle must be capable of penetrating the skin. Once inside, it only translates along its penetration axis and can rotate around this same axis (roll axis) or around the insertion point (pitch and yaw axes; Figure 5).

The needle insertion force comprises stiffness, friction, and cutting forces [66]:

$$F(x) = f_s(x) + f_f(x) + f_c(x)$$
 (4)

Here, x represents the position of the needle tip, f_s is the stiffness force, f_f is the friction force, and f_c is the cutting force.

The stiffness force is generated prior to skin puncture (calculated using the same formula as for the probe). The friction force only occurs within the tissue and depends on its stiffness:

$$\begin{cases}
0 & x \le d_0 \\
(f_0 + b_0)e^{a_0(x - d_0)} + b_0 & d_0 \le x \le d_1 \\
(f_1 + b_1)e^{a_1(x - d_1)} + b_0 & x > d_1
\end{cases}$$
(5)

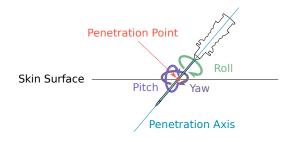


Figure 5: Needle's behavior inside the skin. It can be translated along its penetration axis, rotated around it (roll), or around the insertion point (pitch and yaw)

Here, d_0 represents the initial position of the tissue, d_1 is the perforation position, and f_0 , f_1 , a_0 , a_1 , b_0 , b_1 are parameters dependent on the mechanical properties of the tissue.

The cutting force allows the needle to slice through the tissue. It is a constant force dependent on the compliance of the tissue and is not related to the depth of the needle in the tissue:

$$f_c = c \tag{6}$$

Lastly, due to the constraints imposed by the 3DoF force feedback haptic arm, we did not apply any force to the needle when it rotated around the insertion point.

6. User Study

The objective of the user study was to validate the face and content of UltRASim. For that, two questionnaires inspired by studies validating other VR simulators [30, 67, 68] were used.

The face validity questionnaire consists of 11 questions (Table 2), while the content validity questionnaire consists of 6 questions (Table 3). Both questionnaires use a 5-point Likert scale. The study aimed to determine to what extent field professionals appreciate the appearance and content of the simulator.

6.1. Participants

We conducted this study in the partnering hospital's anesthesia and intensive care department. Eighteen anesthesiologists (11 males, seven females, one left-handed, 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 haptics and rarely played video games. They were divided into two groups based on their expertise level in performing UGRA (as self-declared): 7 experts (including two females) and 11 novices (including five females). The Research Ethics Committee of the Université Paris Saclay approved the study.

6.2. Experimental Procedure

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An experimental session lasted, on average, 20 minutes per participant. Upon arrival, the participants were required to read and sign the consent form and complete a demographic questionnaire. Subsequently, the experimenter explained the procedure and introduced the simulator. The participants were then instructed to settle comfortably, wear the VR headset, hold the haptic arms, and freely explore the system (Figure 1).

After that, the test of the simulator began. Participants were instructed to insert the needle using the ultrasound image guidance following the FNB scenario. To do so, they had to explore the virtual body and locate the femoral nerve while identifying adjacent structures. Then, they had to choose an entry point and insert the needle in alignment with the ultrasound image plane (following an inplane approach). Once near the nerve, they were required to inject the anesthetic and observe its spread around the nerve. The diffusion is calculated based on the needle's position relative to the nerve and the quantity of injected anesthetic. The test would conclude when the participant removed the needle from the virtual body. Participants were not required to complete the entire procedure, as the primary objective was to obtain subjective feedback on the appearance and content of the simulator. Immediately after completing the test, participants were asked to respond to the face and content validity questionnaires. They were then encouraged to provide additional comments or suggestions regarding their experience and potential improvements to the current prototype.

6.3. Results

6.3.1. Face Validity

Answers to the face validity questionnaire are summarized in (Figure 6, left panel). Although feedback from experts (37.66% of responses scoring above 3 and 27.27% of responses scoring below 3) was generally more positive than that of the novices (31.40% of answers scoring above 3 and 39.66% of responses scoring below 3), no statistical difference was observed between the average scores of the two groups (3.11 \pm 0.97 for experts, 2.88 \pm 1.16 for novices).

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The lowest scores (2.45 \pm 1.12 for novices and 2.57 \pm 0.97 for experts) were obtained for question Qf10 (realism of haptic feedback for the needle). Novices rated questions Qf3 (realism of the ultrasound interface) and Qf8 (realism of haptic feedback on the probe) higher (3.27 \pm 0.90 and 2.81 \pm 1.07, respectively) than experts (2.85 \pm 0.69 and 2.71 ± 1.25 , respectively). Conversely, experts rated questions Qf5 and Qf6 (handling of the haptic arm), Qf7 (probe movement), and Qf9 (consistency of needle's visual movements) higher $(3.42 \pm 0.97, 3.42 \pm 0.78, 3.42)$ \pm 1.13, 2.85 \pm 0.89; respectively) than novices (2.72 \pm $1.01, 2.72 \pm 1.19, 2.82 \pm 1.07, \text{ and } 2.72 \pm 1.36; \text{ respec-}$ tively). The highest scores were obtained for questions Qf1 (realism of the VE) for experts (3.71 ± 0.75) and Qf4 (realism of vein deformation) for all participants (3.36 \pm 1.02 for novices and 3.57 ± 0.97 for experts). The remaining questions received moderate scores, but the average was above 3.

6.3.2. Content Validity

The responses to the content validity questionnaire are summarized in (Figure 6, right panel). While the feedback from experts (66.66% of answers with a score above 3 and 7.14% of responses with a score below 3) was generally more favorable compared to novices (59.09% of responses with a score above 3 and 12.12% of answers with a score below 3), no statistical difference was observed between the average scores of the two groups (3.97 \pm 0.97 for experts, 3.57 \pm 1.03 for novices).

All questions received an average score above 3 for novices and experts. The lowest score pertains to question Qc3 (Adequate simulator for UGRA training), with an average score of 3.0 ± 1.00 for experts and 3.09 ± 0.94 for novices. The remaining questions obtained higher mean scores, particularly among experts, notably achieving a score of 4.71 ± 0.75 for question Qc1 (Promising training tool) and 4.42 ± 0.78 for question Qc2 (Simulator suitable for hand-eye coordination development).

6.3.3. Free Comments

After completing both questionnaires, participants provided verbal feedback on their experience with the simu-

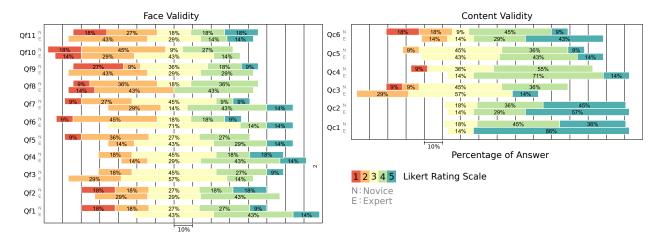


Figure 6: Percentages of respondents by score and by question for the face (left) and content (right) validity questionnaire. For each question, the answers of novices (top line) and experts (bottom line) are displayed separately.

lator and potential improvements to the current prototype.
 In the following, we summarize the most frequent comments.

First, several participants reported lacking support for their arms while manipulating the haptic arms, leading to increased fatigue and reduced movement precision. The experts also noted that the force amplitudes felt during lateral movement of the probe on the skin (probe friction force) were too weak compared to reality. Additionally, although the force feedback of the needle before and during skin penetration (stiffness force and cutting force) was satisfactory, several participants mentioned that its amplitude was too weak once the needle penetrated the skin's surface (friction force), resulting in excessively rapid and less precise movements.

Lastly, participants suggested potential system improvements. For instance, they proposed offering the possibility to reverse the positions of the probe and the needle, allowing to use the simulator for training procedures other than regional anesthesia. The experts also recommended the possibility of using the needle to slightly move the nerve, enhancing precision during the injection of the anesthetic.

7. Discussion and design implications

Our work has aimed to present the design and evaluation of UltRASim, an immersive simulator for training

basic UGRA skills. Our system stands out for its user interface design choices, aimed at increasing its fidelity to support the learning of hand-eye coordination skills.

For that, field studies and collaborative design sessions with domain experts have permitted us to build a task model, identify the skill set necessary to perform the entire UGRA procedure and classify the skills depending on the relevance of learning them through the immersive simulator. This approach was essential to define the system's primary and secondary learning objectives and the fidelity levels of its components. This guided the design of the simulator's first prototype.

The user study aimed to assess this prototype's face and content validity. Although these two aspects typically require validation from domain experts [16], we also found it valuable to involve novices. This decision aimed to increase the sample size and gather feedback from end users.

From a global perspective, 7 out of the 11 questions regarding face validity received positive responses (with an average score above 3). Over 60% of participants found the realism of the VE and the ambient sound satisfactory. However, the visual rendering of the ultrasound screen appeared to be less convenient for experts (only one expert rated it above 3). This could be attributed to its minimalist information, including the ultrasound image, zoom level, and injected product level. The quantity of the injected product was displayed on the virtual US monitor. This

may have been unsettling for experts used to more comprehensive information on such interfaces. In contrast, novices seemed less disturbed, likely due to their limited expertise in using these systems. Discussing with experts could help determine the most relevant information to display on this screen.

In addition, 44% of participants (including 57% of experts) were satisfied by the rendering of vein deformation under the probe pressure. This feature serves as a clinical reference to help identify the anatomical structures displayed on the ultrasound image. It is directly linked to acquiring the third skills group (image interpretation). As a result, it is considered valuable for training purposes and will be included in the simulator.

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On the other hand, using haptic interfaces was more challenging for the participants. Firstly, 50% of the novices found it difficult to grasp and handle them naturally. This could be attributed to the similarity between the styluses used to control the needle and the probe. Replacing them with more realistic 3D-printed shapes of the probe and needle handles could improve this aspect.

Secondly, participants reported difficulty positioning their arms relative to the haptic devices. This hindered the smooth movement of the probe, as in real-life scenarios, clinicians rely on their arm support against the patient's body to better control their movements. Therefore, it will be necessary to design physical supports that allow users to rest their arms while performing the procedure.

The force feedback amplitudes provided by the probe (on the skin surface) and the needle (inside the body) were perceived as too weak, resulting in faster and less precise movements compared to real-world. Thus, 52% of participants were unsatisfied with the haptic feedback experienced. These scores align with those from other subjective evaluations of haptic feedback on VR medical simulators [13, 67, 69]. These studies have highlighted the challenges of reproducing realistic haptic feedback, a critical aspect of learning technical skills in medicine [60, 61, 62, 4], especially hand-eye coordination [70]. Therefore, this aspect must be improved to validate our system.

The first option could be to increase the amplitudes of the needle's and the probe's friction forces to match realworld forces better. This requires more precise simulations of the tissue's mechanical properties. Additionally, using a 6-DoF force feedback arm to control the needle is being considered. The current device does not adequately constrain rotational movements (lateral forces during rotation) of the needle once inserted into the body. To compensate, we had to restrict translational movements (by applying translational forces at the insertion point) and allow yaw and pitch movements around the insertion point without force feedback, which reduced the haptic fidelity.

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Employing a 6-DoF haptic arm would provide rotational forces but significantly increase the simulator's cost (approximately a 300% increase in the price of the physical interface, according to our estimations). Nevertheless, this additional cost is justified by the educational needs of the system. Alternatively, other approaches could be considered, such as using pseudo-haptic feedback to compensate for the lack of force feedback. In this case, modifying the visual behavior of the tool (e.g., reducing its rotation speed) would create the illusion for the user that the tool's movements are constrained by the environment, requiring them to increase their manipulation force to achieve the desired movement [71]. This passive method could be combined with a 3-DoF haptic arm to compensate for the absence of rotational force feedback. Experimental studies will be necessary to explore the effectiveness of each method and its impact on learning outcomes.

Finally, although involving field experts throughout the design process did not uncover all the issues, it proved highly valuable in selecting the system's components. This initial iteration, with a situated evaluation, relied on the availability of a functional prototype of the system. The hands-on experience allowed us to gather feedback from domain experts, bridging the gap between the real world and the simulation, with a particular focus on the fidelity levels of the system components.

For instance, describing haptic sensations verbally can be challenging [13]. By allowing clinicians to test the simulator, they could compare the force feedback provided by the system to their real-life experiences and more easily articulate the relative differences. This approach was highly enriching and instrumental in identifying fidelity-related issues with the system's interface, leading to improvements in subsequent iterations.

In summary, the results of this study lead to the conclusion that the developed simulator is a promising training tool for enhancing hand-eye coordination skills in UGRA. The VE is realistic and reproduces the working environment of anesthesiologists. The virtual ultrasound inter-

face is satisfactory, but improvements are required for the ultrasound interface and image quality. On the other hand, issues related to the fidelity of the interface (ergonomics and haptic feedback) have been identified. Enhancing the fidelity level of these elements will be necessary before the system can be validated.

8. Conclusions, limitations, and perspectives

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This work presents the design of UltRASim, an immersive simulator for UGRA. A user-centered approach was used with strong involvement from domain experts. For this, a field study was conducted to build a task model of UGRA and to identify and characterize the skills required to perform it. This was then combined with theoretical concepts on simulator fidelity to guide the system design. This design approach can be generalized to improve the design of VR medical simulators.

Our approach also involved a user study, allowing us to validate different system characteristics progressively. The study investigated the system's face and content validity, the first two essential steps in validating a simulator. The results revealed several positive aspects of the system design, indicating that it is a promising training tool. However, certain issues were identified, suggesting areas for improvement before validating its usability. These areas include enhancing the fidelity of the haptic rendering, improving the usability of the physical interface, and integrating an armrest to support instrument manipulation. In addition, only simplified representations (cylinders and cuboids) of anatomical structures were used. The decision to represent only the main structures (vein, artery, and nerve) is justified because vascular structures serve as landmarks to locate target nerves during UGRA. Simulation of other scenarios involving different and more complex anatomical structures (e.g., muscles, bones, pleura) is considered in the future to enhance the fidelity to the human body simulation and make the simulator more intricate. Similarly, the simple ultrasound image simulation with Perlin noise should be improved using more sophisticated noise generation algorithms to achieve images that better match those displayed by real ultrasound systems.

Once these improvements are implemented, further evaluation studies will be conducted to validate the other characteristics of the simulator, including its ability to distinguish between novices and experts (construct validity),

its similarity to current training standards (concurrent validity), and its capacity to transfer learned skills to the real world (predictive validity). For these studies, objective performance measurements (e.g., completion time, number of needle insertions, contacts with structures, quality of anesthetic injection,..etc.) will be used. In addition, eye-tracking data could be used to assess how novices explore visual information on ultrasound images to guide their movements. Indeed, learning to see the anatomy through medical imaging systems [72] is an important skill to acquire, as highlighted in our field study.

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In addition, while only one anesthesiologist generally performs UGRA procedures, our field study permitted us to observe learning situations where experts interact and collaborate with novices for teaching purposes. This dimension could be explored in future iterations of our system to introduce the mentorship model into the VR learning process, where the trainees could benefit from interactions with a more experienced peer. In this context, we have already conducted an exploratory study to evaluate the effect of communication modalities on simple tool manipulation skills transfer between an expert and a novice in an immersive environment [73]. Therefore, we plan to introduce such communication modalities in our simulator as we think this approach could improve the learning outcomes, particularly during the early stages.

The validation of our system will provide learners with an alternative and complement to the current training methods while adhering to the anesthesia societies' recommendations to enhance practices and ensure patient safety. The system could also be used in the future to train other needle insertion-based and ultrasound-guided procedures.

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Group 2: image optimization	Learn the importance of the probe pressure
	Learn the importance of the probe alignment
	Learn the importance of the probe rotation
	Learn the importance of the probe tilting
	Coordinated eye and hand movements
Group 3: image interpretation	Identify nerves
	Identify muscles and facia
	Identify vessels, and distinguish between arteries and veins
	Identify bone and pleura
	Identify common anatomic artifacts (pitfall errors)
	Identify vascularity associated with needle path
Group 4: needle insertion and anesthetic injection	Learn to avoid unnecessary tissue trauma
	Learn the in-plane approach, maximizing needle visualization
	Learn the out-of-plane approach
	Learn the benefits and limits of both approaches
	Learn to recognize intramuscular needle location
	Conduct proper ergonomics
	Coordinated eye and hand movements
	 Identify intraneuronal needle location Learn to recognize correct and incorrect local anesthetic sp
	Group 3: image interpretation Group 4: needle insertion and

Table 2: Items of the face validity questionnaire.		
Q#	Question text: To what extent did	
Qf1	the VE seem visually realistic to you?	
Qf2	the ambient sound seem realistic to you?	
Qf3	the visual rendering on the ultrasound screen	
	seem realistic to you?	
Qf4	the vein deformation seem realistic to you?	
Qf5	the haptic arms handling seem complex to	
	you?	
Qf6	the haptic arms handling feel natural to you?	
Qf7	the movements of the probe in the VE seem	
	consistent with your own movements?	
Qf8	the force feedback during the probe manipula-	
	tion seem realistic to you?	
Qf9	the movements of the needle in the VE seem	
	consistent with your movements?	
Qf10	the force feedback during the needle manipu-	
	lation seem realistic to you?	
Qf11	you feel restricted in the needle movements?	

Table 3: Items of the content validity questionnaire.

	ruble 3. Rems of the content variatly questionnaire.
Q#	Question text
Qc1	How promising is this simulator as a training
	tool?
Qc2	How suitable is this simulator for the develop-
	ment of hand-eye coordination skills?
Qc3	How sufficient did this simulator seem to you
	to train UGRA skills?
Qc4	How useful was the ultrasound interface to
	you?
Qc5	How useful was the visual feedback of the
	spread of the anesthetic to you?
Qc6	How useful did you find the audio feedback?