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Development of a lumbar puncture virtual simulator for medical students training: A preliminary evaluation

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Abstract

Background: Lumbar puncture is an essential medical procedure whose objective is to obtain cerebrospinal fluid. Lumbar puncture is considered a complex procedure, mainly for novice residents who suffer from stress and low confidence, which may result in harm to the patient.

Methods: The LPVirSim, has been developed in four stages: i) requirements analysis through user-centred design; ii) prototyping of the virtual environment and the haptic component; iii) preliminary tests with Ph.D. students and physicians using two haptic devices (Omega.7 and Sigma.7); iv) a user study where physicians evaluated the usability and user experience.

Results: The LPVirSim integrates non-technical skills and the possibility of representing different patients for training. Usability increased from 61.76 to 68.75 in the preliminary tests to 71.43 in the user study.

Conclusions: All the results showed good usability and demonstrated that the simulator arouses interest and realistically represents a Lumbar puncture, through the force and visual feedback.

KEYWORDS

haptic simulator, lumbar puncture, medical training, user experience, virtual simulator

1 | INTRODUCTION

Percutaneous procedures are essential in diagnosis and treatments, and in general, consist of the insertion of a needle into soft tissues.¹ One of these procedures is the Lumbar puncture (LP), which is used in diverse areas such as neurology, anaesthesiology, oncology, or geriatrics.² The objective of this medical procedure is to obtain a sample of cerebrospinal fluid (CSF) for diagnosis, such as infections, and metabolic processes; and therapeutics purposes, such as the delivery of medication.³ LP is considered a complex procedure⁴ and it is reflected in novice residents suffering stress due to fear of harming the patient.⁵ As a consequence of this stress the resident's psychomotor performance and working memory may decrease, increasing the possibility of errors.

The LP procedure can be described in three steps as shown in Figure 1: preparation, needle insertion, and post-procedure. In the first step, the physician places the patient in a lateral recumbent or sitting position, then, the physician identifies the insertion site through palpation and by drawing Tuffier's line. In this step, the physician puts on gloves, cleans and sanitises the skin, and applies anaesthetic creams, sedatives or local anaesthesia to eliminate pain or anxiety. For the second step, the physician inserts the needle between the spinous processes of the lumbar vertebrae (L2-L3, L3-L4) with the tip pointing towards the head at a 15-degree angle, passing through the skin, subcutaneous tissue, supraspinous and interspinous ligaments, yellow ligament, epidural space, and dura mater, in order to reach the subarachnoid space and obtain a CSF sample. Afterwards, the physician may remove the needle. Finally, in

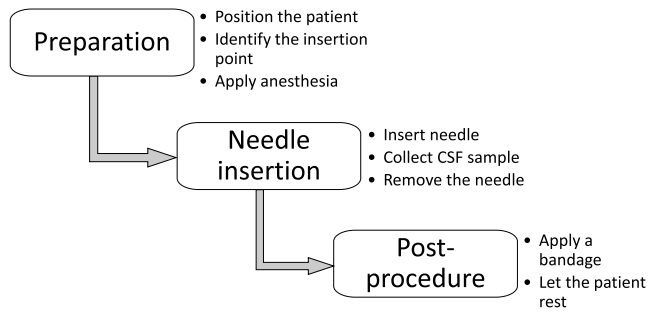


FIGURE 1 General steps of the Lumbar puncture (LP) procedure.

the third step, the physician will apply a bandage on the insertion point and allow the patient to rest.⁶

In Ref. (7) authors conducted a study in which they compared the heart rate and stress of three groups of physicians with different grades of experience performing an LP. The first group, the novices, were physicians or medical students with no LP experience; in the second group, the intermediates, were physicians or students who performed LP regularly, with between 10 and 80 LP performed; and in the third group, the experts consisted of physicians with 100 or more LP performed. With this study, the authors detected that novice LP performers presented a higher level of subjective and physiological stress, mainly before the procedure, compared to intermediates and experts; moreover, if the heart rate of the novices increases during LP, the patient is more likely to suffer from post-dural puncture headache.

In general, LP training consists of “see one, do one, teach one” as is mentioned in Ref. (8), and the disadvantages of this method are reflected in the stress and confidence of the physician, that's the reason why simulation technology is used in medicine, for instance, in LP procedures some studies have shown that the use of simulators increases physician experience, interest, enthusiasm, and confidence in technical skills.^{9,10} These simulators can be physical or virtual. The physical ones can be benches, mannequins, and 3D printed models, while the virtual ones use virtual reality which allows the creation of virtual environments (VEs) where patients' variants can be represented. In addition, different user interfaces can be implemented to interact with the VE, for instance, with a haptic device it is possible for the user to touch and feel virtual objects^{11,12} increasing the telepresence. Virtual LP simulators have been developed in order to eliminate the limitations of physical simulators, such as the limited number of uses due to the material wear, the limitation of simulating the same biomechanical behaviour of the tissues, and the limitation of simulating anatomical variations.¹³ Moreover, it provides the advantage of presenting a learning environment with different objects and stimuli that simulate a real procedure, reducing possible risks and errors¹⁴ like pain, post LP headache, and tissue damage.

In 1994 the idea of a virtual LP simulator with haptic feedback was presented by Ref. (15). Following this proposal, different authors

developed virtual LP simulators with VEs that included a visual representation of the lumbar area and its tissues. However, there are some differences between these simulators, such as the integration of mannequins and a real needle¹⁶; the integration of two haptic devices with the objective of simulating palpation¹⁷ or providing real-time collaboration¹⁸; to increase immersion and interactivity some systems used head mounted display (HMD) for better visualisation of the VE.^{19,20} Finally, some simulators focused on the realistic representation of the anatomy and created the virtual patient from computed tomography data.^{21–24}

The mentioned LP simulators have implemented different characteristics during their development. However in Ref. (25) the authors compared and analysed virtual LP simulators developed since 2000 to identify the basic characteristics that should be considered in the design and development of this type of simulators, such as the possibility of including anatomical variations to represent patients with different characteristics; opacity changes in the tissues according to the position of the needle tip; a representation of CSF sampling, and the use of a haptic device with force feedback.

In this study, the authors describe the design and user experience evaluation of the LPVirSim. The novelty of the proposed simulator compared to others previously developed focuses on the activities and configuration options identified by applying a UCD, in order to develop a complete simulator. For instance: i) the LPVirSim has the option of being used with different haptic devices, representing the possibility of acquiring the software and integrating it with the haptic device accessible to the interested parties; ii) the VE presents the option to modify the biomechanical characteristics of the tissues to represent patients with different conditions (obesity, calcification of the yellow ligament), so that the user can perceive the differences between them; iii) the integration of information regarding non-technical skills such as the ongoing communication and the most important sections of the informed consent.

This paper is organised as follows: Section 2 presents the materials and methods used for the design and development of the virtual LP simulator, describing the haptic component, the VE, and the evaluation of the simulator including preliminary tests and a user study. Section 3 shows the results that describe the user experience and simulator usability. Finally, Section 4 presents the discussion and conclusions.

2 | MATERIALS AND METHODS

The development of the LPVirSim was based on the UCD approach, which means that some physicians provided feedback during the process. This approach has been used in the development of medical applications, for instance, rehabilitation,^{26,27} wheelchair simulator,²⁸ systems of clinical decision support,^{29,30} and simulators.^{31,32} For the development of this simulator, the basic requirements were identified, then the integration and programming of the different components were carried out, and finally, the LPVirSim was evaluated.

2.1 | User requirements

The design of the LPVirSim was based on the characteristics mentioned in Ref. (25) and on 13 requirements obtained through the UCD approach²⁶ with a questionnaire, an interview, and an explanation of the LP performed with a mannequin. i) The questionnaire was applied to nine physicians experienced in the LP procedure; in this questionnaire, they were asked about the activities performed during the LP, the most common mistakes of the novices, and their experience with their first LP on a patient, this questionnaire is available in <https://bit.ly/3AYil9v>. ii) The online interview was carried out with one anaesthesiologist who worked in the Regional Hospital from ISSEMyM in Toluca. The idea of the simulator was presented and feedback was received. iii) Finally, a demonstration of the LP procedure was carried out in a mannequin by a neurologist and

professor of the Faculty of Medicine of the Universidad Autónoma del Estado de México. He explained all the steps during the realization of the LP and mentioned how this procedure is taught to students. Table 1 shows the 13 user requirements.

According to the 13 user requirements the hardware and software were selected, and a general system architecture was proposed. This architecture is shown in Figure 2, where it can be seen that the user interacts with the VE through a haptic device by sending the position of its end-effector. Then, according to this information the virtual needle moves and is checked if the virtual needle collides with a layer (tissue), if this happens, the force feedback is calculated and sent to the user.

The VE was developed in Unreal Engine 4.21 with Nvidia Flex, and the HAPTICO plugin.³³ The hardware integrates a haptic device that provides force feedback, an HTC tracker that permits

TABLE 1 User requirements obtained from the user-centred design approach for the development of a virtual Lumbar puncture (LP) simulator.

Requirement	Description
URQ1	Simulate the correct position of the patient
URQ2	Integrate the aseptic technique
URQ3	Correct the insertion angle of the needle at the moment of insertion
URQ4	Correct insertion position of the needle
URQ5	Identification of the place of the insertion
URQ6	Simulate skin, ligamentum flavum, dura mater and bones.
URQ7	Integrate the non-technical skills
URQ8	The end-effector has to be similar to a needle
URQ9	Integrate theoretical information and audiovisual help
URQ10	Integrate the CSF sampling
URQ11	Animation in the flexion of the spine
URQ12	Changes in the opacity of the layers (at least skin)
URQ13	Simulate the interaction between the needle and the layers

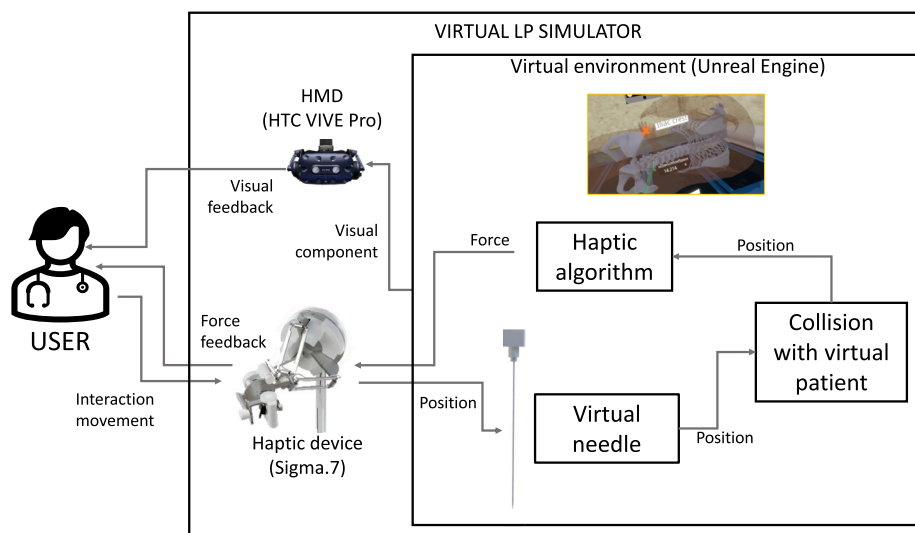


FIGURE 2 Block diagram of LPVirSim that includes a haptic device, a head mounted display (HMD) and the virtual environment (VE).

interaction with menus, and the HTC VIVE Pro as the display system. The LP simulator was developed and tested on a portable computer with 16 GB of RAM, Intel Core i7 as CPU, and NVIDIA GeForce GTX1060 as GPU. The haptic component and the VE are described in the next sections.

2.2 | Haptic component

The haptic component consists of the haptic device and the haptic algorithm. The algorithm calculates and renders the forces that affect the needle during the puncture, while the haptic device provides the force as haptic feedback to the user.

2.2.1 | Haptic device

One of the main features of developing the simulator using Unreal Engine is its ability to detect and work with different haptic devices, due to the implementation of the HAPTICO Plugin with the CHAI3D library.

According to the plugin description, the supported devices are delta.x, omega.x, sigma.x, Novint Falcon, Phantom Omni, Touch 3D, and Razer Hydra. However, the characteristics of each haptic device will limit the simulator features, such as force magnitude and components, that are provided to the user. For example, if the Novint Falcon is used as a haptic device, this one has 3-DoF (degree of freedom) and a custom actuated end-effector should

be designed to measure the virtual needle angle and provide force feedback to it.

It is worth mentioning that during the development of the simulator, two haptic devices were integrated, the Omega.7 with 7-DoF but with a passive rotation, and the Sigma.7 with 7-DoF actuated.

2.2.2 | Haptic algorithm

The haptic algorithm calculates three forces: needle force, control force and control torque. Each force is calculated according to the layer where the tip of the needle is, considering its biomechanical values and width (see Table 2). The needle force is based on a spring-damper model,¹⁸ this force consists of two components, as shown in Figure 3: the tip force which acts in the axial direction, and the friction force which acts on the side of the needle in the normal direction. Its magnitude can be calculated according to the position of the needle tip and the biomechanical values of the layers. Consequently, the force of the needle is calculated according to Equation (1) allowing the user to detect three “pops” during the procedure, the first one when the needle penetrates the skin, the second at the moment the needle pierces the yellow ligament, and finally, at the time the needle pierces the dura and enters in the subarachnoid space.

$$F_{needle} = F_{tip} + F_{friction} \quad (1)$$

TABLE 2 Stiffness, viscosity, kinetic friction¹⁸ and width³⁴ of each tissue considered for the simulator.

Layer (i)	Name	Stiffness (N/m)	Viscosity (Ns/m ²)	Kinetic friction (N)	Width (mm)
1	Skin	327	3.21	0.5	3
2	Subcutaneous tissue	0	2.98	0.5	6
3	Supraspinous and interspinous ligaments	72 ^a	4.06	0.8	30
4	Yellow ligament	920	4.21	1.1	3
5	Epidural space	0	2.98	0.5	6
6	Dura mater	920	4.21	1.1	6

^aThis value of stiffness has been modified from Ref. (18) based on feedback from the physicians. Since the force calculated was higher than the dura mater and in consequence, it was not realistic.

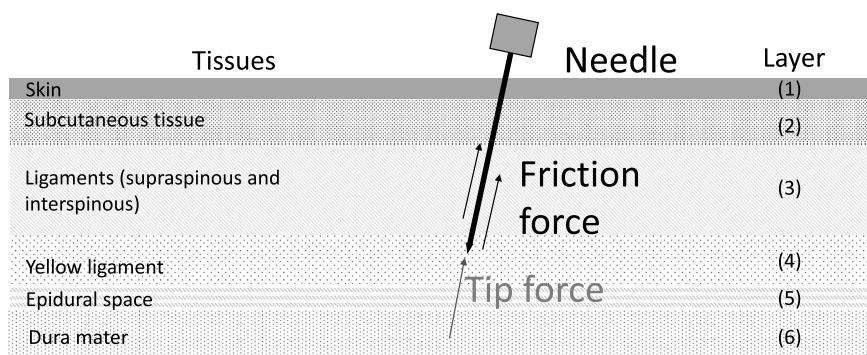


FIGURE 3 Tip and friction force as components of the needle force, passing through the different tissues.

The tip force (F_{tip}) is exerted on the needle tip when it penetrates the different layers. For the calculation of this force, the Hooke's law for stiffness and the damping effect for viscosity were implemented. Equation (2) shows the calculations for the tip force, where k_i is the stiffness of the layer where the needle tip is, $\vec{\Delta x}$ is the penetration distance between the insertion point and the current position of the needle tip, ρ_i is the viscosity factor, and \vec{v} is the linear velocity of the needle tip.

$$F_{tip} = k_i \vec{\Delta x} - \rho_i \vec{v} \quad (2)$$

The Friction Force ($F_{friction}$) is applied along the needle, and represents the adhesion and damping of the tissue. This force is based on the velocity of the needle and the viscosity of the layer. The calculation of the friction force depends on the comparison of the linear velocity with a threshold velocity, this threshold is equal to 0.014 m/s and if the velocity is higher or equal it represents that the needle is having displacement to the layer,¹¹ that is to say the user is moving the needle and it is not static, which would represent that the friction force is equal to zero. Equation (3) shows the calculations of this force, where, ρ_i is the viscosity factor, \vec{v} is the linear velocity of the needle, l_1 is the length of needle penetrated in the tissue, C_i is the kinetic friction of the layer where the needle is, sgn is the sign function (Equation (4)), $\vec{\Delta x}$ is the penetration distance between the insertion point and the current position of the needle tip, it is positive when the needle is passing through the different layers, \vec{v} is the linear velocity of the needle tip, and $|\vec{v}|$ is the unit vector of $\vec{\Delta v}$.

$$F_{friction} = \begin{cases} \rho_i \vec{v} l_1 & v < \Delta v \\ -C_i sgn(\Delta x) (\vec{v}/|\vec{v}|) - \rho_i \vec{v} l_1 & v > \Delta v \end{cases} \quad (3)$$

$$sgn(\Delta x) = \begin{cases} -1 & \Delta x < 0 \\ 0 & \Delta x = 0 \\ 1 & \Delta x > 0 \end{cases} \quad (4)$$

In addition to the calculated force on the needle, a control force was added to keep the needle trajectory fixed according to the insertion point and angle. To calculate this force a proportional and derivative controller was implemented (see Figure 4), and all the parameters were manually tuned, obtaining $p = 350$ and $D = 0.2$ as

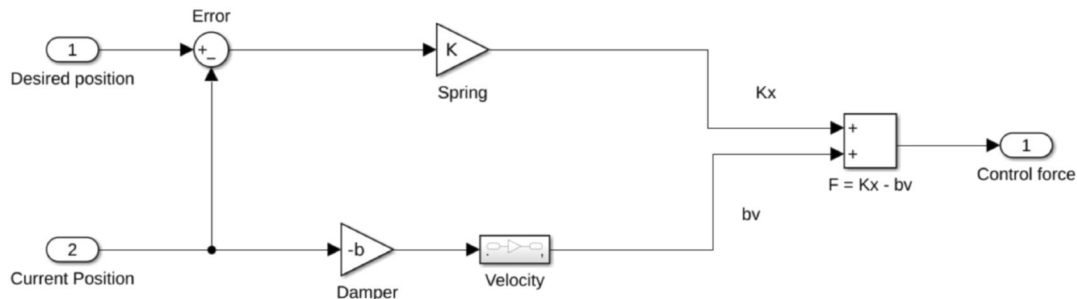


FIGURE 4 Diagram of the proportional and derivative (PD) control ($p = 350$ and $D = 0.2$) to maintain the needle trajectory during the simulation.

the final values, The effect of these values was validated by a physician.

The control force is represented in the VE as an invisible, small cylinder around the needle that helps to keep the trajectory of the user during the puncture. This cylinder follows the needle movement when it is outside the body as shown in Figure 5A. Then, the cylinder is fixed in the position where the needle collides (insertion point) with the skin (see Figure 5B). Moreover, the control force will try to keep the tip of the needle inside the cylinder which represents the expected trajectory of the user according to the insertion point as shown in Figure 5C.

Finally, as part of the force feedback, the torque was calculated to prevent the user from rotating the end effector and its reflection in the VE as the virtual needle. To control this torque, a proportional controller ($\tau = Kx$) was used, the value of the proportional value was manually tuned setting $p = 0.04$. This torque was implemented for haptic devices with four or more actuated DoF, such as the Sigma.7.

2.3 | virtual environment

The VE consists of six scenarios in 3D: Language, Test and Modify, Main Menu, Tutorial, LP, and Post-procedure, Figure 6 shows five of them. In these scenarios, the technical and some non-technical skills were integrated to offer a more complete training:

- The language scenario (see Figure 6A) allows the simulator to be used in different countries, and the user can choose the language of the instructions between English, French and Spanish.
- In the second scenario, Test and Modify, the user can change the biomechanical values of the different layers. Depending on the tissue it is possible to change the stiffness (skin, ligaments, flavum, dura mater) or viscosity (fatty and epidural), at the same time the user can test these changes, going through each layer, or through all the layers (see Figure 6B). These modifications can be saved and used in the LP scenario. It is worth mentioning that when the user starts the simulation, the biomechanical values are configured as "normal values" with the values presented in Table 2, with the objective of representing a standard patient. However, the option to modify the biomechanical values is focused on its manipulation

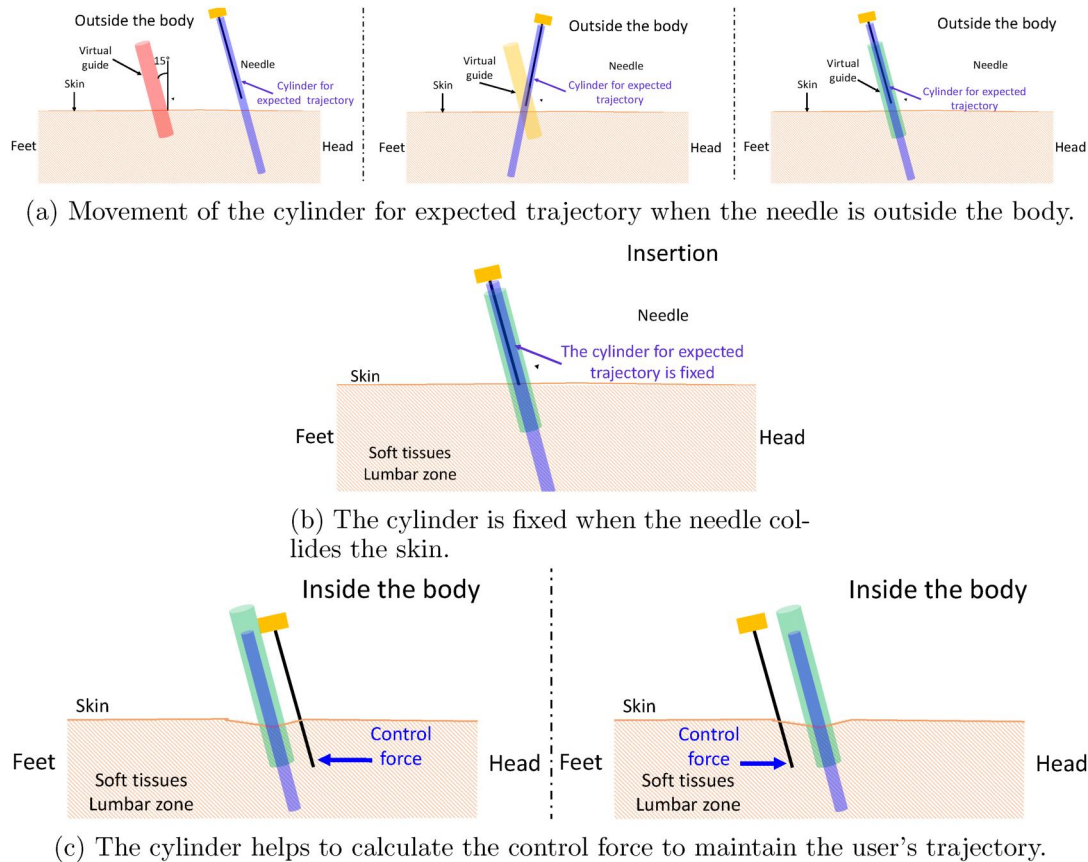


FIGURE 5 Position of the cylinder that helps to calculate the control force according to the needle's position.

only by the instructor. Additionally, this scenario represents an opportunity to simulate different patients. For example, a person with calcification of the yellow ligament will have more stiffness in this structure compared to a healthy person.

- The Main Menu scenario is composed by a screen where the user can read about some activities (non-technical skills) that must be performed before the LP procedure, such as the medical record, the informed consent (see Figure 6C) and the position of the patient during the LP. From this scenario, users can switch to the tutorial.
- The Tutorial consists of two activities that teach how to interact with the different elements of the simulator. The objective of these activities was to familiarise the user with the proposed simulator and learn to interact with the different elements of the VE. In the tutorial, the user had to pop some balloons. In the first activity, the user learns how to control the haptic device to control the virtual needle; and in the second one, the user learns to interact with the virtual guide (see Figure 6D). This guide changes colour according to the needle position as is shown in Figure 5A, if the needle tip is outside the guide, it is red, if the needle tip is inside the guide, but not with the correct angle, the colour is yellow, and finally, when the needle tip is inside the guide with the correct angle, the colour is green and the user can pop the balloons.
- The LP scenario focuses on technical skills, with the objective of enabling the user to train this procedure. In this scenario, a 3D human model was integrated with a bed and a pillow. The human model was modified according to the anatomical description presented in Ref. (35). Also, an animation of the model was integrated where the virtual patient starts in the supine position and then moves to the lateral recumbent position. When this scenario starts, the animation runs, and at the same time, instructions show how to perform the LP. Once the animation finishes, the user can start with the puncture. Additionally, to the force feedback, several visual cues were added to make the scenario easier to understand. These cues include a sphere in the tip of the needle, the name of the layer where the needle tip is located, the current angle of the needle, some anatomical landmarks like iliac crests, and the virtual guide (see Figure 6E). Within the 3D human model, there are visual representations of the bones, ligaments (supraspinous and interspinous), yellow ligament and the dura mater. When the needle is outside the body, the layers are opaque, but when the needle pierces each layer, it becomes transparent to allow the other layers to be seen. In addition, when the user pierces the dura mater, an animation of a CSF sampling starts to play. In this animation, the user can observe how the stylet is withdrawn and how the CSF starts to fill the tube, after this, the stylet returns to its initial position. Moreover, when users remove

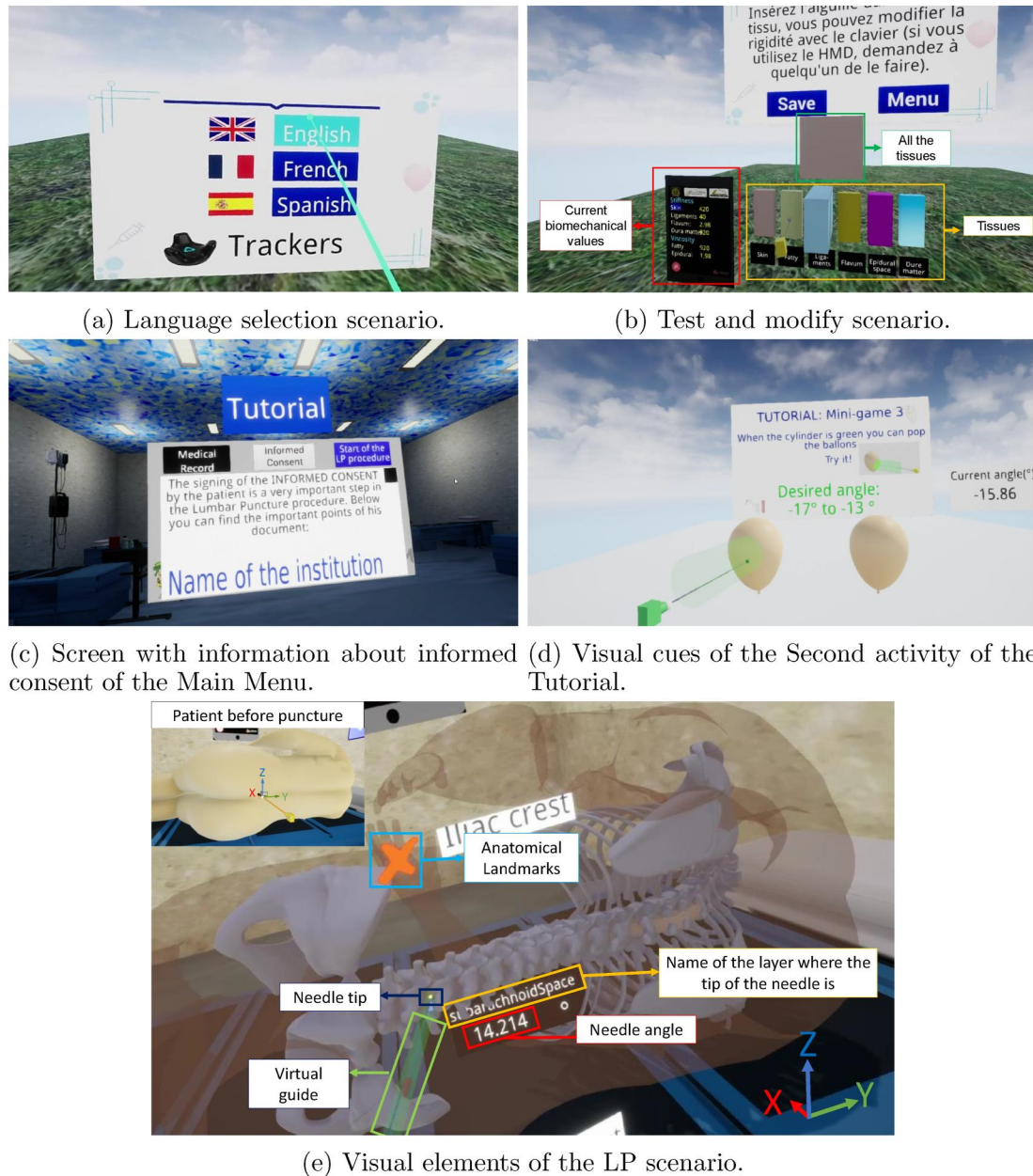


FIGURE 6 Scenarios and GUI of the LPVirSim: Language selection, Test and modify, Main Menu and Tutorial. The Post-procedure scenario is not shown for its similarity to the Main Menu, the difference between them is the information displayed.

the needle after CSF animation, the LP is finished and users can switch to the next scenario.

- In the Post-procedure scenario, the user can observe some information showing the user's performance, such as the number of collisions with the bones, the time spent practising the LP, the number of insertions before a successful LP, and a self-evaluation scale to be filled in by the expert or student. This scale is used in the Université de Montpellier, France, to evaluate medical students, and can be found at <https://bit.ly/3wAo1Ea>. Additionally, the user can watch some videos where the LP is performed, restart a new training, or quit the simulator.

2.4 | Evaluation of the LPVirSim

2.4.1 | Preliminary tests

During the development of the LPVirSim three groups evaluated it in the preliminary tests, they were carried out in different dates with different versions of the simulator (see Table 3). In the first test, three Ph.D. students from the LIRMM used the simulator with the Omega.7. With this group some necessary modifications were detected, mainly that in order to increase the realism of the system a torque should be provided on the end-effector of the haptic device,



Group	Number of participants	Description of the participants	Haptic device	Feedback
1	3	Ph.D. students	Omega.7	SUS
2	7	Ph.D. students	Sigma.7	SUS
3	2	Physicians	Sigma.7	Comments

TABLE 3 Groups of the preliminary tests.

to prevent the user from rotating the needle inside the patient. For this reason the Sigma.7 was integrated instead of the Omega.7. Additionally, usability was measured through the System Usability Scale (SUS) like in Ref. (26), obtaining a score of 61.66 (see Figure 11 in Section 3). In addition, the instructions were not clear, and some visual cues (current layer and angle) were added for a better understanding. According to these results, the system was improved to be tested by the second group.

The second group consisted of six Ph.D. students from the LIRMM. They tested the LPVirSim with the Sigma.7 and provided feedback about the clarity of the instructions, and the position of different components (trackers, base stations). Also, they answered the same questionnaire as the first group, this time the system obtained a SUS score of 68.75 (see Figure 11 in Section 3). According to the feedback received, some minor modifications were made, for example, some words in French were misspelled.

Finally, the third group consisted of two physicians from the University Hospital Center (CHU) of Montpellier who performed LPs as part of their clinical activity, one is an anaesthesiologist, and the other works in emergency medicine. Their involvement focused more on the LP scenario, and whether the system met the objective of simulating this procedure. They did not answer any questionnaires but provided information during and after using the simulator. The received feedback focused more on some of the characteristics that could be added to the simulator, these are mentioned in Section 4.2.

2.4.2 | User study

The study was carried out in a single session, in which at the beginning a general explanation of the simulator operation and the activities to be performed was given. During the explanation, it was emphasised that the test could be stopped at any time the user wished. At the end of the use of the simulator, a questionnaire would be applied and the information collected would be confidential with the purpose of performing an analysis to detect whether the system presented a good user experience.

After the participant understood all the points of the simulator, they were asked to wear the tracker as a wristband and wear the HMD. In the VE, they first had to choose the language, and then complete the tutorial to become familiar with the devices and their interactions. Approximately users spent 10 min in the tutorial, but it depended on the time they finished the two activities. When the participants finished, they could start the LP scenario.

After the participants used the simulator, they were asked to fill out an anonymous online questionnaire (Questionnaire 1) with 52

items to rate the usability with the SUS and the user experience³⁶ with a Likert scale from 1 to 7. The items for the user experience measure the *Interactivity, Challenge, Skills, Flow, Involvement, Loyalty, Vividness, Positive Affect and Focused Attention*, these components are described in Table 4. In addition, participants could express and write extra comments. At the beginning of the questionnaire, the participants were asked about the process of learning the LP. This questionnaire can be found at <http://bit.ly/3luSzgH>.

In this study, seven medical residents from the Hospital Center University (CHU) of Montpellier between 27 and 43 years old participated. The participants have performed LPs during their clinical activity, three of them have practised medical procedures with mannequins and four have experiences with virtual reality in games.

Figure 7 shows the components integrated into the study. First, the user must be seated and wear the HMD, then, an HTC tracker bracelet is placed on the left wrist of the user. Finally, the user can hold the end-effector of the haptic device with the right hand. In addition, two base stations were placed diagonally, oriented to the user (approximately 2 m apart) and calibrated previously. Furthermore, the VE runs in a processor unit (portable computer) that must be placed without restricting the natural movements of the user.

3 | RESULTS

3.1 | Force and trajectories

During the preliminary tests and the user study, the information regarding the force and trajectory was saved in a CSV file. Figure 8A shows the force calculated for the haptic algorithm and provided by the Omega.7 (passive end-effector) during one of the preliminary tests. This figure shows three force peaks: i) When the needle pierced the skin, ii) At the moment, the needle started passing through the yellow ligament, iii) and just after the needle pierces the dura mater. At two moments when the user was passing through the subcutaneous and the epidural tissue, the force was negative, it was caused due to the withdrawal of a few millimetres of the needle. Figure 8B shows the trajectory of the same participant compared with the expected trajectory. It is observable that the user did not follow the ideal trajectory, especially during the yellow ligament and the epidural space, where the maximal distance between both trajectories was 7.9331. However, at the end of the training, the needle reached the expected trajectory. The mean absolute error between these trajectories was 2.3816.

On the other hand, Figure 8C shows the force provided by the Sigma.7 with one of the physicians that participated in the user study.

TABLE 4 Items and description of the components evaluated in the user experience.

Component	Description	Items
Interactivity	Measures the level and type of content a user encounters, it is related to the speed of the system response.	I1: When I play the game there is very little waiting time between my actions and the computer response I2: Interacting with the game is fast I3: The game I played usually load quickly
Challenge	Define the presence of challenges that keep the user engaged.	C1: Playing the game challenges me C2: Playing the game challenges me to perform to the best of my ability C3: Playing the game provides a good test of my skills
Skills	Measures if the level of the user and the simulator allow the challenges to be met.	S1: How would you rate your skill at playing the game, compared to other things you do on the computer?
Flow	Psychological state where the user is totally absorbed in a specific activity.	F1: Do you think you have ever experienced flow in the game? F2: Most of the time I play the game I feel that I am in flow
Involvement	Importance that users give to the simulator.	IV1: I Give myself pleasure by playing the game IV2: I Can say that I particularly like this game IV3: I Have a strong interest in this game
Loyalty	Represents whether the simulator is a desirable product.	L1: Recommend the games I played to others L2: Consider this game your first choice to play/train L3: I Can use this simulator many times
Measures the quality of information that the user receives.		V1: How much did your experiences in the virtual environment (LP simulator) seem consistent V2: How much did your experiences in the virtual environment (LP simulator) seem consistent with your real-world experiences V3: How interesting was your experience? (PL)

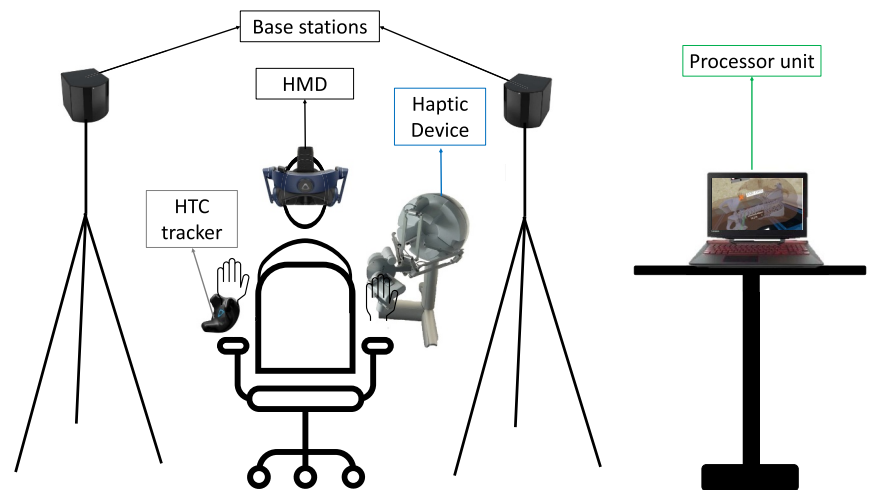


FIGURE 7 Position of components of the Lumbar puncture (LP) simulator.

This figure shows three main peaks when the needle pierced three tissues: i) the skin, ii) the yellow ligament and iii) the dura mater. In addition, in some tissues such as ligaments, flavum and dura mater, some smaller spikes are observed, but according to the feedback

provided by the participants they are not perceived. These spikes occur because the user stops the movement, which means that the displacement and therefore the speed of the needle is zero or near zero. Figure 8D shows a comparison between the trajectory of a

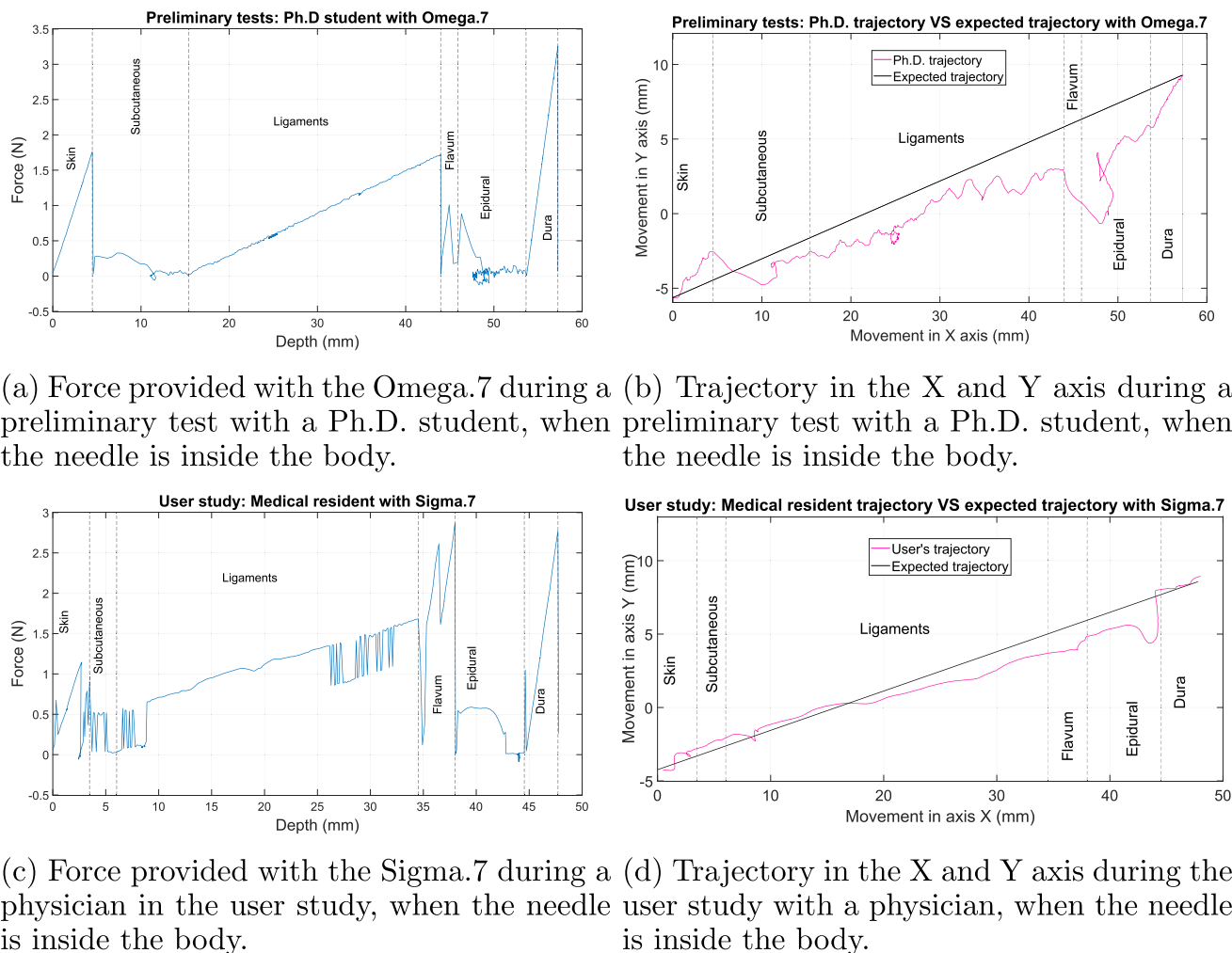


FIGURE 8 Haptic force feedback received by the participant in each layer, and trajectories during the training.

physician during the user study, with the expected trajectory. It is important to highlight that the main difference between the haptic devices is the number of actuated DoF, for instance, with the Sigma.7 for the participants it is possible to feel the restriction in the needle's rotation, and consequently keep the insertion angle during the puncture.

This is represented in the trajectory shown in Figure 8D, where the participant was near the ideal trajectory. The difference between the two trajectories was 2.9832 mm when the user passed through the epidural, and the mean square error was 0.7540 mm.

Comparing the data acquired from tests conducted with the Omega.7 (passive end-effector) and Sigma.7 (actuated end-effector), noticeable differences emerge in terms of the calculated forces and the needle's movement during insertion. These differences are caused by two factors: i) the lack of torque when using the Omega.7 (due to a passive end-effector), and ii) the skills developed with medical training and practical experience. The lack of torque causes the needle to move farther away from the expected trajectory changing the position and the direction of the needle and adding more distance to reach the desired tissues (see Figures 8B and 8D)

and this is reflected in the total displacement on the X axis, where with the Omega.7 the needle moved 57.01 mm, whereas with the Sigma.7 moved 47.77 mm. At the same time, the lack of torque is reflected in the magnitude of the forces using the Omega.7 (Figure 8A) and Sigma.7 (Figure 8C), as can be seen in the forces calculated in the skin, epidural and subarachnoid space.

On the other hand, the influence of the skills and practical experience is reflected in the velocity at which the user moves the needle, and in consequence in the total force, which increases when Ph.D. students (without medical training and practical experience) test the simulator with the Omega.7. In contrast, the Sigma.7 was evaluated by physicians who had performed LP procedures on patients prior to this assessment and their proficiency in the procedure enabled them to execute insertions more accurately.

3.2 | User experience

The results of the user experience are shown in Figure 9, where a boxplot is presented for each component. The first two items (I1, I2)

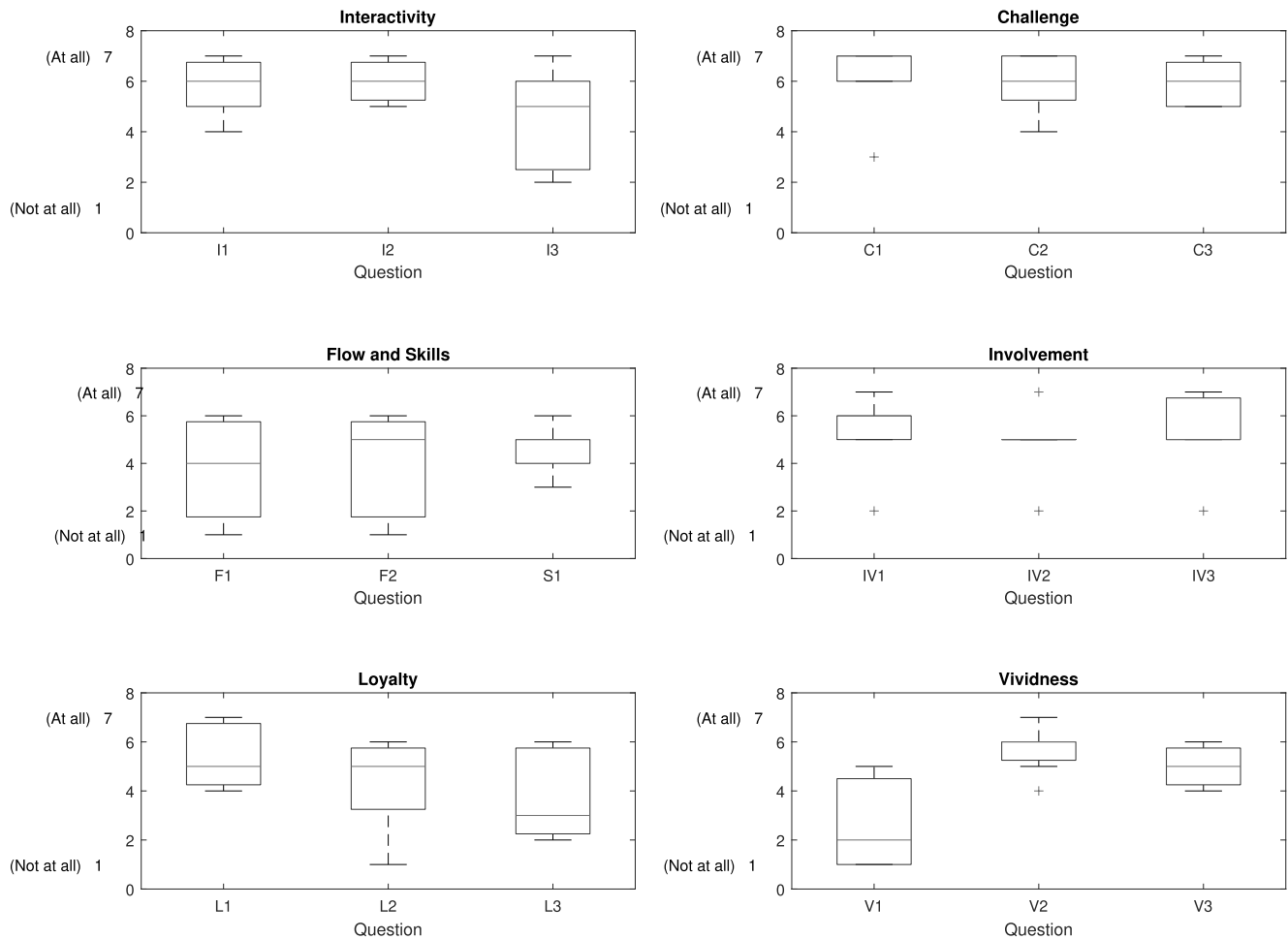


FIGURE 9 User experience results for each component: Interactivity, Challenge, Flow, Skills, Involvement, Loyalty, Vividness.

of *Interactivity* obtained a median of 6, while I3 obtained twice the value of 2 because the time in a transition between two scenarios was long according to the users. Regarding the *Challenge* component, the first item C1 obtained a median of 7 with an outlier of 3, meanwhile C2 and C3 obtained a median of 6. In the *Skills* component, S1 obtained a median of 5, with a lower value of 3 because it took the user a bit of time to understand the system.

The *Flow* was the component with a higher dispersion in the answers, with medians of 4 and 5, in each item, but with low values of 1. This dispersion is presented due to some users having difficulty concentrating because they could hear the surrounding noises (in the real world). The *Involvement* was the component with more outliers. In IV1 the median was 6, with an outlier of 2, because for the user the system was a little hard to use, the same user gave a value of two in IV2 and IV3, meanwhile, the other users enjoyed the simulator. On the other hand, item L3 of *Loyalty* obtained a median of 3 because some users were not sure if they could use the simulator many times. L1 and L2 obtained a median of 5, they could recommend the simulator to other residents, and they can use it additionally to other types of training. Finally, the first item in *Vividness*, V1, obtained the

lowest median with 2, but with a noticeable dispersion in data. In this case, the users felt some inconsistencies between what they saw (VE) and what they listened to (real world). In V2 the median was 6, where users mentioned that the movements they realized in the real world were reflected in real time in the VE. In the last item, V3, users thought that the use of the simulator was interesting.

The results of positive affect and focused attention are presented in Figure 10 where it is possible to observe the positive feeling in the users when training with the developed simulator and even users were not deeply engrossed they were able to conclude the test and therefore the simulation.

Additionally, users mentioned their perception about the feedback. First, the haptic feedback was easily perceptible, and even the users who were not deeply engrossed, were able to conclude the test and therefore the simulation. In addition, users mentioned that they perceived when the needle pierces the dura, and at that moment they stopped the needle. Regarding the visual feedback, users always received this information through the HMD. However, some activities were clearer when they could observe extra information, like the name of the layer where the needle was on or the angle of the needle.



3.3 | Usability

The system obtained an average score of usability of 71.43. With this score, the system can be described as an acceptable product with a grade scale of C³⁷ (see Figure 11).

One of the items in which the participants rated low is the one where they think that a technician is necessary to understand how to use the simulator for the first time.

3.4 | Extra comments

As additional questions, participants were asked whether the simulator represents an LP, with a Likert scale from 1 to 7, being 7 at all and 1 not at all. In this question, a score of 4.57 was obtained. Additionally, the participants think that the simulator realistically represents an LP, it obtained a score of 5.42.

Moreover, the participants contributed with comments and suggestions at the end of the questionnaire. In general, the comments were focused on three points: the first one was to improve the 3D human model and give the possibility to choose the patient's position between lateral recumbent and sitting, to make the VE more realistic; the second was to modify the end-effector of the haptic device to

make it similar to a needle; and the third point was to integrate the possibility of selecting between different patients with anatomical variations.

4 | DISCUSSION AND CONCLUSIONS

4.1 | Discussions

The LPVirSim was developed applying a UCD approach through which the requirements of the procedure were detected, and according to the feedback received in the tests, the usability was improved. During the preliminary tests, the usability of the LPVirSim was in the marginal zone, with a D grade scale as shown in Figure 11, but after the changes mentioned in subsection 2.4.1 the LPVirSim improved to the C grade, representing an acceptable and good system. However, it can be improved to obtain a B on the grade scale or to be described as a good or excellent system according to the adjective ratings. It is important to note that usability is an important part of design evaluation, however, for a valid design implemented in the area of medical learning it is necessary to evaluate the system in a real environment, with medical residents or physicians who need to train this procedure.

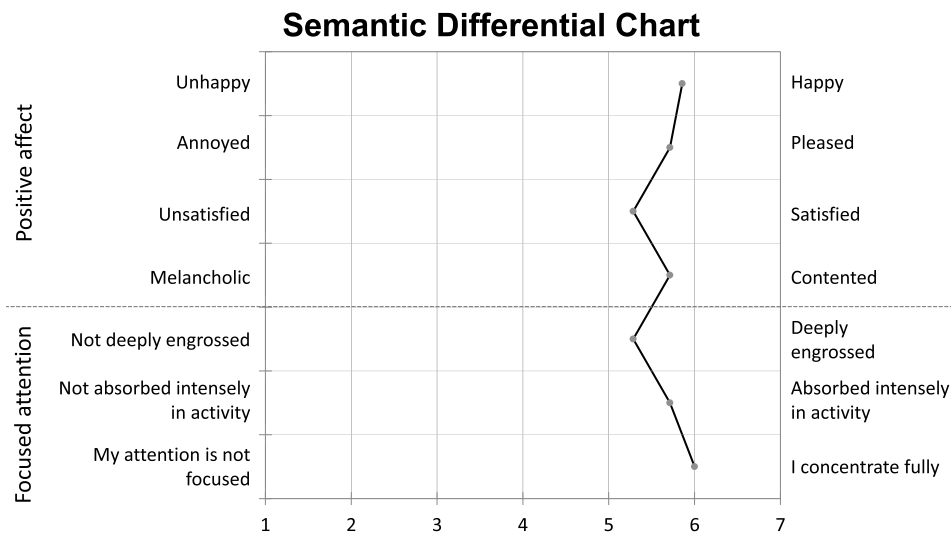


FIGURE 10 Semantic Differential Chart of the positive affect and focused attention components of the user experience.

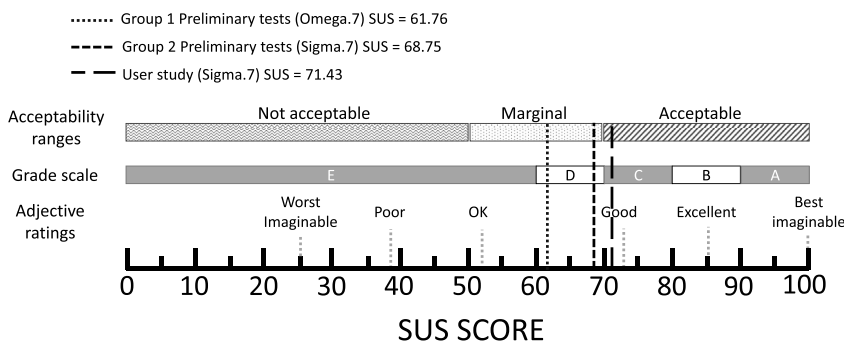


FIGURE 11 Usability scores in different SUS scales obtained in preliminary tests and user studies (modified from Ref. (37)).



In addition to usability, a questionnaire about the user experience was implemented, this questionnaire covers different components regarding the user experience in VEs, that allow for a more accurate detection of improvements, while in other developments^{23,24} a questionnaire with specific and proposed items was applied, additionally, authors received direct feedback from the participants.¹⁸

In general, the user experience evaluation shows that the simulator arouses the interest of people who tested it and that the simulator represents realistically an LP procedure. The results show that the majority of the components of this evaluation obtained a higher answer (>4), except for three items: F1, L3, and V1, which in addition to the feedback and extra comments received by the participants, indicate some opportunity areas for improving the simulator, for instance, the integration of auditory feedback.

As shown in Figure 9, the results obtained in *Challenge* represent a system capable of keeping the user engaged while decreasing the possibility of getting bored. The next component, *Interactivity*, shows that the response time of the system is good, but it can be improved, especially after the transition between the LP and post-procedure scenario. On the other hand, *Involvement* indicates that the simulator integrates a procedure that users consider important, which means they could spend more time training and improving their skills. The results obtained in the *Skills* component can be interpreted as users need to learn how to use the simulator or receive more cues about the activities to perform and provide different levels of difficulty according to the user's skills. The next component, *Loyalty*, shows that the simulator is a desirable product that can be used in the training of this procedure, but it can be improved in order to represent the first choice for LP training. However, the user generally knew how the system worked, but was unaware of additional information such as the cost. The other component, *Vividness*, demonstrates that the quality of the system information being sent is good, but could be better, for instance, in the extra comments from participants, the system could be more consistent with a real experience, if sounds related to the patient's reaction are provided in the VE.

The component *Flow* represents an area where the simulator needs to be improved to provide a better user experience. Due to the scattered data, it can be interpreted that users were not fully absorbed or immersed in the simulator activities, and that users felt that they were not totally in control of the situation.

According to the simulators presented in Ref. (25), this simulator is the only one compatible with different haptic devices, giving the possibility of adapting to different institutions and budgets. However, the force haptic feedback received by the user depends on this device, and their realism and usability will depend on it. This situation is observed in the two tests that were carried out with this simulator with two devices, both with 7-DOF but the first one with 4 actuated DOF, and the other with 7 actuated DoF. This difference is mainly observed in the forces that are calculated in the haptic algorithm. When using the first haptic device, the Omega.7, the user is able to feel the needle go through the tissues and control force, but can rotate the needle freely inside the body; however, with the Sigma.7,

apart from feeling these forces he can also feel the torque, which allows the insertion angle to be maintained throughout the puncture. Also, the difference in using these two devices can be seen in the usability ratings, which are higher when using the Sigma.7. Finally, one of the most recurring comments was that when using the Sigma.7 the system was perceived to be more realistic.

Finally, this simulator proposes the possibility of tuning the biomechanical values according to the patient to represent. For instance, the simulator can represent a patient with calcification in the yellow ligament, if the stiffness of this tissue is modified. The main difference with other simulators is that the expert changing these values can represent different patients, meanwhile, the other simulators can represent two²¹ or four²⁰ predefined patients.

4.2 | Conclusions

In this paper the LPVirSim was designed, built and tested. In order to design a useful tool for physicians and medical students, the development was based on the basic characteristics mentioned by Ref. (25) and on the UCD approach, where 13 user requirements were identified. During the prototyping of the LP simulator, different physicians provided feedback, and according to this, the system was modified, in order to create a user-centred simulator.

This simulator contrasted with the others developed, allows training with different patients, modifying their stiffness and viscosity; integrates NTS for a complete training; and has the possibility of implementing different haptic devices according to the needs of the users. However, for the simulator to be realistic the haptic device must have 4 to 6 actuated DoF, or in the case that the device only has 3 actuated DoF the end effector must be modified to provide torque at the insertion angle. The number of the DoF varies depending on the characteristics of the simulator. If the patient is represented in just one position the haptic device requires 4 actuated DoF. In case the patient is lying down the angle would be yaw or if he is sitting down it would be pitch; if the simulator represents the two positions it must have 5 actuated DoF, the pitch and yaw. In case the haptic device has 6 actuated DoF, it is possible to represent the position of the tip of the needle (where is the bevel).

Preliminary tests were conducted in two groups and the results were used to improve the system until the final version was achieved, with clear instructions and cues to help understand each of the elements of the VE.

With the final version, the user study was carried out, showing that the usability of the system is acceptable, as well as the user experience, and according to the additional questions, the participants agreed that the simulator realistically represents an LP and allows training it.

Finally, some characteristics have to be implemented, according to the feedback obtained in the user study. For instance, it is necessary to increase the telepresence and flow by adding sounds that represent the patient's reaction. Additionally, in order to simulate a complete LP procedure, it is important to integrate the



palpation, the representation, or simulation of all the preliminary activities, such as the anaesthesia and cleaning of the area, the possibility to choose between the sitting and recumbent position, and choose between different patients, for example, elderly, obese, with ossification of the ligamentum flavum, or with different physical complexions.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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