Abstract—Failure rates in spinal anesthesia are generally low in experienced hands. However, studies report a failure rate variation of 1% to 17% in this procedure. The aim of this study is to bring the main characteristics of in vivo procedure to the virtual reality simulated environment. The first step is to model the behavior of tissue layers being punctured by a needle to then make its inclusion in medical training possible. The simulation proposed here is implemented using a Phantom Omni haptic device. Every crucial sensation of the method mentioned here was assessed by a dozen volunteers who participated in two experiments designed to validate the modeled response. Each user answered six questions (three for each experiment). Good results were achieved in certain essential aspects of the process, such as identifying the number of layers, the most rigid layer to puncture, and the most resistant layers to pass through. These results indicated that it is possible to represent many typical behaviors through virtual needle insertion in spinal anesthesia with the correct use of haptic properties.

Clinical Relevance—The idea is to create a spinal anesthesia simulator that could work as a complementary step in training new anesthetists. The use of a simulator avoids introducing the first puncture haptic sensation directly in patients.

I. INTRODUCTION

Virtual reality (VR) techniques in biomedical procedures have been beneficial in many applications [1, 2]. There is a growing use of haptic devices for many applications such as design, games, remote analysis of materials [3, 4], remote diagnosis, training [5-8], and many others. The devices vary from specifically developed [9] to multi-purpose, including tactile gloves [10]. Research on device use in many areas of anesthesia is also growing [11,12]. Spinal anesthesia is one of the most reliable types of regional blocks, but the possibility of failure has been recognized [13]. Published reports indicate that there are procedure failure incidences of between 1% and 17% [14-16]. Keeping track of needle depth during spinal insertion is crucial to the success of the method.

II. MATERIALS AND METHODS

The experiments were presented to 12 volunteers who used the haptic. All the participants were computer science students, aged 18 to 44 years old, with 11 males and one female. Written informed consent was obtained from the participants, who then received a brief explanation about the procedures, before using a sample application for five minutes to acquire knowledge on how to interact in a 3D environment using the haptic device. These experiments are...
part of a project approved by the Research Ethics Committee of the Hospital Universitário Antônio Pedro (Antônio Pedro University Hospital) of the Faculdade de Medicina (Medical School) of the Universidade Federal Fluminense (Federal Fluminense University). This project is registered on Plataforma Brasil of the Brazilian Ministry of Health with the presentation certificate for ethical appreciation 23637019.5.0000.5243.

A. Haptic Devices

Haptic devices provide human-computer interaction that creates the sense of touch for the users while interacting in a virtual environment. This kind of equipment can be set to perform physical resistance to user movements, enabling them to feel virtual objects. Haptic devices offer several movements and feedback options often related to their Degrees of Freedom (DoF). Touch ® haptic [25], also known as Phantom Omni, was the device used in this study. This device offers six (6) DoF for movement: three (3) for axial displacements of its arm on x, y, and z axes, plus an additional three (3) for rotations around these axes. It has three (3) DoF for force feedback, which means the user could have force feedback for the three (3) axial displacements (left and right, up and down, front and back). The device does not support force feedback on rotation through said axes. The resistant forces are applied while the user moves the pen-like part of the equipment.

B. Spinal anesthesia

Physicians and anesthetists rely on manual feedback (force and tactile sensations) to guide their movements in a lumbar puncture procedure. Such feelings must be implemented to correctly simulate the real experience based on penetration of the tissues. The procedure of inserting a spinal needle into the lumbar spine requires the operator to construct a (3D) anatomical image of the body and the tissue layers in their mind [18]. Many layers must be penetrated after puncturing the skin to reach the end point in subarachnoid space. The layers are the subcutaneous fat, supraspinous and interspinous ligaments, ligamentum flavum, epidural space, dura mater, and arachnoid. Fig. 1 illustrates the complexity of the layers of this part of the human body. Needle insertion is a blind procedure, and the appearance of CSF acts as visual identification of the end point. The needle insertion point on the patient's back is defined using surface landmarks such as the iliac crests [18]. An assessment is made on the suitable intervertebral area for lumbar puncture between the second (L2) and third (L3) lumbar vertebrae or between the third (L3) and fourth (L4), for instance.

There are two (2) possible needle insertion approaches in lumbar punctures, midline and paramedian. The midline approach is the most common [17] and involves inserting the spinal needle up to 30 or 40 millimeters (mm) perpendicularly through the skin [17]. The primary layer where it is possible to feel resistance is usually the ligamentum flavum, when the needle operator feels greater puncture resistance [17]. The needle must then advance from 8 to 12 mm to reach the dura mater [17]. Some authors report a popping sensation (a surface tension that is experienced just before surface penetration) when perforating the dura mater [26,27]. The anesthetist then proceeds with slow needle insertion until CSF drips out, thus indicating that the needle has reached subarachnoid space [17]. It is important to note that since CSF flows very slowly through a thin needle, one must not advance more than 1 to 2 mm at a time. Once CSF drips from the back of the needle, a syringe with local anesthetic is attached to finalize the procedure [17].

There are haptic responses that can be used to indicate where the tip of the needle is inside the body. Through the simulation procedure, haptic perceptions must provide tips about needle location to the equipment operator. The success of lumbar anesthesia lies in these tips combined with the mental picture made by the anesthetist of the three-dimensional lumbar spinal anatomy. The anatomy related to the area of spinal anesthesia is detailed in Fig. 1.

The ideal spinal anesthesia simulator should replicate the procedure mentioned above and recreate the real scenario of an in vivo method. Real measured in vivo data from patients could be integrated into the simulator software, so that the resistance would automatically adjust to different body measures. As the needle advances, the resultant force should represent each tissue layer until reaching the subarachnoid space [17]. Some studies are dedicated to researching and analyzing how to model the distance from skin to epidural space in humans, based on height, weight, and ethnic group. Such a model could be used with the addition of dura mater and subarachnoid space depth definition for spinal anesthesia virtual modeling. Most simulators have only three options, such as obese, normal, or aged, which is not enough to represent the full range of complexity of the human body. Simulators based on more general equations [28] could have unlimited patient variation. Trainees planning on performing spinal anesthesia would then be able to practice beforehand on virtual models of patients. The idea is to reduce the learning curve before performing the procedure on actual patients, while making it much more enjoyable for the trainees.

III. EXPERIMENTAL SIMULATION

Open Haptics Touch Device Driver must be installed to develop interactions using the Touch ® haptic device. This driver is available on the company's website [25]. A haptic plugin on the Unity game engine has also been used [29]. Unity is a broadly used tool for developing video games and simulations with or without VR for multiple platforms. This
The plugin offers four different modes enabling the user to interact with virtual objects in the developed application. The present study required the simulation of a needle being inserted through the tissue of virtual patients, so the Puncture interaction mode was selected.

The OpenHaptics driver defines a set of properties that can be applied to any touchable objects in the virtual environment constructed by the developers [25]. Those with more influence using the Puncture mode are Stiffness, Pop Through, Static Friction, and Dynamic Friction. All of the properties receive a floating-point number with values between zero and one as input.

Stiffness controls how hard a surface feels: zero (0) represents a soft surface and one (1) the hardest surface to be rendered [25]. Pop Through controls the amount of force required to go through (puncture) the surface: zero disables the pop through [25] and one means that the maximum rendered force is necessary to go through. Punctured Static Friction controls how hard it is to move inside a punctured shape starting from a static position [25]. The lower limit (zero) represents a frictionless tissue, and the upper limit (one) indicates the most significant amount of friction. Punctured Dynamic Friction controls how hard it is to move inside a punctured shape when motion has already been engaged [25]. Zero represents a frictionless tissue and one represents the maximum amount of friction. Those properties can be used to set up each tissue's behavior to provide the user with a virtual experience that simulates a real procedure. Consequently, Stiffness and Pop Through properties have to be set up to determine the amount of force the user must apply to puncture each tissue. To determine the amount of force needed to move inside a tissue, Punctured Static Friction and Punctured Dynamic Friction must be set up.

Two experiments were constructed to simulate the different sensations anesthetists perceive while executing a spinal puncture. The 3D objects used in the experiments to simulate the internal body layers were simplified and represented as hexahedrons. We opted for this approach because the sensations of puncture and penetration the users can feel while executing each test are the prime goal. Thus, the exact geometry is not essential for the tests proposed. Images of the details of the 3D objects of both experiments can be found in Fig. 2. The arrows of different sizes on the Z-axis illustrate the differences in the 3D objects of each experiment. The first layer (external layer) is a cube, and the other layers have smaller depths for the same width (X-axis) and height (Y-axis), as can be noted in Fig. 2.

The needle size was 65 millimeters (mm). For both experiments, with the increasing force at the interface of each layer, a deformation was introduced. This deformation is a function of the force needed to puncture each tissue. We used a value for the maximum deformation amount of 50 times the Pop through value for each layer, measured in mm. After being punctured, the tissue reassumes the original position (zero deformation).

Table 1 illustrates the values set up for the properties of each layer in the first experiment. The maximum deformation for the first layer for the first experiment (Table 1) is 2.5 mm, which corresponds to 50 times 0.05 (first layer Pop Through).

![Figure 2. 3D objects represent the layers for each experiment: first experiment (a) and second experiment (b).](image)

Table 1. Haptic Properties Used for the First Experiment

<table>
<thead>
<tr>
<th>Property</th>
<th>Layer</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiffness</td>
<td></td>
<td>0.75</td>
<td>0.75</td>
<td>0.75</td>
</tr>
<tr>
<td>Pop Through</td>
<td></td>
<td>0.05</td>
<td>0.15</td>
<td>0.10</td>
</tr>
<tr>
<td>Punctured Static Friction</td>
<td></td>
<td>0.20</td>
<td>0.30</td>
<td>0.30</td>
</tr>
<tr>
<td>Punctured Dynamic Friction</td>
<td></td>
<td>0.30</td>
<td>0.30</td>
<td>0.10</td>
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</table>

The most significant differences could be noted near the right-hand side of the arrows (some are marked inside boxes) in Fig. 3. The smallest differences indicate the strain of moving the needle during deformation. In contrast, the largest differences represent the increase in velocity of needle advance immediately after puncture.

The second experiment has two layers, and its properties are described in Table 2. The curve force versus needle displacement for this experiment is illustrated in Fig. 3 (b).

Table 2. Haptic Properties Used for the Second Experiment

<table>
<thead>
<tr>
<th>Property</th>
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<th>2</th>
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<tbody>
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<td></td>
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<td>0.30</td>
</tr>
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<td></td>
<td>0.30</td>
<td>0.30</td>
</tr>
</tbody>
</table>

The application displays two boxes to the user (named Experiment 1 and 2, each with a model described by the parameters in Tables 1 and 2. A sample execution of the simulation for the two experiments generated the curves of sensation in Fig. 3. A display with numbers shows the amount of needle displacement to the user during the experiment. It starts when there is contact with the first layer. It allows the user to identify the tip position in some of the
questions. Each user manipulated a virtual needle through the haptic device to puncture these two boxes, each one presenting an experiment. The users could not see inside the boxes, relying on the tactile sense felt by their hands through the haptic device.

The number of layers for the two experiments proposed here differs from the original number of layers of the procedure described in section II. The reason is that the idea here is not to represent the whole body or procedure, we are looking to reproduce the most critical and challenging sensations of the process. The other interfaces between layers are simple reproductions of parts of those simulated here.

A. Questions

In the first experiment, users have to answer how many layers they can identify, the starting point of each layer, and the resistance level of each layer. For the second experiment, the participants were questioned on the number of layers, the range (start point and end point) presenting a constant opposition to moving inside a layer, and the most resistance regions. All of these are critical aspects of tactile identification when performing spinal anesthesia.

The questions presented to the volunteers were:

1. How many layers can you feel after inserting the whole needle (for both experiments)?
2. For experiment one, sort the layers in descending order related to their resistance to puncture.
3. For experiment one, what is the starting point of each layer?
4. For experiment two, what are the start and end points (range) of the most resistant layer presenting a constant displacement when maintaining even pressure?
5. For the second experiment, what is the range presenting the most restriction to needle movement?

Questions 1, 3, and 5 address identification of the elastic behavior by the participants, while question 4 is related to plastic behavior. Questions about the initial position (Question 3) or range of the behaviors (Questions 4 and 5) evaluate the feel of each layer's deformation. Each layer starts at its original point and presents a deformation amount immediately before perforation that moves its starting position. Therefore, any answer between the starting point and the dislocated point was considered correct.

IV. RESULTS

A compilation of the participants answers to the questions in each experiment are presented in this section. For the first experiment, the answers were as follows:

- Question 1: Eleven participants (approximately 92%) answered correctly.
- Question 2: Seven participants (58%) answered correctly for all layers. Eleven participants (92%) were right about the least resistant layer, and nine participants (75%) were right about the most resistant layer.
- Question 3: Nine participants (75%) answered correctly for all layers. All twelve participants were right about the second layer. Eleven participants (approximately 92%) were right about the first layer.

After the first experiment, the same twelve participants executed the second experiment and answered the questions as follows:

- Question 1: Twelve participants (100%) were correct in experiment two.
- Question 4: Nine participants (75%) answered correctly.
- Question 5: Five participants (42%) answered correctly. Only two participants missed the starting point. Seven participants (58%) missed the end point.

Below, we report on each of the most important aspects of the procedure covered in these experiments to evaluate the approach in relation to user perception on the behavior of the virtual layers being punctured by a needle.

A. Puncture Resistance

Considering the feelings or sensations of puncture resistance (the subject of question two), only 58% of the users correctly ordered all the layers according to their resistance. This result indicates the need to make a more significant difference in the force needed to puncture each layer to enable such identification. In the same question, many users identified the most resistant layer or the least resistant layer to puncture. This identification is essential to indicate when the needle penetrates the ligamentum flavum (more resistant tissue) or the dura mater (least resistant
tissue). As these two layers are one after the other, the correct identification of one is, in itself, an essential step in the correct simulation of the spinal anesthesia procedure.

B. Elastic behavior

Regarding the identification of elastic behavior (questions 1, 3, and 5), only question five received a score of less than 75%. Nevertheless, even on this question (the one with the worst result) only two volunteers wrongly addressed the starting point of the range with most restriction to needle movement. Therefore, almost all of the participants were able to point out where this layer begins. However, the same result was not achieved with its end, with more than half (58%) missing the end point. Analyzing the responses and the model, the most probable cause of this indicates that the curve used was too high, as there was a significant drop in pressure and large needle displacement when the user left this layer. Thus, if identifying the end of the layer is essential for the problem, it is necessary to reduce the pressure drop in the model to better simulate this behavior.

These experiments indicate the ideal possibility of detecting the number of layers (question one) in all experiments. Identifying the penetrated layers is one of the most critical parts of the procedure of spinal anesthesia. It indicates both the correct determination of the popping sensation of the interface between layers and recognition of the elastic behavior that occurs right before perforating each layer.

Regarding the identification of the beginning of each layer, the subject of question three, it is also important to highlight the number of cases correctly identified (75%). A correct model of depth from the skin to the subarachnoid space should be used to train the anesthetists better. Each layer's starting point is related to the start of the elastic behavior and it is necessary to increase the force to proceed with the advance of the needle at each interface between layers.

C. Plastic behavior

Question four, with a 75% success rate in identification, addresses the great importance of spinal procedure. The identification of being inside the layer presenting the most resistance, that is, feeling a constant pressure against movement through the layer (plastic behavior), is related to the ligamentum flavum, which occurs immediately before reaching the epidural space. The answers to this question confirm that this behavior can be properly simulated.

V. DISCUSSION

The use of a simulator in training can help to attenuate the risks of spinal anesthesia failures related to physicians' lack of skills. This study simulated the behavior of spinal needle penetration through the various ligaments and tissues of the body. A high-fidelity spinal simulator requires features such as a palpable spine, the ability to accommodate various patient positions, adjustable needle insertion inclinations, and certain other principal aspects. Here, the goal was to correctly simulate the essential haptic sensations of needle puncture during the spinal anesthesia procedure. One such sensation is the depth judgment that is crucial to the technique, another is the identification of the transitions between tissues. The resistance variation in each tissue is another aspect considered. The tests have shown that settings already presented in the programmable haptic tools are able to represent these behaviors.

Corrêa et al. indicated that human perception evaluations are little explored in the field of haptic interaction for needle insertion training [5]. They also cite a predominance of subjective tests for user validation of the proposed solutions. In the present study two user perceptions were considered for the assessment of the simulators, the identification of transitions between layers and when users felt the most resistant tissue to needle movement. Both were measured through a subjective analysis using needle depth versus time plots, as in Magill et al. [20]. Another study described a very sophisticated simulator but without user assessment [18]. In contrast, a commercial simulator was tested by 45 anesthetists presenting good feedback on simulation quality in many aspects. However, this simulator lacked realism in questions regarding the correct entry point and insertion angle of the needle [19], which are critical elements of an in vivo procedure. The needle entry point is also out of the scope of a simulator coupled to a pneumatic cylinder. This simulator was tested by eight users (two experienced and six novices), the focus being the assessment of user skills through the simulator rather than the validation of the simulator itself [21]. On the other hand, Färber et al. define both a way to evaluate the users of their implementation and a questionnaire for user validation of the simulator based on user judgment [22]. Another study tested a low-cost 3D printed phantom approach against a commercial simulator with comparable results (subjective test). However, this model lacks variability as it simulates only one body case for each printed phantom [23]. Thus, to construct more objective criteria, in the present study we focused our experiments on asking questions with expected answers rather than questionnaires to validate users' opinions. As such, the responses seek to indicate whether a specific behavior can be correctly mapped.

Furthermore, a 3D model of a pregnant woman's body has already been developed for simulation. Fig. 4 illustrates some images of this model, developed using 3D Studio Max modeling software [30] based on the 3D female body of an interactive 3D human anatomy model [31]. By achieving greater realism and accuracy of simulation, anesthetists will be better trained with the implementation, which will improve patient safety by minimizing the risk of failure in such procedures.

![Figure 4. Aspects of the 3D model of a pregnant body developed for the simulator with different levels of transparency: (a) Body, bones and muscles (red surface). (b) Bone, vertebrae and ligaments.](image-url)
VI. CONCLUSION

The main contribution of this study is to virtually reproduce the main haptic sensations necessary to simulate spinal anesthesia. Experiments that can be done to assess these relationships are also suggested. The experiments demonstrated that haptic tools enable efficient simulation of the behaviors with great simplicity. More objective criteria were used to validate the behaviors instead of only using users' opinions, like the most common assessments from many previous simulators.

The presented model can be adapted to any number of tissues and has flexibility for different aspects of patient variation, which could be applied to each layer in the developed 3D model. We intend to include these in further steps, constructing a simulator allowing customizable body shapes, weights, and heights. Another personalized aspect of the simulator will be to respond according to the user's expertise. A user with better skills in the first phase will advance more quickly to a second phase, while users identified as having lower skills will have to repeat the process at the lower level with greater accuracy to advance further. If implemented in the training center as a requirement, this approach could prevent patients from being attended by a person with low qualifications.

REFERENCES


