Clinical User Study Design

A SYSTEM TEST PLAN

submitted by

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Virtual Reality Drilling Simulator for Laminectomy (Team 19)

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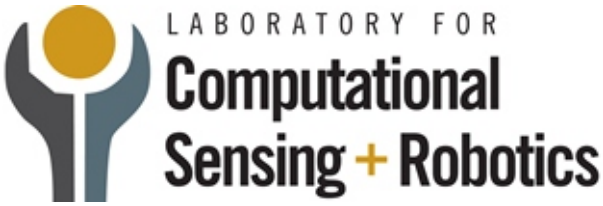

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ACKNOWLEDGEMENT

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Many noble hearts contributed immense inspiration and support for the successful completion of the project. We are unable to express our gratitude in words to such individuals.

We would like to express our deep regard to Dr. Rachel Bronheim, Dr. Michael Raad, and Dr. Amit Jain for collaborating with us in helping organize the user studies. When the residents were busy evaluating faculty or learning new techniques, the team worked hard to organize a schedule for us students to have a successful user study. It has been a pleasure working with the Johns Hopkins Orthopaedic Department.

ABSTRACT

We are evaluating the use of a colored virtual-reality (VR) drilling navigation platform as part of pre-operative planning and surgical training for laminectomy and mastoidectomy surgeries. This image-guided navigation system is build on top of the AMBF platform and provides a dynamic color overlay for drilling that indicates safe anatomies (shown as green), sensitive structures that require caution (shown as yellow), and restricted structures (shown as red). We plan to assess clinical utility by conducting user studies for laminectomy surgeries where participant surgical performance is compared against non-colored navigation.

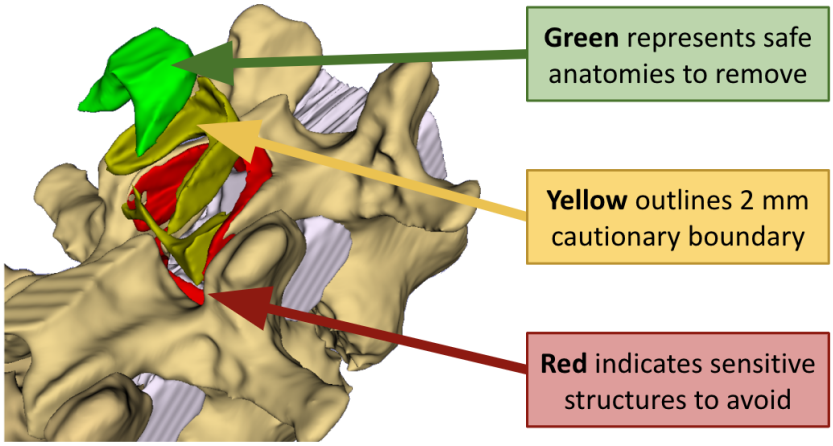


Figure 1: **Colored Overlay** Expanded view from 3D Slicer displaying the three colors (red, yellow, green) and their associated representations.

IRB APPROVAL

The user study proposed in this document was submitted to the Johns Hopkins Internal Review Board (IRB) under the title "Virtual Laminectomy Drilling Comparing Colored Voxel Region Representations with Audio/Visual Warnings using a Head-Mounted Display" under principal investigator Dr. Amit Jain. The application was approved on **March 16, 2023** with the IRB number **IRB00351495**.

As a part of the IRB study, all team members completed the Researchers (CITI), Human Subjects Research – Biomedical Research (CITI), Conflict of Interest and Commitment. **No personal identifiers were collected throughout the study**.

The study proposed to examine and improve methods of augmented drill navigation in surgery, specifically performing laminectomies. Drilling in these spine surgeries requires precision drilling in a specific area and to a specific depth. Delicate anatomy such as the spinal cord needs to be avoided, and often a 1 mm layer is kept in the superior half, protecting the vertebral foramen anatomy, which the spine surgeon can easily break off when removing bone. Additionally, enough bone needs to be preserved so as to preserve the structural integrity of the spine segment. Drilling for these surgeries can be particularly challenging and taxing on surgeons, and various navigation methods have been developed to improve drilling. These include audible noises and speech, colors to direct drilling regions, and similar. This study will test several different navigational cues, or combinations of cues, to participants as the subject to assist in the drilling task.

Following each session, participants were asked to complete a short survey about the drilling and navigation methods which were tested. This survey asked about the effectiveness of the drilling platforms tests and participant's preferences to these systems. The survey will also ask if participants are a medical professional or not. If so, it will ask how many years participants have been a practicing medical professional, and if participants perform drilling procedures on a frequent basis.

The IRB application was revised on **April 18, 2023** to allow for the inclusion of the NASA Task Load Index (NASA-TLX) Survey. The NASA-TLX survey is a widely used tool for measuring perceived workload across a variety of tasks and settings. Originally developed by NASA in the 1980s, the NASA-TLX has become an essential instrument for assessing cognitive, physical, and emotional demands associated with a task.

The importance of the NASA-TLX survey lies in its ability to provide detailed insights into the nature of a task's workload and the factors that contribute to it. By evaluating different dimensions of workload such as mental demands, physical demands, and time pressure, the survey can identify areas where a task may be particularly challenging or where improvements can be made.

LIST OF FIGURES

CHAPTER 1

PLANNING THE STUDY

1.1 Dependencies

Dependencies for User Study				
Dependency	Need	Status	Planned	Hard
CT scans segmentations for laminectomy	Segment anatomy according to ENT surgeons	Completed	2/20	2/20
Full IRB approval for user study at JHH	Organize and execute user study	Completed	3/6	3/12
3D Slicer	Make segmentations	Completed	2/20	2/20
IRB documents for laminectomy study	Review prior user study protocols	Completed	2/20	2/20
Study participants	Participate in clinical study	Completed	3/5	3/17

1.2 Segmentations

One of our first tasks was producing accurate segmentations utilizing the software 3D Slicer and CT spine scans. One of the initial feedback from our clinical partners (i.e. Dr. Amit Jain) was that the previous segmentations were not accurate or realistic for ENT surgeons. Spending time Given that we had to segment 5 different spines, each with 3 different segments (L1, L2, & L3), we decided to tackle this task by first developing a segmentation protocol that would be reproducible.

The segmentation protocol is as follows:

Listing 1.1: Segmenation Protocol in Slicer 3D

1) Open Segment Editor, **and** orient **in** P–axis
2) Create appropriate cuts
   Create a new segment L1
   Add L1_inf_cut_zone **and** L1_min_inf_cut_zone
   Subtract the L1_spinous_process_cut
   Hide the L1 prior segmentations & spinous cuts
3) Enter markups
   Select lines
   Mark a line with endpoints at the indents of spine
   Follow markup as seen below

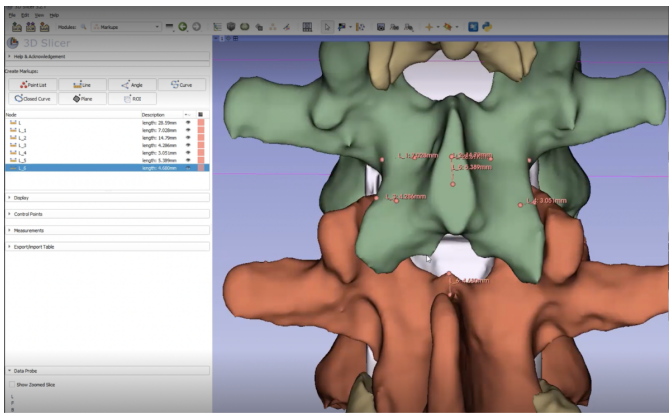


Figure 1.1: **Markups to Guide Segmentation** Line must not be above the pars.

4) Make a new Segment in Segment Editor
   Name it "initial_cut"
5) Navigate to Segment Editor —> Scissors
   Operation: Fill inside
   Shape: Free–form
   Slice Cut: Unlimited
   Editable Area: Invisible all visible segments
   Modify other segments: Allow overlap
6) Hide Vertebral Formaen View and L1–L3 vf_hazard
7) Select Segment initial_cut
   Follow outline as see in graphic seen below

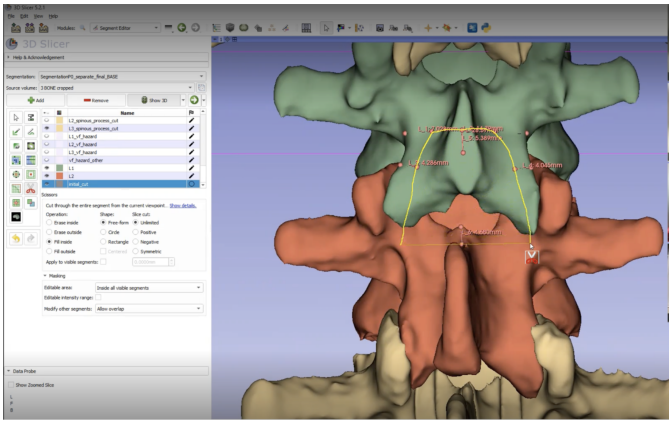


Figure 1.2: **Initial Cut Segmentation** Follow markups from step 3)

8) Navigate to Segment Editor —> Scissors
   Operation: Erase inside
   Shape: Free–form
   Slice Cut: Unlimited
   Editable Area: Inside initial_cut
   Modify other segments: Allow overlap
9) Select Segment initial_cut and remove depth from segment
   Follow graphic below

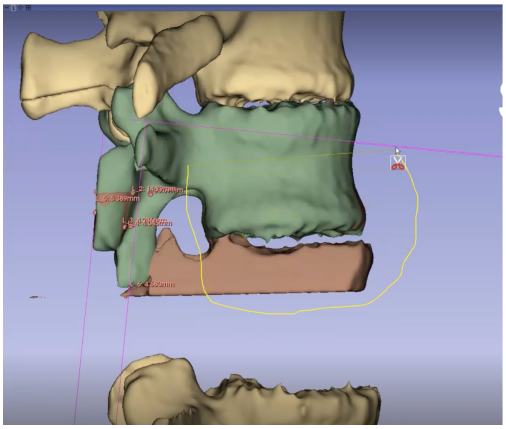


Figure 1.3: **Remove Depth from Initial Cut** To remove the overlap of Lamina segment.

10) Make a new Segment in Segment Editor
    Name it "L1_B"
11) Navigate to Segment Editor —> Scissors
    Operation: Fill inside
    Shape: Free–form
    Slice Cut: Unlimited
    Editable Area: Inside initial_cut

Modify other segments: Allow overlap

12) Select Segment L1_B and follow graphic below

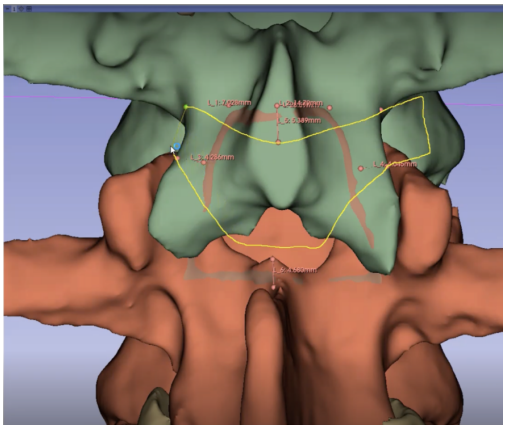


Figure 1.4: **The Cut for L1 B**

13) Make a new Segment in Segment Editor
Name it "Segment_X"

14) Navigate to the Logical Operators
Add Initial_Cut – L1_B

14) Make a new Segment in Segment Editor
Name it "L1_A"
Go to Logical Operators and copy Segment_X into L1_A
Erase the bottom portion

15) Make a new Segment in Segment Editor
Name it "L1_C"
Go to Logical Operators and copy Segment_X into L1_C
Subtract out L1_A
Erase the right portion

16) Make a new Segment in Segment Editor
Name it "L1_D"
Go to Logical Operators and copy Segment_X into L1_D
Subtract out L1_A, L1_C

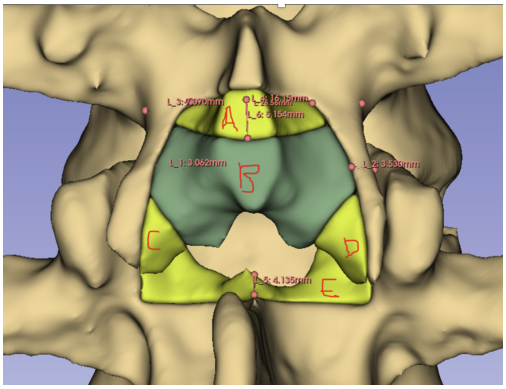


Figure 1.5: **Final Segmentation** All Pieces that Participants will Drill Out

17) Reassign the colors for the individual pieces

We ultimately were able to generate 20 segmentations that were validated by Dr. Amit Jain and other ENT surgeons.

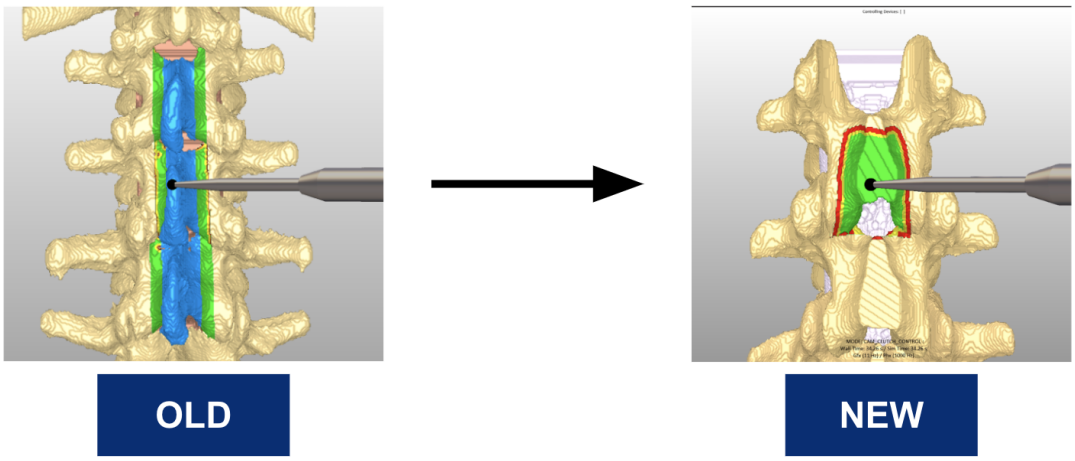


Figure 1.6: **Updated Segmentations** More realistic laminectomies to help guide surgeons

1.3 Recruitment & Logistics

We initially proposed utilizing a flyer and email to spread the word, but when looking back upon the IRB protocol, we realized the application specified that we were only allowed to recruit participants for our user study through word of mouth. So instead of modifying the IRB protocol, we ultimately decided to rely on our clinical partners, namely Dr. Rachel Bronheim and Dr. Michael Raad to recruit residents, medical students, and fellows. Dr. Amit Jain and anyone involved in organizing the user study was prohibited.

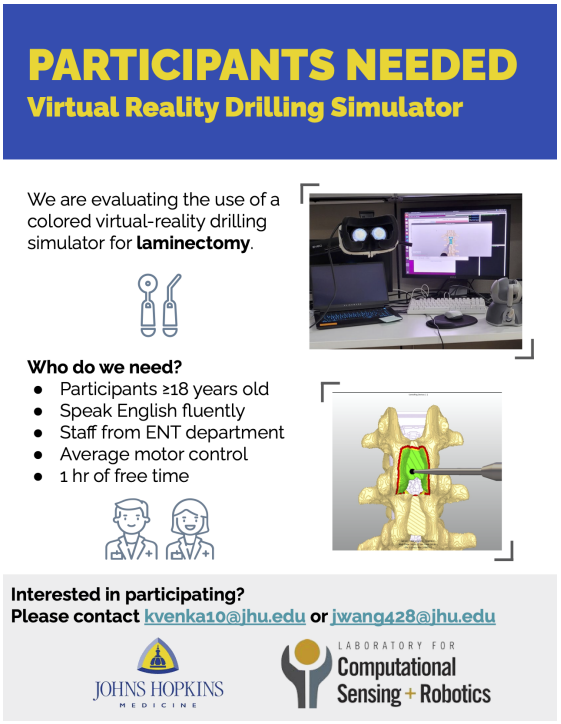


Figure 1.7: **Proposed One-Pager**

Given that residents are extremely busy with packed schedules, we ultimately decided to visit the Johns Hopkins Outpatient Center (JHOC) on the resident's "Education Days". These sessions were dedicated times where all the residents gathered in one location, and thus made the perfect environment to recruit residents from. So on 4-6, 4-13, 4-27, and 5-4, we as a team went to go perform user studies.

CHAPTER 2

STUDY DESIGN

2.1 Proposed Design & Purpose

We propose a comparative study design to evaluate the clinical utility of VR navigation using colored-navigation for laminectomy surgeries. The navigation color scheme is green, yellow, and blue, indicating anatomies that are safe to drill, require caution while drilling, and unsafe to drill. The colored-navigation method will be compared to a non-colored-navigation method. The goal of this study is to perform a comparative analysis of colored VR navigation platform to determine its potential benefit in preoperative planning and surgical training.

We will recruit up to 10 subjects. Each subject will conduct 12 operations over 1 hour. Inclusion criteria are male/female medical personnel working (e.g., clinicians, surgeons, attendings, fellows, residents, NPs, PAs) at the Johns Hopkins Hospital (JHH) with self-reported average vision and motor control and fluency in English. Participants will all be greater than 18 years of age. Participants will be recruited with the help of faculty mentors.

Subjects will be seated with their drilling arm resting on an arm rest while holding a robotic haptic device (Phantom Omni). The device mimics a handheld surgical drilling tool by providing force and stiffness feedback as the user probes different anatomy in view. Users will use the VR head set to immerse themselves in the operating room. Subjects will be asked to mimic a laminectomy drilling with or without colored-navigation. Subjects will be timed on 10 operations and the objective is to do these cases as accurately and quickly as possible.

The colored navigation system has red voxels indicating sensitive structures that should not be drilled; drilling red volumes results in a breach that flashes a red

warning alert. Yellow voxels indicate the user is drilling near a sensitive anatomy, and a yellow warning will recommend caution. Green voxels are safe drilling regions, and no continuous warnings will be provided for drilling here. Blue voxels indicate anatomy is optional for drilling. Subjects will first be given two practice cases, one with colored-guidance and one without, to become accustomed to this platform.

The following figure indicates the study design. The collection of 10 spines will be in randomized order. The first two cases are the aforementioned untimed practice cases; the subsequent 10 cases are timed, 5 with colored-guidance and 5 without. Each subject sees the cases in a different randomized order, to counterbalance navigation conditions. After the practice phase, subjects receive a 1 min break; during the evaluation phase, subjects receive a mandatory 1 min break after 4 cases.

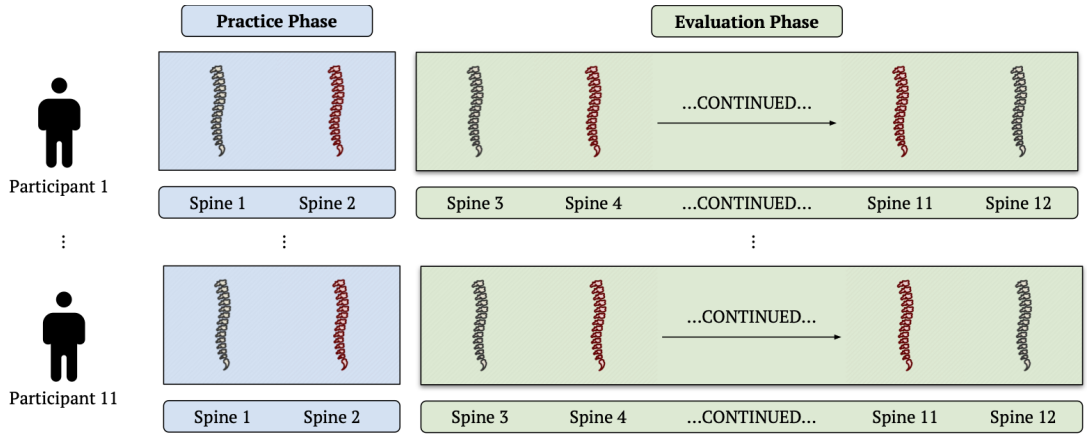


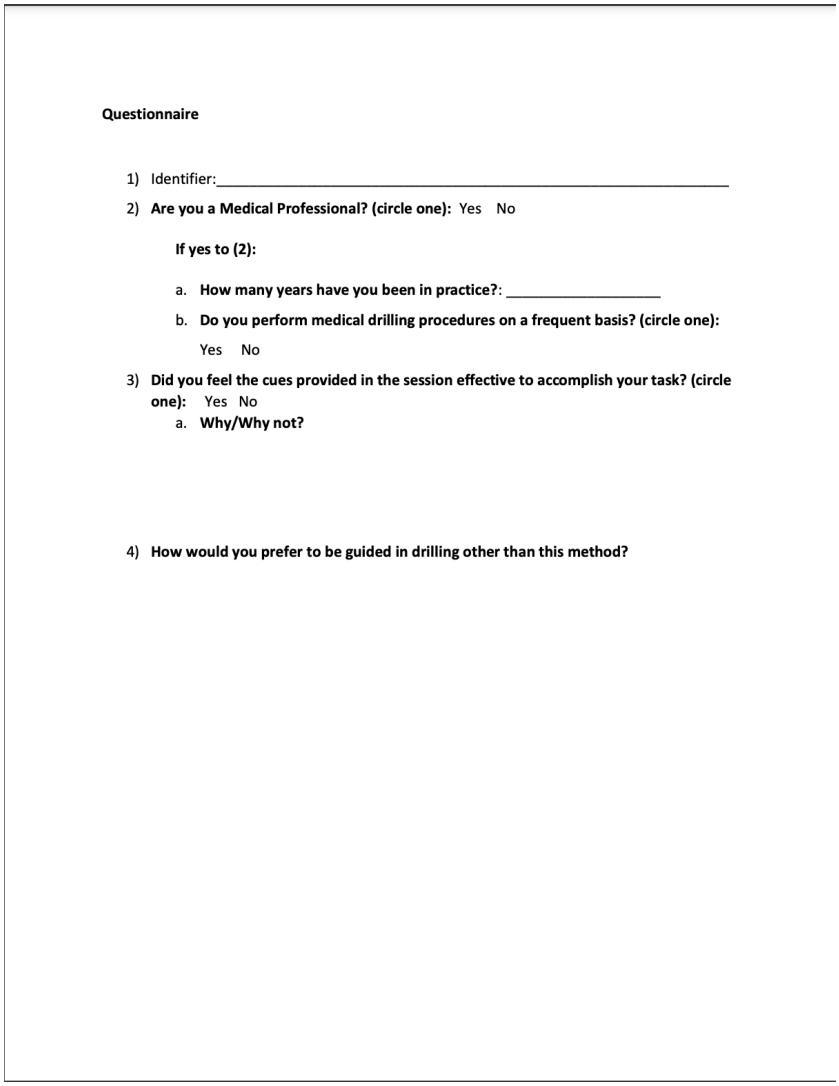
Figure 2.1: **Laminectomy Study Design** We overview the laminectomy study design. The first phase is the Practice Phase where participants are given two cases (colored v.s non-colored) to familiarize themselves the VR platform.

For each operated case, we collect: number of voxels removed (stratified also by navigation color), number of breaches into sensitive anatomy, force applied. Additionally, subjects will be interviewed about navigation preferences using the NASA-LTX framework. This survey asks the subject whether they are a medical professional, if they have prior/current experience in drilling operations, and their post-session thoughts on the colored-navigation.

2.2 Subjective Questionnaires

Following the measured cases, participants were asked to complete a short questionnaire about the drilling and navigation methods which were tested. This

questionnaire will ask about the effectiveness of the drilling platforms tests and participants' preferences to these systems. The questionnaire will also ask if participants are a medical professional or not. If so, it will ask how many years the participants have been a practicing medical professional, and if participants perform drilling procedures on a frequent basis. This questionnaire allows for the collection of feedback about the system and additionally provides opportunities to stratify participants based on surgical experience.



Questionnaire

1) Identifier:_____

2) **Are you a Medical Professional? (circle one):** Yes No

   If yes to (2):

   a. **How many years have you been in practice?:** _____

   b. **Do you perform medical drilling procedures on a frequent basis? (circle one):**

      Yes No

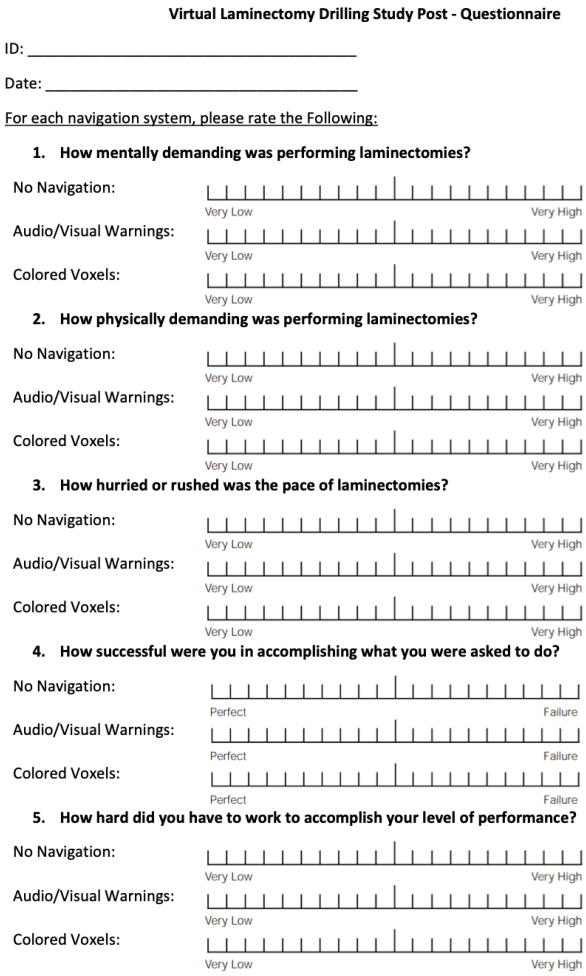
3) **Did you feel the cues provided in the session effective to accomplish your task? (circle one):** Yes No

   a. **Why/Why not?**

4) **How would you prefer to be guided in drilling other than this method?**

Figure 2.2: **Questionaire.** This form surveyed participants about the two navigation methods presented: color and non-colored guidance. It also surveyed participants about their expertise and experience performing drilling procedures, allowing for stratification of results.

The NASA-TLX survey was also provided to participants after mending the IRB protocol. The survey allowed for the quantification of cognitive load experienced by participants by having participants rate the following measures on a scale of 1 to 20: Mental Demand, Physical Demand, Temporal Demand, Performance, Effort, and Frustration.



Virtual Laminectomy Drilling Study Post - Questionnaire

ID: _____

Date: _____

For each navigation system, please rate the Following:

1. **How mentally demanding was performing laminectomies?**

No Navigation: Very Low — Very High

Audio/Visual Warnings: Very Low — Very High

Colored Voxels: Very Low — Very High

2. **How physically demanding was performing laminectomies?**

No Navigation: Very Low — Very High

Audio/Visual Warnings: Very Low — Very High

Colored Voxels: Very Low — Very High

3. **How hurried or rushed was the pace of laminectomies?**

No Navigation: Very Low — Very High

Audio/Visual Warnings: Very Low — Very High

Colored Voxels: Very Low — Very High

4. **How successful were you in accomplishing what you were asked to do?**

No Navigation: Perfect — Failure

Audio/Visual Warnings: Perfect — Failure

Colored Voxels: Perfect — Failure

5. **How hard did you have to work to accomplish your level of performance?**

No Navigation: Very Low — Very High

Audio/Visual Warnings: Very Low — Very High

Colored Voxels: Very Low — Very High

Figure 2.3: **NASA-TLX Survey.** This form surveyed quantified cognitive load felt by participants.

2.3 Script for Conducting Study

To carry out our user studies and not introduce any bias with any participant, we opted to write a script to be read to each and every participant.

SCRIPT FOR CONDUCTING LAMINECTOMY USER STUDIES

Thank you for participating in our study.

Before we start, take time to read and sign our consent form which goes over the study. We'll ask you a few questions for understanding, and then your signature.

Take as much time as you need. We'll do another brief explanation afterwards.

Here's the consent form [HAND OVER CONSENT FORM TO THEM]. Let us know when you've finished reading.

[WHEN FINISHED READING]

Could you answer these 3 questions for clarification:

[ANSWERS QUESTIONS]

Great. Please sign below.

[COLLECT IRB IDENTIFIER (NOT NAME) FROM PARTICIPANT] Now PLEASE pay careful attention. We'll be reading basic instructions to you to outline the specifics of this study. This might seem a little boring or mundane, but we read these to keep testing consistent between participants.

Your task is to perform a laminectomy, or to drill out a specified volume of bone as directed in each session. Each session will include two practices and 12-14 other laminectomy drilling tasks.

To make this laminectomy you use this haptic stylus (the pen-like object attached to the haptic device here [POINT TO HAPTIC DEVICE]) which controls a virtual drill to drill out the bone in the L1, L2, and L3 segments of a simulated spine. This device provides vibrations and also stiffness feedback of the anatomy you see and will drill. Use a proper 2-handed grip at all times to control the surgical drill as you have been trained. A 3D visual of the spine which you will drill will be displayed via the VR headset here [POINT TO VR HEADSET] representing a surgical microscope. Headphones will convey the sound of drilling to help you detect when you are drilling bone along with the vibrations of the haptic tool.

Take some time right now to adjust your chair to a comfortable height for sitting and distance from the desk and haptic device. Adjust the arm rests, and correctly position the VR headset to a comfortable viewing level. You can move its position closer to your face and also change the viewing angle.

Your task is this: mimic the final cut you see as close as possible while avoiding penetration into the vertebral foramen (in other words, plunging too far). The vertebral foramen is shown in a very light off-blue (almost white).

You will be shown laminectomy segment to remove using two different visualization

methods.

No Image-guidance Method

[PULL UP THE NO-IMAGE TEST CASE WITH THE CORRECT REFERENCE PHOTO ON THE SCREEN]

For this method you will see a 2D image on the desktop monitor showing the outline of the area to cut. You will need to match the boundaries of this visual drilling as close as possible without penetrating into the vertebral foramen. Look at the desktop monitor for reference and back in the VR headset to drill out the volume. Each test will be timed, and you are to complete each task as quickly as possible in a well-controlled manner. The timing begins when you start drilling bone and stops with the last bone segment you drill so your time will not be affected by me switching or starting your session. We will first let you practice drilling on each case in a test that is not timed.

Both methods use the same function of controlling the drill. The first button

At times, the drill may get stuck due to the nature of the drilling task....

You may also press CNTRL-R or ask me to reset the drill in the home location.

Take a minute now to put on the headset and drill a laminectomy, copying the outline on the screen. Feel free to ask any questions.

[ALLOW USER TIME TO COMPLETE THE DRILLING, ANSWER ANY QUESTIONS, HELP CLARIFY WORKING THE DRILL WHERE NEEDED]

Color-Boundary Guidance Method

[PULL UP THE NO-IMAGE TEST CASE WITH THE CORRECT REFERENCE PHOTO ON THE SCREEN]

This method displays colored boundary overlays on the bone you need to drill. Drill out the green and yellow zones but do not drill out red zones. The yellow zones are 1mm thick zones boundaries acting as “slow-down” or “careful drilling” reminders.

This case will not show a colored plunge boundary in the inferior portion of the spine where the ligamentum flavum generally resides. As this layer is generally protected by the ligamentum flavum when drilling, you do not have to worry as much about drilling into the vertebral foramen in these “uncovered” areas.

Take a minute now to put on the headset and drill a laminectomy, copying the outline on the screen, or using the color guidance cues. Feel free to ask any questions.

[ALLOW USER TIME TO COMPLETE THE DRILLING, ANSWER ANY QUESTIONS, HELP CLARIFY WORKING THE DRILL WHERE NEEDED]

We'll now begin the test. Remember you are free to take a break or leave the study at any time.

After every 4 tests you will be required to take a break from drilling cases for at least 1 minute which will be timed by the test proctor.

Following the test you will be asked to complete a short NASA-TLX survey. This survey is an assessment for measuring subjective mental workload during a task. This survey will ask about the effectiveness of the drilling navigation methods and your preferences to these systems. The survey will also ask if you are a medical professional or not. If so, it will ask how many years you've been a practicing medical professional, and if you perform drilling procedures on a frequent basis.

Remember: these tests are timed. Please use two hands when drilling. Copy the image as closely as possible. Do your best to avoid drilling into the vertebral foramen and red zones. Be sure drill out green and yellow zones.

Please put on the headset and we will begin.

[BEGIN TEST]

[END OF TEST]

Now that you've completed the drilling portion, please fill out this brief NASA-TLX survey and questionnaire.

[SURVEY, HAVE THEM PLACE IDENTIFIER NUMBER/NAME ON TOP]

Thank you again for your time participating! We really appreciate your help today.