

Evaluating the clinical utility of a colored virtual-reality drilling navigator for assisting laminectomy and mastoidectomy surgeries

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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 built 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 two user studies for laminectomy and mastoidectomy surgeries where subject surgical performance is compared against non-colored navigation. We also aim to incorporate new graphical user interface (GUI) features into the existing software, specifically a depth perception interface and a synchronized data extraction pipeline.

1. Clinical Motivation

Laminectomy is a delicate surgical procedure that involves removing portions of the lamina, a vertebral bone that covers the posterior of the spinal canal covering the spinal cord. This procedure is typically recommended for patients who experience spinal stenosis, or narrowing of the spinal canal, which can cause pain as the bony tissue pinches spinal nerves [1]. The surgeon must mill out enough lamina to alleviate the pressure on the spinal cord and nerves while also preserving enough bone to maintain the structural integrity of the vertebrae. In the U.S. alone, there are 500,000 laminectomies performed annually [2]. These operations are done manually and require significant operative skill.

To ensure the safety of the procedure, the surgeon must be wary to not drill past the thick ligamentum flavum (LF). Drilling the superior-most and inferior-most parts of this geometry requires careful navigation as the LF serves as a protective barrier between the spinal cord and the bony vertebrae. A single misstep during drilling could lead to inadvertent puncture of the spinal cord, resulting in life-altering consequences for the patient [2]. But even with the utmost care, incidental durotomy (puncturing of the dura) has been reported to occur in up to 11.3% of cases [3–5].

Mastoidectomy is a surgical procedure performed to treat infections in the air-filled cells of the mastoid bone, and it is estimated that around 60,000 of these surgeries are performed annually in the United States [6]. However, the procedure carries significant risks due to its complexity, which includes the need for drilling into parts of the temporal bone to reach the internal auditory canal. This puts vital anatomical structures, such as the facial nerve and the semicircular canal, at risk of damage, which can result in severe consequences such as partial or total loss of hearing or even death of the patient [7].

Because of these risks, performing a mastoidectomy requires high precision, and surgeons must cope with a significant cognitive load during the procedure. In fact, research has shown that the cognitive load for surgeons can peak at around 10% above average during the later, more complex stages of the surgery [8]. Despite the challenges, mastoidectomy remains a critical procedure for treating infections in the mastoid bone, and it is essential that surgeons are trained and prepared to manage the cognitive load and perform the procedure safely and effectively.

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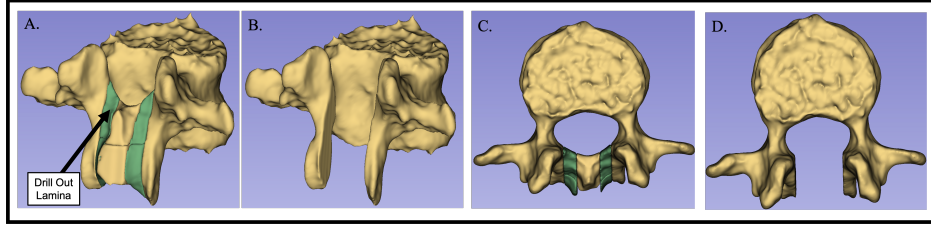


Figure 1: **Laminectomy Segmentation.** We visualize a segmentation of a vertebrae. We can see the isometric views (A, B) and top-down views (C, D). The green regions on the model (A, C) are regions of the lamina to be removed in laminectomy by drilling. (B, D) show the results of an open laminectomy.

Research efforts have been devoted to improving the training of new surgeons in laminectomy and mastoidectomy through the use of physical and mixed-reality simulator systems [7, 9]. In this project, we use a novel color-guided virtual-reality (VR) platform for surgical tasks. The VR platform creates a color scheme overlaid on the visible anatomy that indicates where the user should drill; this coloring is generated using the Colored Sine Distance Field (SDF)-boundary drilling navigation (CSDN) method. We propose three contributions: 1) conduct a comparison study of CSDN methods to non-navigated methods for laminectomy, 2) conduct a feasibility of using CSDN for mastoidectomy tasks, and 3) develop code to improve the current VR GUI and data extraction pipeline.

2. Prior Work

Current surgical robotics systems such as Stryker’s Mako robot [10] and Intuitive’s da Vinci [11] require human-directed navigation for successful operation [12]. Furthermore, these systems lack standardized training protocols which reduces clinical adoption due to operative difficulty [13]. Implementing training programs to accompany new medical robotics has led to better surgical outcomes and less adverse complications [14].

Virtual reality (VR) or mixed reality systems show promising chances to fill in this need. Surgical simulation has been iteratively used by trainees for skills training across multiple disciplines owing to a learning environment that mitigates patient harm. Research has found that compared to non-VR training, VR training enhanced objective OR performance, decreased operation duration, and lowered the number of intraoperative errors [15]. VR systems have also found applications in pre-operative planning. Medical image data are manipulated to accurately plan surgery in a computer environment and then transfer that virtual plan to the patient using customized instruments.

PhD candidate Hisashi Ishida, Assistant Research Scientist Adnan Munawar, and Postdoctoral Fellow David Usevitch have developed a virtual drilling simulator using CSDN for training in laminectomy and mastoidectomy surgeries [16]. The simulator allows surgeons to control a virtual drill using a haptic device and provides a patient’s anatomical volume created from CT scans for simulation. The system’s guidance algorithm calculates the distance between the drill and the nearest anatomy and provides real-time feedback to the surgeon. Additionally, a novel algorithm based on SDFs of sensitive anatomical structures speeds up the computation of the closest anatomy.

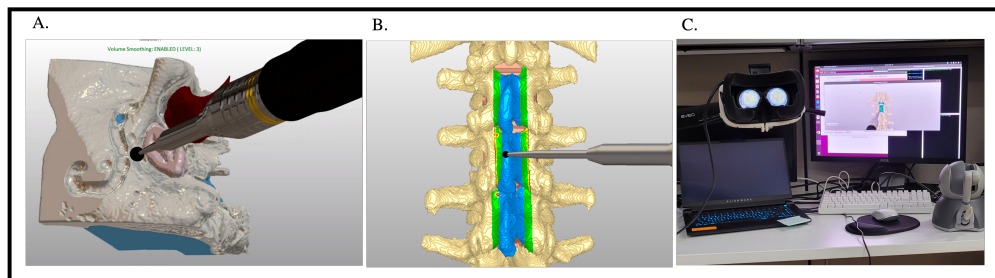


Figure 2: **Visualization within VR Drilling System** (A) presents the VR drilling system for mastoidectomy. (B) presents the VR drilling system for laminectomy. (C) presents the current setup of the system.

This study aims to examine and enhance virtual drill navigation methods for laminectomies and mastoidectomies. These surgeries require precise drilling in specific areas and depths, while avoiding delicate structures such as the ligamentum flavum. The drilling depth usually leaves a 1 mm layer of bone that the surgeon can remove easily. Laminectomies require drilling in a line, while mastoidectomies can be performed in various shapes. Surgeons find drilling for these surgeries challenging, and several navigation methods, including visual cues and audible feedback, have been developed to improve accuracy. This project will look to validate the benefits of colored VR navigation.

3. Project Goals

Our project is centered on clinically validating the use of a CSDN VR drilling platform as a navigation and training tool for orthopaedic & ENT surgery.

3.1. Conduct a comparative user study for laminectomy

The LCSR group has a prototype of the colored VR drilling platform and is expected to receive IRB approval for a user study experiment by the beginning of March. We plan to execute a comparative user study, perform data analysis, and report final results that assess the clinical benefits of CSDN. We hypothesize that subjects will perform better (quantified by accuracy of milled anatomy) when provided color-guidance as opposed to non-colored navigation. These results will be part of a submission to *IEEE Transactions on Medical Robotics and Bionics*.

3.2. Conduct a feasibility study for laminectomy

We aim to conduct a smaller user study (3-5 subjects) that assesses the feasibility of CSDN VR navigation for mastoidectomy. We will report subject accuracy and duration during operations and compare this to prior literature on mastoidectomy. We will draft a shorter clinical paper, in the style of Razavi 2019 [17], for submission to *Otology and Neurotology*.

3.3. Augment user VR experience for future clinical applications

We plan to improve the user feedback (Figure ??) provided by the VR drilling platform by implementing a depth perception interface that visualizes the physical limits of the user's workspace. We also plan to design a synchronized data extraction plugin that obviates the need for multi-threaded Python scripts to interface with Robot Operating System (ROS). These features will be developed in parallel to conducting user studies and are scheduled for integration with VR setup before the mastoidectomy feasibility study.

4. User Study

4.1. Laminectomy Study Design

We propose a comparative study design to evaluate the clinical utility of VR navigation using CSDN for laminectomy surgeries. The navigation color scheme is green, yellow, red, and blue indicating anatomies that are safe to drill, require caution while drilling, unsafe to drill, and optional to drill, respectively. The CSDN method will be compared to a non-navigated VR system. 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.

This study will take place over the upcoming two months (Mar-Apr 2023). We will recruit up to 10 subjects. Each subject will conduct 14 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 >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 CSDN. Subjects will be timed on 12 operations and the objective is to do these cases as accurately and quickly as possible.

The CSDN VR platform colors each voxel based on the drilling risk of its associated anatomy. Red voxels indicate 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 CSDN and one without, to become accustomed to this platform.

Figure 3 indicates the study design. The collection of 14 spines will be in randomized order. The first two cases are the aforementioned untimed practice cases; the subsequent 12 cases are timed, 6 with CSDN and 6 without. Each subject sees the cases in a different randomized order, to counterbalance navigation condition. After the practice phase, subjects receive a 1 min break; during the evaluation phase, subjects receive a mandatory 1 min break after 4 cases.

For each operated case, we collect: number of voxels removed (stratified also by navigation color), number of breaches into sensitive anatomy, number of red/yellow warnings, drilling time per case, and final thickness of lamina after operation. Additionally, subjects will be interviewed about navigation preferences using the NASA-LTX framework [18]. 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 CSDN.

4.2. Data Analysis

4.2.1. Comparison of Navigation Methods

We plan to organize these results into three side-by-side box plots. The x-axis contains two conditions: control (non-colored navigation) and CSDN navigation. Three metrics are plotted on the y-axes: 1) average number of breaches per subject, 2) average final thickness of lamina per subject, and 3) average operation time per subject between. Two-sample t-tests will be used to compare metrics between conditions.

4.2.2. NASA-TLX Survey Response

We will report the subjects' average number of years in medical practice, percentage of subjects that regularly performed drilling procedures, and anecdotal preferences for CSDN. We will also stratify drilling accuracy and time by surgery experience (0-1, 2, 3, 4+ yrs).

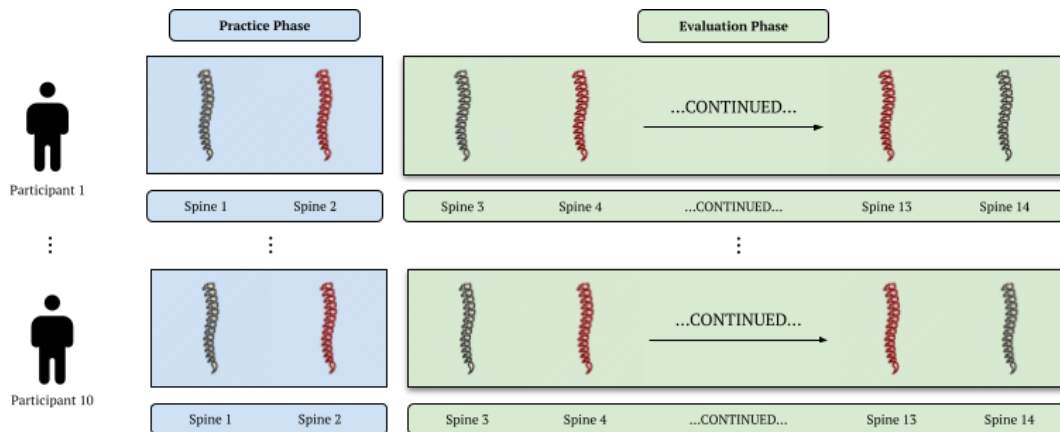


Figure 3: **Laminectomy Study Design** We overview the laminectomy study design. The first phase is the Practice Phase where participants are given two cases (CSDN and non-CSDN) to familiarize themselves the VR platform. No measurements are made during this phase. Next is the Evaluation Phase, where participants are to work through 12 drilling cases (6 CSDN, 6 non-CSDN; random sequence for counterbalancing). Outcomes are measured during this phase for results reporting.

5. Technical Approach

5.1. Depth Perception Interface

Users benefit from haptic feedback to determine their relative virtual position and which anatomy they are drilling. However, the physical workspace has constrained dimensions, and users misinterpret the stylus

hitting the phantom base itself to be haptic feedback. We'd like to incorporate a depth interface in the GUI meant to alert users when the stylus is near contact with the phantom base (Figure 4).

We plan to do this by using the pre-defined coordinates of the stylus relative to the phantom base [19, 20]. Consider the phantom base to be the origin. We ask users to calibrate the system by extending their stylus as far out in front of the base as they can. This establishes the z -axis depth. We will empirically set a z -distance threshold t to the $x - y$ plane, wherein if the stylus is within a distance t from the base, the marker will turn red and warn impending contact with the phantom base.

We will unit test the design interface by manipulating the depth and coordinates of the stylus.

5.2. Synchronized Data Extraction

The current data extraction pipeline is written in Python using `data_record.py`. This module runs simultaneously with the AMBF simulator and extracts pose information using the `rospy` package. However, this multi-threading risks delayed data extraction and therefore incorrect measurements of user motions.

We plan to overcome this challenge by building a C++ plugin that directly captures ROS outputs and extracts the left/right stereo images, depth point cloud, segmentation mask, drill/camera poses, removed voxels, and drill burr changes. We will also design unit tests with a practice user study session to ensure correct data extraction.

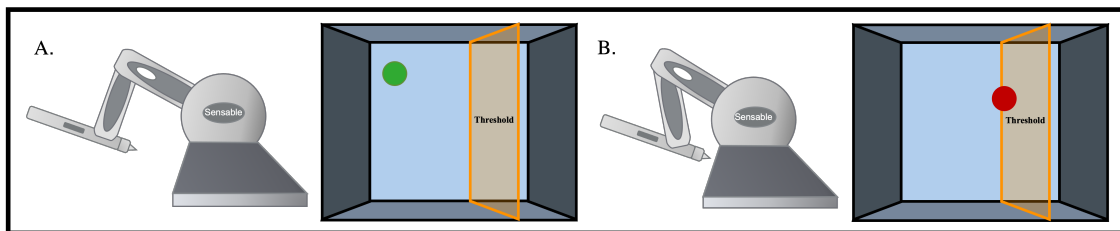


Figure 4: **Depth Perception** Schematic of depth perception interface with top row being the physical workspace and bottom row depicting the intended GUI interface. (A) Stylus is not within contact threshold with base. (B) Stylus is within contact threshold with base. Marker turns red when near the threshold.

6. Deliverables

	Activities	Results
Minimum	Familiarize with 3D Slicer software and practice segmenting a lumbar spine CT scan	A reproducible written protocol for segmenting lumbar spine CT scans using 3D Slicer software
	Segmenting lumbar spine CT scans following the written protocol	15 locally-saved segmentation files of lumbar spines
	Build virtual-reality platform locally and upload lumbar spine segmentations to GUI	Ready-to-use laptop with virtual-reality colored navigation GUI for laminectomy user study with the 15 lumbar spine cases
Expected	Conduct 10 laminectomy user sessions at JHH and locally extract raw data from user recordings	10 × 16 locally saved hdf5 files of user data extracted for each virtual-reality session
	Performing data analysis and drafting results with mentor feedback	Written results section for laminectomy paper for submission to <i>IEEE Transactions on Medical Robotics and Bionics</i>
	Discussions with ENT surgeons to determine relevant anatomy for mastoidectomy navigation and practice segmenting inner ear structures in 3D Slicer	A reproducible written protocol for segmenting inner ear CT scans using 3D Slicer software
	Segmenting inner ear CT scans following the written protocol	15 locally-saved segmentation files of lumbar spines

	Build virtual-reality platform locally and upload inner ear segmentations to GUI	Ready-to-use laptop with virtual-reality colored navigation GUI for mastoidectomy user study with the 15 inner ear cases
	Implement a depth perception interface	A program that visualizes phantom position in reachable workspace (input: phantom stylus coordinate, output: mini-GUI with marker indicating user depth in workspace)
Maximum	Conduct 4 mastoidectomy user sessions at JHH and locally extract raw data from user recordings	10×16 locally saved hdf5 files of user data extracted for each virtual-reality session
	Performing data analysis and drafting results	Written results section for mastoidectomy manuscript to be submitted to <i>Otology and Neurotology</i>
	Literature review and discussions with mentors and ENT surgeons	Written first-authored draft for <i>Otology and Neurotology</i> evaluating the feasibility of a colored virtual-reality navigation system for mastoidectomy procedures
	Implement a C++ plugin for data extraction	A program that synchronizes data extraction with user recording during virtual-reality session (input: user pose and drilling progress, output: extracted data file)

Table 1: Deliverables

7. Milestones and Timeline

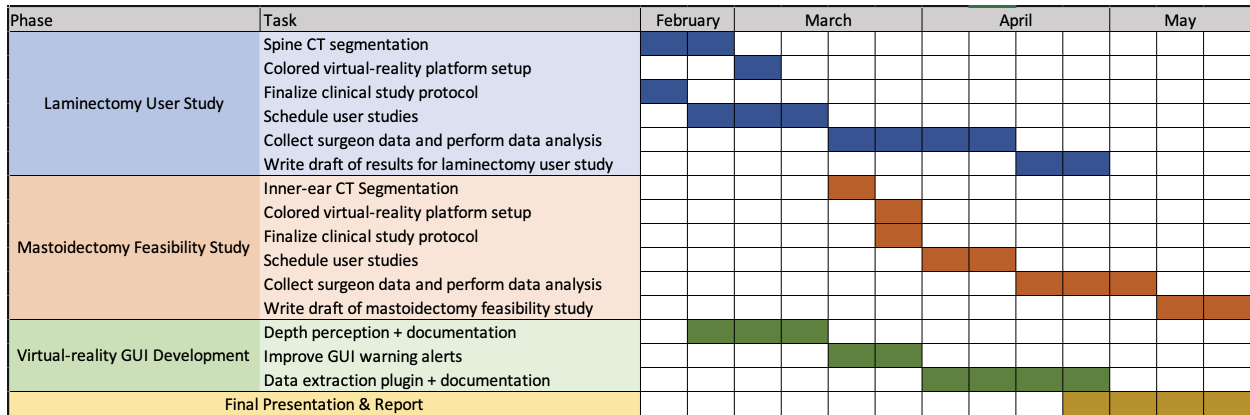


Figure 5: **Timeline**

Phase	Milestone	Exit Criteria
Phase 1: Laminectomy User Study	Spine CT segmentation	Five lumbar spines saved as 15 segmentation files of CT scans of L1-L3 regions
	VR platform setup	VR platform with GUI that loads segmented spines with color overlay
	Finalize user study protocol	Written and mentor-approved protocol for data collection and analysis

	Schedule laminectomy user studies	Confirmed laminectomy sessions (including monitoring assignments for team members) with up to 10 subjects
	Perform data analysis	Draft of results section for <i>IEEE</i> paper comparing navigation methods and interpreting NASA-TLX survey results
Phase 2: Mastoidectomy Feasibility Study	Inner Ear CT segmentation	5 segmentation files of CT scans of inner ear anatomy
	VR platform setup	VR platform with GUI that loads segmented ears with color overlay
	Schedule mastoidectomy user studies	Confirmed mastoidectomy sessions with up to 5 subjects
	Collect user data and perform data analysis	Drafted results for mastoidectomy feasibility paper
	Draft feasibility paper (in the style of [17])	Manuscript for submission to <i>Otology and Neurotology</i>
Phase 3: VR GUI Development	Depth perception interface	Functional, unit-tested, and documented Python script that builds a workspace model, captures the current phantom pose as input, and marks the relative position
	Synchronized C++ data extraction	A C++ plugin that captures user pose and drilling progress from ROS and outputs extracted data metrics

Table 2: Milestones

8. Dependencies

Dependency	Need	Status	Contingency Plan	Planned	Hard
Full IRB approval for user study at JHH	Organize and execute user study	Ongoing	N/A	3/6	3/12
Github access	Locally build VR system	Completed	N/A	2/20	2/20
CT scans & prior segmentations for laminectomy	Segment anatomy according to ENT surgeon recommendations	Completed	N/A	2/20	2/20
3D Slicer	Make segmentations	Completed	N/A	2/20	2/20
Linux machine and VR glass	Locally running VR simulator for laminectomy and mastoidectomy studies	Ongoing	Use lab's VR glasses and (if needed) borrow a linux laptop	3/6	3/12
Access to hospital	Collecting clinical study data	Not started	N/A	3/6	3/12
Access to drafted manuscript and IRB documents for laminectomy study	Review prior user study protocols	Completed	N/A	2/20	2/20
Swipe access to LCSR lab	Access to VR glasses	Ongoing	N/A	2/25	3/3

Study participants	Participate in clinical study	Ongoing	N/A	3/5	3/17
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Table 3: Dependencies

9. Management Structure

We have a team of three engineers with multidisciplinary backgrounds in software development, engineering design, robotics, and biomedicine. We hope to leverage our complementary skill-sets effectively in our team by following the management structure in Table 4.

We plan to meet twice a week (at either Brody Learning Commons or Zoom, depending on availability/progress). We are meeting with mentors once a week to relay progress and ask questions.

We are using Microsoft Teams as the primary communication platform. Software development will be done collaboratively on GitHub. Write-ups/reports will be drafted in Google Docs and submitted formally using L^AT_EX. Presentations are made in Google Sheets.

Team Member	Responsibilities
Jonathan Wang	Lead team in segmenting spine CT scans
	Design a reproducible protocol for segmenting lumbar spine CT scans in 3D Slicer
	Design a reproducible protocol for segmenting mastoidectomy CT scans in 3D Slicer
	Lead team in segmenting mastoidectomy CT scans
	Organize logistics and ensure reproducible user and data collection protocol for laminectomy and mastoidectomy user studies
	Oversee laminectomy and mastoidectomy user studies
	Draft mastoidectomy clinical paper
Kesavan Venkatesh	Lead team in outlining project goals and presentations/reports
	Organize IRB training for all team members and add team to both spine and ear IRBs
	Organize practice data collection sessions for both laminectomy and mastoidectomy user studies
	Participate in the first data collection session for laminectomy and mastoidectomy user studies
	Oversee laminectomy and mastoidectomy studies, collect user data, and contribute to data analysis
	Draft laminectomy results section
	Draft mastoidectomy clinical paper
Yi Wang	Locally build the colored virtual-reality navigation drilling system
	Lead software development for the current GUI, including adding a depth perception interface
	Synchronize the data extraction pipeline using C++
	Oversee laminectomy and mastoidectomy studies and collect user data
	Lead team in data preprocessing and analysis for laminectomy and mastoidectomy user studies
	Draft laminectomy results section
	Draft mastoidectomy clinical paper

Table 4: Management Structure

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