Robotic Bone Drilling Assessment

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1 Introduction

1.1 Summary

Bone drilling in a mastoidectomy procedure requires a high degree of precision and accuracy as to avoid damages of critical structures near the drilling site. When performing the procedure, the surgeon holds the surgical drill free-handedly, and is thus prone to the negative effects of hand tremors. The Robotic Ear Nose and Throat Microsurgery Systems (REMS) was developed to address the issue of tight spaces near sensitive anatomy in minimally invasive Head and Neck surgeries. To test the effectiveness of this system in assisting the bone drilling process, we plan to design and conduct several surgical studies comparing the use of the system to free hand use of the drill.

1.2 Background and Significance

A mastoidectomy, a type of surgery that involves the removal of a portion of the mastoid bone, may be performed for several purposes. The most common is to remove diseased mastoid air cells resulting from ear infections. Another reason is to approach other structures in the ear, such as when inserting cochlear implants into the inner ear.

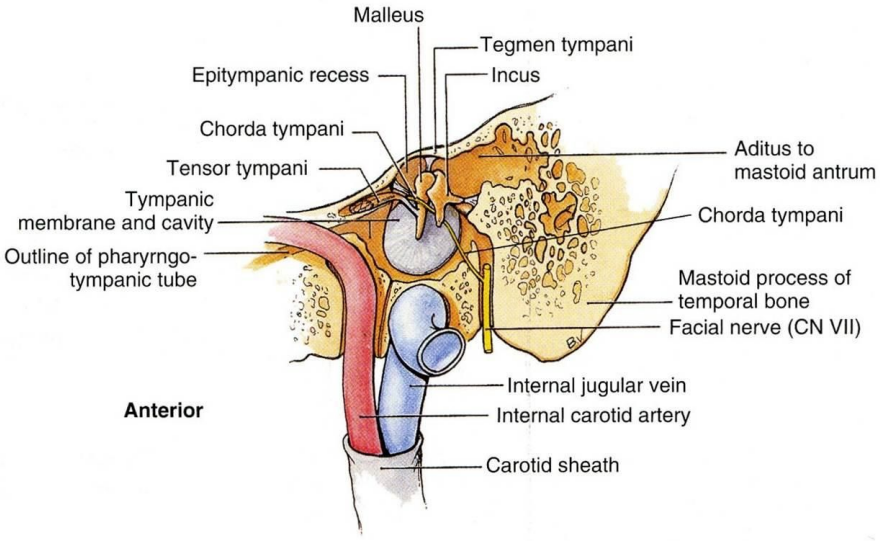


Figure 1: Anatomical Structures Surrounding the Mastoid

(Image from StudyBlue flashcards)

The diagram above shows the anatomy of a portion of the ear. The mastoid bone is the light tan structure that consists of air spaces. As can bee seen, there are many other anatomical structures located near the mastoid. These include large blood vessels like the jugular vein and the carotid artery, which when ruptured will lead to excess bleeding. They also include the eardrum (tympanic membrane) and the organ of balance detection (not shown in diagram), which are crucial for hearing and balance functions. Another big concern is the facial nerve, which is responsible for control and sensation of the face. Due to all these important structures that run close by the surgical site, there is little room for error during the surgery.

Special attention is given to the facial nerve, which according to an online source, has a risk of damage of around 1~3% [1]. However, later analysis has revealed that the risk of damaging the facial nerve is between 4~10% [2] for revision procedures, double the rate than for initial surgeries. In light of this new finding, ensuring the safety of mastoidectomies is necessary to avoid harming the patient's quality of life, because damage to the facial nerve can impede the patient's ability to function socially.

Due to the elevated risk of injuries in the revision surgery, the effectiveness of the initial surgical procedure is also a priority. The main causes of revision surgeries are:

- Cholesteatoma formation [2][3]
- Narrow meatoplasty [2][3][4]
- Persistence of air cells [2][3]

The accuracy of the system assisting the surgeon is important for ensuring the complete removal of infected air cells, however this should be combined with an accurate assessment of air cell removal. Remaining infected cells lead to recurring infections and surgeries due to their ability to reproduce within the mastoid. Accurate assessments for meatoplasty, the widening of the opening of the ear, are also needed, and can potentially prevent the need for revision surgery. Meatoplasty is necessary to ensure proper cleaning and ventilation of the ear [4]. Cholesteatoma forms from the weakening of the eardrum, and from infection of the middle ear. A more informative description of the etiology of cholesteatoma formation is currently unavailable.

Prevention of cholesteatoma will depend on avoiding contact of the eardrum and ensuring the complete removal of infected air cells [5].

Since the presence of infected air cells is responsible for most of the causes of revision surgery, their removal will be the primary measure of effectiveness of surgery. Reducing the number of revision surgeries will decrease the number of patients with facial nerve injuries, and decrease the burden on the resources of hospitals, surgeons, and the patients they serve.

A possible solution that addresses the safety and effectiveness issues of the surgery presented above is the REMS, a cooperatively controlled robot that assists the surgeon in tool manipulation. Surgical tools can be attached to the robot's tool holder, and the surgeon then holds the tool directly when operating. A foot pedal is used to modulate control gains. Asides from being able to stabilize the surgeon's movements by mitigating hand tremors, the system can also set virtual fixtures that limit the robot's movement to a predefined axis or plane. We plan on designing and conducting studies to justify that the use of the robot indeed brings better surgical results in terms of safety, effectiveness and/or surgical time.

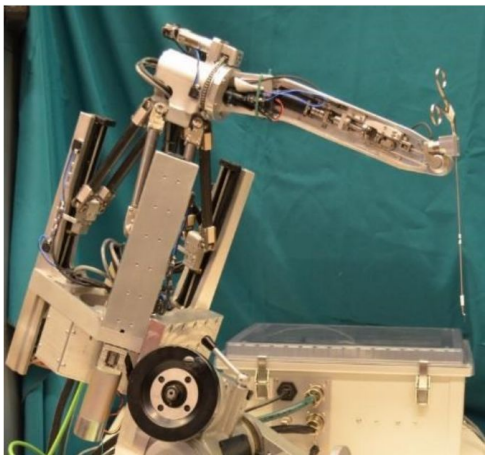


Figure 2: REMS

(Image from Kevin Old's dissertation: Robotic Assistant Systems for Otolaryngology-Head and Neck Surgery)

2 Technical Approach

Three groups of people will be recruited to test the safety of the device: laymen, surgeons in training, and senior surgeons. These subjects will test the safety of a mastoidectomy under

three conditions: without robotic assistance, with the elimination of hand tremors, and finally hand tremor elimination with robotic guidance (such as virtual fixtures). The primary criterion for assessing the safety of the mastoidectomy is the avoidance of the facial nerve. During a trial, a simulated surgical procedure will be deemed a failure if the simulated facial nerve is touched by a tool. The results from these trials will be tabulated and compared to published data.

Laymen will need to meet certain requirements before they're considered suitable for the experiment. They must be able to understand the objective of the mastoidectomy, and that they must avoid contact with the facial nerve. Since surgical experience is the variable in question, laymen will be given the same briefing as the surgeons. This will help eliminate the confounding variable of one group having unclear directives. Furthermore, all test subjects must not be familiar with the Galen or similar robotic systems. All subjects will be given similar orientation and training for the Galen robot, to ensure robot-specific experience is evenly distributed among all participants. At a minimum, they must understand that the robot eliminates hand tremors, and can enforce virtual fixtures. The briefings for all participants will be explained both using usual technical terms and simple English, to reduce the effect of vocabulary on the experiment.

The effectiveness assessment will include the same groups of people from the safety assessment. The protocol for this experiment will be the same, but the primary criteria for success will be the complete removal of diseased tissue. The surgical time assessment will also share the same protocol, but will measure the time required to remove all diseased tissue.

(Combining all assessments into one experiment is being considered. Currently all assessments are assumed to be separate experiments.)

3 Project Plan

3.1 Deliverables

Minimum

Safety assessment

The safety assessment is the top priority since injuries to the facial nerve are devastating to the patient. At a minimum, a report will be made at the end of the project quantifying the

improvement in safety when using the robot. At least three groups of people will be tested: laymen, surgeons in training, and senior surgeons. Each group will operate in three situations: without robotic assistance, with the elimination of hand tremors, and finally hand tremor elimination with robotic guidance (such as virtual fixtures).

Expected

Effectiveness assessment

In addition to the safety assessment, the improvement in surgical effectiveness will be assessed. In the context of a mastoidectomy, complete removal of diseased tissue with no need for revision surgery is considered optimal. This effectiveness assessment will either be a separate report, or be integrated with the safety report. The same groups used in the safety assessment will be used for this too.

Maximum

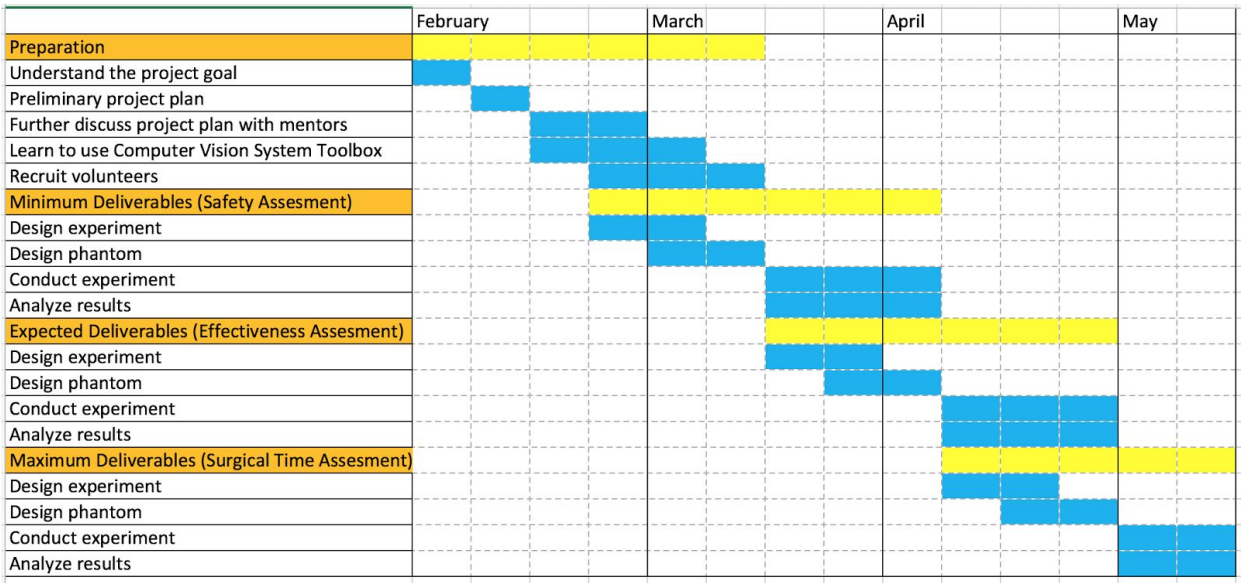
Surgical time assessment

Lastly, the time required of the surgery will be assessed, using at least the same three groups as before. A report will be made quantifying how quickly the surgery was performed.

3.2 Dependencies

- Access to 3D printer to build phantoms
- Access to robot/surgical drills/mock OR
- Recruitment of volunteers for study (laymen, surgeons in training, and senior surgeons)
- Scheduling of mock operations

3.3 Timeline



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