Robotically Assisted Cochlear Imaging and Access

600.446 Computer Integrated Surgery II

Project Proposal

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➢ Project Summary

Cochlear implants are electronic devices that are used to restore hearing to individuals with severe-to-profound sensorineural loss via direct stimulation of the auditory nerve. Implantation requires the insertion of an electrode into human cochlea. This project aims at developing a safe robotic approach for minimizing intracochlear trauma during electrode insertion and consequently preserving the natural residual hearing in patients. For this purpose, OCT-imaging techniques will be integrated with the steady-hand robot. By imaging and modeling the cochlea, and eliminating hand-tremor the system will assist in placing a cochlear implant electrode array into the cochlea with the right position and orientation.

➢ Bacground and Specific Aims

Cochlear implants aim at direct stimulation of the auditory nerve via an electrode array placed inside the cochlea. The state of the art for this operation is a facial recess approach to the middle ear. After the cochleostomy is performed by recess, the array is manually inserted into the scala tympani using special tools such as claws and alligator forceps. Scala tympani is separated from the other two fluid filled compartments inside the cochlea only by a thin basilar membrane as shown in Figure 1. Basilar membrane is a very delicate layer, which accommodates the inner hairy cells that generate the neural activities associated with hearing. Hence any damage on this layer will cause hearing loss or deafness.

Combined electrical and acoustic stimulation (EAS) is a new technique to restore hearing to patients with severe hearing loss, but still with some residual hearing, by amplifying the residual hearing via a hearing aid and simultaneously stimulating the cochlear nerve via an implant. For this strategy, it is very important to preserve the patient's residual hearing during implant surgery. However, using the conventional manual methods, most of this residual hearing is often lost due to various operatively caused traumas [1-10]. The traumas can be attributed to two main sources: cochleostomy, and electrode insertion into scala tympani.
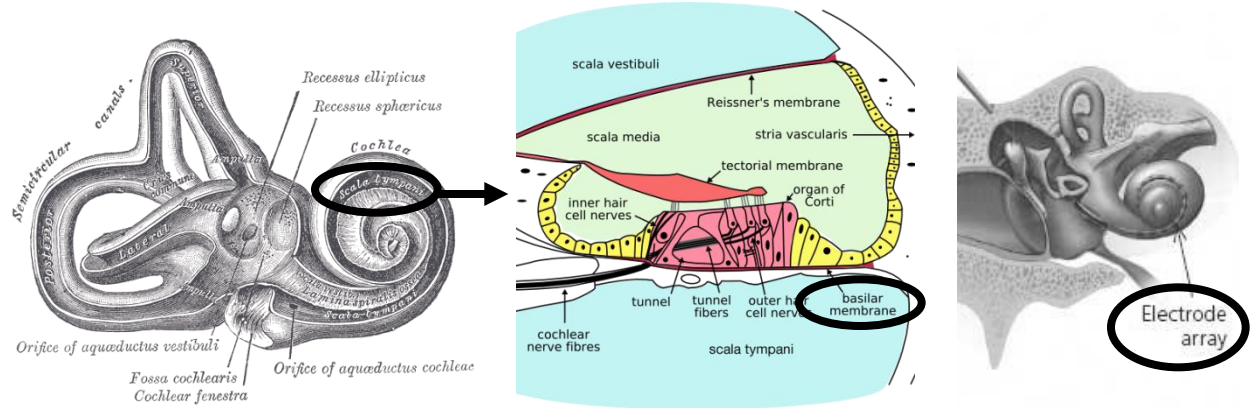
Figure 1 - Scala tympani location and anatomy inner ear. The electrode array is inserted in scala tympani where basilar membrane is located.

As a remedy for the first source, a bone-attached Gough-Stewart parallel robot was proposed to reduce the risk of damaging the facial nerve and the trauma during cochleostomy [18,19]. By using CT scans of the patient, safe optimal trajectories to the cochlea were determined, according to which chorda tympani was drilled.

In order to reduce the insertional trauma, which is the second greatest trauma source, different electrode designs with different insertion behavior were developed recently. More flexible straight implants with lower stiffness were used instead of preformed models. However, patients having a preformed electrode array have shown better results compared to the patients with a straight array [13] since the distance between the active electrodes and cochlear nerve in the central axis of cochlea is minimal for preformed configuration, providing a better perimodiolar position for the electrodes as shown in Figure 2 [11,12].

(a)   (b)
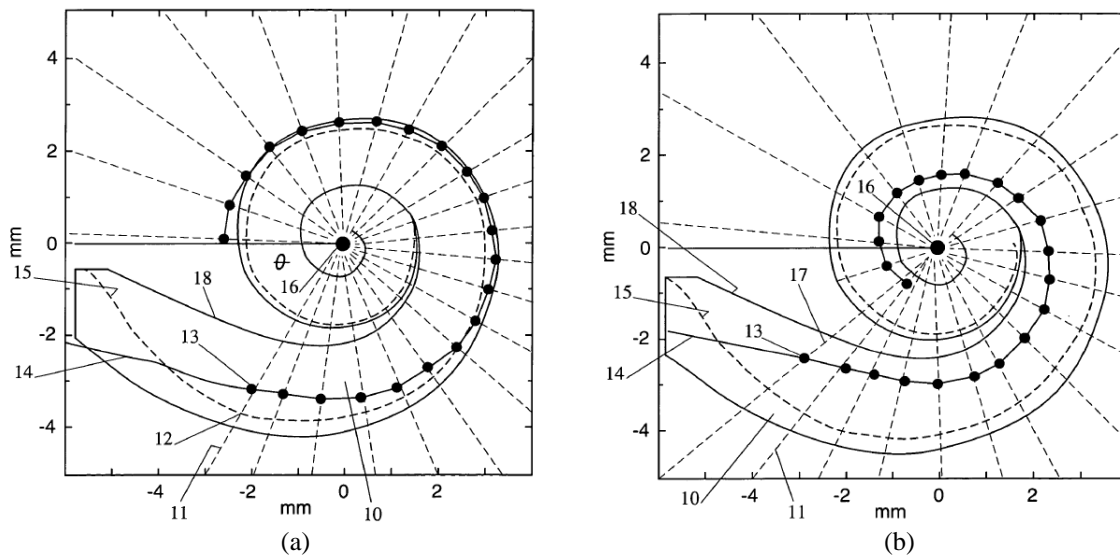
Figure 2 - (a) Position of a straight array far from cochlear nerve (b) Perimodiolar position of preformed array [12].

Currently, an implant that is soft and flexible enough for causing no trauma with perimodiolar placement does not exist. Thus, using a preformed electrode with the right positioning and orientation is still the best alternative. An illustration of this type of electrode from Cochlear Ltd. (Contour Advance electrode) is shown in Figure 3.


Figure 3 - Cochlear Nucleus 24 Contour Advance Practice Electrode. After stylet retraction, the array turns to its preformed state [11].

The array is held straight with a platinum wire stylet. The straight electrode is inserted into cochlea until reaching the basal turn. Then the platinum stylet is held fixed and silicone electrode carrier is gradually pushed off the stylet inside the cochlear canal. As the stylet is withdrawn, the electrode turns back to its precurled state to follow the inner wall of the cochlea. This method is called Advance Off-Stylet (AOS) technique.

In order to have a model that can describe the geometrical features, curling behavior of these electrodes was analyzed [20]. In this study, an image-processing algorithm was used to detect electrode shape from a series of images. An automatic image-processing procedure was developed to determine the complete curvature of the electrode array by identifying the multiple platinum contacts of the electrode. Consequently, bending characteristics of the electrodes were mathematically modeled by combining a spiral and additional linear functions. The linear terms had to be introduced to represent the initially straightened electrode position as well as the soft tip. Then using a fitting algorithm for nonlinear least-squares problems, a complete mathematical description of the electrode array was provided. The system was tested for curling behavior as a function of stylet extraction. By using such a model, effects like intracochlear wall contact and applied forces could be estimated when realistic anatomical models are integrated into the simulation.

The need for an atraumatic implant insertion and correct placement of the electrode within the scala tympani in AOS has promoted research into a number of automated insertion tools [11, 14-17]. The electrode array was inserted via forceps while a hook was used to retract the stylet. Both of these actions were performed robotically, which also eliminated hand-tremor problem. In these studies the main focus has been on applied insertion forces. Safe insertion forces were defined based on taken measurements. Suddenly increasing forces indicated touching cochlear walls as a result of either incorrect orientation of

the electrode or reaching the basal turn. In this project, we aim to provide similar assistance in AOS by OCT imaging to build a 3-D cochlear model instead of force sensing. In this way, the critical location for drawing the electrode array off stylet can be intraoperatively identified, and any intracochlear trauma can be prevented before touching walls of the cochlea.
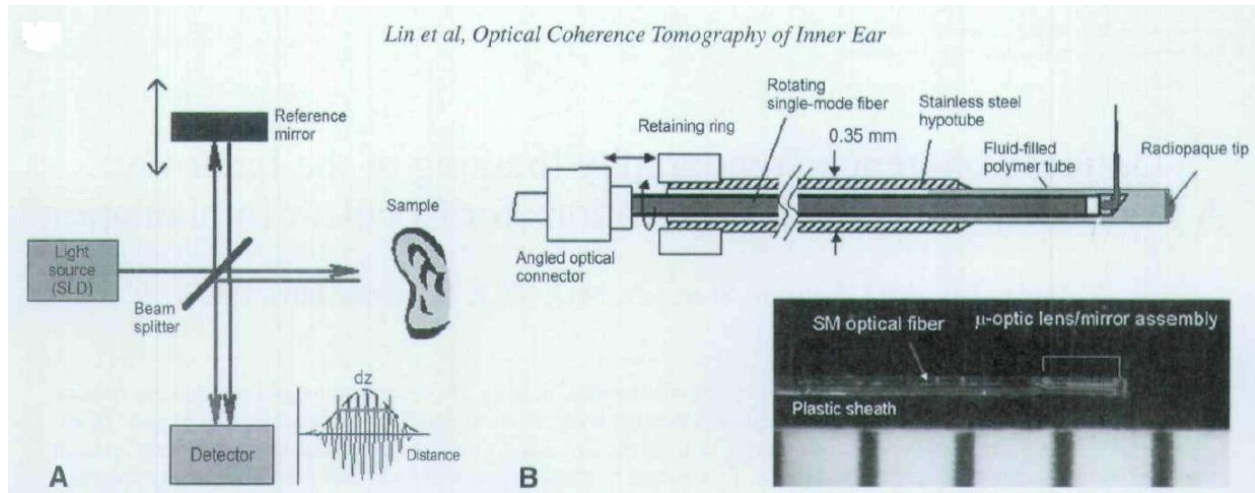
Figure 4 - Schematic of OCT Imaging System [21]. (a) Basic interferometry principle of OCT. (b) Detailed schematic of rotating OCT probe.
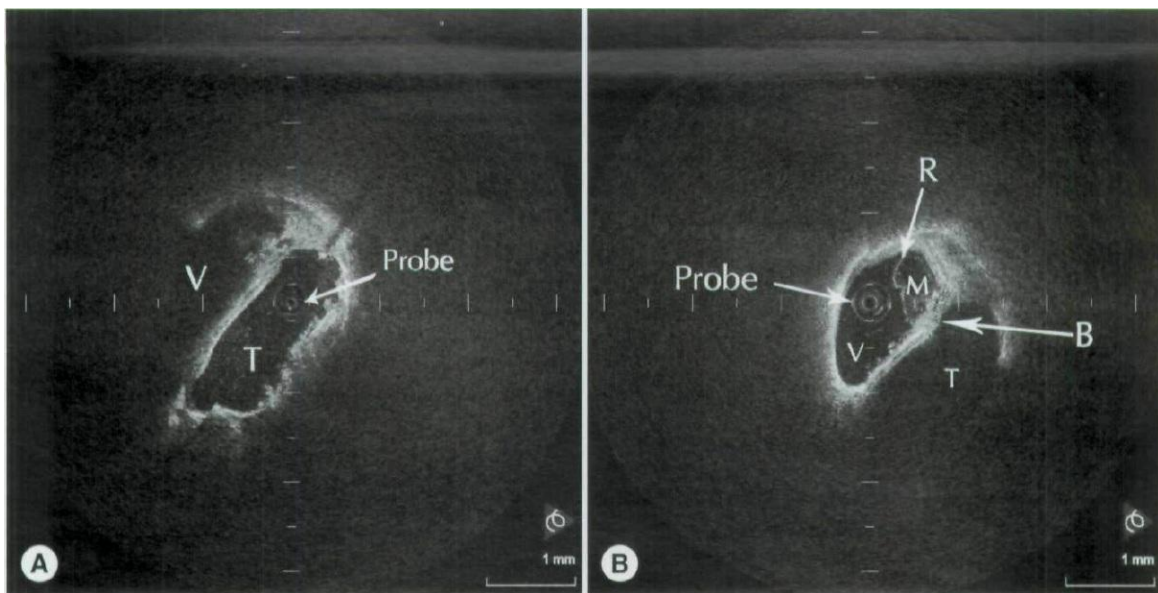
Figure 5 - OCT imaging of inner ear obtained with 0.5 mm probe at 3.1 Hz. [21]. (a) Within scalar tympani (b) Within scala vestibuli.

Several studies has already been done in suing the OCT for imaging of the inner ear and cochlea [20-24]. A relevant study demonstrated catheter-based OCT imaging of the cochlea in live mice and a fresh human cadaver [21]. The system schematic and results are shown in Figures 4 and 5. Accordingly, two

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OCT catheters were constructed by LightLab Imaging, Inc , and used in this study: one axial-imaging 0.35-mm-diameter catheter and one 0.8-mm-diameter catheter. Each catheter consisted of a thin single-mode optical fiber in the center of the imaging probe extending to its tip. Since catheter-based OCT allows unprecedented real-time viewing of microscopic structures of interest through a small, flexible catheter, it has great potential for a the Cochlear implant surgical procedure.

> ## **Technical Summary of Approach**

Since the procedure relies highly on the imaging data that we are supposed to have from the OCT , the plan is organized as follows.

We first insert the OCT imaging probe and acquire the lateral images of the first section of the cochlea and reconstruct the 3D image of that.(Minimal) Next, we advance the probe and try to image the whole cochlear canal and reconstruct the whole 3D view of it. It is expected since we may be limited by bending of the oct fiber and the resulting quality of the image at the same time the rotation and mechanical strength of the imaging catheter may limit us.

Based on the model contracted from our imaging module we then insert the electrode and assuming that we have a reliable geometry model of the electrode we make sure that the probe alignment is maintain during this insertion.

However if the geometrical model is not reliable, i.e. the variation is considerable, and misalignments of the electrode structure is harmful for the critical structures of the cochlea such as basilar membrane, it is not possible to insert the electrode without the real-time intraoperative imaging. Therefore in this alternative approach, we should either use the OCT probe as the electrode stylet or insert it at the same time with the electrode. hence, the surgeon can reorient the electrode using the real-time feedback from the OCT in case the electrode is in the vicinity of the tissues of the cochlea. Visual and audio cues will be generated in the distance goes below a certain threshold.

The alignment control during the insertion can be done using either virtual fixture or manually by the surgeon provided with the audiovisual cures.

The electrode deployment procedure needs a mechanism to fulfill its objectives. The proposed mechanism incorporates two separate tools which are capable of grasping and releasing the stylet and electrode array respectively. In the beginning of the implantation procedure after chocleostomy, the stylet and the electrode are grasped by the tools and the surgeon inserts it in the opening on the inner ear by looking through the microscope. This mechanism is attached to the EyeRobot system which was developed for research on retinal microsurgery. The initial insertion stops while the distal end of the electrode is at the

appropriate position. This position is obtained from the reconstructed model of cochlea generated in the previous step as well as length, landmarks and geometrical features of the electrode. Next, the electrode is disengaged from the grasping tool while the stylet is still grasped and deployment(stripping phase) begins. The deployment procedure is initially performed manually (Minimal) however a semi automatic deployment mechanism using linear actuator is expected in which the control of the actuator is achieved by the surgeon. The maximal deliverable would be a fully automatic robotic system for insertion of the electrode array in which the distal end of the electrode is in the safe distance of the surrounding tissue using the real-time OCT feedback.

In order to facilitate an integrated user-friendly interface needs to implemented software will include a user interface. This software integrates both the appropriate information from the OCT system as well as control features of the robot. Its maximal goal is to be used as the navigational interface which shows the desired as well as actual trajectory of the electrode array, however at the very least (Minimal) it would be capable of displaying the 3D model of the cochlea and the minimum distance of the electrode from the surrounding tissues which based on the different alternative discussed with regard to using a intraoperative probe can be either observed distance or actual distance.

In addition to this user interface model, and for the virtual fixture approach a virtual environment should be implemented that encompasses the allowable and forbidden regions based on the model generated in the previous step by the OCT. In case the electrode distance goes below a certain threshold the counteractive force would be generated so the it cannot touch the critical surroundings of the inner ear anatomy. Additionally since we are dealing with sub millimeter structures the stiffness o the virtual walls should be high enough to ensure a reliable navigation inside the inner ear. Appropriated GUIs would be implemented to display some landmarks in the robot and electrode array.

➢ **Deliverables**

o <u>Minimal</u>

OCT-adapter design and fabrication for the steady-hand robot
Tooling design and fabrication for electrode insertion with the steady-hand robot
Procedure workflow for robotically assisted implantation

o <u>Expected</u>

Software for controlling the motion of OCT probe inside the cochlear canal
3-D reconstruction software for building cochlear canal model from OCT images
OCT scanning videos and images
Implant insertion videos and images

o <u>Maximal</u>

    OCT system demonstration

    Implant insertion demonstration

➤ **<u>Validation and progress evaluation</u>**

We have weekly meetings with our engineering and clinical mentors. Part of the aim of these meeting is to evaluate the progress at the end of each task. The evaluation and input from the surgeons would be particularly helpful throughout these meetings. The clinical applicability of each phase of the project would be analyzed and modifications would be done accordingly.

During testing period, most of the experiments will be conducted using artificial cochlea phantoms. The surgeons will be asked to evaluate the robotically assisted procedure based on:

1. Intracochlear damage (number of hits and forces on Scala-Tympani walls.

2. Operation time

3. Final electrode position.

➤ **<u>Timeline</u>**

Period	Task	2/13	2/20	2/27	3/5	3/12	3/19	3/26	4/2	4/9	4/16	4/23	4/30	5/7
Planning Period	Literature Survey	█	█				Spring Break							
	OR visit		█											
	Detailed Problem Definition and Conceptual Designs		█	█										
	Evaluation of Concepts			█										
	Project Proposal Presentation			█										
Design and Fabrication Period	Design of OCT Adapter (CAD Model) and Ordering Materials				█	█								
	Design of Implant Manipulating Adapter (CAD Model) and Ordering				█	█								
	Development of OCT Control Software					█		█						
	Development of 3-D Reconstruction Software							█	█					
	Fabrication of the First Prototype							█	█					
OCT Testing Period	OCT Tests on Temporal Bone Model									█	█	█		
	Modifications and Debugging									█	█			
	OCT System Demonstration												█	
Robot Testing Period	Electrode Insertion Tests on Temporal Bone Model											█	█	█
	Modifications and Debugging											█	█	
	Electrode Insertion Demonstration													█
Final Presentation														█

➤ Dependencies

	Dependency	Plan/Source	Status/Comments
1	OCT imaging system	Schedule with Dr. Kang's lab	Scheduled
2	CI procedure Observation	Schedule with Dr. Niparko's assistant	Done
3	Weekly meeting with engineering and clinical mentors	Schedule with the team	Scheduled
4	Advance Electrode Arrays	Cochlear	We have 3; will probably need more eventually
5	Biohazard and blood pathogen training	registered	Done/In progress
6	Temporal bones	Drs. Niparko & Chien	Promised
7	Cochlear phantom with video capture capability	Ask Cochlear for loan of their phantom	Alternative is build our own. In this case, some parts would be helpful.
8	CISST libraries	Training	Training acquired
9	3D anatomical model of the inner with the relevant structured	Ordered	On the way

➤ Management Plan

Weekly meeting with mentors for establishing goals under engineering and medical experience.

Weekly team meeting on Wednesdays and Saturdays for sharing updates, discussion, further planning, and revising plans.

We are planning to spend a total of 50 hrs per week on this project.

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