Force-Sensing Forceps for Cochlear Implant Surgery

Project Proposal

EN 601.656 Computer Integrated Surgery II

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Project Description & Goal

During a cochlear implant surgery, an electrode array is inserted into the cochlea, following the the curvature of the inner membrane. The position of this electrode is crucial to overall performance of the implant, and improper insertion could also lead to trauma. However, currently there are no established methods for guidance, monitoring, or feedback to the surgeon and the insertion process is entirely reliant on surgeon dexterity.

From studies using 6 DOF force sensors to measure the electrode insertion force, the average force measured for atraumatic insertion is around 20 mN, while for traumatic insertion is around 60 mN (Seta, 2017). These forces are tiny and are outside the resolution of a surgeon. Lastly, an assessment conducted in 2017 reported that the trauma rate of the surgery was 17.6% (Hoskison, 2017). The goal of the project is to develop force-sensing forceps that can report force measurement intraoperatively, thereby facilitating successful and safe insertion procedure.

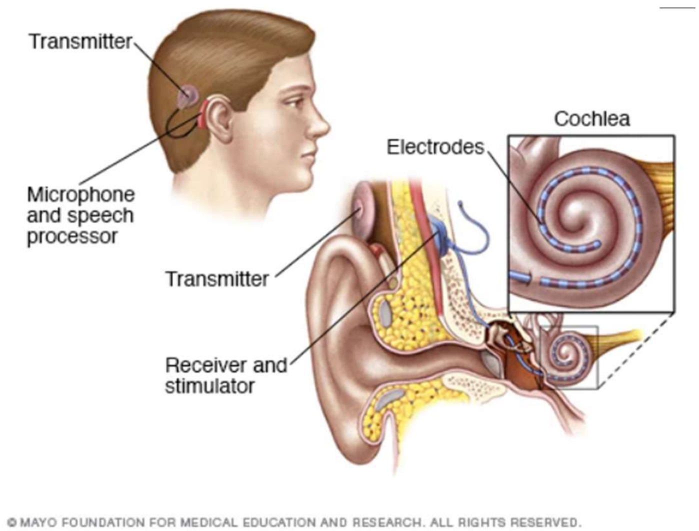

Figure 1. Cochlear implant and inserted electrode array inside the cochlea

Prior Work

A modified version of the commercial forceps used for electrode insertion was designed, prototyped, and tested prior to this semester. The design consisted of a mechanically weakened region near the front end of the forceps. These regions deflect accordingly to the electrode insertion force, and a mounted strain gauge measured strain, which was converted to force. This design was met with two main challenges: 1) pinching the forceps also caused deflection in the weakened region, which added onto the insertion force, which is what we are actually interested in. The design failed the effectively isolate this noise from the force we are interested in. 2) Because we only mounted one strain gauge, the forceps could only measure 1 DOF force effectively. Because the orientation of the electrode relative to the forceps is inconsistent, 3 DOF force measurement is required.

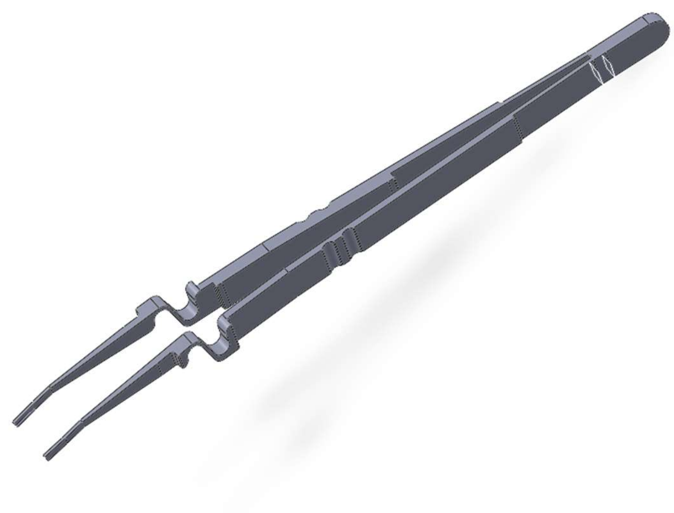

Figure 2. Prior 1 DOF force-sensing forceps model

Goal

Prior work strongly suggested a new design for the forceps is required. The new design will be based on a 3 DOF force-sensing forceps used for vitreoretinal surgery, developed by Dr. Iulian Iordachita. The design has two advantages: 1) a consistent actuation method allowing for better pinching force isolation method and 2) 3 DOF force sensing availability. The ultimate goal of this semester is to design the new forceps and prepare a functional prototype.

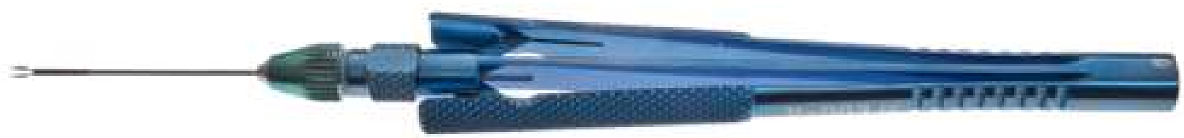

Figure 3. Commercial vitreo retinal forceps model

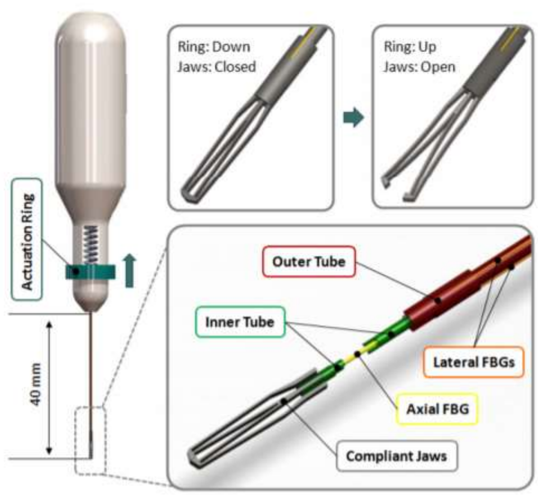

Figure 4. 3 DOF force-sensing vitreoretinal surgery forceps developed by Dr. Iordachita

Significance

Although there have been multiple attempts at measuring safe electrode insertion force, none were performed with a hand-held tool in-vivo. The design of this project can be used intraoperatively and can deliver more actual force measurements within actual clinical settings.

A successful design of force sensing forceps also has a potential for collaboration with Galen Robotics to produce a robot-assisted feedback mechanism. A possible auditory feedback to the surgeon can thereby facilitate successful atraumatic insertion of the forceps and overall improved cochlear implant performance.

Technical Summary of Approach

There are multiple constraints that need to be taken under design consideration. First, the design must be ergonomic. This includes not only the most obvious as size and shape, but also should not obstruct the view of the surgical site and also should avoid new features or techniques that add onto the current surgery process. Surgeon should be able to use the forceps without too much training. Second, the design must have a feature to isolate pinching force from insertion force. Third, the design must have 3 DOF force sensing availability.

The basic geometry of the forceps should be determined by calculating expected deflection via beam deflection equation.

$$\delta_{\max} = \frac{Pl^3}{3E} \quad (1)$$

Where $\delta = deflection, P = pressure, l = length, E = Young's\ Modulus,\ I = second\ moment\ of\ inertia$

Calculation should also be assisted with CAD and simulations of finite element analysis. Below is a current CAD model.

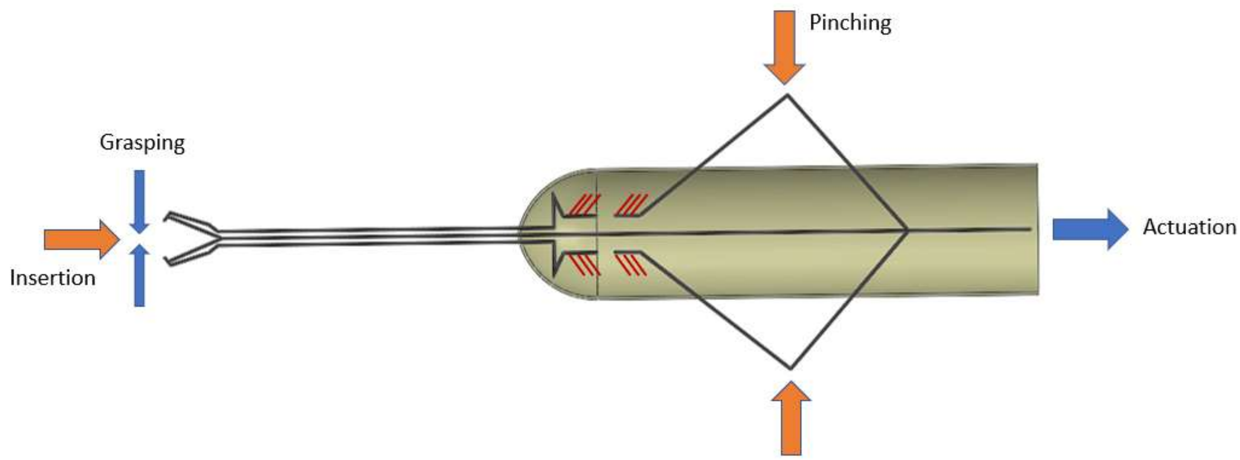

Figure 5. CAD model and general schematic of the design

Here, the jaws of the forceps are actuated by pinching the actuation legs. The legs are grounded in the front, so pinching results in pulling of the middle segment and closing of the jaw. Sensors will be attached in the cruciform region, measuring 3 DOF forces.

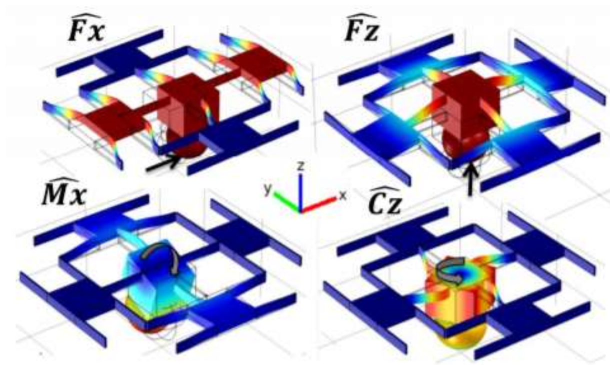

Figure 6. MEMS 6 DOF force measurement cruciform design

The cruciform design references a MEMS 6 DOF force measurement design. Here, the 4 connectors to the middle segment is subjected to both lateral and axial translation and also torque. For our purposes, the inner segment will not be directly connected to the lateral segment and will be subjected to pulling force from the actuation mechanism. The lateral segments will experience both axial and lateral forces, which will translate into the deformation of the connected cruciform region similarly to the above MEMS 6 DOF force measurement design. Finally, we are only interested in 3 DOF for our purposes and will not apply sensors to measure torque. Once the design is finalized, a final CAD model and the result of the FEA will be prepared as a document.

The design will then be prototyped. Depending on the geometry of the design, some parts will need to be produced via Electric Discharge Machining (EDM), CNC Milling, and rapid prototyping as needed. The plastic case for the forceps will most likely be 3D printed or even injection molded.

Finally, calibration study and testing will be performed with Dr. Galaiya. For calibration study, a known weight will be lifted using the forceps and he strain will be recorded. The recorded data will be analyzed using Dewesoft X3 and MATLAB. Then, electrode insertion study will be performed using a plastic and acrylic cochlea model. The model will also be set on top of a scale, and force measurement from the scale will be used to compare the strain measurement collected with the forceps.

Figure 7. From left, electrode insertion test with plastic cochlea model, scale readings measured underneath, and analyzed data using MATLAB

Deliverables

	Deliverables	Date
Minimum	Completed final design	11-Mar
	Final CAD model	23-Mar
	Report of Finite Element Analysis results	23-Mar
Expected	Fabricated prototype with sensors attached	20-Apr
	Preparation for calibration and test rig	4-May
	Plan for further tests	4-May
Maximum	Report of calibration data analysis	TBD
	More tests under different conditions	TBD
	Plan for design iteration and future work	TBD

Table 1. Deliverables

The bare minimum of the semester is to have a final design, with completed CAD and FEA analysis. While the final FEA analysis will be done the same time as the CAD, a document for all analysis will be prepared as well after starting to prototype. Finished prototype, with sensors attached, should be ready by the end of the semester. With that, calibration and testing will be prepared as the project is expected to continue after the semester is over.

Timeline

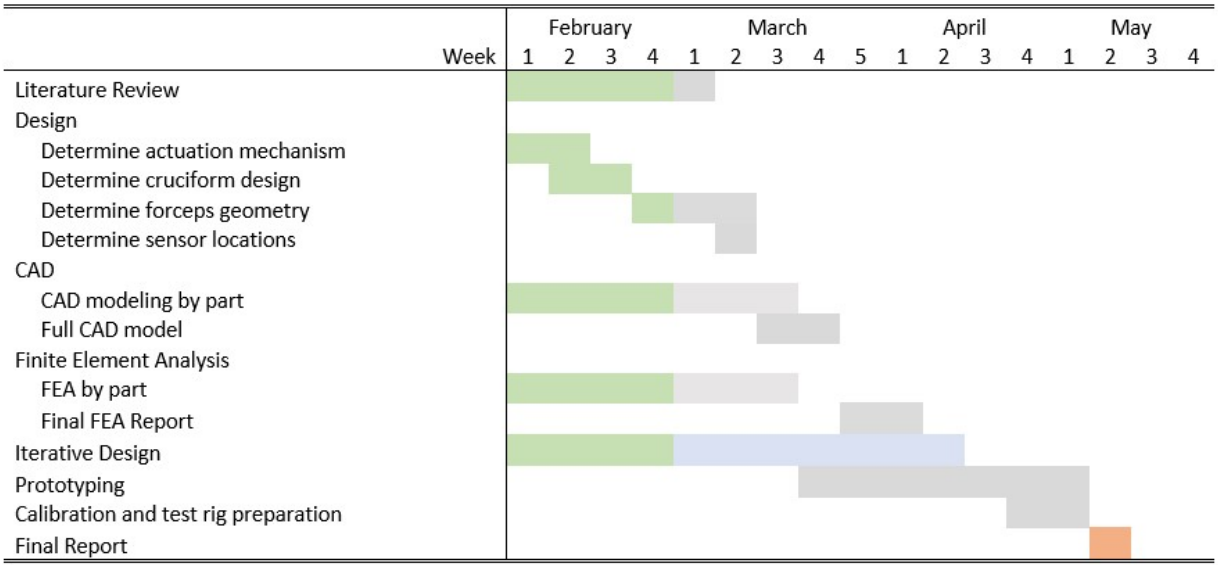

Figure 8. Gantt Chart

Above is the prospective timeline for the entire design process. In the designing stage, determining forceps geometry is the most crucial process and hence been allocated the most time. First, the actuation mechanism should be determined: this will include determining which part of the forceps will be grounded, where hinges will be introduced, and how the jaws will close accordingly. Next, the cruciform needs to be designed to measure the axial and lateral forces. Once the general design is drafted, the specific dimensions of these features will be determined. This is the most important step, since the geometry will not only determine the overall performance of the forceps but also its resolution of the force measurement.

To assist the design process, CAD modeling and finite element analysis (FEA) will be performed in parallel. Once a final design is produced, a final CAD model and a summary of resulting FEA will be prepared.

Finally, prototyping will begin as soon as the design is completed. Most of the dependencies including time and budget are from this stage, so prototyping has been allocated time of about half the semester. A final functional prototype with sensors attached is expected to be done by the end of the semester.

List of Dependencies & Plan for Resolving

If the prototype is planned to be built in the campus, there may be some difficulties based on change of school policies for in-campus activities. If students are not allowed on campus, I will ask Anna Goodridge to run the machine, but prepare all the necessary stl files and G-codes.

If the manufacturing is to be outsourced, there will be a major time dependency based on their lead time.

If the prototype is functional, testing will need to accommodate to Dr. Galaiya's availability and also will depend on school policy with maximum number of people in a single room (Mock OR). If maximum number of people is reached, some people may have to participate via Zoom.

Below table is the calculated estimated cost. The source for the budget is still under discussion and needs to be resolved. Dr. Deepa Galaiya is currently looking to allocate some budget, and this will be discussed during LCSR general meeting on February 24th.

Component	Category	Material	Quantity	Price	**Total Price $**	**Rounded Price $**
Professional gauge installation	Service	Old forceps		675		
Strain gauges	Sensors		6	66 per 10	66	150
Jaws material	Material	Al 7075	1	31	31	60
Jaws EDM time	In-house machining		6 hrs	40/hr	240	350
Jaws	OOH Machined part	Al 7075	1	963	963	1500
Pincher	Material	Al 7075	2	31	31	60
Pincher EDM time	In-house machining		4 hrs	40/hr	160	250
Pincher	OOH Machined part	Al 7075	2	235	470	650
Tube	OOH Machined part	Al 7075	1	525	525	700
Cruciform	OOH Machined part	Al 7075	1	381	381	500
Handle (clamshell)	OOH Machined part	SLA Accura	2	74	148	250
			In house Option1		**1582**	**2320**
			OOH Option 2		**2553**	**3750**

Table 2. Estimated budget

Team Members

- Justin Kim (kkim141@jhu.edu)
  Undergrad Whiting school of engineering, Mechanical Engineering with Biomechanics Concentration, Robotics Minor, Senior year

Mentors

- Primary Mentor: Anna Gooridge (anna.goodridge@jhu.edu)
  Mechanical Engineer, LCSR

- Principal Investigator: Prof. Russell Taylor (rht@jhu.edu)
  John C. Malone Professor, Department of Computer Science
  Director, LCSR

- Surgeon Mentor: Dr. Deepa Galaiya (gdeepa1@jhmi.edu)
  Assistant Professor of Otolaryngology – Head and Neck Surgery

- Secondary Mentor: Prof. Iulian Iordachita (iordachita@jhu.edu)
  Research Professor, Department of Mechanical Engineering

Management Plan

- **Weekly general LCSR lab meetings** on Wednesday
  Here, I will report weekly progress.

- **Weekly meetings with Anna Goodridge** on Monday
  I will find out how to best progress based on the feedback received from the general lab meeting and consult with Anna.

- **Scheduled meetings with Dr. Iordachita**
  If needed, I will schedule separate meetings with Dr. Iordachita for his consult.

- Scheduled meetings with Dr. Deepa Galaiya
  If needed, I will schedule separate meetings with Dr. Galaiya for her consult, and to schedule calibration and testing.

Reading list

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