Force-Sensing Forceps for Cochlear Implant Surgery

Final Project Report

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. The goal of the semester was to 1) develop a full CAD model of the new design, 2) FEA simulation of the new design, 3) Prototyping of the design, and 4) Calibration and testing.

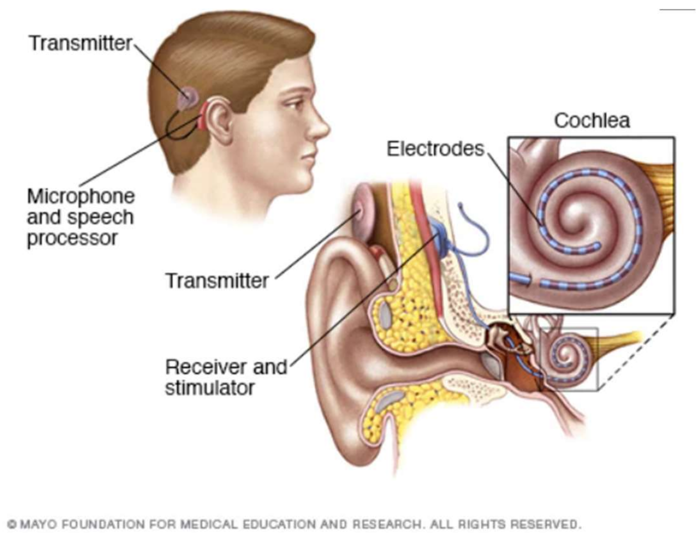

Figure 1. Cochlear implant and inserted electrode array inside the cochlea

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

Technical Approach

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.

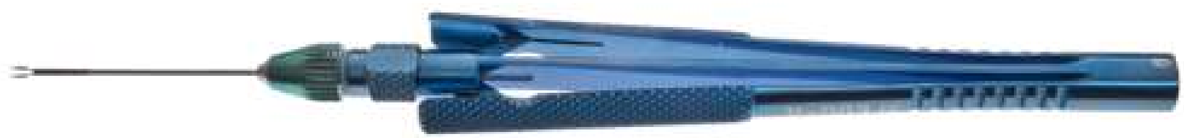

Figure 3. Commercial vitreo retinal forceps model

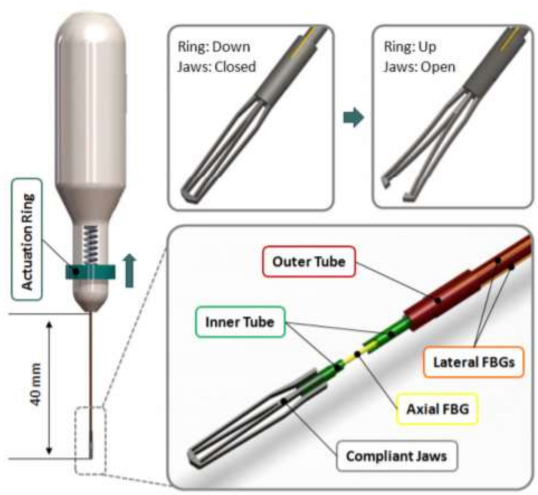

Figure 4. 3 DOF force-sensing vitreoretinal surgery forceps developed by Dr. Iordachita

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.

Results

Jaw Design

The final CAD model of the forceps is shown below:

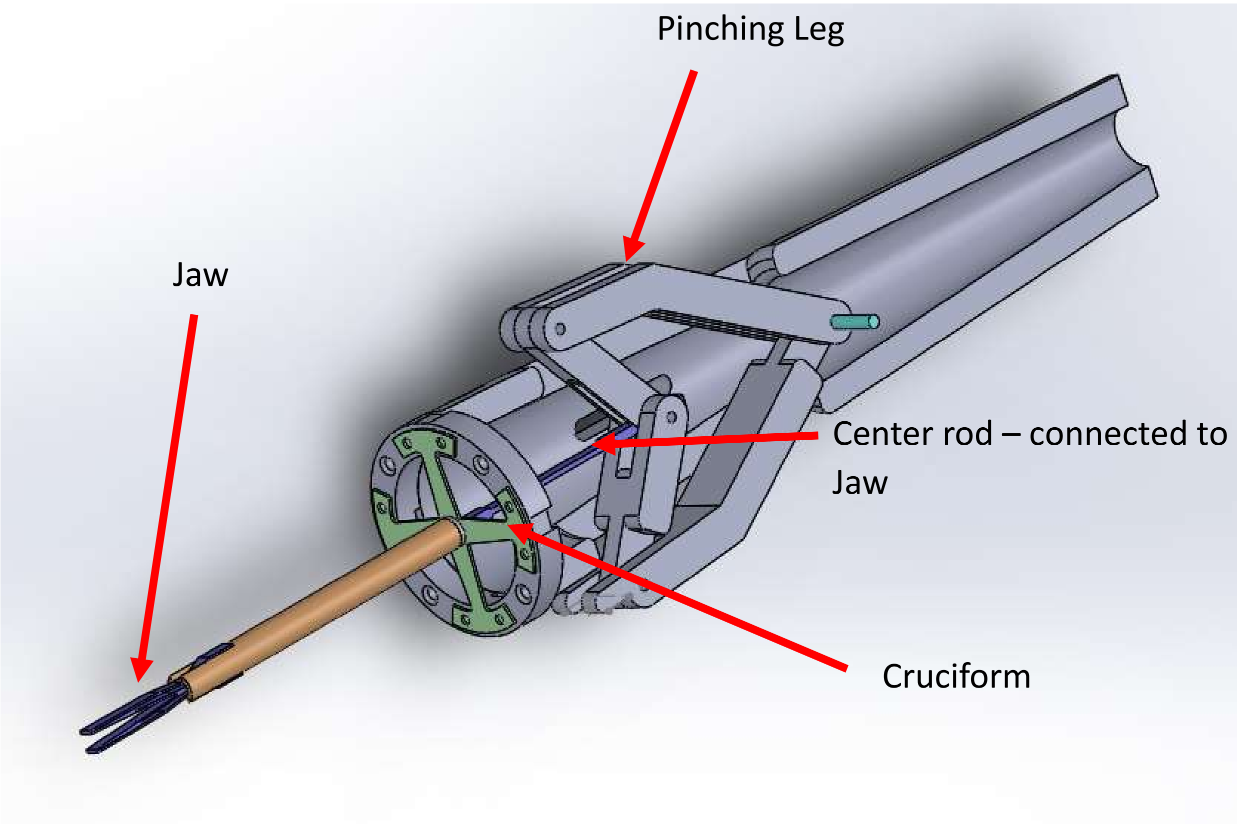

Figure 5. Final CAD model of the forceps

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.

With the help of Dr. Galaiya, preliminary ergonomic geometric constraints were set for each component. The jaw portion of the forceps need to be less than 12 mm in width when closed in order for the tip to be able to fit into hole created during the mastoidectomy. This portion would also have to be longer than 10 mm. The entire length of the long rod portion, including the jaw and the shielding rod (orange in Figure 5), need to be 40 mm for optimal ergonomics. The cruciform needs to be less than 25mm in diameter in order to prevent obstructing the surgeon sight while handling the forceps. The length of the entire body is same as the commercial forceps used for the electrode insertion: ~140 mm.

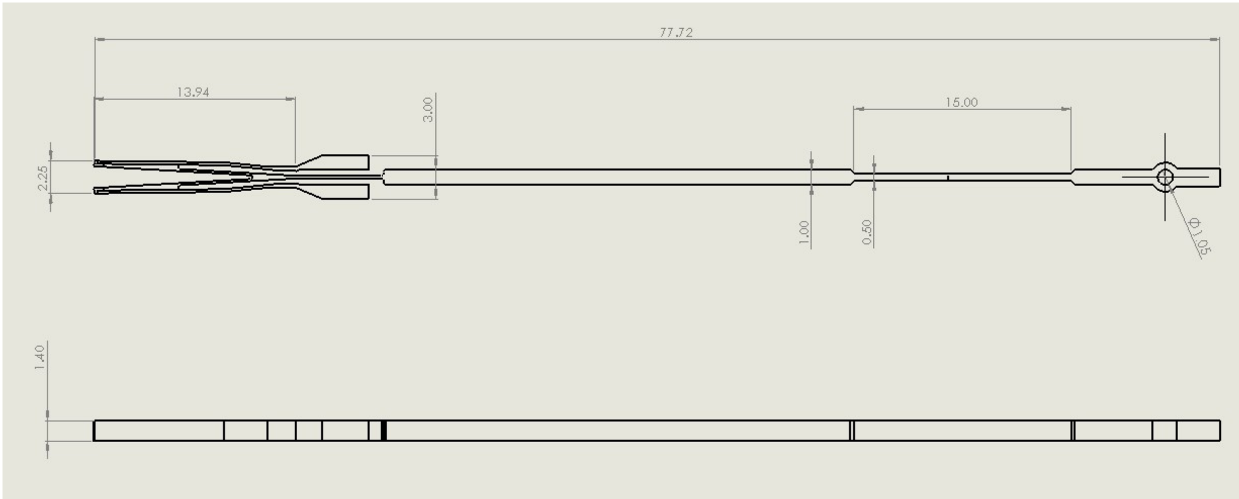

Figure 6. Important geometries of the jaw portion

Towards the end of the jaw, a section is thinned out for the length of 15 mm to provide a small compliance for the strain gauge that will be attached to measure axial insertion force.

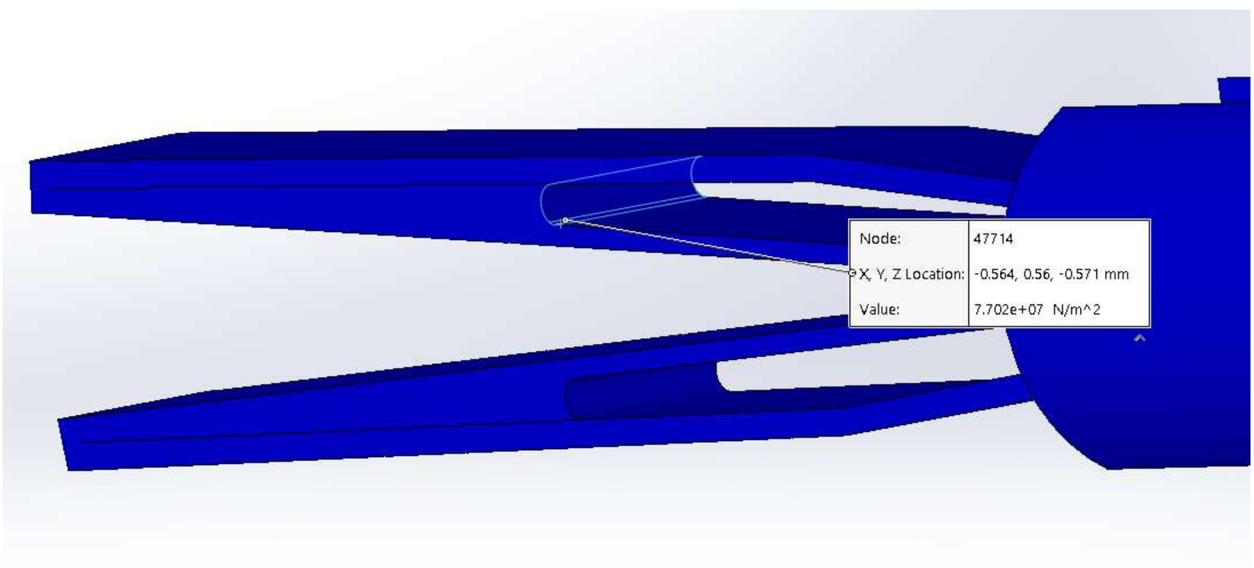

Figure 7. Force concentration during actuation

When fully actuated, or when the jaws are closed, force concentration occur at the inner curve of the jaw as seen on Figure 7. Due to this force concentration, mild material such as aluminum are not suitable since the stress concentrated exceeds its fatigue stress. Hence, stainless steel 316 was chosen to avoid fatigue failure.

Due to its high complexity, EDM (electric discharge machining) was chosen as a prototyping method for its high resolution. With this method, however, all of the inner corners need to be larger than the diameter of the wire used for the cutting (0.05”).

Cruciform Design

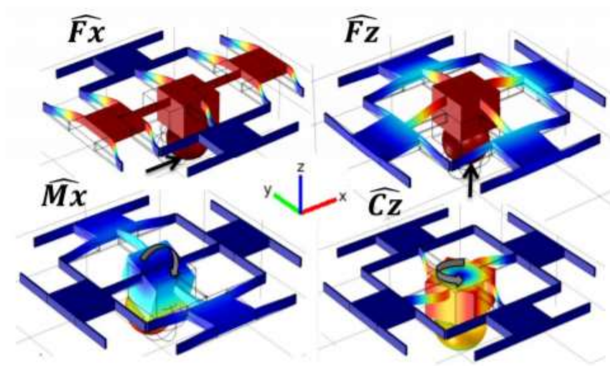

Figure 6. MEMS 6 DOF force measurement cruciform design

The cruciform design references a MEMS 6 DOF force measurement design. Here, the 4 connectors to the middle segment are 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.

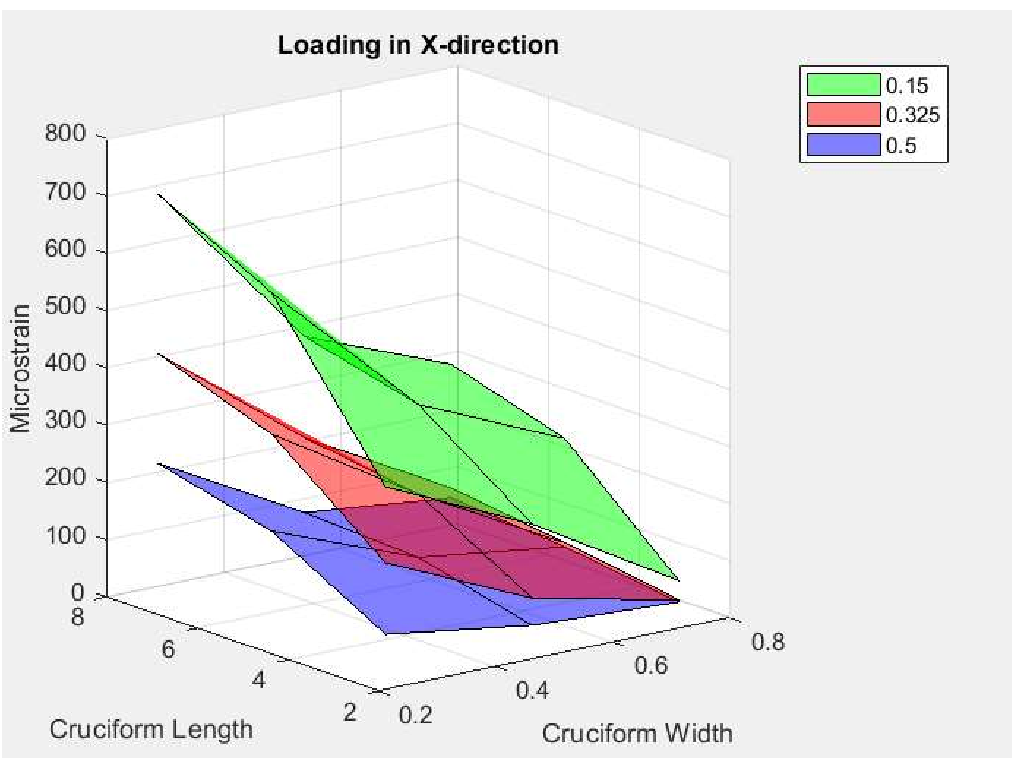

Figure 7. Cruciform strain at various length, width, and thickness

Strain was measured at the same point at the cruciform by varying its length, width, and thickness. The study result is shown in Figure 7. As shown, cruciform thickness is the biggest contributor to the magnitude of strain, with its length as the second most influential factor. Changing the width, especially at a higher thickness, did not change the strain significantly. Because our goal is to maximize the sensitivity of the cruciform, higher strain is desired. Hence, we sought to maximize the cruciform length and minimize its thickness.

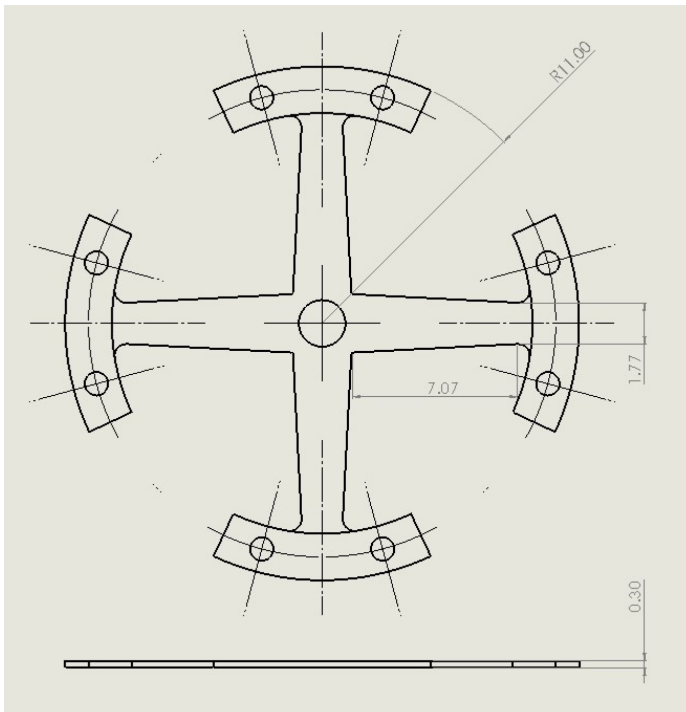

Figure 8. Important geometries of the cruciform

Figure 8 represents the final design of the cruciform. Each leg of the cruciform must be longer than the size of a 5 mm by 1.5 mm strain gauge. For ergonomic purpose, the diameter of the cruciform must be kept around 20 mm. With this boundary, optimization study to determine the size and thickness was performed.

The cruciform experiences strain both from the insertion of the electrode and the actuation of the jaw. Strain at both conditions are simulated using finite element analysis (FEA). Aluminum 6061 was the chosen material for cruciform.

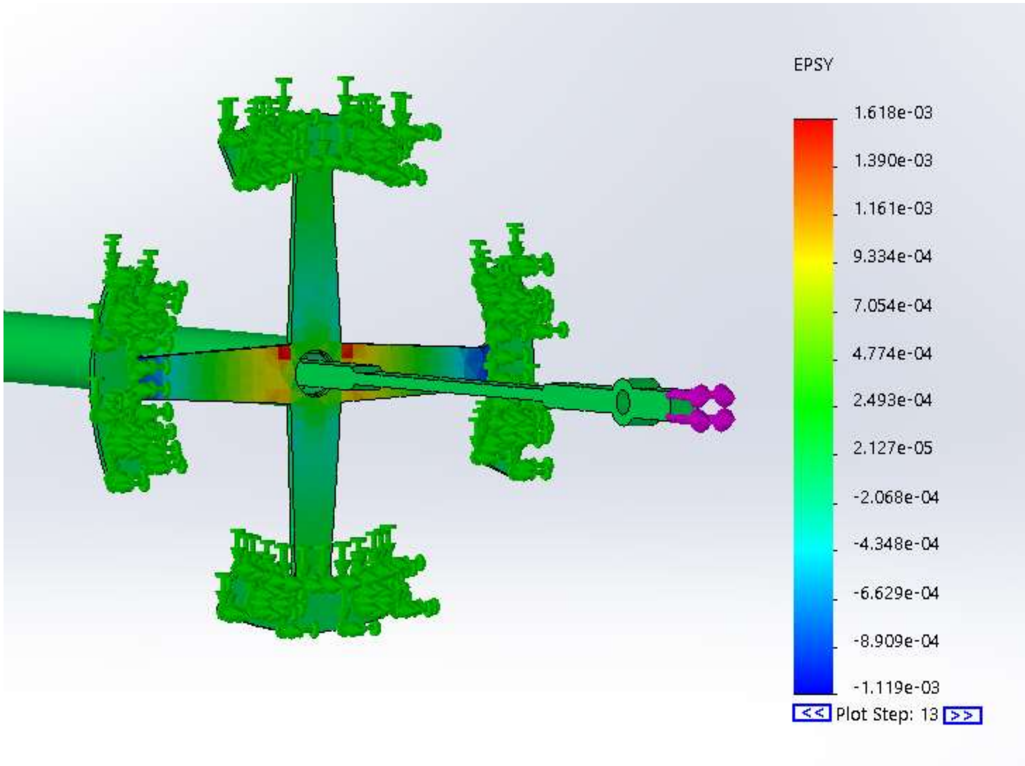

Figure 9. Strain result from actuation alone

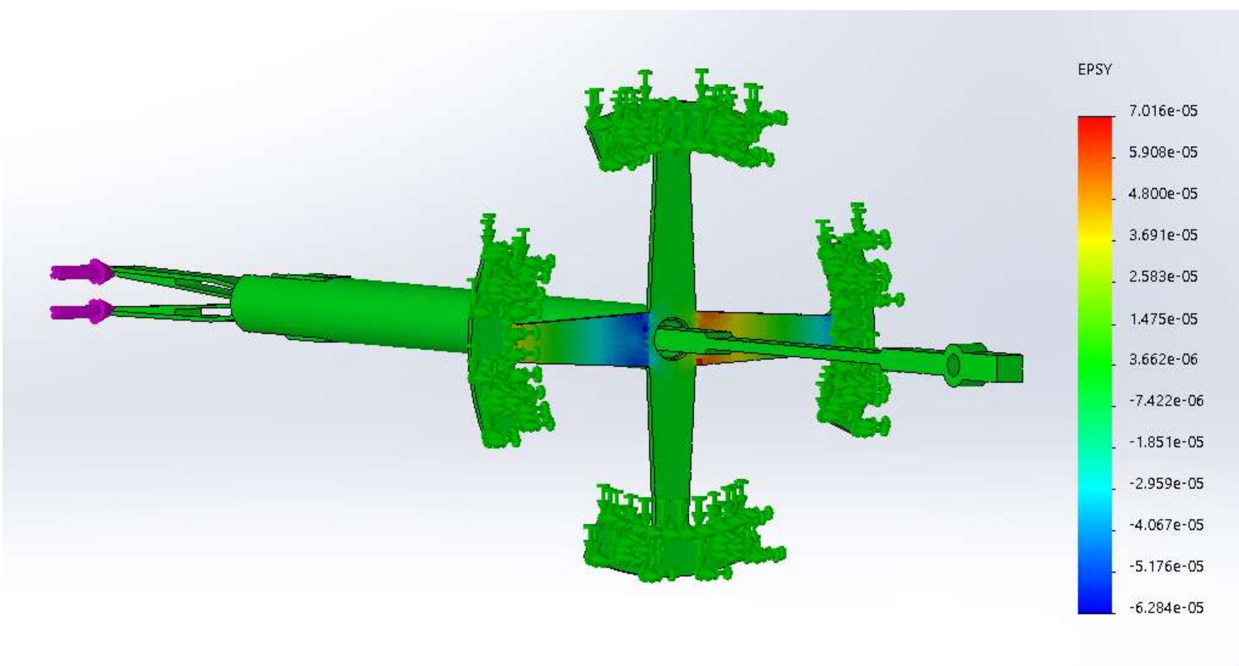

Figure 10. Strain result from lateral force (x)

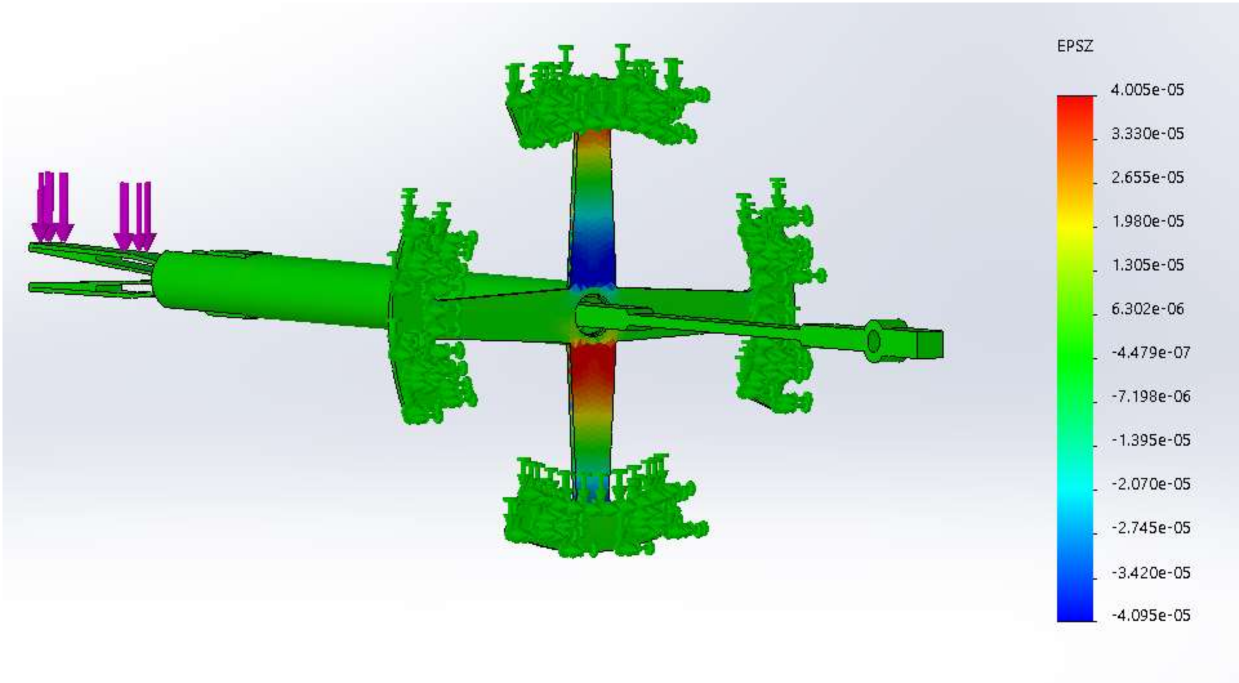

Figure 11. Strain result from lateral force (y)

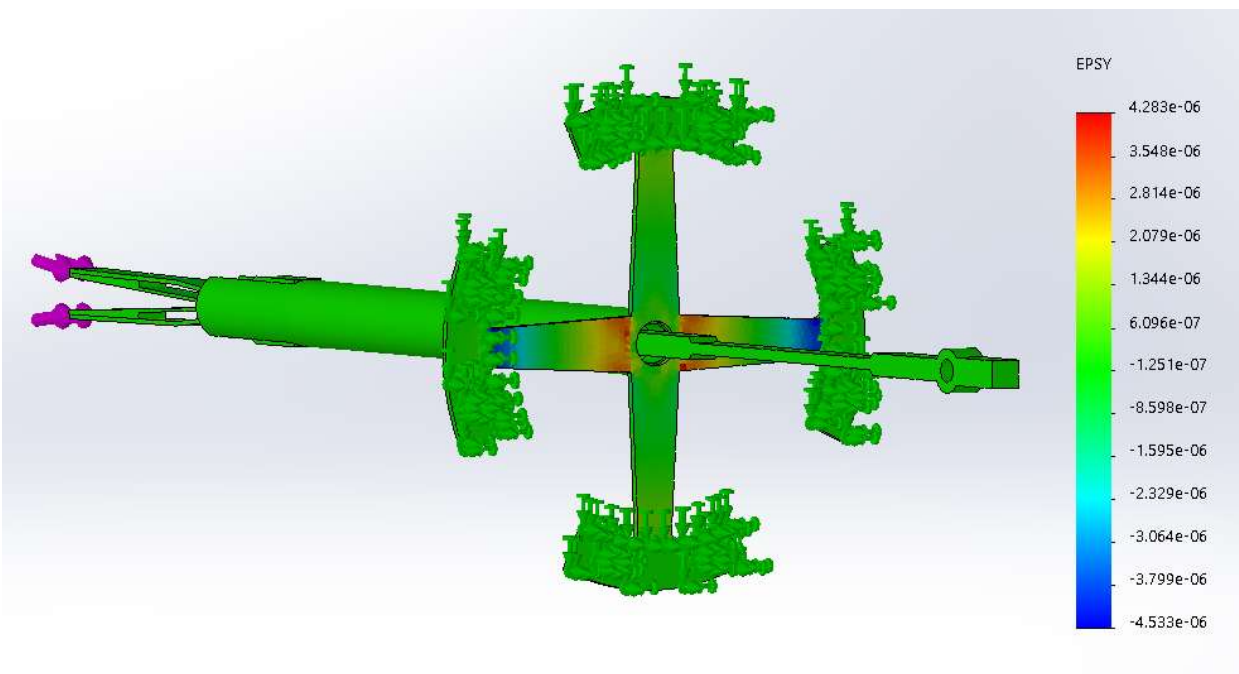

Figure 12. Strain result from axial force (z)

Direction	Microstrain
Actuation	400
Lateral (x)	40
Lateral (y)	40
Axial	28

Table 1. Microstrain at the active region of the strain gauge at varying loading directions

The target strain for the strain gauge resolution is on the order of 10 microstrain. As seen in Table 1, this requirement is met. However, the strain experienced by the actuation is 10 times higher than the strain experienced by the insertion force. In order to detect the relatively smaller strain caused by the insertion force, strain gauge with a suitable dynamic range is to be chosen.

Case & Actuation Design

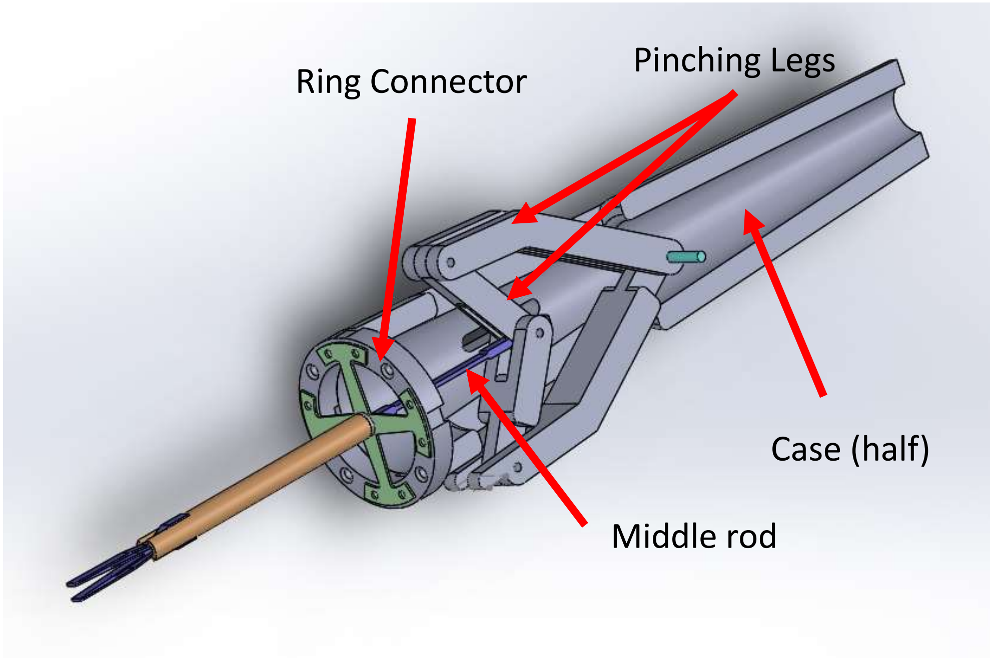

Figure 13. Case design

The case is joined by two separate pieces and is connected to the cruciform via a ring connector. All of these components are fabricated using 3D printing and joined using 1mm screws. 1mm heat-set inserts are used.

Actuation is achieved by pinching of the pinching legs, which results in pulling of the middle rod and closing of the jaw. The middle rod will be connected to the pinching leg with a spring. With the current design, closing of the jaw is achieved by a very tiny displacement of the middle rod. By using a connecting spring with a small spring constant K, this tiny displacement can be amplified by a large motion of the pinching leg, giving the surgeon more control over pinching.

Connecting the middle rod and the pinching legs with a spring also provides compliance for the cruciform to deform by the insertion force. If all the linkages were rigid, then insertion force at the tip of the jaw would rely solely on the deformation of the middle rod. By connecting the middle rod with a spring with a lower rigidity than the cruciform itself, we allow easier deformation by the cruciform by the displacement of the middle rod caused by the insertion force. This way, we amplify the deformation caused by the insertion force.

The pinching legs itself will be connected using an M2 shoulder screws.

Prototyping

Part	Material	Method
Jaw	316 SS	In house - EDM
Rod	6061 Aluminum	In house - EDM
Rod joint	6061 Aluminum	Outsourced - CNC
Cruciform	6061 Aluminum	Outsourced - CNC
Ring	Plastic	In house - 3D Print
Case	Plastic	In house - 3D Print
Actuation Legs	Plastic	In house - 3D Print
Actuation Pins	SS	McMaster
Screws	SS	McMaster

Table 2. List of components, its materials, and prototype method

For each component of the design, material and prototype method are chosen. Currently, the jaw is fully prototyped using EDM.

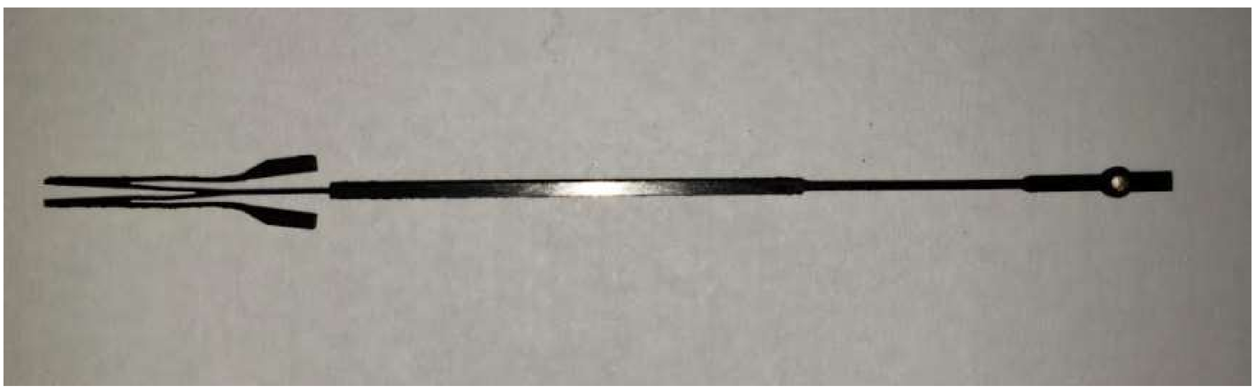

Figure 14. Prototyped jaw and middle rod

Orders for the strain gauges are placed. Currently, the design of the cruciform is still being optimized. Because the case geometry depends on the geometry of the cruciform, prototyping of the case and the cruciform will continue once the design is finalized. Since the case and the components for the pinching mechanisms are planned to be 3D printed, they are expected to be fabricated relatively rapidly and do not pose dependencies such as outsourced cruciform.

Calibration & Testing

The prototyped jaw will be used to measure force required for actuation. Although 8N force was normally used for all FEA simulation, an actual measurement is also required. A special fixture is developed to fix the jaw so that the actuation can be performed and measured without other components of the full assembly.

Once the forceps is fully prototyped, assembled, and the strain gauges are mounted 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. Both the CAD model and FEA simulations are finished, and thus the minimum requirement is met. Finished prototype, with sensors attached, was the expected goal by the end of the semester. However, due to some delays in the designing process and also a dependency in prototyping the jaw (in-house, but requested for professional manufacturing), the expected deliverables were not met for the semester.

Reflection

From the work, I learned that investing time to investigate and document the design requirements thoroughly in the earlier stage of the design could save a lot of time later on. In hindsight, I realize that a lot of the delays in the designing process was caused by discovering new design constraints or failing to meet a design criterion that was ignored in the earlier process. However, the design itself was an iterative process, and returning to the previous stage of the developmental process was unavoidable. I also ran into several challenges that really could not be anticipated (mostly by the sheer complexity of the design), and given the situation, I adapted to the best of my ability and adjusted my schedule prioritizing the quality of the work over meeting milestones with poor quality.

With that, through the life of this project, I gained a tremendous amount of experience in optimizing a novel and complex design while meeting numerous design constraints and preferences for different manufacturing methods.

Future work

Depending on the result of measuring the actual force required to close the jaw, another iteration of the design may be required. This work will continue to the summer.

Prototyping will also continue through the summer. Once finished, calibration will be performed by lifting known weights and measuring the measured strain. Then, test runs using actual electrodes and cochlea model will be performed with the help from Dr. Deepa Galaiya.

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.

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

- **Meetings with Dr. Deepa Galaiya by schedule**
  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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