Artificial Prosthetic Tongue

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In partial fulfillment of the requirements for the

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Abstract:

Oral cancer can result in the loss of a patients' tongue through total glossectomy, the surgical removal of all or parts of the tongue. Patients that lose their tongue have difficulty with speech, deglutition and mastication. Current tongue prosthesis lack the ability to move for mastication and deglutition and are mainly for cosmetic purposes. The goal of this project was to investigate and develop a self-contained prosthetic tongue that could aid in deglutition by moving bolus from the front of the mouth to the back of the mouth. Previous iterations of the project used pneumatic and electromagnetic actuation techniques for the silicone tongue prosthetic. While both methods showed promise, they had multiple issues. Pneumatic methods involving air pumps are challenging to miniaturize while still achieving the necessary actuation. The electromagnetic actuation technique using magnets and solenoids results in a miniature system but the amount of actuation produced to move the bolus is insufficient. Multiple bolus and actuation testing were carried out on electromagnetic and pneumatic powered silicone tongues to verify these problems. Additional research was done to explore alternative designs and it was determined that a linkage system mounted into a silicone cast might be the most efficient method to move the bolus from the front to the back of the mouth. The development of this new prosthetic tongue design entailed creating silicone molds, printing linkage systems and jaws, and developing new circuits. The circuit used a TinyDuino and MOSFET. A force sensor was used to trigger actuation of the tongue when bolus was placed on it. Two micro-servo motors were also used to actuate the linkage system. A functional mandibular Hawley retainer was added to hold the tongue to increase ease of use. The initial prosthetic tongue prototype was tested on actuation height, bolus movement and functionality within an anatomically sized, resin-printed jaw set. Redesigns to the circuit and linkage system were done based on initial testing results as a major problem was the bolus getting stuck on the upper palette. The final circuit design contained an EMG sensor to trigger actuation and a single servo motor with a gear system to actuate the tongue. Kinematic analysis and finite element analysis on the finalized linkage system were carried out. The prosthetic tongue succeeded in moving bolus from the front of the mouth to the back when lying at an 5^{o} angle and actuating between 1.8 - 2.31cm. The paper will describe the development process, challenges and future work.

Copyrights

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Nomenclature

Bolus - partially masticated/chewed food

Mastication - AKA chewing; the process of by which food is crushed and ground by the teeth

Poly Implant Prostheses (PIP) Silicone -

PDMS - Polydimethylsiloxane; a mineral-organic polymer used in fabrication and prototyping of microfluids (plastics)

Deglutition - swallowing

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1. Introduction

The world of healthcare and medical devices is continually advancing. Specifically the field of prosthetics, where people who have lost limbs such as legs and arms, can now use prosthetics to walk or pick objects up again. This however, leaves out the market including prosthetic tongues, which has been an area that is strongly lacking in progress.

In the United States, about 53,000 new oral cancer cases occur every year[1]. In 2021, there were about 54,000 new cases in the US and about 377, 713 new oral cancer cases worldwide[2]. Oral cancer is typically caused by tobacco use, excessive alcohol use, exposure to UV rays from the sun and tanning beds and the Human Papillomavirus (HPV)[3]. Treatments for this cancer vary depending on the severity of the patient's case, but common treatments are radiation, chemotherapy, targeted drug therapy and surgery[3]. Usually more than one treatment is used in conjunction with one another such as radiation and chemotherapy or surgery and chemotherapy. In the cases where surgery is done to remove parts or all of the tongue, which is called a partial or total glossectomy (respectively), patients afterward end up having a hard time with deglutition (swallowing), speech, and mastication.

The current tongue prosthesis available are mostly static and made for aesthetic purposes[4]. They lack the ability to help patients with deglutition and speech. Seen below in Figure 1.1 is a mandibular denture flange with a silicone tongue that is one of the types of static prosthetics given to a patient who has had a total glossectomy[4]. Over time, with a lot of rehabilitation and therapy, some patients can get back a little bit of speech and swallowing ability, but they will always have some difficulty.

Figure 1.1: (left) A mandibular denture lingual flange with a silicon tongue reproduced as is from [4], (right) Denture Palatal Augmentation Prosthetic (PAP) as reproduced from [4]

The first iteration of the tongue prosthetic was developed by a graduate student, Francis Araya. He developed a tongue prosthesis that used the soft robotic approach involving a silicone tongue moved by a pneumatic pump. designed and created a soft robotic tongue using a pneumatic actuator to mimic the movement of the tongue[5]. We consider Araya's version of the prosthetic tongue as Iteration 1. This iteration 1 prosthetic tongue involved multiple design iterations related to the size and the internal air chambers in order to mimic the movement of the tongue s. The final tongue design consisted of three air chambers (front, middle and back of tongue) and three air pumps, one for each chamber. Araya ran displacement tests to determine how well the pneumatic system worked which revealed a tongue could be actuated by filing a silicone cavity using an air pump. This proved it was possible to build a prosthetic tongue that could fit in an oral cavity and actuate using a pneumatic system with pneumatic networks (PneuNet). However, the iteration 1 tongue had a major problem with air leakage in the PneuNet structures and was unable to move bolus on the tongue.

The next iteration (iteration 2) by Bridges et. al[6], verified Araya's pneumatic actuator design and improved the iteration 1 tongue design by rearranging the PneuNet structures and decreasing the size of the tongue to better fit the oral cavity. The iteration 2 tongue also had a much more complex control module, as it utilized only one air pump but 3 two way valve solenoids to direct air current to each chamber one at a time. In addition to this, the circuit also incorporated an LCD display and a pressure sensor (for the inner tongue pressure). Even though Bridges et. al. improved the pneumatic system greatly, they were unable to get the bolus to move from the front of the tongue to the back. In addition to pneumatics, Bridges et. el. experimented with magnetic actuation as a way to replace the pneumatics, which proved to be plausible. However, most progress on this iteration was limited as COVID-19 inhibited much of the collaborative work and building of the prototype.

Iteration 3 by Vasquez et. al[7] team designed, created and tested a prosthetic tongue prototype that moved using an electromagnet. Vasquez et al. ran many tests to quantify the electromagnetic force to help position the solenoid and magnet for effective actuation of the bolus. Their focus was also on miniaturization since it is important to have all the controls within the confines of the oral cavity and tongue with no projections. The magnetic actuation was able to lift the tongue by 1 cm but that amount of lift is insufficient to to move bolus from the front of the tongue to the back. The iteration 3 tongue was slightly bigger (by .5cm in length and 5.2cm in width) than the iteration 2 tongue as it accounted for the back one-third of the tongue that goes into the esophagus.

As indicated above, all three previous iterations had various challenges and the bolus could not be moved from the front of the tongue to the back. Therefore, our project aims to utilize the advances from the previous attempts and develop a tongue prototype that would move the bolus from the tip to the back of the tongue.

The goals of our project are as follows:

1. Design: Develop an improved mechanism and actuation method to allow for easier flow of the bolus from the tip to the back of the tongue
2. Size: Develop an accurate oral cavity system to enable demonstration of the actuation system of the tongue prosthetic. Develop the tongue to look even more anatomically correct and fit into the simulated oral cavity
3. Controls: Continue miniaturizing actuators and control systems to fit within the confines of the tongue and oral cavity
4. Validation: Create and carry out testing protocols to check tongue function.

With the completion of these goals, we would have a more usable prosthetic tongue prototype, which would work better for those in need of an artificial tongue.

The rest of this report goes as follows. Chapter 2 outlines the work done in previous iterations. Chapter 3 contains our background research on information from anatomy and physiology of the tongue, oral cancer and glossectomy, to mosfets and solenoids. Chapter 4 will discuss our project requirements and methodology of redesigning and creating the prosthetic tongue. In chapter 5, we will go through the thought process that led to our design process of the tongue prosthesis, and chapter 6 will discuss the redesign of the control module and its iterations. Chapter 7 will Go through the final design verifications through simulations and testing of the final prototype. In chapter 8 we will discuss final design considerations which include environmental, economic and societal impacts of this project and chapter 9 will contain the conclusions and discussions pertaining to this project and recommendations for future teams.

2. Previous Iterations

In this section, we will review the previous iterations of this project. By doing this, we were able to come to an understanding of how this project has progressed as well as ways we could make improvements to it this year.

2.1 Iteration 1: Araya 2019[5]

Francis Araya created the first prototype of a dynamic tongue in 2019 [5]. He used a pneumatic system as a way of actuation.

2.1.1 Prosthetic Design

Araya's design of the prosthetic tongue (iteration 1) went through multiple iterations to improve the design and miniaturize it. The first few iterations had three layers of silicone Eco-flex 00-30 and the inlet tubes at the back of the tongue as seen in Figure 2.1. This changed, as the final design had two layers of silicone Eco-Flex 00-30: the bottom-layer, and the top layer. The top layer, as seen in Figure 2.2 below, had rows of air chambers (structured PneuNets) and was divided into three parts with a front, middle, and back. As seen in Figure 2.1, each section had a different inlet tube connected through the bottom layer, so they could be inflated separately. The inlet tubes were placed on the bottom because it made them more accessible and reduced the possibility of air leakages. The overall dimensions of the final silicone design was 2.4-in long, 1.8-in wide and .24-in tall.

One of the major problems with his design was the silicone would tear apart when the tongue was inflated, where the top layer and bottom layer were glued together. This would cause air leakage and the prototype to be unable to perform well or at all. The prototype aso had issues with lateral expansion of the silicone.

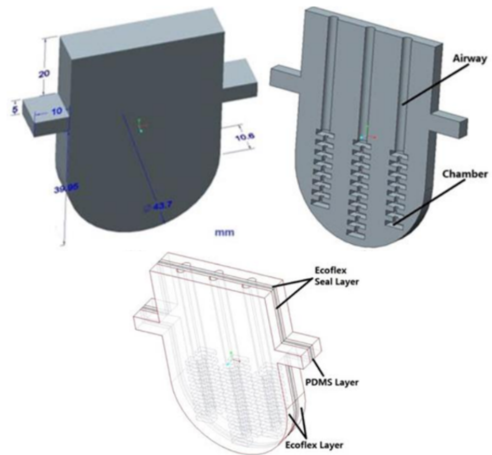


Figure 2.1: Three layers of initial design of Iteration 1 tongue as reproduced by [5]

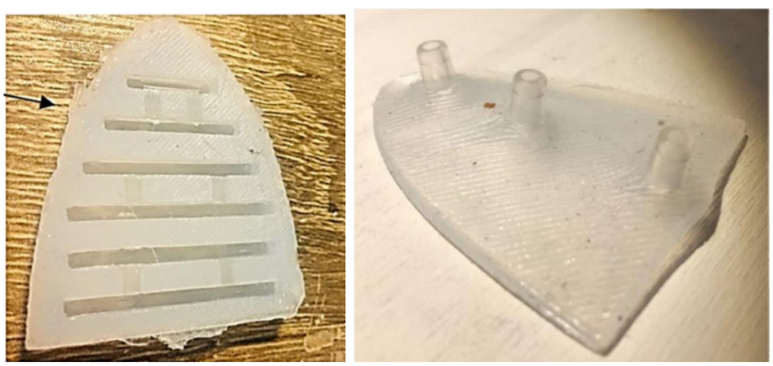


Figure 2.2. Silicone prototype the top layer (left) and bottom layer (right) of Araya's Final Prosthetic Tongue Design reproduced as is from [5]

2.1.2 Control Module

The control module consisted of an Arduino Uno microcontroller, three two-way solenoid valves, three 4.5 psi pneumatic air pumps and wires and tubes. Each pneumatic air pump was attached to one of the sections of the tongue: front, middle and back. For the final testing, a structure was 3D printed to hold the control module, the three mini pneumatic pumps, the microprocessor unit and the prosthetic tongue, shown in Figure 2.3. This prosthetic tongue in Figure 2.2 contains a skin color pigment to be more life-like, but is still the final tongue prototype design. The tongue was mounted by putting the input tubes through the slot in the structure and then the output ends of the tubes were placed on their respective solenoid valves. Due to the open nature of the platform, the tongue was able to be observed at all angles during testing.

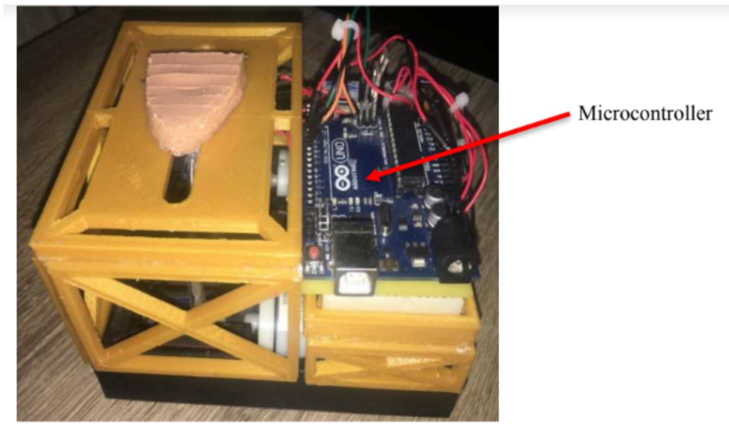


Figure 2.3. Control Module, mini pumps, and prosthetic tongue testing set up. The red arrow point to the microcontroller as reproduced from [5]

2.1.3 Testing

Araya ran tests on the prosthetic tongue to analyze displacement of the tongue during actuation and to compare it to the pressures and height found in previous research.

There were two different tests done: manual actuation and air pump actuation. The manual actuation displacement test used three 100ml syringes where each syringe was pushed in so that the tongue prototype moved in a wave-like motion from front to back, seen in Figure 2.4 is the air pump actuation done using the control module and 3D printed platform.

During the final testing done with the control module and platform, the prosthetic tongue prototype was moved using the three mini air pumps. For all of the displacement testing, black beads were placed over each section of the tongue (which can be seen in Figure 2.5) and videos were taken from the side view with a ruler placed in the background. These videos were then taken and put into a tracking software called Tracker[6] to find the displacement of the tongue. Araya was able to get the prosthetic tongue to actuate a maximum of 0.417 inches in the front section, 0.45 inches (1.143cm) in the middle section and 0.242 inches in the back section.

Even though Araya did not use pressure sensors to get the internal pressure readings of the air chambers, theoretical pressures for force per length of the chambers were determined by using the rated 6.5psi value of the air pumps. The theorized pressure in the air chambers was much lower than what was found in research, therefore the theorized deflection was also lower.

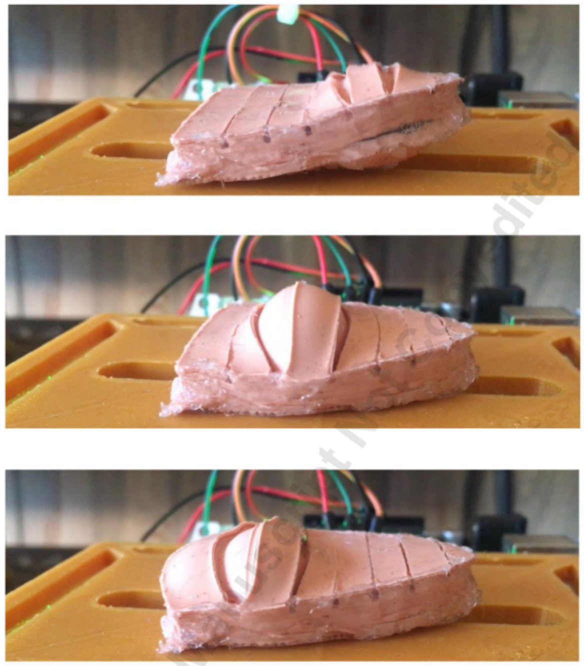


Figure 2.4: Actuation of the front (top), middle (middle), and back (bottom) sections of Araya's Final Tongue Prototype as reproduced from [5]

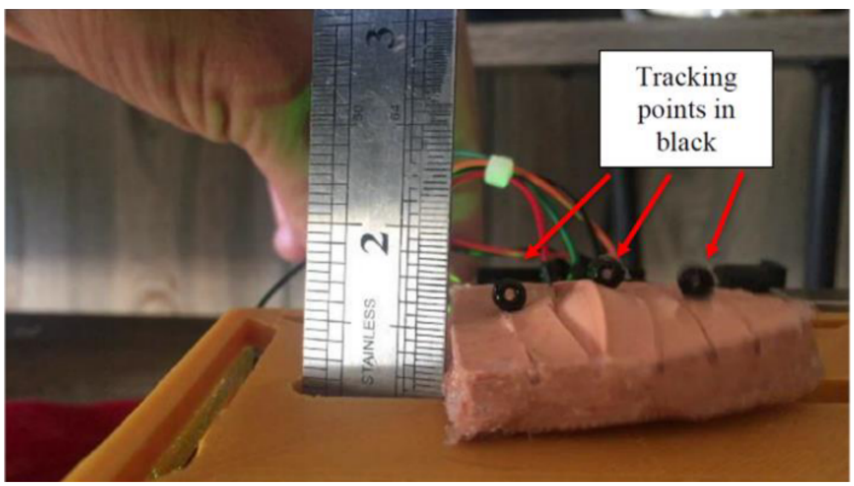


Figure 2.5: Tracking points and ruler placement for displacement testing as reproduced from [5]

2.1.4 Conclusions

Overall, the iteration 1 prosthetic tongue prototype was a great start to this project series. It displayed the ability to actuate the three chambers in a wave-like motion similar to that of a real tongue to get food from the front of the mouth to the back. Yet, there were a few difficulties and recommendations for future teams. The most notable problems were with the air leakage in the PneuNet structures and the design and size of the controls. It is possible to decrease the air leakage by having better quality silicone, silicone sealant or adhesion, and changing the locations of the input tubes. The design and size of the control module is too large to fit inside of the oral cavity. So future teams would need to miniaturize and condense it. Another improvement to the control module would be to add a pressure sensor so the pressure inside the PneuNet structures can be monitored as the tongue actuates.

Further improvements would be to create a smoother bolus contact surface as the serrations and gaps in the iteration 1 tongue inhibited the movement of the bolus. The iteration 1 tongue also had problems with ballooning in the upper section of the tongue which was advised to future projects to be fixed with improving the manufacturing process of molding the top layer of the tongue.

2.2 Iteration 2: 2019 - 2020 Bridges et al. Prosthetic Tongue MQP [7]

Following the Araya Thesis, Bridges et al.[7] improved upon the iteration 1 design and created a prosthetic tongue using pneumatic actuation that could fit inside the oral cavity to aid in deglutition[7]. This group initially focused on five goals: achieving an actuation time of 1 second, integrating a retainer and prosthesis into the oral cavity, body safety, creating a testing module, and validation through simulation and testing[7]. The following sections will provide an analysis of their design and final results.

2.2.1 Prosthetic Design

Bridges et al. created a tongue prosthetic out of the same two-part silicone SmoothOn Ecoflex 00-30 that Araya used. There were four main redesigns: the first one using Iteration 1 but with different PneuNet structures, the second design was the same as the first redesign using PolyUrethane, the third redesign was considered the single component design (and most successful), and finally the fourth redesign using a linkage system. Five prototypes of a rear entrance design for the inlet tubes and five prototypes of the bottom entrance design, seen in Figure 2.6, were made for the redesign of Iteration 1. Only one successful prototype of the polyurethane model was made and the third redesign, which we will consider Iteration 2, was composed of silicone Eco-flex 00-30 and Polyvinyl Alcohol (PVA) for the PneuNet structures.

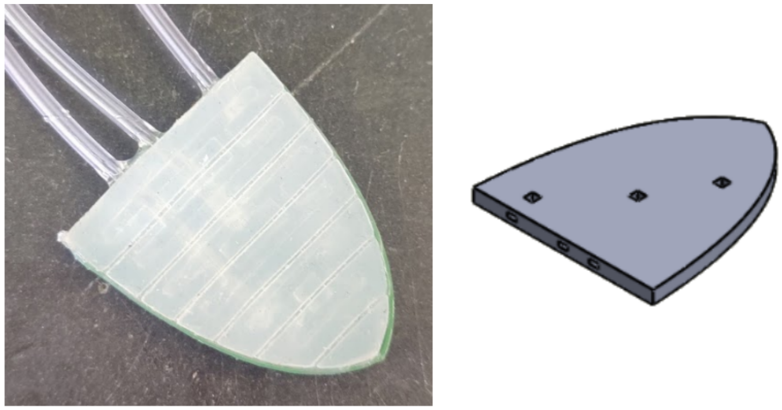


Figure 2.6: Rear entrance design (left), bottom entrance design (right) as reproduced from [7]

Each of these redesigns went through the following steps for flow process and design: create design, 3D print molds, cure elastomer, connect parts using glue (if needed), test pressurization, go back to reglue parts if needed and retest pressurization after, attach to casing and finally attach to retainer. The first two designs never made it past the pressurization testing as the seal kept breaking where the glue was within 5 cycles. The third design (iteration 2) was able to go over 20 cycles of pressurization testing and get to testing with the control module.

The first redesign using Araya's design changed the Pneunet structures as seen in Figure 2.7. These redesigns enlarged the area where the air pressure could exert force, causing a more centrally distributed distribution which would be better for bolus. The redesigns of the air chamber in Figure 2.6 were not fully tested or prototyped due to the team's limited lab access because of the COVID -19 Pandemic. The second design is not much different from the first as the material changed to polyurethane but the molds remained the same aside from a thinner top section (Figure 2.8). Only one prototype of the polyurethane mold was made, but the plasma bonding failed to be strong enough to resist tearing during pressurization.

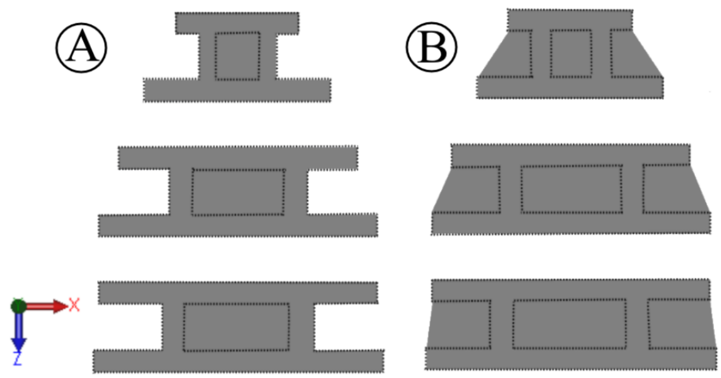


Figure 2.7: New interior design channels and the dotted overlay is shows the old structures as reproduced from [7]

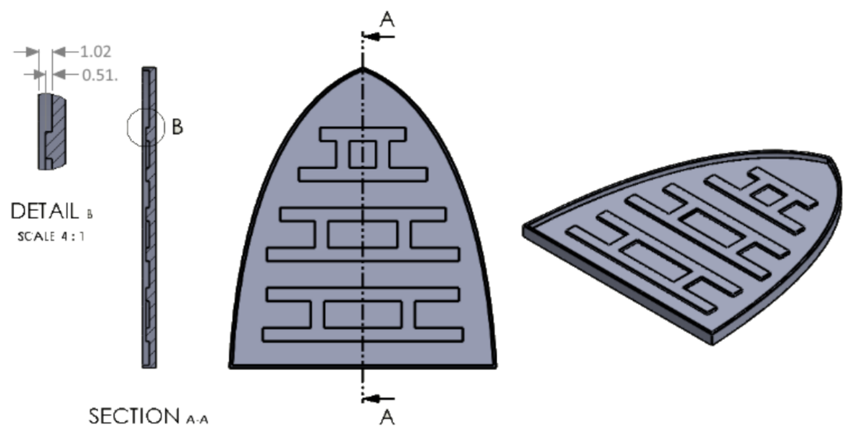


Figure 2.8: Top of the polyurethane mold as reproduced from [7]

The third design (Iteration 2) of the tongue was measured to be 40mm x 35mm which could fit inside of their oral cavity which contained a bottom and top jaw. The dimensions of the bottom jaw of the oral cavity are 5.2x3.8x2.22 cm and the top jaw is 9x6.4x1.7cm making the overall height about 3.92cm. The three air chambers inside of the tongue were made of PVA, which can be seen in Figure 2.9, so that once the silicone was poured over the mold (Figure 2.10) and cured, the PVA could be dissolved over a few days in water. Through testing of PVA, Bridges et. al. realized they needed to scrap away or squeeze out the softened PVA after it had been sitting in water for 24hrs as this would get the PVA to dissolve faster.

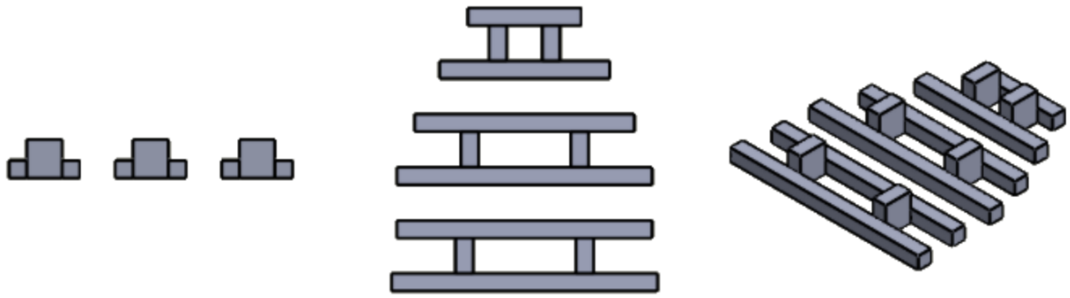


Figure 2.9: PVA channel inserts for iteration 2 as reproduced from [7]

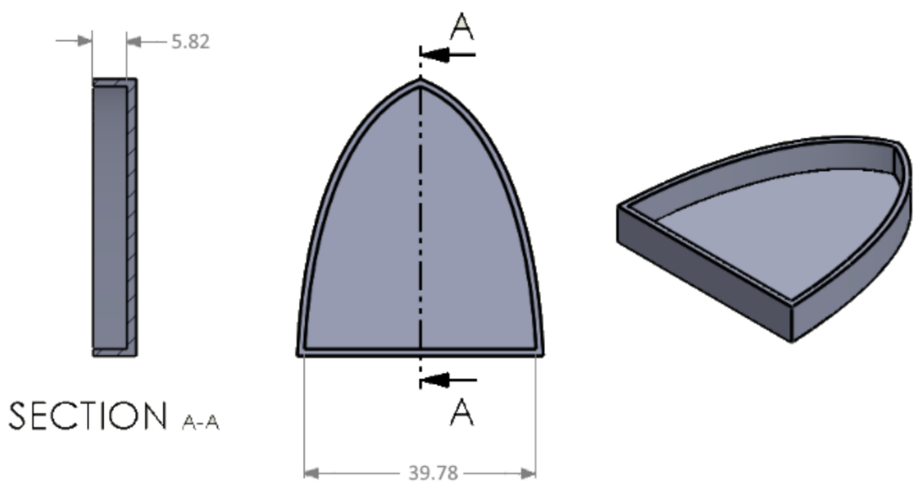
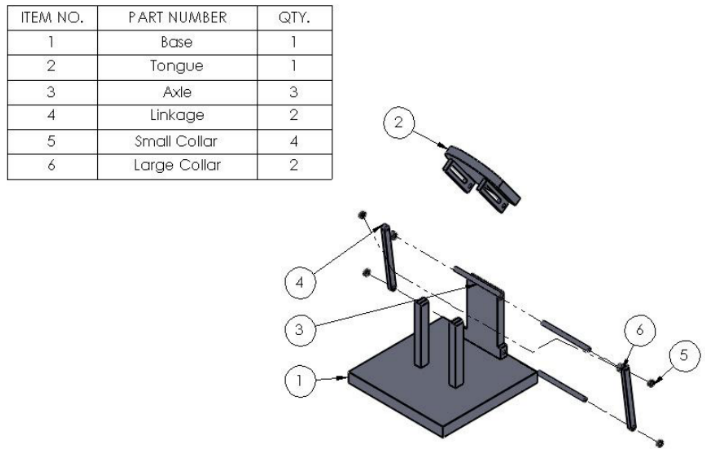


Figure 2.10: Third design (iteration 2) single component mold as reproduced from [7]

The fourth design consisted of a linkage system to actuate the tongue, seen below in Figure 2.11. The system worked by having a motor attached to an axle that connected to the linkage and tongue. As the motor rotated the axle moved backwards, causing the tongue to angle up and back, thus actuating the tongue and moving bolus. Bridges et. al was able to simulate the actuation movement in Solidworks, seen below in Figure 2.12. The whole linkage system was able to be 3D printed and easily scaled in Solidworks, but the smaller the printed parts, the more likely they were warped and broke during operation within the system. If the parts were to break within the patient's mouth, it would be a choking hazard. A control system would need to be integrated into the system and retainer which added more concerns, so Bridges et. al. decided it was best to focus on the silicone designs.



ITEM NO.	PART NUMBER	QTY.
1	Base	1
2	Tongue	1
3	Axle	3
4	Linkage	2
5	Small Collar	4
6	Large Collar	2

Figure 2.11: Linkage system design diagram of components and assembly as reproduced from [7]

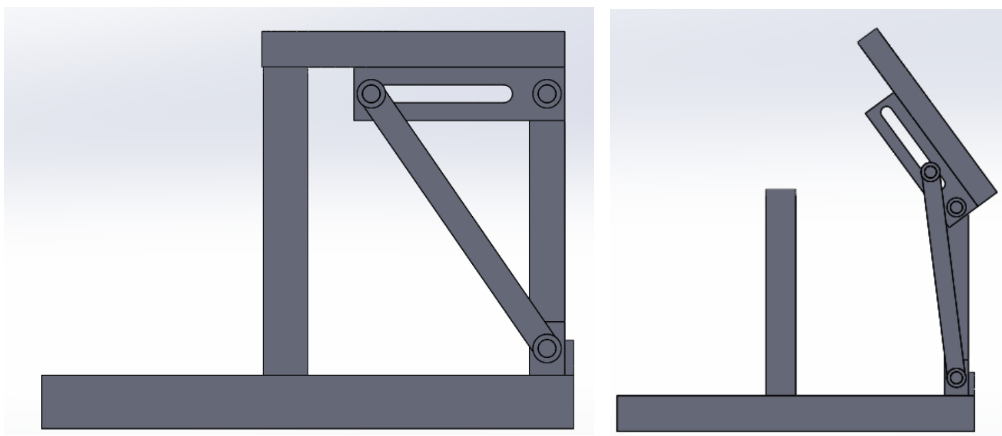


Figure 2.12: Linkage system in resting state (left) and fully moved (right) as reproduced from [7]

In addition to redesigns, Bridges et. al created a casing and retainer for the prosthetic tongue. The casing went on the bottom half of the prosthetic tongue to try and reduce the lateral expansion of the tongue that was seen in Araya's trials. The bottom of the casing was hollow to allow room for the inlet tubes as seen below in Figure 2.13. Loctite glue was used around the casing rim to attach the tongue and retainer. As for the retainer, it consisted of wire (19 - 20 gauge) and plastic and was based on removable Hawley retainers, seen in Figure 2.14, commonly used in dentistry.

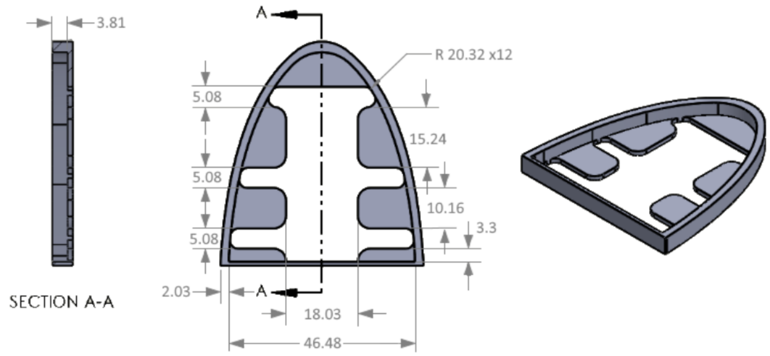


Figure 2.13: Casing Design as reproduced from [7]

Figure 2.14: Hawley retainer

2.2.2 Control Module

Based on Araya's control module and needed improvements to it, the Bridges et. al team designed a new control module to actuate the tongue and get pressure sensor readings. A 3D printed structure was made to hold all of the components of the control module.

The initial new designs electrical components consisted of 3 mini air pumps, 3-way solenoid valves, an Arduino UNO with a Bipolar Junction Transistor (BJT), three Honeywell low pressure sensors, a 20x4 character LCD screen, and an I2C SPI serial monitor. As seen in Figure 2.15, the 3D printed structure was stacked, so the 5 volt. Air pump was on the lower layer across from the solenoid valves, and the solenoid valves were underneath the prosthetic tongue testing platform. The platform had screw attachments to secure the bottom oral cavity which would hold the prosthetic tongue.

To run the control module, new code needed to be made and as a result, four different programs were created: one for each inflation channel and one to inflate all of the channels in a certain sequence. The user could pick which program they wanted by pressing one of the four buttons connected to the Arduino. Other programs were also added to the Arduino to test displacement for multiple channels and to control the inflation time so the team could actuate to a specific height or pressure. Internal pressure sensor readings, from the 3 Honeywell pressure sensors, were displayed on the LCD screen in almost real-time. These readings were printed and stored into a CSV file so they could be used as comparison to the displacement readings.

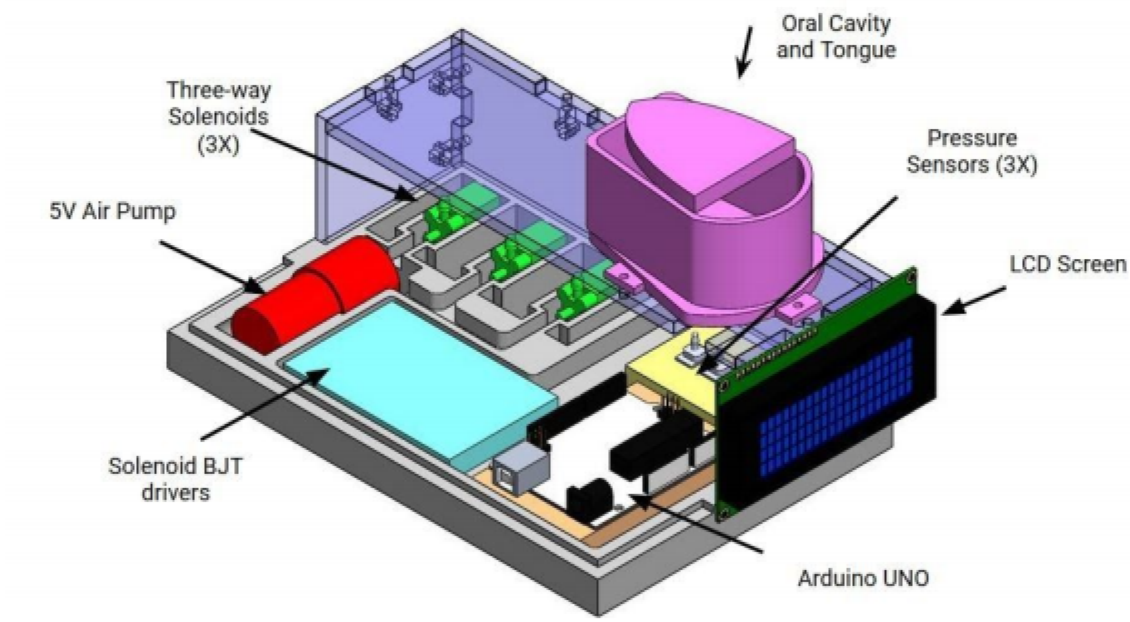


Figure 2.15: 2019-2020 MQP Control Module Testing Setup as reproduced from [7]

The final control module was downsized from three pumps to one 5V air pump with an output pressure of 100kPa to supply air to the prosthesis, but still contained all of the other parts. This was because having an air pump for each section of the tongue was too much pressure and was causing the PneuNet structures to burst. Once it was just one air pump with t-connectors on the solenoids, the sections of the tongue inflated enough without bursting. The final circuit design for the control module, seen below in Figure 2.16, was never built as Bridges et. al did not have enough time due to the time constraints caused by the COVID-19 Pandemic.

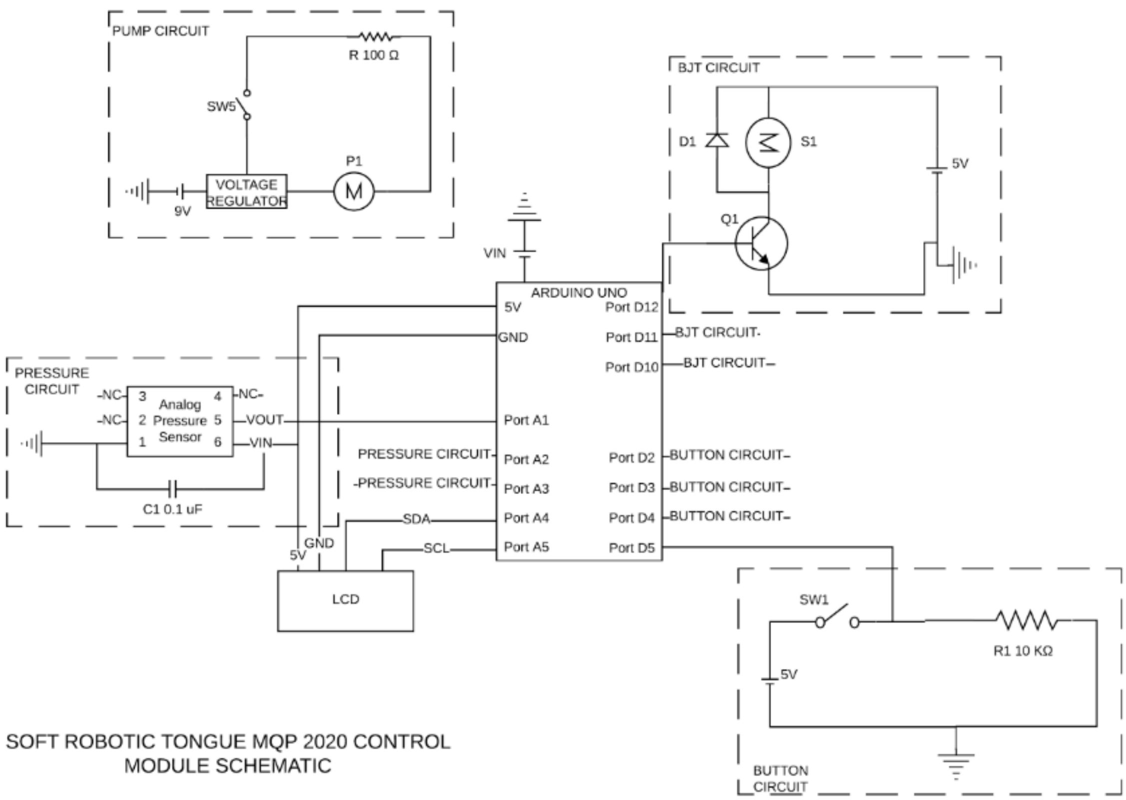


Figure 2.16: Electrical schematic for 2019-2020 MQP final control module as reproduced from [7]

2.2.3 Testing

Bridges et. al ran magnetic actuation tests, pneumatic tests that included an initial pressurization test and bacterial testing.

For magnetic actuation, a test was done with iron oxide particles and another test was done with large magnets of 5 mm width. The iron oxide particles were put in silicone (Ecoflex 00-30) to create a mixture of 20% by mass and then placed in a slablike mold. Once the silicone had cured, a test was done by running a magnet over the silicone slab to observe if the silicone would move due to the iron oxide particles in the silicone. The particles were attracted to the magnet and the slab surface moved a little. As a result, a test was done with larger magnets to see if the silicone would lift if there was a stronger magnetic attraction. Bridges et. al designed a mold to hold several of these large magnets seen in Figure 2.17 below. This mold allowed for 4mm of silicone to be cured over the magnets. When the silicone cured, a bead was placed on the silicone over each magnet so the tracking software could be used to track the displacement. A magnet was then run back and forth above the silicone/magnet mold and a video was taken of it. The results validated magnetic actuation as a possible way to actuate the tongue as the average displacement was 11mm and the maximum displacement was 15mm. However, the magnets would tend to twist and bend the silicone to align the poles so the next team would need to keep this in mind.

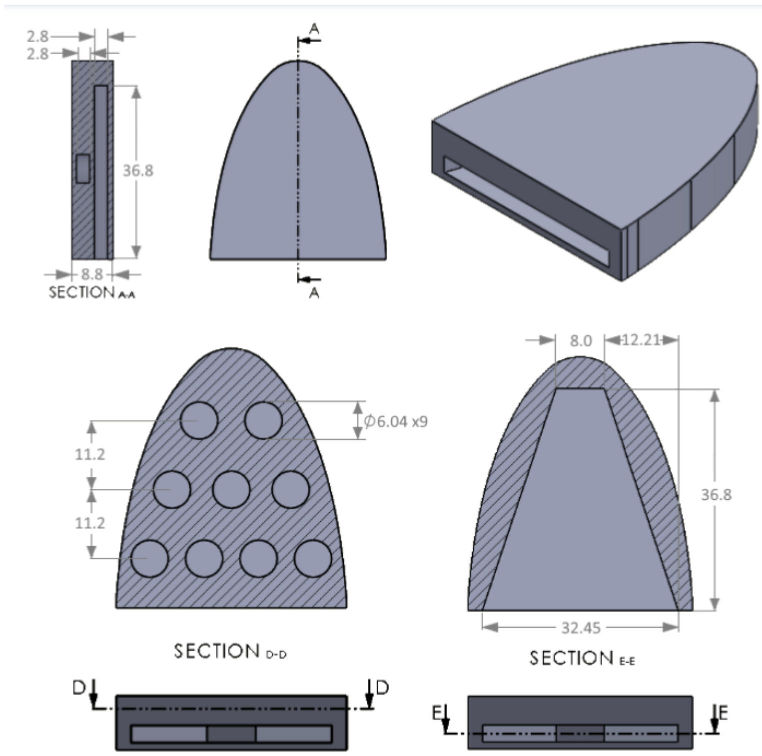


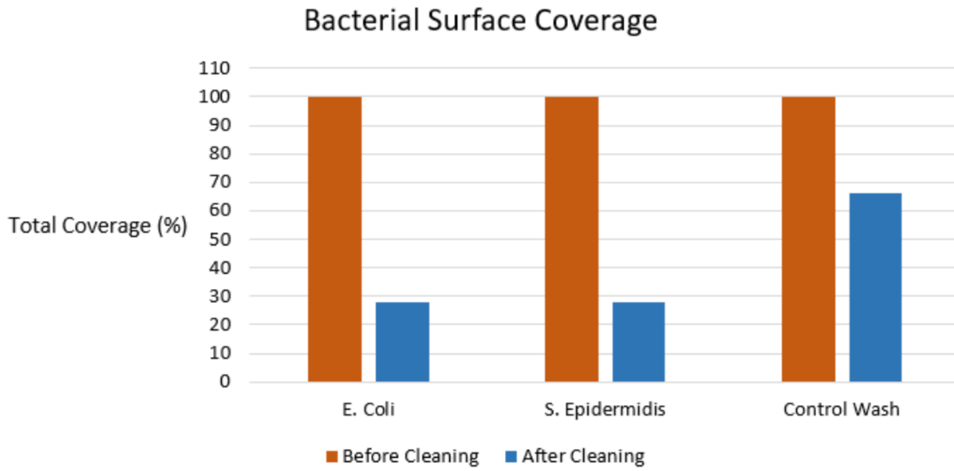
Figure 2.17: Solidworks Magnetic Prototype Drawing as reproduced from [7]

For the pneumatic testing, an initial manual test and simulations in Abaqus were done. The initial test was done using three 100ml syringes pushin 20ml of air in at a time and then withdrawing the air after fully inflating the PneuNet chamber. However, no concrete data was collected from this test. Since the control module and tongue prototypes were unable to be put together, simulations of pneumatic actuation were done in a software called Abaqus. These simulations gave theoretical data on the maximum pressures of each redesign. The maximum pressure before failure was 0.524 MPA for the preliminary design, 0.242MPa for the Early Redesign, 0.32 MPa for Redesign 1 and 0.221 for Redesign 2.

To ensure the silicone was safe to be placed in the oral cavity for extended periods of time, Bridges et. al performed bacterial adhesion testing for the bacteria *Escherichia coli* and *Staphylococcus epidermidis*. Those two bacteria were chosen as they have a long history of study, easy to access and relatively easy to test for. LB agar was used as a control material and had each bacteria swiped on a piece of the material. In the initial test, both species of bacteria were streaked onto plates with silicone and polyurethane, incubated for 24 hours and then compared to the LB agar plate. Any bacteria that was on the experimental plates was considered negligible as it was much less than the bacteria populations normally inside the human mouth. A following bacteria test was done with a mixture of broth and sugarcane as it would be more realistic since the bacteria would come in contact with food being eaten. The initial test was repeated but with the broth mixture poured over it. The plates were then left alone for 24 hours, after which the broth was poured out to see the materials. A 0.01mg/mL of Triphenyltetrazolium chloride (TTC) was used to indicate if any of the bacteria was present. The tests revealed the same as the initial tests, which were there was negligible bacteria growth.

Another test was done to determine the best way to sterilize the materials. Since the bacteria did not seem to grow on the silicone or polyurethane for the previous test, LB agar was used for the sterilization test. The bacteria species were cultured on the agar plates then the plates were placed under warm water with a dissolved denture tablet for 5 minutes. After 5 minutes, the plates were taken out and rinsed with a spray bottle of water. A control agar plate was made through the same steps but not rinsed with the denture tablets. The results, seen below in Table 1, showed the denture tablets cleaned the plates fairly well and the bacteria surface coverage was less than 30% compared to the 65% of the control group.

Table 1: Characterization of denture tablet efficacy



2.2.4 Conclusions

Bridges et al. were able to make a successful control module that could control each air chamber individually as well as together, running finite element analyses on each redesign and a promising redesign that could use pneumatic actuation. However, the pneumatic system has many components, especially the air pumps, that cannot be downsized any further, making it nearly impossible to fit inside the oral cavity.

Bridges et al. made some recommendations for future teams such as to incorporate manufacturability and integrate mechanics, run tests to determine needed actuation height to move the bolus, and miniaturize the control module to fit inside the oral cavity with the tongue. The tongue design also only accounted for the first two-thirds of the tongue and to have a closer to full-size tongue, the retainer would need to be redesigned.

The outstanding limitations of this MQP team was in the size and methods of actuation. They were able to inflate two of three areas of the prosthesis. The size and shape of the tongue proved to be too small to replicate a human tongue. The natural shape of the tongue extends backwards past the length of a retainer. The components are also too large to fit into a person's oral cavity. One limitation of pneumatics is the possibility of puncturing and air leakage.

2.3 Iteration 3: Vasquez et al. Prosthetic Tongue MQP [8]

Following Bridges et. al, Vasquez et al.[8] continued work off the previous year's project to create a prosthetic tongue with a focus on shrinking the prototype as well as working towards mimicking a more realistic biocompatible tongue. In addition, the system also changed from using a pneumatic actuator system to a magnetic actuator system for tongue movement. The following sections will provide an analysis of their design and final results.

2.3.1 Prosthetic Design

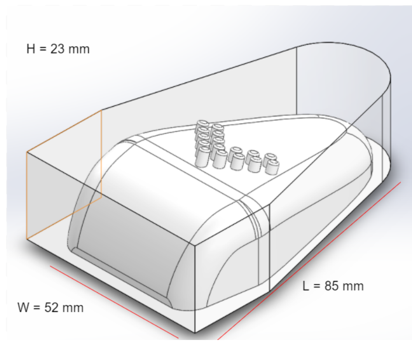


Figure 2.18. Final Prosthesis Dimensions of 2020-2021 MQP as referenced from [8]

Their tongue design was larger than the previous years with dimensions of 85 mm in length and 52 mm in width compared to Iteration 1, which was 40mm length and 35mm width. This new tongue prototype, seen above in Figure 2.18, might have been larger itself but the associated surrounding electronics were miniaturized besides needing fewer components compared to the previous two iterations. It also had papillae added to the top of the tongue to aid in moving the bolus by adding a surface the bolus could grip onto. The components were able to be minimized as they did not need to have a pump which had been taking up a lot of the space. They also gave the tongue height of 23.2 mm compared to the Bridges et al.[7] prototype that had a height of 17 mm and used a somewhat flat prosthetic in order to allow for a more accurate tongue representation and to accommodate the components. They determined their actuation method by using a decision matrix while weighing a breast pump against magnetic actuation. This was done to compare the benefits of using a pneumatic system vs magnets, and the team found that magnetic actuation would better suit their purposes. The main magnets used were N52 rectangular magnets, which are neodymium magnet grade with an energy product or BHMax of 52 Megagauss Oersteds. The N52 magnet is the strongest, most expensive and more brittle of the NIB magnets. This magnet would be placed inside the polymer tongue. These magnets would then be moved by the magnetic pull solenoid running on about 12V. An image of the circuit can be seen in Figure 2.19.

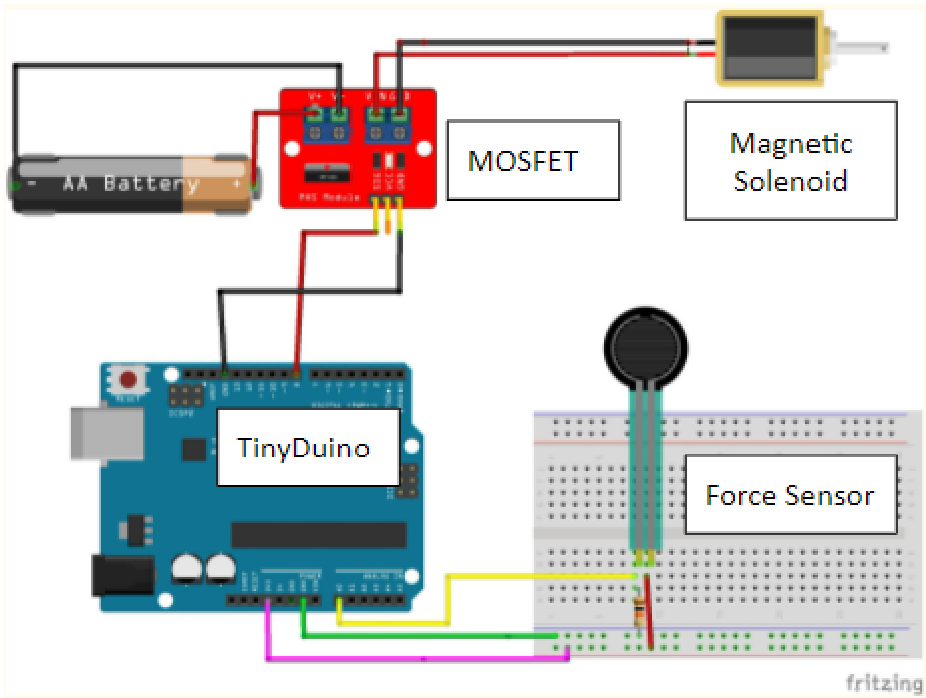


Figure 2.19. Circuit diagram of Iteration 3 showing the force sensor, TinyDuino, MOSFET and magnetic solenoid circuit as reproduced from [8]

The project previously used an Arduino, which would be encumbrance for practical use, so the current group used a smaller version of it, known as a TinyDuino. A TinyDuino is a third party arduino system that is a modular stack of circuit boards that closely resembles how the arduino pro/mini. A TinyDuino [9] was used in order to miniaturize the circuit so that all of the components could fit inside the tongue but still have enough power. The goal of a smaller circuit was achieved by stacking multiple TinyDuino on top of one another, while connecting the auxiliary components such as the mosfet, solenoid, and force sensor. A TinyDuino Hall sensor and Wireling Accelerometer were also used to calculate the actuation height of the tongue [10].

Final testing of iteration 3 included: Simulation of Magnetic Fields in ANSYS, Magnetic Field Mapping, Displacement Testing & Results, and Bolus Testing. Results from the testing showed that 2 mm of thickness was sufficient to protect the silicone from puncturing and protect the patient from the electronic components, and the ANSYS simulation revealed that the solenoid could produce a magnetic field that reached approximately 30 mm away from the end of the iron core. The largest portion of the strength of the solenoid was within the first 12.5 mm away from the solenoid. Ultimately the bolus was not able to move from the tip of the tongue to the back in this iteration and more strides need to be taken in order to allow for more complex movement in the tongue.

The team, which produced this iteration, discussed future improvements to the project. Those included focusing on materials selection for biocompatibility, increased movement control, and continued sensor exploration. They believed research into medical grade silicones should be a priority to increase biocompatibility and safety to the patient. Additionally, more trials of various magnet combinations and placements can be performed to see what will allow for maximum displacement based on the magnetic field quantification. Further sensor explorations could aid the patient triggering tongue movement with less food placed on the tongue.

2.3.2 Control Module

The control module for this iteration took a departure from previous iterations by getting rid of as many extraneous pieces and focusing purely on minimal data collection while attempting to maximize actuation. The usage of a TinyDuino also allowed for the group to store the control module almost fully inside of the tongue.

Their control module makes use of the vacant hole inside their prosthetic design to fit the TinyDuino, pressure, and the solenoid. The circuit is then placed inside a 3D printed acrylic oral cavity. Not all of the circuit is able to fit inside of the tongue however, and part of the TinyDuino module hangs out behind the tongue along with the mosfet used to power the solenoid.

The control module code has two main parts to it. The first is that it takes in the reading from the pressure sensor and then determines if the threshold pressure has been met. Then it turns the solenoid on for 2 seconds. It then will infinitely loop this for as long as the tinyduino has power.

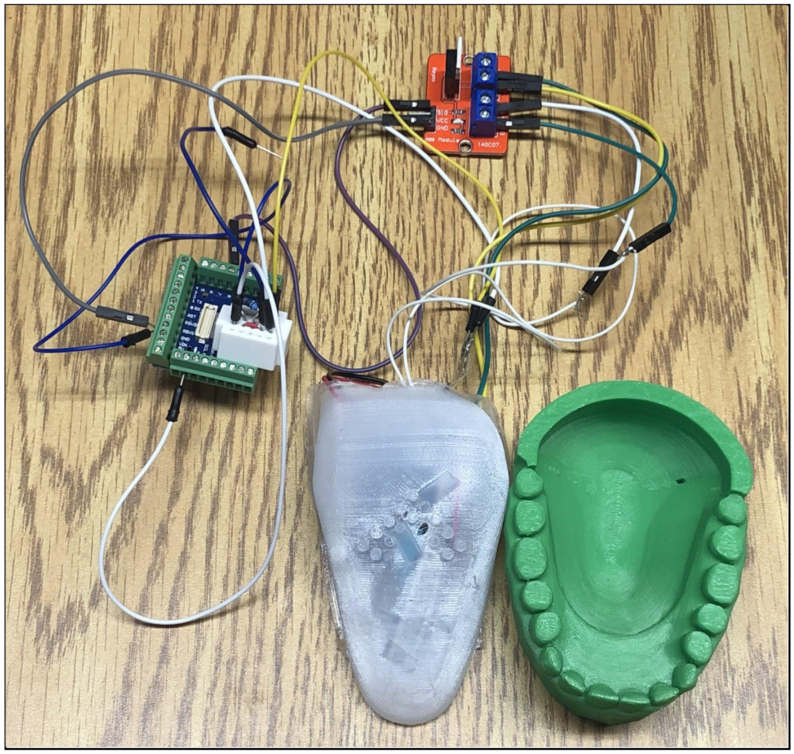


Figure 2.20. Final Circuit of Vasquez et al. MQP from as reproduced from [8]

2.3.3 Testing

The 20-21 MQP team did testing on solenoid to magnet distance actuation, flex sensor resistivity at different curls, and tongue actuation utilizing the magnet, which can be seen in Figure 2.20.

The magnetic distance testing was done by placing the neodymium magnet just close enough that it moves to the unpowered solenoid. They then marked the position the magnet moved to the solenoid from and never placed it closer than that to the solenoid. Afterwards they place the magnet a slightly further away distance away from the minimum so that the solenoid cannot pull it unpowered. They then power the solenoid and see if it pulls the magnet. If it does, they repeat the previous two steps of pushing the solenoid further away and powering the solenoid until the magnet is no longer pulled. They repeated this test for each solenoid and magnet they have.

The flex sensor testing done to determine its effective range and sensitivity was done by first putting the pressure sensor into the tongue and running their pressure sensor test code. They record the unaltered tongue's pressure sensor reading. Then they put 5ml of water on the tongue and recorded the pressure sensor value. They clean off the tongue and once again record the unaltered tongue's reading. They repeat these steps for 5g of food, and then 5g of food and 5ml of water recording each resistance reading. They then averaged these values to create the threshold that they would use in all of their future testing for actuation.

Finally for the tongue displacement testing they equipped a wireling to the arduino so that they could precisely measure the actuation of the tongue. The testing begins by activating the solenoid and then once the tongue actuates record the wireling data.

2.3.4 Conclusions

The 20-21 prosthetic tongue MQP was able to make a control module system that allowed for automatic control of the prosthetic. This group also made steps to make a more human looking tongue, and their ability to miniaturize their system more compared to the previous system is admirable as well. This reduction in size came with a cost however, in the form of a reduction in actuation. This reduction in actuation was so severe that they were unable to move bolus in the end.

The recommendations this group made for future teams was to focus on better movement control, material selection for biocompatibility, and to continue to look into other sensor types. Continued research into more sensitive sensors would allow for more precise detection making the system more accurate and allowing for less bolus to be needed to trigger actuation.

Although the tongue was not able to actuate as much, this group had the first departure from an air pump circuit and attempted to incorporate a circuit directly inside the tongue to save space. This team also wanted to put special emphasis on the mental ramifications of having a human looking tongue, and how customization would be important to customers in the future.

3. Additional Research

In this chapter, we will discuss more of our background research regarding the oral cavity and tongue movement, biocompatible materials, possible effects on the human body and motor actuation.

3.1 Anatomy and Physiology of the Human Tongue

In order for us to have a good starting point, we needed to know and understand the anatomy and functions of a tongue and oral cavity. In this section, we will go over the parts of the tongue and oral cavity and how they interact.

3.1.1 Muscles/sections of Tongue and Mouth

The mouth or oral cavity contains the tongue, cheeks, gums, teeth, and palate. The average size of the tongue is 7.9-8.5 cm x 5.0-6.4 cm x 1.7 cm with an average volume of 47.07 ±7.08 cm^3 [11]. The tongue is made up of two main parts: the first being the oral tongue, which consists of the first two thirds of the tongue (the part of the tongue that can be seen when stuck out of a person's mouth), frenulum, uvula, lip, and salivary glands; the second being the base of the tongue which is the back one-third of the tongue[12]. The tip and sides of the tongue are movable sections and can perform complex movements. The back of the tongue refers to the upper surface of the tongue and has many sensory cells for our senses of taste and touch. The root, or base of the tongue anchors the tongue and cannot move freely. It is connected to the floor of the mouth and cannot be seen from outside. It requires less effort for moving the tongue vertically than horizontally.[12]

Located on the tongue are also taste buds referred to as papillae. Chemicals that interact with the taste buds in the tongue are referred to as "tastants," which interact with gustatory cell receptors in the taste buds, resulting in the transduction of a taste sensation. The five broad categories of taste receptors are (1) sweet, (2) salty, (3) sour, (4) bitter, and (5) umami. The lingual papillae are divided into vallate (or circumvallate), fungiform, filiform, and foliate papillae[13]. These parts of the tongue can be seen in Figure 3.1 below.

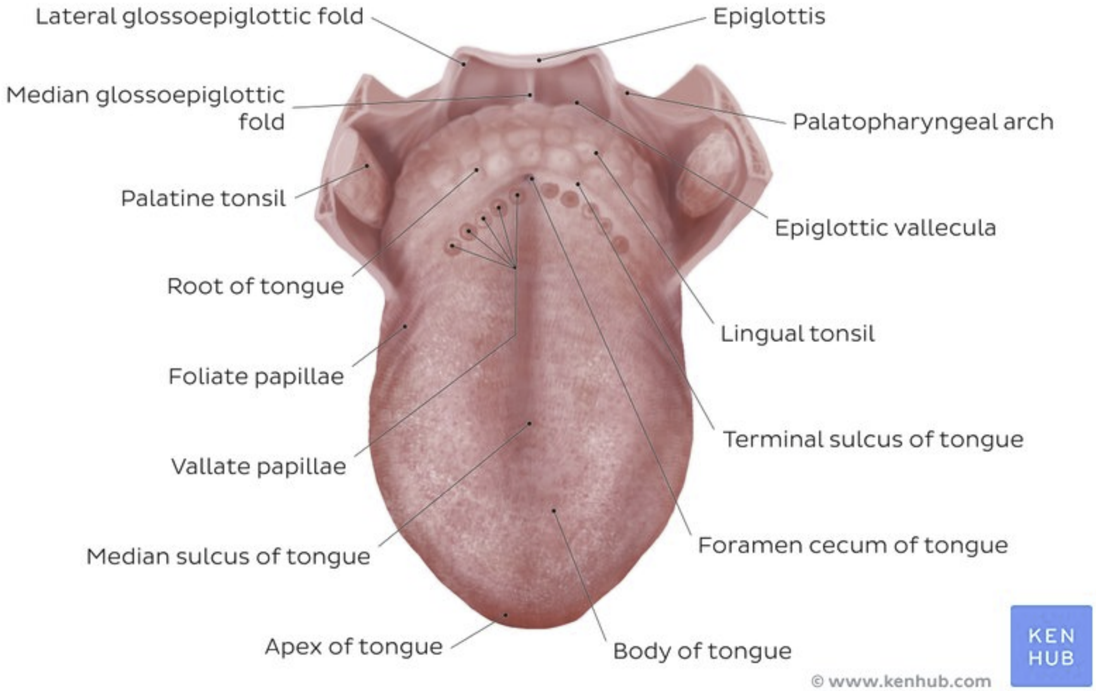


Figure 3.1. A labeled diagram of the parts of the tongue as reproduced from [13]

3.1.2 Purpose and Movement of Tongue

The tongue is used in deglutition, speech, swallowing and mastication. For our project, we will mostly be focusing on the position of the tongue during mastication to deglutition as it is too intricate to add speech to the function of our prosthetic tongue. The average tongue length is about 3 inches and consists of about eight muscles and 10,000 taste buds.

The position of the tongue is determined by the position of the hyoid bone, which controls the angle and length of the floor of the mouth that the tongue rides on[11]. The hyoid bone, tongue and relating muscles can be seen in Figure 3.2 below. The volume of the oral cavity in which the tongue and muscles are is 51.47 ± 6.46 cm^3 [11].

Deglutition and mastication have an oral, pharyngeal, and esophageal stages (each one is named for the location of the bolus as it passes from the mouth, into the pharynx, and down the esophagus) There are a total of five stages to deglutition and mastication. The first being transportation where the food is placed inside the mouth. The food is placed on the tongue and the mouth is maximally opened. During the process of taking a bite, the food is cradled on the anterior-middle part of the tongue and the back part of the tongue is pushed up[14]. As the mouth closes, the tongue starts to push up and once the mouth closes, the tongue does a twisting movement to get the food to move back. The second stage is processing the food inside the mouth, which starts with the hyoid bone and tongue surface cycling. This cycling causes the bolus to be pushed to the anterior of the tongue. Once this happens the third stage, the second part of transport, happens. The tongue performs a ‘squeeze back’, which is where the tongue repeatedly rises so the tip and anterior surface comes into contact with the hard palate, compressing the bolus[14]. Figure 3.2 below references the muscles used in deglutition which include the omohyoid, sternohyoid, thyrohyoid muscle and sternothyroid muscles[14]. The fourth stage is forming the bolus and deglutition. There are two different types of ways a person holds bolus in their mouth before swallowing: the first type will hold the bolus between the tongue and the palette, the second type will hold the bolus on the floor of the mouth[14]. When swallowing, the anterior of the tongue expands back, causing the bolus to move to the back of the tongue, as the back of the tongue drops so the bolus can slide past the pharynx[14]. In a study done by Peng et al.[14], using a ‘cushion-scanning’ US technique for echocardiography, they obtained the speed of tongue surface movement in five stages of swallowing liquid. These stages were recognized as: Mean values for all phases were 10.34 mm/sec, with a standard deviation of 2.10, with a total range of 2.10 (minimum) to 32.43 (maximum), N = 165. It was reported that the calculated fastest speed was 305.67 mm/sec during the first phase of transport.[14]

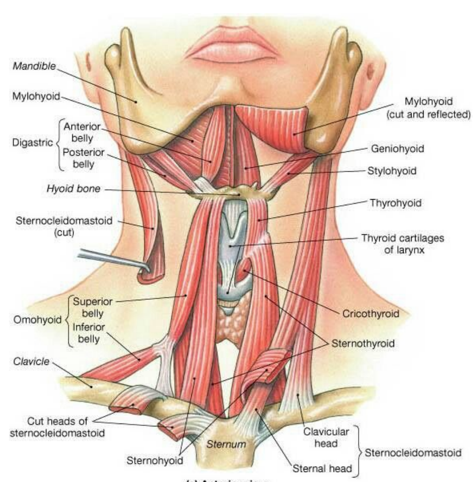


Figure 3.2. Diagram of all the bones and muscles relating to the tongue reproduced as is from [14]

3.2 Oral Cancer, Glossectomy and Current Prosthesis

In the United States, about 53,000 new oral cancer cases occur every year[1]. In 2021, there were about 54,000 new cases in the US and about 377, 713 new oral cancer cases worldwide[2]. There is no exact known cause of oral cancer, but high risk factors include high-alcohol consumption, tobacco use, exposure to UV rays from the sun and tanning beds, and the Human Papilloma Virus (HPV)[3]. The most common forms of treatment for oral cancer are chemotherapy, radiation therapy and targeted drug therapy which are usually combined to make a more effective treatment. However, if the cancer does not respond and continues to worsen, surgery to remove the cancer from the oral cavity will be done, which is called a glossectomy.

A glossectomy is a surgery done to remove any or all parts of the tongue from the mouth. Patients can have a partial glossectomy, where less than 50% of the tongue is removed, or a total glossectomy, where more than 50% of the tongue is removed[4]. Those who have a total glossectomy end up with a large open oral cavity, which results in loss of speech, and pooling of saliva. To fix this problem, patients can get a tongue prosthesis that can help them regain more speech and deglutition back.

Most of the current prosthesis are static and are made of silicone rubber and acrylic resin[4]. These prostheses can help aid in deglutition and speech by shaping the cavity. For deglutition, the static prostheses have a trough-like formation at the back to guide the bolus through the pharynx. For speech, the static tongue prostheses have a flat, wide anterior elevation and an elevated posterior[4]. Generally, all of these prosthetics need intense rehabilitation for patients to be able to regain some speech and swallowing ability.

Recently, Shayan et. al designed and tested a new dynamic prosthetic tongue using nitinol strips[15]. The final prototype was composed of superelastic nitinol strips and acrylic resin, which can be seen below in Figure 3.3. The tongue is moved by the closing of the mouth, so when the ends of the nitinol strips are pressed down by the teeth, the middle section of the strips bends. This then causes the tongue to actuate which can be better seen in Figure 3.4. The blue tubes were used as guides for the nitinol strips to move through the acrylic resin. These blue tubes were bent at certain angles to increase the height of the tongue. Then, angle of the tubes was tested at 90^0, 120^0, and 150^0 and the length of the tubes was also tested to determine what length worked best. A certain length was needed to guide the nitinol, but too much length would get in the way of bending. Some bending of the nitinol strips was needed so when the jaw closed, it would move the tongue. Testing was done using a cadaver head and oral cavity with pressure sensors placed underneath the prosthetic tongue[16].

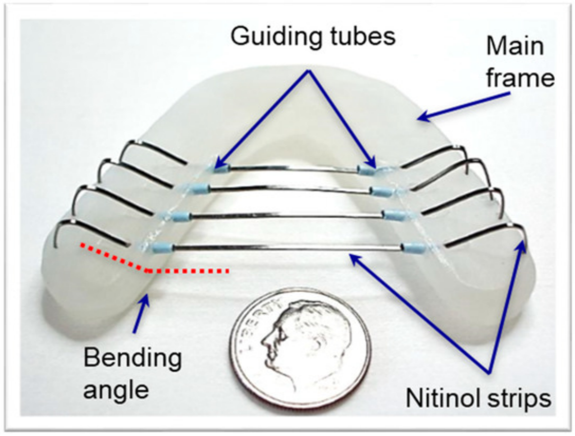


Figure 3.3: Shayan et. al prosthetic tongue prototype as reproduced as is from [16]

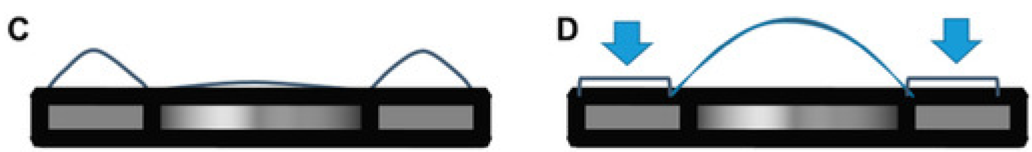


Figure 3.4: Actuation of the Shayan et. al prosthetic tongue as reproduced from [16]

The results of the testing showed that when the length and the diameter of the tubes were increased, the resistance from friction decreased in movement of the nitinol wires. The conditions with the least resistance was the tube at 15^0 and 6Fr catheter diameter. To see the actuation of the prototype inside the cadaver, an x-ray was used as reproduced in Figure 3.5. The applied force angle inside of the cadaver mouth was different than expected and was about 153^0, causing a higher central actuation of the tongue. The highest pressure recorded using the Iowa Oral Performance Instrument (IOPI) pressure sensors was about 12 kPa[16].

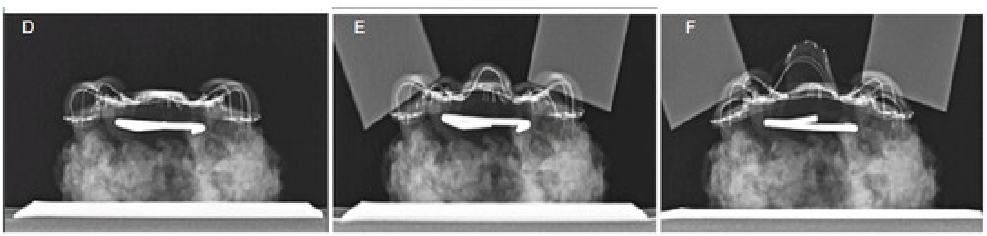


Figure 3.5: X-ray images of the TPAD: (D) before applying the force, (E) after applying the force in the anterior position, and (F) in the posterior position as reproduced as is from [16]

3.3 Biocompatible Materials

In this section, we will discuss various biocompatible materials that are currently being used or can possibly be used in the oral cavity for a prosthetic tongue. Previous iterations of the project used silicone Ecoflex 00-30, which was biocompatible with the body, but the density was too high at 1.07g/cc[17] and we wanted a less dense material so that the tongue would move with less resistance (require less energy to move) with a density of about 1.03g/cc. In addition, the 3D printed parts that were made of ABS or PLA are not biocompatible. Both of these problems caused our team to explore different materials for the retainer and the molding/casing of the tongue.

3.3.1 - Poly Implant Prostheses (PIP) Silicone Materials

In the area of silicone prosthesis, one strong contender for durability and variability is PIP (Poly implant Prosthesis), more specifically the silicone material. Taken from an article researching its application in mammary and other forms of implants [17], PDMS (Polydimethylsiloxane) is one of the most widely applicable polymers for non-medical and medical use, especially in breast implants shown below in Figure 3.6. Below, Figure 3.7 shows a comparison between a more viscous mammary implant versus a solid finger joint implant made of the same material. From them, we can see that PDMS is not just suited for less rigorous parts of the body, but also parts that experience more wear such as the joints.

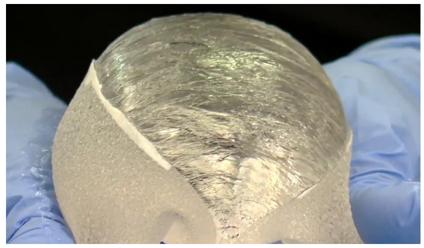


Figure 3.6: Silicone breast implant cut open as reproduced from [18]

Figure 3.7. PIP Mammary Implant (left) PIP Joint Implant (right) as reproduced from [18]

Silicone with PDMS has a consistency more specific to a mammary implant, which consists of a soft gel and casing. This could prove to be useful if components were inserted into a casing around the prosthetic tongue to protect the user and add texture to the tongue. Previous Iteration 3 of the tongue had problems with the bolus getting stuck to the silicone of the tongue which was noted in Vasquez et al. report. Having a tongue with less friction should result in a tongue that can process bolus quicker. PDMS on its own comes in a viscous liquid or gel form, however, when introduced to a process referred to as “cross-linking,” it gives it an opportunity to become a product with a wide range of flexibility, texture, and firmness. Cross-linking is when select nano particles of a filler, Silica (SiO_2), is added to the liquid PDMS gel to create a range of silicone rubbers.

This filler, when combined in different ratios, can increase the strength, and malleability of the rubber, as more silica creates more solid rubber and vice versa. The casing is made of the same material, cured as the lesser cross-linked gel is placed in it. This material is extremely versatile as the process of cross-linking can be accurately controlled. More specific to a mammary implant, which consists of a soft gel and casing, our team believes this could prove to be useful if components could be inserted and the prosthetic can act as tongue would in texture and function. variability is the PIP implant.

3.3.2 - Biomedical Grade Resin

Biomedical grade resin is considered any resin that passes the ISO biocompatibility tests for medical devices. Normally, a resin is considered biocompatible when it complies with the ISO 13485 - medical device regulations and ISO 10993 - Biological evaluation of medical devices[19]. We are specifically looking at biocompatible resins that are evaluated under the ISO 10993 guidelines for managing biomedical risk, pass the ISO 18562:Biocompatibility of Breathing gas Pathways devices and the ISO 7405: Dentistry- evaluation of biocompatibility of medical devices used in Dentistry[20, 21, 22]. These guidelines directly correlate to our project as the prosthetic tongue will be going into the oral cavity, which is similar to dentistry. Generally, biomedical resin comes in a variety of types based on the application of the resin; some are elastic, others are durable and others are made to be used in high temperature applications. All of these biocompatible resins are able to be used on and/or in the human body for long periods of time as they have to comply with the ISO standards that were listed previously. However, exactly how long some resins can stay in or on the body vary depending on manufacturing. Though if it complies with all of the ISO dentistry implant standards, it can stay in the body for an indefinite amount of time.

Most biocompatible resins need to be cleaned to prevent bacteria from growing on them, especially if the resin application is in the mouth, like a retainer. Recently, a study by Cheng et. al showed that antimicrobial resins composites can be used to decrease biofilm growth (bacteria), specifically resins that contain silver and the NAg compound[23]. The silver ions are hypothesized to deactivate the vital enzymes in bacteria, leading to cell death[23]. This was done through having Ag-doped bioactive glass mixed with a dental composite and then interacting with *Escherichia coli* and *Streptococcus mutans*[23]. Strong dental bonding agents can also be used in conjunction with or separate from the resins to help prevent bacteria from growing by getting rid of the gaps in between the resin and other dental parts[23]. Unfortunately, most of these additives are hard for a college team to acquire, but we may be able to incorporate dental bondings agents to test in our project.

3.4 Effects on the Human Body

To get a dynamic prosthetic tongue to work, there needs to be electronics placed in the oral cavity. These electronics must be small scale in order to fit inside the mouth as the cavity being used is only 51.47 ± 6.46 cm^3 in volume with a rough area of the floor of the mouth being around 74 mm x 54 mm x 20 mm [11]. This can be done by using microcontrollers, printed circuit boards and small coin batteries. Microcontrollers (MCUs) are used in the medical field in wireless heart rate monitors, cycle cadence monitors, blood pressure monitors and more[25]. This is because they can have high efficiency using low amounts of power. For example the microcontroller we used should be able to run off of a single 3V coin battery for about 16 hours. Printed circuit boards are boards that connect various points together, which can be seen through the lines and pads printed on the board[26]. They can be used to condense the wiring of circuits because the connections are inside the board. In the Vasquez et al. MQP[8], the group used a breadboard and a TinyDuino that together with its wires took up about 83.6mm x 54.6mm with some of the wires making the circuit larger, with the PCB the size was reduced to 74mm x 36mm. Testing on whether or not the materials widely used in PCBs are safe for repeated use has been done numerous times and the results have shown that no negative symptoms arise from it such as cancer or decrease in functionality[27]. Seen below in Figure 3.8, is the TinyDuino circuit used by Iteration 3.

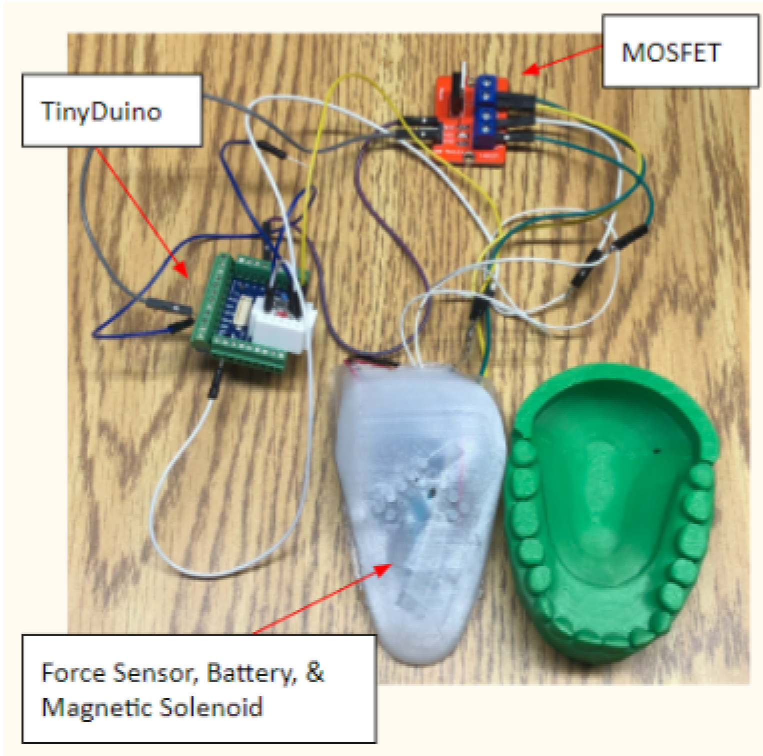


Figure 3.8: 2020- 2021 MQP full circuit as reproduced from [8]

In addition, magnets can be used inside the body. Open field aluminum-nickel-cobalt (alnico) magnets were the first kinds of magnets about to be used in the human body but they are susceptible to corrosion from saliva and have a weak retentive force[28]. Assuming the magnet is sintered (a process by which it is made) alnico magnets have a magnetic force of about 11-71 kJ/m^3 [29]. Since then, new magnets have been made from samarium and neodymium, which have a stronger force per unit size, especially in a closed-field system. Samarium is usually paired up with cobalt and neodymium is usually paired up with iron and boron. Assuming they are sintered, samarium magnets usually have a magnetic force of about 95–255 kJ/m^3 [30] and neodymium magnets have a force of about 207–406 kJ/m^3 [31]. In a closed-field system, the samarium and neodymium are four times stronger than the previous magnets. These are used in dental applications like overdenture implants, which are when implants are drilled into the mandibul and then a denture is connected by those implants[32]. This can be seen below in Figure 3.9.

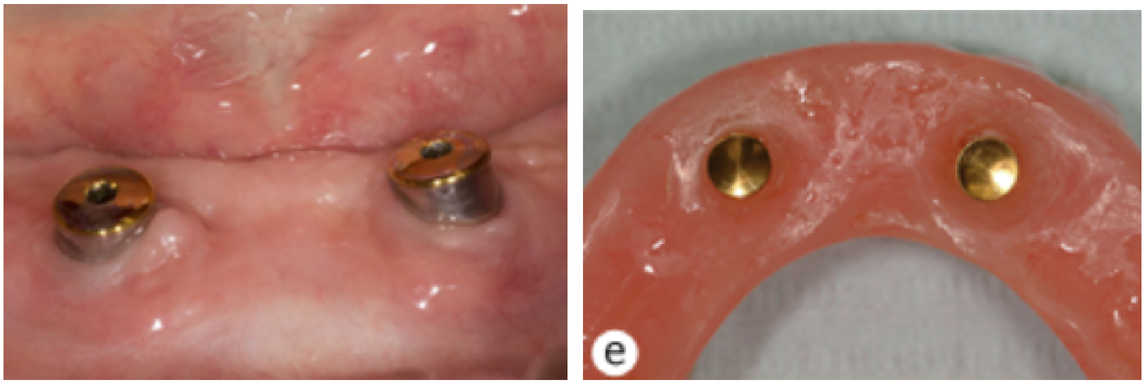


Figure 3.9. Overdenture implants, magnets drilled into the mandible (left) and magnets on the denture (right) as reproduced from [32]

3.5 Motor Actuation

Moving a prosthetic such as a tongue requires fine movement generated within a small space. Actuation could be achieved through air pumps or magnetic solenoids, but these forms of actuation have issues with downsizing, creating the proper motion required to move the bolus, and power issues. For actuation in other prosthetics with fine movement such as hands, micro motors are utilized to allow for fine controlled movement. In addition, micro motors do not have as high power draws when compared to solenoids, with micro motors running anywhere from 1.5V to 12V at around 50mA while solenoids generally want 12V at 500mA. Common batteries that are small enough to fit in oral cavities such as AA batteries at 1.5V and A23 batteries at 9V should be able to run the motors at their nominal values but struggle to run solenoids for long periods of time.

There are two main types of motors that we could choose to utilize, brushless and brushed DC (direct current) motors. In a general sense both types of motors work by generating a small electric field that will attract the other magnets inside the motor to give it force to turn creating motion [33]. The difference between them is that brushed DC motors rub their magnets together to form a mechanical state machine. This causes it to not need a communicator but also to create more excess heat and eventually these parts will wear down and need to be replaced/repaired. Brushless motors however do not have these brushes and thus require less upkeep, however they require electronic speed controller devices which used to be expensive. Brushless motors have other advantages to them however besides less upkeep, nowadays they are also more efficient, reduced electromagnetic interference, and a higher torque to weight ratio[33].

4. Project Goals and Methodology

In this chapter, we will go over our patient criteria, improvements planned, goals for this project and standards we must meet as well as testing criteria and protocols for actuation, bolus and force sensor testing.

4.1 Initial Client Statement and Criteria

After having a glossectomy, patients have difficulty eating and swallowing especially without a tongue prosthesis. The existing tongue prosthetics are limited in their functionality and cannot be easily controlled by the patient, thus a prosthetic tongue that can move bolus from the front of the mouth to the back of the mouth to aid in deglutition is needed.

According to our assumptions for the basis of our prosthetic tongue design, the patient must have had a full glossectomy with some lower jaw teeth still intact and with most of their swallowing capability left.

4.2 Improvements Planned From Past Work

Based on our background research and testing from A term, we plan on implementing a printed circuit board, using biocompatible resin and biocompatible silicone.

Specifically, Vasquez et al.[8] suggested making the control circuit smaller using a PCB as there were still many wires that could cause the unit to shock the patient. They also suggested we use biomedical grade silicone and resin for the tongue prosthesis and retainer.

4.3 Goals for this Project

The main goal of our project is to create an artificial prosthetic tongue that can automatically move bolus from the tip of the tongue to the back. In addition, the tongue must be biocompatible with the human body as well as fit inside the oral cavity. Since we are integrating biocompatible silicone and a PCB, we need to redesign the tongue to fit those components better and stay inside the oral cavity. To theoretically validate our electromagnetic designs, we will simulate the various possible magnet and solenoid combinations to see which will produce the largest actuation.

The goals of our project are as followed:

1. Design: Develop an improved mechanism and actuation method to allow for easier flow of the bolus from the tip to the back of the tongue
2. Size: Develop an accurate oral cavity system to enable demonstration of the actuation system of the tongue prosthetic. Develop the tongue to look even more anatomically correct and fit into the simulated oral cavity
3. Controls: Continue miniaturizing actuators and control systems to fit within the confines of the tongue and oral cavity
4. Validation: Create and carry out testing protocols to check tongue function.

4.4 Standards

The production and use of prosthetics is regulated by various organizations like the International Standards Organization (ISO) as well as regional standards like the United States Food and Drug Administration (FDA) and European Union Medical Device Regulations (EU MDR). We used these standards to guide us in choosing biocompatible silicone and resin to use in the prosthetic tongue.

Specifically, we referenced ISO 14949:2001 and ISO 22794:2007[34, 35]. ISO 14949:2001 is for implants for surgery using two-part addition-cure silicone elastomers, which is the kind of silicone we will be using as it mirrors the formation of breast implants[34]. ISO 22794:2007 applies to implantable materials used in dental devices for filling and augmenting bones in oral and maxillofacial surgery[35]. In addition to those two, we also referred to ISO 14801 and ISO 19429:2015, which deal with dental implants, the designation system of the implant and the load testing required before implantation[20].

For electronics,there are a couple standards that would need to be followed for the tongue to be considered medically safe. The first is ISO 60601-1-11:2015 which states the standards for electrical medical equipment[36]. Another standard that would apply is the IEC 61000 which considered the standards from implantable electronic devices[37]. Some of the tests the devices are required to pass are magnetic immunity, RF radiated immunity and conducted emissions.

4.5 Completed Iteration 3 circuit

The control circuit from Vasquez et al.[8] contained a solenoid, microcontroller, MOSFET, mini breadboard, some resistors, a battery and Arduino code to run the circuit. We originally used last year's Arduino Uno to ensure that we understood the layout and function of the circuit and then implemented the TinyDuino which has all the capabilities and runs on the same code as the Arduino Uno, but is made up of stackable 20mm by 20mm TinyDuino[9] shields. The circuit shown in Figure 4.1.

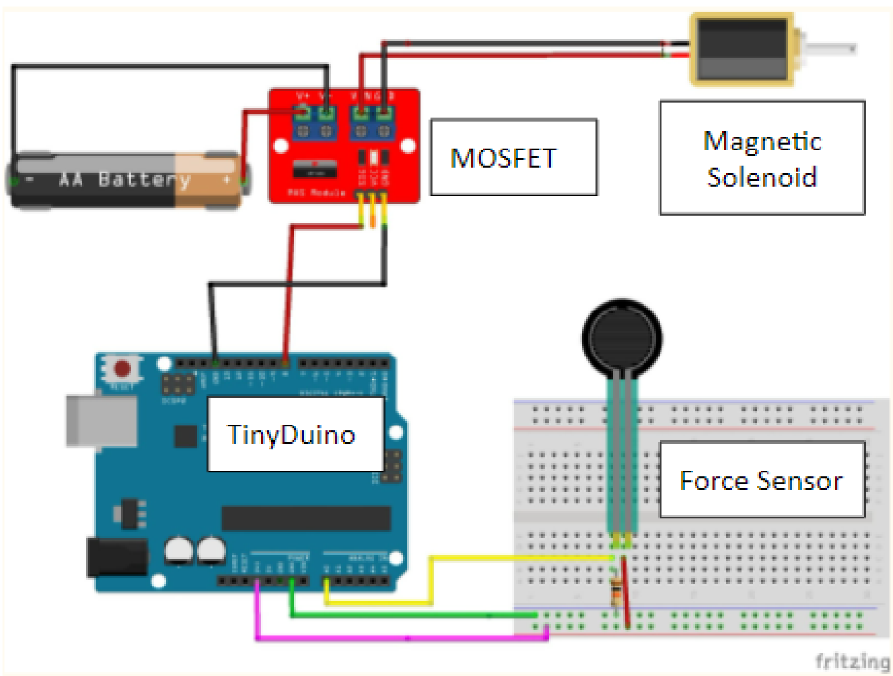


Figure 4.1: Vasquez et al. Circuit Diagram as reproduced from as reproduced from [8]

Some difficulties we faced when trying to integrate the circuit included issues initially getting the solenoid to work. We realized that the solenoid was a push pull solenoid and pulses on for 2 sec and off for 200 ms. Our solenoid works for 200-300 ms using 100 ms on and 900 ms off. Once we got the solenoid operating correctly, we had to try and fix our circuit so that our solenoid did not overheat. We attempted to correct this issue using a light emitting diode (LED).

After ordering a new solenoid and getting it working, we connected the battery, MOSFET, TinyDuino, and force sensor. We then used the code from the 2020-2021 MQP group to get our force sensor up and working.

4.6 Solenoid and Actuation testing

To test the solenoids' magnetic actuation, the circuit shown above in figure 4.1, was set up and forced to constantly run the solenoid when powered. To start, the solenoid was placed to the right of the box shape shown in Figure 4.2, and then one of the N52 (neodymium) magnets was placed about 10 cm away from the solenoid, out of the electromagnetic field range. Then using a pencil, the magnet was slowly pushed towards the unpowered solenoid until it pulled itself to the solenoid. A line was drawn at the distance where the magnet was initially pulled to the solenoid. These lines were then measured to the solenoid which is shown in Figure 4.2. Each line represents where a magnet was pulled to the solenoid from. This was repeated 3 times with both solenoids. Then the solenoids were turned on and the testing was repeated another 3 times for each solenoid. These distances for each line can be seen below in Table 2 and refer to the lines in Figure 4.2. The solenoids used were as follows: Black solenoid of 12V DC, silver solenoid of 12V DC, and a red solenoid of 9V. After each test, the solenoid was allowed to cool off so that it would not affect the testing. Each solenoid has different preferences for duty cycles while functioning, but they all require 12 volts to power according to their datasheets for best operation.

Table 2: Solenoid Distance testing distances

Number	**Distance (cm)**	**Number**	**Distance (cm)**
1	6.3	5	5.7
2	5.1	6	5.3
3	3.3	7	2
4	4.2	8	1.8

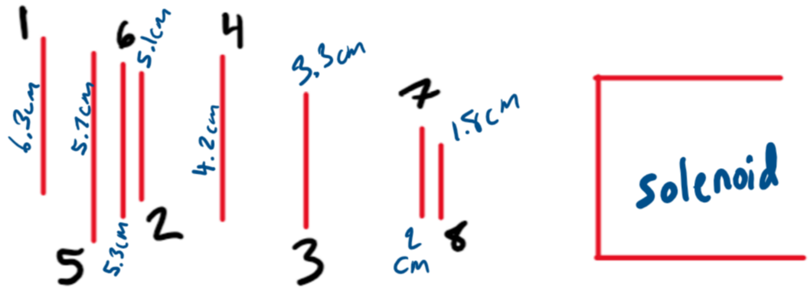


Figure 4.2: Solenoid distance testing results where each line represents where a magnet was initially pulled to the solenoid

Figure 4.3: Three solenoids tested: Black solenoid (left), silver solenoid (center), and the red solenoid (right)

From this testing, we were able to see that the black solenoid could pull the magnet from about 3 cm away while unpowered and while powered, it could pull from about 6 cm away. The silver solenoid pulled from about 2 cm unpowered as well but could only pull from about 4 cm away. Finally, the red solenoid was the least powerful of the three, pulling the magnet from about 1 cm away when unpowered and barely able to pull from further away when powered on. Figure 4.3 shows all the different solenoids that were tested.

An important note to keep in mind when dealing with the solenoids, is that they can operate at temperatures up to around 90^{o} celsius according to their datasheet and they tend to heat up rather quickly within seconds while operating with their preferred scenarios. When the solenoids begin to heat up more, although they will still function, they could inhibit other parts of the circuit's functionality.

4.7 Force Sensor/Bolus Testing

After completing the solenoid circuit, the team moved to the re-creation and integration of the force sensor circuit. Once we had the force sensor connected to the TinyDuino and the rest of the circuit, we recorded reading from the force sensor at rest from both sides, from inside the tongue with and without items placed on top, as well as with and without the TinyDuino also inside of the tongue.

The initial force sensor data and readings we collected are seen in Table 3 below. This table initially takes readings of the force sensor at rest (default alone) without any force being applied to it. The next two measurements are of the force sensor when it is bent with strips inward (toward stripes) and outward (away from strips) which can be seen in Figure 4.4. The next reading (in tongue default) is when the force sensor is stripes face down inside of the tongue (Iteration 3) without any force being applied.

Table 3: Initial Force Sensor Data

Condition:	**Measurement:**
Default alone	50240 Fsr Ω
Toward stripes	24265 Fsr Ω
Away from stripes	119533 Fsr Ω
In tongue default	57750 Fsr Ω
Bolt on tongue	57385 Fsr Ω
Resting when in tongue with TinyDuino	54558 Fsr Ω
Bolt on tongue with TinyDuino	53938 Fsr Ω
Flipped over (stipes down) at resting in Tongue with TinyDuino	46882 Fsr Ω
Add bolt (stripes down) in Tongue with TinyDuino	47208 Fsr Ω
Added 3 large washers and bolt on Tongue with TinyDuino	48139 Fsr Ω

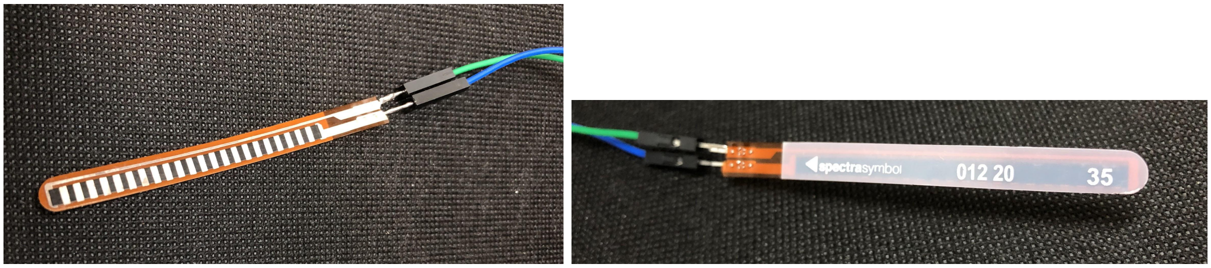


Figure 4.4: Stripes up (left) and stripes down (right) of the force sensor

In addition to testing if the force sensor works in the control circuit, we tested how the force sensor reacts to different boluses, which can be seen in the lower half of Table 3 and in Table 4 and figure 4.5. Seen in Table 3, a bolt weighing 4.53g was placed on the tip of the tongue to see if the force sensor would register the weight. A bolt was used because it was what was on hand and we estimated it weighed about 5g. The next reading was of the force sensor at rest inside the prosthetic tongue with the TinyDuino inside the tongue as well. This reading was taken because the TinyDuino rested internally on the force sensor, causing a change in the readings. The bolt was then added to see if the force sensor would still register the weight of the bolt. These last three tests were then repeated with the force sensor placement reversed (stripes down) to see how the sensor readings changed.

We then tested using 3 washers that had a total weight of 5.42g, and took recordings of the resistance and voltage readings of the force sensor, seen below in Table 4. These three washers were used in place of bolus as it did not matter since the readings were just to indicate if the sensor could register the weight, not trigger the movement of the tongue. With the three washers, we decided to stack them and place them in three different locations: the tip, middle and back of tongue seen below in Figure 4.5. This was to determine the differences in readings the force sensor got depending on the location of the bolus. These results indicate that the sensor can register the weight of bolus through the 3mm of silicone, which means it should activate the solenoid to turn on when bolus is placed on the tip of the tongue. However, bolus will not be registered by the force sensor when it is placed on the back of the tongue as the resistance reading goes down and the code would only turn on the solenoid when the resistance increases past the threshold. A new piece of code would need to be added to add a lower threshold to trigger the solenoid, but people do not put food that far back on their tongue initially so the idea was discarded. Nevertheless, new code should be added to calibrate the force sensor between each actuation as the force sensor does not reliably go back to its initial resistance after a force has been applied and released.

Table 4: Second round of bolus testing readings

	Stripes face down (orientation of force sensor)	
Object on tongue	**Resistance (Ω)**	**Voltage (mV)**
None	23670	1485
3 washers tip of tongue	23783	1480
3 washers middle of tongue	23825	1476
3 washers back of tongue	23557	1490
None	23783	1480

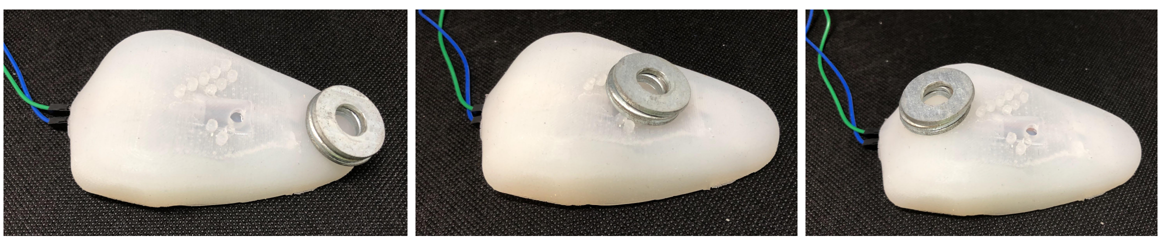


Figure 4.5: 3 washers on the tip of tongue (left), middle of tongue (middle) and back of tongue (right)

4.8 Silicone testing

Before applying new materials in addition to electrical testing, tensile strength, elongation, and volume/shrinkage were tested on both new and previous materials. Materials used by the 2020-2021 MQP were Smooth-On EcoFlex 00-30[17] and the new materials tested were Smooth-On EcoFlex 00-10[38] and a mixture of both Silica and PDMS Oil.

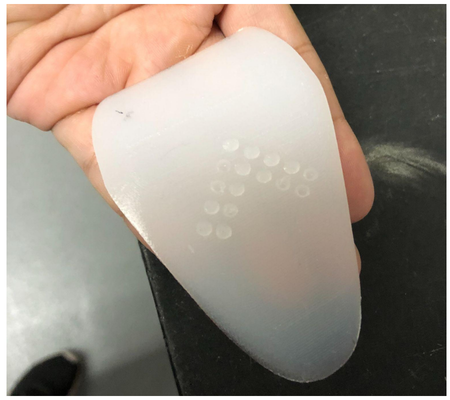


Figure 4.6: Molding and Result of Smooth-On EcoFlex 00-30[17]

The molds used for all of these tests are the same, taken from Vasquez et al.[8] which can be seen above in Figure 4.6. Using these molds along with the following testing protocol ensures that testing is thorough. Firstly, Smooth-On EcoFlex 00-30 reported a tensile strength of 200 psi and a 100% modulus of 10 psi. A 100% modulus is the tensile force at 100% elongation. It also reports 900% elongation before failure as shown on their website[17]. After it cured, seen below in Figure 4.7, some of its qualitative properties included a smooth finish, but a lot of friction when touched.

Figure 4.7: Molding and Result of Smooth-On EcoFlex 00-10[38]

This silicone comes with a lower grade on the Shore A Hardness scale of a 10 (like a rubber band) compared to the 00-30 silicone which has a Shore A Hardness of 30 (like a pencil eraser). We decided that a more flexible silicone, meaning one lower on the Shore A Hardness scale, would better imitate the malleability of a human tongue. The SmoothOn EcoFlex website for the 00-10 silicone reported a tensile strength of 120 psi and 100% modulus of 8 psi. It also reported 800% elongation before failure. Although these values are lower than the specs of the 00-30 silicone, we do not believe we will use over 22.5psi (amount of pressure from air pumps in

Iteration 2) since we determined the pneumatic system would not work best for actuation of the tongue. Other qualitative property differences between the 00-10 and 00-30 silicone include a more tacky and sticky finish and cleaner finish once cured.

Table 5: Volume Table for Fume Silica and PDMS Oil Testing

Silica Content by Volume	Tongue Mold Volume	Silica Volume (mL)	PDMS Volume (mL)	Marker
24%	34.92 mL	8.38	26.54	Pink
26%	34.92 mL	9.08	25.84	Red
28%	34.92 mL	9.78	25.14	Blue
30%	34.92 mL	10.48	24.44	Orange
32%	34.92 mL	11.17	23.75	Purple
34%	34.92 mL	11.87	23.05	Green
36%	34.92 mL	12.57	22.35	Black

Seen above in Table 5 are the tested percentages of Silica to PDMS from 24% to 36% by volume. This testing needed to be done as it was unknown if the percentages of each component (Silica and PDMS) was by volume or by weight. To run these tests, it was assumed that the percentages were by volume not weight. If the silicone failed to cure in the 8 hour time frame that it was supposed to cure in, then the percentages were wrong and needed to be done by weight. Each tongue percentage had a colored piece of tape (a marker) next to it so we would remember which mold was for what percentage.

Our testing protocol for this testing went as follows. First, we organized a space with all materials ready at hand and followed all safety protocols for the potentially hazardous materials (PDMS and Fume Silica). We cleaned all molds (Figure 4.7) and measuring materials with Isopropyl alcohol and wipes before beginning our tests. In this experiment, we measured out both ingredients in separate beakers and slowly scooped the silica powder into the PDMS oil in small increments whilst stirring in between. We then tapped out the larger bubbles, used cotton swabs and alcohol to clean around any edges, and set the mold aside to cure. The results proved that the curing process of PIP silicone requires percentages by weight as the mold did not cure because there was not enough silica to reach the desired total volume. This will aid us in future materials testing and we will then be able to get its proper volume, 100% modulus, max tensile strength, and max elongation.

5. Prosthesis Design

This chapter will discuss the faults in previous iterations' actuation systems that led to our design iterations and final prototype. Additionally, improvements on a pneumatic system using a breast pump were analyzed, but a linkage system was eventually chosen for actuation in the final prototype. In order to decide which linkage design to prototype, a decision matrix was used. From there, an accurate jaw model was made with the rest of the components, which were made to fit perfectly inside the jaws.

5.1 Feasibility Study

Our prosthetic tongue design concepts began with retesting the previous iterations' actuation systems as well as manual actuation testing . This provided a basis for the testing of the final actuation design. Since Bridges et al. and Vasquez et al. performed silicone and bacteria testing, this team focused on the other component interactions.

5.1.1 Actuation Testing

Initial actuation testing was done manually using a person's hand. As seen in Figure 5.1 below, the second iteration silicone tongue (by Vasquez et al.[8]) would sit flat on a person's hand. Then, upon curling the fingers,the tip of the tongue can be moved. This will ensure the movement of the bolus. This mimicked the realistic movement of the tongue to get food from the front of the mouth to the back. It was found that the tongue curled the best when it rested on the fingertips, so it was assumed the actuation system worked best when the tip of tongue curled first. Seen in Figure 5.1 is the set up used for manual bolus testing of the second iteration. In addition, actuation testing was done with each iteration tongue resting at a 19.76^{o} to see if it could lessen the actuation height needed to move the bolus. In Figure 5.2, the 19.76^{o} the tongue rested at can be seen. This angle resulted in a 0.061cm reduction of actuation height at the tip of the tongue that would be needed for the bolus to fall back.

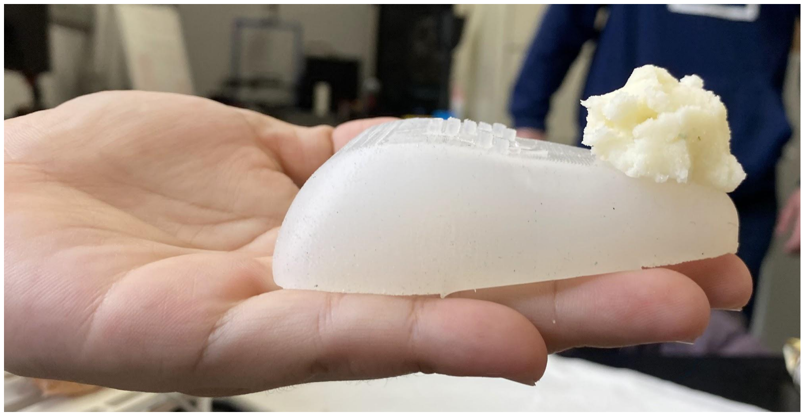


Figure 5.1: Bolus on second iteration tongue

Figure 5.2: 19.76° of how the tongue was anchored at this angle

The next rounds of actuation testing was performed to validate the results that were described in Sections 2.2 and 2.3. This meant the second and third previous iterations' circuits, molds and system set-ups were rebuilt nearly completely.

The pneumatic system was first moved manually by air pumping with a 15 ml syringe as shown in Figure 5.3 and then tested with a 12V air pump. The manual testing went poorly as the tongue would keep moving and not stay in the frame of the videos needed to track the actuation height. During this process, it was determined that each of the three chambers could inflate. Then, a 12V air pump was added into the first iteration of the pneumatic circuit. In order to determine what the maximum actuation was, only one air pump and section needed to be inflated at a time. The original Bridge et al.[7] team used three air pumps however, the same actuation results were gathered whether one or three pumps were used. A displacement software called Tracker[6] was used to determine how high each tongue moved by taking a video with a reference measure and placing it in the software. A point on the tongue, denoted by a black bead or plastic piece seen in Figure 5.4, was then put in the Tracker[6] software and its displacement was measured. The testing videos can be seen in **Appendix A**. There were three holes at the back of the tongue, one hole for each air chamber, that were each inflated 3 times and recorded for the Tracker software. The results showed the second iteration pneumatic tongue moved the most in the central chamber at an average of 0.78 cm from the original resting position.

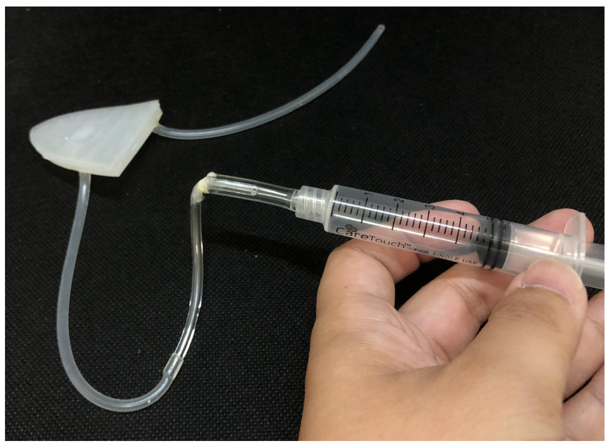


Figure 5.3: Manual Air Pumping of Iteration 2 prototype

Figure 5.4: Snapshot from video of first iteration, middle chamber, trial 2 that was used in the Tracker software

Bridges et al. had recorded problems such as air leaks between chambers due to an insufficient amount of sealing between silicone layers. This was evident in our trials while inflating the front air chamber. Due to this issue, the actuation led to the tongue barely moving. Air could also be felt blowing out from the front of the tongue.

The next round of testing involved the iteration by Vasquez et al.[8]. In this iteration, we used two neodymium magnets and a magnet and solenoid. The testing with two magnets was done with one magnet inside the tip of the silicone tongue and the other magnet being held by a person. Videos were taken to determine the amount of actuation caused by the magnet's attraction in the front, right and left side of the tongue, with three trials of each side while the tongue was inside a lower jaw model as seen in Figures 5.5 and 5.6. The magnet actuated the tongue's tip to move through a height of 1.26cm, which is higher than the pneumatic system by 0.48cm. Testing with the solenoid and magnet only used the magnet in the tip of the tongue and not the sides. It resulted in an average of 1.26cm actuation.

Figure 5.5: Tongue actuating by magnets with one magnet in tip of tongue (not visible outside) and the other being held by finger on the left side of the image

Figure 5.6: Manual magnetic testing with second iteration tongue with magnet in the tip of tongue with second magnet being held by a person

One of the setbacks this team had with the solenoid circuit was that it was inconsistent, and would stop working during testing. The solenoid would heat up at times to around 320℉, which would be unsafe to use in the oral cavity. Even when testing was done with safety gloves, our team would need to stop testing for the solenoid to cool down so it would not fry the circuit.

5.1.2 Bolus testing

Bolus testing was performed next to see if the previous iterations could move 5g of bolus from the tip of the tongue to the back of the tongue through their actuation methods. Both previous teams recorded they were unable to successfully move the bolus from the front to back of the tongue. These testings were to validate their results. All bolus testing for this section was done with a bolus ratio of 1 Tbsp. of instant mashed potato to 1.5 Tbsp. of hot water and a 5g spoonful of bolus placed on the tip of the tongue. Instant mashed potatoes are a good representation of bolus because it has a very similar consistency to chewed food or partially masticated food.

Using the Bridges et al. final tongue design, pneumatic testing with bolus was done using the air pump system and manually with 15 mL syringes. This was done to see if we could get 5g of bolus to move using pneumatic actuation. Each air chamber had a syringe attached to it and to actuate the tongue, all three syringes were pushed in at the same time. There were 5 trials in total; each trial started by placing 5g of bolus on the tip of the tongue and then actuating it. The outcome of which way the bolus landed was recorded in each trial. This manual testing was a little difficult as the tubes had a tendency to fall out when air was pushed into the tongue. When the tubes stayed in, the bolus would either stay in the same place or fall off the side or front of the tongue; rarely would it fall to the back of the tongue. The bolus would not move when the tongue moved too little, as seen below in Figure 5.7. When the tongue moved enough, the inflated tongue created a bulbous shape as seen in Figure 5.8, which did not give the bolus any direction to go specifically, resulting in the bolus going whichever side of the bubble it was on.

Figure 5.7. Iteration 2 tongue actuating too little

Figure 5.8. Example of bulbous actuation of pneumatic system from Iteration 2 bolus testing

For the third iteration tongue, manual and solenoid testing were done. With the manual testing laying flat in a person's hand, the bolus would often get stuck in the middle because of the small pocket that would form from the bent silicone seen below in Figure 5.9. However, when the tongue was laying at a 19.76° angle (as seen in Figure 5.10), the bolus would always fall backwards. Solenoid and magnet testing with bolus was less successful. When the tongue did not actuate enough (which is less than 1cm), the bolus would not move. When the tongue did actuate enough (at least 1cm, but usually more), the bolus would get stuck in the middle of the tongue, the same problem as with the flat manual testing.

Figure 5.9: Small pocket formed in middle of tongue during manual testing

Figure 5.10: Manual bolus testing at a 19.76° angle of the second iteration tongue

5.2 Improvements on Pneumatic System

The purpose of recreating the Bridges et al. system from Section 2.2 was to understand the circuit and components used. In the 2020 model, the main component of the circuit was air pumps. The previous project team used air pumps to actuate the tongue. Throughout the year, Bridges et. al. came up with multiple designs. Each of the redesigns went through a design process: initially the design was created, 3D molds were printed and made with silicone and then once those parts were put together, tested the pressure in the different channels. One of the designs consisted of three air chambers inside the tongue which were made of PVA, which allowed for the PVA to dissolve after a couple of days once the sillione was poured over the mold. As we analyzed the Bridges et. al.[7] design, our team realized that this model did not successfully complete the task of moving bolus from the tip of the tongue to the back of the mouth. The air pump system did not actuate the tongue enough to move the bolus at all. The problem was that there was significant air leakage as well as no control (bolus could fall sideways or off the front during tongue actuation) in bolus movement resulting in the bolus to roll off the tongue in different directions.

In order to improve upon this model, our team did research on air pump systems, kinematic systems, and any possible methods of how to control air leakage. We bought different silicone grades, seen in chapter 3.31 and 4.8, and even brought silicone sealant to help with air leakage, but we still ran the risk of puncture of air leakage. To minimize air leakage in molds, we printed new molds and used different grade silicones to identify the most appropriate grade for our objective. Silicone has different shore hardness. Because we wanted our tongues to be on the softer side but still be rather solid, we bought A-221-01 silicone, which compares to the texture of rubber bands. This silicone worked better than the previous silicone used in the 2019 and 2020 models.

Another idea we had was creating a bimetallic strip within the tongue[39]. A bimetallic strip is used to convert a temperature change into mechanical displacement. Usually the strip consists of two different types of metal which expand at different rates when they are heated. The different expansion rates cause the flat strip to bend when heated and then rest when cooled. An example of a bimetallic strip is shown below in Figure 5.11.

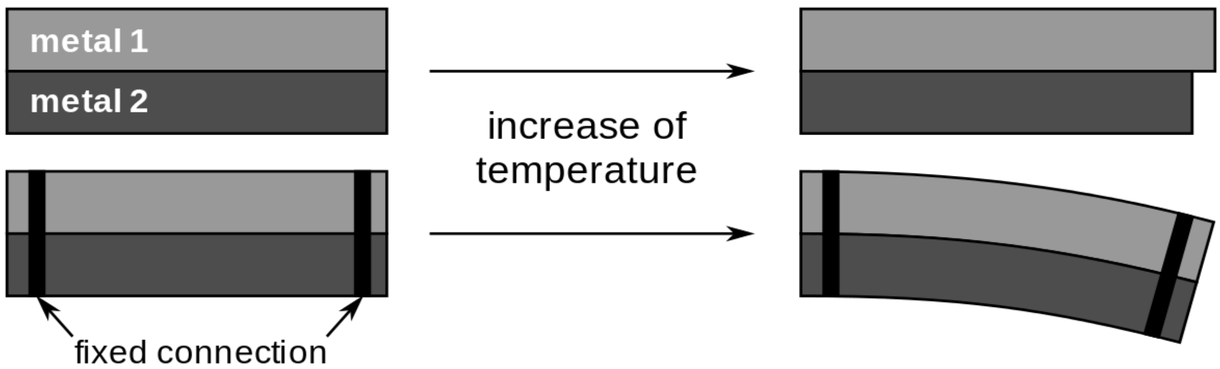


Figure 5.11. Example of bimetallic strip

We were trying to determine if this was a design we could implement into a tongue. We did some more research on silicone temperature and if this would be safe to put in someone's mouth. Silicone is really popular because of its tolerance for extremes of temperature. Most silicone can handle temperatures between -60°C up to +230°C. This is because silicone has a low thermal conductivity. This means that it transfers heat at a much slower rate than other materials. The one downside is that the amount of time silicone spends exposed to these extreme temperatures can determine how well it performs during application. Therefore, we scratched the idea thinking it would not be safe to put in someone's mouth and would be very difficult to fit inside the oral cavity.

Another idea we had was changing the size and shape of the tongue. This was to help with tongue movement and hopefully move bolus from the tip of the tongue to the back of the mouth. We found another project made by Kavindu Sandaruwan that worked by making a soft robotic finger moved by air to curl. We thought this was a very practical idea, considering the tongue and finger have similar movements, and the finger model was similar in size to a tongue. We 3D printed and made a mold of the finger and tested by pumping air into the system. Again, the issue with a model like this is air leakage and risk of puncture. It was difficult to make a mold without ripping it, and silicone sealant/adhesive would not perfectly seal the tongue. A model of the soft robotic finger is shown below in Figure 5.12.

Figure 5.12.CAD model (left), 3D printed model (middle), 3D printed model in silicone (right) of the Model of soft robotic finger as reproduced from [40]

Next, our team researched different types of air pump systems, and specifically breast pumps. We chose to analyze breast pumps because they are a small portable pumping system that is relatively easy to acquire. There are three basic types of breast pumps: manual, battery-powered, and electric pumps. Manual pumps are placed on the body and a handle is squeezed to create suction. Some manual pumps have a small tube, which is pumped in and out of a larger tube to create a vacuum. Specifically, bicycle horn pumps consist of hollow rubber balls which are attached to the breast-shield to help create a vacuum. The other types of breast pumps, battery-powered and electric, use batteries or a cord plugged into an outlet to power a small motorized pump that creates suction. Usually they have one or more long tubes connecting the breast-shield to the eclectic pump and the pump has a control panel with a switch to control the degrees of suction. To test to see if breast pumps would work as a way to actuate the tongue, we ordered two different electric breast pumps to test with; the Lansinoh Smartpump 2.0 double electric breast pump[41] and the Bellababy Double Electric Breast Pumps[42]. The Lansinoh pump has a vacuum power of 33.33 kPa (250 mmHg) and the Bellababy pump has a maximum vacuum power of 39.99 kPa (300 mmHg). We tested on different types of models to determine what worked best and if this idea was worth progressing with. Our team tested with Arraya's tongue and a couple iterations of Bridges et. al. models which can be seen in Figures 5.13 and 5.14. We used small plastic tubes to connect the breast pump to the tongues. While the breast pump did actuate the tongues a bit, it was not nearly enough to move bolus. Videos of the breast pump trials can be seen in **Appendix B.** Our hypothesis was that there was not enough medium or air inside the sealed tongue to actuate it enough. Therefore, using breast pumps as a control module was not successful in moving bolus so the team moved onto a new actuation system using linkages. Two photos of the breast pumps used in the tests are shown below in Figure 5.15.

Figure 5.13: Breast Pump connected to tongue mold

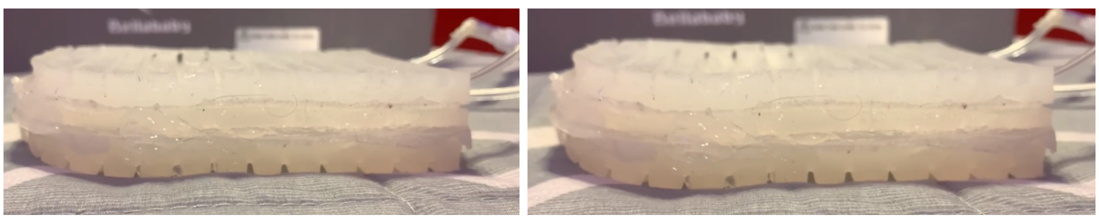


Figure 5.14: Araya's tongue natural (left) vs. actuated (right)

Figure 5.15. Lansinoh (left)[41] and Bellababy (right)[42] breast pumps used in tests

Unfortunately the improvement to the pneumatic system with the breast pump did not hold much promise. However, the robotic finger curling system seemed promising as the curling motion of the finger mirrored that of the tongue and could move in the vertical direction.

5.3 CAD Modeling

The project required many parts to be designed, innovated, and printed. All parts were created in Solidworks and Blender and then printed through a ELEGOO Mars 2 Pro resin printer[43]. Since a linkage system was determined to be the most promising actuation system, several iterations of two different designs were made in addition to all the other parts.

5.3.1 Tongue

The first part made was the tongue mold because it was the most important component. Dimensions for the second iteration were based on the average size of a human tongue and oral cavity found from background research, which led to the maximum dimensions of the first tongue iteration to be 8cm long, 5.5cm wide and 2cm tall, seen in Figure 5.16. The front slope of the tongue was made less steep than the third iteration by Vasquez et al. which was originally 16.3^{o} and this years' is 11.25^{o}, compared below in Figure 5.17 . This change was made due to the bolus getting stuck in the middle of the tongue during manual bolus testing in chapter 4.7. The lower slope would also make it sit flatter inside of the jaw, therefore easier for the bolus to move to the back of the mouth. Seen below in Figure 5.18 is the final iteration of the tongue which was 6 cm in total length, 5cm wide and 2cm tall. The length of the tongue was changed so it would not interfere with the gear system (for more information on gear system look at chapter 5.3.5).

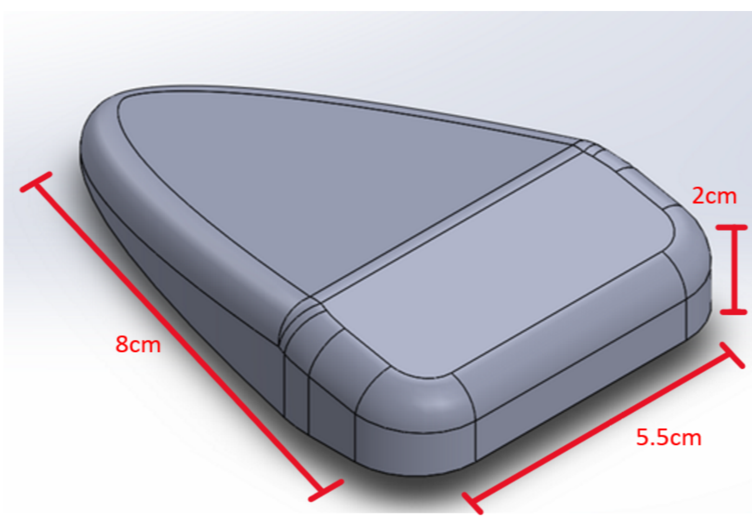


Figure 5.16: Iteration 1 of this projects tongue

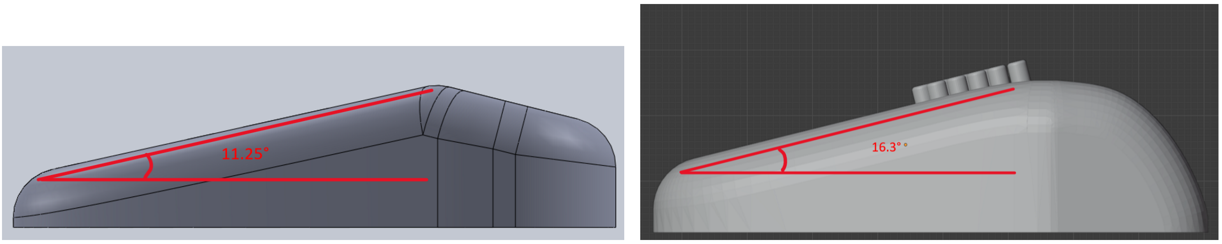


Figure 5.17: Slope of our tongue (left) compared to Vasquez et al. tongue (right)

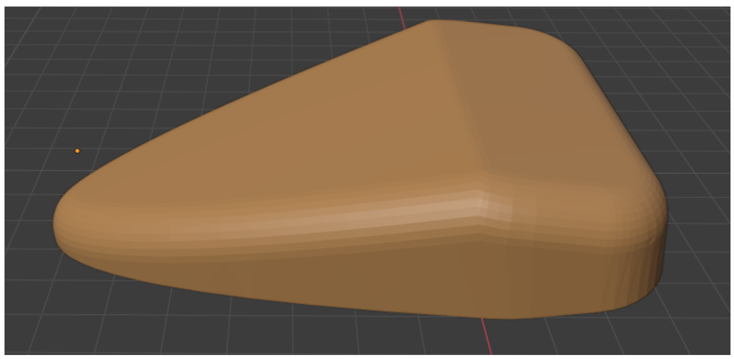


Figure 5.18. Final tongue design

5.3.2 Jaw Model

Next, the focus was on rebuilding a jaw system consisting of an upper and lower jaw as it would be needed no matter what actuation system was chosen. The lower jaw was responsible for holding the tongue, retainer and gear system so it was a high priority to get done. The jaws from the Bridges et al.[7] team had the backends cut out and links were added to the back end of each jaw to allow for a connection that would open and close the jaws like an actual human skull. Additionally, there were rectangular extrusions added to the lower jaw to hold in the servo motor (seen in Figure 5.19) and holes were cut into the bottom to allow screws to adhere it to the testing base, which will be further explained in later sections. The final design for the jaw system can be seen below in Figure 5.20. There was some difficulty within the Blender with the meshes overlapping that could cause 3D resin prints to fail. Several prints of the upper and lower jaws were made as dimensions needed to be refined and some prints failed due to improper supports, printer and LCD malfunction, and slicing software difficulties.

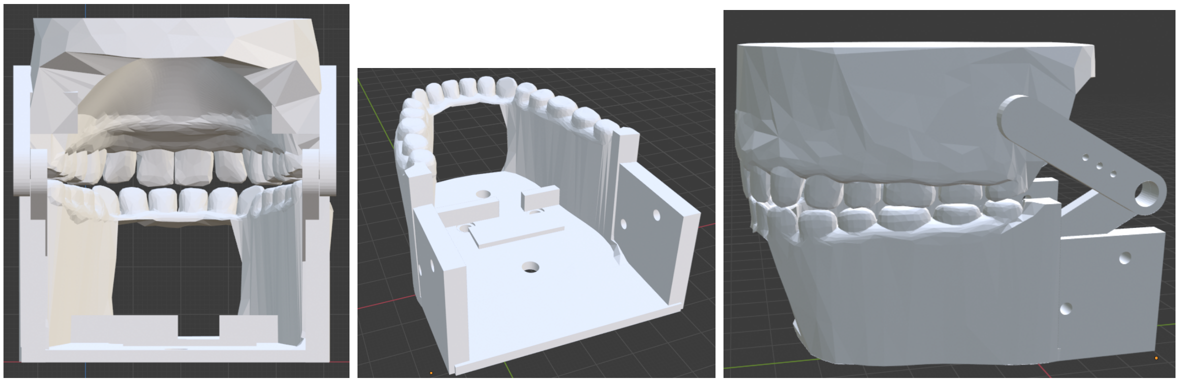


Figure 5.19: Open Backside (left), rectangular extrusions (middle), and side view of links (right) of Final Jaw Design

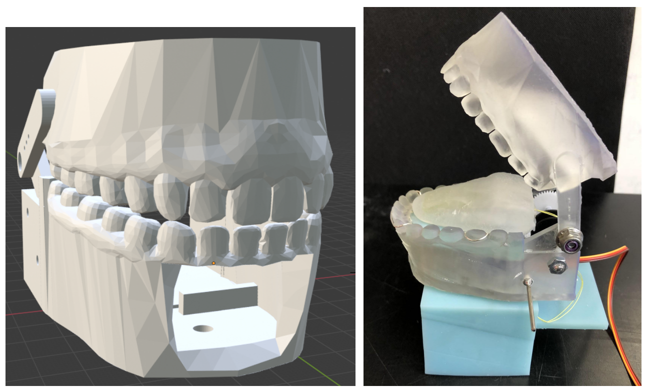


Figure 5.20. Front view (left) and open jaws (right) of Final jaw system design

5.3.3 Mandibular Hawley Retainer

Once the jaw system was complete, the mandibular Hawley retainer was designed. From initial manual actuation testing, about a 16° angle worked best for moving bolus, but research stated the human tongue set at more of an 8° angle. Therefore, the first couple iterations of the retainer were made to sit at an 8° angle and printed at 0.6cm thick with two holes going through the part (one 1.5cm from the front and 1 cm from the backend).This is shown in Figure 5.22. These holes were used to hold the wires that hold the retainer in place. The front hole holds a write that goes around the front teeth, before the canines, and the second hole holds two wires, one for the left and right side of the mouth. These two wires go around the left and right side of the second molars. The final retainer had a 1.4cm by 3cm indent in the top of it to hold the neodymium magnet that is used to hold in the linkage system and prosthetic tongue which can be seen below Figure 5.20. The retainer ended up resting in the mouth at a 5° angle so it would not inhibit the servo motor sitting underneath.

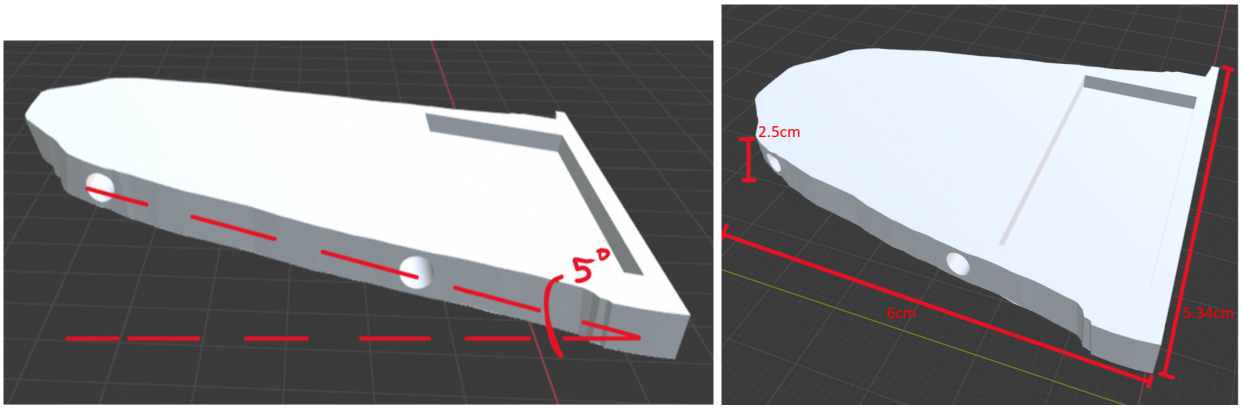


Figure 5.21. 5° angle the retainer rests at (left), indent that holds the magnet (right) of the Final mandibular Hawley retainer design

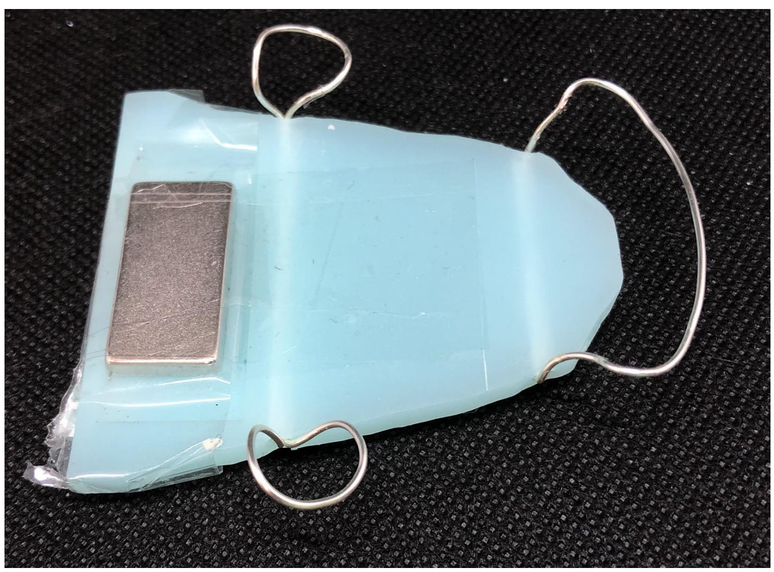


Figure 5.22: Picture of complete retainer

5.3.4 Linkage System

After designing a retainer to hold the tongue in place, there needed to be means of actuation. Several actuation design ideas were improvements to the first and second iteration actuation systems (pneumatics and electromagnetic), however after observing how each system actually moved, it was decided to go with a new actuation system using linkages. The team came up with 5 different designs and then compared each one using a design matrix to determine which two designs to prototype seen in Figure 5.21. Design 1 consisted of a servo motor that would pull a string to actuate the linkage system upward inside the tongue. Design 2 also had a servo motor but the tongue would rest in the up (actuated position) and the then linkage system would pull it down to allow food to be placed in the mouth (opposite concept of Design 1). Design 3 contained a solenoid that would be placed in the roof of the mouth via retainer while the tip of the tongue had a magnet. The solenoid would turn on and attract the magnet to actuate the tongue. Design 4 is a linkage connected by silicone joints (the circles), that would work similar to a door hinge, and a string actuates the linkage when pulled. Design 5 is the design closest to the current iteration as it utilizes joints connecting each of the linkage pieces. The ends of the linkages have their corners cut off so that they are all cut at the same angle which is 30^{o}. Then when the string is pulled that is routed through the linkage system, the system would be able to make a curling motion. Design 6 contains a linkage system on the underside of the tongue with the servo motor inside the tongue. And Design 7 is based on the interlocking joints of a 3D printed slug[47] which is similar to stacked ball joints. It would have attachments on the top of the print to allow a string to go through it for actuation. There were three initial final designs determined by a decision matrix seen in Table 5 (with the corresponding designs in Figure 5.23). Design 1 and 5 were combined as it was determined to be too difficult to try to get 3 different linkage systems to work. The first final linkage system design used the angled cuts from the finger into a slimmer design to fit inside of the silicone tongue. The second final linkage system design was Design 7. We then planned to test each of these systems in two prototype designs where it would be easy to switch between the two different linkages. This prototype system consisted of the linkage system that would go inside the tongue and curl upward to move the bolus by itself, which can be seen in Figure 5.24. The second design contained the same linkage system, but it would only actuate half the needed height and a solenoid sitting in the roof of the mouth inside a retainer would attract the magnet sitting in the tip of the tongue the rest of the needed height.

Table 5. Decision Matrix for final prototype actuation designs

	Usability	Assembly Time	Scalability	Cost	Manufacturability	Actuation Time	Total #s

Design 1	3	3	4	4	3	3	20
Design 2	2	4	3	4	3	3	19
Design 3	2	2	1	2	4	3	14
Design 4	2	4	3	4	3	3	19
Design 5	3	3	3	4	4	3	20
Design 6	3	3	3	4	3	3	19
Design 7	3	4	3	3	4	3	20

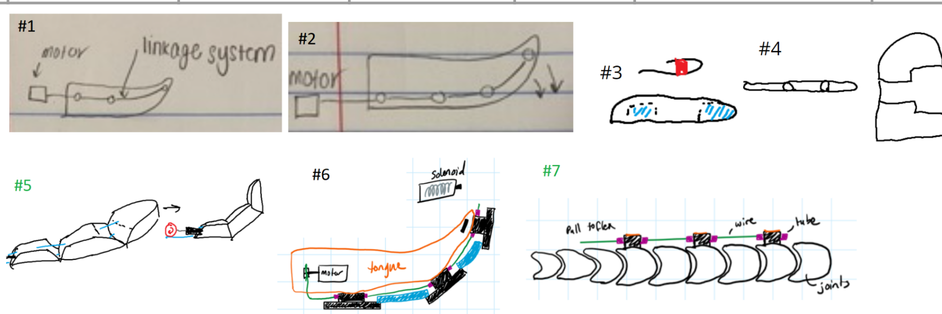


Figure 5.23. Corresponding (clockwise from top left) actuation system designs that are compared in Table 5

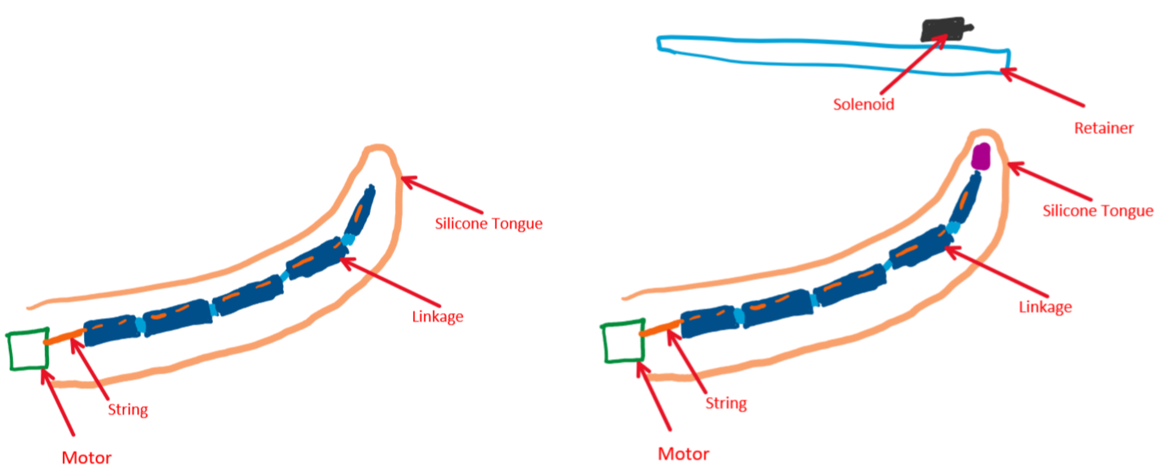


Figure 5.24. Initial Final Design 1 (left) and Design 2 (right) drawings

The next step was to design the actual linkage system, which started with the two final designs. It was determined to be difficult to design a set of interlocking ball joints so a slightly different concept was created. This was an interlocking (puzzle) linkage system based on the interockjoints of a FDM printed slug or dragon but using pin joints instead of ball joints[44]. The 3D printed slugs and dragons can be seen in videos on Youtube[44]. Seen below in Figure 5.25. is the first iteration of the puzzle linkage system which had three sections, was 6.9cm in total length, 2cm in width, and 1cm. There was no limit on how much this system rotated as the interlocked joints had full range of motion. This was thought to provide the best actuation. This first iteration was never tested as .6cm proved to be unable to fit inside the tongue, so the next iteration was thinner. The final iteration (Figure 5.26) consisted of six pieces, with the front piece being half the size of the rest to allow for the most rotation in the tip of tongue. It was .75cm wide, .485cm tall and 6.813cm long in total with very loose joints. The puzzle linkage system iterations were easy to print as all of the joints printed together and no assembly was needed, but it had a tendency to roll into itself inside the tongue instead of actuating the tongue which led to it not being used in the final design.

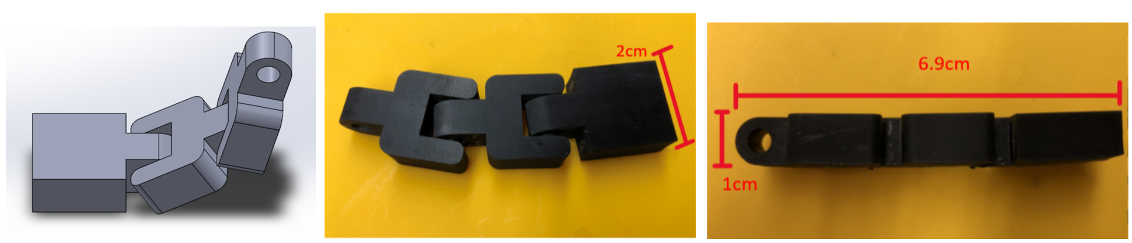


Figure 5.25. CAD model(left), Top view (middle), side view (right) First iteration of puzzle linkage system design

Figure 5.26. Top view (left) and side view (right) of Final iteration of puzzle linkage system

The second design was a hinge-based linkage system which followed a similar concept of tendon-driven robotic fingers[45]. Originally, it had 3 sections or 'plates' with angled cuts and then horizontal holes that lined up where wires would go through to keep the plates together. Then there were two vertical holes that went through each plate to hold the fishing line which was tied to the front end of the front plate (also the smallest plate). When the fishing line was pulled, the plates would all fold up or curl into each other at 2*(180 - the angle the ends were cut at). Seen in Figure 5.27, the first iteration of this hinge system was dimensioned at: smallest/front plate - 2cm long x 2cm wide x .5cm thick, middle plate - 2cm long x 3cm wide x .5cm thick, and back/largest plate - 2cm long x 4cm wide x .5cm thick. All plates were cut at a 60° angle so the total rotation or curl was 120° and the total length was just over 6 cm. This design was changed so there were 4 plates and each end of the plate was cut at 14° so the rotation would be 84° seen below in Figure 5.28. Seen below in Figure 5.29, the final iteration was decreased to 2.4cm wide at the widest part, 6 cm long in total, and the end edges were rounded so it would not cut the silicone tongue. This final iteration of the hinge linkage system was used for the final prototype.

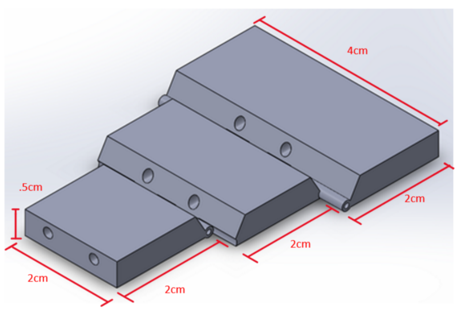


Figure 5.27. First iteration hinge joint linkage system design

Figure 5.28: Side View of Cut Angle on the Middle Plate of First Iteration Hinge Linkage System Design

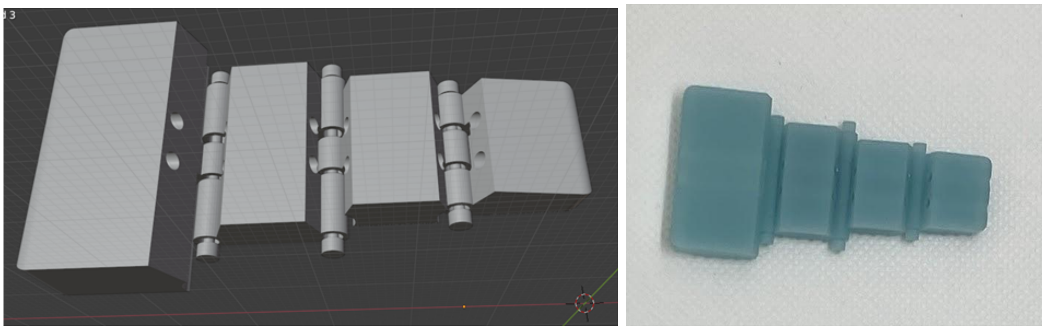


Figure 5.29. Final iteration of hinge linkage system

5.3.5 Gearbox Design

Once the linkage system was found, the next problem was getting to actuate it. Servo motors were decidedly the best choice since they were small and could fit in the mouth cavity, and had decent torque. One micro servo had .1569 Nm of torque (1.6kg-cm) and was used initially but it was not strong enough to pull the linkage system up inside the silicone tongue, seen below in Figure 5.30. Therefore, the system was then switched to two servos with one on each fishing line string of the hinge linkage system. However, both servos would not fit within the oral cavity, so a gearbox system was created to double the torque of one micro servo to .3138 Nm (3.2 kg-cm). The first gearbox iteration, seen below in Figure 5.31, consisted of 4 gears: Gear A was on the servo, Gear B meshed with Gear A but on a separate shaft, Gear C was on the same shaft as B and meshed with Gear D, Gear D had a spindle attached to it to pull the fishing line to actuate the tongue. Gear A and B had a gear ratio of 1.5 and Gear C and D gear ratio was 1.33 which led to an output torque of .3138 Nm.

Figure 5.30: Testing with one servo (left), and two servos (right) before gearbox

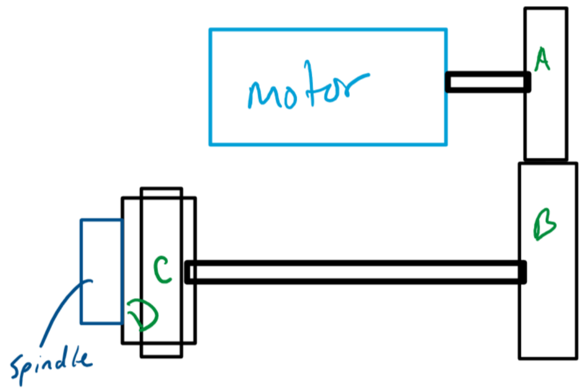


Figure 5.31. First iteration of Gearbox design

The final iteration of the plastic gear system can be seen below in Figure 5.32 and it had a gear ratio of 2.2 was used with 3 gears in a row. The first gear, Gear A, had 20 teeth and was attached to the servo motor, the middle gear, Gear B, has 34 teeth and was idler, and the third gear, Gear C, has 44 teeth and was on the same gear shaft as a spindle which the fishing line wrapped around when the gears turned. The spindle has an inner diameter of 1.5 cm and rotated 90º since the servo motor rotated a full 180º. There were many difficulties in getting the gears to line perfectly within the lower jaw since the resin print does not print small holes with great accuracy, so the gear shafts ended up slightly off from one another, not allowing them to turn and stopping the system. A stress analysis of the gearbox system was done and determined that the displacement is negligible due to the stresses being small (.3452 Nm). Further discussion of the analysis is in Section 7.1.2.

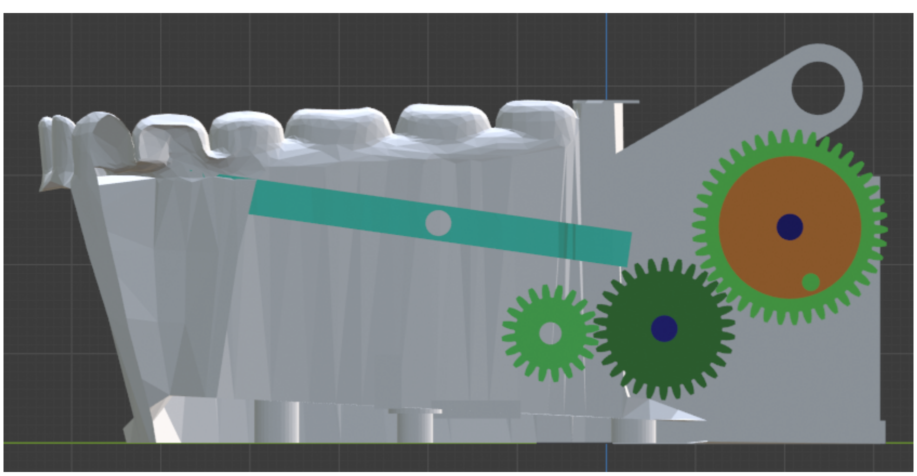


Figure 5.32. Gearbox Final Design Inside of the Lower Jaw

5.3.6 Testing Base Design

Lastly, a testing base was needed to hold all of the components of our final prototype. This went through a few different iterations as it was initially thought the entire circuit would fit into it, but the wireless EMG sensor circuit needs to be on a person to function. The first iteration of the testing base was large, a total of 18cm long, 10cm wide and 7cm tall and can be seen below in Figure 5.33. It ended up being too big to print in one piece in the resin printer so the second iteration split the testing base into 3 pieces: servo holder, jaw holder and connector piece, seen in Figure 5.34. The servo holder base was made to hold the servos, the connector piece connects the servo and jaw holders together, and the jaw holder uses a latch system to hold down the lower jaw. Another iteration was made after the system was downsized to one servo, so the servo holder base part was no longer needed and it went to just the jaw holder base. The jaw holder base was then modified by putting two holes horizontally, so two screws could go through to adhere the lower jaw to the base and getting rid of the latch system. These holes were then changed again in the final iteration so they were lined up vertically instead of horizontally, so the screw heads did not get in the way of the servo resting on the bottom of the lower jaw seen in Figure 5.35. A new ledge was also made off a side of the base to set the servo circuit onto during testing. The final iteration can also be seen below in Figure 5.35 with the ledge protruding from the right and two holes placed vertically in the top plate.

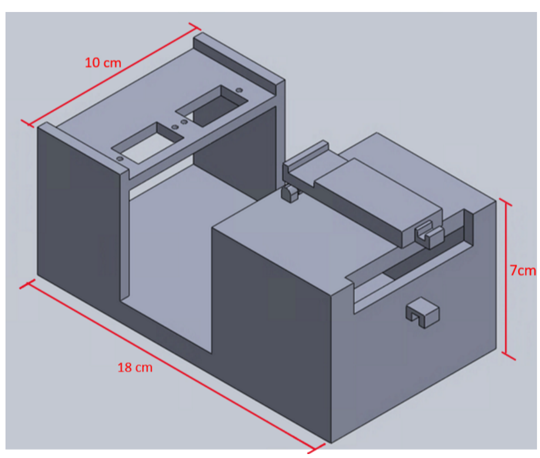


Figure 5.33. First Iteration of the testing base

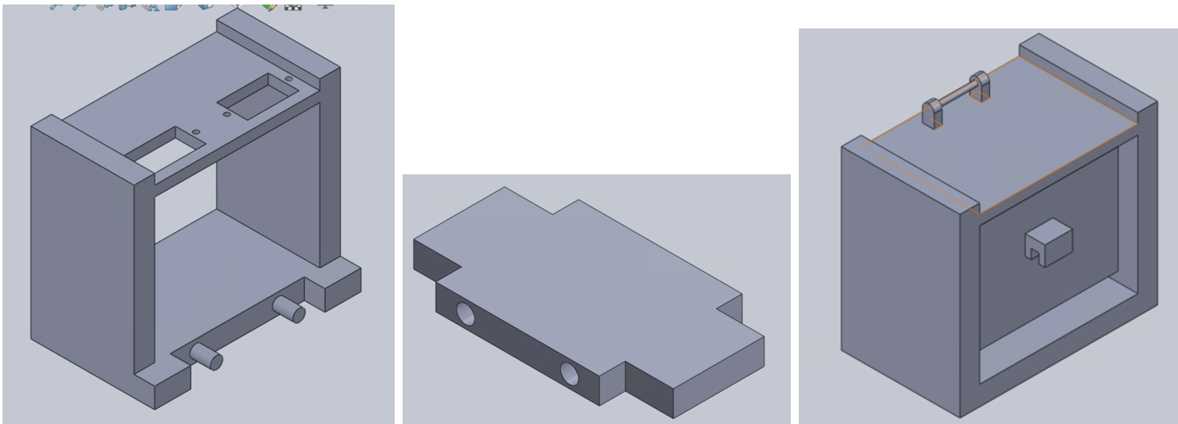


Figure 5.34: Testing base split into 3 parts: servo holders (left), connector piece (middle), and jaw holder (right)

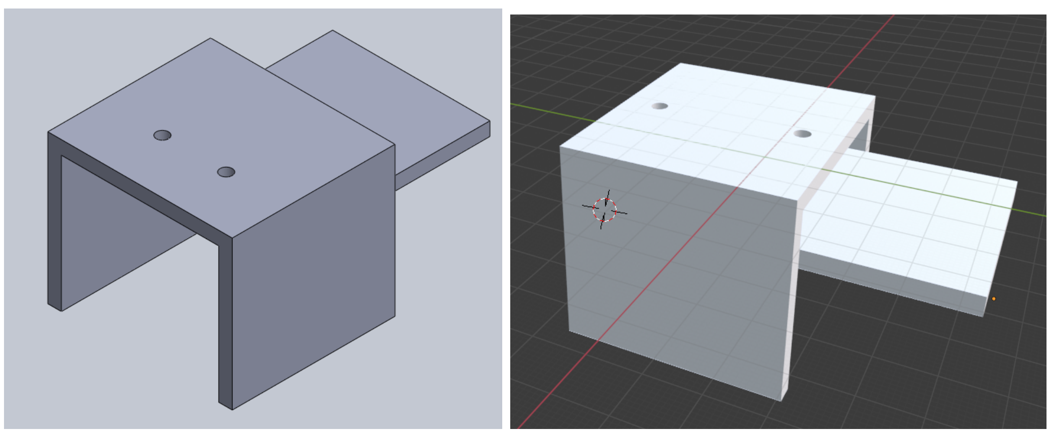


Figure 5.35. Horizontal Holes of 3rd iteration Testing Base (left) Compared to Vertical Holes in Final Iteration of Testing Base (right)

5.4 Summary and Conclusions

From initial testing of the previous iterations as well as manual testing, we were able to determine the best way to get the tongue to actuate high enough to move bolus which was a linkage system. Next, multiple designs of linkage systems were created and two were chosen by decision matrix. These designs were then modeled and 3D printed. Many other parts were 3D printed in a resin printer including a testing base, jaw model and retainer.

6. Control Module Design Iterations

This chapter will discuss the design iterations of the control module and additional electrical components. Several circuit design iterations were done as the project evolved from using a solenoid to a linkage system. A TinyDuino [9], which was a microprocessor unit used by Vasquez et al., was continued to be incorporated into this project's circuit designs.

6.1 Printed Circuit Board (PCB)

The benefits of using a PCB includes being products at a lower cost, it is widely available, has a long shelf life, low electronic noise, compact size, lower probability of error, as well as tight connections and short circuits avoided among many other things[46]. There are regular PCBs as well as flexible PCBs, which have benefits such as reduced space and weight, as well as all of the benefits of a regular PCB. The team had originally planned to incorporate a printed circuit board (PCB) instead of using the Arduino, and MOSFET in order to miniaturize the circuit and allow for the components to be self-contained in the tongue. Unfortunately, because of time constraints we were unable to complete a PCB for this project iteration. With a flexible PCB, the team would be able to create even more space inside of the tongue. The PCB would have included the following components:

- Parts to mimic an arduino
    - ATMEGA16U2
    - A 16 MHz crystal oscillator 2x 22pF Capacitors
- IRF520 MOSFET
- An A23 9V battery holder
- A 3V coin battery holder
- Connectors for solenoid and pressure sensor
- A 10k resistor to create a voltage divider with pressure sensor

The first iteration of the PCB can be seen in Appendix C.1, which shows off both the schematic and the PCB gerber file. This first iteration was made by directly taking the 2019-2020 MQP solenoid schematic and converting its parts to a PCB through a PCB editor using mostly placeholder parts. The size of this first iteration was 90mm by 168mm which was far bigger than the tongue, but this iteration also had a bunch of dead space on the board. The next iteration as seen in Appendix C.2 integrated the arduino in a more graceful manner by directly implementing the main ATMEGA328P microcontroller into the PCB using a 24Mhz crystal oscillator and two 22pF capacitors to properly implement the arduino board on a PCB. By using these parts, we were able to get full Arduino functionality while getting rid of any unused pins. This would also take up less space than the TinyDuino since there are not as many loose wires and the PCB can be implemented along the base of the tongue. The next two iterations, seen in Appendix C.3 and C.4, main goal was decreasing the size of the PCB so that it could properly fit within the tongue by moving parts around and also to recreate the PCB by using parts that are readily available for purchase. The final iteration, which can be seen in Appendix C.5, is the same as the previous iteration except it uses thicker traces (the copper conductor on PCBs) for anything that runs power through the PCB so that it can properly handle the power without damaging the PCB.

6.2 Force Sensor, Servo and Solenoid

The next circuit iteration the team had was a force sensor, servo and solenoid combination. The force sensor would rest inside of the tongue and as bolus was added the resistance would change, causing the solenoid to start pulsing, pulling the magnet in the tip of the tongue upwards. The goal of this circuit was to increase the actuation of the 2019-2020 MQP by adding in a servo to first move the tongue then the solenoid would clamp the tongue to the top, allowing for quick actuation times and more accuracy. This circuit, seen in Figure 6.1, had the issue however of needing to run power for both the servo and the solenoid which not only made the circuit huge but also still had all the downsides of using a solenoid. The next circuit iteration uses a stronger servo so that the solenoid is not needed to fully actuate the tongue. This code can be seen in Appendix D.

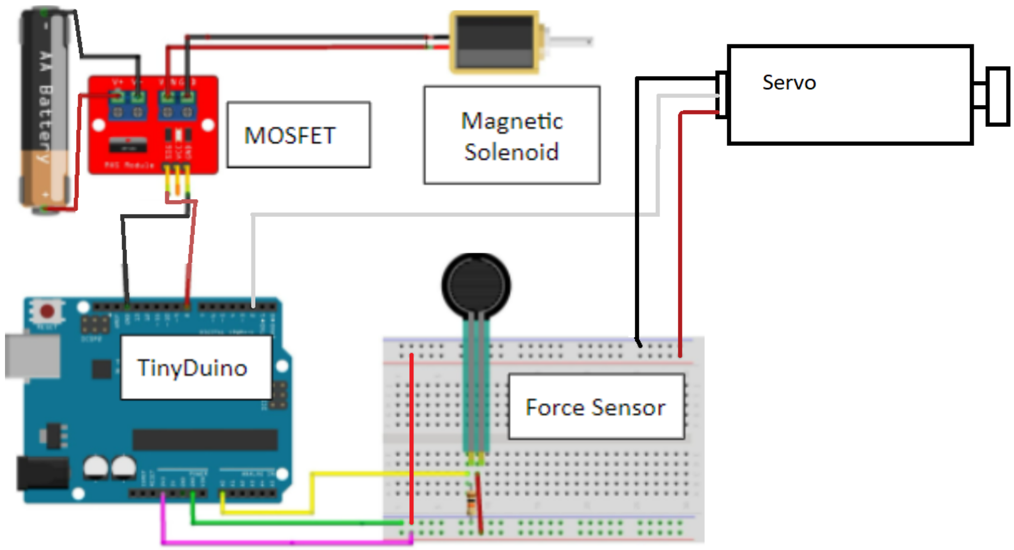


Figure 6.1: Diagram of force sensor, servo and solenoid circuit

6.3 Force Sensor and Servo

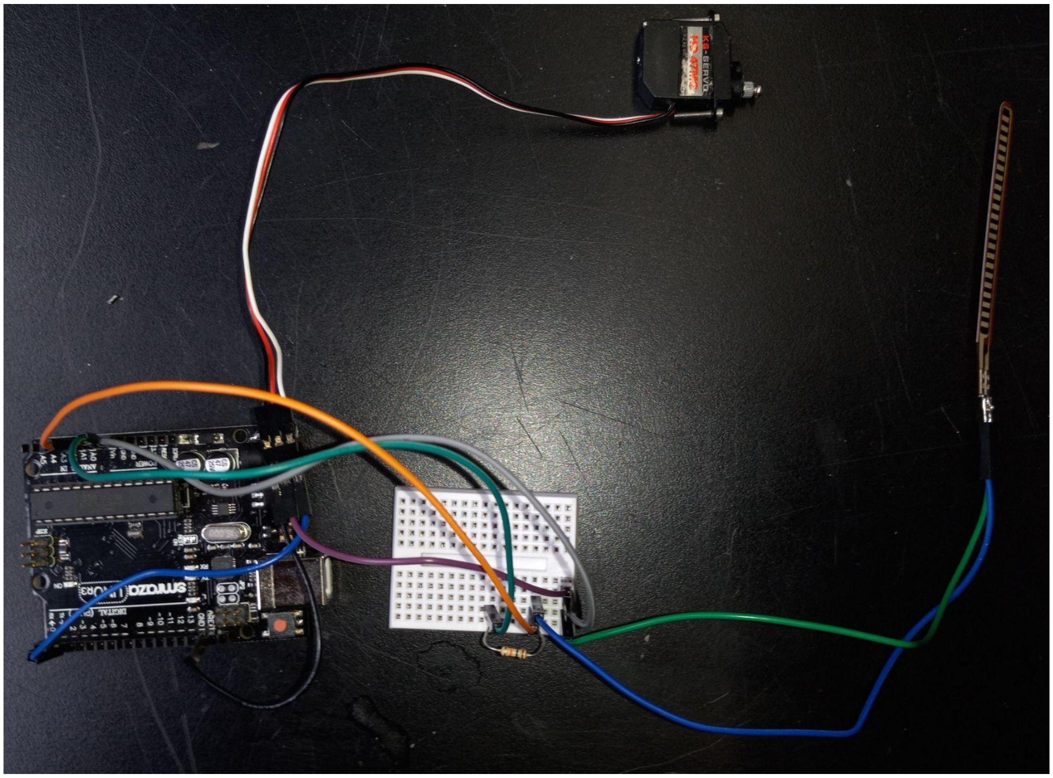


Figure 6.2: Diagram of force sensor and servo circuit

This circuit iteration consisted of a force sensor and a servo, which can be seen above in figure 6.2. As the previous iteration, the force sensor would rest inside of the tongue and as bolus was added the resistance would change, causing the servo to move, pulling up the linkage system. The servo, seen in Figure 6.3, in this system has about double the torque as the previous servo at .2451 Nm (2.5 kg-cm) whereas the previous servo had .1176 Nm (1.2 kg-cm) and is thus able to pull the tongue more effectively. The servo is still not powerful enough by itself and requires a second servo to properly actuate the tongue. A circuit diagram of the two servos and force sensor circuit can be seen below in Figure 6.4. A method for increasing a single servo's torque instead of using a second servo, is to either use a pulley system or a gear system. Our group decided to work with a gear system due to our familiarity with the topic and the simulations were easier to come by for us (see chapter 7 for more in depth on the gears). Since the servo only requires 5V to properly function, it can be run off of the arduino/TinyDuino itself and does not require external power allowing us to downsize the circuit just a bit more. This code can be seen in Appendix D.

Figure 6.3. Miuzei micro servo SG90

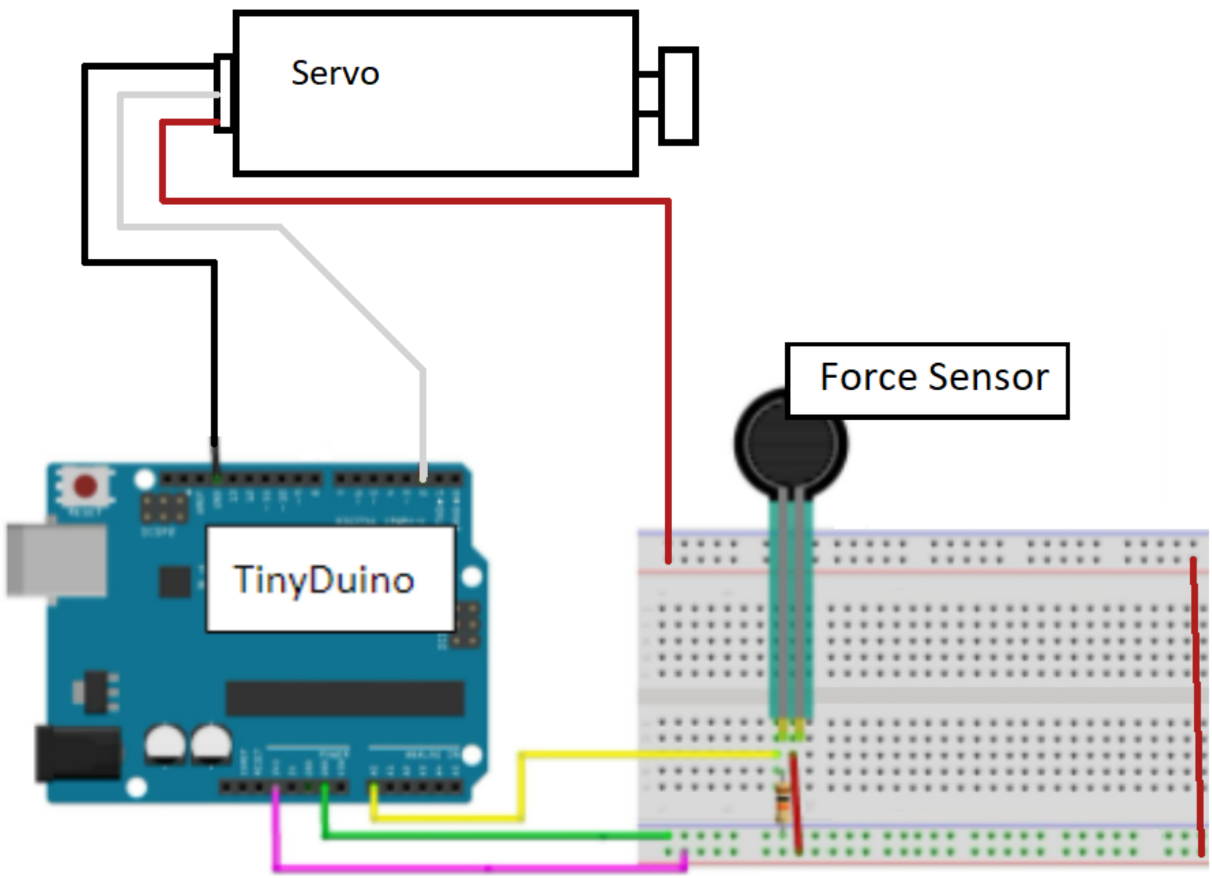


Figure 6.4: Diagram of force sensor and servo circuit

6.4 Wired Electromyography Sensor (EMG), Servo and Solenoid

The team then decided to switch over to using an electromyography sensor (wired), servo motor, and solenoid circuit which can be seen in Figure 6.5 and Figure 6.6. The EMG sensor measures small electrical signals generated by your muscle impulses when you move them. The EMG sensor our group decided on using was the myoware muscle sensor kit (which is now retired in favor of their new muscle sensor v3), due to its low cost and easy implementation. It utilizes a basic biomedical electrode sensor to attach to the user and requires 3.3V-5V to function. The impulses can be generated by simple movements such as flexing your arm, lifting up your arm, and wiggling your fingers. The team wanted to implement this as it would be more sensitive than the force sensor, allowing for the tongue to move with more accuracy. The team had originally planned to have a servo and solenoid in the circuit as well so that once an impulse was detected the servo would pull the linkage system up and the solenoid would pull the magnet in the tip of the tongue for more actuation. After testing however the team found that the solenoid was an extraneous part of the system that took more power than it was worth and a second servo could be used instead. The code for this circuit can be seen in Appendix D.

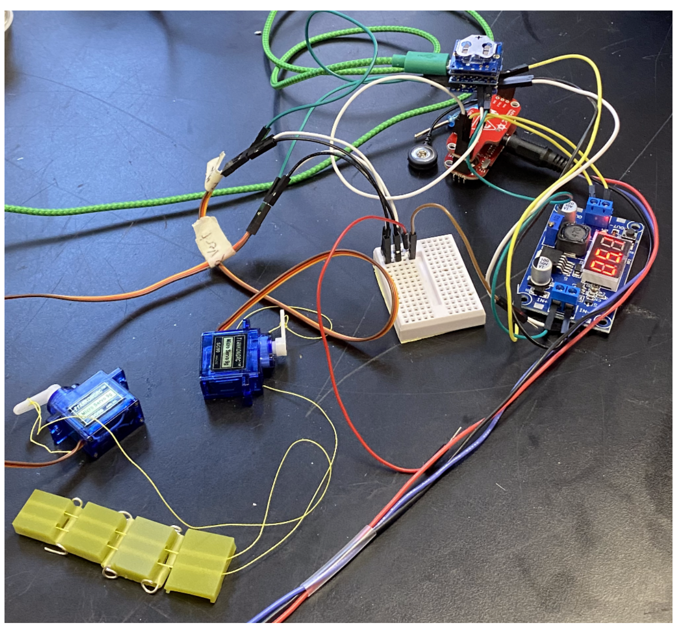


Figure 6.5: Diagram of EMG sensor, Servo and Solenoid Circuit

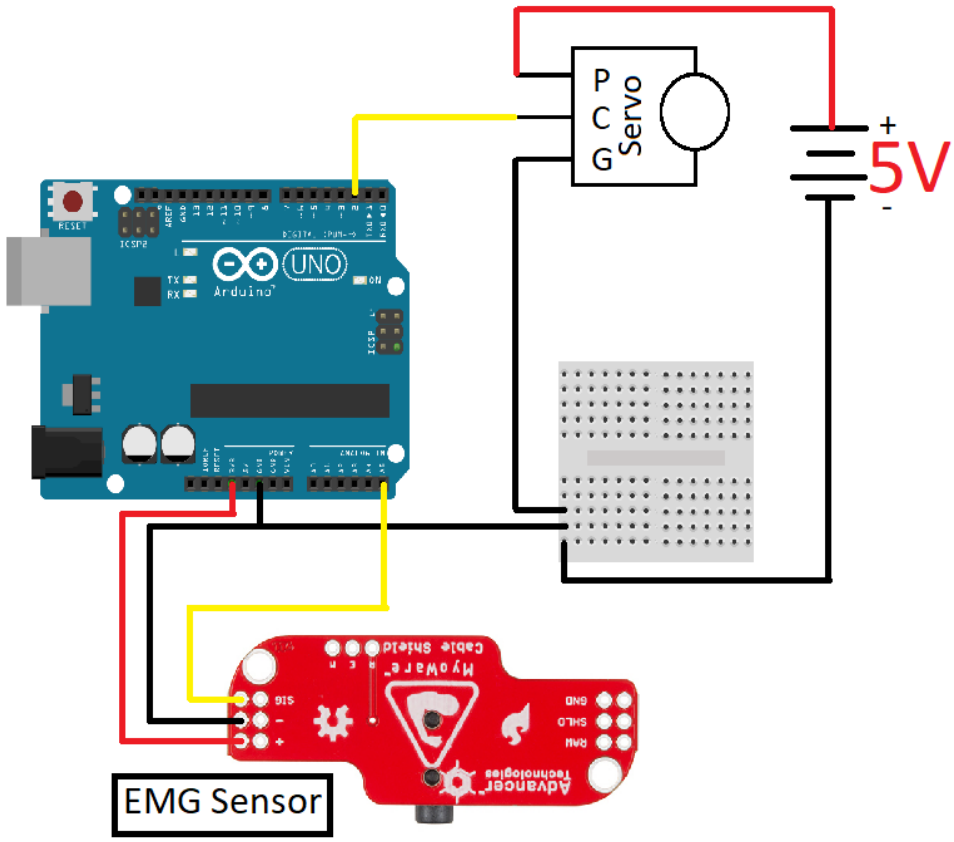


Figure 6.6: Schematicof EMG sensor, Servo and Solenoid Circuit

6.5 Wireless Electromyography Sensor (EMG) and Servo

For the last iteration of the circuit, the team had the wireless EMG sensor and a servo which can be seen in Figures 6.7 and 6.8. As in the last iteration, when the impulse was detected, the servo would move, and pull up the linkage system in the tongue. In addition, the circuit was also split into two circuits. Both circuits had a transceiver attached to them to communicate with one another. The circuit that will rest on the outside of the body had the EMG sensor so that it could detect muscle motion and then using the transceiver send the activation signal to the other circuit. When the other circuit receives the signal it would activate the servo causing the tongue to actuate. For our tests, the EMG sensor was hooked up to the arm of the user but in the future we plan to hook the EMG sensor up to the users face to detect jaw movements and actuate the tongue using those muscles. During this iteration, the code, which can be found in Appendix D, was also improved to no longer use delays and instead utilize timers, so that the transceivers could send data as quickly as possible for accurate readings and a more reactive system. The final code can also be seen in Appendix D.

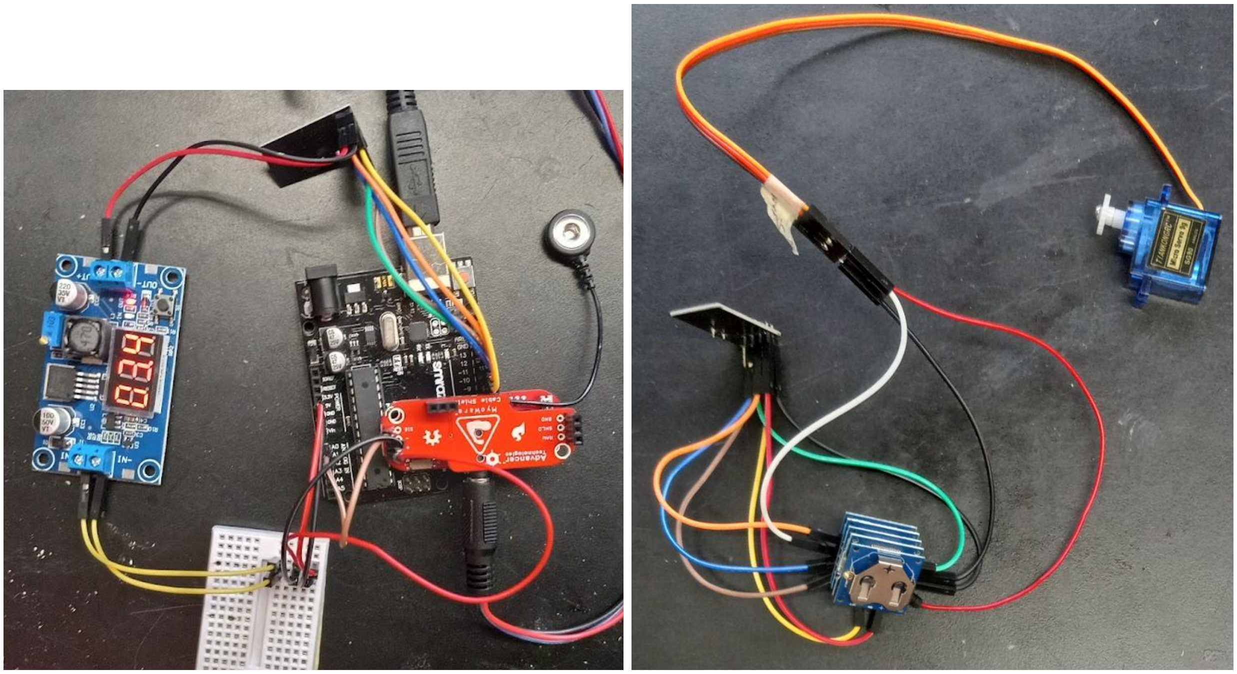


Figure 6.7: Implementation of Wireless EMG Sensor and Servo Circuit

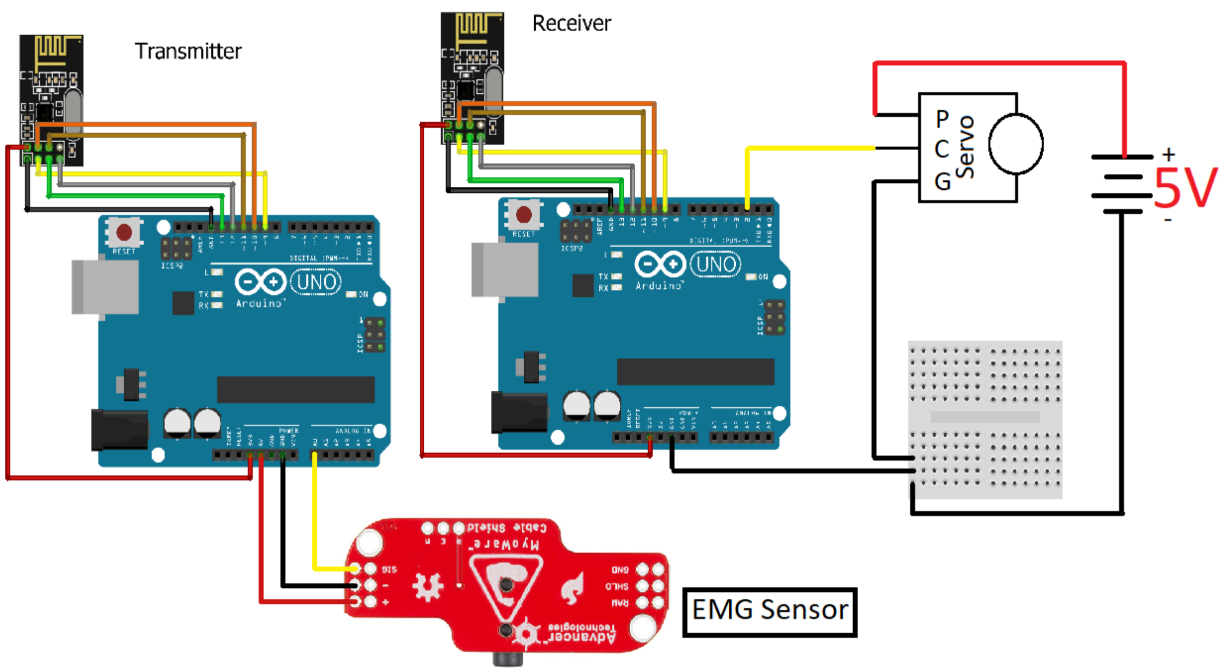


Figure 6.8: Schematic of Wireless EMG Sensor and Servo Circuit

6.6 Planned Improvements

The new actuation system we created can be further improved upon with some simple changes. To get a more natural reading from the EMG sensor, it could be utilized on a user's jaw instead of their arm so that the motion of them chewing would activate the tongue motion to move food around in their mouth. In addition to this setting up the system to work off batteries would also allow for a more portable system.

Next to improve the actuation itself, instead of using a simple timer based system where the tongue activates for only a certain amount of time before falling back down a more robust method of utilizing the EMG sensor could allow for more acute movement by basing the actuation off of the muscle reading. The TinyDuino driving the servo part of the circuit could also be replaced by a PCB to miniaturize the more so that it will fit into a user's mouth, while also allowing for more varied types of batteries to be used which would allow for remote servo usage. An upgrade to the servos directly would be to use a micromotor instead that has a higher gear ratio allowing for faster actuation and would also require less gears allowing for more miniaturization of the system.

Currently the circuit is entirely uncovered and poses a health risk to users currently. To be used in the future in a patient's mouth, the circuit should be encased in silicone or another container.

6.7 Summary and Conclusion

The control module of the prosthetic tongue, although not the smallest of all the iterations, has the highest possibility of actually fitting within a user's mouth so far. This is due to the control module being split in two and having the actuation module controlled by an external module that rests on the user's arm. The control module was able to send signals to the servo to accurately control the system and also allow for quick testing and calibration so that the process could be somewhat streamlined during testing. With this being said, the control module still has a long way to go as it needs to be battery powered to ever see any use and the components themselves are prone to malfunctioning. For example, during testing the EMG sensor would often start to read values incorrectly after being used for a while. In addition to this, if there are too many devices nearby the RF transceivers seem to experience interference and send data very slowly if at all.

7. Final Design Verification

This chapter will discuss our testing protocols that were used to evaluate the success of the final prototype. The main objective used to measure success was if 5g of bolus could be moved from the front of the mouth to back of the mouth consistently, or 95% of the time or more. Other criteria for success included miniaturization, consistent circuit functionality, and actuation time.

7.1 Simulations

To determine the robustness of the design and the forces needed to get the prototype to function, simulations done in Solidworks and ADAMS software of gearbox and linkage systems respectively. An analysis of a simulation was also done on the solenoid to determine its possible functionality in the oral cavity.

7.1.2 Linkage Simulation

A linkage analysis simulation was done in ADAMS software to determine the forces needed to actuate the tongue as one servo did not have enough torque, which can be seen in **Appendix D**. The analysis was done by doing a rough approximation of the system by replicating the amount of linkages, the angle of connections, and the weight of each linkage. The force of the string pulling the linkage system was approximated with a force acting on the tip of the linkage system pointing towards the base linkage. Something that the system did not originally account for was that the mold surrounding the linkages not only weighed them down but also added more force that opposed the actuation. The simulation also lacked the ability to properly account for all the friction between parts and the silicon of the tongue so there is some error in the calculations for expected needed force. In addition to all this the goal for the system was that it had to actuate within 1 second so that it could be responsive. The simple system for the linkage system that only utilized the weight of the linkages was generally straightforward and only required a force of about 1.2 kg-cm which was able to be handled by our original servos quite easily. It can be seen below in Figure 7.1.

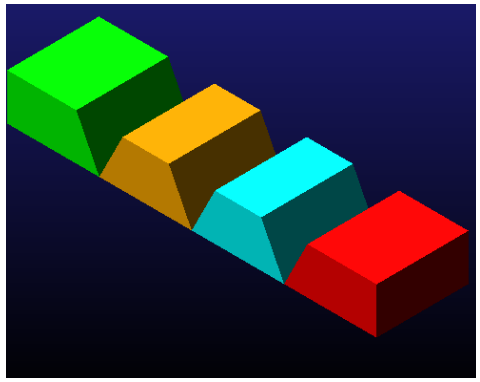


Figure 7.1. Screenshots of Linkage system analysis in ADAMS Software

For the next iteration that simulated both the linkage system and the forces of the tongue on said system, a force of 0.3 Nm was added uniformly along the piece opposing the direction of curling to represent the force of silicon pulling against the linkage system. There was also another base added to mimic the table/retainer holding up the linkage system as it kept falling downwards without it. This system, seen below in Figure 7.2, ended up requiring a force of about 0.336 Nm to achieve the same amount of actuation in a similar amount of time. This required our group to switch to a more powerful servo as the previous servo would most likely be unable to move the tongue even with the addition of a second servo. Our group ended up utilizing an SG90 micro servo which has a stall torque of 0.176 Nm with a max torque of 0.245 Nm. This servo was chosen mostly for its low cost and small size to torque ratio, along with its quick actuation time. Using a gear system it is possible to transfer some of the servo speed into torque allowing for a single servo to actuate the tongue. All linkage simulations can be seen in Appendix E.

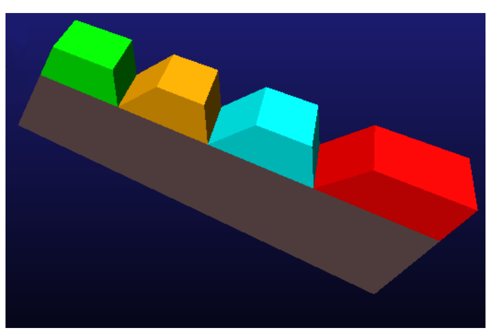


Figure 7.2. Screenshots of Linkage system analysis accounting for table in ADAMS Software

7.1.2 Gearbox Simulation

As previously stated in chapter 5, a gearbox was created to downsize the circuit system to one servo motor, but in order for the linkage system to work, it needed .33 Nm of torque, which was more than one servo had. Originally, two servos were used to actuate the linkage system, but they both could not fit into the oral cavity, so a gearbox system was made to double the torque of one servo motor.

The design consists of three gears in a line with one another. The first gear, Gear A, is the smallest, has 20 teeth and is attached to the servo. The second gear, Gear B, is the middle gear and is attached to the first gear shaft. It is considered idle since there is no motor attached to it. The third gear, Gear C, is the output gear, has 44 teeth and is on the second gear shaft. The gear systems can be seen below in Figure 7.3. A spindle, the piece the linkage string wraps around, is also attached to the second gear shaft. The resulting gear ratio is 2.2, which makes the output torque 0.3452 Nm. This was enough torque to actuate the linkage system. The analysis proved the gear system to be sturdy enough to handle use for a day's worth of meals (3).

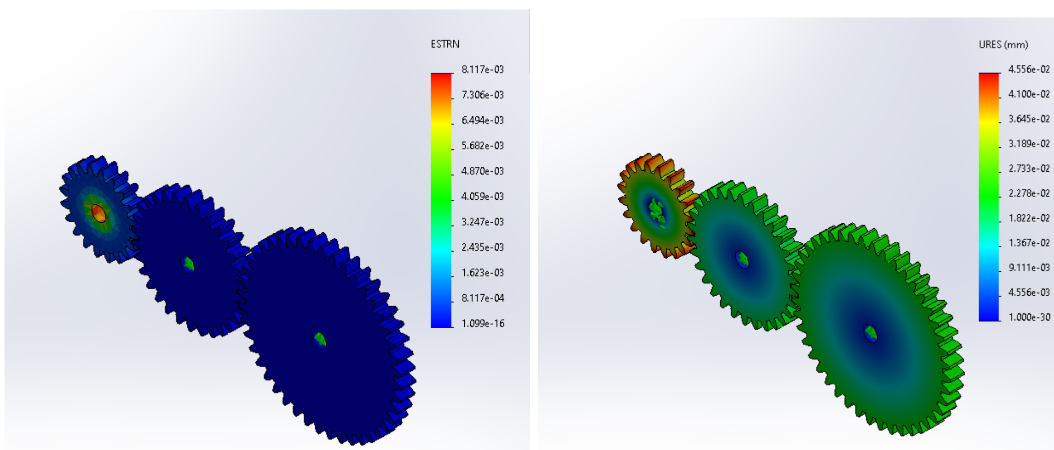


Figure 7.3. Gear stress analysis (left), displacement analysis (right) in Solidworks

The stress analysis revealed that there was little deformation of the gears. The maximum displacement that occurred with a torque of .3452 Nm was 0.0455mm which is .3% of the smallest gear's (Gear A) pitch diameter. All gearbox simulation files can be seen in Appendix E.

7.1.3 Solenoid Simulation Analysis

A solenoid analysis was conducted by Solenoid Systems[47], which determined that the solenoid could not be used inside the oral cavity due to excess heat emitting, seen below in Figure 7.4. [47] The specifications of the solenoid were: solenoid stroke of 7mm, solenoid force of 6.25 Newton, and minimum operating voltage of 9.8V. These specifications were similar to the solenoid used during testing in the following sections. In the case study, a transient steady state thermal analysis was set up and performed in Solenoid System's Virtual Development platform. The team determined from this study, as well as from Figure 7.5, that the solenoid can heat up to 160 degrees celsius in approximately 15 minutes. This is what made the team decide not to use the solenoid in the new iteration as it heats up dangerously high and would not work well in the oral cavity.

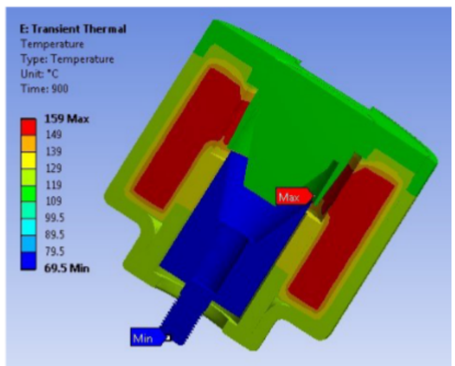


Figure 7.4. Thermal analysis of Solenoid in Solenoid System's Virtual Development platform as reproduced from [47]

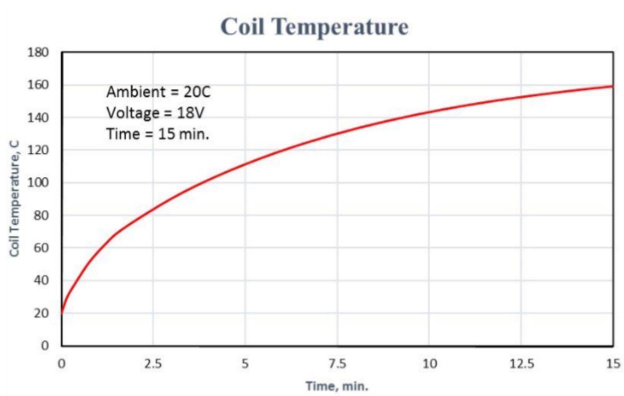


Figure 7.5 Graph of solenoid coil temperature over a 15 minute time span as reproduced from [47]

7.2 Final Actuation Testing and Results

To determine if the final prototype was successful, actuation testing using the tracker software (Tracker)[6] was done. Six trials of the actuation of the linkage system were recorded and then analyzed; the data collected from each trial can be seen below in Table 6. Each trial was run by having a person trigger the EMG sensor (by flexing their muscle) and then having the circuit wirelessly signal the servo circuit to turn on and actuate the linkage system and tongue. A measuring tape was held up next to the final prototype as the tongue moved for reference for the Track software. Once the tongue actuated one time, the power to the servo circuit was cut so the circuit could reset. It was plugged back into a computer (power source) to start the next trial. These trial videos can be seen in Appendix F. The setup can be seen below in Figure 7.6, where the silicone tube represents a person's arm and the circuit can be seen in Figure 7.7.

Table 6. Final Actuation Testing Results

Trial	**Actuation Height (cm)**	**Trial**	**Actuation Height (cm)**
1	2.308	4	2.43
2	1.68	5	2.55
3	2.31	6	2.627

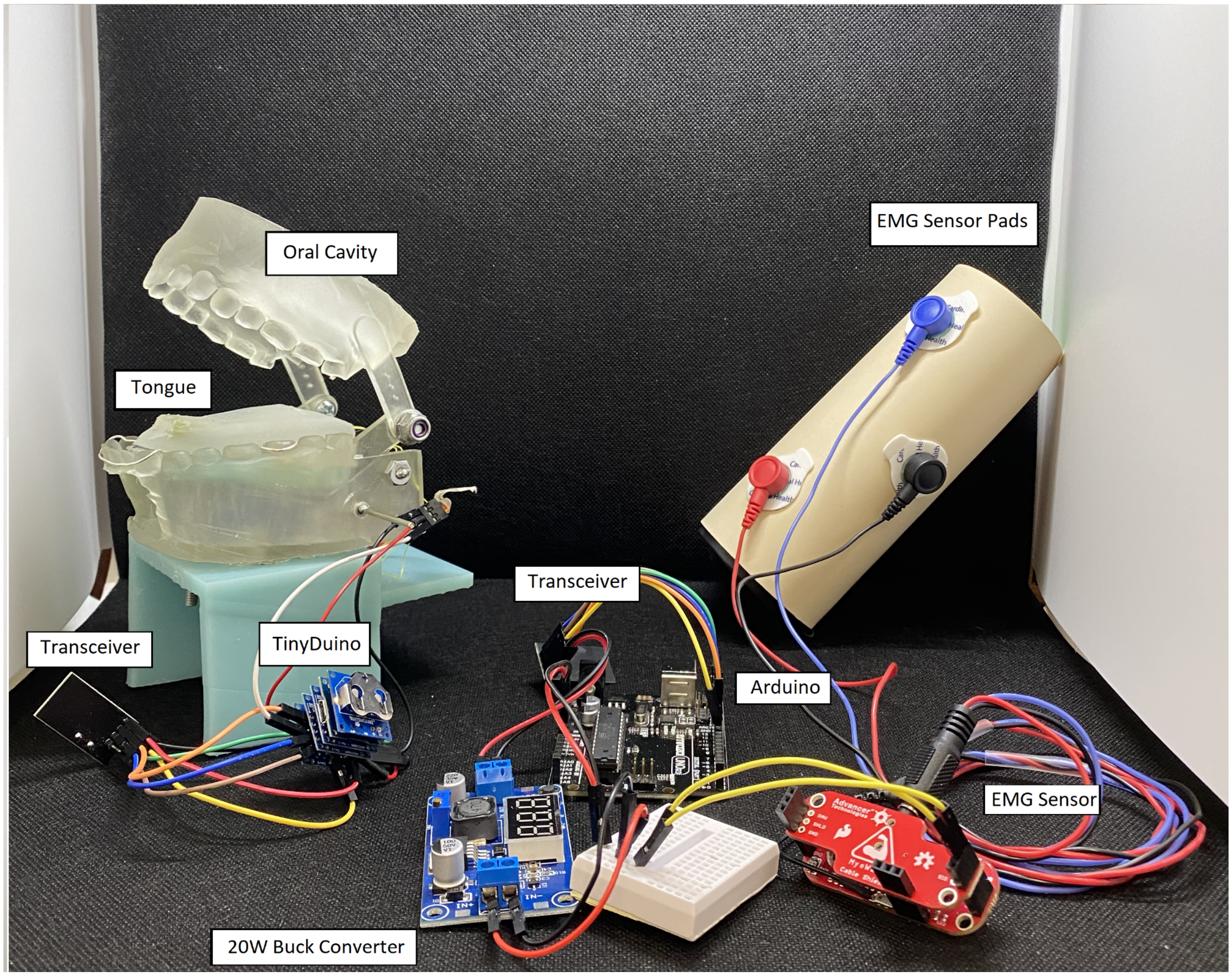


Figure 7.6: Setup of Actuation Testing of Final Prototype

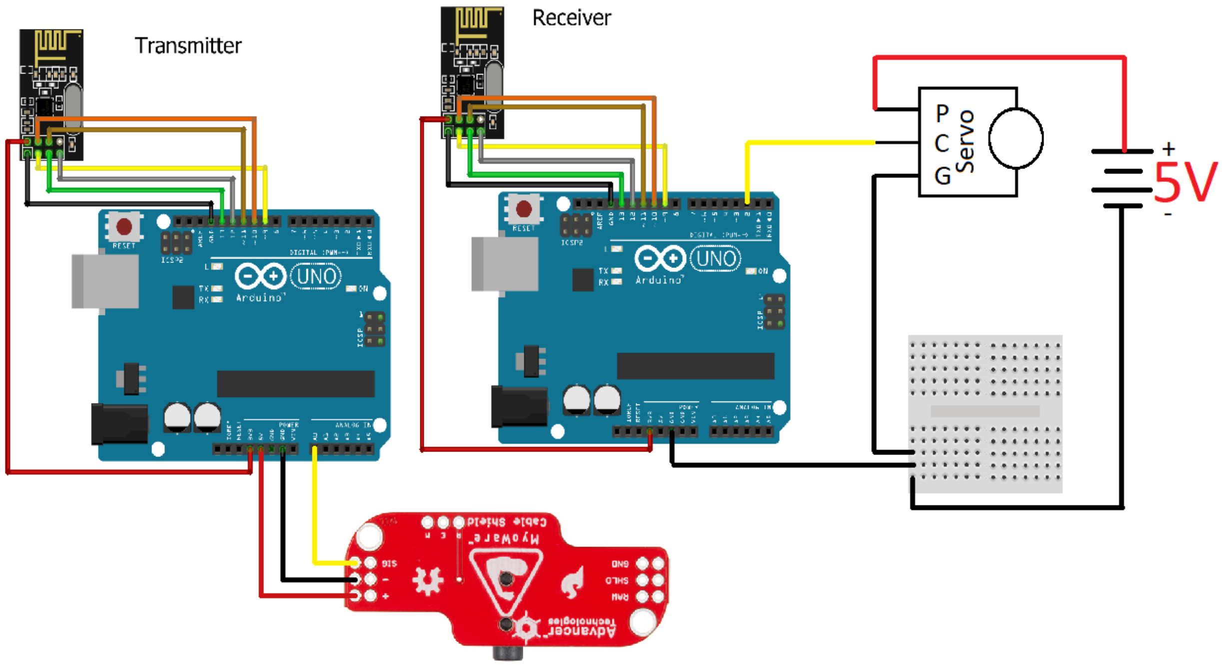


Figure 7.7: Final Prototype Schematic

From this data, the tongue actuated to an average height of 2.317 cm with 0.3452 Nm of torque and no bolus on it. This average is 2 or more times higher than Iteration 2 and 3 of the tongue. Some screenshots of the actuation videos can be seen below in Figure 7.8.

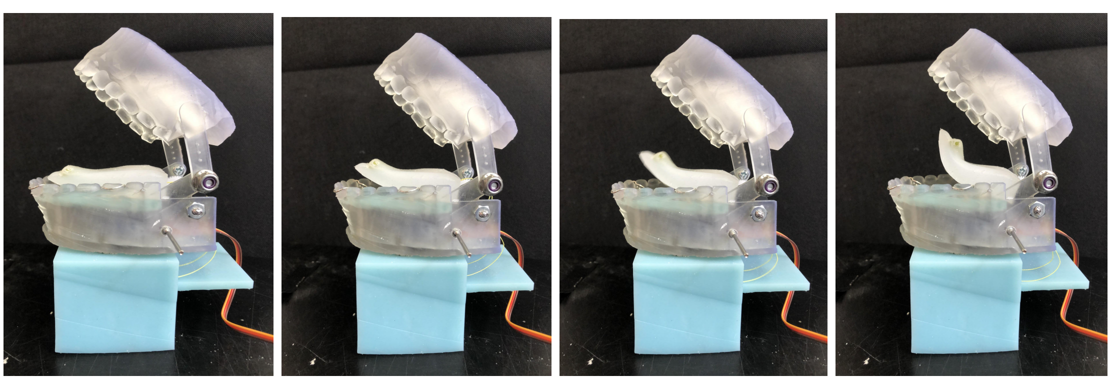


Figure 7.8: Screenshot from actuation test video

7.3 Final Bolus Testing and Results

The next testing done was bolus testing. Four different weights (2g, 3g, 4g, 5g) and a ratio of 2:4 (2 tablespoons of instant mashed potatoes and 4 tablespoons of hot water) of bolus were tested. This bolus ratio was used because it was thick enough to hold its shape but soft enough that a patient could eat it as long as they had most of their swallowing capabilities. Videos were taken of each trial and it was noted whether or not the bolus moved off the tongue and which direction. These videos and screenshots of the videos can be seen in Appendix G. As shown in Figure 7.9, the oral cavity was open for all the trials recorded in Table 7. Coconut oil was used in these trials as lubricant to imitate saliva and make the silicone tongue less sticky. Some trials were done with the oral cavity (which can be seen in Figure 7.10) closed but all of them failed as the bolus would get stuck between the upper palate and tongue and no measurements were taken as it was not possible to clearly see the movement of the tongue.

Table 7: Final Bolus Testing for iteration 4 prototype

Bolus weight	Bolus Ratio 2:4
3g	
Trial 1	Fell backwards into throat
Trial 2	did not move, stayed on tip of tongue
Trial 3	Fell backwards into throat
4g	
Trial 1	Fell backwards into throat
Trial 2	Fell back to middle of tongue, but not all the way
Trial 3	Fell backwards into throat
5g	
Trial 1	Slid backward on tongue but did not fall off
Trial 2	Fell of side
Trial 3	Fell off side

The tongue was able to move 3g and 4g of bolus from the tip of the tongue to the back of the tongue four out of the six trials. During one of the trials the tongue was able to move the bolus, but not all the way back. If more trials were run, had there been more time, the results would have shown a more accurate representation of the tongues bolus moving capability. For 5g of bolus, the bolus was larger than the tip of the tongue, which can be seen below in Figure 7.9. This caused the bolus to easily roll off if it was not balanced correctly before the trial began. The bolus was also so large that it would get stuck when the jaw was closed, seen in Figure 7.10.

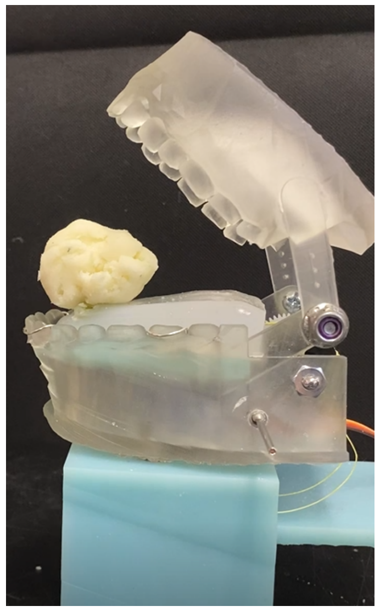


Figure 7.9: 5g of Bolus on Iteration 4 Final Prototype

Figure 7.10: Closed oral cavity

The actuation height of the tongue of each trial from Table 7 was also recorded and these values can be seen below in Table 8. These displacements were found through the Tracker[6] software. Videos taken for Tracker contained a ruler in the background for the software to reference and then the bolus test trial was run. The videos were then put into the software and the point just under the bolus was tracked in each video frame to get the actuation height of the tongue.

Table 8: Actuation Height of Final Prototype During Bolus Testing

Bolus weight	Actuation Height (cm)
3g	
Trial 1	1.07
Trial 2	2.46
Trial 3	2.91

4g	
Trial 1	2.29
Trial 2	2.38
Trial 3	2.32
5g	
Trial 1	2.26
Trial 2	2.45
Trial 3	2.16

The average actuation height of the tongue with bolus on it was 2.25cm.

7.4 Summary and Conclusions

In all, the testing verification revealed our final prototype to be successful in certain areas needing improvement in others. The prototype was able to move bolus from tip of tongue to back but not as consistently as expected. Further testing of bolus ratios, weights and lubricants would increase the parameters of success.

The linkage simulation analysis showed that the linkage system needed at least 0.336 Nm of torque to actuate the tongue to 2.3cm with no bolus and to 1.1cm with 5g of bolus on the tongue. The gear system was made to increase the output torque of one servo motor to .3452 Nm in order to move the linkage system. These three gears were revealed to be robust enough to last a day of meals (3) as the maximum deformation of the gears was .3% of the smallest gear and the maximum stress was $.117 \times 10^{-3}$ N/m^2. The solenoid simulation case study analysis showed that the solenoid heats up to dangerously high levels (160ºC in 15 minutes), making it unsuitable for use in the oral cavity.

From the data we collected during actuation testing, it was found that the tongue actuated to an average height of 2.3cm with 0.3452 Nm of torque and actuated 3.3cm with no bolus on it.

This average resulted in being 2 or more times higher than Iteration 2 and 3 tongue actuations. This is also the first Iteration to get bolus to move from the tip of tongue to back of mouth. During bolus testing, the tongue was able to move 3g and 4g of bolus from tip to back of tongue in more than half of the trials. With more time and trials, the results of our testing would have more accurately described the tongues capabilities. We found the best amount of bolus to be between 3g and 4g. A 5g bolus is too big for our human sized oral cavity mold, as it would hit the top of the oral cavity and not be able to move backwards. The 5g bolus would also be too large for a patient with trauma to the oral cavity to swallow as trauma to the oral cavity typically causes problems with deglutition[48].

8. Final Design Considerations

This chapter will discuss our project in a more broader scope pertaining to global applications such as impacts on economics, ethical concerns and societal influences. Moreover, we will be discussing health and safety concerns, manufacturability, and environmental impact.

8.1 Economics

Prosthetics is a very profitable section of the medical industry, especially when there are only a couple of functional prosthetics in the field such as artificial prosthetic tongues[49]. A company would be able to make a good profit by selling a limited product. Having the artificial tongue enter the medical industry would also increase awareness of oral cancers and increase accessibility. Patients should have most or all of the medical expenses pertaining to the prosthetic covered by health insurance as it would greatly improve the quality of life. Preferably, the electronic and silicone components would last at least a year before needing to be replaced and replacements would be readily available and simple.

This project had a budget of $2,500, thanks to the Women's Impact Network[50], to purchase materials to develop an artificial prosthetic tongue prototype. An ELEGOO Mars 2 Pro resin printer was bought, which was $500, to 3D print many of the components of the prototype and then multiple bottles of various resins, from eSUN and ELEGOO, were bought to print the needed components which cost about $300. Additionally, electrical components were bought including a new TinyDuino board, EMG sensor, RF transceivers and receiver, and sensor gel pads for this iteration. These electrical components cost about $150 in total, not including the extra parts needed to remake the previous iteration's circuits. Each of the silicone tongues cost about $3 to make. The retainers only cost a couple dollars of resin but in actuality they would cost more as 3D scans of the patient's mouth would be needed to create them.

In total, the silicone, resin, electronics (TinyDuino, RF Transceiver, EMG sensor), servo and gears cost about $209 per oral cavity/tongue setup.

8.2 Societal Influence

This artificial tongue would influence society by bringing glossectomy, oral cancer and oral prosthetics to light. Current oral prosthetics could also greatly improve if more researchers were aware of the lack of functional oral prosthetics and motivated to improve them. This could then prompt medical companies to start producing prosthetic tongues. In return, this would improve the quality of life of patients who have lost their tongues.

8.3 Ethical Concerns

For the project to be considered successful in its most final stage, a final prototype must be tested inside a patient's oral cavity. In order for the tongue to be placed inside a person's mouth, multiple biocompatibility and safety tests need to be run to ensure the patient's wellbeing. At this point in time, it would be unethical to test this prototype in a patient's mouth as it would be a safety hazard with the exposed electrical components as well as too large for the oral cavity. Future proper FDA regulated testing[51] will take into account all possible hazards, fix them, and go through rigorous safety testing before undergoing human trials.

8.4 Health and Safety Concerns

There are many health and safety concerns that go with this project as the final product would go directly into the person's mouth. The tongue must be biocompatible, otherwise the user could get injured and the project and its components would need to be re-evaluated to determine what parts needed to be refined. To ensure the patients health and safety, thorough research and numerous tests will be done to prove the safety of the components.

Considerations also need to be made with possible malfunctions of the circuit or gear system. Since this prototype incorporated a removable tongue and retainer, it would be relatively easy to fix the circuit if it was inside the tongue. However if the gear system were to malfunction, it may require more invasive procedures like surgery. Both the gear system and circuit would need some form of alert system to notify the user of a malfunction.

8.5 Manufacturability

The current state of the prototype is unable to be mass produced and distributed to total glossectomy patients. This is due to the highly customized parts of the prototype as the retainer, gear shafts and servo need to be referenced to the patient's oral cavity. Additionally, there is no quality control or processes in the formation of the silicone tongue, which would be needed if a company wanted to mass produce it. A ELEGOO resin printer was used for all the 3D printed parts, but a more precise printer with biocompatible resin (used in all the prints) would need to be used so printing and curing times would be consistent. The SmoothOn Ecoflex silicone is biocompatible but is considered lower quality than the silicone used in medical prosthetics, so a company may want to change to a better quality silicone.

Even though the mandibular Hawley retainer already has a well-known process in dentistry, the project's retainer needs to sit at a 5°angle in the lower jaw and be completely filled in (as there is no need for space in the middle since the patient does not have a tongue). Each retainer would have a slightly different edge pattern due to the differences in patients teeth.

The circuits currently need soldering to make most connections, but if a PCB was implemented, the manufacturability of the circuit would improve significantly. This would also miniaturize the components needed to be put into the oral cavity, therefore decreasing the amount of silicone used.

8.6 Environmental Impact

The environmental impact of the prosthetic tongue is currently negative as the silicone and resin printed parts are unable to be recycled and would most likely end up in a landfill. There is not really any way to recycle silicone, especially when it is being used in a medical application. However, biodegradable resin is possible to use, but it may not have the same tensile strength as the regular resin.

As for the electrical components, the Environmental Protection Agency (EPA) has clear instructions on how to recycle certain components[52]. The EPA website recommends that electronics be brought to a Responsible Recycling (R2) certified recycling center because they are up to code on the standards (set by the EPA) and recycling protocols of electronic recycling. These recycling protocols ensure recycling and reuse of electronics is maximized and human exposure to the environment is minimized. To find a certified R2 recycling, follow the instructions provided on the EPA website[52].

8.7 Discussion

This section will compare and discuss the testing results to the original goals of the project as stated below:

1. Design: Develop an improved mechanism and actuation method to allow for easier flow of the bolus from the tip to the back of the tongue
2. Size: Develop an accurate oral cavity system to enable demonstration of the actuation system of the tongue prosthetic. Develop the tongue to look even more anatomically correct and fit into the simulated oral cavity
3. Controls: Continue miniaturizing actuators and control systems to fit within the confines of the tongue and oral cavity
4. Validation: Create and carry out testing protocols to check tongue function.

8.7.1 Design: Develop an Improved Mechanism and Actuation Method

This project was able to improve upon the actuation system using a linkage system to move bolus from the front of mouth to back of mouth. The linkage system was designed with four plates and angled cuts to control the rotation of the system; more detail can be referenced in Section 5.3.4. It actuated the tongue to a height of 2.31cm, without bolus, and 2.26 cm (with bolus) which was over two times the actuation height of Iteration 2 &3. This actuation method was also the first actuation method to get bolus to move from the tip of the tongue to the back of the mouth.

8.7.2 Controls: Miniaturizing Actuators and Control Systems

One of the main driving forces for selecting a proper actuation system was the size of the actuator and how quickly the device could actuate the system. The air pump was able to quickly actuate the system but did so inaccurately and required a lot of space for proper actuation as described in Section 4.6. The solenoid was somewhat smaller, but it took a while for it to actuate and in addition its range of actuation was very low as described in Sections 2.2 and 4.7. Another issue with the solenoid was that it tended to heat up to about 160°C (320°F) after only 15 minutes of use which is about the time of a single meal. The servo is able to move the tongue quickly in a confined space but requires a gear system to make its torque greater (.3452 Nm) as one servo did not provide enough torque as described in Section 7.1.2. This slows down the actuation time of the tongue. In the end, we decided that for our iteration, a servo system would work best as we were able to make up for this system's lack of torque by utilizing a gear system.

8.8 Challenges

The team worked diligently to develop a functional artificial prosthetic tongue that would move bolus from the tip of the tongue to the back of the mouth. The team was successful in achieving this goal, however, the prototype is not refined enough to be integrated into the human oral cavity. Some of the challenges that were faced over the course of this project include: the COVID-19 Pandemic, teamwork difficulties, spindle slipping, circuit size, minimization, manufacturability, and the time needed to move the bolus.

Due to the COVID-19 pandemic, the reliability of the group became more complicated as we had to adapt to zoom and in person meetings when members either tested positive or became close contacts. The pandemic also affected the availability of parts as we had to face some delayed shipping or even some parts that were out of stock and unavailable due to limited quantity. Along with those challenges, the team faced some teamwork difficulties. There was a clash in work ethics and lack of communication as well as varying levels of interest. This caused the team to be unexpectedly downsized which caused delays.

Some issues faced in terms of our final iteration include spindle slipping. The shaft that the spindle was on was not large enough. This caused the spindle to sometimes slip or spin on the shaft and loosen the fishing wire, not allowing the tongue to actuate to its full potential. If the spindle was tighter on the shaft, there would not be slipping and the fishing wire would be fully pulled, leading to even higher actuation. Another challenge faced was the size of the circuit as the team did not have enough time to miniaturize it, leading the components to be outside of the tongue. The team would have liked to have all components of the circuit sealed inside of the tongue to allow it to be self contained. The team also faced a challenge powering the circuit as it either had to be plugged into a computer or external power source. The main challenge with this was timing, as there was not enough time to try and move the circuit over to being battery powered.

The consistency of the circuit was also a challenge, as it was sometimes unreliable due to the frequency it was on and other devices in the buildings interfering with the signal. In testing the circuit transceivers were able to communicate quite effectively. When presenting in halls however, surrounded by masses of other projects, our transceivers seemed to be reading random data. We attempted to fix it on the spot by changing the frequency on which they communicated, but this did not improve the connectivity issue by much. Along with this, issues also arose due to some feeble wires breaking and using too large solder. This would cause our circuit to read the EMG sensor incorrectly and imprecisely. To solve these issues we re-soldered and implemented a 20W buck converter which can be seen in Figure 7.6 in Section 7.2. Lastly, we worked hard to get actuation time down to 1 second. However, after implementing the EMG sensor and the circuit troubles we had, the team did not have enough time to work through the sensitivity issues mentioned, causing the actuation time to be longer than 1 second. During testing the EMG sensor would often randomly stop working and read values far less precisely. Possible reasons we thought of for this might be that our solder job was poor, or that the device itself was not getting enough power. With these we tested again but still got the same inconsistencies in readings now and again.

9. Conclusions and Recommendations

This chapter will discuss our conclusions and future recommendations for this project. All of our conclusions are based on the information and testing of prototypes in the previous chapters.

9.1 Conclusion

Our goal of this project was to develop an artificial prosthetic tongue which would aid in deglutition by moving bolus from the tip of the tongue to the back of the mouth. Our approach proved that using a linkage and gear/motor system in conjunction with an EMG sensor (Electromyography Sensor) was successful in completing our project goal. The use of the Tinyduino allowed us to miniaturize the circuit to be smaller than the previous iteration. However, due to time constraints and other challenges mentioned in Section 8.8, we were not able to miniaturize the circuit enough to be self contained inside of the tongue itself. Our approach and accomplishments allow for further advancements of oral prosthetics.

The integration of an EMG sensor allowed the tongue to be actuated with the muscle impulse caused through movement in a person's arm and fingers. The gear, linkage and servo system allowed for enough torque to be able to raise the tongue prosthetic high enough (2.25 cm with bolus and 2.317 cm) to be able to move the bolus from the tip of the tongue to the back of the mouth. Improved versions of the prosthetic allowed the team to come up with a final iteration that mimics a realistic human tongue as well as can function to carry food from the tip of the tongue to the back of the mouth. The tongue we ended up with in the final iteration was 6.5 cm x 5.5 cm x 2 cm. To connect the tongue prosthetic to the oral cavity, a retainer was used with a strong neodymium magnet.

The unit consisted of the oral cavity which had the gear system, servo motor, and spindle housed in it. An EMG sensor was fixed on a person's arm. When the person flexed and a muscle impulse was registered, a signal was wirelessly transmitted that would cause the servo to turn 180°, turning the first gear in the gear system (Gear A). This would then turn the rest of the gears, leading to the rotation of the spindle as it was on the same spindle as the last gear. The rotation of the spindle would pull the fishing wire attached to it and lift up the linkage system in the tongue, allowing bolus to move from the tip of the tongue to the back of the mouth. The integration of the EMG sensor allowed for reduced circuit as well as more sensitive prosthetic movement as opposed to a force sensor. Using biocompatible materials, which was proved by Vasquez et al., allowed for an improved tongue prosthesis size and shape.

There is still work to be done in order to refine the design of the tongue as well as miniaturize components enough to have it ready for human testing. The progress of having bolus move from the tip of the tongue to the back of the mouth shows a lot of promise for the future designs and iterations. The testing carried out evaluated sensor sensitivity, actuation and thickness. Actuation testing revealed about 2.3 cm of actuation by the tongue which was greater than that of Vasquez et. al. The project was able to achieve and redesign an artificial prosthetic tongue which used an EMG sensor, gears, servo motor, and spindle, that successfully moved bolus from the tip of the tongue to the back of the mouth. The tongue was attached to the oral cavity through the use of a neodymium magnet and has potential to become self-contained.

9.2 Recommendations for Future Work

Future improvements to this project should focus on creating a better shaft for the spindle to rest on, replacing the TinyDuino with a PCB, having the circuit self-contained in the tongue, as well as run the system using a battery. Research into components which would aid in miniaturizing the circuit and having a self contained tongue should be a priority. Finding ways to integrate the EMG sensor more effortlessly would also be an important goal. More trials should also be conducted once some of the challenges are addressed as this will aid significantly in the functioning of the artificial prosthetic tongue device.

9.2.1 Create a Shaft for the Spindle

As mentioned in section 8.7, one of the challenges the team faced was that the spindle would slip and the linkage system wire (fishing line) would not turn as much. This caused the linkage system to not be able to lift as high as possible, which is why in some trials the bolus could not move from the tip to the back of the tongue. We recommend the next team to change the shaft of the spindle so that there is no spindle slipping.

9.2.2 Replace Tinyduino with a PCB

In order to miniaturize the circuit further, we recommend implementing the use of a PCB. We recommend exploring the options listed in section 6.1, which include a flexible PCB over the use of a regular one. PCBs are fairly inexpensive and are able to be mass produced easily. The PCB has lower risk of electrical shock as all the parts are self contained in the board. Having a flexible PCB which is bendable, the circuit could get rid of the arduino and TinyDuino circuits to be able to bend the PCB to be contained inside of the tongue itself.

9.2.3 Have Circuit Self Contained in the Tongue

In order to have a more realistic tongue as well as make it easier to be used in a human, we recommend having the circuit, linkage system and servo be self contained inside of the tongue. Once the circuit is miniaturized, various ways to seal the components inside of the tongue can be explored such as encasing the components themselves in a type of waterproof pouch, or to seal the entire system inside using silicone.

9.2.4 Run System Using a Different Power Source

The team is currently using the computer and a digital power source to power the circuit. However, when the prosthetic is to be used in a human there will not be the ability for these external power sources. We recommend that additional research be done to convert the circuit to being powered by a coin battery. Something that could be explored further is the idea of using saliva to generate power for the tongue[52].

9.2.5 Biocompatible Resins

The Vasquez et al. team[8,53] performed bacteria tests on the SmoothOn EcoFlex 00-30 silicone to determine if it could be cleaned easily and if it was bacteria resistant, for more information refer to Section 2.2.3. These tests should be done on each resin printed part that will be inside the oral cavity to ensure the resin will not harbor bacteria. A comparison test should also be done between various types of resin to see which brand and type works best in the oral cavity.

9.3 Team Reflections

This MQP fulfills the requirement for the undergraduate engineering degree and challenges students to research and design a project for the duration of one year. The 2021-2022 Artificial Prosthetic Tongue Team is grateful for the opportunity we had to learn and make mistakes while striving to reach the end goal. We were able to use our knowledge from our personal experiences as well as academic knowledge to create a better iteration than the previous. The project provided us all with a real world experience of working on a team, coming up with new and creative designs and solutions to problems, navigating teamwork as well as taught us the importance of making mistakes and learning from them.

We were fortunate to have a mechanical engineer and two electrical engineers on our team. This allowed us to come up with ideas that we could not have thought of on our own and consider ideas and obstacles from different angles. With the help from our advisors, we were given the opportunity to learn and grow not only academically but as individuals as well. We were able to take a problem and troubleshoot and consistently work together to solve it.

The team also participated in WPI's Touch Tomorrow event where we helped WPI promote STEM projects for high school and middle schoolers.Some pictures of us at this event can bee seen below in Figure 9.1. During this event, the team showcased our final prototype with the previous years' iterations: electromagnetic and pneumatic actuation. While presenting, the team came across a few speech pathologists as well as parents who expressed their excitement about such a necessary prosthetic. Overall, the project was an enriching experience that allowed the team to learn and grow as well as appreciate how complex the human body is. We are thankful to our advisors and our team members for making this such a joyous and memorable experience.

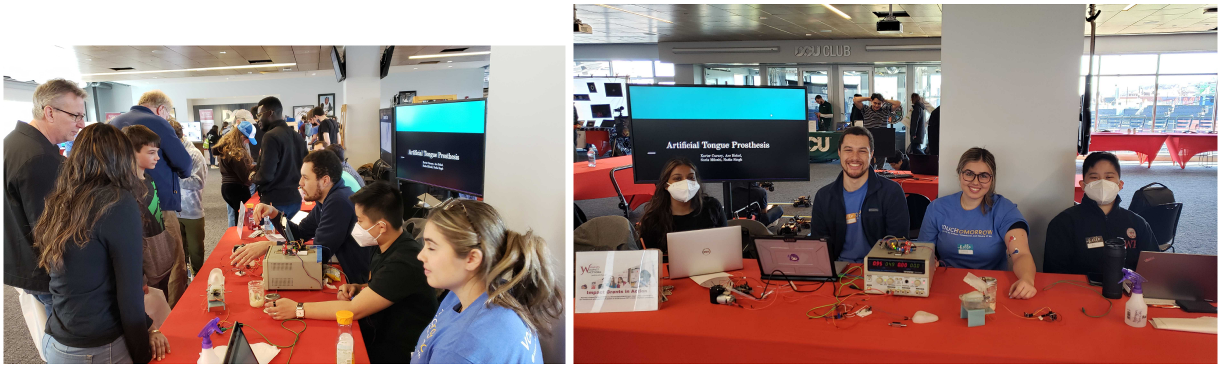


Figure 9.1: This Year's team at Touch Tomorrow Event

9.3.1 Personal Reflections

Xavier Curney

During this MQP I developed a lot of skills that were underutilized in my other classes. For example, one of the main skills I utilized during this MQP was researching related topics and general presentation skills. Reading plenty of papers on tongues got tiring quickly so learning how to pull useful information on them and how to incorporate that knowledge into the project or sharing that knowledge with group mates was of utmost importance. In addition to this, compiling said information into a clear and concise way for our weekly meeting was another unexpected challenge I faced. My way with words is lacking and elaborating was never my strong suit, but as the weeks went by I got better and better, or so I hope. The classes most similar to this experience was definitely ECE2799 which had a similar weekly check up and also required its members to think of solutions to complex problems.

Another big departure the MQP took from the norm for me was that it required thinking of real world solutions instead of ideal by the book ones. For example, sometimes parts would not work and would require replacing or an idea we came up with itself was flawed and we needed to change it and start over. These setbacks although annoying really made me value my planning time far more to try and think of better solutions and where they could possibly fail.

A big non-technical skill I tried to hone during my time on this project was properly documenting changes I was making with my daily reports and to take pictures of the circuits as we were making them. At the time when I was taking these pictures or documenting notes I felt as if I was doing it an excessive amount, but after I looked back hoping to remind myself what I had been thinking, I almost always wished I had written more or taken a picture from a different angle. This helped me to realize I should be going even further with the notes I take on keep and even then I still feel I could have written more. A good example of this is the code I wrote for the solenoid and servo. The previous group had implemented them using delays, so I tried to improve upon it by using timers instead so that the system would not stall. Due to the way I wrote it, I had trouble finding which parts were necessary to its continued function and which were excessive pieces that could be removed. With more notes and comments I could have made it very easy for myself.

Ace Holod

I believe this MQP was a great capstone to end my time at WPI. It challenged me to think outside the box and solve problems quickly. I gained new skills, both technical and non-technical, that improved myself as an individual and as a project member.

This project required a lot of knowledge I learned in most of my classes, especially my engineering courses and even some of my humanities courses. Specifically, my CAD classes (ES 1310, and ES 3323), Stress (ES 2502), statics (ES 2501), Modeling and Analysis of Mechatronic Systems (ME 4322) and Advanced Engineering and Design (ME 4320) gave me the skills to analyze the linkage and gear systems in the final prototype. ME 4320 particularly helped me learn skills to tackle large projects by breaking them into pieces and setting a timeline.

In terms of the skills I learned from this project, the most important skills were Blender, Solidworks and resin printing. I already had a background in Solidworks, but I learned more about implementing gears and stress analysis as it was imperative to create the gearbox system. I was familiar with Blender from previously working with another professor, but was able to improve my skills as half of the CAD models were created in Blender.

Additionally, I gained leadership and organizational skills throughout this project. Many times, I led the team in meetings and I kept everyone organized along with our files and testing results. It was crucial for this project for everything to be organized so we knew what was done and what needed to be done and by when.

Nadia Singh

Looking back, I am so thrilled that I got the opportunity to work on a project like this. This project made me truly understand the idea behind project based learning as well as opened my eyes to some of the problems faced by society that I hadn't thought about before.

I was able to utilize the skills that I had learned in my previous classes, including ECE 2799 (Electrical and Computer Engineering Design), ECE 2019 (Sensors and Circuits), ECE 2010 (Intro, circuits) and ECE 2049 (Embedded Computing in Engineering Design). These classes taught me the importance of delegating tasks in a group setting as well as keeping myself accountable for various parts of the project. I was able to apply knowledge I learned about the implementation of sensors as well as creating and modifying code and circuits. In class we always learned theory or did lab assignments that had us follow detailed instructions so it was interesting to see these skills applied in a way where I did not have instructions to follow but rather was challenged to create the path with my teammates. I have also taken a lot of classes that were theoretical and not hands-on, so it was a nice learning experience for learning and applying my theoretical knowledge.

I have learned a lot of new skills throughout the course of this project, including solidworks, how to use a resin printer as well as the curing and cleaning process, about biocompatible silicone, about the function of a tongue and the oral cancer statistics in the United States. I also was able to enhance my time management, teamwork skills, and public speaking/presentation skills. I enjoyed being able to showcase all of the new things I learned as well as the progress my team and I made on Project Presentation Day as well as at the STEM event Touch Tomorrow. Overall, I'm thankful for the experience as it has allowed me to grow academically and personally in more ways than I could imagine.

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Appendix

Appendix A - Actuation Videos

Iteration 2 Tongue

https://drive.google.com/drive/folders/1-61bacsVgOu5XC0TyPodpN9HFDJCqQsv?usp=sharing

Iteration 3 Tongue

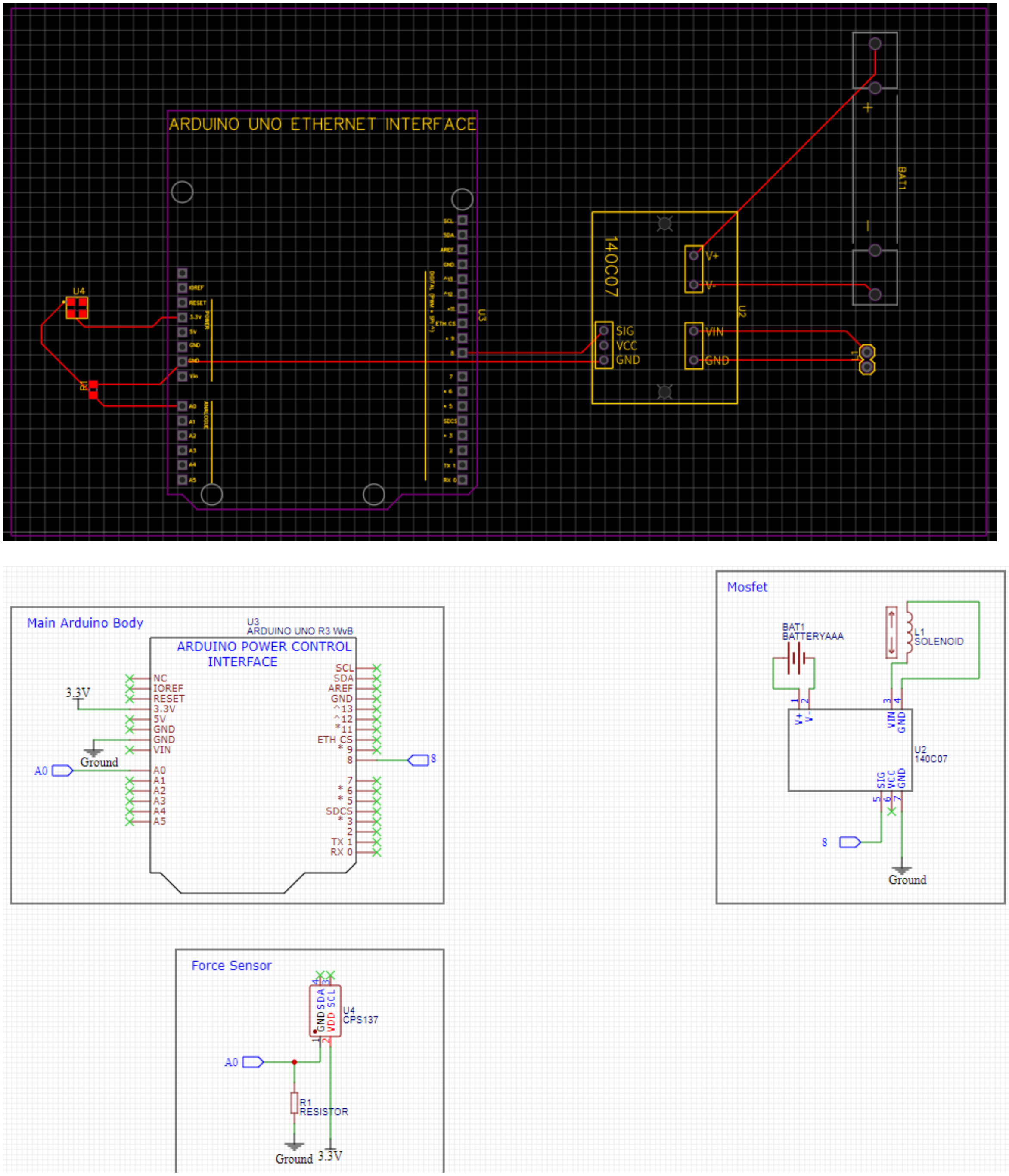
https://drive.google.com/drive/folders/1-42t_45EMzPBBs9WmOn1f5sjL6Ld7cBr?usp=sharing

Appendix B - Breast Pump

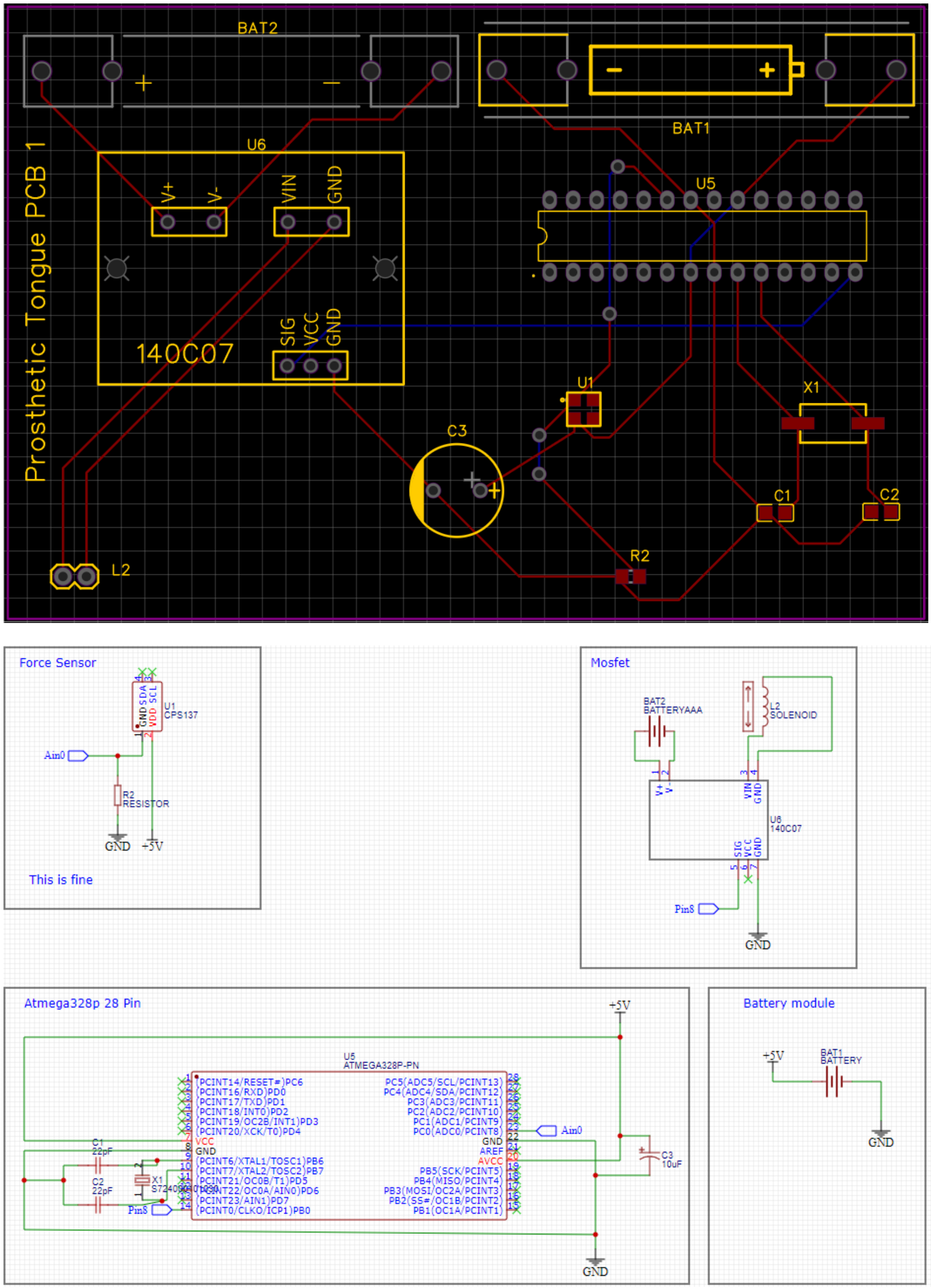
Link to the google drive where you can find videos of the breast pumps actuating different silicone tongues.

Breast Pump Testing

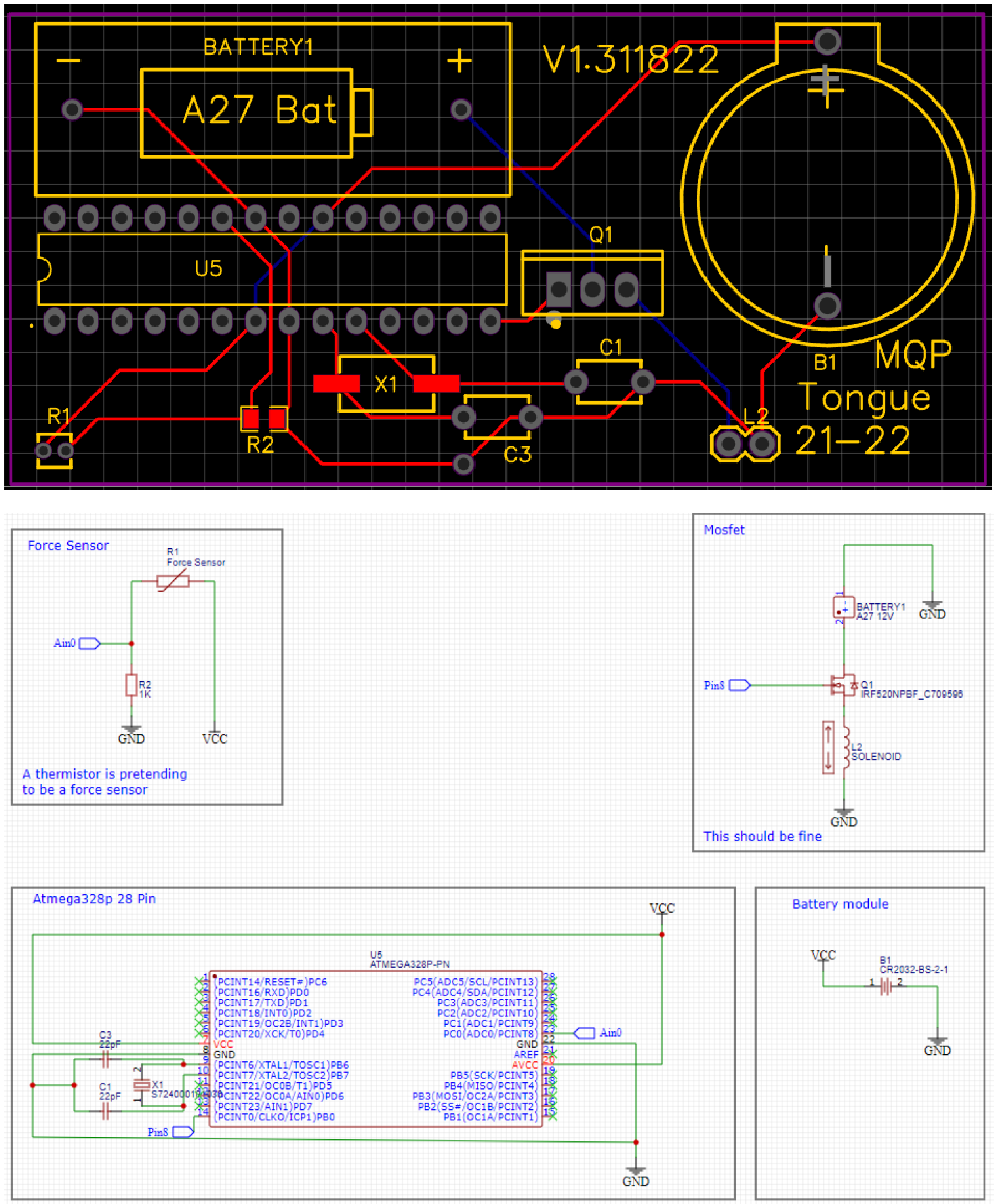
Appendix C - PCB Designs



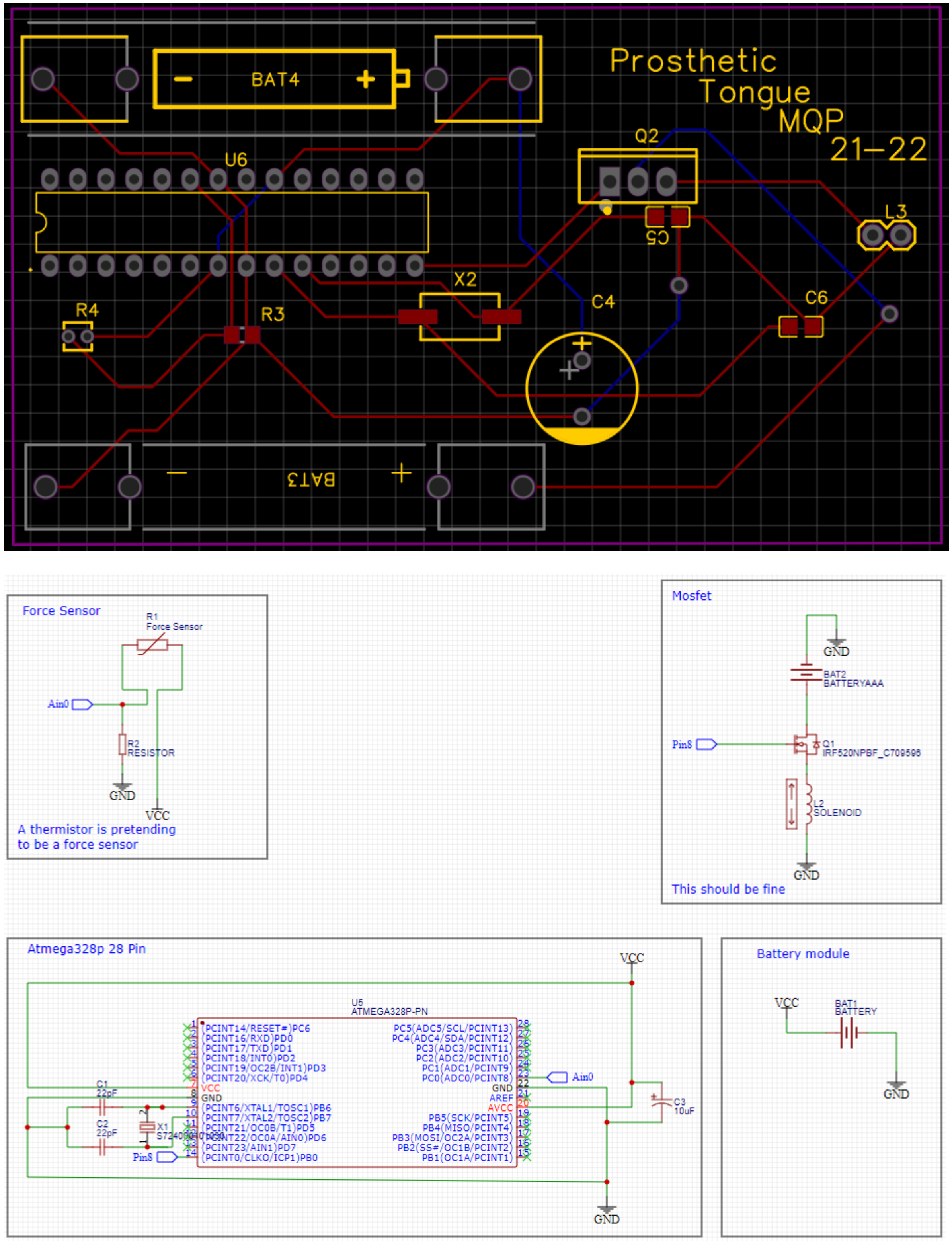
C.1 - Iteration 1 - Converted arduino circuit to pcb software



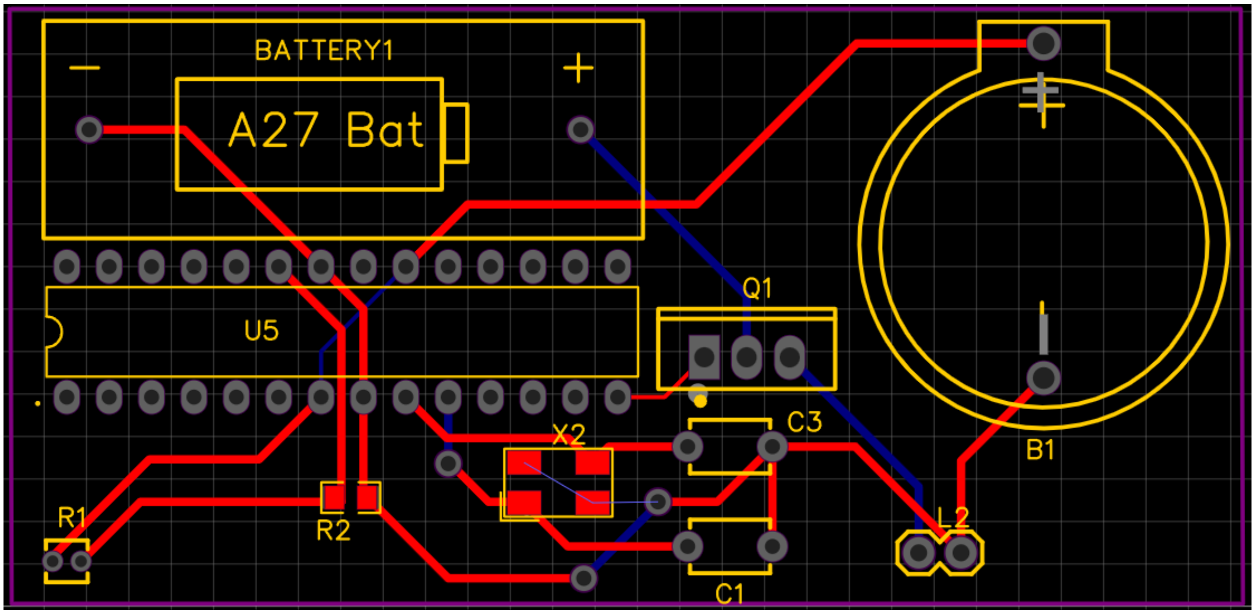
C.2 - Iteration 2 - Added parts to recreate an arduino instead of the arduino itself

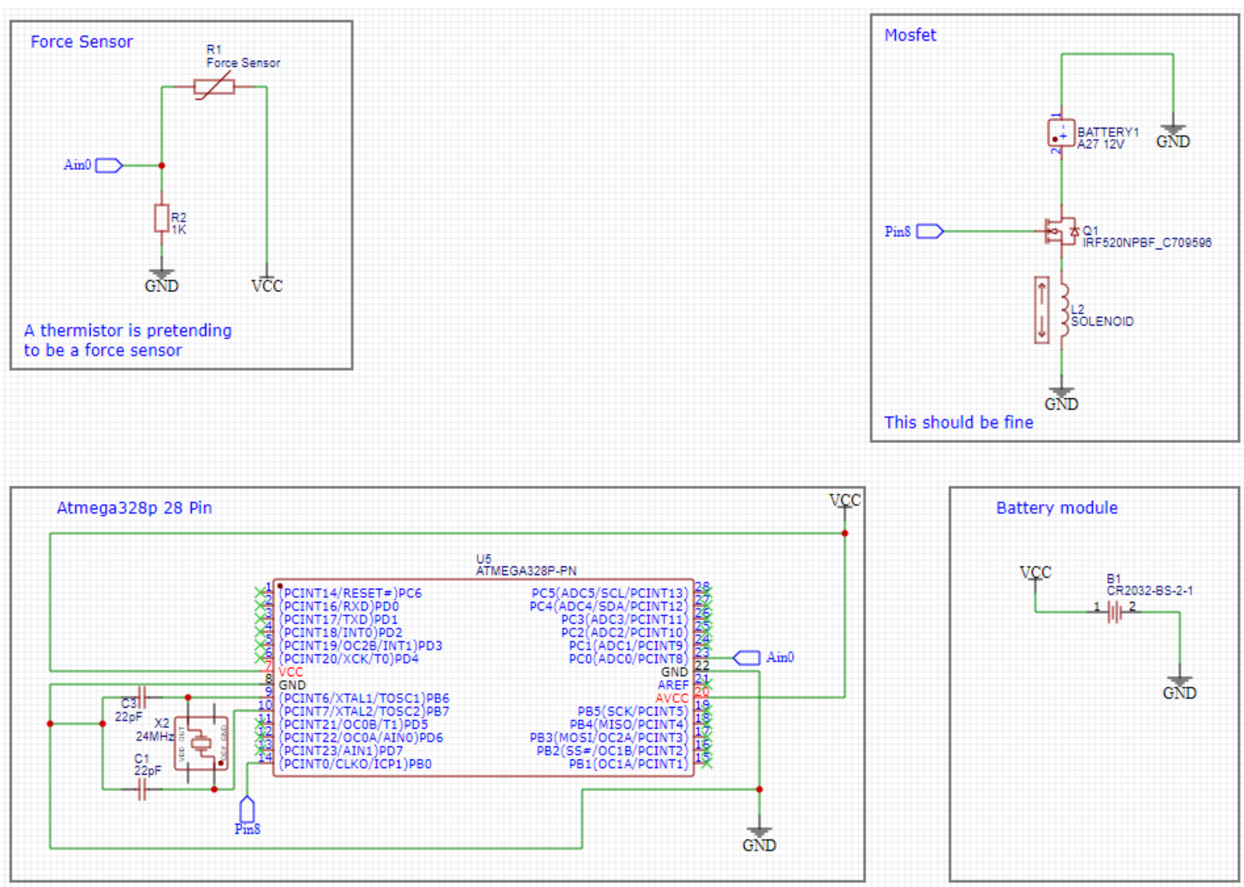


C.3 - Iteration 3 - Tried to reorganize parts to make device smaller



C.4 - Iteration 4 - Added parts that were in stock and mostly used surface mount parts





C.5 - Iteration 5 - Readded coin battery holder and made some wires thicker for voltage transfer

Appendix D - Link to Circuit Iteration Code

Link to code and all its iterations

https://github.com/XingLi18/2021-2022-Prosthetic-Tongue-MQP

Appendix E - Linkage and Gearbox Simulations

Link to google drive where all simulations are (gearbox and linkage system)

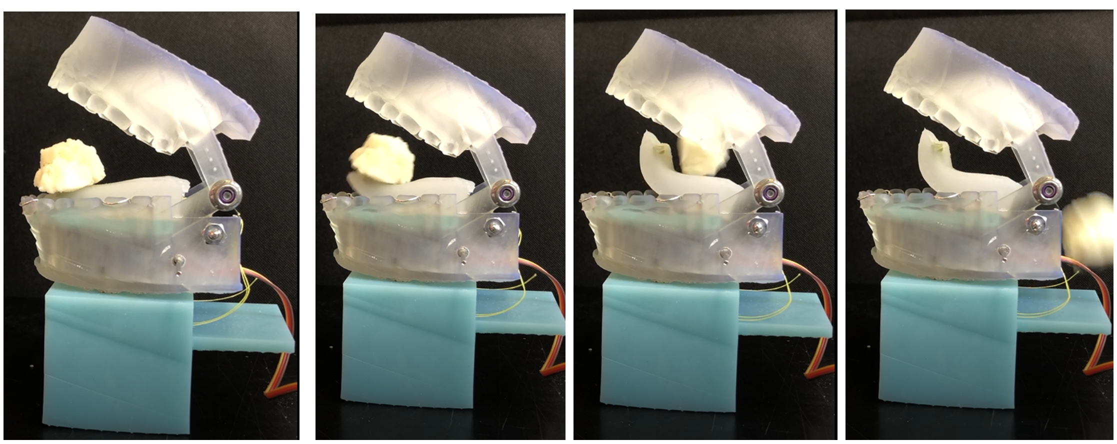
Simulations

Appendix F - Final Actuation Testing Videos

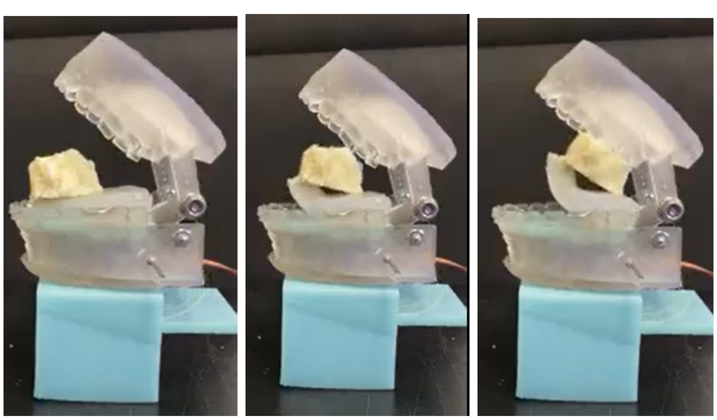
Folder in Google Drive

https://drive.google.com/drive/folders/1pVxy2sUDtGzxSrx7iZX8FcfwqrTD35zh?usp=sharing

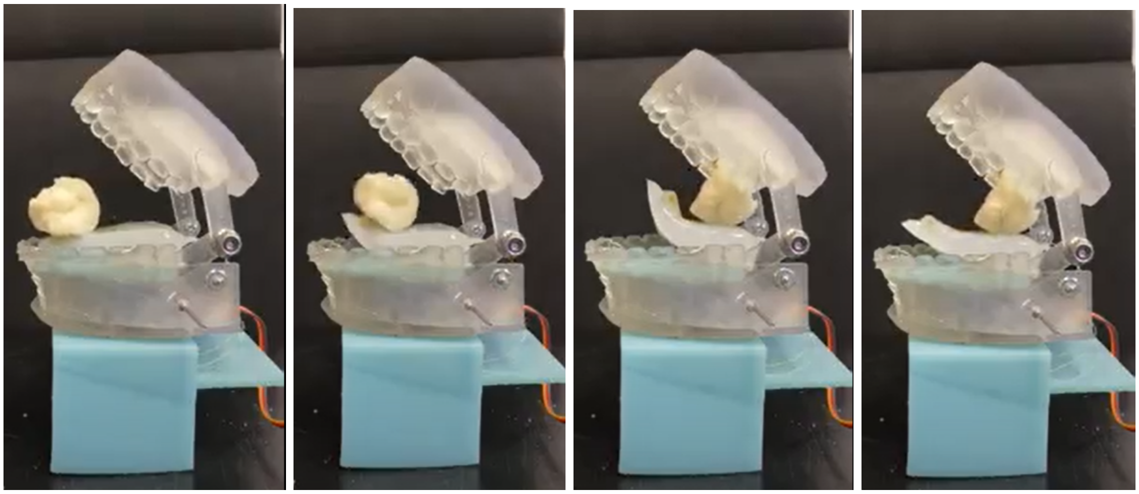
3g Trial 3 - fell backward down throat



4g Trial 2 -fell back to middle of tongue



5g Trial 1 - fell off front/side of tongue



Appendix G - Final Bolus Testing Videos

Folder in Google Drive

https://drive.google.com/drive/folders/104FomXqVAe28mt6keG2ArgetOx7M98IV?usp=sharing

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