An Improved Actuation System for an Artificial Tongue Prosthesis

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Submitted By:

Tatyana Barthold (BME)

Hope Soucy (BME)

Luese Ufuah (BME/ME)

Marc Voorhees (ME)

Declan Williams (RBE)

In partial fulfillment of the requirements for the Degree of Bachelor of Science

Advised by:
Professor Pradeep Radhakrishnan (ME/RBE)
Professor Dirk Albrecht (BME)

Acknowledgments

Our team would like to thank Professor Pradeep Radhkrishnan for all the help and assistance towards the development of this project. We express our gratitude to Professor Albrecht (BME) for his advice and assistance with the design of the oral cavity simulations. Additionally, we would be unable to have completed this project without the assistance of Ms. Barbara Furhman, (ME), who assisted us with our purchase orders and provided us with the supplies we needed to complete our project. Our team sincerely thanks The Women's Impact Network for sponsoring this project and giving us the financial support we require to carry out our research. We also like to thank the participants who gave their time and assisted us with data collection.

Furthermore, we would like to thank our families and friends for their encouragement and support throughout the course of this project. Their constant support has been critical in assisting us in reaching our objectives.

Finally, we would like to thank the whole professors and staff of the Department of Biomedical Engineering for establishing an environment that stimulates innovation and research. We are appreciative of the possibilities to explore our interests and improve our skills.

Thank you to everyone who helped make this project a success.

Abstract

A total glossectomy can cause communication, swallowing, and chewing issues for oral or oropharyngeal cancer patients. This project attempted to develop a self-contained prosthetic tongue that could assist in swallowing by transporting food from the front to the back of the oral cavity. Current tongue prostheses are used for cosmetic reasons, while there are few solutions that address feeding issues that glossectomy patients may face. One example is a glossectomy spoon that inhibits a user's ability to swallow food in an efficient or natural way. Past iterations of the prosthetic used pneumatic, electromagnetic, or mechanical linkage actuation methods and experienced a number of limitations, including the ability to move the bolus, to fit within the oral cavity, and to require surgical implementation. The previous linkage design successfully moved the bolus, however, it lacked miniaturization. After several ideations of designs, it was determined that a fewer number of links supported by a return spring system with a silicone pad would be ideal to move the bolus from the front to the back of the oral cavity. This apparatus would then be housed inside a retainer along with the entire control board, the motor and gear system, and eventually the battery. To ensure the system was operating in an accurate environment, an oral cavity simulation was developed as well as a fatigue testing of over 250 iterations of all portions of the device to ensure that it would maintain usability over long periods of time. This paper will describe the developmental procedures, outcomes, challenges, and future work.

Executive Summary

Summary of Background Information

According to the American Society of Clinical Oncology, an estimated 54,000 adults will be diagnosed with oropharyngeal cancer in the United States. The primary treatment path for an oral cancer patient is a glossectomy, the surgical removal of all or part of the tongue.

Bioimplants have emerged as a promising solution for dental disorders and other medical applications. Healthcare and medical devices are continually advancing within the field of bioimplants. Market survey reports expect the global bioimplant market to grow to $115.8 billion with an annual growth of 10.3%. Biomaterials can be either synthetic or natural and are intended to perform appropriately within a biological environment. Bioimplants can be utilized for replacing or re-establishing the function of a devastated disintegrated tissue.

The current market for tongue prosthetics is shallow. Many current prosthetic designs are static and are made for aesthetic purposes. These designs are not geared towards creating a prosthesis that is about to mimic the function of the tongue.

Functional tongue prosthetics have been explored at Worcester Polytechnic Institute (WPI), a private institution in Worcester, Massachusetts. First starting with a graduate student's air pump design to simulate the actuation of the tongue. Undergraduate senior capstone project groups, called Major Qualifying Project (MQP), have continued to work on and develop the prosthetic. Groups have moved from an air pump system to a magnetic actuation system to using a linkage system EMG to assist with the actuation movement. These groups have continued to miniaturize and increase the effectiveness of the prosthetic's ability to move a bonus from the front to the back of the mouth.

Summary of Project Methodologies

The team developed objectives and requirements for tongue actuation devices. There were five main goals identified that were deemed important to achieve: Design, Size, Control, Validation, and Safety. The design goal was to develop an improved mechanical actuation system that uses a smaller motor than the previous iteration. The size was to miniaturize the tongue to ensure that mechanical parts are easily implantable into the retainers as well as the oral cavity. The Controls were determined to develop a system with greater reliability than previous iterations and less prone to signal disturbance. Validation was determined by the ability of the device to move bolus similarly to a patient recovering from a total glossectomy. Lastly, the goal of safety was determined by the material chosen for the tongue prosthesis, more specifically if the material was biocompatible and durable. As part of the design goal, design criteria and prioritization in the form were developed and shown in a decision matrix. The matrix was designed by the team on a scale from 0 to 1 with 0 being the least important and 1 being the most important. The design criteria were: duration, displacement, size, integration, fatigue, and safety. The most important criterion that was identified by the team was safety. From these design criteria as well as the goals developed for this project, a final design was chosen for development.

The prosthetic tongue was designed with a motor and actuation control using a battery and a microcontroller. We created a slider design to better enhance the movement of the bolus in the oral cavity by combining elements of the prior and current designs. The first two links of the tongue from the previous iteration were placed on a sliding rail by this slider. The tongue itself was smaller and required less torque for vertical displacement while being able to produce higher horizontal displacement as a result of mounting the system on the rail.

Summary of Results, Conclusion, and Recommendations

The final oral cavity prototype was tested to continually gauge the temperature of the oral cavity. The LM35DZ temperature sensor was used in these trials. The graph in Figure 3 shows that the actuation device did not exceed a temperature above 37 ℃, the threshold temperature of the human oral cavity. In order to determine if the final design meets the criteria for the designated purpose, which is to move bolus from the front of the mouth to the back of the throat. Boluses of different masses, 3g, 4g, and 5g, were used to test. In total there were 3 testing conditions, jaw opened, jaw closed, and jaw closed with artificial saliva. Each condition was tested 10 times with 2 different gear ratios. The results showed that the majority of the trials had success in moving the bolus from the tip of the tongue through the oral cavity. The artificial actuation device requires four AA batteries for every 80 actuations, indicating that each actuation requires a significant amount of energy. With a total of 190 actuations showing no deformation to any structural or mechanical pieces, it is clear that the device can maintain its structure and function effectively while being powered by AA batteries. However, this also highlights the importance of considering the long-term costs and sustainability of using disposable batteries in such devices. As research in battery technology continues to advance, it is essential to explore alternative and more efficient power sources that can ensure the longevity and effectiveness of these artificial actuation devices while minimizing their impact on the environment.

After the results were concluded the team recommended that new gear adaptors should be developed to make custom gears that use square shaft holes. Another recommendation would be to input a retainer tilt by adding a retainer wire to support the front of the retainer. For the miniaturization of the device the team suggested PCB integrations, this would reduce the number

of wires as well as the shrinkage of the power source. Lastly, the development of a system that integrates well with all parts of the oral cavity environment to improve the movement of bolus with artificial saliva would help mimic the device's accuracy in the oral cavity.

Authorship

Section	Author	Editor
Abstract	Luese Ufuah, Tatyana Barthold	Declan Williams, Hope Soucy
Executive Summary	Tatyana Barthold	Hope Soucy
Introduction	Hope Soucy	Tatyana Barthold
Tongue Mechanics	Hope Soucy, Tatyana Barthold, Luese Ufuah	Hope Soucy
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Problem Statement	Marc Voorhees	Hope Soucy, Luese Ufuah
Standards	Tatyana Barthold	Luese Ufuah, Hope Soucy
2022-2023 Design Ideas	Marc Voorhees	Tatyana Barthold, Declan Williams
Design Criteria	Marc Voorhees	Hope Soucy, Declan Williams
Design Matrix	Marc Voorhees	Hope Soucy, Declan Williams
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Modeling the System	Marc Voorhees, Declan Willaims	Hope Soucy, Declan Williams
Printing Iterations	Marc Voorhees	Luese Ufuah, Hope Soucy
Control Module Design	Declan Williams	Hope Soucy

Section	Author	Editor
Gear Train Design	Declan Williams	Hope Soucy
Final Design	Declan Williams	Hope Soucy
Artificial Saliva	Tatyana Barthold	Hope Soucy, Luese Ufuah
Oral Cavity Simulation	Tatyana Barthold, Hope Soucy	Hope Soucy, Luese Ufuah
Boluses Recipe Testing	Marc Voorhees, Declan Williams	Hope Soucy
Temperature Testing	Luese Ufuah, Tatyana Barthold	Hope Soucy
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1. Introduction

Bioimplants have emerged as a promising solution for dental disorders and in other medical applications such as neurological issues, disfigurement, cardiovascular disease, orthopedic issues, and other conditions [1–5]. Healthcare and medical devices are continually advancing, especially in the field of bioimplants. The bioimplant market is increasing exponentially with the growth of the aging population, changes in lifestyle (especially ones that lead to chronic disease), technological advancements, and increased awareness of cosmetic implants [5]. Market survey reports expected the global bioimplant market to grow to 115.8 billion dollars by 2020 with a compound annual growth of 10.3% during that estimated period [6].

To meet this demand, bioimplants have been introduced to restore, support, or enrich the function of human tissue. These developed biomaterial applications are different from biological materials such as bone or tissue [7, 8]. Biomaterials can be either synthetic or natural and are intended to perform appropriately within a biological environment [9]. Bioimplants have a wide variety of procedures such as replacing to re-establish the function of a devastated or disintegrated tissue, modifying the function of a body part, assisting in healing, and correcting irregularities for cosmetic purposes [10].

Medical devices, such as prosthetics, can assist those who have lost an extremity or some other part of their body. Prosthetics are able to simulate the same function as the lost body part. The general prosthetic market is geared towards prosthetic limbs such as arms and legs [11], [12]. A quick search on “prosthetics” on Google Scholar shows that there are many scientific publications on prosthetic extremities. Meanwhile, if you search for “tongue prosthetic” the

search becomes more of a scavenger hunt to find relevant articles. Leaving a large gap for functional prosthetic tongues, where progress is much slower and less funded.

The tongue is an organ composed of skeletal muscle used for mastication, actuation, speech, and respiration. There is a shortage of organ donors. This places a demand on researchers to discover new ways to either mimic or replicate organs [13, 14]. There are over 54,000 oral cavity and oropharyngeal cancer cases per year in the United States [15]. Oral cancer most often occurs as a malignant mass that is often found in the tongue, tonsils, oropharynx, gums, and floor of the mouth [15]. Oral cancer has several linked causes such as tobacco and excessive alcohol use, as well as exposure to UV rays and Human Papillomavirus (HPV). Treatments for oral cancer can vary based on the severity of the mass [16].

The primary treatment path for an oral cancer case is a glossectomy. A glossectomy is the surgical removal of all or part of the tongue and is used to describe a variety of procedures where a small portion to the entirety of the tongue is removed [17]. If there are no contraindications to the surgery, removal of the tongue will take priority over chemoradiation therapy [18, 19]. There are many different procedural approaches to a glossectomy that are used to perform the removal of malignant or potentially malignant tumors from the oral cavity [18–20].

The current market for tongue prosthetics is shallow. Many current prosthetic designs are static and are made for aesthetic purposes. These designs are not geared toward creating a tongue that is able to mimic the function of a tongue. There are a few case studies showing that some aesthetic prosthetics have been adapted to function for those who only have proportions of their tongue remaining with the assistance of physical and speech therapy [21].

Functional tongue prosthetics have been explored at Worcester Polytechnic Institute (WPI), a private institution in Worcester, Massachusetts. First starting with a graduate student's air pump design to simulate the actuation of the tongue [40]. Undergraduate senior capstone project groups, called Major Qualifying Project (MQP), have continued to work on and develop the prosthetic . Groups have moved from an air pump system to a magnetic actuation system to using a linkage system EMG to assist with the actuation movement [42]. These groups have continued to miniaturize and increase the effectiveness of the prosthetic's ability to move a bonus from the front to the back of the mouth.

Like any prosthesis, the loss of a body part can decrease the quality of life and loss of functional abilities, prosthesis development, and rehabilitation has the potential to restore the function of the lost body part and increase the quality of life [12]. Our goal for this device is to increase the quality of life of a patient post a total glossectomy. By being able to move a bolus from the front to the back of the mouth, the device will assist in the feeding process.

This paper will follow a specific structure. First going into the literature review as chapter 2, covering vital information that the team used to inform their decision in designing the device. Chapter 3 will cover previous iterations of the MQP projects and their results, which the team used to understand the potential directions that this project can span and learn about the project as a whole. Methodology is covered in chapter 4 and shows the beginning of our project, what our initial plans were and how we were going to achieve and validate our design. Our design process is discussed in 5, going over design criteria developed. Chapter 6 will go into how we intended to mimic the oral cavity and our justification for doing this in order to validate our design. Chapter 7 span into the testing that our team conducted in order to validate our design. Next our final design is discussed in chapter 8, and final design considerations are discussed in

the next chapter. Chapter 10 transitions into improvements of our design in comparison to the previous iteration's. The conclusion of our overall project and experience in designing our device is covered in chapter 11. While chapter 12 covers future recommendations to guide future MQP teams. Our team individually reflects on their experience in chapter 13. References used throughout the paper can be found in the following the conclusion. The appendix is the last portion of this paper and will include parts referenfced throughout the paper that was unable fit within the main text of our report.

2. Literature Review

Chapter two will discuss further information needed in order for us to develop the whole picture of why we were developing our device. This section will explore the basics of the tongue and its mechanics. As well as look into oral cancer, common treatments, and the patient population to inform us about who we aim to make the device for. As well as potential materials and characteristics that would best suit the goals of our design.

2.1 Tongue Mechanics

Understanding the mechanics of the tongue provides a better outlook on its role in the oral cavity. In terms of this project, knowledge about the tongue's mechanisms and structure provides background on how the eating process works and what muscles help to conduct this process. A comprehension of this influenced the final design of the tongue actuation device. While the goal of the device is not to mimic the motion of the tongue but its function.

The human tongue is primarily a skeletal muscle [22]. It is composed of voluntary muscles that knowingly contract and relax. Skeletal muscles are made of muscle fibers that contain sarcomeres. These sarcomeres produce cells that induce force and are the basic part of muscle tissue. The behavior of the tongue is based on the structure and arrangement of the myofibrils. These fibers interweave in patterns within the different muscle groups of the tongue. Due to these patterns, the tongue has high strength as well as high maneuverability. Besides skeletal muscles, there are groups of muscles in the tongue that serve different purposes for the tongue's movement and shape. In the research article The biomechanics of the human tongue is composed of different muscles of the tongue and their function [22], [23]. For this project an

important muscle to note is the Styloglossus (SG), which is one of the muscles used for swallowing in the oral cavity, the Hyoid Bone is used to support the structure of the tongue and has a significant role in the swallowing process as well. The Digastric (DG) muscle is what allows for the mouth to open and the Palatoglossus (PG) is the muscle that lifts up the posterior part of the tongue to assist in the feeding process. As mentioned previously there are many muscles in the tongue that allow for the functionality of the tongue to perform different desired actions. The human tongue will constantly maintain some firmness, even when in a relaxed state. This is caused by sustained firmness in a tongue with relaxed muscle, muscle fibers remain contracted even in a relaxed state.

2.1.1 Mechanics when eating and swallowing

The tongue is a critical component for orofacial movements such as chewing, swallowing, speech, and respiration. For the team's project, we will be focusing on the tongues' involvement in chewing and swallowing. The tongue contributes to the formation, placement, maintenance, and pushing of a bolus. The tongue also impacts swallowing by evoking the swallowing reflex [28]. Kayjee et al. researched certain pressure at certain points on the roof of the mouth when the process of swallowing occurred [24]. This was done with a Plantae sensor attached to the roof of the mouth, this sensor had 5 channels attached to it. Each channel determines a place to determine different pressures at different regions as seen in Table 1.

Table 1: Plantae Sensor Channels and Their Respective Regions in the Oral Cavity.

Channel #	**Region Affected**
1	Anteromedial region
2	Mid medial region
3	incisive papillae and posterior edge of the hard palate
4	posterolateral regions of the hard palate
5	posterolateral regions of the hard palate

The table above shows the different regions of the oral cavity that activate when swallowing and their respective sensor channels.

It was important for the team to understand which areas of the mouth received the most pressure to determine for our design where sticking points of the bolus could occur. Meaning, that the team's device would actuate where there were points that potentially could interfere with the movement of the bolus.

2.2 Oral Cancer

An estimated 54,00 adults will be diagnosed with oral or oropharyngeal cancer in the United States [15]. Some of the most common forms of treatment for these types of cancers include radiation therapy, chemotherapy, or a glossectomy.

2.2.1 Glossectomy

The term glossectomy describes the partial or total removal of the tongue in order to remove potentially or cancerous masses from the mouth [18]. It is used as the primary treatment for oral cancer. The procedure removes malignant or potentially malignant tumors or masses from the oral cavity [17].

There are several different procedures and classifications of glossectomies. First, there is the partial glossectomy where less than one-half of the tongue is removed [25]. Next, there is the hemiglossectomy where half of the tongue is removed. Following that is the subtotal glossectomy where more than one-half of the tongue is removed, but not the entirety. Lastly, there is the total glossectomy where the entirety of the tongue is removed. Figure 1 below shows the potential removal approaches to a glossectomy and what is classified as a partial, hemi, subtotal, or total glossectomy.

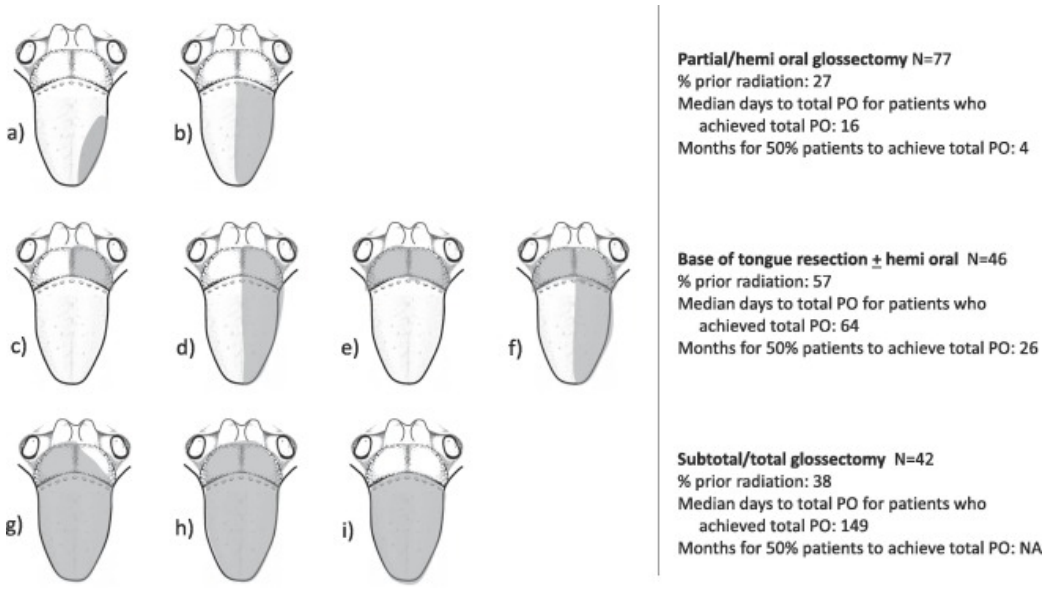

Figure 1: Different Glossectomy Approaches. Reproduced as if from [22].
The above figure shows various types of glossectomies ranging from partial to full.

There are three different surgical approaches to a glossectomy namely, transoral glossectomy, lip-split mandibulotomy, and transcervical pull-through [18–20, 25]. These surgical approaches vary based on the severity of the cancer as well as the surgeon's preference. The transoral glossectomy is the most common of the three procedures, as it is the least invasive and most straightforward approach. This procedure removes the tongue tissue within the oral cavity.

The lip-split procedure requires splitting the upper cleft and lower portion of the lip. This gives the surgeon more space to work in but is more invasive than the transoral glossectomy. This procedure is more time-consuming and has an increased risk for various complications. The transcervical approach enters the oral cavity from the bottom of the mandible, the lower portion of the jaw below the chin. This allows for the release of the tongue from the neck through the bottom of the mouth. This is another invasive and time-consuming procedure but there is less exposure compared to the lip-split mandibulotomy.

The importance of this information, allows our group to understand that there are various approaches to a glossectomy. The type of glossectomy can have different effects on the patient. Our group wants to develop a prosthetic for those who have undergone a complete glossectomy. As the patient has no functional tongue, which also allows us to have the greatest amount of space within the oral cavity to fit our design. Another key piece to developing our design is the patient population that will make up the potential customers for our design.

2.2.2 Glossectomy Patient Population

With a male-to-female ratio of roughly 3:1 among patients, oral cancer mostly affects men, who are also more likely to have glossectomy or the surgical removal of the tongue. In a study, Chen et al. looked at the traits of patients who had glossectomies and made predictions on recovery based on those traits [25]. They discovered a connection between oral cancer development and subsequent glossectomy and past or present smoking. Nearly half of the patient group who had glossectomies also frequently drank heavily. Body mass index (BMI) and the

incidence of oral cancer or glossectomy, however, were not significantly correlated, as the research population's distribution of weight classes was even.

According to Chen et al.'s research, BMI does not appear to be a significant risk factor for getting oral cancer or requiring a glossectomy, although factors like smoking and alcohol use may enhance the likelihood [25]. This demonstrates the multifaceted nature of glossectomy and oral cancer, with numerous risk factors and probable causes potentially contributing to the onset of both disorders. The impact of additional putative risk factors on the incidence of oral cancer and subsequent glossectomy in the patient population may require more investigation. It might be helpful to establish suitable therapies and support for patients who have glossectomy by being aware of the features of the patient population. The various risk factor analysis of glossectomy recipients from various studies can be seen in Table 2 below.

Table 2: Glossectomy Population Characteristics

Study	**% Male**	**Smoking history (% population)**	**Excessive alcohol (% population)**	**Mean age (years)**	**% Overweight/Obese**
Katna et al.	68	95%	N/A	48	N/A
Pyne et al.	69	N/A	N/A	53	N/A
Chen et al.	69	83	51	59.5	37

The table above shows the characteristics of the people that received a glossectomy from various studies.

2.2.3 Glossectomy Recovery and Complications

After a glossectomy, a patient can remain in the hospital for a week [18, 21]. Recovery can last several weeks before the pain begins to subside. Oral hygiene during the recovery period is pertinent to avoid infection. The patient also has to pay special attention to what they eat and are typically put on a regulated diet to ensure they are eating soft foods. Many patients will likely

go to physical and speech therapy to regain control of any remainder of their tongue and intrinsic muscles in and around the oral cavity. One device that is used to assist in this recovery is a glossectomy spoon (seen in Figure 2) which is used to assist in the feeding process by pushing food to the back of the mouth [26]. This device can range from 200-400 dollars.

Figure 2: Glossectomy Spoon. Reproduced as if from [23].
The glossectomy spoon is a device used post-glossectomy that overtakes the role of the tongue during recovery by manually pushing a bolus down the throat.

There is a list of complications that can follow a glossectomy. Some of the symptoms include pain, bleeding, and infection [27, 28]. Some patients have to get additional surgery for further removal of the tongue or an additional procedure on their neck due to muscle loss. Dysarthria, slurred speech due to weak oral muscles, is common as the muscles within the mouth have been removed or altered during the procedure making them weaker. As these muscles are vital for the shape and position of the tongue.. Speech and swallowing functions need to be relearned via speech and physical therapy. In more extreme cases, patients experience salivary fistula where there is a lack of communication between the salivary glands or ducts in the mouth

[29]. Another more severe complication is osteoradionecrosis, bone cell death, which occurs when radiation is paired with a glossectomy.

2.2.4 Glossectomy Prosthetics and Glossectomy Rehabilitation

The population of glossectomy patients may also be influenced by underlying medical disorders such as cardiovascular disease, diabetes, and immunosuppression. These diseases can have an impact on the surgical technique, perioperative treatment, and overall recovery of glossectomy patients. Tumor features such as size, location, and stage are also important in deciding the amount of the glossectomy and subsequent healing outcomes [26].

Prosthetics, sometimes known as tongue or palatal obturators, are custom-made devices used to restore speech and swallowing function following glossectomy. These prosthetics are normally composed of biocompatible materials and are designed to fit securely in the mouth cavity, effectively sealing the gap left by tongue removal [26]. There are two types of prostheses: palatal obturators and speech assistance prosthetics.

Palatal obturators are used to repair oronasal fistulas, which are aberrant connections between the oral and nasal cavities that might develop following a glossectomy [21]. By preventing food and liquids from entering the nasal cavity and enhancing the airway for speech production, these obturators aid in the restoration of normal speech and swallowing function.

Speech aid prostheses, also known as palatal augmentation prostheses, are intended to replace lost tongue volume and offer support to the soft palate. Both of which are important in speech production. These prosthetics can be custom-fitted to the patient's unique demands and can be utilized to restore articulation, resonance, and intelligibility of speech.

Following a glossectomy, rehabilitation may also include a combination of therapies such as speech therapy, swallowing therapy, and oral motor exercises. Speech therapists play an important role in helping individuals with glossectomy restore speech and swallowing function by performing exercises to strengthen the residual tongue muscles and improve articulation and resonance. Other rehabilitation techniques may include dietary changes, such as texture changes to facilitate safe swallowing, and counseling on coping strategies for the emotional and psychological issues that may develop following glossectomy.

Evidence suggests that using prostheses and rehabilitation procedures after a glossectomy can considerably improve speech and swallowing outcomes. For example, found that using palatal obturators in individuals who had glossectomy increased speech intelligibility and reduced aspiration risk [27]. Katna et al. conducted another study that emphasized the value of speech therapy in enhancing articulation and resonance in patients with glossectomy [28].

Prosthetics and rehabilitation procedures, such as palatal obturators and speech therapy, are critical in the healing and rehabilitation of patients after glossectomy. These interventions can aid in the restoration of speech and swallowing function, the improvement of the general quality of life, and the reintegration of patients into their everyday activities. To optimize functional outcomes, healthcare practitioners must identify and treat the particular needs of individuals undergoing glossectomy, as well as provide appropriate prosthetic and rehabilitative interventions.

2.3 Biomaterials

Biomaterials are important in the development of prosthetic devices, such as tongue prostheses. Several variables must be addressed when selecting a material for an implant,

including biocompatibility with live tissues, osseointegration, corrosion resistance, and mechanical qualities [7]. These variables are critical in ensuring the implant's safety, effectiveness, and ability to survive the physiological demands of the oral cavity environment.

Surface modification enhances the performance of metallic alloys. Based on the corrosion rate, an implant can be toxic [30]. An implant using metallic alloys may have to be modified to enhance its useful properties, especially when used for body implants. As the metal corrodes, harmful metal ions enter the body’s fluid and lead to the implant's failure in addition to having harmful effects on the body’s cells.

Stainless steel does not corrode under an oxygen-containing atmosphere. Stainless steel is used for internal bone fixators, sternal wire, and bone fixation wire [7, 8, 10]. Stainless has good torsion properties and elongation. Cobalt-based alloys what good tensile strength and wear resistance but poor plasticity. Corrosion resistance is better than that of stainless steel. Titanium alloys have excellent tensile strength and wear resistance with fair plasticity. Lower Young’s modulus than both cobalt-based alloys and stainless. Titanium alloys are used in bone fixators due to their lower modulus. Titanium materials are able to form thin sheets of titanium oxide which prevents corrosion.

The surface modification allows for biofunctional, corrosion, and tri-biocorrosion-resistant implants [30, 31]. One is bioactive coatings which can simulate a better chemical composition of the surface the implant is in contact with. It can also improve the strength of the implant or other mechanical properties. Another surface modification is a passivation-oxide layer on metallic implants, which is important for the implant's biocompatibility and corrosion resistance [32]. Ion beam surfacing allows for better biocompatibility, wear resistance, and corrosion resistance by creating layered formations on a

substrate [33]. Surface texture is also used to reduce corrosion, increasing biocompatibility and promoting osseointegration. Examples of metals/metallic alloys include stainless steel, cobalt-based alloys, titanium-based alloys, and magnesium-based alloys.

2.3.1 Implant material

The substance of the implant is critical in the development of a tongue prosthesis. The implant's biocompatibility is critical, as it must be compatible with the living tissues of the oral cavity without generating unfavorable reactions or inflammation [34]. The material should also exhibit osseointegration qualities, which allow the implant to integrate with the surrounding bone to give stability and support [30].

Corrosion resistance is another important consideration when choosing implant materials. The oral cavity is a constantly exposed environment to saliva, food, and other fluids, which can promote corrosion of the implant over time. As a result, the material utilized for the prosthetic tongue should be corrosion-resistant to ensure its longevity and performance [34]. Mechanical qualities of the implant material are important in addition to biocompatibility and corrosion resistance. To endure the mechanical forces involved in swallowing and chewing, the material should have adequate strength, hardness, and durability [28]. It should also be flexible enough to allow for natural tongue motions during swallowing and chewing without affecting structural integrity [34].

Finally, choosing an acceptable implant material is an important aspect of the construction of a tongue prosthesis. To ensure the safety, effectiveness, and longevity of the prosthesis in the oral cavity environment, the material should have biocompatibility, osseointegration, corrosion resistance, and adequate mechanical qualities. This research was vital for informing us about the possible materials that our design could be composed of.

2.3.2 The Lotus Effect

The lotus effect is a material's self-cleaning property as the material is superhydrophobic [35], [36]. This was inspired by the lotus flower whose waxy leaves and texture effortlessly clear off dirt and water from its surface. Titanium dioxide is the lead ceramic in biomaterials in terms of superwettability. Titanium dioxide along with many other materials can be "doped" which alters some of its properties. This allows for it to be antibacterial. Titanium oxide had low conductivity contributing to its thin surface electrochemical oxidation layer. This gives it good mechanical properties. The properties of titanium oxide and other materials to be doped and have their surface characteristics changed, allow us to explore further surface characteristics that can benefit our design. Superhydrophobic material could assist our device in keeping clean from food particles as well as bacteria.

2.3.3 Superhydrophobic Biomaterials

Firstly, a biomaterial can be either a synthetic or natural material that is intended to interact with biological systems to evaluate, treat, augment, replace, or regenerate any tissue, organ, or function in the body [7, 9, 37]. The superhydrophobic characteristics allow for the material to self-clean and can assist in recovery, preventing the extra hassle of either device removal or infection [31]. These materials can control protein absorption, can be used for drug delivery, and increase cellular interaction while preventing bacterial growth [32].
Some superhydrophobic biomaterials include Polyethylene glycol (PEG) and polymethyl methacrylate (PMMA).

2.4 Oral Cavity Characteristics

This section examines the oral cavity's properties, such as the existence of germs and biofilms, the temperature, and the relevance of saliva. It discusses how bacteria cling to various surfaces and build biofilms, as well as how dental gadgets might provide new growth channels [38]. It also mentions the three primary bacterial strains linked to biofilm production, as well as the most frequent type of biofilm present in the oral cavity - dental plaque [39]. The part also discusses the temperature of the oral cavity and how it helps bacteria survive. Finally, it discusses the nature and significance of saliva in the oral cavity, including its involvement in digestion and biofilm formation.

2.4.1 Bacteria and Biofilm

Bacteria tend to attach to different surfaces, grow, and form colonies. The adhesion depends on the type of surface characteristics which can either inhibit the growth of bacteria or accelerate the growth of bacteria. Biofilms are when microbes (bacteria and ect.) form a permanent attachment to the surface and are very common [40]. In the oral cavity, oral biofilms can typically be found, especially in response to a foreign body being added to the environment. The formation of oral biofilm is a multi-step process and can be caused due to the interaction between the accumulation of saliva in the oral cavity and microorganisms, which can adhere to both oral soft surfaces, like a person's gums line and oral hard surfaces, like teeth. In terms of dental devices like dentures, palatal orthodontic appliances, and palatal obturators, biofilms are likely to grow given the fact that these foreign bodies allow for new avenues of growth [39], [40]. The majority of dental devices are made of dental resin material, meaning the surface roughness as well as the surface free energy influence the adhesion of microbial and may even

increase this adhesion to these products [31]. There are three main strains of bacteria that are associated with biofilm formations, streptococci, actinomycetes, and lactobacilli. The most common biofilm found in the oral cavity is dental plaque, unlike regular biofilm that grows at a slower rate, dental plaque grows fast in the oral cavity [32].

2.4.2 Temperature

The oral cavity temperature is around 37℃ unless one is sick and their whole body temperature rises due to a fever. The reason for the temperature is to support the survival of bacteria in the oral cavity oral [41]. As previously mentioned not all bacteria are bad, bacteria are needed for the survival of the environment.

2.4.3 Saliva

Saliva comes from 3 different glands in the mouth, the parotid, submandibular, and sublingual glands, and is primarily composed of water. On top of water, saliva is also composed of electrolytes, proteins, peptides, and in some cases, nasal secretion [38, 41]. Saliva is known to be the main mode of transmission in the oral cavity, its natural properties include a pH of 6-7 and different types of proteins and enzymes that help break down food and fight out the formation of biofilms [39]. Salvia is very important to the overall health of the oral cavity and functionality of the oral cavity.

3. Previous Iterations

The four previous iterations of this project were reviewed for an advanced understanding of the overall progression of the project and techniques for improvement. Previous MQP groups

used air pumps, electromagnetic actuation, and servo-based linkage systems with EMG. Looking into the previous iterations assisted in determining the actuation method.

3.1 Iteration 1: Araya 2019 [42]

In 2019, The first prototype of the prosthetic tongue was created by Francis Araya, using a pneumatic system for actuation. This iteration initiated a series of other projects attempting to develop an actuation device for a tongue prosthesis.

3.1.1 Artificial Design

In the first iteration, Araya designed a silicone prosthetic tongue that underwent different technical phases. The dimensions of the final design were 2.4 inches in length, 1.8 inches in width, and 0.24 inches in height. As seen in Figure 3 below, the first set of iteration included inlet tubes at the posterior tongue and three layers of siliconeEco-flex 00-30 material. However, in the final design, the prototype included two layers of the siliconeEco-flex 00-30 material with the top layer acquiring three sections of structured PneuNet rows acting as air chambers. The three sections were divided into front, middle, and back. The bottom layer of the final design included an inlet tube connected to each section of the top layer. Figure 4 below shows both layers of the final design. These tubes provided support for respective inflation and reduced possible air leakage.

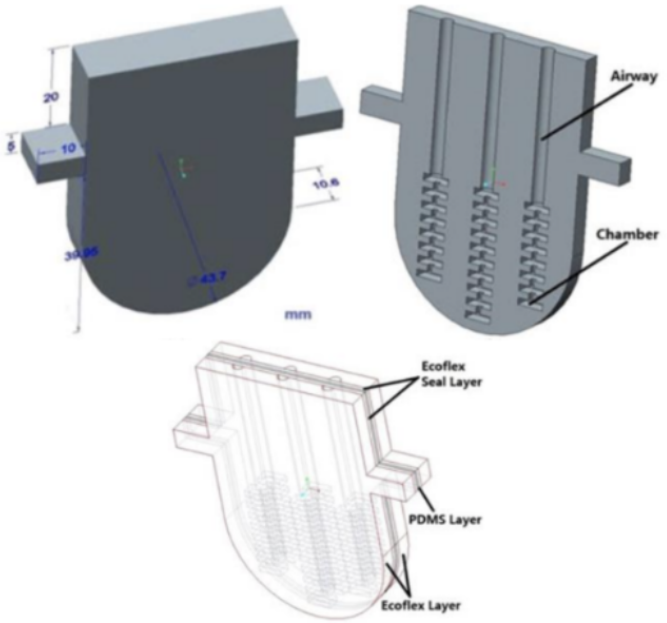

Figure 3: The First Iteration of the Tongue. Reproduced as if from [42].
The first iteration of the pneumatic tongue included three layers with the center layer have pneumatic channels.

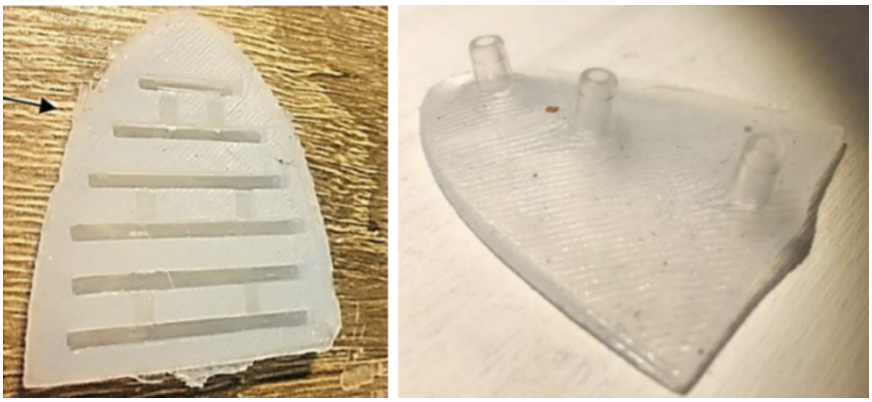

Figure 4: The Final Silicone Artificial Tongue Design. Reproduced as if from [42].
The final version of the silicone tongue included a top layer (left) with pneumatic channels and bottom layer (right) with attachments to the pneumatic pumps.

3.1.2 Control Module

The components of the control modules included an Arduino Uno microcontroller, three two-way solenoid valves, three 4.5 psi pneumatic air pumps, and wires and tubes, as seen in Figure 5 below. The pumps were connected to an inlet tube in each section of the tongue. The

cover portion of the tongue was 3D printed and utilized to hold the control module components together, acting as a protective coat. In the final design, this portion allowed for the prototype to be keenly observed and contained a skin color pigment for a more realistic look. For the final appearance, the inlet tubes were placed through respective slots in the cover portion of the tongue and the ends of the tubes were placed respectively on the solenoid valves.

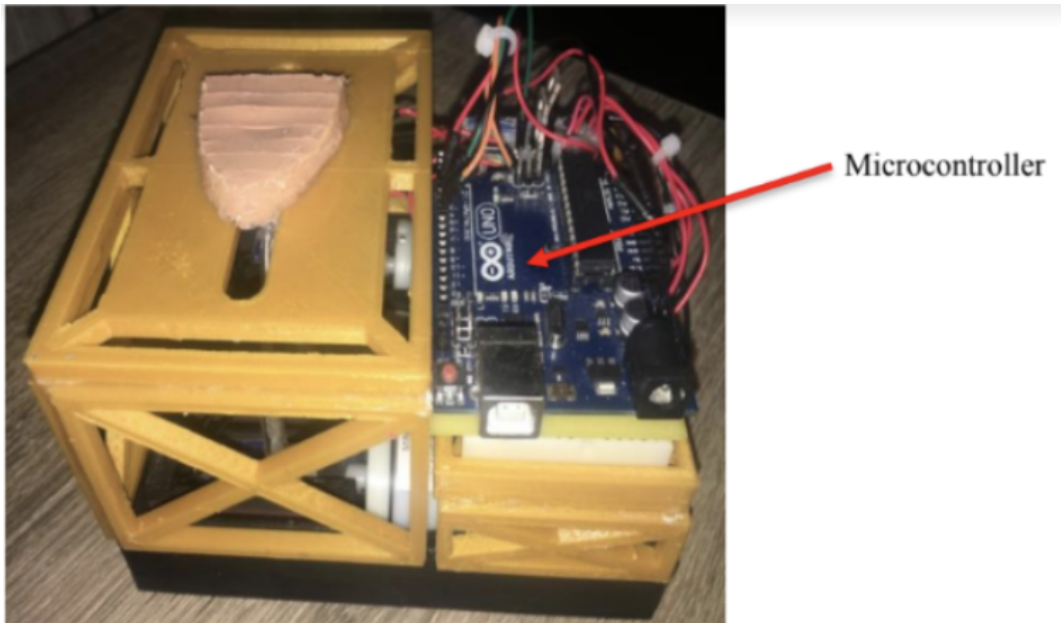

Figure 5: Complete Set of Final Silicone Artificial Tongue Design. Reproduced as if from [42]. *The final design set up included a control module, mini pumps, and a prosthetic tongue. The microcontroller is also labeled in the figure.*

3.1.3 Testing

Araya performed both manual actuation and air pump actuation tests on the prosthetic tongue to examine the displacement during actuation. The analysis of the tests was compared with height and pressure values from previous research studies. The manual actuation test consisted of three 100ml syringes being pressed into the prosthetic tongue to make a wave-like motion in the tongue from anterior to posterior. The air pump actuation test consisted of the control module and 3D printed cover as shown above in Figure 6. Three mini pumps were using

to move the prototype for displacement results. In both testing procedures, black beads served as markers in each section of the prototype and a video of the side view was recorded. The recording was put into Tracker[34], a tracking software, where the tongue's displacement was determined.

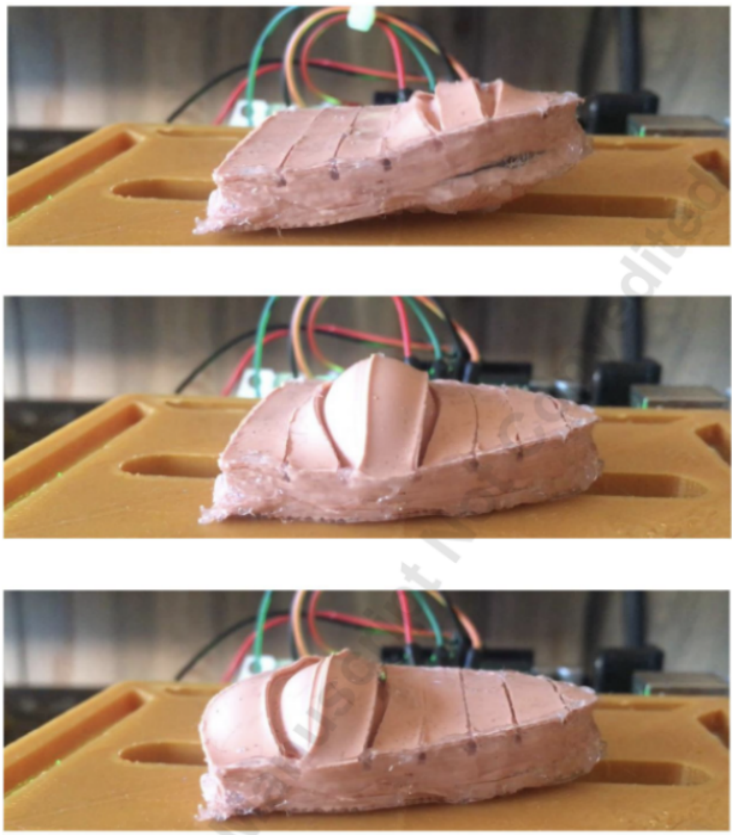

Figure 6: Actuation of Final Tongue Prototype. Reproduced as if from [42].
The figure above shows the actuation of the final tongue prototype. The channel filled with air from the front to back.

3.1.4 Results

As a result, the prosthetic tongue actuated a maximum of 0.417 inches in the anterior section, 0.45 inches in the mid-section and 0.242 inches in the posterior section. Internal pressure readings of the tongue were not observed, however, the air pumps presented a 6.5psi value, which was used as theoretical pressure for force per length. The theoretical pressure values in the

air chambers were less than those of the values found in previous research studies. The process of collecting actuation measurements with a ruler can be seen in Figure 7.

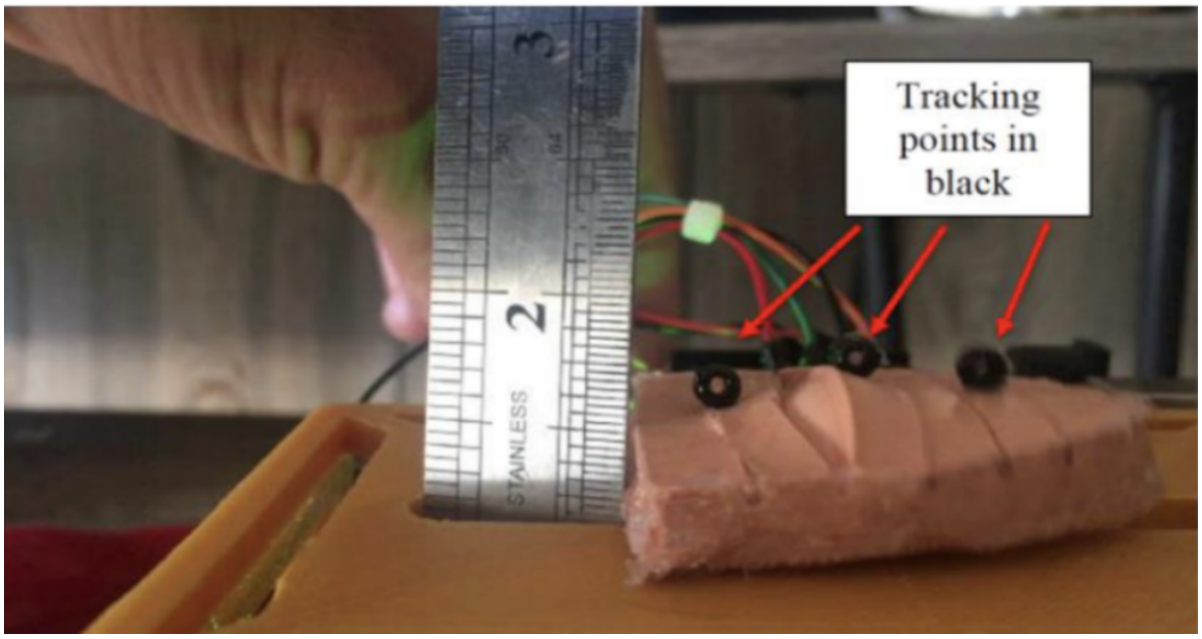

Figure 7: Displacement Test of Final Tongue Prototype. Reproduced as if from [42].
The displacement testing of the final tongue actuation included tracking markers on each section of the actuation cycle measured visually with a ruler.

3.1.5 Conclusions

To conclude, iteration 1 successfully created a firm foundation for the progression of the prosthetic tongue. The tongue was able to meet the goal of moving in the three chambers, to create an actuation movement from the anterior to the posterior side.

Limitations that occurred in this iteration include the design and size of the controls, as the tongue was too large to be positioned in the oral cavity. Thus, miniaturization of the tongue was needed. Additionally, a pressure sensor was needed for pressure monitoring in the control module during actuation. Another barrier in this iteration was the air leakage in the PneuNet formation. The inflation of the silicone material caused multiple tears in both layers of the tongue

despite the glue bondage of the layers. This caused air leakages, ultimately affecting the tongue's performance. A suggestion to address this was utilizing better quality silicone, silicone sealant, or adhesion, and changing the locations of the input tubes. Another limitation that occurred with air pumping was the inability to expand the silicone in the lateral direction.

The restriction of bolus movement occurred due to tears and gaps in the material, thus, using a bolus with less friction may be beneficial. Difficulty also resulted in inflation in the superior section of the tongue due to the molding assembly of the top layer of the tongue.

3.2 Iteration 2: O'Neil et al. 2020 [43]

The O'Neil et al team continued Araya's project and determined ways to improve the prosthetic tongue overall. For example, in this second iteration, essential goals included an actuation time of one second, integrating a retainer with a prosthesis into the oral cavity, body safety, creating a testing module, and validation through simulation and testing. This section will discuss how the second iteration achieved the creation of a prosthetic tongue that aids deglutition and is suited for the oral cavity.

3.2.1 Prosthetic Design

The material used in this iteration remained SmoothOnEcoflex 00-30. However, there were four total remodels before determining the most feasible design. A design flow process was determined based on these remodels with an emphasis on the creation of the design, 3D print molding, cure elastomer, sealing parts using glue (if needed), test pressurization, confirmation of seal hold and retesting of pressurization, integration of casing, and integration of retainer.

Firstly, there was a design that completely resembled the first iteration's design except there were different PneuNet structures. Another design completely resembled this first design except it contained PolyUrethane. There was a third design, which was the most successful, containing silicone Eco-flex 00-30 and Polyvinyl Alcohol (PVA) for the PneuNet structures. This model was considered to have a single component. And the last design utilized a linkage system. For redesigning the first iteration, Bridges et al. manufactured five prototypes each for both the posterior and inferior openings of the tongue; two of these prototypes can be seen in Figure 8 below. The air chambers in this model were not developed due to restricted lab access. The third remodel successfully underwent over twenty rounds of pressurization testing. The first two remodels failed within five cycles of pressurization testing due to the inability of the glue to hold the parts together.

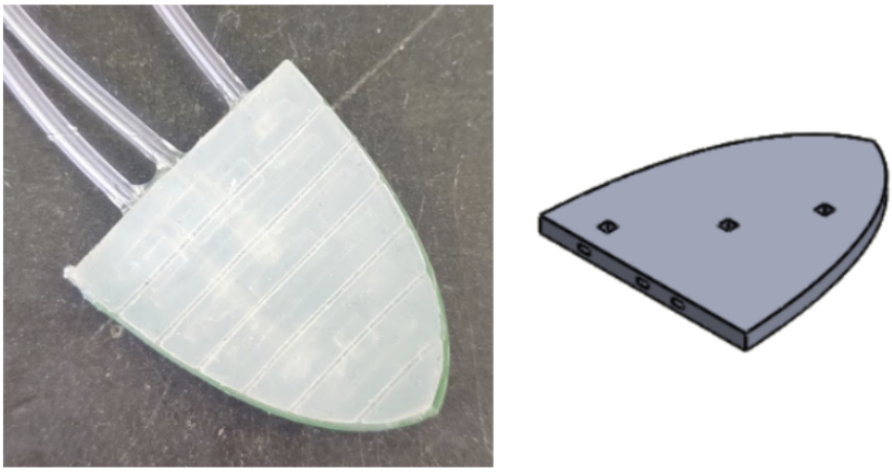

Figure 8: Rear Entrance for Pneumatic Tubing from 2020 Project. Reproduced as if from [43].
Shown in the figure above is the posterior opening model (left) and the inferior opening design (right) of the third prototype.

The first remodel was created using Araya's design with altered Pneunet structures as seen below in Figure 9. In this remodel, a single prototype was created and the air pressure was

able to exert an equally distributed force due to the larger area, causing better bolus movement. The second remodel is very similar to the first design with the change of a thinner superior section and polyurethane instead of silicone material as seen below in Figure 10. This prototype failed pressurization testing due to the low strength of the plasma bond.

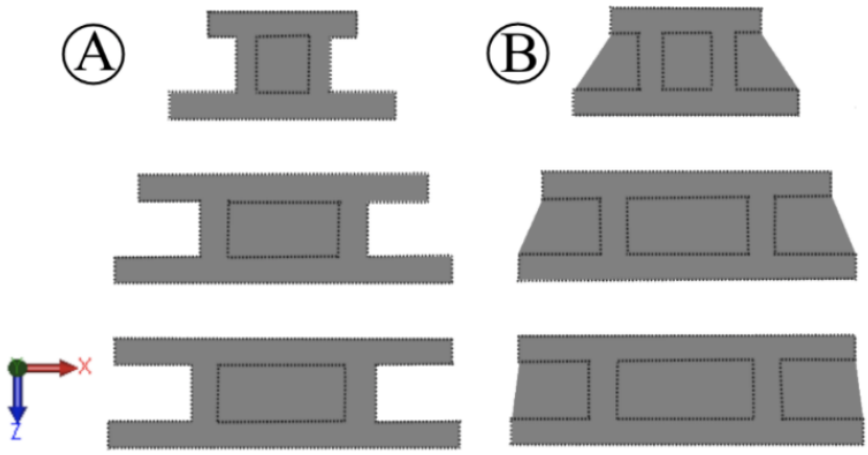

Figure 9: Interior Design Channels. Reproduced as if from [43].
In the figure above, the interior design channels can be seen with the dotted overlay depicting the previous iteration structures [43].

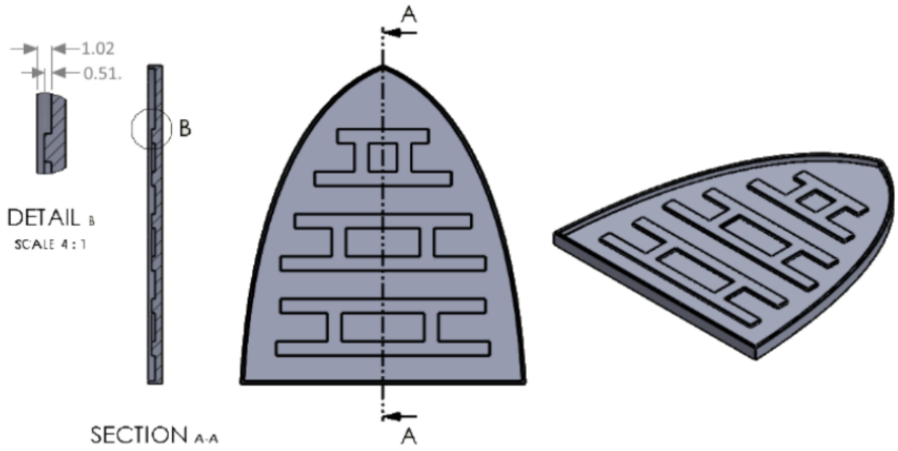

Figure 10: Primary Design Middle Mold from 2020 Project. Reproduced as if from [43].
In the figure above, the Polyurethane mold for the middle layer can be seen.

In the third remodel, the three chambers inside the tongue were created with Polyvinyl Alcohol (PVA), which allowed for the dissolving of PVA material in water after the silicone cured over the mold, as seen in Figures 11 and 12. The dimensions of the third remodeled tongue were 4 cm x 3.5 cm, miniaturized enough to fit inside the oral cavity consisting of a top (9.0 cm x 6.4 cm x 1.7 cm) and bottom (5.2 cm x 3.8 cm x 2.22 cm) jaw and an overall height of 3.92 cm. After testing the prototype, it was found that the team needed to scrape out the spongy particles of PVA after twenty-four hours for a faster dissolving time.

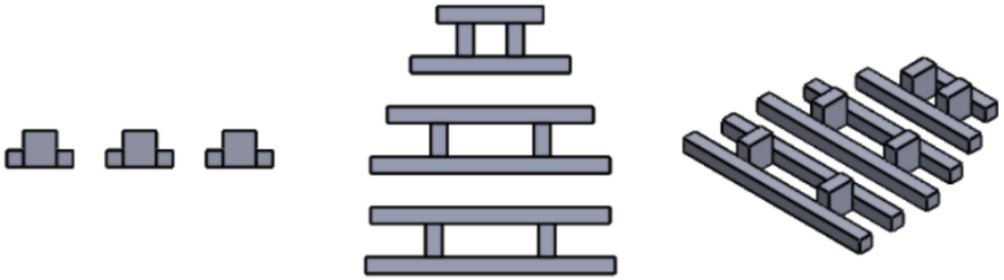

Figure 11: PVA Chambers from 2020 Project. Reproduced as if from [43].
The figure above shows the third iteration of the PVA chamber channels for the prosthetic tongue.

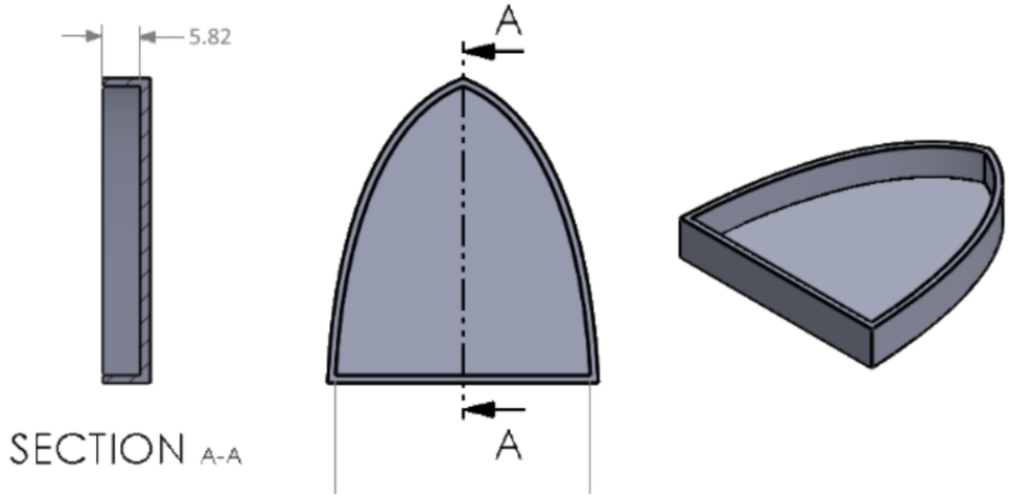

Figure 12: Single Component Mold from 2020 Project. Reproduced as if from [43].
The figure above shows the third iteration of the single component mold for the prosthetic tongue.

The fourth remodel consisted of a linkage system to actuate the tongue by connecting a motor to an axle. The linkage system consisted of components: base, tongue, axle, linkage, smaller collar, and larger collar, as seen in Figure 13 below. The axle held the linkage and tongue together and the tongue was able to incline upwards for bolus movement as the motor rotated and the axle moved backward. The actuation movement of this model was successfully scaled and simulated in Solidworks, and 3D printed, as seen in below Figure 14. It was found that a control system was needed in the linkage and retainer, which caused complications, thus, the silicone design was determined to be optimal.

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

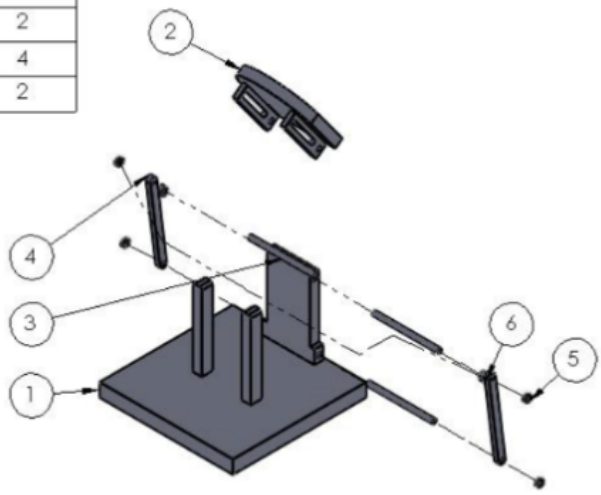

Figure 13: Diagram of Linkage System Components for Assembly. Reproduced as if from [43].
The figure above shows an exploded view of the a potential linkage system assembly.

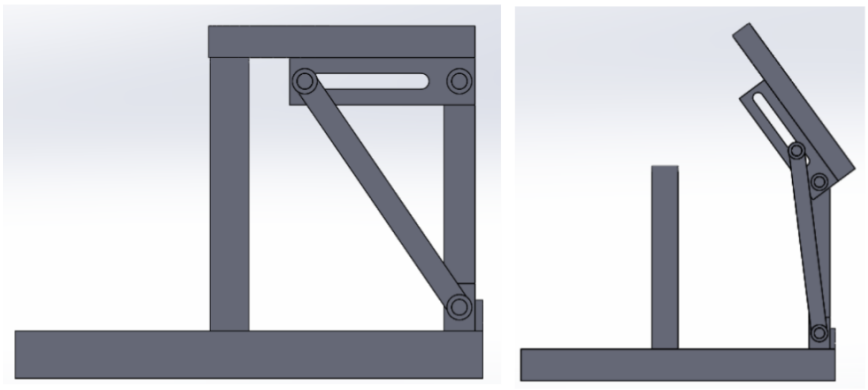

Figure 14: Linkage System Simulation. Reproduced as if from [43].
The figure above illustrates the resting position (left) and end of actuation position (right).

Along with the four remodels of the prosthetic tongue, the team created a retainer and casing. The retainer was acquired from the removable Hawley retainer design (see Figure 15) and consisted of a 9 - 20 gauge wire and plastic, shown in the figure below. The casing was put on the inferior side of the tongue to reduce lateral expansion, a complication seen in the first iteration. The hollow design of the casing allowed for the inlet tubes to have space, as shown below in Figure 16. To bond the tongue and retainer, Loctite glue was applied around the casing.

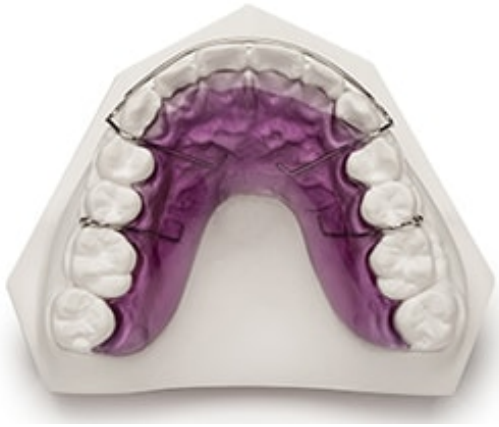

Figure 15: Hawley Retainer Design. Reproduced as if from [43].
The figure above shows the hawley retainer on a plaster upper jaw.

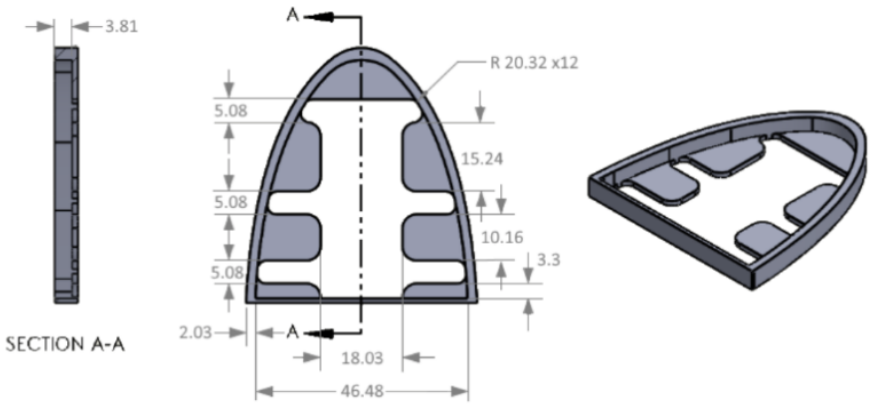

Figure 16: Casing Design. Reproduced as if from [43].
The casing design was used to prevent lateral expansion of the pneumatic tongue.

A new control module was created in this iteration. Electrical components of the initial control module design 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, an I2C SPI serial monitor. A 3D-printed structure was created to hold these electrical components together. This 3D structure was designed in layers, as seen in Figure 17 below, with the 5V air pump and solenoid drivers next to the solenoid valves. The oral cavity and tongue platform were structured above the solenoid valves with screws to hold them together.

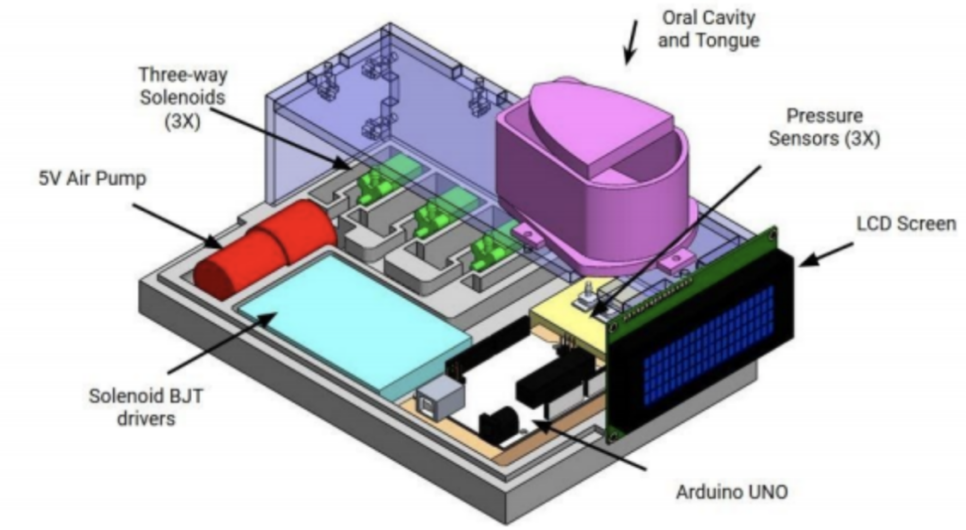

Figure 17: Control Module Testing Setup. Reproduced as if from [43].
The final control module testing set up with labeled components can be seen above.

A new code was generated to run the control module, resulting in four different programs. The purpose of the programs was to control each inflation channel, inflate all of the channels in a certain sequence, test displacement for multiple channels, and control the inflation time for the actuation of a specific height or pressure. Four buttons were connected to the Arduino for the team to select a program of interest. Three Honeywell pressure sensors were used to obtain internal pressure readings. Approximal data was presented on the LCD screen and compared to the displacement readings.

In the final design of the control module, as seen in Figure 18, below, all components remained the same except there contained one 5V air pump instead of three, to produce 100kPa of air supply to the tongue. One air pump allowed for sufficient pressure throughout the prosthetic and limited ruptured PneuNet structures, contrary to three air pumps. The final design of the control module was not manufactured due to lab time constraints.

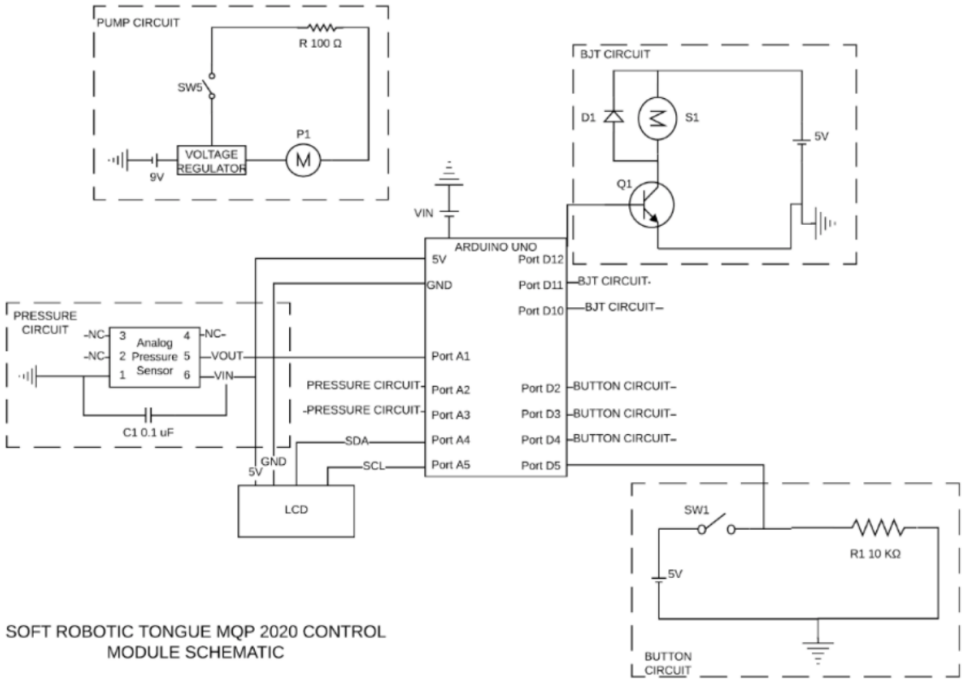

Figure 18: Schematic of Final Control Module Design, Reproduced as if from [43].
The schematic of the wiring of the electrical components from the control module can be seen above.

3.2.2 Testing

A series of tests, including magnetic actuation tests, pneumatic tests that included an initial pressurization test, and bacterial testing were performed to ensure that the goals of the prosthetic were met. The magnet actuation test was done to observe the strength of the silicone material. Iron oxide particles were added to Ecoflex00-30 silicone to make 20% by mass mixture and inserted in a mold that held together the components (including magnets) and allowed for curing of 4 mm of silicone, seen below in Figure 19. To test if the mixture was fully cured, large magnets hovered over the mold to observe silicone movement. Iron oxide particles attracted to the magnet and there was some silicone movement, thus, a larger magnet was used to test for a stronger magnetic attraction. After the mixture was cured, markers were placed on each magnet, and tracking software was used for obtaining displacement measurements. As a result,

the average displacement was 11mm and the maximum displacement was 15mm, verifying magnetic actuation is a valid technique for tongue actuation. Despite the ability to magnetically actuate, conflicts would arrive in the prosthetics due to the magnets bending and torquing to align the poles.

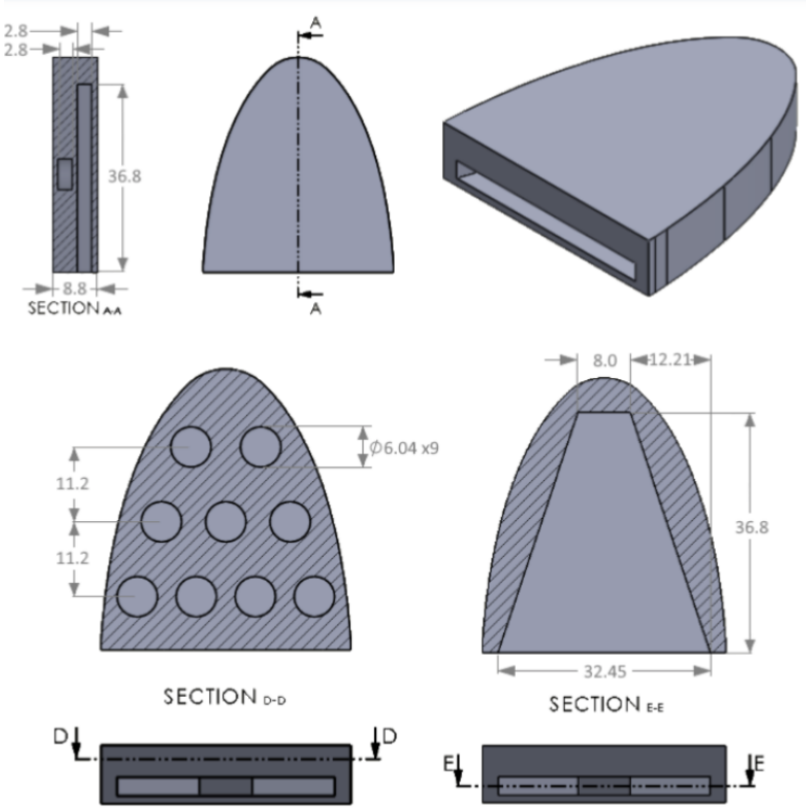

Figure 19: Solidworks of Magnetic Prototype from 2020 Project. Reproduced as if from [43].
The figure above shows a SolidWorks of the Magnetic Prototype from the 2020 project. The circles on the bottom left image shows locations of small magnets.

The pneumatic testing was performed with simulations using an element analysis software called Abaqus. As a result, theoretical data on maximum pressure was collected for each redesign of the iteration. These simulations gave theoretical data on the maximum pressures of each redesign. The maximum pressure before failure was 0.524 MPa in the preliminary design, 0.242MPa in the EarlyRedesign, 0.32 MPa in Redesign 1, and 0.221 in Redesign 2.

Bacterial adhesion tests were performed to ensure the safety of silicone material inside the oral cavity over time. Two forms of easily accessible bacteria were used for this testing: Escherichia coli and Staphylococcus epidermidis. Both bacteria strains were swiped and then brushed onto plates with silicone and polyurethane which were then incubated for 24 hours. Both bacterial strains were swiped again and then brushed onto separate plates with pieces of LB agar, the control material. Both plates were compared. Bacteria strains that were found on the experimental plates were considered insignificant because they resulted in much fewer bacteria than the number of bacteria found in the average mouth. For a more feasible examination, another bacterial adhesion test was performed with broth and sugarcane, mixed and poured into the plates to submerge the silicone and LB agar. After 24 hours, the broth was poured out for the inspection of the materials. 0.01mg/mL of Triphenyltetrazolium Chloride (TTC) was for the validation of bacteria on any of the materials. Bacteria that were found on the experimental materials were again considered insignificant due to the decreased amount of bacteria on the material than in the average mouth.

To test for possible techniques to sterilize materials, bacterial series were cultured onto LB agar plates. A dissolved denture tablet was added to the plate and the plates were then submerged in warm water. After five minutes, the plates were rinsed with water from a spray bottle. For control, a bacterial series was cultured onto an LB agar plate, however, there was no dissolving and rinsing of denture tablets. As a result, the denture tablets caused fewer bacteria to reside on the surface, as seen in Figure 20, with less than 30% of bacteria compared to the 65% of bacteria in the control group.

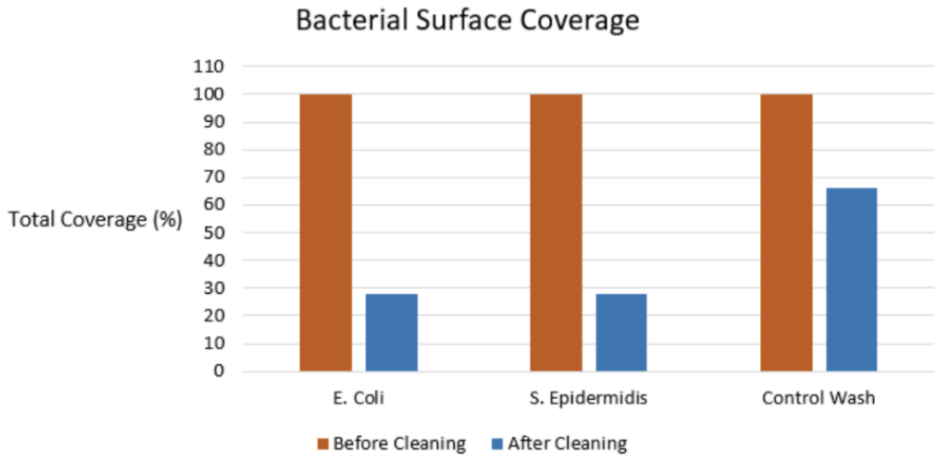

Figure 20: Sanitization Effectiveness of Denture Tablet. Reproduced as if from [43].
The figure above shows the change in various bacteria coverage from a denture tablet compared to a controlled wash.

3.2.3 Conclusions

Bridges et al. were successful in developing a control module that could control individual air chambers. In each remodel, they were able to use a finite element analysis and an optimal redesign that could incorporate pneumatic actuation. The pneumatic system, on the other hand, has many components that cannot be downsized, making it inappropriate for the oral cavity. Limitations of this iteration included the size and methods of actuation. The components were too large to fit inside the oral cavity. Despite the inflation of two sections in the prosthetic, the shape and size rendered it too small to replicate a human tongue. Another limitation was the pneumatic system's ability to puncture and cause air leakage. Despite the linkage system being 3D printed and easily scaled in Solidworks, the smaller printed parts were more likely to break during operation within the system. If the parts break within the patient's mouth, it causes a choking hazard.

Some recommendations made by Bridges et al. were to integrate biomechanics and manufacturability tests to determine the required actuation height for bolus movement. Also,

miniaturizing the control module would allow it to fit in the oral cavity. Lastly, redesigning the retainer to account for all sections of the tongue instead of the first two sections would be beneficial.

3.3 Iteration 3: Vasquez et al. 2021 [44]

Vasquez et al continued the prosthetic tongue project and determined ways to improve the size and replicate a human tongue. For tongue movement, this iteration did not utilize the pneumatic actuator system, but the magnetic actuator system instead. With final dimensions of 85 mm in length, 52 mm in width, and 23.2 mm in height, as seen below in Figure 21, this tongue design was larger than that of previous iterations. The control module was successfully miniaturized but obtained more components than the previous two iterations. A papillae layer was added to the superior surface of the tongue to create a less frictional plane for the bolus to move easier [15]. This section will discuss procedures performed by the third iteration in the creation of a prosthetic tongue, as well as their designs and results.

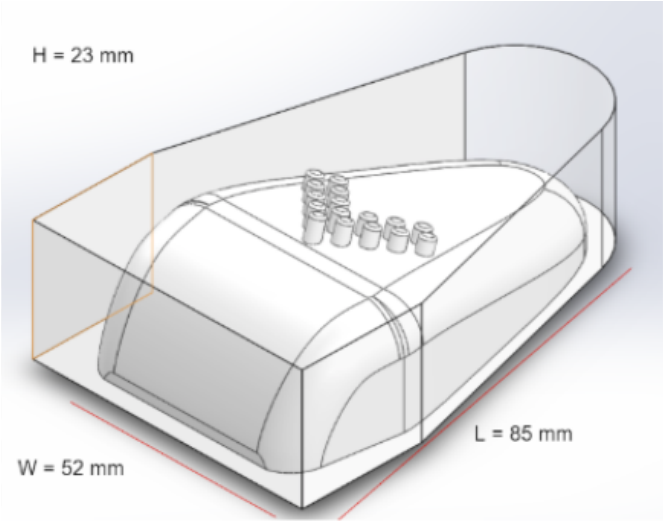

Figure: 21: Prosthetic Tongue Design. Reproduced as if from [44].
The figure above shows the dimensions of the prosthetic tongue design's mold.

This iteration did not integrate an air pump, which allowed for the control module to be miniaturized. A papillae layer was added to the superior surface of the tongue to create a less frictional plane for the bolus to move easier. The actuation method was determined using a decision matrix that compared pump actuation and magnetic actuation processes and outcomes. The magnetic actuator system was more suitable for tongue actuation.

N52 rectangular magnets, neodymium magnet grade, were used with an energy product or BHMax of 52 Megagauss Oersteds. N52 magnets are strong and brittle NIB magnets and were objected to inside the tongue, pulled by a magnetic pull solenoid (12V), as seen in Figure 22.

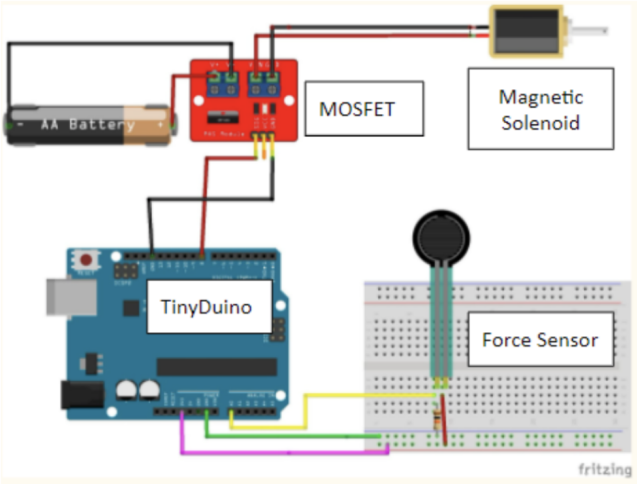

Figure 22: Circuit Diagram of Magnetic Actuation. Reproduced as if from [44].
The figure above shows the wiring of the control module for the magnetic actuation device with all the components labeled.

Due to the larger size of the Arduino, and the obstructions it caused from previous iterations, a TinyDuino was used in the third iteration. A TinyDuino is a miniature version of an Arduino and contains a sufficient amount of power. Stacked on top of one another the TinyDuino was used to miniaturize the entire circuit to fit inside the prosthetic tongue and programmed to

calculate the height of actuation. Other components such as the MOSFET, solenoid, and force sensor were connected to the TinyDuino.

The following processes were performed for testing: simulating magnetic fields, magnetic field mapping, displacement testing, and bolus testing. Through testing, it was found that 2 mm is a sufficient thickness for the tongue to restrict rupturing and promote an impenetrable casing for the electrical components. The simulation of magnetic fields was performed using the ANSYS simulation software and as a result, the solenoid was able to produce a magnetic field of a travel length up to approximately 30 mm away from the end of the iron core. Overall, the prosthetic tongue was unable to move from the tip to the back of the tongue and further improvements could be made to address the limitations.

Future improvements suggested by the team included utilizing better biocompatible materials for the oral cavity, focusing on movement control, and sensors. A recommendation they made for biocompatible materials in the oral cavity was medical-grade silicone. Also, a variety of combinations of magnet placements would allow for the determination of maximum displacement. Additionally, further research on sensors could help the patient in different deglutition scenarios pertaining to bolus size.

3.3.1 Control Module

For the control module, this iteration concentrated on maximizing the actuation of the tongue, thus, many components used in previous iterations were removed. The overall use of the TinyDuino allowed for the control module to nearly sit inside the tongue. A MOSFET was used to power the solenoid. A two-part code was written for the control module to function. These codes determined if the level of effective pressure was met, using readings from the sensor. The

solenoid then powers on for two seconds. This code was then infinitely looped only when the TinyDuino was powered. The final circuit for the prosthetic tongue can be seen down below in Figure 23.

Components of the control module, including theTinyDuino, pressure, MOSFET, and the solenoid were used to construct a circuit that stayed in the acrylic 3D printed oral cavity structure. Some sections of the circuit such as the TinyDuino module and MOSFET were not able to fit inside the tongue.

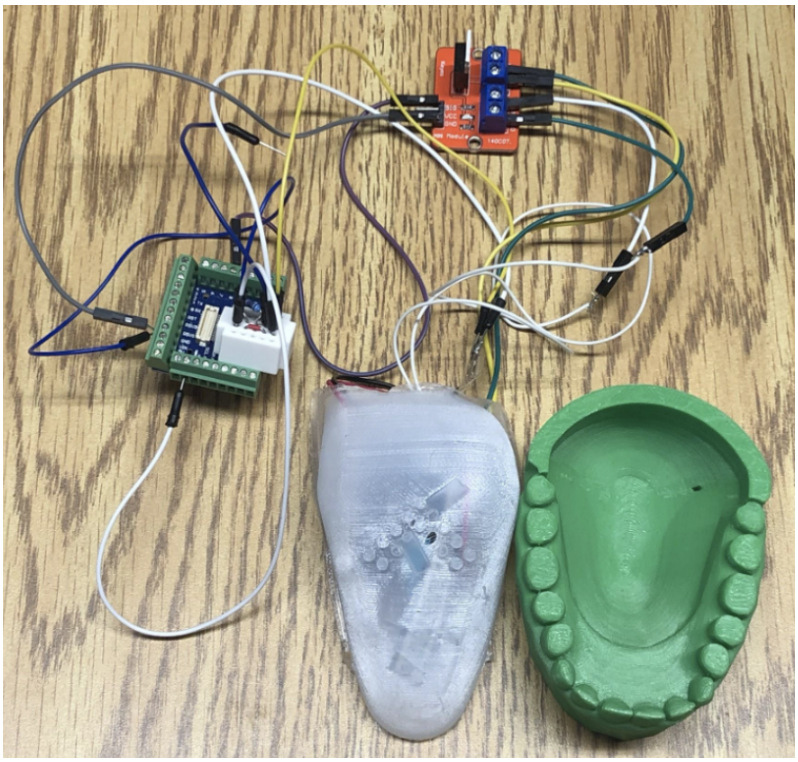

Figure 23: Circuit Design for Prosthetic Tongue. Reproduced as if from [44].
The figure above shows the final circuit for the magnetic actuation tongue. Note the TinyDuino and MOFSET were not able to fit within the tongue.

3.3.2 Testing

Vasquez et al performed testing on tongue actuation, distance actuation via the solenoid and magnet, flexibility sensing at different curls.

For magnetic testing, the neodymium magnet was placed in a way that it could move to the unpowered solenoid. The movement positions were recorded and the team was sure of not placing the magnet beyond the marked distance to the solenoid. When the solenoid was powered the team observed whether the magnet would attract it. If attraction occurred, the team repeated the trial by moving the solenoid further and powering it until there was no attraction between the magnet. This test was performed for each solenoid and magnet.

To perform the flexor test, the pressure sensor was placed in the tongue and the pressure sensor test code was run. The pressure reading of the vacant tongue was observed and recorded. Then 5 ml of water was added to the tongue and the pressure reading was observed and recorded. After, the tongue is emptied and the pressure reading of the vacant tongue was observed and recorded again. This procedure was repeated 5g of food, and again for mixed 5g of food and 5ml of water and all pressure readings were recorded. The values were averaged to make a threshold resistance value for actuation testing.

Tongue displacement testing was performed by connecting a wiring to the breadboard of the arduino to accurately measure the tongue's actuation. The solenoid was powered and wireling data was recorded once the tongue had actuated.

3.3.3 Conclusions

In this iteration the prosthetic tongue was formed into a more human-like design and components were successfully miniaturized compared to previous iterations. The control module allowed for automatic control in the prosthetic. Although the prosthetic was miniaturized, a reduction in actuation occurred, resulting in the tongue's inability to move the bolus.

Some recommendations made by Vasquez et al were to incorporate better movement control, biocompatible material, and sensitive sensor types for accurate detection.

Overall, the team made great progress in this project, with miniaturization techniques and uninvolving the air pump circuit to free up space for a circuit to reside directly inside the tongue. Additionally, a human-like tongue was a highlight feature of the design to address mental ramifications that a patient may have.

3.4 Iteration 4: Holod et al. 2022 [45]

Holod et al continued the prosthetic tongue project and determined ways to improve the circuit wiring and the biocompatibility of the tongue, integrating biocompatible silicone and a PCB. The team started off by retesting all previous iterations, specifically the actuation system and manual actuation testing to get a basis for the components. The team also focused primarily on component interactions since the previous two iterations had performed silicone and bacterial testing. This section will discuss procedures performed in the fourth iteration of the creation of a prosthetic tongue, as well as their designs, performed testing, and results.

3.4.2 Final Prosthetic Design

For tongue movement, this iteration utilized a linkage system in place of an actuationsystem in the final prototype of the prosthetic tongue. The prosthetic design was determined with the retesting of components from previous iterations. Multiple designs of the linkage system were modeled and the final prototype was determined with a decision matrix, then 3D printed. An accurate jaw model, retainer, and the base tester were 3D printed in a resin printer.

Design 2 was a hinge-based linkage system, a similar concept to the tendon-driven robotic fingers. It ultimately contained 4 sections or ‘plates’ with angled cuts of 14 degrees, allowing for 84-degree rotation, seen below in Figure 24. Dimensions of the plates were: front/smallest plate - 2 cm long x 2 cm wide x 0.5 cm thick; middle plate - 2 cm long x 3 cm wide x 0.5 cm thick; and back/largest plate - 2 cm long x 4 cm wide x 0.5cm thick. They also included holes that horizontally lined up for wires to go through and hold all plates together. Two vertical holes in each plate held a finishing line that was tied to the front end of the front plate and allowed for the plates to fold or curl into each other when the line was pulled. The edges of the linkage system were rounded, limiting the penetration of silicone. Design 2 was ultimately selected for the final prototype.

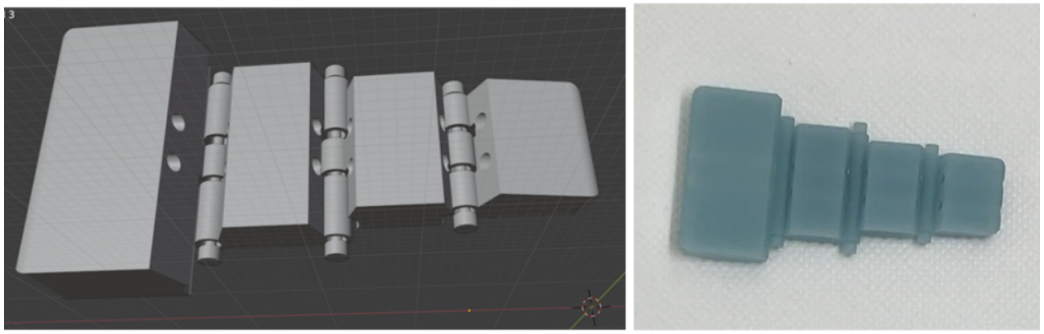

Figure 24: Final Prototype of Hinge Linkage System. Reproduced as if from [45].
The figure above shows the final prototype of the hinge link system. The link system at this point contained four links connected with resing printed pins and actuated with the two fishing lines.

3.4.3 Control Module

As the project progressed from using a solenoid to a linkage system, several circuit designs were developed. The TinyDuino, a microprocessor used in the Vasquez et al iteration, was integrated into this project's circuit designs. The team refrained from using a solenoid because it heated up dangerously high and it was determined that it would not be a good fit for the oral cavity. The team had ultimately decided to utilize a gear system instead of a force Sensor, servo, and solenoid, because of their familiarity with the topic.

A gearbox was created to double the torque of one servo motor, consisting of three uniformed gears. Gear A was the smallest and had 20 teeth and was attached to the servo. Gear B, the middle gear, was attached to the first gear shaft with no motor attached to it. Gear C was the output, located on the second gear shaft gear with 44 teeth. The gear systems can be seen below in Figure 25 as a SolidWorks analysis. The resulting gear ratio was 2.2, which made the output torque 0.3452 Nm, enough torque to actuate the linkage system. The gear system was also proved to be strong enough to handle use for three meals a day. The maximum displacement that occurred with a torque of .3452 Nm was 0.0455mm which is .3% of Gear A’s pitch diameter.

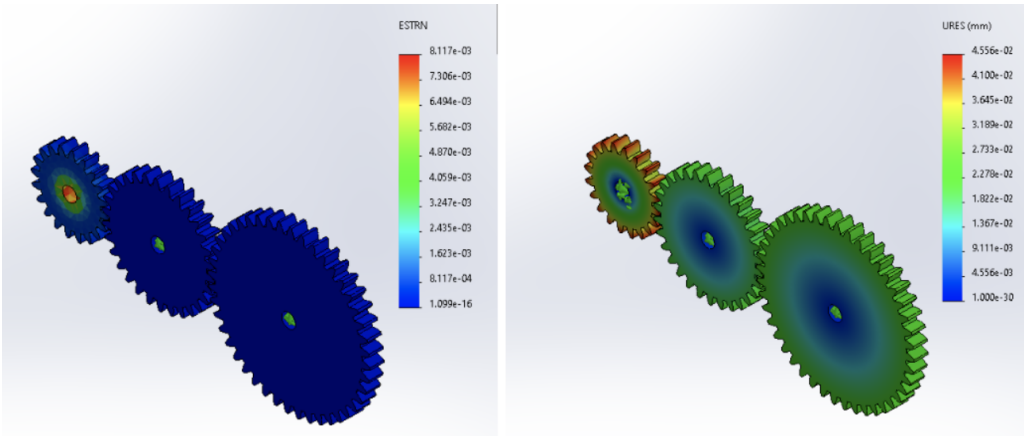

Figure 25: Solidworks Simulation of Gear Train. Reproduced as if from [45].
The figure above shows the SolidWorks simulation of the gear train with the stress analysis (left) and the displacement analysis (right).

A wireless electromyography sensor (EMG) and a servo was used for the linkage system in the tongue to be pulled up when the impulse was detected, seen in Figures 26 below. A circuit was split in two, both acquired a transceiver for communication. One circuit, on the exterior body, had an EMG sensor connected to it to detect muscle motion at the flex of a muscle. Through the transceiver, this circuit then sent an activation signal to the other circuit to activate the servo for tongue actuation.

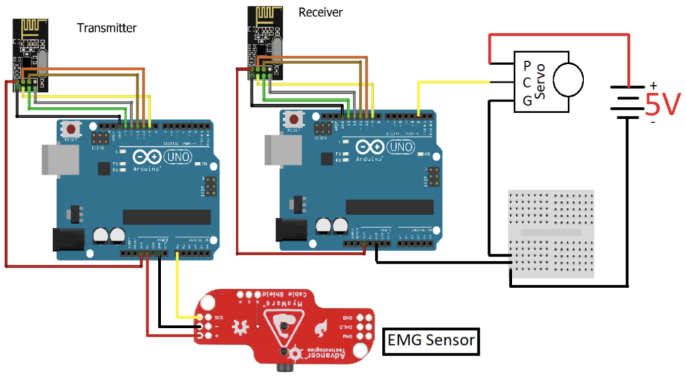

Figure 26: Wireless EMG Sensor and Servo Circuit Schematic. Reproduced as if from [45].
The figure above shows the circuit schematic of the control module with both the wireless EMG sensor and the actuation control.

3.4.4 Testing

For the final actuation testing of the prototype, the Tracker software was utilized and recorded six trials of the actuation of the linkage system, which were later analyzed. A team member flexed their muscle in order to trigger the EMG sensor for the circuit to wirelessly signal the servo circuit to operate the actuation of the linkage system and tongue. The testing setup can be seen in Figure 27 below. A measuring tape was used to verify the data from the tracking software, which can be seen below in Table 3. After one tongue actuation, the servo circuit power (computer) was disconnected and then reconnected for the circuit to reset for the next trial.

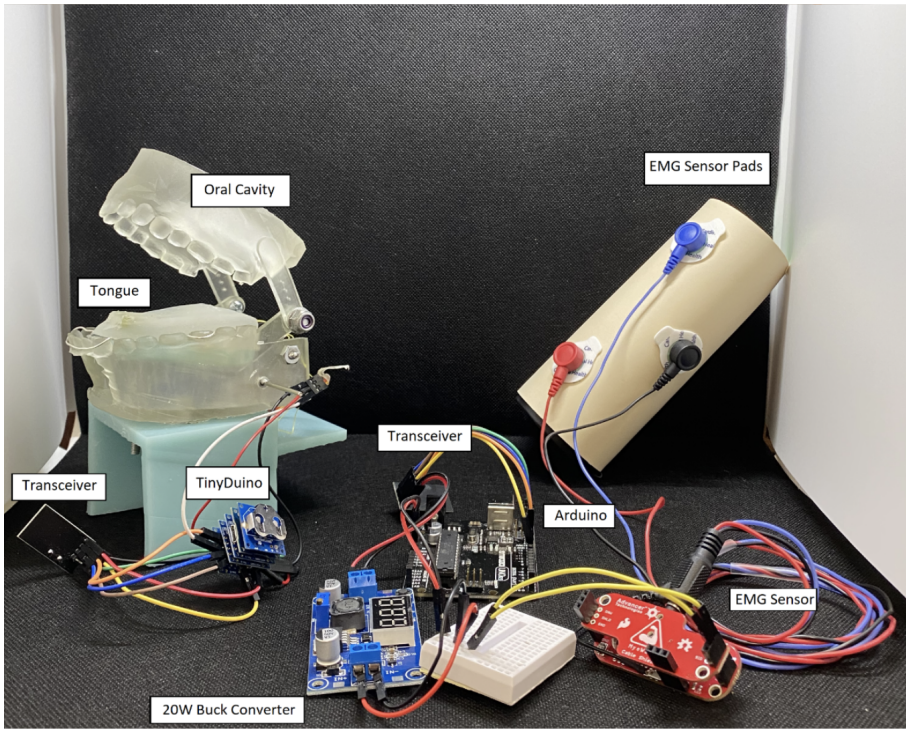

Figure 27: Actuation Testing Setup for Final Prototype. Reproduced as if from [45].
The figure above shows the afinal prototype of the 2022 tongue design with all of the components labeled.

Table 3: Results of Final Actuation Testing, reproduced as if from [45].

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

Table 3 shows the results of the final actuation testing. The table includes the trial number and the actuation height in centimeters for each trial.

The tongue actuated an average height of 2.317 cm with 0.3452 Nm of torque with no bolus; two or more times higher than the heights and torques of Iterations 2 and 3. Screenshots of the actuation testing from the video are represented below in Figure 28.

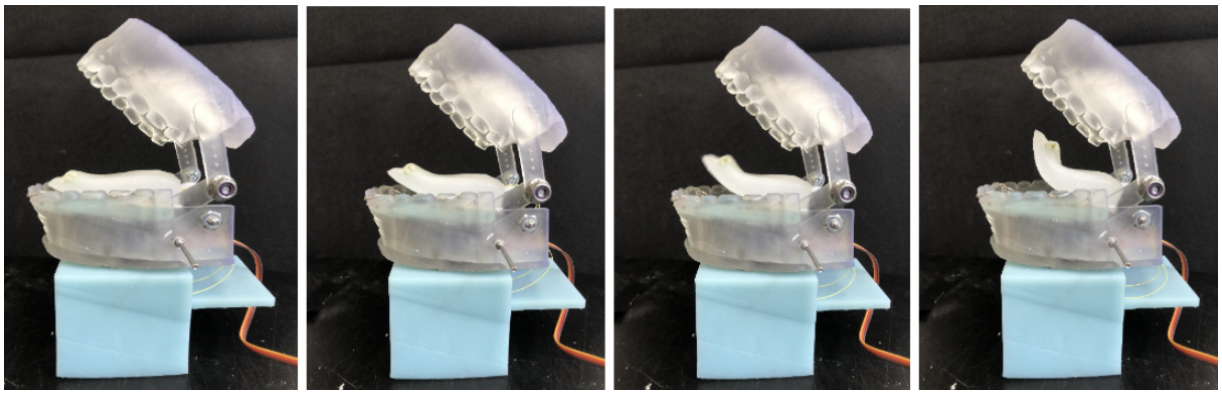

Figure 28: Screenshot of Actuation Test from Video. Reproduced as if from [45].
The figure above shows the a screenshot of an actuation test. The images progress left to right along the actuation cycle.

For bolus testing, four different weights of bolus (2g, 3g, 4g, 5g) with a 2:4 ratio of 2 tablespoons of instant mashed potatoes and 4 tablespoons of hot water were used. This bolus mixture was thick enough to hold its shape and soft enough for swallowing if possible in the

swallowing cavity. Each trial was video recorded and the bolus movement was observed. The average actuation height of the tongue with bolus on it was 2.25 cm. To imitate saliva and limit tackiness, coconut oil was applied to the silicon tongue. The initial setup for bolus testing can be seen in Figure 29.

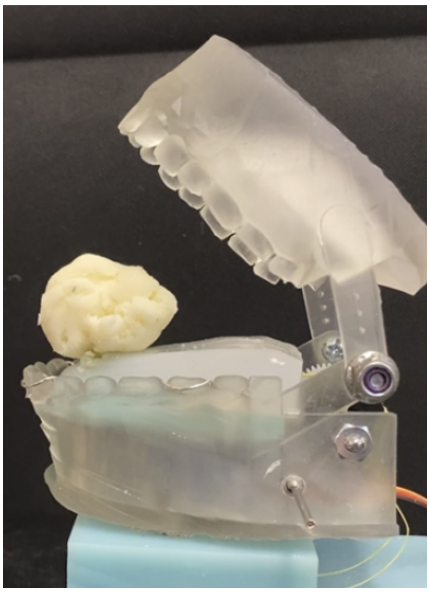

Figure 29: 5g of Bolus on Final Prototype. Reproduced as if from [45].
The figure above shows the placement of the bolus on the prosthetic tongue for bolus testing.

3.4.5 Conclusions

In this iteration, a linkage, gear, and motor system in conjunction with an EMG sensor (Electromyography Sensor) was used to successfully create an artificial prosthetic tongue that aids in deglutition, moving bolus from the tip of the tongue to the back of the mouth. Tongue actuation with muscle impulse was observed using the EMG sensor. The gear, linkage, and servo system provided enough torque for the deglutition of the tongue. A retainer was used to connect the tongue prosthetic to the oral cavity.

Some recommendations made by Vasquez et al were to replace the Tinyduino with a PCB for miniaturization. Also, possibly converting the circuit to be powered by a coin battery, as a

computer power supply is inconvenient for a patient. Another possibility is using saliva as a power supply. Additionally, a comparison test between different types of resin to observe which type works best in the oral cavity was recommended.

Overall, the team made great progress with the project. Also, a PCB was not used due to time constraints, the team was still able to hypothetically not involve a Tinyduino and move bolus for deglutition.

3.5 Key Takeaways

The creation of a functional prosthetic tongue went through four iterations, which were mentioned in the previous sections. The first iteration included internal air chambers/air pumps as the actuation mechanism, paving the way for the development of functioning prosthetic tongues. However, it encountered issues such as bolus inability and air leakage in the PneuNet structure. The second iteration improved on the first by utilizing a single air pump with three two-way valve solenoids, reducing the size of the tongue to better fit the oral cavity and demonstrating magnetic actuation as a possible replacement for the pneumatics. Despite this, it struggled to transport the bolus from the front to the rear of the tongue. The third generation used electromagnetic actuation and integrated all controls within the oral cavity without any protrusion, however, it still couldn't transfer the bolus from the front to the rear of the tongue. Finally, the fourth iteration successfully moved the bolus using EMG and a solenoid motor as the actuation mechanism. The circuit, however, was too huge to fit comfortably within the tongue. Overall, the iterations show progress toward producing a viable prosthetic tongue, but more effort is required to overcome technological hurdles before it can be fully functional and comfortable.

4. Methodology

This chapter will go over all the factors and considerations that allowed for the creation of the final prototype. The methodology chapter will consist of the problem statement, the regulations, and standards, the design ideas created by the team, a list of seven design criteria and their importance to the project, as well as a design matrix developed by the team to determine the relevance and importance to the development of the actuation device.

4.1 Problem Statement

The problem statement for this year's project is as follows:

Developing an artificial tongue prosthesis for patients after undergoing a total glossectomy procedure that can move the bolus from the front of the mouth to the back of the throat. The model should be able to fit into an average oral cavity and be biocompatible.

4.2 Standards

ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

The following standard was considered important to this project because it expresses the regulations of medical devices to evaluate the biocompatibility of the device with the human body. Since biocompatibility and safety were determined to be a top priority by the team this standard was taken into consideration during the development of the prototype.

This standard was developed to protect humans from the risks involved in using medical devices. The categorization of medical devices is based on the nature of the device and how long that device has contact with the body. According to the standard, there are 4 types of medical

devices for the categorization of the nature of body contact: non-contact medical devices, surface contacting medical devices, externally communicating devices, and implant medical devices. For the categorization by time spent contacting the body: limited exposure, prolonged exposure, and long-term exposure. Based on this standard, this project would be categorized as limited exposure, mucosal membrane, and medical device.

ISO 7405:2018 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

The following standard was considered important to this project because this standard ensures that any dental devices are safe for the intended users. Since the team's project is focused on creating a retainer for the actuation device it would be considered a dental device.
The ISO 7405:2018 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry standard provides regulations in how to evaluate the biocompatibility of medical devices used in dentistry. The standard provides a framework and outline on the necessary test that should be performed for a material being used in the oral cavity. It also outlines how to ensure that when manufacturing these materials and devices, safety and effective actions are being taken to ensure the well-being of the user.

4.3 2022-2023 Design Ideas

After reviewing the previous iterations and conceptualizing improvements, the team came up with a multitude of mechanical and biological schemes to create an actuation device. These ideas were without detailed quantitative data and used as proof of concepts to gain a common understanding of methods to develop an artificial tongue that could successfully actuate

and move a bolus from the front to the back of the mouth. This allowed the team to have possible designs and individual specifications that would be combined into a common solution.

4.3.1 Drawbridge Design

The drawbridge design was a surgically inserted actuation device that acted similarly to a medieval drawbridge. The design started with two-stepper motors implanted on either side of the coronoid process. These motors would pull up an artificial, biocompatible silicone tongue that was spoon-shaped to hold a bolus. The tongue would lift into the oral cavity until gravity forced the bolus down the ramp of the silicone tongue and into the throat. This design and portrayed in Figure 30.

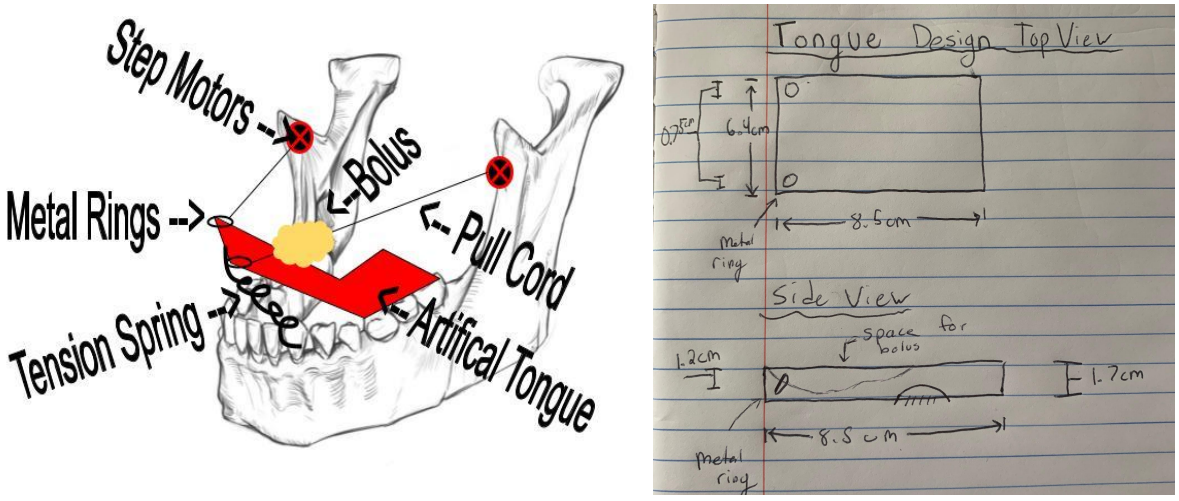

Figure 30: Drawbridge Design.

The figure above shows the isometric view of the drawbridge design (right) and 2D views with dimensions (right). This design was not used by the team as it added another invasive surgery for the patient.

This design utilized gravity to be the key mechanism component of actuation. The design was eventually nixed by the group, as it required surgical implementation and the goal of the team was to make a retainer-based actuation device.

4.3.2 Three Rocker Slider

This design was a mechanical method of actuation that involves three rockers of various sizes. These rockers, increased in size as they progress into the oral cavity, and rotated in unison along similar axles to move the bolus deeper into the oral cavity until it reached the throat. As pictured in Figure 31 below**,** the rockers spinning left large crevasses that allowed boluses to slip through the apparatus and prevent further actuation.

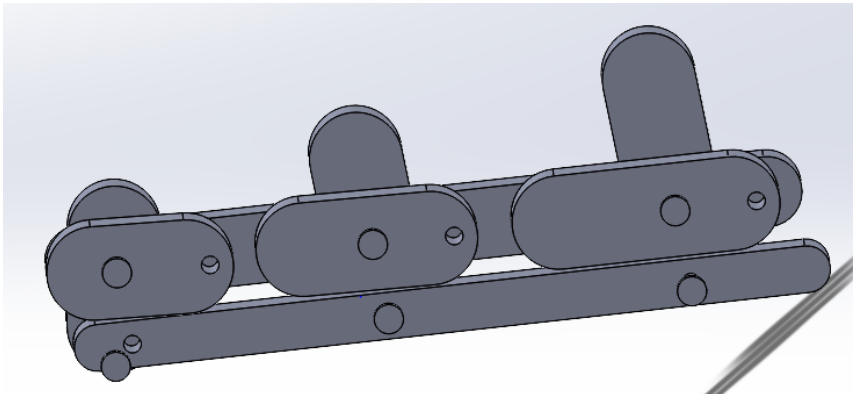

Figure 31: Three Rocker Solidworks Design
The figure below shows ones of the initial actuation designs, the three rocker slider. The design was developed in SolidWorks and eventually dropped by the group due to it's incompatibility to assist with actuation within an oral cavity.

Additionally, this design was 0.6 cm too tall for the oral cavity and would need to be scaled down to fit within a human mouth. Vertically scaling down of this design would prevent the bolus from making it from the front to the back of the mouth. For these reasons, the team decided to cancel further improvements to this design idea and move to another design that was more likely to successfully move a bolus.

4.3.3 Linked Tongue

The linked tongue design was loosely based on the Holod et. al design. The linked tongue was assembled of two linked structures that moved in unison and are powered by a singular servo motor. The servo would spin a pulley that pulls two strings to force the linked pieces to contract. The contraction of the linkage system would move the bolus from the front to the back of the mouth. Pictured in Figure 32 below, the linked tongue design's motion resembles the function of a biological human tongue as it moves a bolus from the front of the mouth to the throat.

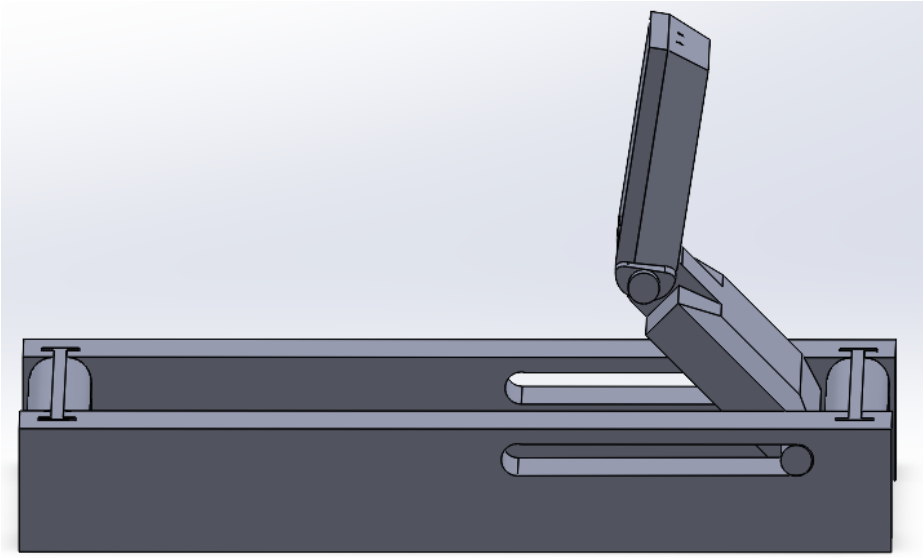

Figure 32: SolidWorks Design of Linked Tongue.
The figure above shows an initial design of a tongue linked. This was further developed by the team in order to make their final linkage system design.

The issue with this design was the components that held the base together were less than 3 mm thick. This caused them to not be structurally sound over time and were likely to fatigue. Additionally, the open base created a large orifice for pieces of a bolus to fall into and get stuck, leading to the potential mechanical failure of the device. Finally, there is no way to return the

linked tongue to the beginning stage and prepare for a new bolus. The key takeaway from this design was the actuation of the tongue links and slider rail combination. This combination could be implemented on a multitude of base and retainers giving design flexibility while mechanically assisting in the bolus movement.

4.3.4 Slider Tongue

The final design of the 2022-2023 team was the slider tongue design. This simple design could be built into a retainer that could easily be removed from the user's oral cavity for maintenance, repair, and battery replenishment. Additionally, this slider was designed to prevent any bolus pieces from getting caught in any orifices of the apparatus. The single servo motor would rest between the retainer and the tongue base to prevent any damage to the motor. The motor would use a string in a pulley system to pull the slider from the front of the mouth to the throat to swallow. After the movement was completed, the slider would be brought back to its home by a tension spring. This is pictured in Figure 33 below.

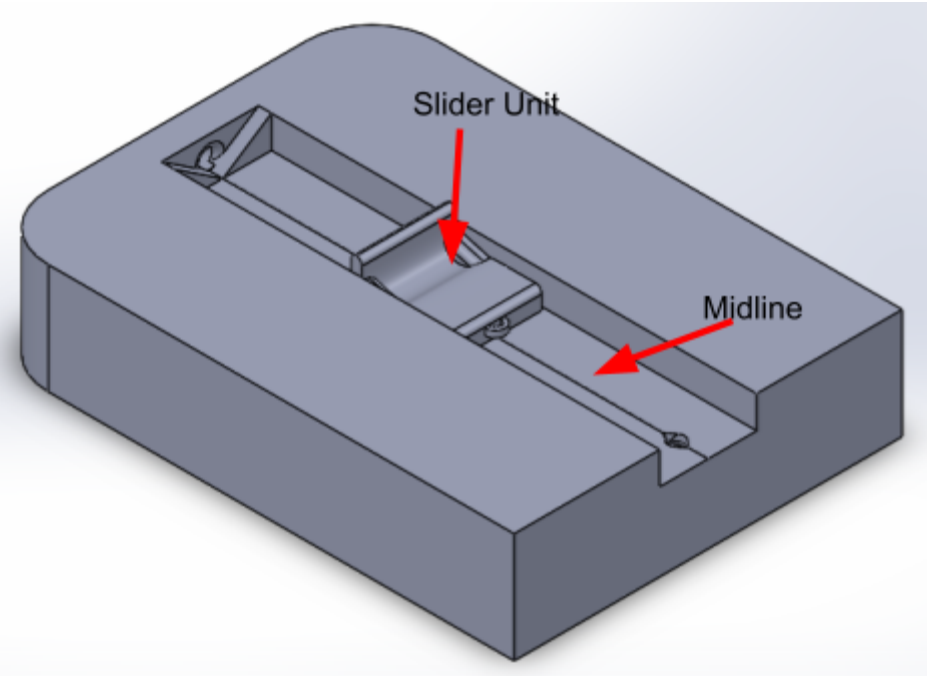

Figure 33: SolidWorks Slider Tongue Design.
The figure above shown the isometric view of the slider tongue design. This designed was inspired by the motion of the glossectomy spoon, one of the few solutions for patients who have undergone a total glossectomy.

This design proved to have too small of a slider for a proper bolus, as the tested boluses ranged from 1-1.5in in diameter and the slider was 0.75in across. For this reason, it was not chosen to be the final design, however, there were key takeaways from it. The unified base allowed for an easier print that is less likely to fatigue as well as a semi-hollow base to fit the motor and battery. Additionally, the rounded front end of the base would more naturally fit within an oral cavity rather than a perfectly rectangular apparatus would.

4.4 Design Criteria

Design criteria regulate the boundaries of product development and set the standards for any attempt at a solution. The team used design criteria to allow themselves, advisors, and future readers to have a common understanding of what specific parameters and requirements are

necessary for a solution. This creates transparent goals in accordance with the problem statement. After defining the problem statement, the team was able to set our end goal of creating an actuation device that can move a bolus to the rear of the oral cavity. Each group member designed different devices based on previous attempts and their ingenuity to achieve this goal. For this project, the team conceptualized the following criteria: duration, displacement, size, integration, fatigue, and safety. While design prioritization criteria may not be all the criteria that are needed in a product, it states the most important criteria so that developers know what their products must have. Each design focused on satisfying the design criteria based on its prioritization score. Each design was presented to the group and would be rated against a decision matrix, to be further discussed in the next section, which was used to compare each design. This section will elaborate on the design prioritization criteria and the decision matrix.

4.4.1 Duration

The first major design criterion is duration. This design requirement is set by the length of time it takes the product to conduct one full cycle of artificial actuation. While it takes a fully functioning person about one second to swallow, it was agreed upon that the product needs to be able to complete its bolus displacement more effectively and efficiently rather than quickly. This is still one of the major design criteria because the product needs to be able to move the bolus to the rear of the oral cavity without taking an egregious amount of time that would prevent the user from eating near the pace of the average person.

4.4.2 Displacement

The displacement is defined as the supplanting of the bolus by the product to the rear of the oral cavity to allow users to swallow their food. This criterion is determined by the mechanisms of each design and how it will force the bolus from start to finish. Additionally, artificial enzymes will fall into this category to assist in the breaking down of food as users chew and prepare a bolus for actuation. This criterion relates most to an actual tongue because it serves the purpose of moving around food as it is being chewed and then preparing it for swallowing.

4.4.3 Size

The size of the product is indubitably paramount and falls only behind safety in terms of importance because any user requires the product to fit within the oral cavity to accomplish the goal of moving a bolus into the rear of the oral cavity. The size criteria include the total mass and footprint of the product. If the product is outside the range of the size criteria, it will inhibit the functionality of the prosthetic. For example, if the prosthetic is too large, it will inhibit the user's ability to chew, swallow, and speak.

4.4.4 Integration

The integration criteria cover the establishment of the product into the user's oral cavity and whether or not it can be easily removed. Some product designs require surgical implementation for the user to use the product while other designs are similar to a retainer and may be removed and replaced when necessary. The team hopes to design a retainer-style product to improve the quality of life of the user and to make product maintenance simpler. A surgically

implanted device would require more work to clean, upkeep, and recharge compared to a device that can be removed and then work on.

4.4.5 Fatigue

The fatigue criterion is set by the ability of the product to maintain its structural and mechanical ability. If the product's usability is compromised by the acidic enzymes and other biological components within the oral cavity, then the product will require a lot of maintenance. Having a low material fatigue rate will ensure that the products will have a long lifespan and will remain usable during continuous work. This is very important because the average person swallows 500-900 times daily and the device needs to be able to support that design requirement for extended periods [46], [47].

4.4.6 Safety

Safety is the most important criterion because this product will be inside the oral cavity of its users and it needs to be mostly inert to be biocompatible. Regardless of how effective the product can be, its effects will be futile if it causes further damage to the patient. Therefore no moving or static pieces such as sharp edges or electrical components should cause discomfort or future damage to the oral cavity. In addition to the biocompatibility of the product, safety entails the product’s user-friendliness. Our prosthetic must be user-friendly, entailing a short learning period that allows the user to be able to utilize it.

4.4.7 Design Prioritization Criteria

Design prioritization criteria are factors within the solution of a goal-satisfying product. These criteria are put on a hierarchy of importance to the product and its users. After finalizing the six previously described criteria, they were ranked against each other as shown in Table 4. If a criterion in a given row was more important than a criterion in the column it was given a one. While if it was less important it was given 0 and equally important was given 0.5. Finally, the Xs were used to prevent comparing a criterion against itself. After completing the comparison table, the most important criteria in order of precedence were safety, size, integration, displacement, fatigue, and duration.

Table 4: Design Prioritization Comparison

	Duration	**Displacement**	**Size**	**Integration**	**Fatigue**	**Safety**	**Total**
Duration	X	0	0	0	0	0	0
Displacement	1	X	0.5	0	1	0	2.5
Size	1	0.5	X	1	1	0	3.5
Integration	1	1	0	X	1	0	3
Fatigue	1	0	0	0	X	0	1
Safety	1	1	1	1	1	X	5

The table shows the priority of each design criteria rated against each other with rows compared to columns. The total then shows the order of precedence of the criteria.

4.5 Design Matrix

A design matrix is used to compare multiple different designs and give them a score on pertinent categories. After each member of the team created one or more designs, they were all presented and the group decided upon the four most likely designs to choose to be the final product that we can continually improve and adapt. This is important because it allowed everyone to focus their efforts on improving one design. This allows for each team member's strong suits and expertise to be present in the final design. The design criteria matrix was made by the team assigning a score to each of the team's designs for each of the following categories: implementation, biocompatibility, usability, cost, and ability to move a bolus. Each score was a number between 1-5 with 1 being the lowest score and 5 being the highest score. Each design then had a total score reflecting its potential for further improvement. The entire process of the score is summarized in Table 5 below. Currently, the biocompatibility and cost criteria are not able to be judged between designs because each design is similar in its size, pieces, and materials so all would have been equal. After the team made unbiased rankings for each design, it was concluded that the team's first design will be the basic model that we follow through with and continue to improve upon.

Table 5: Design Criteria Matrix

Design #	Implementation	Biocompatibility	Usability	Cost	Ability to move bolus	Total
Linked Tongue	5	-	3.5	-	5	13.5
Three Rocker Slider	5	-	2.5	-	2.5	10
Slider Tongue	5	-	3	-	4	12
Drawbridge	5	-	3.5	-	3	11.5

The table shows how the team rated each design in each design category. One was the lowest rating and five was the highest rating. The "-" symbol means it was not evaluated in a given category.

5. Designing the Tongue Prosthetic

This section describes the design process for the tongue prosthetic. The process began with understanding what aspect of previous year's design worked best. Our team also used their design ideas to start the initial phase for developing our design. Cmponents were modeled in SolidWorks and then 3D printed until our design could be properly pieced together. The mechanical components consisted of tongue links, a base, a pulley, and a retainer. The control module was similar to components that worked in the previous year and looked for alternatives that are smaller in size. Included in the control module are the motor, microcontroller, battery, and actuation control sensors. The final design was made by combining the mechanical and control components into a complete functional system.

5.1 Observations of the 2022 Design

The 2021-2022 MQP design [43] was a vast improvement upon previous iterations of the project as described in Section 3.4.0 (Iteration 4). However, some aspects were left to be desired, especially miniaturization. The previous tongue links worked well, but the prosthetic tongue does not need to have an identical motion to the real tongue. The team determined that mimicing the motion of the tongue was not necessary to achieve our goal of moving a bolus form the front of the mouth ot the back of the throat. For instance, the glossectomy spoon that is currently used pushes the food to the back of the throat with a physical bar. We incorporated aspects of the old design and the current spoon to come up with a slider design, which would further improve the movement of a bolus in the oral cavity. This slider would take the first two links of the tongue from this iteration [43] and put them on a sliding rail. The benefit of putting the system on the

rail is the tongue itself is smaller and requires less torque for vertical displacement while being able to achieve more horizontal displacement. The rails would create more space for control components like a motor and a printed control board. The entire slider system would additionally be easier to incorporate into a retainer housing component, allowing for the device to easily be placed or removed from the oral cavity.

5.2 Modeling the System

The first step to redesigning the system was developing a 3D model in SolidWorks. This allowed for easy prototyping with a 3D resin printer. For the slider itself, there were four key parts to model the tongue namely the tongue links, pulley, base, and retainer.

5.2.1 Tongue links and Slider Pin:

The links for our tongue design were inspired by last year's design, however, we utilized the front two links and made them 5mm shorter within the base of our design. The pins holding the links together are secured by a 1.5 mm stainless steel rod. Stainless steel is a commonly used material in dental implants and possesses better mechanical properties than a resin-printed rod [30], [37]. Each rod will have resin-printed collars attached to them, with the back set of collars being much wider to fit within the slider rail socket. The dimensions of the first version of our tongue links can be seen below in Figure 34.

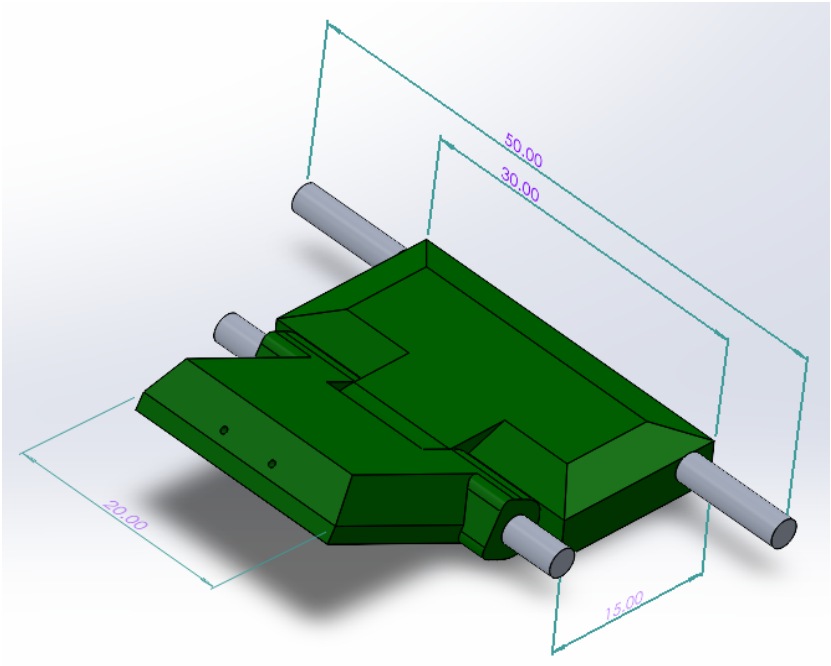

Figure 34: Tongue Linkage System Version 1.
This figure provides the dimensions of the first version of tongue links model from the previous years design.

Throughout the design process, the tongue links went through minimal changes. An offset was added to the link connections to allow for an angle of 60° between the links when fully actuated, this change is shown in red in Figure 35 below. The pin holding the links together was replaced with fishing line to allow for the 60° angle during actuation. The dimensions of each link are in Figures 36 and 37 below, with the front tongue link being 10 mm wide and the rear link being 15mm wide.

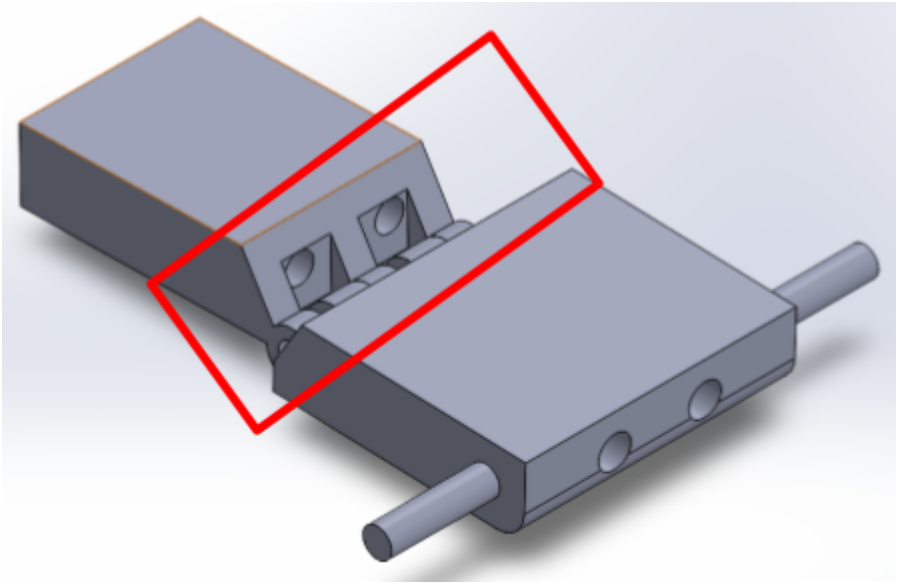

Figure 35: The Final Tongue Links.
Shown in red are the updated connections between the two links. The hole for the back pin was 1.60 mm in diameter.

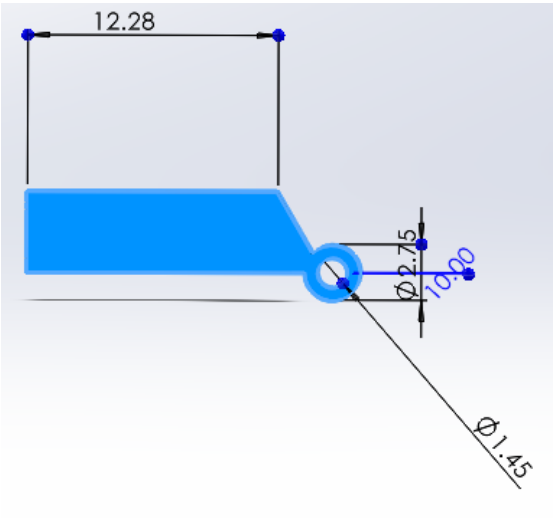

Figure 36: Final Dimensions of the Front Tongue Link.
This figure shows the final dimensions of the front tongue link. Not shown is the 1.8 mm hole for the actuation line.

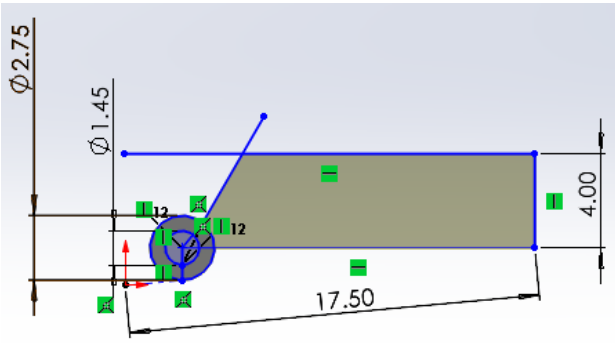

Figure 37: Final Dimensions of the Rear Tongue Link.
This figure shows the final dimensions of the rear tongue link. Not shown is the 1.6 mm diameter hole for the steal slider rod or the 1.8 mm hole for the actuation line.

5.2.2 Base:

From our research, we observed that we would have to keep the tongue within the dimensions given in Table 6 below. This added a limitation to the size of our design. Which added to our challenge of miniturizing our design to fit within the oral cavity.

Table 6: Average Tongue Dimensions from [36].

	Length	**Width**	**Height**
Minimum	7.9 cm	5.0 cm	1.7 cm
Maximum	8.5 cm	6.4 cm	

The dimensions above show the range of dimensions of the oral cavity. These dimensions were used to help create a limit in the size of our design. Since the oral cavity is rather small, miniturizttion was an important aspect of our design.

Other decision criteria we followed were to create an area for control components in our design. This would allow for fewer individual components within the oral cavity. After we had the initial tongue links and pins designed, the base was developed and is shown in Figure 38 below. We created a rounded front to better resemble the natural shape of the front of the lower jaw. The rails were designed to allow the tongue to reach the back of the mouth. While preventing the links from going too far forward and backward with the oral cavity. We then created anchor points to allow for stainless steel return springs to be attached to the base. The return springs allowed the tongue to reset to the starting position as the motor unwinds the pulley. These return springs reduce the power required for the system by not using an electromagnetic field as seen in Vazquez et al. [42] and Holod et al. [43] to hold the tongue in position. A ramp was then added to the base, allowing the tongue to be positioned near the front of the mouth, similarly to where the tip of the tongue would be positioned. The reasoning behind

this described position is it will be more of a natural position for placing a bolus within the oral cavity while opening up more space for control components.

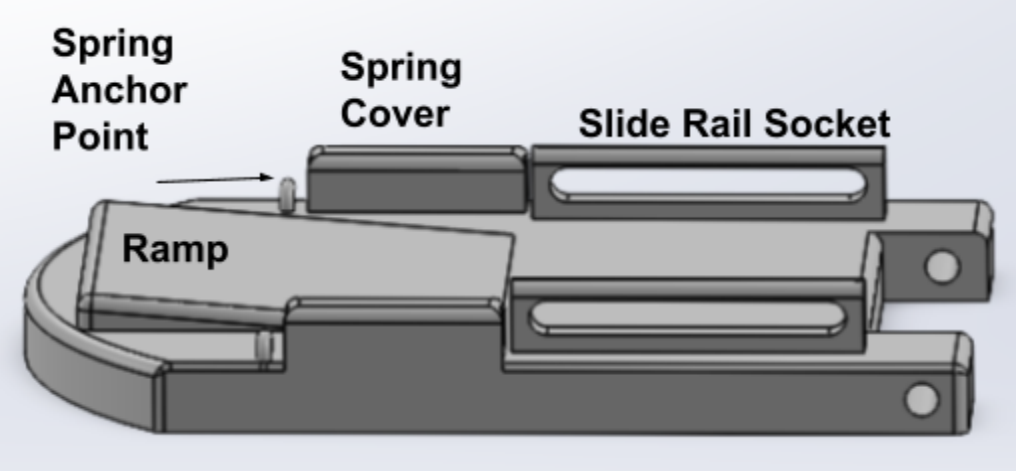

Figure 38: Initial Base Design.
The figure shows the key components of the initial base design.

After initial prints, it was apparent that adjustments were needed, see Section 5.3.3 (3D Print 3) for the reasoning for behind the base's design changes. The primary change was to ensure that it fit the oral cavity and retainer. Thus caliper measurements (shown in Figure 39 below) were taken of our printed oral cavity to inform the future adjustments. The ramp was then removed and the spring covers (shown in red) were combined with the slider socket (shown in teal). The aforementioned changes in the spring covers can be seen in Figure 40 below.

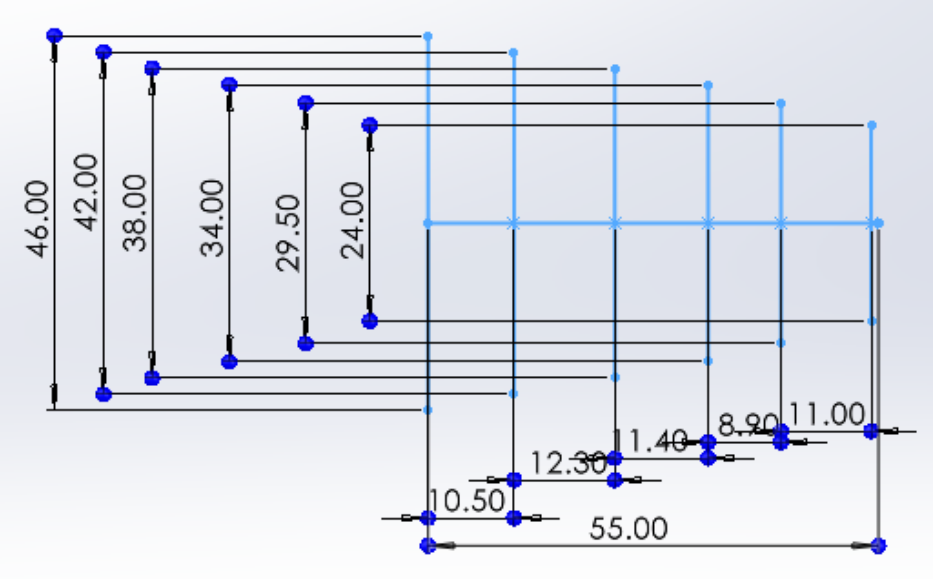

Figure 39: Caliper Measurements of the Printed Lower Jaw.
Each vertical line was measured from the center of the inside of each tooth. The horizontal line was measured from the center of the front teeth to the back of the teeth.

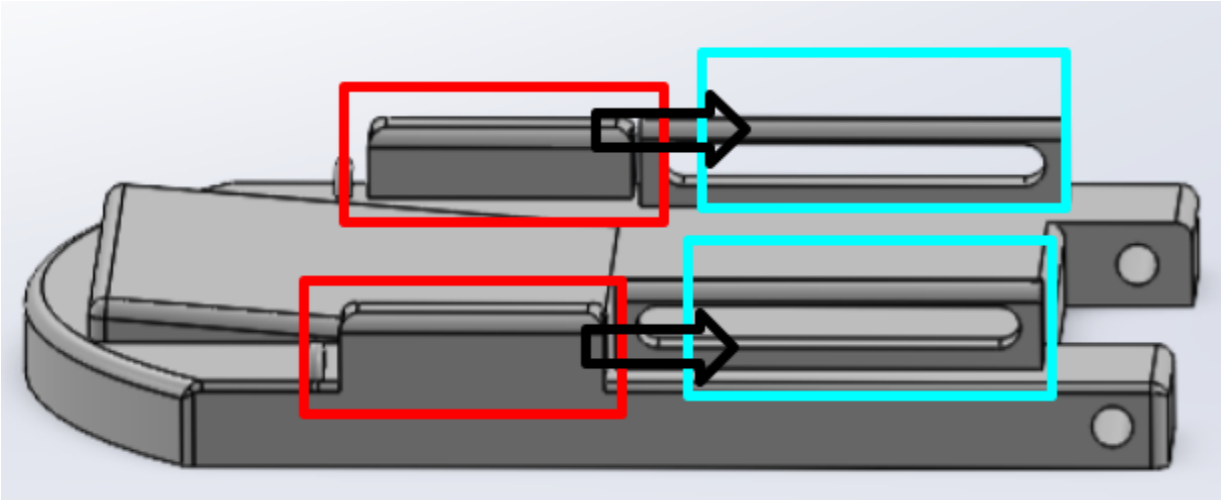

Figure 40: Spring Cover Changes in Base.
The above figure illustrates how the spring cover (red) will be combined with the spring rail sockets (teal).

Other minor modifications were made to the thickness of components and the addition of a socket (shown in red) to the underside for the base to be tied to the retainer using the holes

shown in teal. The final design of the base is shown in Figure 41 with dimensions of the final design shown in Figures 42, 43, and 44 below.

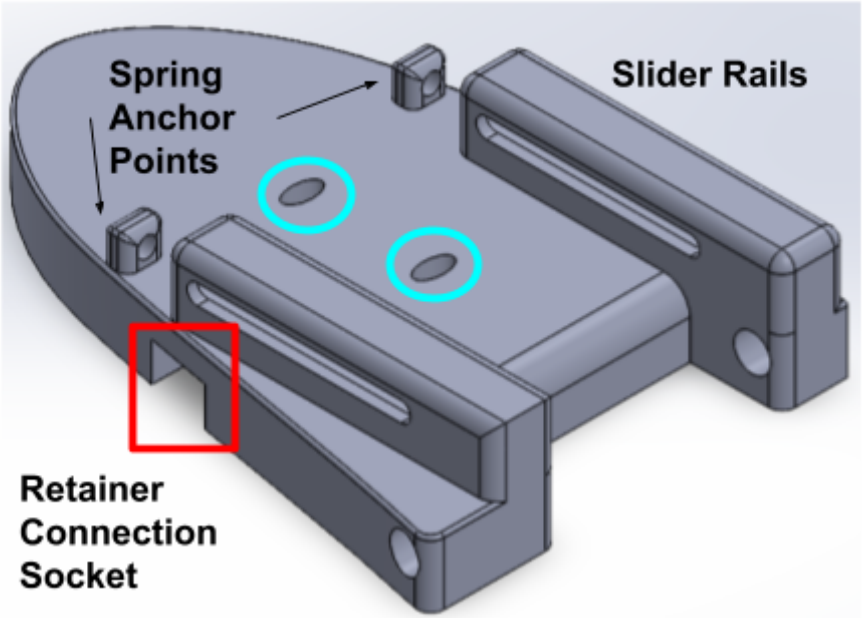

Figure 41: Final Version of the Base.
The above figure shows the key components of the final version of the tongue base.

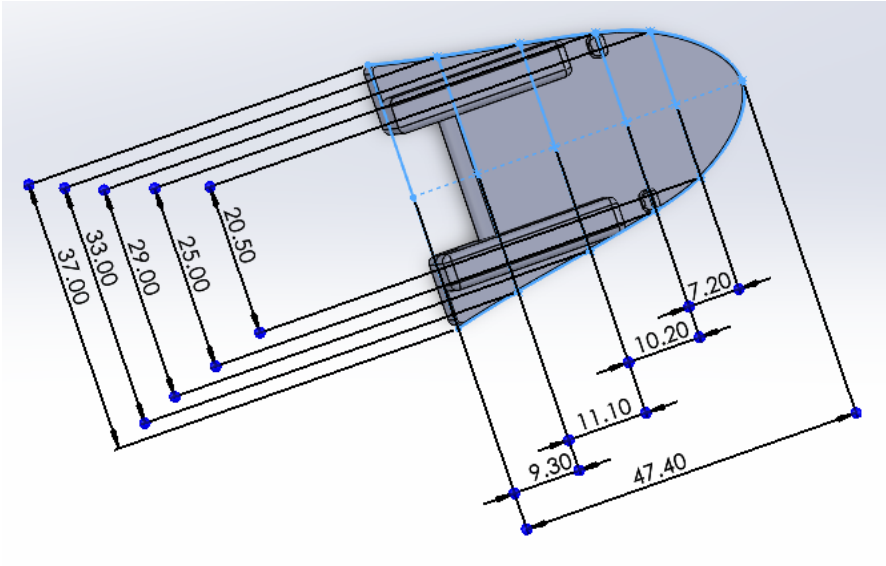

Figure 42: Shape Dimensions of Final Base Design.
In this figure, the dimensions used to make the shape of the base are shown.

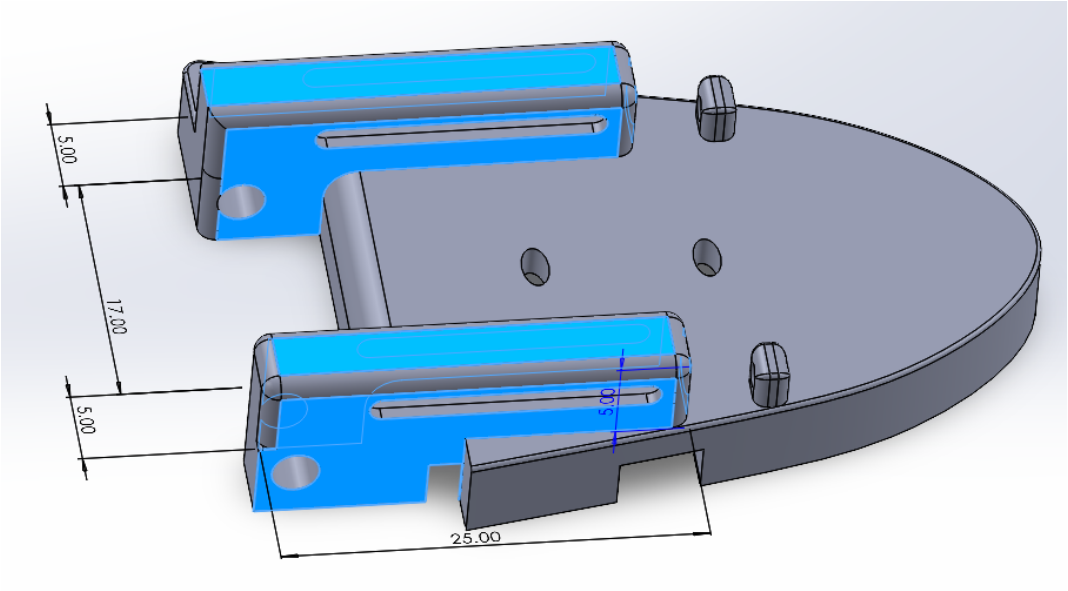

Figure 43: Slider Spring Cover Dimensions of Final Base.

The above figure shows the dimensions of the slider spring cover of the final base.

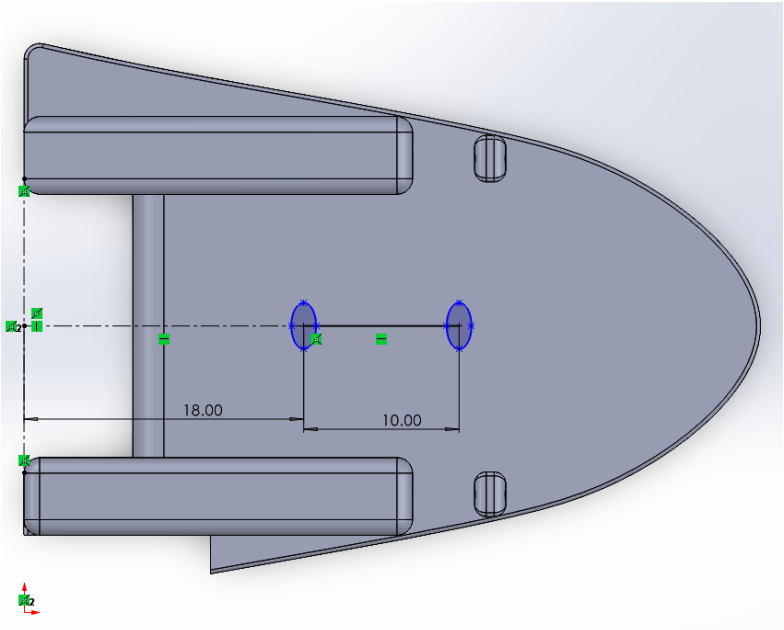

Figure 44: Locations for the Base Tie Down.

In this figure, the location of the tie downs for the base attachment to the retainer is shown.

5.2.3 Pulley:

After the tongue and base designs were drafted, we redesigned the pulley from last year's model. One key difference from last year's design is the pulley has a square bore for the axle. The purpose of the square cross-section was to prevent the shaft slippage. Which was one of the imporvements out team recognized from last year's model where the axle had a circular cross-section. The pulley system (see Figure 45) was composed of two pulleys with a built-in spacer that extended the surface area. This allowed the axle to have greater contact and further prevent shaft slippage as well as keeping the forces more in line with the tongue during actuation.

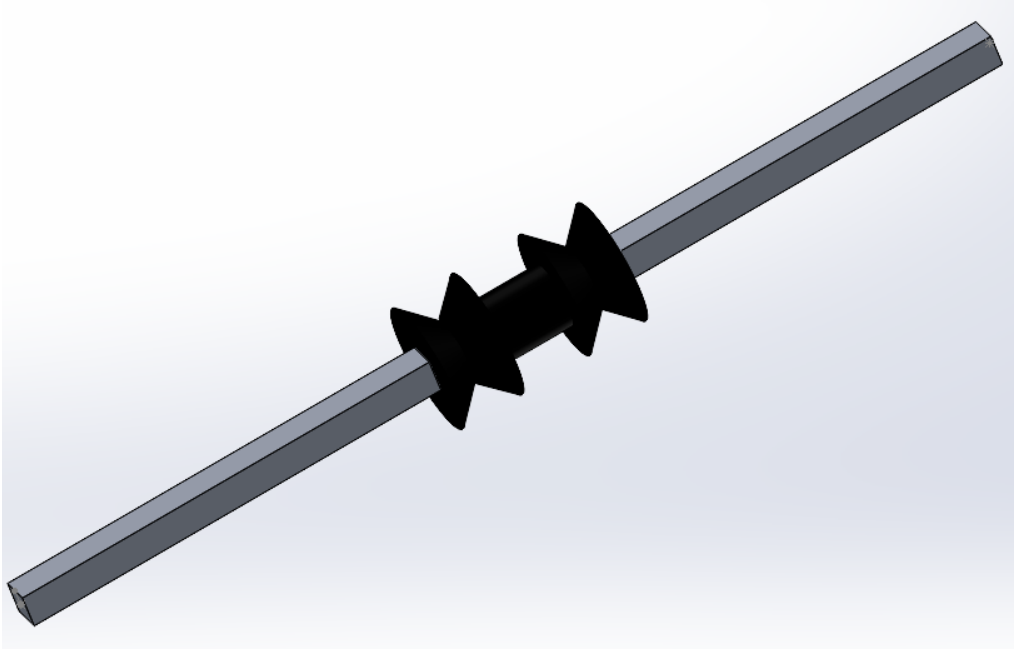

Figure 45: Initial Design of the Pulley.
The figure above shows the initial design of the pulley.

One thing missing from the initial modeling of the pulley was an attachment point for the fishing line that actuates the tongue links. To solve this attachment problem, a bar (highlighted in the figure below) was added between the two pulley wheels. The size of the hole for the pulley

shaft took numerous printing iterations to find the correct tolerancing. The final pulley design can be seen in Figure 46 below along with dimensions.

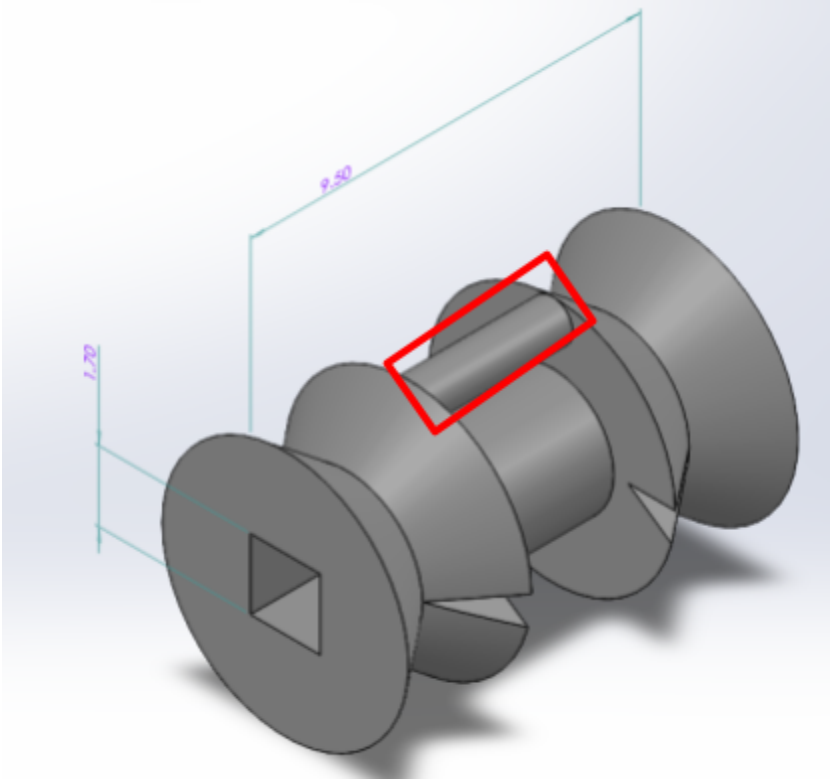

Figure 46: Final Pulley Design.
The pulley was 6mm tall. Shown in red is the attachment for the actuation line.

5.2.4 Retainer:

The initial retainer design had wings that sat on the teeth in the rear of the jaw as the base would sit on top of stilts to provide space for other components. After examining test fits (see more in Section 5.3 (3D Printing Iterations), it was apparent that the retainer suffered from the same problem as the base and needed to be reshaped. Once the retainer was reshaped, we had to make it much taller to fit the internal components such as the gears and the servo motor. After that, we added a bar for the base to be secured to, support walls for components, and a hole for

the idle gear shaft. The initial retainer design and the final design can be seen in the Figure 47 below. The final dimensions of the retainer can be see in Figures 48 and 49 below.

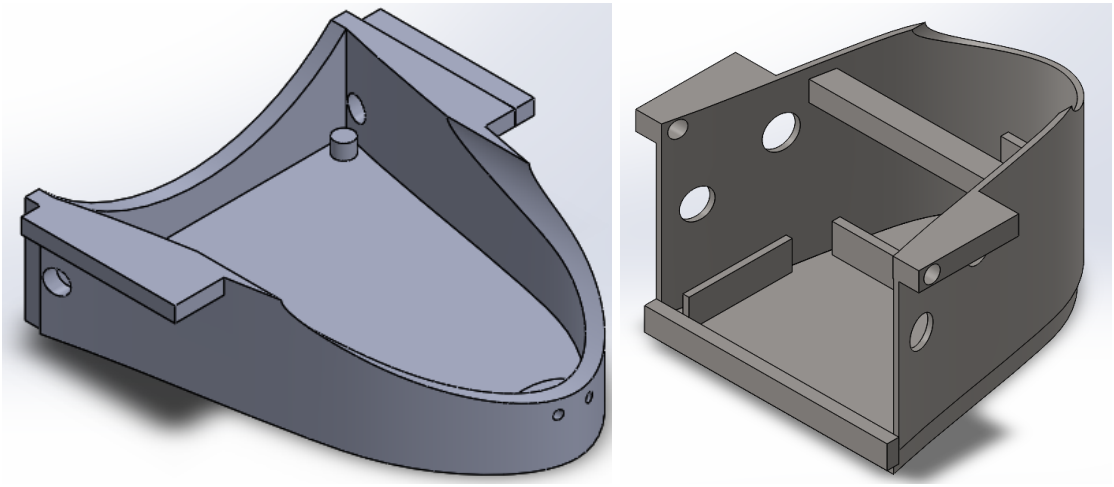

Figure 47: Retainer Design Comparison.
The table showsa comparison between initial retainer design (left) and the final retainer design (right).

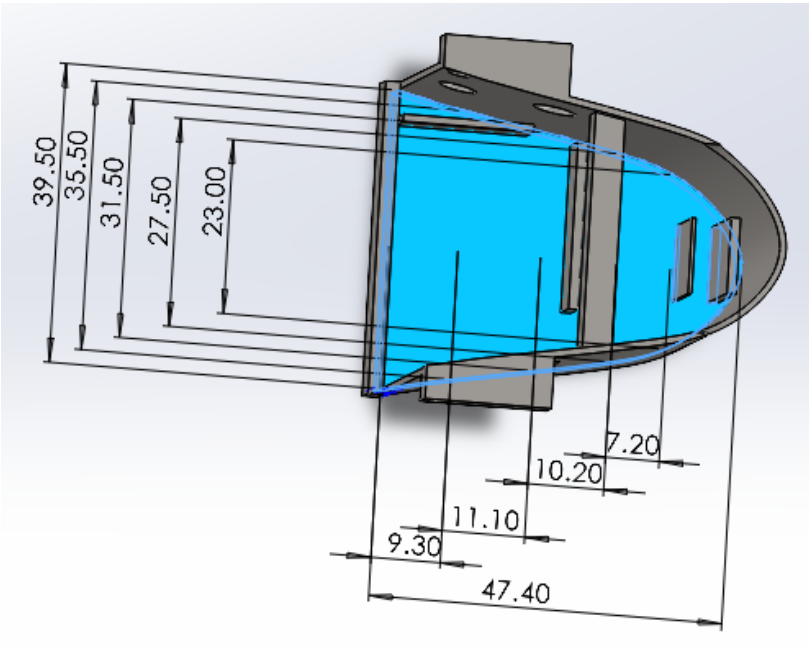

Figure 48: Dimensions of Retainer Shape.
The figure shows the dimensions used to create the final retainer shape. The walls of the retainer were 0.9 mm thick and the entire device was 33.75mm tall. The supports for internal components were not precise and ranged between 0.5mm to 1.5mm thick.

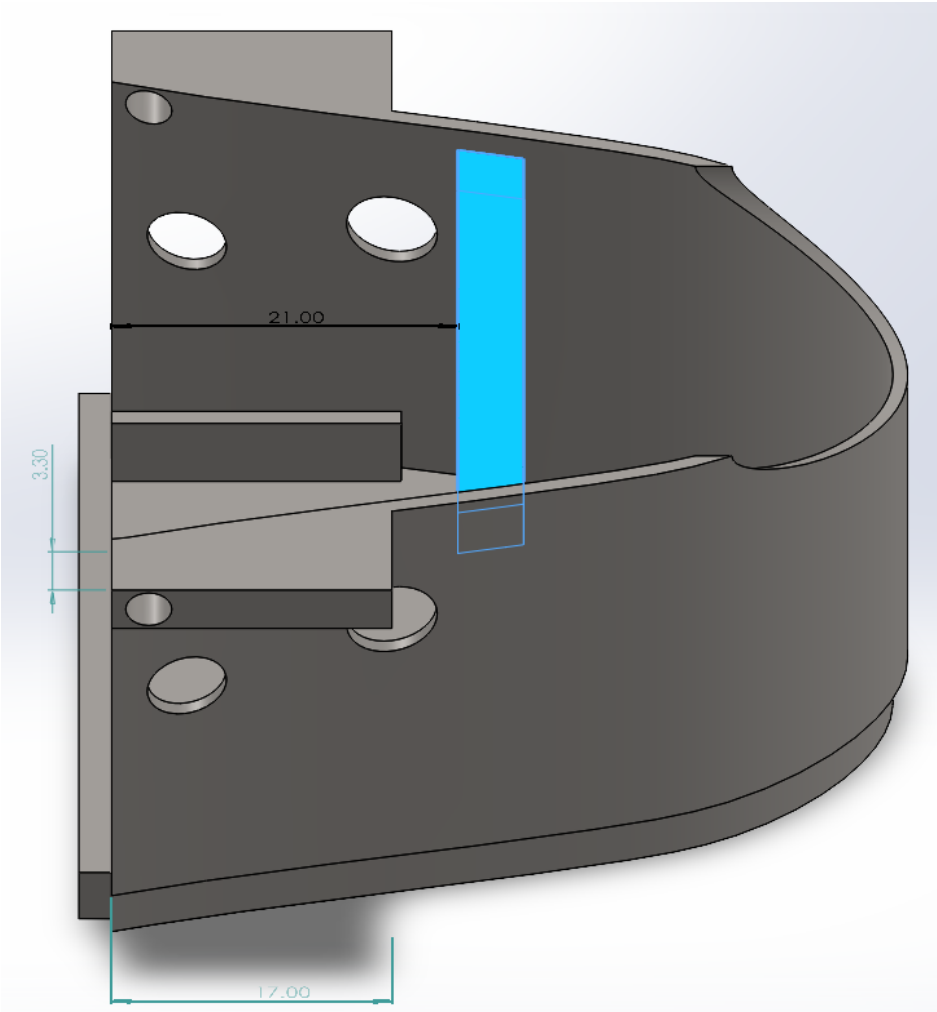

Figure 49: Dimensions of Retainer and Base Support.
The figure shows the dimensions of the retainer wings and the distance to the 3.5mm x 4.0mm base support bar.

5.3 3D Printing Iterations:

5.3.1 3D Print 1:

The first 3D print resulted in a successful print job and gave the team a very good perspective of what changes needed to happen as is shown in Figure 50 below. This iteration was printed using a Lulzbot Taz-6 3D printer using PLA and then constructed with stainless steel rods. This is not going to be the printing device or materials for the final project, however, this is

being used to save money and prototype pieces without having to use slower printing devices with more accuracy. The majority of these changes were needed because the extremely small size of many of the prints prevented the pieces from fitting together correctly. This was corrected by scaling the inner pieces down 5% to ensure that the printing tolerances did not affect sizing and to fit other pieces correctly. Additionally, we were able to file down some of the pieces in order to allow the team to make post-printing fixes to the pieces. Although many fixes were needed, the pieces overall were well constructed and printed as expected to build the actuation device and its retainer.

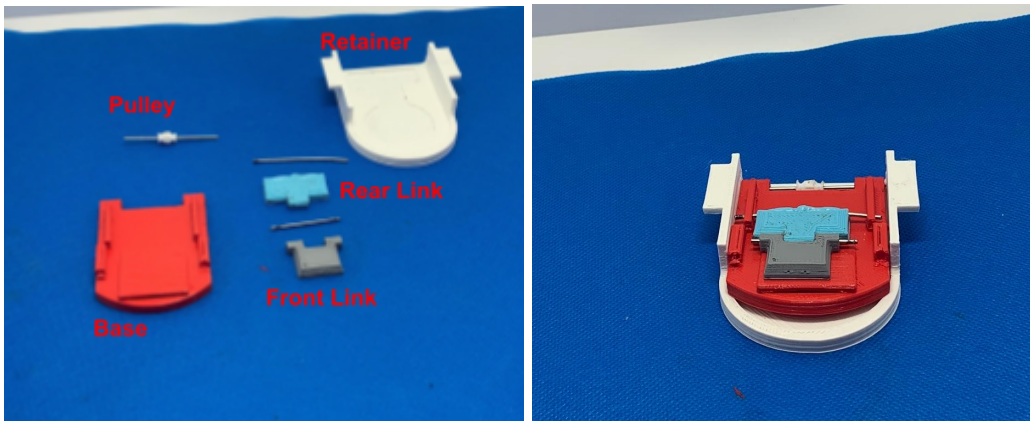

Figure 50: First Print of Tongue Prosthetic.
Left shows the individual pieces of the first device print while the Right image shows the completed build of the first iteration of printing.

5.3.2 3D Print 2:

The second round of printing the prototype was much less promising. This iteration was printed using a Lulzbot Taz-6 3D printer using PLA, and then paired with 2 stainless steel axels . The print job failed three separate times, preventing us from getting the pieces in a timely manner. Using pieces that could be salvaged, the team was able to see how our recent corrections had affected the pieces and this led to a few more small changes to the design. Additionally, we

researched why the print jobs were consistently failing and discovered that the bedding of the printer was too hot. To alleviate this problem, we have added a raft feature to our pieces with the goal of preventing the pieces from failing again. The addition of the raft feature to all future prints severely improved this printing quality of the project.

5.3.3 3D Print 3:

At this point, the team was ready to move on to resin printing. Resin printing takes longer than FDM printing and is more expensive, however, the results of the resin printing tend to be significantly better as compared to the FDM printing. The first resin print used the ELEGOO Mars 2 Pro printer with eSun Hard-Tough Resin in combination with the 1.8.1. edition of Chitubox splicing software. The prints were cleaned with isopropyl alcohol and cured for 10 minutes inside of the ELEGOO Mercury machine. These printers printed with zero errors, unlike what had been happening with the Taz-6 printers and the material seemed stronger than the plastic. However, the pieces to the touch felt rough, and sticky, addition it had some sharp edges where there were supposed to be rounded surfaces. The results of this print can be seen in the Figure 51 below.

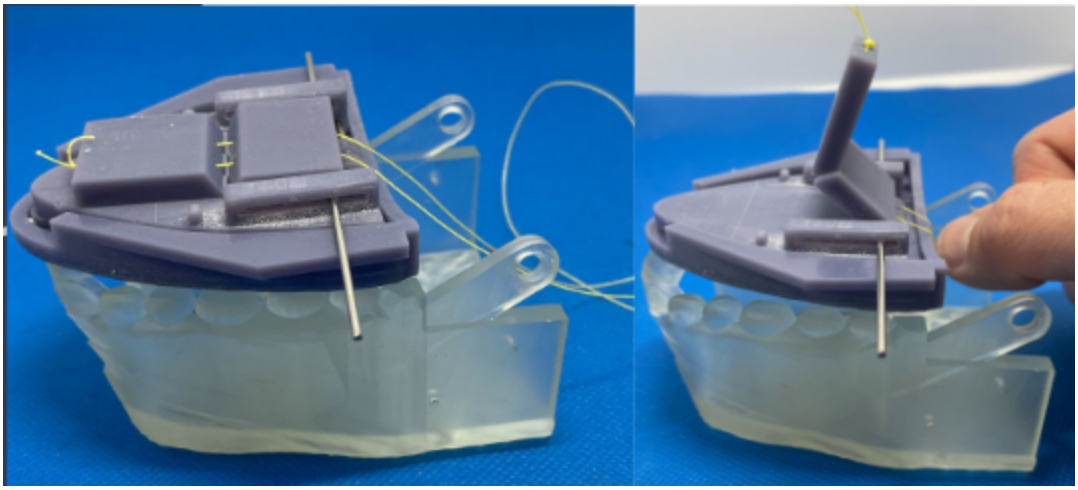

Figure 51: Third Print of the Prosthetic Tongue.
This figure shows the resin printing pieces all put together and manually actuated to show a proof of concept of how the motor power device will actuate. However, it also shows that major changes were needed to the shape of the device to allow the device to fit within the jaw.

5.3.4 Print 4:

The fourth print showed very good results after improving the printing quality by slowing down the print. Additionally, this allowed for many of the smaller components such as the pulley, to be made with greater detail. This print job was done using the exact same printers and resin specification as the third print trial. This was the first print where all of the pieces successfully fit each other as well as fit into the oral cavity. The results of this printing iteration can be seen in the figures of the final device throughout the rest of the paper.

5.4 Control Module Design

The control module is the subsystem of the tongue prosthetic that controls the actuation of the system. Conceptually this system is different from its predecessor because it does not have wireless communication for activation. The current design includes a SG90 servo (see section 5.4.1 Motor), a Seeed Studio Xiao nRF52840, four 1.5V AA batteries, and two GD-03 thin-film force sensors. The system actuates based on a reading from one of the thin film force sensors and

then the motor will rotate clockwise to wind the pulley. The other thin film force sensor will rotate the servo counterclockwise unwinding the sensor meanwhile the return springs pull the links back to the front of the mouth. A model of the circuit is in Figure 52 below. The documented code and a schematic of the circuit can be found in Appendices B and C.

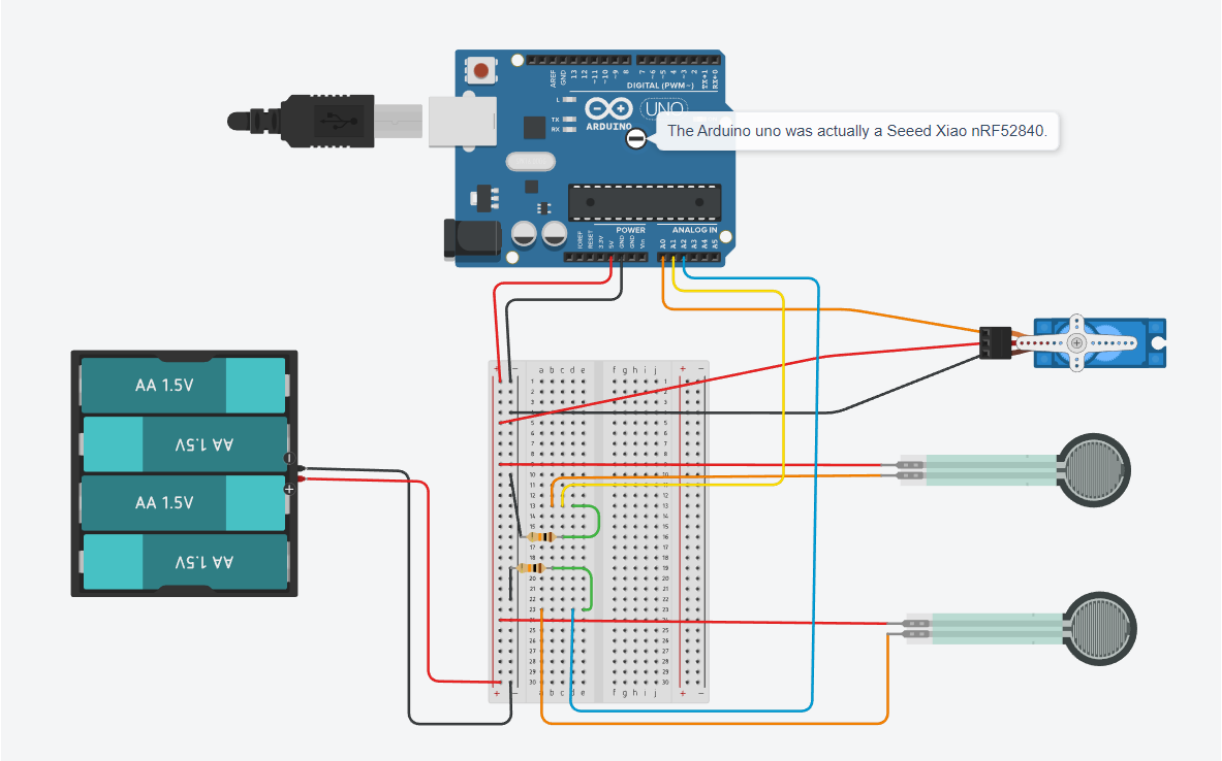

Figure 52: TinkerCad Model of the Control Circuit.
Above is a TinkerCad model displaying the wiring of the control circuit. Note the Arduino Uno used in the diagram was actually the Seeed Studio Xiao nRF52840.

5.4.1 Motor

Initially, other motors were considered as a possible replacements for the previously used SG-90 servo. The HS-70 MG was the front-running replacement motor. However, after a comparison between the two motors was conducted the HS-70 MG was considered not to be a viable option due to size. The comparison between the two motors is in Table 7 below.

Table 7: Summary of Potential Motor Specifications.

Parameters	**SG-90 (used last year)**	**HS-70 MG**
Operating voltage	4.8V - 6V	4.8V - 6V
Stall Torque (4V)	0.127 Nm	0.235 Nm
Stall Torque (6V)	0.147 Nm	0.294 Nm
Max Torque	0.245 Nm	0.294 Nm
Dimensions (L x W x H)	23 mm x 12 mm x 28.5 mm	23.6 mm x 11.6 mm x 29 mm
Rotation	0-180°	0-194°

The table shows a comparison between two potential motors for the tongue. The SG-90 was used for continued development.

The primary reason the SG-90 was selected again was its ratio of power to size. After preliminary tests, the SG-90 needed two modifications to be a feasible option in the prosthetic. The first modification was cutting the wings, shown in red in Figure 53 below, off of the SG-90 to fit within the retainer. The second modification was making the motor a continuous drive motor by cutting the gear stop and the potentiometer off.

Figure 53: SG-90 Wing Modification.
The figure shows the wings in red that had to be cut off the servo to fit within the device. The other modifications were internal and described in the section.

5.4.2 Microcontroller

Last year a combination of the Arduino Uno and TinyDuino were used. However, the issue was the size and the TinyDuino did not fit within the device. Due to making a complete change in the control system and with little experience making PCBs, the team opted for a prototyping board. The first consideration was the Arduino Nano but at 45mm x 18mm it was still too large. The next two options were the Seeed Studio Xiao nRF52840 and the QT Py because of their size. After attempting to run a servo with both chips, the Seeed chip was selected because it could easily be flashed with new code in the Arduino IDE and only needed additional libraries. The comparison between four of the five chips mentioned above is summarized in Table 8 below.

Table 8: Summary of Potentional Microcontroller Specifications.

Parameters	**Seeed Studio Xiao nRF52840**	**QT Py**	**Arduino Nano**	**Arduino Uno (used last year)**
Dimensions (L x W)	21.52 mm x 17.5 mm	~21.52 mm x 17.5 mm	45 mm x 18 mm	68.6 mm x 53.4 mm
Operating Voltage	5 V	3.3 V	5V	7-12 V
Analog/PWM Pins	6/11	9/9	8/9	6/6
Clock Speed	64 MHz	48 MHz	16 MHz	16 MHz
Flash Memory	1 MB	256 KB	32 KB	32KB
RAM	256 KB	32 KB	2 KB	2 KB

The table shows a comparison of the potential microcontrollers. The Seeed Xiao chip was the one the team used for tongue prosthetic development.

5.4.3 Battery

After an examination of the components that consumed the most space within the prosthetic, the battery was identified as the leading culprit. The motor and microcontroller combined needed around 5-6V and 560mA to power the prosthetic. Initially, the search for a more size-efficient power supply started by looking for one battery. However, there was no singular battery that could supply the power requirements. The plan then was to power the motor and microcontroller separately, but after testing that did not seem viable either. Therefore, the design was to include 2 ER2450T batteries in series to meet the voltage requirement. Without the system completely assembled, the two ER2450T batteries worked. When the entire system was complete the batteries did not work due to the high current drain needed. Thus, the power supply remained the same as in previous years and 4 AA batteries were used to supply the entire system. A summary of the battery specifications of the ER2450T batteries is in Table 9 below.

Table 9: Summary of Battery Specifications

Parameters	**1 ER2450T**	**2 ER2450Ts in series**
Voltage	3.6 V	7.2 V
Capacity	500 mAh	500 mAh
Max Continuous Current	5 mA	5mA
Max Pulse Current	15 mA	15 mA
Battery life	53 minutes	53 minutes

The table shows the specifications of one ER2450T and two ER2450T connected in series.

5.4.4 Actuation Control

Last year, the prosthetic was actuated based on an external emg sensor transmitting to a receiver attached to the tongue. The transmission was very noisy and likely would not work when the device was placed into an actual oral cavity. In an effort to simplify the activation of the tongue, a GD-03 thin-film force sensor (shown in Figure 54 below) was used. The force sensor was placed on the wings of the retainer and when one side was pressed, the tongue would actuate and the opposite side would reset the device. The sensors were set up as a voltage divider with 10k Ohm resistors. The code for the actuation control can be found in Appendix B and a schematic of the control module can be found in Appendix C.

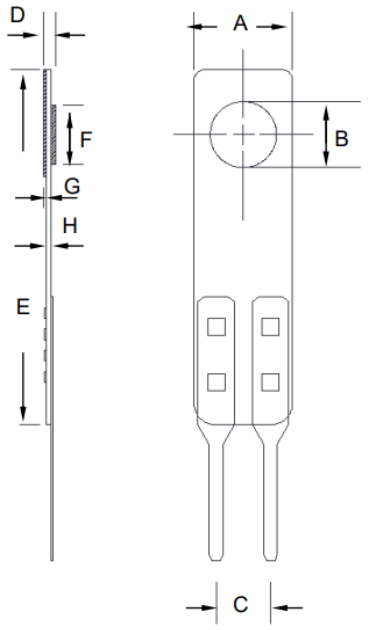

Figure 54: Force Sensors Used in Design.
The dimensions of the sensor are as follows: A 3.0 mm, B 4.6 mm, C 16.7 mm, D 0.2 mm, E 2.54 mm.

5.5 Gear Train Design

In our final design, the device had two tension springs with a spring rate of 0.189 N m, a bolus of 3-5g and individual links. During torque calculations, assumptions were made to make the calculations simplier, such as combining the links into one moment arm. After completing the torque calculations (see Appendix D) it became abundantly clear that the SG-90 servo with max torque of 0.245 Nm would not be able to actuate the device without a gear train. From the calculations, the device would need a minimum torque ratio of 0.0282. Due to the ratio seeming to be to extremely small, two different gear trains were designed. The first was a 4:3 ratio and the other was a 16:30, both of which can be seen in Figure 55 below.

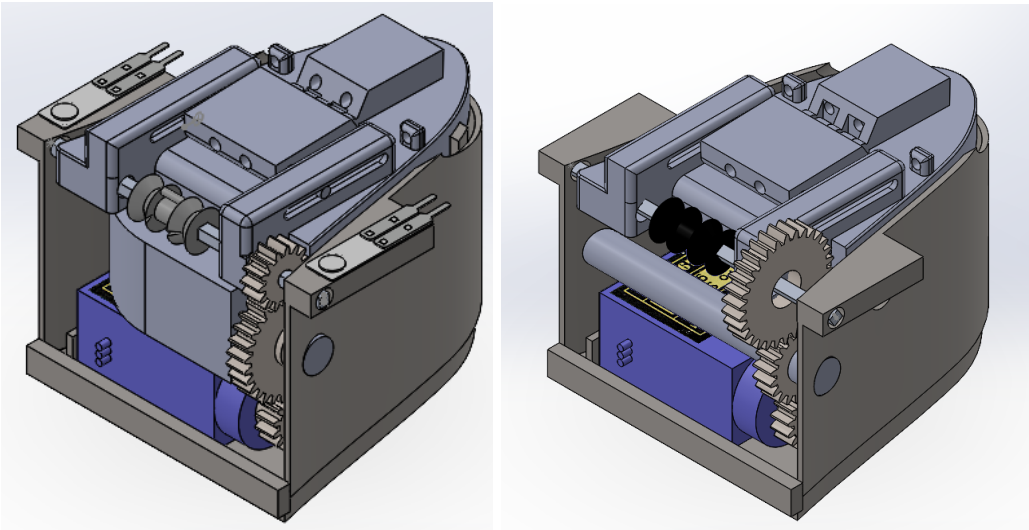

Figure 55: Comparison of 4:3 and 16:30 Gear Ratio.
In the figure the 4:3 gear train can be seen on the left while the 16:30 gear train can be seen on the right.

The 4:3 gear train contained a 16 tooth driver gear, a 30 tooth idle gear, and a 15 tooth driven gear. The 16:30 gear train contained a 16 tooth driver gear, a 20 tooth idle gear, and a 30 tooth driven gear. All the gears had a 20 ° pressure agle. After the gears arrived, two retainers were designed to place the shaft for the idle gear in the correct locations. The shaft hole on the left was the same diameter (5 mm) but differed in location, as seen in Figure 56. To allow the gears to be implemented in the design the gear hubs had to be cut off and they had to either be drilled out to fix the idler gear shaft or shift adaptors needed to be implemented. Both gear trains were tested with the bolus movement testing, fatigue testing, and kinematic analysis. However the 4:3 gear train was the only one tested in temperature testing (see Section 7.0 Testing and Section 8.0 Final Design Verification for more information). Ultimately the 16:30 gear train was the one selected for the final design.

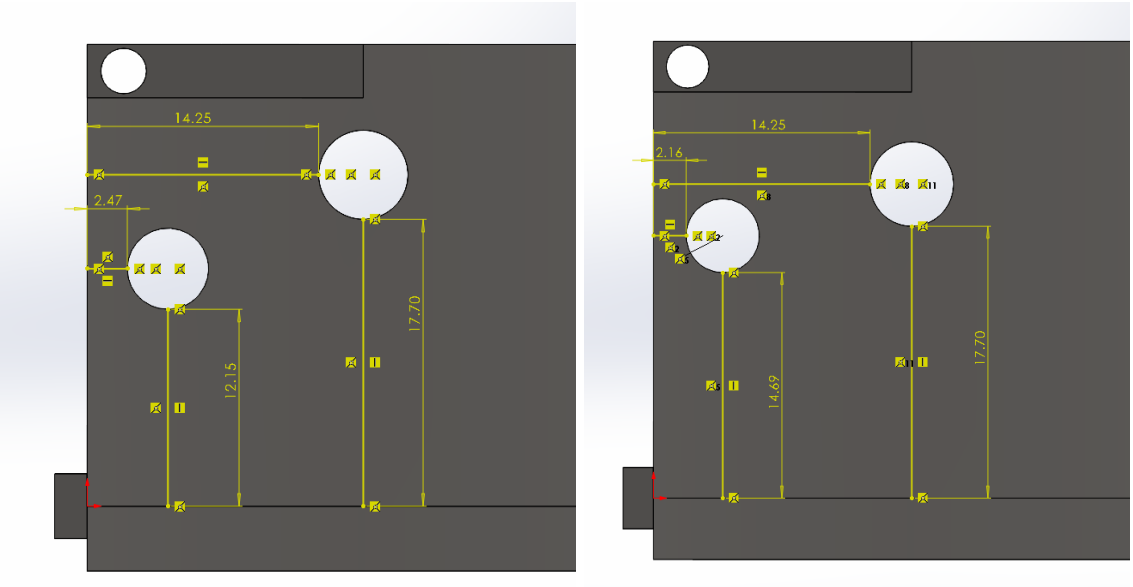

Figure 56: Comparison of Idle Gear Locations.
The image on the left shows the location of the 30 tooth idle gear for the 4:3 gear train. While the image on the right shows the location of the 20 tooth idle gear for the 16:30 gear train.

5.6.0 Final Design

The final design can be seen in the Figure 57 below. The additional wires outside of the retainer were initially planned to be put inside of the reatiner. However, the flexible prototyping board that was needed to do that never arrived. In the process of assembling the prosthetic, many components needed to be modified. For instance, sanding down rough spots in the resin or drilling holes to make them slightly larger due to errors in printing. Additionally, electrical tape was used to help hold the motor in place. Figure 58 shows an exploded view of the prosthetic that can be seen in the accompanying Table 10, which acts as a legend. All SolidWorks files for the final design and prototypes can be found in Appendix A.

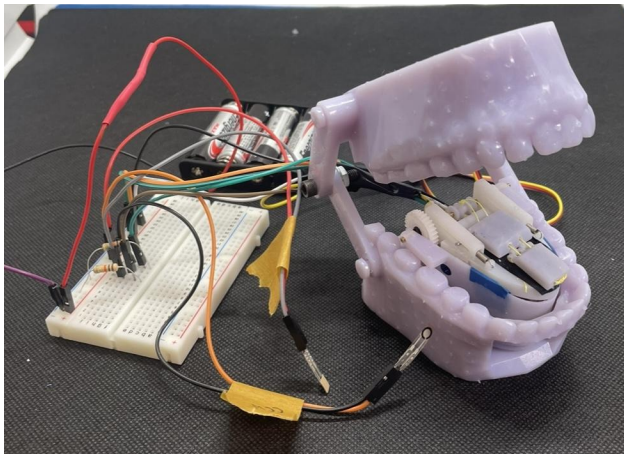

Figure 57: Completed Final Design of Tongue Prosthetic.
The figure above shows our team's final design. Including the simulated jaw, retainer housing group, control group, and batteries.

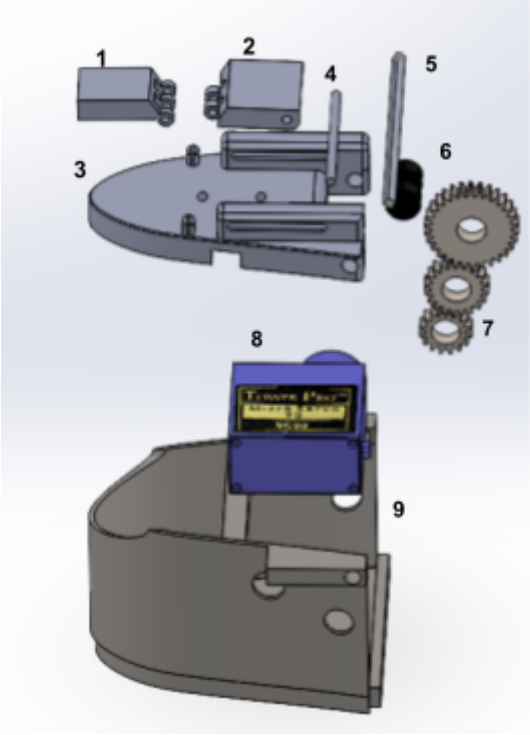

Figure 58: Exploded View of Components
The figure above shows the actuation device's design components in SolidWorks

Table 10: Names of Components Corresponding to Exploded View

1. Front Link
2. Rear Link
3. Base
4. Slide Rod
5. Square Pulley Shaft
6. Pulley
7. 16:30 Gear Train
8. SG90 Servo
9. Retainer
Not Shown: Microcontroller Chip, 10k Ohm Resistors, Return Springs, GD-03 Thin Film Force Sensors

The table above shows the component names for the labeled figure on the left.

5.6.1 Potential Mechanical Failures

Due to the prosthetic having many moving components, there is a large potential for a mechanical failure. Table 11 shows potential mechanical failures. However, during our prototyping and testing none of the listed failures occurred.

Table 11: Possible Mechanical Failures the our System

Piece	**Failure**	**Effect**
Front pin	Collars in pins break	Free floating parts within the mouth
Back pin	Collars in pins break	Free floating parts within the mouth
		Actuation not functioning correctly
Base	Back pin socket breaks	Springs get jammed and cannot reset tongue to original position
		Tongue cannot function
	Spring socket breaks	Spring gets jammed and cannot reset tongue to original position
	Spring eyelet breaks	Spring slams into back pins and tongue cannot reset into original position
	Tongue ramp beaks	Tongue gets stuck and cannot actuate
	Base breaks	System cannot attach to retainer and tongue is unable to actuate
Pulley	Pulley slips	Tongue does not actuate correctly, or at all
	Pulley breaks off	Pulley pieces are a choking hazard and are free floating within the mouth

Table 11 shows the system's potential mechanical failures, including the impacted item, the type of failure, and the accompanying effect. The table describes many scenarios that may occur in the system and how these failures may impair the device's overall function. This information is valuable for recognizing potential problems that may arise during use and generating relevant solutions.

Table 11 Continued: Possible Mechanical Failures the our System

Piece	Failure	Effect
Spring	Springs get jammed by food or other failure	Tongue does not reset to original position
	Spring fatigues and breaks	Tonge cannot reset to original position
		Pieces of spring are free floating within the mouth
Pulley Axle	Axle wraps	Pulley spins irregularly
	Axle shears	Pulleys could fall off resulting in a failure to actuate
Motors	Motor overheat	Motor gets to hot and burns patient, could melt resin material, or just not actuate tongue properly.
	The motor gets contaminated with food	Motor won't properly cool leading it overheating or internal components breaking.
	Overcurrent is applied to the motor	Motor breaks and cannot actuate the tongue. It could also lead to an overheating issue.
	Moisture causes the motor to fail	If too much moisture gets into the motor it could overheat or just not function correctly.

Table 11 shows the system's potential mechanical failures, including the impacted item, the type of failure, and the accompanying effect. The table describes many scenarios that may occur in the system and how these failures may impair the device's overall function. This information is valuable for recognizing potential problems that may arise during use and generating relevant solutions.

6. Mimicking the Oral Cavity

The oral cavity is a very complex system in the human body with many different characteristics. To meet the goal of biocompatibility, the team created an environment for testing the tongue actuation device. As mentioned previously, the oral cavity has a lot of different characteristics that influence the functionality of the tongue. Three main features of the oral cavity were researched: temperature, bacteria, pH levels, and moistness (saliva). With this research, the team created a design that would accurately represent how the auction device would perform in the oral cavity environment, which is displayed in Figure 59.

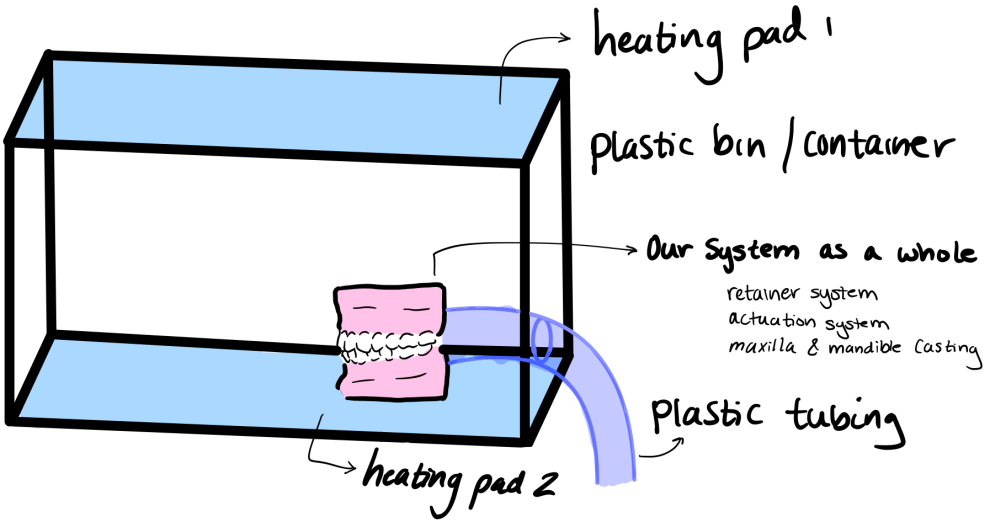

Figure 59: Preliminary Sketch of Oral Cavity Simulation.
The figure above shows the initial design for simulating the oral cavity. The simulation was used to perform temperature as well as bolus testing.

6.1 Artificial Saliva

Artificial saliva can be utilized in medical research for multiple functions and purposes. In the team's case, artificial saliva was used to test the impact of how the tongue's actuation device would function. The research was conducted on the different types of artificial saliva and what characteristics would be important for testing. The artificial saliva picked was "Artificial Saliva for Medical and Dental Research" from Pickering Laborites [48]. The characteristics of this product are Sodium Carboxymethyl Cellulose. The formula is used to increase the viscosity of the solution and make it behave similarly to natural human saliva with a pH of 6.8. Specifically, this product is only used for medical research on dental devices.

6.2 Oral Cavity Simulation

In order to test whether our design is capable of working within a physiological environment, the team mimicked this environment before it can be tested on people. The way in which this environment is going to be recreated in a controlled setting. This is through the use of artificial testing saliva, where the manufacturer predetermines the pH, ions, and other factors. The use of a simulated bolus predetermines the size, weight and other factors. The bolus is going to test whether the tongue is able to react and effectively actuate the bolus when within a simulated physiological environment. Artificial saliva will be used in order to lubricate the mouth and test whether the components of saliva may interfere with the actuation or the longevity of the device.

The oral cavity simulation developed by the team consists of two heating pads, a plastic bin, and acrylic tubing. The heating pad was used to regulate heat, the bin was to keep the device, and the tube was used to put in the wires outside of the environment.

7. Testing

This section of the report outlines the setup for the variety to tests used to verify our actuation device. The types of tests conducted include bolus movement, temperature, and fatigue testing. This section will also briefly discuss the steps, rationale, and brief overview of the results from each test. The results from each test can be found in section 8.0 (Final Design Verification).

7.1 Bolus Recipe Testing

When a person is chewing, the masticated food forms a bolus. A bolus is partially digested food that is prepared for deglutition, and swallowing, after being thoroughly masticated. In order to test our product's ability to move the bolus into the rear of the oral cavity, realistic boluses must be created, tested, and able to be recreated exactly to limit the number of variables in the experiments and trials. A simulated bolus can be easily created using instant mashed potatoes and some water. Specific ratios used by our team can be seen in the table below. This necessity led to the testing of different bolus recipes, using varying ratios of instant mashed potatoes to water, to develop an artificial bolus that can replicate the characteristics, mass, and shape of a typical bolus. Table 12 below shows the different recipe trials and a description of each outcome.

Table 12: Various Bolus Recipes and Their Representation of a Human Bolus

Test Ingredients	Results
5g IM 2.5 Tbsp W	Bolus was flaky and overall dry. Would not represent a real bolus well
5g IM 2 Tbsp W	Bolus is smaller, very flaky, and dry. Lots of spare powder that was untouched by water.
5g IM 3 Tbsp W	Most massive bolus of the three. Still seemed dry but no flakes and held together well.
4g IM 2 Tbsp W	Bolus was flaky but stayed together. I noticed it was similar in size to the first two 5g boluses.
4g IM 2.5 Tbsp W	Dry spots but still together. More massive than 5g IM and 2 Tbsp W.

In the table above, the results from testing various recipes for bolus making. Acronyms and abbreviations: IM; instant mash, W; water, g; grams, tbsp; tablespoon.

Table 12 Continued: Various Bolus Recipes and Their Representation of a Human Bolus

Test Ingredients	Results
4g IM 3 Tbsp W	Very few dry spots on this bolus and was slightly more massive than the previous test.
3g IM 2 Tbsp W	This bolus was flakey and full of dry powder. Not a good bolus.
3g IM 2.5 Tbsp W	This bolus is well held together and has no flakes, however, it is not the consistency that would make a good bolus.
3g IM 1.5 Tbsp W	Way too dry, and flaky, and a bunch of powder is left.
5g IM 5 Tbsp W	This bolus (located at the top of the plate) was much more massive than the other 5gIM trials. I came to the conclusion that in the majority of my previous trials, I was not using enough water, which then prevented the varying masses of IM from expanding to their full form.
3g IM 4 Tbsp W	This new bolus test resulted in a perfect-sized bolus. However, the consistency was too watered down and acted more like pudding. To counteract this, I next tested 3g IM and 3 Tbsp W.
3g IM 3 Tbsp W	Located on the topmost plate, this bolus was the perfect recipe for our tests. It had the same size as the unlimited water 3g IM test, but it also had the correct consistency of a human bolus.

In the table above, the results from testing various recipes for bolus making. Acronyms and abbreviations: IM; instant mash, W; water, g; grams, tbsp; tablespoon.

After testing, the final recipe of 3g Instant Potatoes and 3 Tbsp of boiling water proved to be the best artificial bolus for its size, characteristics, and mass. This recipe is also easy to recreate for any future testing. This recipe was continually used during bolus movement and compression testing, which is further discussed in the below sections.

7.1.1 Bolus Compression Testing

Now that the boluses were similar to a typically formed bolus and easy to replicate, it became time to test the compression strength of the formed boluses. This is important because as the team develops and puts together the mechanical actuation device. It is necessary to know how much force the bolus can take before it becomes unrepairable and deforms. This compression testing was performed with a Mecmisin Multitest 1 Compression and Tension Force machine. Four trials were run on the boluses with over 600 data points each to create an extensive stress-strain comparison graph. This graph, located below in Figure 60, showed the yield strength of the boluses to be 20Pa. Subjectively, this is a low number, indicating that our device has to potential to deform the bolus. This could lead to a piece of the bolus getting trapped in mechanical parts of our actuation device such as the springs or linkage system, leading to a possible mechanical failure or difficulty cleaning the device.

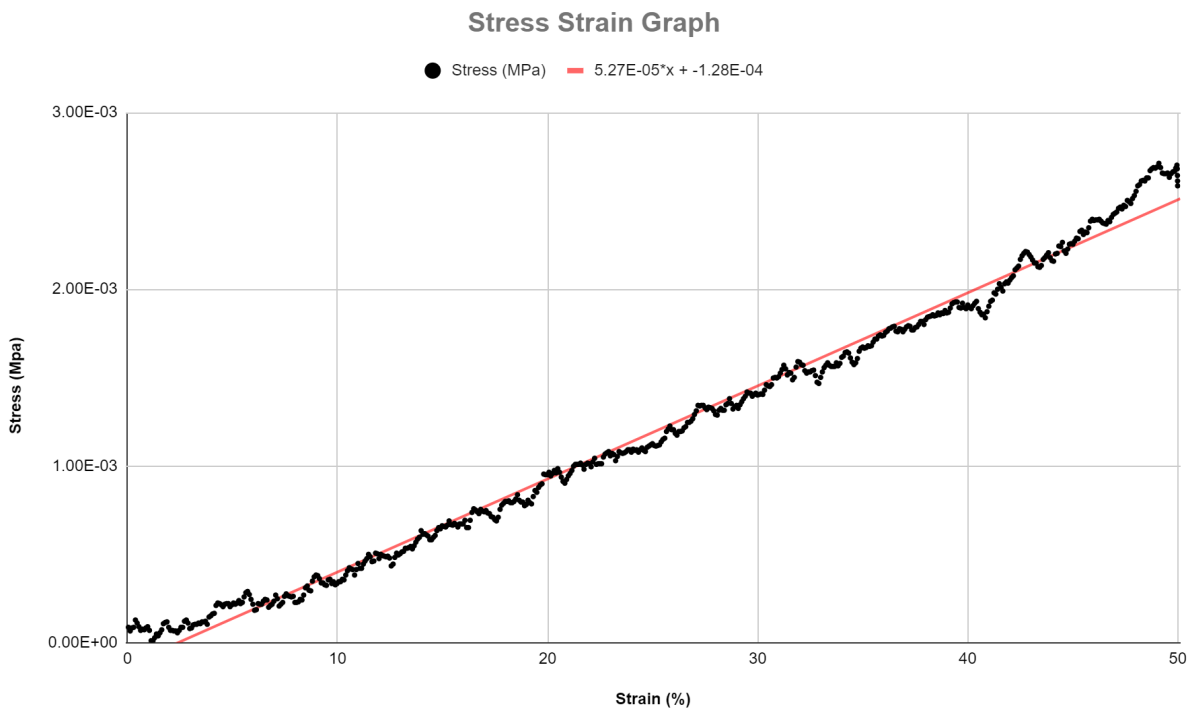

Figure 60: Stress-Strain Graph of Bolus Compression.
The graph above shows the stress-strain curve of a bolus during compression testing. This was used to determine the strength of the bolus and the possibility of deformation during actuation.

7.1.2 Bolus Movement Testing

Bolus movement testing was used to determine the feasibility of the prosthetic to aid in its purpose of helping a patient swallow. We used this test to measure our device's ability to move a bolus from the back of the mouth, testing varying conditions such as bolus weight and open or closed mouth position. This testing method was implemented on both the 16:30 and 4:3 gear train in order to determine which gear train was best for the final design. As previously mentioned, three different bolus weights were used, 3g, 4g, and 5g, and were made using the recipe discussed in Section 7.1 (Bolus Recipe Testing). Each bolus was tested 10 times in the following conditions: jaw open (see Figure 61), jaw closed, and jaw closed with saliva (both

closed jaw conditions can be see Figure 62). The jaw open test was used mainly as a comparison to the tests implemented in previous years. The jaw closed condition more accurately simulated the scenario the prosthetic would actually be used by a patient recovering from a glossectomy. The results from this section of testing is discussed in Section 8.1 (Bolus Movement Testing Results) of this report. Refer to Appendix E for a video of our device moving a bolus during bolus testing.

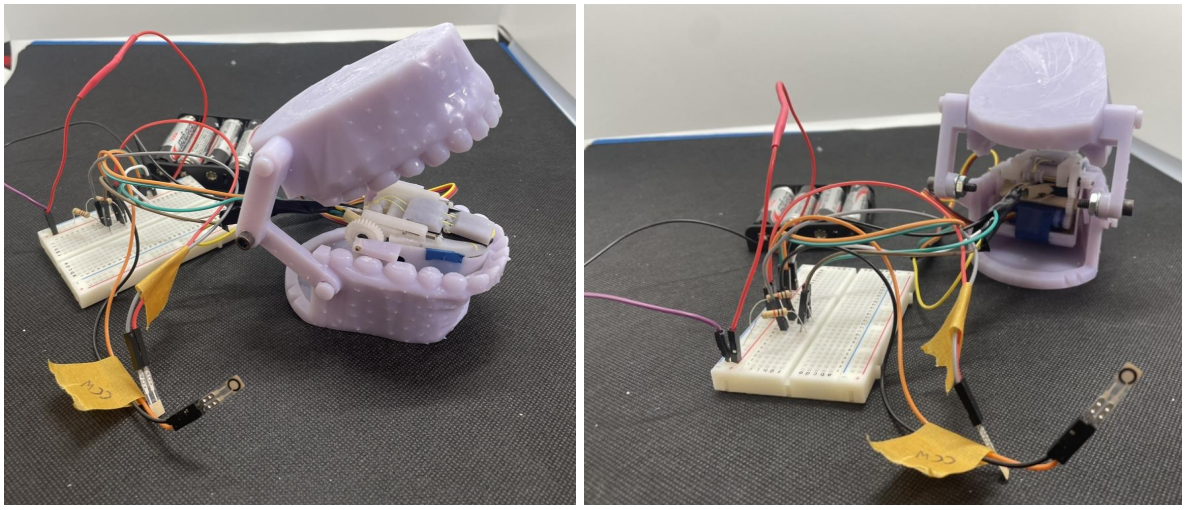

Figure 61: Open Jaw Test Setup.
In these images, the open jaw test setup can be seen. The side profile of the open jaw (left) while the rear profile of the open jaw (right).

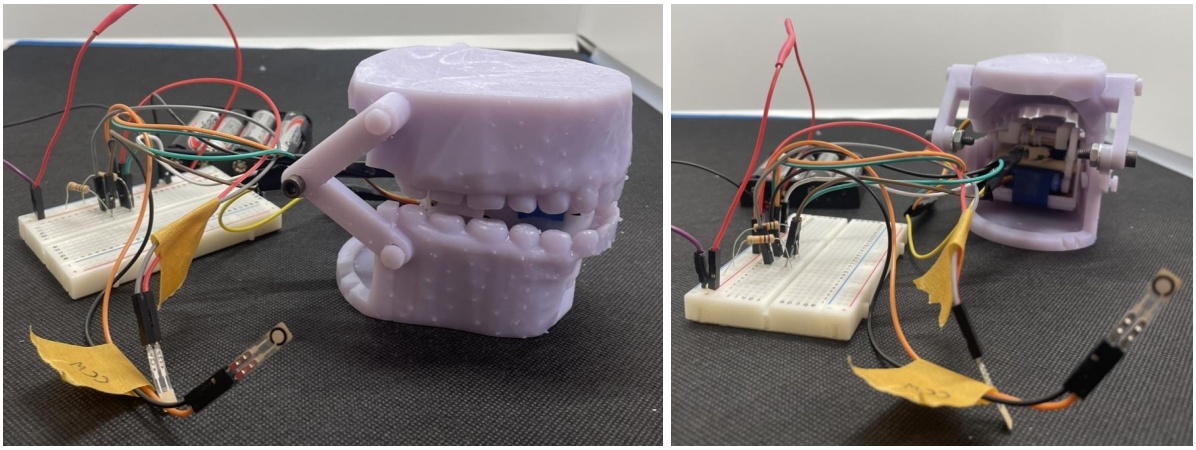

Figure 62: Closed Jaw Test Setup.
In these images, the closed jaw test setup can be seen without the artificial saliva. Note the physical jaw setup did not change with the addition of the artificial saliva. The side profile of the closed jaw (left) while the rear profile of the closed jaw (right).

7.2 Temperature Testing

Temperature testing was conducted to determine whether the device would maintain a temperature similar to the oral cavity. If the temperature increased too much due to either friction or the motor, it could put a patient at risk. To determine if the final prototype was successful in maintaining a consistent temperature, we tested various locations on the device continuously while actuating within a simulated oral cavity at 37.1 degrees Celcius. In order to regulate the temperature of the oral cavity simulation, utilizing a temperature sensor that offered temperature feedback was essential. As the simulation used a continuous heating application, utilizing two heating pads, and required the temperature to be maintained around 37.1 degrees Celcius, respective to the standard oral cavity.

The team chose from a wide variety of methods that are employed to carry out the operation of determining the temperature, such as infrared sensors, thermistors, and thermocouples. Shown in Figure X is the initial setup and materials needed for simulating the oral cavity. In order to regulate the temperature of the oral cavity simulation, utilizing a temperature sensor that offered temperature feedback was essential. As the simulation used a continuous heating application, utilizing two heating pads, and required the temperature to be maintained around 37.1 degrees Celcius, respective to the standard oral cavity.

The use of an analog-to-digital (ADC) temperature sensor and thermocouples was determined to be the best method for temperature feedback. Both sensors are easily accessible

due to their low cost, small size, and low energy requirements, analog-output temperature sensors are widely used. The output of the sensor is determined using an ADC converter in a number of systems that employ such sensors, such as Arduino. A thermocouple is a temperature-measuring device composed of two dissimilar metal wires that are joined at one extremity and connected to a thermocouple thermometer or similar device at the other end. Thermocouples provide temperature readings over a wide range of temperature ranges with the right design and can measure the voltage as well as current. The circuit's output voltage would be detected and then converted to temperature. Depending on the type of thermocouple used, the junction's function determines the voltage magnitude.

Unfortunately, the team was unable to get the thermocouple temperature sensor to be calibrated correctly. After plotting the data from ten trials, the graph did not generate a linear regression. Although ten trials were conducted, the temperature did not range from 0 to 100 degrees Celsius. Thus, the team was ultimately unable to incorporate the derived regression equation into the Arduino IDE code, referenced in appendices, to accurately relay average and calibrated temperature measurements.

Consequently, the team concluded that using LM35DZ temperature sensors would be better due to time constraints. The LM35 is a high-precision integrated circuit temperature sensor that has an accuracy of 0.5°C and can measure temperatures in the range of -55°C to +150°C. With a sensitivity of 10mV per degree Celsius, the sensor generates an output voltage that is directly proportional to the temperature being measured.

The LM35 is easy to use, inexpensive, and accurate. In industrial, automotive, and consumer electronics, as well as other applications involving temperature measurement and control, it is frequently employed. The LM35 is simply interfaced with microcontrollers,

analog-to-digital converters, and other circuits and does not require any external calibration or trimming.

To set up the LM35, the right pin was connected to the ground, and the left pin to power (4V to 30V) (the flat side of the sensor facing a team member) of the Arduino board. An analog voltage that was directly proportional (linear) to the temperature in degrees Celsius was present on the center pin, as seen below in Figure 63. An Arduino code was also generated to read the LM35 temperature sensor. All of the results from this section of testing is discussed in section 8.2 (Temperature Testing Results) of this paper. A video taken for temperature can be found in Appendix F.

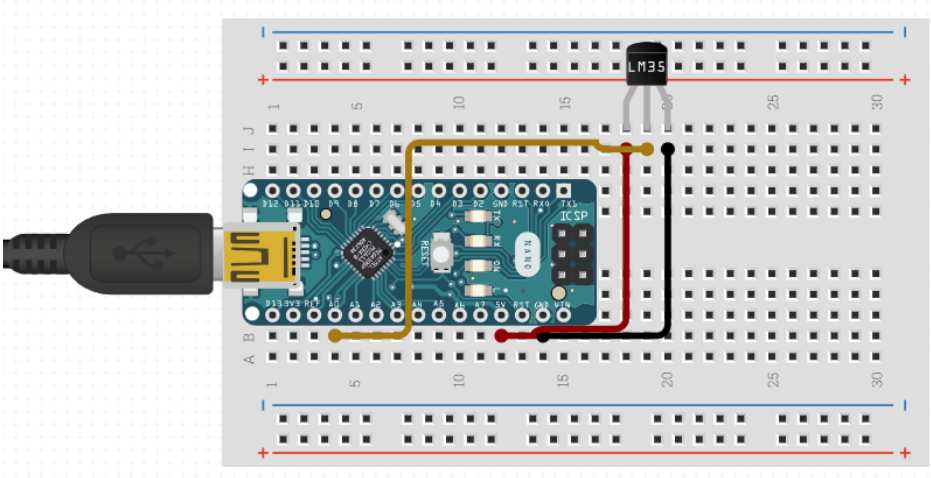

Figure 63: Experimental Arduino Nano setup with the LM35 Sensor.
The figure above shows the wiring of the LM35 sensor and the Arduino Nano used during temperature testing. Note the actual wires used were about half a meter long.

7.3 Fatigue Testing

Fatigue testing was completed to determine if the tongue can hold up for a full day's worth of swallowing, which is roughly 500-900 times [46], [47]. The testing did not have a

separate setup, rather it was an assessment of the wear each mechanical component accrued through the various other testing procedures. The total actuations from bolus movement and temperature testing were added up and the components of the device were assessed after these tests. All of the results from this section of testing are discussed in Section 8.3 (Fatigue Testing Results) of this report.

7.4 Kinematic Analysis

The group performed kinematic analysis on actuation devices to develop kinematic data. The kinematic data was used as a form of validation for our device. Videos were taken of the device's actuation (without bolus). Logger Pro software was used to determine the final angle of actuation of the device. Through the Video Analysis function seen in Figure 64, points were plotted during each frame of the video providing 5 different outputs: time in seconds, x coordinates in millimeters, y coordinates in millimeters, x velocity in millimeters per second, and y velocity in millimeters per seconds. These data points were used to then calculate the angle at each coordinate.

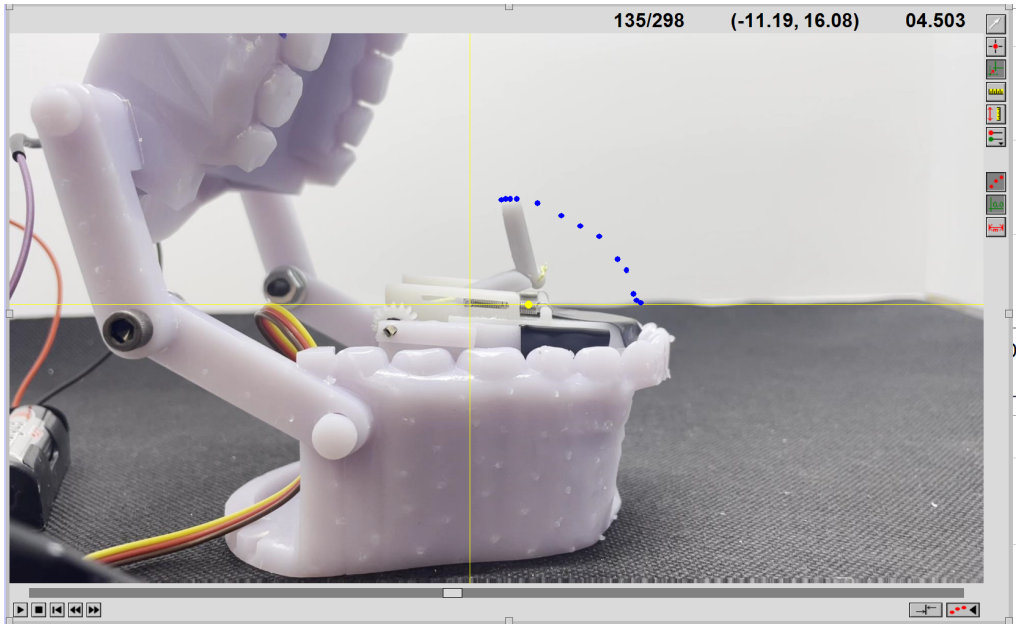

Figure 64: Video Analysis in Logger Pro of Final Actuation of the Device.
The figure above shows how the kinematic analysis was conducted with Logger Pro. Each frame received a blue dot at the tip of the front link.

8. Final Design Verification

This section covers the results from the testing described in Section 7.0 Testing of this paper. The results included in this section are the movement of bolus, testing of temperature at certain points of the device, fatigue testing, and kinematic data analysis. With these results from this section the team was able to determine how well the device meets the desired goals and objectives set in previous chapters.

8.1 Bolus Movement Testing Results

In the bolus movement testing, we defined a successful movement (see in Figure 65) as the bolus starting in the front of the mouth and moving to the back of the mouth.

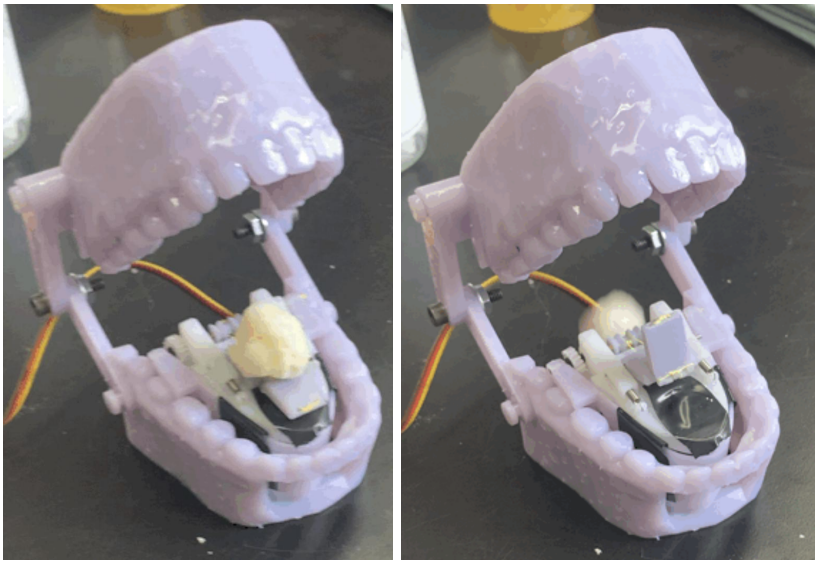

Figure 65: Example of a Successful Bolus Movement.
The left image shows the starting location of the bolus, while the right image shows the location of the bolus after a successful movement.

Both gear trains successfully moved a 3g bolus 100% of the time. The two gear trains were able to move a 5g bolus accurately with a success rate of 90%. However, the 4g bolus only moved 80% by the 4:3 gear ratio and 50% by the 16:30. This disparity was likely caused by the placement of the bolus during testing, as the bolus had a tendency to fall out of the mouth or to the side. The open mouth position used during bolus movement testing was more beneficial for comparisons to previous design iterations (Holod et al.) rather than in the practical application of the device. The closed jaw tests were more informative from a practical standpoint as it displayed a more accurate simulation of our device's intended use by a patient. The 4:3 gear train was unable to move a bolus with the simulated jaw closed. The 16:30 gear train was successful 40% of the time, no matter the bolus weight. When artificial saliva was introduced with the closed jaw, the 3g bolus was the only bolus weight that could successfully move from the front to the back of the mouth,t which occurred 20% of the time. The cause of the failures was the

artificial saliva would lead to the breakdown of the larger boluses. The closed jaw saliva tests were only conducted five times for each bolus weight due to the continual breakdown of each bolus tested. The main reason the 16:30 gear train was more successful in the closed jaw test was it actuated differently due to higher torque than the 4:3 gear train. The difference between the two actuation movements will be discussed more in section 8.4 (Kinematic Analysis Results). The results of the bolus movement testing are summarized in Figure 66 below.

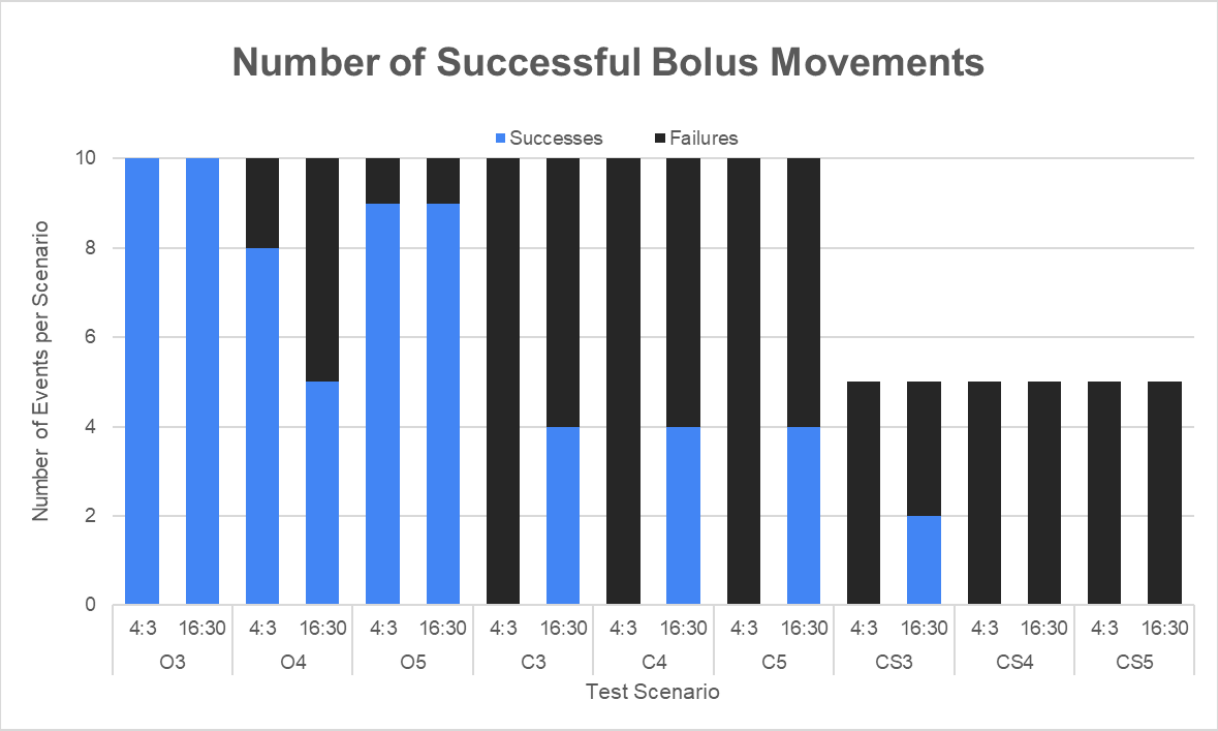

Figure 66: Graph of the Number of Successful Bolus Movements.

The graph above shows the comparison of successes and failures of each gear train from the bolus movement testing. A successful bolus movement was defined as a bolus starting in the front of the mouth and moving down the throat. The number in each test scenario was the weight of the bolus in grams. The O means open jaw, with no saliva, C means closed jaw with no saliva, and CS means closed jaw with saliva.

8.2 Temperature Testing Results

After completing the temperature testing at four different points on the device, it was determined that the actuation device did not exceed a temperature of the threshold of 37 ℃. The average temperature at the springs was determined to be 32.2℃. The average temperature at the pulley was 31.1 ℃. Under the base the average temperature was 32.3 ℃. The average temperature of the upper palate was 31.8 ℃. The greatest change in temperature was 1.46 ℃, which occurred at the springs. A summary of the average temperature and maximum change in temperature can be seen in Table 13 below. None of the locations measured demonstrated that they would significantly heat up and either lead to degradation of our device or harm of the patient. The temperature measured at each location is shown in Figure 67 below. Individual graphs for each location can be found in Appendix H.

Table 13: Summary of Temperature Testing Results

Region Measured	Average Temperature	Maximum Change in Temperature
Springs	32.2 ℃	1.46 ℃
Pulley	31.1 ℃	0.98 ℃
Under the Base	32.3 ℃	1.46 ℃
Upper Palate	31.8 ℃	0.98 ℃

Table 13 shows the average temperature and maximum change in temperature of the four measured regions of the tongue after ten actuations.

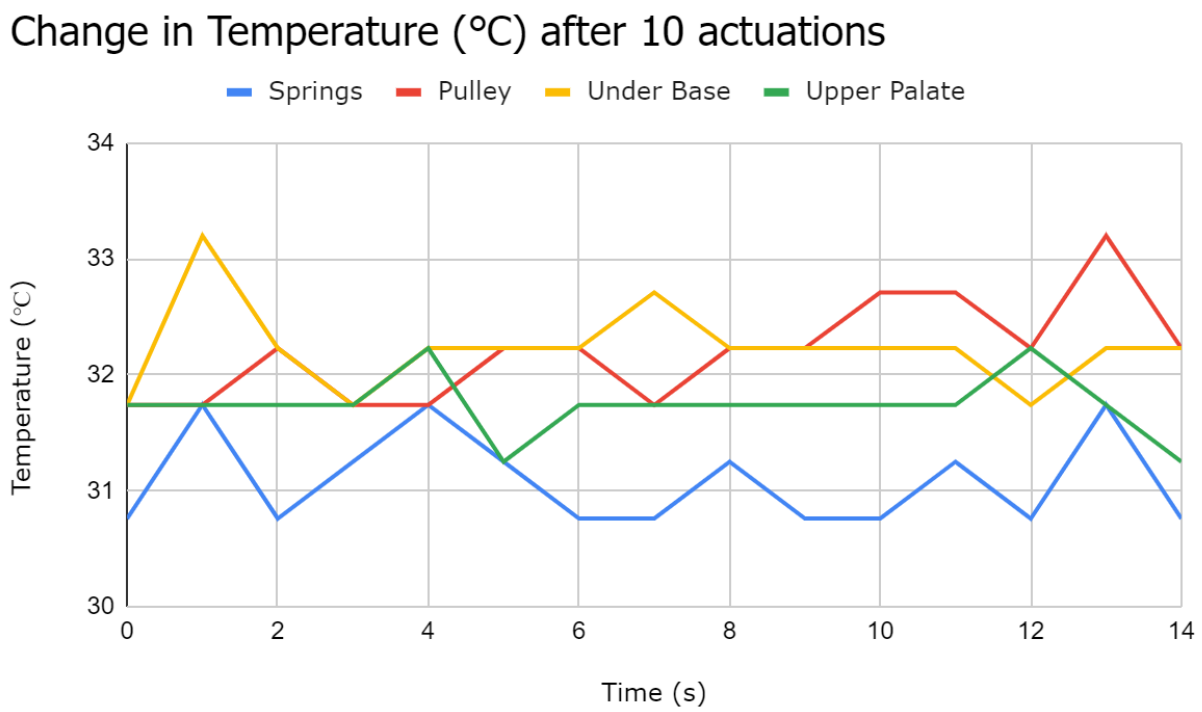

Figure 67: Combined Graph of the Temperature Change.
The graph above shows the temperature change at various locations in ℃ after ten actuations.

8.3 Fatigue Testing Results

As mentioned in a previous section, fatigue testing was compiled from the total actuations completed during bolus movement and temperature testing. Post the testing, prosthetic underwent the number of actuations summarized in Table 14 below:

Table 14: Total Actuations on the Tongue Prosthetic

Parameters	**4:3 Gear Train**	**16:30 Gear Train**	**Base and Retainer**
Temperature Testing	40	0	40
Bolus Movement Testing	60	90	150
Total Actuations	100	90	190

Table 14 shows the total actuations on each component of the design. The gear trains have less actuations because they were swapped halfway through testing.

After testing, the component with the most fatigue was the batteries due to the fact that the batteries had to be changed after 80 actuations. Each actuation was 1.2 seconds with 600 milliseconds for both the activation and reset phase. The gear trains only suffered damage in the makeshift heat shrink adaptors shown in Figures 68 and 69 below:

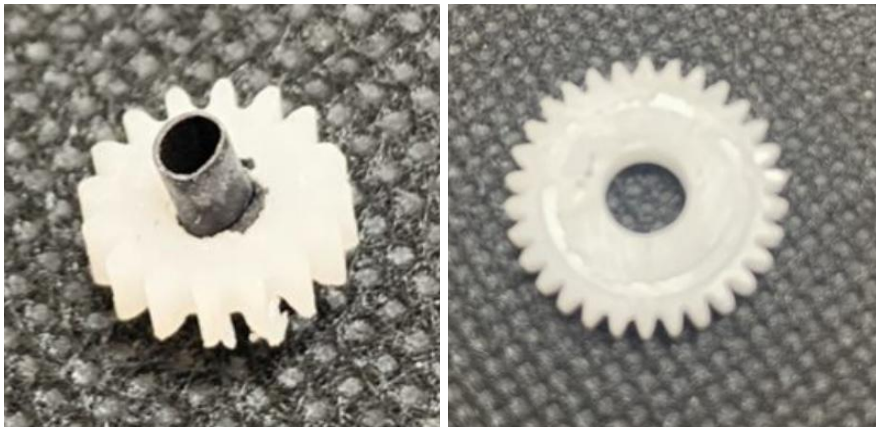

Figure 68: 4:3 Gear Train Fatigue Results.

The figure above shows the fatigue of the 4:3 gear train after 100 actuations. The 15 tooth driven gear (left) and the 30 tooth idle gear (right).

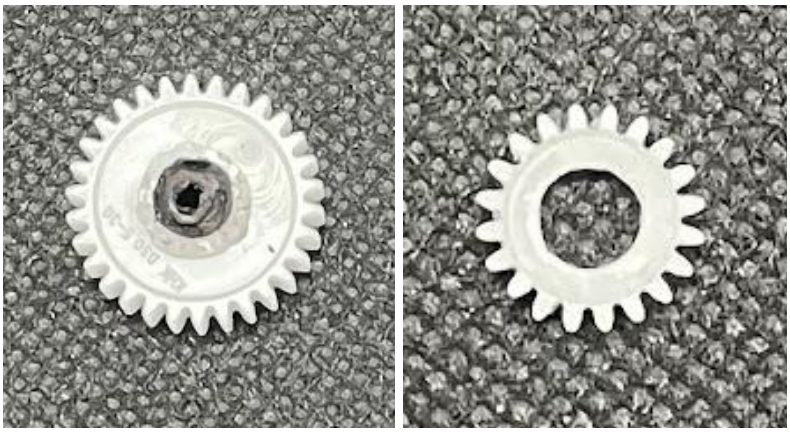

Figure 69: 16:30 Gear Train Fatigue Results.

The Figure above shows the fatigue of the 16:30 gear train after 90 actuations. The 30 tooth driven gear (left) and 20 tooth idle gear (right). Note the shaft holes are not perfectly circular because they were hand drilled.

Overall, the retainer and base components had no significant deformation from the tests as can be seen in Figures 70 and 71 below. 600 actuations were not tested as previously described in the test setup (Section 7.3 Fatigue Testing). The number of batteries and time needed to complete all 600 actuations were not feasible at the time of testing.

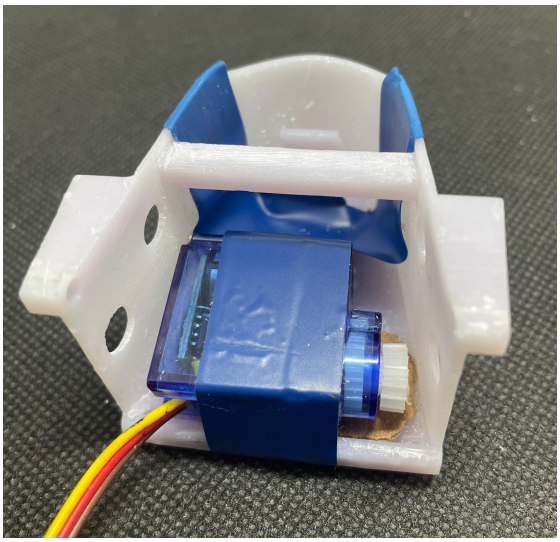

Figure 70: Retainer After Bolus Movement and Temperature Testing

The figure above shows the fatigue of the retainer at the conclusion of all testing. Note the blue tape was only to assist in securing the servo motor.

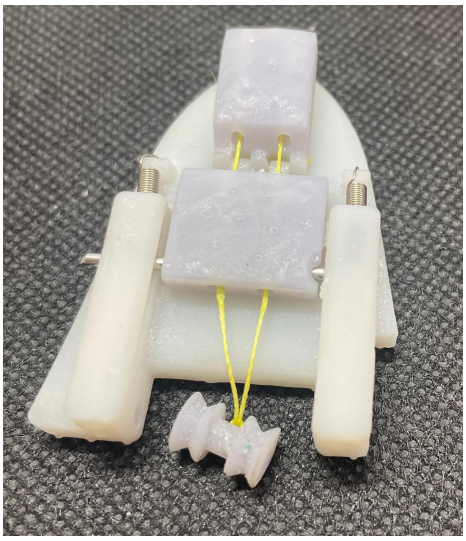

Figure 71: Base Components After Bolus Movement and Temperature Testing

The figure above shows the fatigue of the base and its components at the conclusion of all testing.

8.4 Kinematic Analysis Results

The goal of this analysis was to determine the change and final angle of actuation for the tongue prosthesis, through Logger Pro. The final angle of the actuation device was determined to be 73.13°, this can be seen in Figure 64 in Section 7.4.0 Kinematic Analysis. All other angles as well as the angle and data set can be found in Appendix G.

9. Final Design Considerations

These statements go into different considerations and standards that were examined when completing the tasks mentioned in previous chapters. Exploring the impact that the actuation device may have, goes beyond engineering. It is critical that other societal and economic impacts are also considered.

9.1 Economics

Economically, the creation of a self-contained prosthetic tongue could be extremely advantageous for oral cancer patients who have undergone total glossectomy. The prosthetic would help in swallowing, which is important for hydration and nutrition. Although the project description does not include the prosthetic tongue's price, it is most likely a considerable expenditure. For patients who experience difficulty eating and drinking following a total glossectomy, the advantages of better swallowing function might, however, exceed the expense of the prosthetic. The prosthetic would also eliminate the need for more expensive treatments like feeding tubes or continued speech therapy, which would save money over the long run for both individuals and healthcare systems. From a business standpoint, there might be opportunities for businesses to create and produce the prosthetic tongue and even grant licenses to other medical device manufacturers. However, the potential income and profitability for businesses engaged in its development may be constrained by the size of the market for this kind of gadget. Despite potential development and market hurdles, the prosthetic tongue project may

prove to be a worthwhile investment for both individuals and healthcare systems due to the potential benefits for patients.

9.2 Environmental Impact

This project may have environmental implications that should be taken into account. Silicone, metals, polymers, and electronics are some of the materials that will be used to create a self-contained prosthetic tongue. Environmental problems including pollution and the depletion of resources could possibly be exacerbated by the manufacturing, use, and disposal of these materials. Thus, it is crucial for the project to take into account the environmental impact and sustainability of the materials and procedures used. During the design process, many parts were developed using various polymers. Parts developed in the early stages and cannot be used for our final design will add to the environmental impact of our device. Another thing that needs to be taken into consideration is the wear and tear of our device. In a clinical setting, the patient is expected to use our device daily and for approximately 600 actuations. The batteries needed to assist with the patient's feeding process will lead to a large use of batteries over time. Rechargeable batteries can be used to decrase this environmental impact.

Second, using humans or animals as test subjects for the creation of an oral cavity simulation will eventually be necessary. If animals were utilized, injury and suffering should be kept to a minimum while ethical considerations and animal welfare are taken into account. Informed consent and ethical standards should be followed if there were any human subjects involved to safeguard their welfare.In addition to aiming for sustainability and moral behavior

throughout the development and testing phases, it is crucial for the project to take into account the potential environmental impact of the materials, processes, and methods employed.

9.3 Societal Influence

The goal of this device is to help improve the lives of patients, who have undergone a total glossectomy, by making the process of eating easier. If the product is given a larger platform and marketed to a general population, greater awareness of oral cancer would be an outcome of manufacturing this product. Since there are already products on the market for the current issue, this device would just be added to the list of solutions without causing significant disruptions.

9.4 Political Ramifications

There should be no major changes or effects on politics due to this product. As mentioned previously, this product is meant to assist total glossectomy patients with the process of eating, this should have no interjection from a political standpoint. The only aspect where this product could potentially have ramification is in the health care system and health affairs. There is the potential of policies being in place determining the cost, administrations, and manufacturing of the product. However, since there are similar products currently on the market to help, there should not be too much of a difference when producing and marketing the actuation device created by the team.

9.5 Ethical Concerns

An important ethical question is how a prosthetic tongue will affect people's social and psychological well-being. Patients may experience embarrassment or stigma if their prosthetic tongue is obvious or noticeable. If their prosthetic is visible, patients could be concerned about how others will view them or treat them. Their social interactions and self-esteem can suffer as a result.A patient's mental health and general wellbeing may be impacted by the psychological effects of using a prosthetic tongue, which may also include emotions of frustration, embarrassment, or shame. Because of the changes in their physical appearance and their capacity to speak and eat regularly, patients could also experience a sense of loss or bereavement.

To allay these worries, future iterations should create a prosthetic tongue that is discreet and does not affect the patient's social relationships or sense of self. This might entail creating a prosthetic tongue that is at once comfortable, practical, and attractive. Patients should be able to easily integrate the gadget into their everyday routines without experiencing any major disruptions if it is simple to use and maintain. Before it is widely utilized, it is essential to make sure that the prosthetic tongue is safe and effective, even though it may help those who have had their tongues amputated due to oral cancer. Clinical trials involving human subjects must be used to properly test the prosthetic tongue's effectiveness and safety.

The safety of the device must be evaluated by researchers while clinical trials are taking place by keeping an eye out for any participant discomfort or negative side effects. The effectiveness of the gadget should also be evaluated by comparing how effectively it facilitates swallowing to other therapies or a control group. Clinical trials frequently have several stages and are made to collect information on the safety and efficiency of the technology over an extended period of time.

The prosthetic tongue's effectiveness and safety must be examined using additional techniques in addition to clinical studies, like computer simulations and laboratory experiments. These tests can offer insightful information about the mechanics and potential dangers of the device, which can be used to guide the design of clinical trials and regulatory approval procedures.

Before using the prosthetic tongue, patients must be informed of any possible dangers. Patients must be made aware of the device's possible advantages as well as its hazards and restrictions in order for them to decide whether or not to use it.

9.6 Health and Safety Concerns

To protect the wellbeing of patients, potential health and safety issues with the creation of a self-contained prosthetic tongue for oral cancer patients who have had total glossectomy must be taken into consideration.

The risk for infection or inflammation brought on by the prosthetic tongue is one of the main worries. There is a chance that the prosthetic will introduce bacteria or other pathogens that could cause infections because it will be in contact with the oral cavity. Making sure the materials used in the prosthetic are biocompatible and do not have any negative effects on the body will be crucial. To avoid the accumulation of germs or other impurities, regular cleaning and maintenance methods will also need to be created and maintained.

The possibility of choking or aspiration while swallowing is another issue. As food is moved from the front to the rear of the oral cavity by the prosthetic tongue, a malfunctioning

device may increase the danger of choking or aspiration. To guarantee that the prosthetic is dependable and safe for patients to use, adequate testing and safety measures will be required.

Finally, the potential effects on patients' quality of life must be taken into account when developing the prosthetic tongue. Although the prosthetic may enhance swallowing ability, it could also result in discomfort or other issues that could have an adverse effect on the health of the patient. Patients who wear the prosthetic should be regularly monitored, and any issues or concerns should be addressed promptly.

Overall, the creation of a self-contained prosthetic tongue for people with oral cancer is a promising advance that may enhance many patients' quality of life. To make sure that the gadget is both efficient and secure for patients to use, it is crucial to address health and safety issues.

9.7 Manufacturability

While creating a self-contained prosthetic tongue, there are a number of additional aspects and considerations that must be taken into account.

The gadget must, first and foremost, be made to fit properly inside the oral cavity and not to irritate or distress the patient. In order to make sure that the device is pleasant to use and does not obstruct the patient's ability to speak or swallow, user testing may be necessary.

The components of the gadget must also be strong enough to endure the strains of frequent use in the oral cavity. In order to lower the danger of infection or allergic responses, they must also be biocompatible. To guarantee that the equipment is safe for use, the materials should also be simple to sterilize.

To fulfill demand, the production process must thirdly be scalable. This may entail adopting computer-aided design and manufacturing (CAD/CAM) strategies to increase productivity and accuracy or automating specific production-process phases. Moreover, quality control procedures must be in place to guarantee that each device produced satisfies the necessary criteria for effectiveness and safety.

The gadget must also be inexpensive and available to those who require it. To make sure that the item is covered by insurance and reimbursed at a fair rate, this may entail collaborating with insurance carriers and healthcare organizations.

In conclusion, careful consideration of a variety of characteristics, such as comfort, durability, biocompatibility, scalability, quality control, and price, is necessary when designing and producing a self-contained prosthetic tongue. The gadget must be safe, efficient, and available to people in need, therefore cooperation between the project team, manufacturers, and healthcare professionals is crucial.

9.8 Sustainability

The development of a self-contained prosthetic tongue to help oral cancer patients swallow has the potential to benefit society and the environment.

The project intends to address the demands and difficulties of people who have had a total glossectomy because of oral cancer from the standpoint of social sustainability. These individuals struggle with chewing, swallowing, and speech, which can lower their quality of life. The goal of the study is to enhance the patients' capacity to speak and eat by creating a functional prosthetic tongue.

A notable technological accomplishment is the creation of a prosthetic tongue that can successfully transfer the bolus from the front to the back of the oral cavity using fewer links supported by a return spring system with a silicone pad. The design could decrease the amount of materials utilized, improve the prosthetic's longevity and efficacy, and possibly lower the cost of production.

In terms of environmental sustainability, the prosthetic's potential for enhanced longevity and use of less materials in its construction mean that fewer resources will be needed for its creation, usage, and disposal. This might lessen the prosthetic's production- and disposal-related environmental effect.

This project's sustainability advantages align with the Sustainable Development Goals (SDGs) of the United Nations, especially SDG 3 (Good Health and Well-Being) and SDG 9. (Industry, Innovation, and Infrastructure). The initiative promotes innovation and technological advancement in the medical device sector while enhancing the health and wellbeing of oral cancer patients by providing them with a functional prosthetic tongue.

10. Improvements to last years Design

The 2021-2022 project was a huge improvement compared to its predecessor, this year was an improvement on last year's work. From a design perspective, the current version is significantly smaller, and it moves a bolus more effectively. In testing, we mimicked the oral cavity and conducted fatigue testing.

10.1 Miniaturization

From visually comparing this year's version of the tongue is significantly smaller than last year's (see Figure 72 below). While we were not able to put all of the wires in the mouth that was due to a flexible prototyping board not arriving in time rather than a space issue. Both designs have an external power supply, so there are no improvements in that area. The one area in the current design that is bigger than the previous year is the thickness from the top of the base to the bottom of the retainer. However, there are no external shafts attached to the jaw, which would not be plausbile in apatient without the addition of another invasive surgery. Additionally, the current design can more easily be removed from the oral cavity due to the retainer and that no permanent changes were need to be made to the oral cavity.

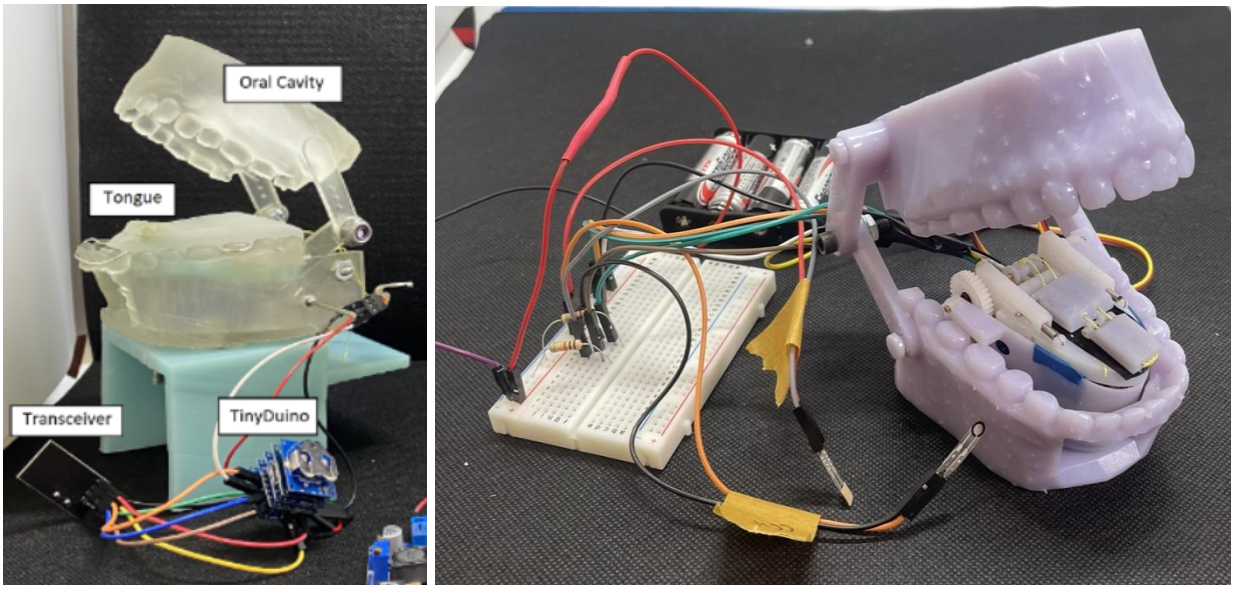

Figure 72: Comparison of Final Designs.
The figure above shows the difference in size between the two designs. The image on the left was from last year and does not contain the power supply so it is negligible in the comparison (reproduced as if from [45]). The image on the right is from the current prosthetic. Note the breadboard on the right was supposed to replace with a flexible prototyping board so that all the wires would fit inside the device.

10.2 Bolus Movement

Our final design was able to have a bolus movement high success rate than late year, while also testing a greater variety of conditions. Last year's tongue could be a 3g bolus two out of three trials, a 4g bolus two out of three trials, and a 5g bolus zero out of three trials with the jaw open and using coconut oil for lubrication. This year, bolus movement testing was a lot more thorough including open jaw, closed jaw, and closed jaw with artificial saliva. The open jaw and closed jaw without saliva were recorded as successes out of ten trials. While the closed jaw with saliva was recorded as successes out of 5 trials due to boluses breaking down see section 8.1 (Bolus Movement Testing Results) for more information. The testing results of the 16:30 gear train are summarized in Table 15 below. The current design is 33% and 24% more likely to successfully move a 3g and 5g bolus respectively. While the 4g bolus was less successful, it was due to the bolus falling off the sides and not because the bolus was unable to be moved. The variants of closed jaw movement were a substantial improvement as neither version was reported in the previous year's results.

Table 15: Testing Results for 16:30 Gear Ratio.

Test type	Bolus Weight		
	3g	4g	5g
Open jaw Without Artificial Saliva	10/10	5/10	9/10
Closed Jaw Without Artificial Saliva	4/10	4/10	4/10
Closed Jaw With Artificial Saliva	2/5	0/5	0/5

The table depicts the ability of the 16:30 gear ratio to move a given weight bolus. The results are written as x successes out of x trials.

10.3 Mimicking the Oral Cavity

A simulated oral cavity for testing is a new component from all of its predecessors. The tongue was actuated in a plastic tub heated to 37 ℃ to determine if the heat would cause issues with the device. The device did not above 1.5 degrees Celcius above the simulated oral cavity's set temperature (37.1 degrees) in any area that would cause damage to the device or the patient. The tongue was tested for bolus movement with artificial saliva instead of coconut oil. We did not test the tongue in a fully moist environment due to exposed electrical components. Simulating the oral cavity environment ensures that future works can validate if design improvements would operate in a physiological environment. Bringing the design one step closer to getting into the hands of a patient.

10.4 Fatigue Testing

A new testing requirement this year was fatigue testing. The current version actuated 190 times with around 100 tests on each gear train. Overall the only components of our design that

fatigued were the batteries and the heat shrink gear adaptors. Due to the fact that this was a new testing requirement, there is nothing to compare with previous years. However, the tongue will confidently last a meal's worth of actuations and the AA batteries can easily be swapped out.

11. Conclusion

The design of our device was overall successful. Our team was able to achieve our goal of miniturizing the design. This was especially true for the retainer housing group, the portion within the oral cavity, and in comparison to last year. The miniaturization many large components allowed for a majority of our design to be contained within the oral cavity. Our final design was mostly restricted by the types of batteries that were currently available on the market. Smaller batteries were unable to sufficiently supply the motor, leaving our actuation device incapable of movin a bolus.

The verification of our device showed that our final prototype was successful in several vital design aspects. Our tingue was able to successfully actuate 72.13 degrees using a gear ratio of 16:30. Our design was tested using two different gear rations, 4:3 and 16:30. Both gear ratios were tested, 16:30 was used for our final design due to it having a higher success rate than the 4:3 gear ratio in terms of moving a 3g and 5g bolus from the front to the back of the oral cavity. Bolus testing was composed of multiple conditions, using 3g, 4g, and 5g boluses, in addition to testing in an open and closed mouth position. Additional fatigue testing was conducted, allowing for the estimated total numner of actuation before the batteries needed to be exhcanged, which was determined to be 80 actuations. Fatigue testing also allowed us to assess the quality of our design’s components after completing a total of 190 actuations.

12. Future Recommendations

The largest problem holding the current design back from being used by a patient is miniaturization. The ways to further miniaturize the design would be making a PCB, moving the pulley down to a lower shaft, and reducing the motor size. Research would need to focus on reducing torque requirements because that will reduce the stall torque requirements and reduce current draw from the batteries. Additional work still needed for the tongue is adding a retainer wire to level the device, solving the reset problem, sealing the tongue, improving shaft adapters for gears, and adding silicon link pads to the mouth.

12.1 Making a Printed Circuit Board

Making a print control board would vastly improve miniaturization as all of the components excluding the power supply would fit within the retainer. Ideally, the PCB would be able to fit within the red semicircle shown in the Figure 73 below. While the PCB would vastly aid in miniaturization, it would also allow for the device to be sealed from fluids in the oral cavity.

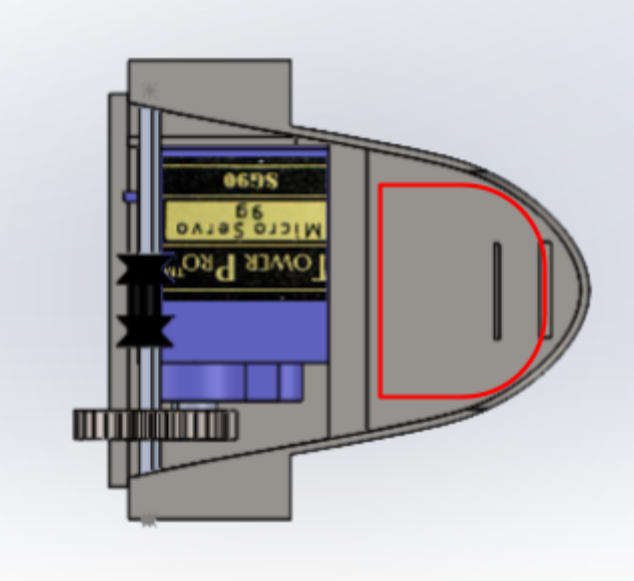

Figure 73: Potential Circuit Board Location.
The figure shows the potential location of a printed circuit board (PCB) in red. The PCB would need to be a box or flexible enough to stack vertically to not interfere with the actuation of the device.

12.2 Moving the Pulley Down

In Figure 74, moving the pulley from its location in the red box down to the shaft shown with light blue, will potentially have numerous benefits. The first is the overall height of the design would shrink. Reducing the total number of gears from 3 to 2 would allow for less torque loss due to gear inefficiency. The second gear could be larger, increasing total torque as there would be more space. Additionally, the pulley would get more movement from the tongue links as it is offset by a greater margin and there would not be an exposed gear that could damage the upper palate. While these improvements could potentially be great, it needs to be tested. The pulley may have to be built into the shaft to prevent the pulley from being too weak that it would break when the gears are turning.

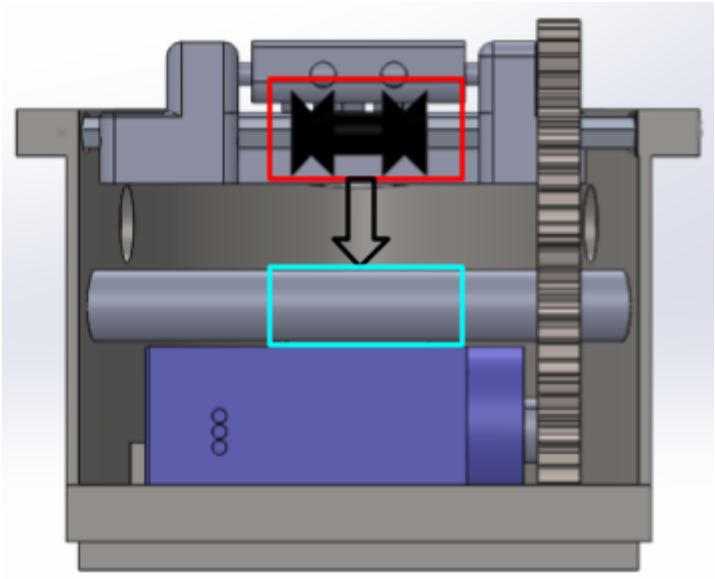

Figure 74: Potential Change in Pulley Location.
The figure shows the potential location change of the pulley. The pulley is currently in the red rectangle and could move down to the teal rectangle. Note to complete this move the pulley may need to be built into the idle gear shaft.

12.3 Reducing Motor Size

Making some of the above changes may reduce the total torque needed, however the largest issue in miniaturization is motor size. If significant progress in reducing torque is made, the motor may be able to be shrunk. The largest issue in picking a motor will be its dimensions and the large torque requirement further exacerbate the problem. One possible solution could be taking the motor out of its original casing and building a modified case that better suits the dimensions needed.

12.4 Reducing Power Requirements

Reducing power will be difficult as there is a current tradeoff with size. However, if the torque requirements can be reduced, then it may be possible to fit batteries in the retainer. On the

other hand, if they can't fit, a reasonable solution may be to make a long wire that can plug into the device and leave the power supply outside of the mouth.

12.5 Adding a Retainer Wire

Through our testing we found that the best way to move a bolus with our design is to have the device level or slightly lifted in the front. The retainer wire would help solve that issue and prevent the retainer from sliding into the oral cavity. The red circles would be where the wire would connect and then wrap around the two canine teeth as shown in red in Figure 75.

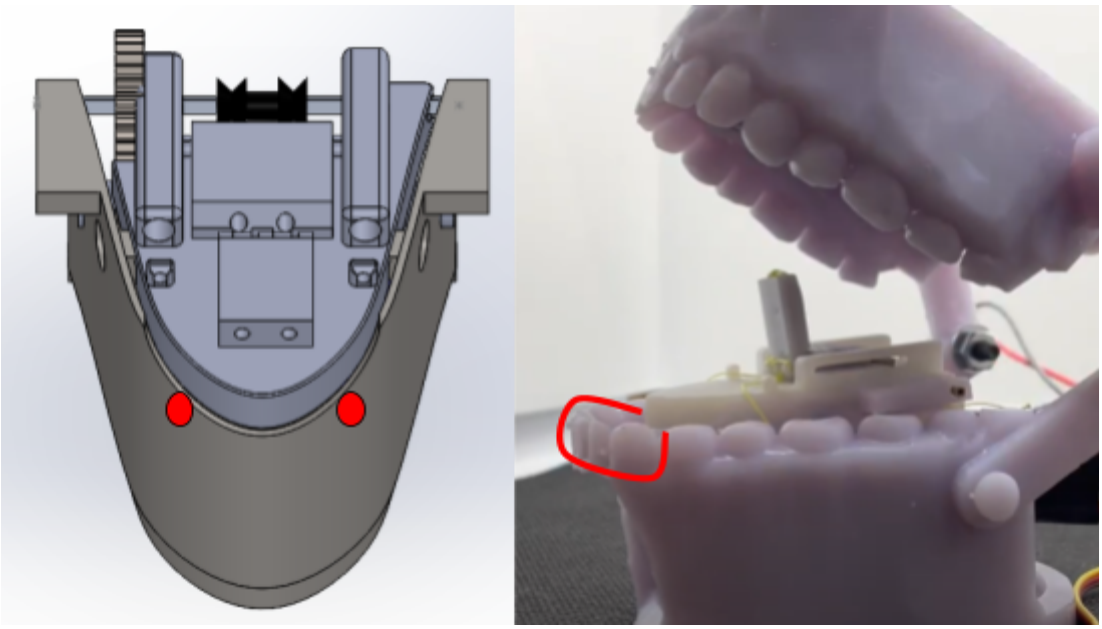

Figure 75: Potential Retainer Wire Location.
The figure shows how a potential retainer wire could be added to the design. The wire would attach through red holes (left) and would wrap around the canine teeth (right).

12.6 Solving the Reset Problem

A large problem with our actuation is the front link resetting to be flat after a complete actuation shown in Figure 76 below. The team was unable to figure out a solution to this problem and gravity does not provide enough force for the reset as we hoped.

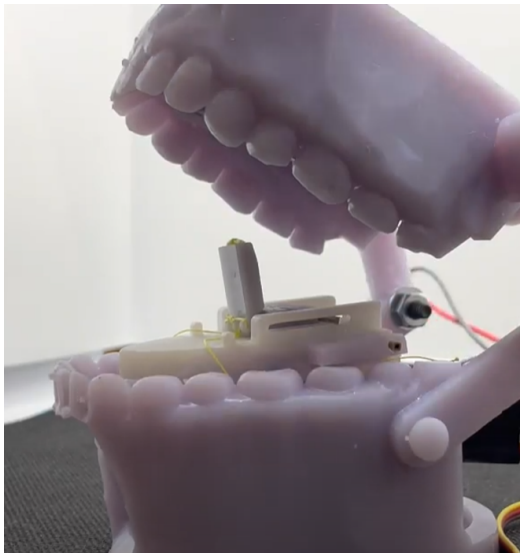

Figure 76: Reset Problem in Final Design.

The figure above shows the rest problem with the current version of the tongue. This problem occurs during the reset phase of the actuation cycle. The problem is the front link will not return to a flat position on the base.

12.7 Sealing the Device

Beside miniaturization, another large issue with trying to use the device in the oral cavity is fluid. The oral cavity is a moist environment and generally, electronics and moisture do not work well together. As a result, a future team would need to seal the device which was unable to be done this year. If the recommendations of making a PCB are followed the device will need a back plate then all of the edges would be sealed to keep the retainer dry internally.

12.8 Making Shaft Adapters for the Gears

The shafts used for the gears were not the perfect size, and this caused the gears to not spin perfectly straight. Shaft adaptors were made from shrink wrap for the shaft with the pulley. While it worked for testing, it is not an optimal solution and will result in additional power loss through the gear train. To prevent this shaft adapters should be made with a keyhole, so solder could be added to a round shaft. In doing so the round axles would not slip on the gears and the gears could spring smoothly.

12.9 Adding Silicon Link Pads

With the links being made of resin and making contact with the upper palate damage could occur. There were designs for molds to add silicon to the links however, time was a limiting factor in attaching them to the top of each link. Once pads are added fatigue testing would have to be done as well as actuation testing. The pads would add weight to the linkage further increasing torque requirements.

12.10 Movement with Saliva

To add a form of validation to the device, ensuring that the device can function in a moist environment is highly suggested. This means that bolus movement should be achieved with artificial saliva. In the team's case, bolus movement was not achieved because when testing with the artificial saliva the bolus broke down, thus not allowing it to move through the linkages system. This is part of the natural properties and purposes of salvia, to break down food and lubricate it for it to then be swallowed. If a system is meant to be placed in the oral cavity, it

should be able to adapt and function with the saliva and manage the breaking down of food in the mouth.

13. Team Reflections

This section describes the lessons learned from each team member on the project.

13.1 Reflections from Tatyana Barthold

I think overall the project had a lot of success. I enjoyed working with a team of hardworking individuals. The project definitely presented its challenges in terms of printing as well as building in a timely manner which for the most part was out of the team's control. One thing I wish we as a team could have focused more on was more research on how to make this device survive in the oral cavity. Seeing how different components would react to the artificial saliva and the proteins and enzymes in it would really give a more defiant conclusion on if this device would survive in the oral cavity. Some of these components that could've had more testing would be the springs and the dental resin. I also wish we could mimic the bacteria growth in the oral cavity to determine how the components of the device would react to the bacteria and determine if biofilm formation and negative foreign bodies responses would be an issue in the long run.

Overall I enjoyed the project very much and the group that I had. I would wish that more biomedical/biology testing could be performed however due to the time constant of four terms this would not be possible. I learned a lot of time management in the project and how to allocate time wisely because two semesters is not very long for a research project. I also learned more

about the importance of testing in a natural environment and ethical impacts in general. One key takeaway from this project is understanding the importance of validation.

I felt that a lot of the 3000 and 4000 level BME courses prepared me well for this project, more specifically BME Design course and the BME data analysis course at WPI.

Finally, I'd like to thank our advisors for their support during this project. Their contributions and skills have not gone unnoticed and are greatly appreciated. This goes for the faculty and staff who also expressed interest and assistance in our project.

13.2 Reflections from Hope Soucy

This project was a great experience. It allowed for us to work with those who had a large range of skillsets. These skillsets were able to allow us to further develop the project beyond the designing phase. The team worked well together and was able to utilize each other's skillsets to help to push the project further. The team overall communicated well together, ensuring that everyone got the assistance they needed.

Researching many aspects of the project was enjoyable, especially since the project had such a specific goal. Through this we were able to learn a lot about oral cancer, glossectomy, the tongue and its mechanics. These topics related more to my major. While I also had to research topics that didn't relate to my major as much or I knew little about, such as batteries and potential Arduino codes and setup that we could use for temperature testing.

Many of the BME classes had aspects that could be applied to this project. BME 3000 and 4000 levels help with project designing, as that is typically a final project within 4000 level courses. This project required a lot of support from teammates, professors, and our advisors. I am appreciated to all that helped our team during the development of our project.

13.3 Reflections from Luese Ufuah

I wanted to take time to think about the job we recently finished together. It's difficult to think that we started this project less than a year ago and have finally finished it. I am happy with the work we have completed and grateful for all of your help and advice during the process.

We encountered numerous hurdles along the process, ranging from managing limited resources and short deadlines to navigating unanticipated roadblocks. However, I am impressed with how we confronted these issues head-on and collaborated to overcome them. Our team's effort and commitment to this endeavor were nothing short of outstanding.

Looking back, I believe that the open and transparent communication that we maintained throughout the project was a crucial aspect in our success. We were all encouraged to contribute our views and perspectives, which resulted in more informed decisions and better outcomes. I'm also proud of how we used our pooled expertise and experience to devise novel solutions to the difficulties we faced.

I am especially satisfied with the quality of our work, as indicated by the measurements and statistics we just discussed. The fact that we were able to complete the project ahead of schedule and under budget is a tribute to our team's diligence and hard work.

Finally, I'd like to thank our advisors for their assistance and support throughout this process. Their thoughts and skills were vital in keeping us on track and achieving our objectives. I appreciate their interest in our staff and project.

I am really proud of the job we have completed and the journey we have taken together. I am honored to have worked with an amazing team of professionals and grateful for our advisers' support and assistance. Thank you for allowing me to be a part of this endeavor, and I look forward to the next challenge we will face together.

13.4 Reflections from Marc Voorhees

This MQP will be one of my most cherished memories from my college times. Not because it was easy or always super fun, but because it was challenging and helped me learn a lot about the practical matters of my degree as well as how my mechanical experience plays into the work being done by BMEs and RBEs. In hindsight, there are multiple aspects I should have prioritized for this project and others I prioritized too much. Thankfully, I will learn from this invaluable experience in order to continually better myself and my engineering ability.

My experience from classes such as ES2502, ME4821, and ME4429 contributed exponentially to this project, and I was able to look back on my notes and learnings from those classes to ensure that all calculations and 3D models are correct and without faults.

I want to end this with a massive thank you to my teammates, advisors, and other staff who assisted me along the way. You all were very supportive of my busy schedule and last minute emergencies and we were able to work through them all. Good luck to the next iteration of students tackling this project!

13.5 Reflections from Declan Williams

This MQP was very interesting due to its contrast to other projects I worked on at WPI. The size restriction within the design process prove to be challenging and I learned a lot. In no other project at WPI did I ever have to deal with a size limitation as most of the projects came with everything needed to succeed. I found it to be an extremely interesting experience designing a mechanical system and the electrical control components. While there was some nervousness at the beginning of testing because I did not want to see a design I worked so hard on fail, I had a large sense of relief and joy when it out performed previous teams.

The largest tips I could give to future teams is to start the design process early, but do not rush to failure. There were many failed attempts and had we started designing earlier, we would have been able to use the numerous new ideas we had towards the end of the project. The lack of time to implement our new ideas was by far the most frustrating aspect of the project.

The team worked very well together because everyone fell into self assigned roles so no one stepped on each others toes. Although there were times we had to slow down progress due to errors in communication.

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Appendices

Appendix A: Link to folder containing all of the solid works models

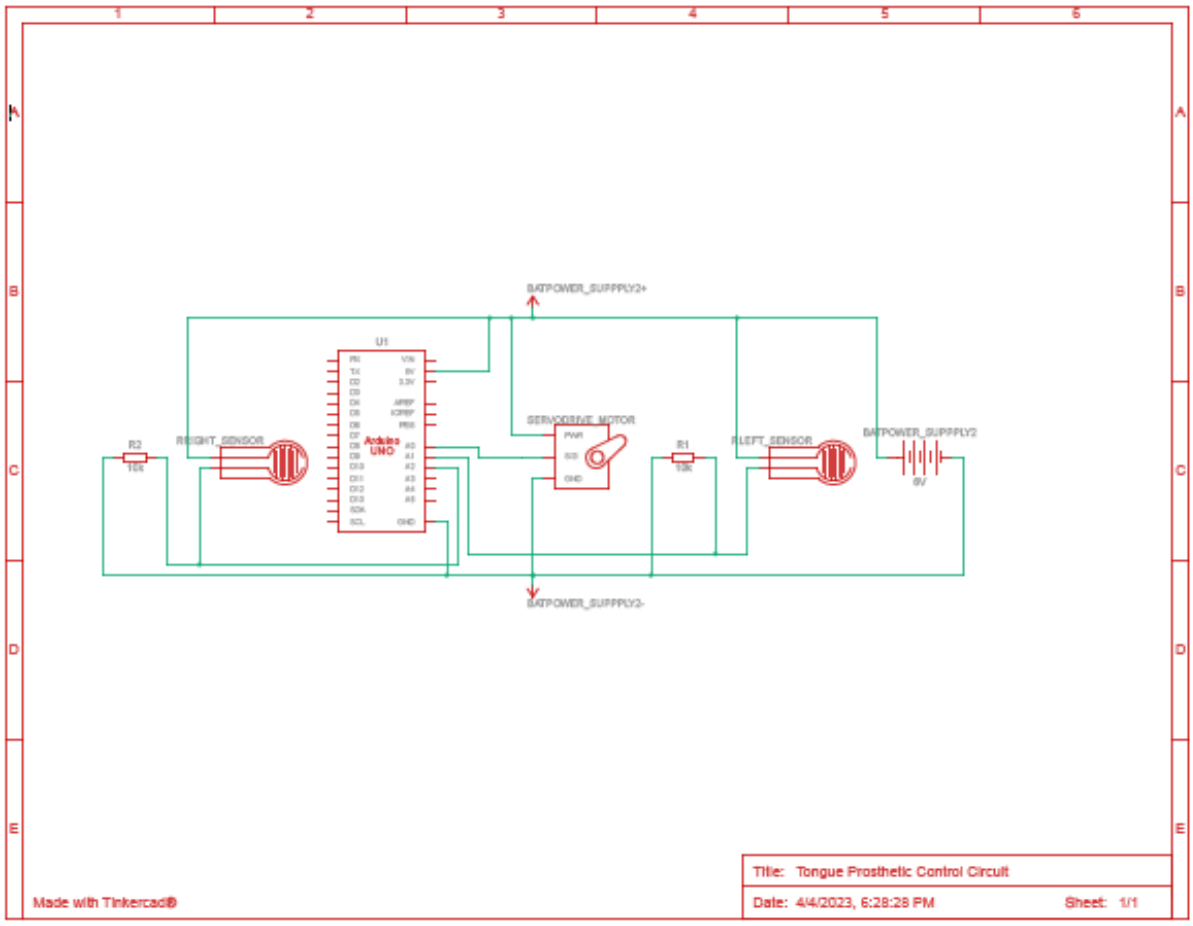
https://drive.google.com/drive/folders/1xjGgc7hE0hQA-fkBrxVRvbPBMvSWXTid?usp=sharing

Appendix B: Documented Code

```
/*
  Tongue Control
  Version 1.0
  This code is designed to run on the Seeed Xiao nRF52840 Sense.
  The code functions on force inputs from thin film force sensors.
  If the left sensor has a reading above 200 the a green LED will
  light and the motor will rotate to the 0 position. If the right
  sensor has a reading above 200 the red LED will light and the
  motor will rotate to the 180 position.
*/
#define GreenLEDpin 10 // set the GREEN led pin to D8 pin on board
#define RedLEDpin 9 // set the RED led pin to D7 pin on board
#define LeftTouchpin A1  // set the Left sensor pin to A1 pin on board
#define RightTouchpin A2 // set the Right sensor pin to A2 pin on board
#include <Arduino.h>
#include <Adafruit_TinyUSB.h> // for Serial
#include <Servo.h> // for servo
Servo myServo;  // create servo object to control a servo
//initalized sensor reading variables
int LeftTouchReading;
int RightTouchReading;
void setup() {
    // attaches the servo on pin A0 to the servo object
  // initialize digital pins for LED as an output.
  pinMode(GreenLEDpin, OUTPUT);
  pinMode(RedLEDpin, OUTPUT);
```

```
}
// the loop function runs over and over again forever
void loop() {
  // read sensors
  LeftTouchReading = analogRead(LeftTouchpin);
  RightTouchReading = analogRead(RightTouchpin);
  //turn LEDs off
  digitalWrite(RedLEDpin, LOW);
  digitalWrite(GreenLEDpin, LOW);
  if (LeftTouchReading > 200){
    myServo.attach(A0);
    digitalWrite(GreenLEDpin, HIGH);
    myServo.write(0); // rotate toward back of mouth to actuate tongue
    delay(650);
    myServo.detach();
  }
  if (RightTouchReading > 200){
    myServo.attach(A0);
    digitalWrite(RedLEDpin, HIGH);
    myServo.write(180); // rotate toward front of mouth to reset tongue
    delay(650);
    myServo.detach();
 }
  delay(500); //Delay 500 ms.           // wait for a second
}
```

Appendix C: Schematic of Control Circuit



Appendix D: Torque Calculations

```
front_link_length = 0.016375; % in meters

rear_link_length = 0.016375; % in meters

total_link_length = front_link_length + rear_link_length; % 0.0328m

total_link_mass= 0.0008 + 0.001 + 0.00388; % 0.0057kg

bolus_mass = 0.005; % kg

total_mass = total_link_mass + bolus_mass; % 0.0107 kg

Force_on_links = total_mass * 9.8; % 0.1047N

Torque_from_links = Force_on_links * total_link_length; % 0.0034 Nm

Spring_Constant = 0.189 *2; %2 springs with 0.189 Nm, 0.3780 Nm
```

```
Spring_max_length = 0.016; % m

Spring_offset_from_pulley = 0.00475; %m

Force_from_springs = Spring_max_length * Spring_Constant; % 0.0060 N

Torque_from_springs = Force_from_springs * Spring_offset_from_pulley; %
0.000028728 Nm

Total_Torque = Torque_from_links + Torque_from_springs; % 0.0035 Nm

Torque_Supplied_by_sg90= 0.245 *.5; % Nm, .5 is to reduce stress on motor,
0.1225 Nm

Torque_ratio = Total_Torque/Torque_Supplied_by_sg90; % 0.0282
```

Appendix E: Video of testing bolus movement

https://youtu.be/G4gGNC9avWk

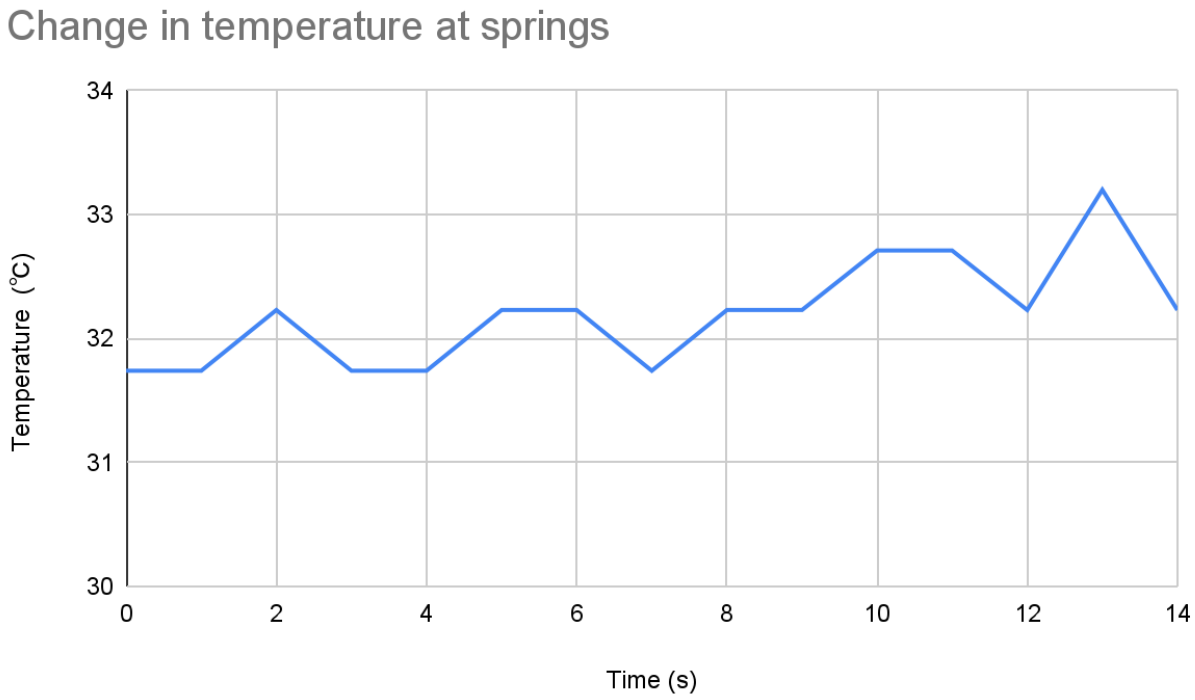
Appendix F: Video of testing, temperature

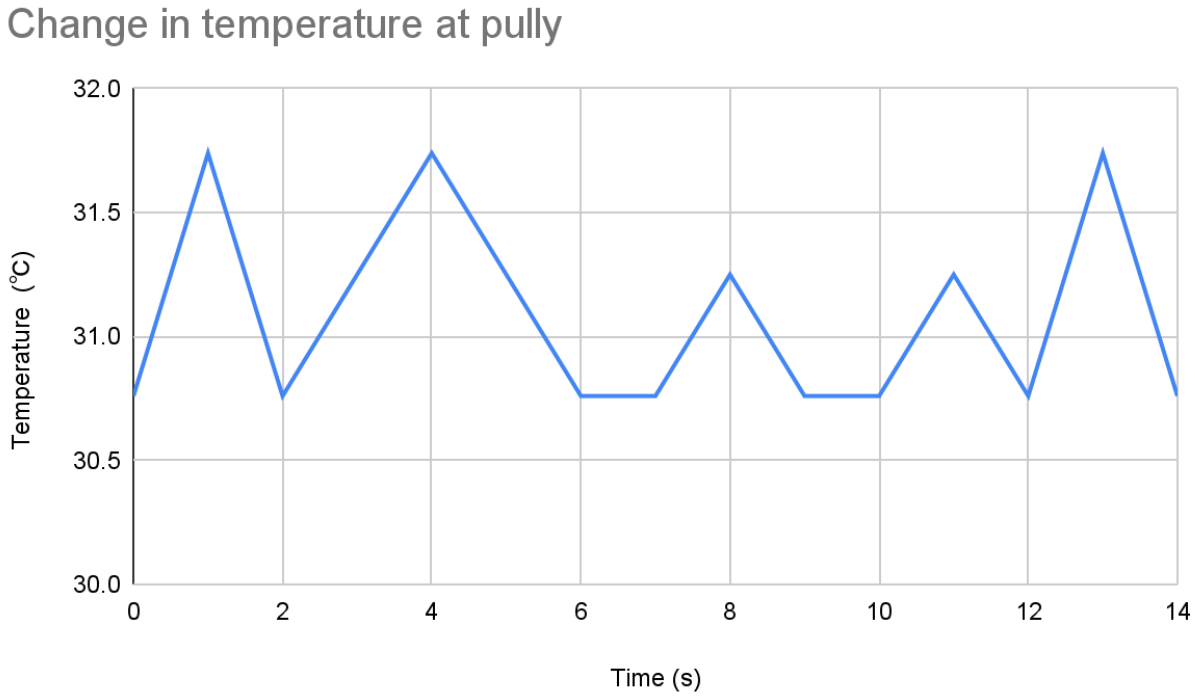
https://youtu.be/60hq45m9eiU

Appendix G: Video of testing kinematic analysis

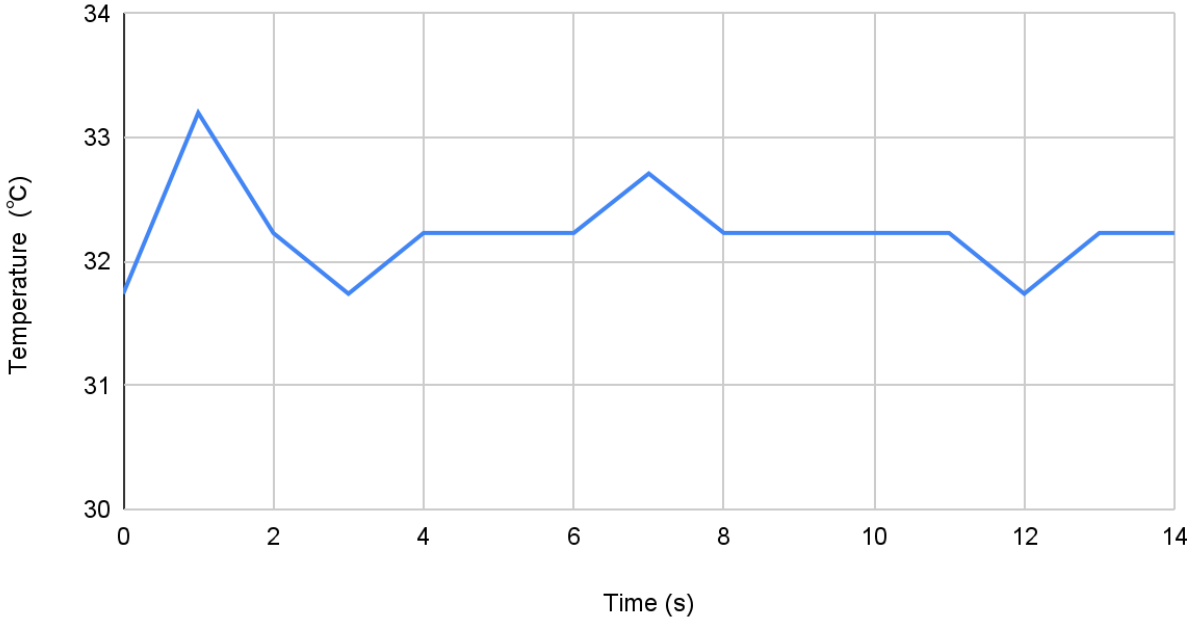
https://youtu.be/tkoQGxWFRWM

Appendix H: Graphs of Temperature Testing Data





Change in temperature under the base



Change in temperature at Upper Palette